Fear of Hypoglycaemia in Childhood Diabetes.

by Priya Tah

A thesis submitted in partial fulfilment of the requirements for the degree of Doctor of Philosophy in Medical Sciences.

Mental Health and Well-being, Division of Health Sciences, Warwick Medical School, University of Warwick.

September 2016
Contents

List of figures ............................................................................................................. IX
List of tables ............................................................................................................. X
Abbreviations ........................................................................................................... XII
Acknowledgements ................................................................................................. XIV
Declaration ............................................................................................................... XV
Abstract ..................................................................................................................... XVI

Chapter 1 Introduction ............................................................................................. 1

1.1 Type 1 Diabetes Mellitus (T1DM) ..................................................................... 1

   1.1.1 Treatment .................................................................................................... 2
   1.1.2 Impact of T1DM ......................................................................................... 3

1.2 Hypoglycaemia ................................................................................................. 4

   1.2.1 Frequency of hypoglycaemia ................................................................. 6
   1.2.2 The Diabetes Control and Complications Trial (DCCT) ......................... 7
   1.2.3 Impaired awareness ................................................................................. 10
   1.2.4 Cognitive dysfunction ............................................................................. 12
   1.2.5 Dead in bed ............................................................................................... 15

1.3 Fear of hypoglycaemia in children and young people (CYP) and parents .......... 17

   1.3.1 The Hypoglycaemic Fear Survey ............................................................ 17

1.4 Predictors of fear of hypoglycaemia ............................................................... 18

   1.4.1 Severe hypoglycaemia as a predictor of fear of hypoglycaemia .......... 18
   1.4.2 Anxiety as a predictor of fear of hypoglycaemia .................................... 20

1.5 Impact of fear of hypoglycaemia .................................................................. 20

   1.5.1 Fear of hypoglycaemia and diabetes management ............................... 20

1.6 Detection of hypoglycaemia by parents ....................................................... 22

1.7 Parental anxiety and diabetes ...................................................................... 23
2.10 CYP and parent participation: variations in completion of measures............... 60
2.11 Practical issues......................................................................................... 64
Phase two: Qualitative research method.......................................................... 65
2.12 Design...................................................................................................... 65
2.13 Sample ..................................................................................................... 65
2.14 Qualitative measures.............................................................................. 66
2.15 Procedure ............................................................................................... 72
2.16 Data analysis........................................................................................... 73
  2.16.1 Thematic analysis ............................................................................ 73
  2.16.2 Reflexivity ....................................................................................... 75
Chapter 3 Results: Recruitment, participation and descriptive statistics ............... 77
  3.1 Participant recruitment........................................................................... 77
  3.2 CYP demographics .............................................................................. 78
  3.3 CYP and HbA1c .................................................................................... 80
    3.3.1 Differences in HbA1c levels, by demographics.............................. 80
  3.4 Insulin Regimen ................................................................................... 81
  3.5 Parent demographics ........................................................................... 83
  3.6 Breakdown of parental occupation......................................................... 84
  3.7 Response Rates.................................................................................... 84
  3.8 Summary of Chapter 3......................................................................... 84
Chapter 4 Results: Self-reported frequency of hypoglycaemia and relationship to awareness of hypoglycaemia and HbA1c................................. 86
  4.1 Self-reported frequency of hypoglycaemia............................................. 86
    4.1.1 Definition of hypoglycaemia: ......................................................... 86
  4.2 Self-reported episodes of Severe Hypoglycaemia .................................. 88
    4.2.1 Definition of severe hypoglycaemia:................................................ 88
4.3 Group comparisons of self-reported frequency of hypoglycaemia and self-reported episodes of severe hypoglycaemia........................................................................................................ 90

4.4 Parental reports of frequency of hypoglycaemia and episodes of severe hypoglycaemia......................................................................................................................... 95

4.5 Comparison of episodes of reports of SH between CYP and parents .................. 102

4.6 The relationship between the frequency of hypoglycaemia and hypoglycaemia awareness.................................................................................................................. 103

4.7 The relationship between the episodes of severe hypoglycaemia and hypoglycaemia awareness............................................................................................................. 105

4.8 Frequency of Hypoglycaemia and HbA1c............................................................................. 108

4.8.1 CYP.................................................................................................................................. 108

4.9 Summary of Chapter 4......................................................................................................... 108

Chapter 5 Results: Fear of Hypoglycaemia........................................................................... 110

5.1 Fear of hypoglycaemia in CYP ......................................................................................... 110

5.2 Difference in fear of hypoglycaemia between age groups ........................................ 111

5.3 Differences in fear of hypoglycaemia, by demographics ............................................ 113

5.3.1 Fear of hypoglycaemia and insulin regimen............................................................... 113

5.3.2 Fear of hypoglycaemia and gender ............................................................................. 114

5.3.3 Fear of hypoglycaemia and HbA1c.............................................................................. 114

5.4 Parental fear of hypoglycaemia....................................................................................... 115

5.4.1 Comparison of parental HFS scores, by age group..................................................... 117

5.4.2 Comparison of parental HFS scores, by CYP’s insulin regimen .............................. 117

5.5 Relationship between CYP and parental fear of hypoglycaemia ............................. 117

5.5.1 Under 11 group vs parental HFS scores ................................................................. 119

5.5.2 Adolescent vs parental HFS scores .......................................................................... 120

5.6 CYP HbA1c and parental fear of hypoglycaemia ......................................................... 121

5.7 Fear of hypoglycaemia and self-reported frequency of hypoglycaemia .................. 122

5.8 Fear of hypoglycaemia and self-reported episodes of severe hypoglycaemia ....... 122
Chapter 5: Primary factors associated with fear of hypoglycaemia

5.8.1 CYP .................................................................................................................... 122
5.8.2 Under 11 years ................................................................................................. 123
5.8.3 Adolescents ...................................................................................................... 124
5.8.4 Parental HFS scores, all CYP .......................................................................... 124
5.8.5 Parental HFS scores, under 11 ........................................................................ 125
5.8.6 Parental HFS scores, adolescents .................................................................. 125

5.9 Summary of Chapter 5 ....................................................................................... 125

Chapter 6 Results: Secondary factors associated with fear of hypoglycaemia .... 127

6.1 CYP anxiety and HbA1c ....................................................................................... 129
6.2 CYP anxiety and insulin regimen ....................................................................... 129
6.3 Relationship between anxiety and fear of hypoglycaemia ............................... 130
6.3.1 CYP (whole cohort) ....................................................................................... 130
6.3.2 Under 11 ....................................................................................................... 131
6.3.3 Adolescents .................................................................................................... 131
6.3.4 Parents ........................................................................................................... 131
6.4 Quality of life and fear of hypoglycaemia .......................................................... 132
6.5 Relationship between quality of life and demographic data ............................ 133
6.5.1 CYP ............................................................................................................... 133

Figure 10: Scatter graph to illustrate relationship between QoL and HbA1c. ........ 134

6.6 Relationship between quality of life and fear of hypoglycaemia ..................... 134
6.6.1 CYP ............................................................................................................... 134
6.6.2 Under 11 ..................................................................................................... 135
6.6.3 Adolescent .................................................................................................... 135
6.6.4 Parents ........................................................................................................... 135
6.7 Self-care and fear of hypoglycaemia .................................................................. 136
6.8 Relationship between self-care and demographic data .................................... 137
Figure 11: Scatter graph to illustrate relationship between self-care and HbA1c. ........ 138
6.9 Relationship between self-care and fear of hypoglycaemia ........................................ 138
6.10 Multivariate analysis of fear of hypoglycaemia ......................................................... 139
6.11 Multivariate analysis of CHFS-Total in Under 11 group ............................................ 140
6.12 Multivariate analysis of CHFS-Total in adolescent group .......................................... 141
6.13 Multivariate analysis of PHFS-Total in mothers ......................................................... 142
6.14 Multivariate analysis of PHFS-T in fathers ............................................................... 143
6.15 Summary of Chapter 6 ......................................................................................... 144

Chapter 7: Discussion (Quantitative phase) ........................................................................ 147
7.1 Prevalence of hypoglycaemia ..................................................................................... 147
7.2 Fear of hypoglycaemia ............................................................................................. 150
  7.2.1 Fear of hypoglycaemia and severe hypoglycaemia ................................................. 152
  7.2.2 Fear of hypoglycaemia and anxiety ................................................................. 153
  7.2.3 Fear of hypoglycaemia and CYP health-related quality of life ......................... 155
  7.2.4 Multivariate analysis of hypoglycaemia fear survey ............................................. 155
7.3 Challenges in this research ...................................................................................... 156
7.4 Implications ............................................................................................................. 158
7.5 Future research ....................................................................................................... 160
7.6 Summary of Chapter 7 ......................................................................................... 164

Chapter 8: Qualitative analysis ......................................................................................... 165
8.1 Summary of method .............................................................................................. 165
8.2 Demographics ........................................................................................................ 165
8.3 Results of thematic analysis .................................................................................. 166
  8.3.1 Burden ............................................................................................................. 166
Figure 12: Thematic analysis ..................................................................................... 167
  8.3.2 Negative emotions ....................................................................................... 167
Appendix 14 – Substantial amendment number 4 ......................................................... 264
Appendix 15 – Information sheet (CYP) ............................................................................ 266
Appendix 16 – Information sheet (Parent) ......................................................................... 270
Appendix 17 – Consent form CYP aged 16+ ..................................................................... 274
Appendix 18 – Assent form ............................................................................................... 275
Appendix 19 – Parent consent on behalf of child ................................................................. 276
Appendix 20 – Parent consent form .................................................................................... 277
Appendix 21 – Letter of invitation (interview) ................................................................. 278
Appendix 22 – Participant information sheet (interview) ................................................... 280
Appendix 23 – Consent form CYP aged 16+ (interviews) .................................................. 283
Appendix 24 – Participant information sheet for younger children (interviews) ............... 284
List of figures

Figure 1: Questionnaire packs by age group.................................................................41

Figure 2: Translation of phrases from U.S. to U.K English for the PedsQL measure..54

Figure 3: Participant recruitment..................................................................................77

Figure 4: Self-reported frequency of hypoglycaemia by age group ...............................87

Figure 5: Self-reported episodes of severe hypoglycaemia in CYP
since diagnosis, by age group......................................................................................89

Figure 6: Comparison of frequency of hypoglycaemia between CYP
with normal vs impaired awareness of hypoglycaemia.............................................104

Figure 7: Comparison of frequency of severe hypoglycaemia between CYP
with normal vs impaired awareness of hypoglycaemia.............................................106

Figure 8: Difference in fear of hypoglycaemia between age groups............................112

Figure 9: Differences in fear of hypoglycaemia by insulin regimen...............................113

Figure 10: Scatter graph to illustrate relationship between QoL and HbA1c............134

Figure 11: Scatter graph to illustrate relationship between self-care and HbA1c......138

Figure 12: Thematic analysis..........................................................................................167
List of tables

Table 1: Cronbach’s alpha co-efficient.........................................................51
Table 2: Completion issues encountered with specific measures.................62
Table 3: Interview schedule (CYP)..............................................................67
Table 4: Interview schedule (parents).........................................................69
Table 5: CYP demographics.....................................................................79
Table 6: Parent demographic data.............................................................83
Table 7: Self-reported frequency of hypoglycaemia (%) by age group..........91
Table 8: Self-reported frequency of severe hypoglycaemia (%) by age group..92
Table 9: Self-reported frequency of hypoglycaemia (%) by insulin regimen...93
Table 10: Self-reported frequency of severe hypoglycaemia (%) by insulin regimen.....94
Table 11: Parent-reported frequency of hypoglycaemia (%), all CYP.............96
Table 12: Parent-reported frequency of severe hypoglycaemia (%), all CYP.....97
Table 13: Parent-reported frequency of hypoglycaemia (%), under 11 group...98
Table 14: Parent-reported frequency of severe hypoglycaemia (%), under 11 group.....99
Table 15: Parent-reported frequency of hypoglycaemia (%), adolescent group......100
Table 16: Parent-reported frequency of severe hypoglycaemia (%), adolescent group...101
Table 17: Self-reported number of episodes of severe hypoglycaemia in preceding years.........................................................................................................107
Table 18: HFS Measure (Mean plus/minus SD)..........................................111
Table 19: Relationship between fear of hypoglycaemia and HbA1c levels........114
Table 20: HFS measure parental scores (Means and SD)..............................................116
Table 21: Comparison of all CYP and Parent HFS scores...........................................118
Table 22: Comparison of U11 and parental HFS scores.............................................119
Table 23: Comparison of Adolescent and parental HFS scores.................................120
Table 24: Correlation between CYP HbA1c and parental HFS scores.........................121
Table 25: State and trait anxiety scores for CYP and parents....................................128
Table 26: State and trait anxiety scores for U11 and parents.....................................128
Table 27: State and trait anxiety scores for Adolescents and parents.........................129
Table 28: Health-related quality of life scores for CYP and parents..........................132
Table 29: Health-related quality of life scores for U11 and parents............................133
Table 30: Health-related quality of life scores for Adolescents and parents...............133
Table 31: Self-Care scores for Adolescents and parents............................................136
Table 32: Parental proxy reports of Self-care............................................................137
Table 33: Regression analyses to identify significant predictors of FoH in Under 11 group......................................................................................................................140
Table 34: Regression analyses to identify significant predictors of FoH in adolescent group......................................................................................................................141
Table 35: Regression analyses to identify significant predictors of FoH in mothers of CYP with T1DM.................................................................................................142
Table 36: Regression analyses to identify significant predictors of FoH in fathers of CYP with T1DM.................................................................................................143
Abbreviations

ANOVA - Analysis of variance
BG - Blood glucose
CGMS - Continuous Glucose Monitoring System
CHFS - Child Hypoglycemia Fear Survey
CHFS-B – Child Hypoglycemia Fear Survey Behaviour subscale
CHFS-T - Child Hypoglycemia Fear Survey Total score
CHFS-W - Child Hypoglycemia Fear Survey Worry subscale
CNS - Central nervous system
CSII - Continuous subcutaneous insulin infusion
CYP - Children and young people
DCCT – Diabetes Complications and Control Trial
FoH - Fear of hypoglycaemia
GEH - George Eliot Hospital
HbA1c - Glycosylated haemoglobin
HFS - Hypoglycaemic Fear Survey
HFS-B - Hypoglycemia Fear Survey Behaviour subscale
HFS-T - Hypoglycemia Fear Survey Total score
HFS-W - Hypoglycemia Fear Survey Worry subscale
HRQoL - Health-related quality of life
IAH - Impaired awareness of hypoglycaemia
ISPAD – International society for pediatric and adolescent diabetes
LRI - Leicester Royal Infirmary
MBSR - Mindfulness-based stress reduction
Mdn - Median
MRI - Magnetic resonance imaging
MTS - Mesial temporal sclerosis
NPDA - National Paediatric Diabetes Audit
PedsQL - Pediatric Quality of Life Inventory
PHFS - Parental Hypoglycemia Fear Survey
PHFS-B - Parental Hypoglycemia Fear Survey Behaviour subscale
PHFS-T - Parental Hypoglycemia Fear Survey Total score
PHFS-W - Parental Hypoglycemia Fear Survey Worry subscale
PTSD - Post-traumatic stress disorder
QoL - Quality of life
SD - Standard deviation
SCI - Self-care inventory
SCI-R - Self-care inventory revised
SLC - Sudden loss of consciousness
SMBG - Self-monitored blood glucose
SH - Severe hypoglycaemia
STAI - State trait anxiety inventory
STAICH - State trait anxiety inventory for children
STPI - Spielberger trait personality Inventory
T1DM - Type 1 Diabetes Mellitus
UHCW - University Hospitals Coventry and Warwickshire
URN - Unique reference number
Acknowledgements

I would like to thank my family and friends for supporting me throughout my PhD, you know who you are! Special thanks go to my husband, my parents and my children, Meghna and Avinaash, who have been extremely patient and understanding while I have been undertaking my research.

I would like to extend my gratitude and appreciation to my supervisors, Dr Krystyna Matyka, Professor Cathy Lloyd and Dr Peter Sidebotham, for their advice, guidance and support. It has taken a long time to get here but I would not have been able to do this without you.

Finally, I would like to thank all of the children, young people and parents who gave their time and shared their experiences to help me to conduct this research study and understand the impact that diabetes has on families.
Declaration

This thesis is submitted to the University of Warwick in support of my application for the degree of Doctor of Philosophy. It has been composed by myself and has not been submitted in any previous application for any degree.

The work presented (including data generated and data analysis) was carried out by the author.
Abstract

Hypoglycaemia is an unavoidable consequence of treatment of Type 1 Diabetes Mellitus (T1DM). Symptoms are often embarrassing and distressing and can lead to the development of fear of hypoglycaemia (FoH). This fear can have a negative impact on diabetes management and can lead to further medical complications.

210 children and young people (CYP), aged 3-17 years and 190 parents from diabetes paediatric clinics across the West Midlands, UK, completed questionnaires exploring the prevalence of hypoglycaemia, FoH and links to hypoglycaemia awareness, self-care, quality of life and anxiety. Demographic information and HbA1c data were also collected.

Results indicated that hypoglycaemia and severe hypoglycaemia (SH) are a problem for CYP in the UK. Hypoglycaemia Fear Survey (HFS) scores were higher in parents than in CYP (Total HFS 37.1±14.9 vs. 50.2±17.8 vs. 45.2±18.0, CYP vs. mother vs. father, respectively, p<0.01). Adolescents with prior experience of severe hypoglycaemia (SH) had higher HFS scores compared to those without (t=-3.61, p<0.001). Trait anxiety and SH explained 23% of the variance in HFS scores in adolescents. Trait anxiety explained 37% of the variance in HFS scores in under 11 year olds, 18% in mothers of under 11 year olds, 6% in mothers of adolescent and 10% in fathers of adolescents. There was no correlation between HFS and HbA1c. Qualitative analyses identified ‘Burden’ as an overarching theme from CYP and parent interviews. ‘Negative emotions’ and ‘Living with diabetes’ emerged as the key themes of analysis.

This research study adds to existing findings on the prevalence of hypoglycaemia, severe hypoglycaemia, FoH and possible related factors, by focusing on the paediatric population and their parents, in the UK, for which there is limited research. Qualitative analyses also provided novel reports of the experience of T1DM for CYP and their mothers. Implications of this research could lead to the development of an FoH and anxiety management programme for CYP and their parents. The findings of this study also help to raise awareness of this very real and current issue in diabetes management.
Chapter 1 Introduction

This chapter aims to introduce the reader to Type 1 diabetes mellitus (T1DM) and the effect that it has on paediatric populations and their parents. Research focusing on hypoglycaemia (low blood sugar) and its associated biological and psychological outcomes will be discussed with regards to the paediatric population. Particular focus will be made on the concept of fear of hypoglycaemia and its impact on diabetes management. Studies exploring the effects of hypoglycaemia on the parents of children with T1DM will be discussed. In addition, diabetes management in relation to glycaemic control will also be explored in both the paediatric and parent population.

This chapter will help to build a picture of existing research in the area of fear of hypoglycaemia (FoH) and other aspects of living with diabetes for children and adolescents with T1DM and their parents. The research will go towards informing the current research study, which aims to add to the growing body of FoH literature, especially for a UK population sample.

1.1 Type 1 Diabetes Mellitus (T1DM)

Type 1 diabetes mellitus is an autoimmune disease, commonly diagnosed in childhood, which impairs the body’s ability to produce insulin (required to regulate blood glucose levels). The condition results in pancreatic β cells being destroyed, leading to absolute insulin deficiency (1). The causes of T1DM are unknown; however, it seems that a combination of factors such as the presence of autoantibodies, environmental triggers (i.e. virus or infection) and genetic susceptibility, may all contribute.

T1DM in CYP can present with a number of common symptoms including hyperglycaemia (high blood glucose levels), a frequent need to go to the toilet, excessive thirst, excessive
hunger, weight loss and diabetic ketoacidosis (DKA, whereby the body breaks down tissue to use for fuel in the absence of glucose) (2).

The prevalence of T1DM is high and increasing at a dramatic rate (3, 4). Taking into account the number of new cases of T1DM across Europe between 1989-2003, Patterson et al. (4) predicted that new cases of T1DM would double in children younger than 15 years, between 2005-2020. This will have serious implications for healthcare providers, therefore effective planning of services is needed to ensure these CYP receive appropriate care. There has also been a shift in the type of diabetes diagnosed in childhood. T1DM was historically known as juvenile diabetes, with Type 2 diabetes commonly referred to as adult-onset diabetes. With obesity (a risk factor in the development of Type 2 diabetes) increasing in the paediatric population (5) however, this is no longer the case. Type 2 diabetes is now diagnosed in an increasing number of paediatric cases (6). Although the focus of this thesis is T1DM it is important to understand that the impact of diabetes is even more far reaching.

1.1.1 Treatment
Treatment of T1DM is aimed at achieving optimal blood glucose levels by using insulin to manage this. Insulin treatments vary. At the time of carrying out the study intensive (multiple daily injections (MDI)) regimens were replacing the twice daily insulin regimen. Twice daily regimens, though limit the number of injections a patient has to administer are also inflexible and do not allow variations in CYP’s diets. Current practice has moved away from twice daily insulin injections and newly diagnosed patients are more likely to start on an intensive regimen (7). Intensive regimens, including multiple daily injections and continuous subcutaneous insulin infusion (CSII, also known as pump therapy) are better able to mimic the role that insulin plays in healthy CYP (8). MDI allows patients to adjust their insulin requirements according to their lifestyle by injecting a long acting insulin (basal) once or twice a day, accompanied by faster acting insulin which can be adjusted according to each meal they eat. In order to manage their BG levels patients need to carry
out regular BG monitoring to ensure that they adjust their insulin appropriately (9). Continuous glucose monitoring (CGM) has been identified as a more accurate indicator of BG levels. This system allows measurement of interstitial fluid around the cells in the body via a device worn under the skin (9). When used in combination with MDI, CGM has been found to reduce HbA1c (estimate of BG levels over the preceding few months) (10). CSII or pump therapy is increasingly becoming the preferred method of therapy, especially in CYP with suboptimal diabetes control (9). Technological advances mean that pumps are better able to calculate adjustments to insulin and show evidence of improved glucose levels post meal (11) and increased satisfaction from CYP using this type of therapy (12, 13). These intensive therapies also reduce the risk of diabetes-related complications, as will be discussed in more detail in the next section (14).

1.1.2 Impact of T1DM

The impact of diabetes is multifaceted. In addition to the impact on physical health it can also impact CYP psychologically. Sub-optimal management of diabetes can lead to future complications; microvascular and macrovascular. Such developments can have serious implications for the health of CYP living with T1DM.

The impact of T1DM on physical health is well documented (15-18). As well as the more immediate impact of diabetes, namely hypoglycaemia (which will be discussed in the next section), T1DM can also give rise to long-term problems such as micro- and macrovascular complications. Long-term hyperglycaemia (high blood glucose levels) can lead to damage to blood vessels, both large arteries (macrovascular) and smaller capillaries (microvascular) (17). Microvascular complications include nephropathy (kidney disease), retinopathy (eye disease) and neuropathy (nerve damage) (16). Longitudinal studies in adolescents have shown that those who are able to achieve optimal BG levels consistently are able to decrease the likelihood of microvascular complications (18). Similarly, macrovascular complications are thought to be reduced when BG levels are managed well.
The Epidemiology of Diabetes Interventions and Complications Research Group (20) examined the presence of cardiovascular disease in a cohort of patients who had previously taken part in the Diabetes Control and Complications Trial (DCCT). Those patients who had been in the DCCT intensive treatment group experienced 42% less cardiovascular disease events than those in the conventional treatment group. Some studies have also found evidence of the impact of microvascular complications on the development of macrovascular problems. The DCCT follow up study (20) found that microvascular diseases, specifically nephropathy and neuropathy, can increase the likelihood of developing macrovascular complications. This highlights the importance of managing BG levels long term.

The impact of T1DM goes beyond the effects on physical health. The constant management of blood glucose levels can also have a psychological impact on CYP (21). Research on psychological disorders in CYP with T1DM are conflicting, however, it does seem that living with diabetes is associated with higher psychological distress (22). Links between anxiety and depression with poor self-care have also been reported (23) although the impact of this on glycaemic control is less pronounced (24).

The psychological impact of T1DM extends to parents of CYP with diabetes. This is discussed further in sections 1.7 and 1.8. Further to the physical and psychological impact of T1DM, there is also evidence of its impact on QoL. This will be discussed in more detail in section 1.9.

1.2 Hypoglycaemia

Hypoglycaemia is an unavoidable but common consequence of treatment of Type 1 Diabetes Mellitus (T1DM). The prevalence of hypoglycaemia in patients with T1DM in the UK is under reported, however, a number of contemporary studies have specifically looked
at the prevalence in the CYP population (25-27). These studies will be discussed after explaining hypoglycaemia in more detail. Incidences of hypoglycaemia occur when a person’s blood glucose (BG) level drops and becomes too low. The brain depends on a continuous supply of glucose for fuel. When blood glucose levels in the body fall, the amount of glucose to the brain also decreases (28). If left untreated, hypoglycaemia can have serious implications for the health of those who experience these episodes (29). The biochemical definition of hypoglycaemia is recognised as blood glucose levels of 3.9mmol/L (30). Diabetes patients whose blood glucose levels fall to this level should take action to increase their BG levels to avoid further complications. Hypoglycaemia can be defined according to the severity of an episode. Generally mild and moderate episodes of hypoglycaemia are grouped together as, in paediatric populations, parents will often support their child in treating both mild and moderate episodes of hypoglycaemia (30). Mild and moderate episodes of hypoglycaemia are those where BG levels fall to 3.9mmol/L whether or not associated with symptoms. Severe episodes of hypoglycaemia will often need to be treated with the help of another person. In paediatric cases as this is likely to be the norm for any episode of hypoglycaemia, a severe episode is generally recognised as an episode associated with severe deprivation of glucose in the brain (neuroglycopenia), leading to coma/convulsions (31). Associated symptoms of hypoglycaemia include sweating, shaking, heart pounding and irritability (mild hypoglycaemia) and are usually easily treated. However, in extreme circumstances, where a severe episode of hypoglycaemia occurs, this can lead to unconsciousness/convulsions and even death (32, 33). Those suffering from hypoglycaemia can alleviate symptoms by taking a fast acting carbohydrate followed by a longer acting carbohydrate, for example drinking fruit juice followed by eating a digestive biscuit. In more extreme circumstances, where a person becomes unconscious, they would need to be treated with an injection of glucagon, or intravenous glucose to increase BG levels (34). Symptoms of hypoglycaemia can further be categorised as autonomic and neuroglycopenic (29). Autonomic symptoms occur when hypoglycaemia triggers the autonomic nervous system which produces a physiological response that is interpreted by the individual as hypoglycaemia, for example, shaking, sweating, and anxiety. Neuroglycopenic symptoms are a response to glucose deprivation in the brain and can lead to the more severe symptoms of hypoglycaemia,
including seizures, convulsions, coma and death (29, 35). Incidents of severe hypoglycaemia (SH), where a patient requires assistance to be treated, have been found to increase when patients attempt to maintain tight control of their diabetes (by maintaining optimum HbA1c levels of around 48mmol/mol). HbA1c levels give clinicians an estimate of blood glucose levels over the previous few months, to get an overall picture of diabetes management (36). Therefore, those individuals who attempt to maintain a tight control of their BG levels can be at greater risk of experiencing hypoglycaemia and associated symptoms. Other risk factors for hypoglycaemia include young age, a history of severe hypoglycaemia and loss of hypoglycaemia awareness (30).

1.2.1 Frequency of hypoglycaemia
The frequency of hypoglycaemia is difficult to determine, especially in children and young people. This is due to a number of reasons, which will be discussed. Documenting the frequency of hypoglycaemia often relies on the memory and recall of these events. In young children then, this can be confounded by factors such as an inability to recognise or understand that they are experiencing hypoglycaemia, or difficulty verbalising this, especially if they experience mild hypoglycaemia. Parents are often the source of information in these cases but again, their reports of hypoglycaemia are not likely to be accurate and they will more than likely report the more severe episodes of hypoglycaemia, as it is during these episodes that they may notice changes in their child’s behaviour. Therefore the prevalence or frequency of hypoglycaemia is likely to be under-reported for this age group. Studies have attempted to use more stringent methods to try to identify how frequently hypoglycaemia occurs in younger children. Tasker et al. (37) tried to overcome issues of recall by developing a technology based method of collecting data on mild hypoglycaemia. Interestingly, for this study, mild hypoglycaemia was defined as either BG levels indicative of hypoglycaemia or experiencing symptoms of hypoglycaemia. Children aged between 7-18 years old were either asked to monitor hypoglycaemia on a daily basis using a paper diary, a computer based interview or mobile phone. Researchers concluded that by using the technology based methods of data collection that there was a significant increase in reports of mild hypoglycaemia compared to previous reports. This
supports the idea that experience of hypoglycaemia is likely to be higher than reports of hypoglycaemia.

The frequency of severe hypoglycaemia is perhaps easier to determine than mild or moderate hypoglycaemia. This is due to the fact that symptoms are more pronounced and obvious and often the child or young person will need significant help in treating such an episode, which in itself might make the incident more memorable. Studies reporting on the frequency of severe hypoglycaemia in this population suggest that severe hypoglycaemia (characterised by a seizure, coma or severe impairment due to unconsciousness) is more prevalent in younger children than in adolescents (38). This is not surprising considering older children/adolescents are more likely to recognise and treat a milder episode themselves, whereas younger children may rely on their parents or caregiver to recognise the symptoms and treat accordingly. In a recent study, Johansen et al. (39) analysed patient records of children and adolescents with diabetes between 1998 and 2009. They found that the prevalence per se, of severe hypoglycaemia remained unchanged during the study period. However, more intensive insulin regimens did seem to provide some protection from the incidences of severe hypoglycaemia. These studies again reinforce the idea that mild, moderate and severe hypoglycaemia is prevalent amongst children and adolescents and therefore is a problem for those managing T1DM, further discussion follows below.

1.2.2 The Diabetes Control and Complications Trial (DCCT)

The Diabetes Control and Complications Trial (14) was a longitudinal trial carried out on a very large sample of diabetes patients and explored various aspects of diabetes and diabetes management in adults and adolescents. 1441 patients were assigned to either intensive (multiple daily injections (MDI/CSII)) or conventional (twice daily injections) diabetes therapy and were followed for an average of 6.5 years. The aim was to assess the beneficial outcomes of intensive therapy (MDI/CSII) on diabetes, which required patients to maintain optimum BG levels. Long term hyperglycaemia (high BG) can lead to the
development of microvascular complications such as retinopathy (eye disease), nephropathy (kidney disease) and neuropathy (nerve damage). These microvascular complications can ultimately lead to morbidity/increased risk of morbidity/mortality (14). Intensive therapy (MDI/CSII) was found to delay or slow progression of these complications, with a study specifically looking at an adolescent sample (18). Although overall results of the DCCT showed that tight glycaemic control reduced microvascular complications, it was also reported that 65% of patients in the intensive treatment therapy (MDI/CSII) group suffered at least one episode of SH during the study, compared with only 35% in the conventional (twice daily injections) therapy group (14, 40). Severe hypoglycaemia in this trial was defined as an episode which resulted in patients having BG levels below 50mg/dL and required assistance in treating their hypoglycaemia or episodes which required treatment using glucagon or intravenous glucose (40). Subsequent episodes of SH were predicted by previous experience of suffering from SH (40).

In a review of hypoglycaemia in children, Jones and Davis (41) highlighted the effects of intensive therapy on the frequency of episodes of severe hypoglycaemia. They reported that increased intensity of therapy in one clinic was linked to an increase from 4.8 episodes of coma/seizures induced by hypoglycaemia/100 patient-years to 15.8 episodes/100 patient-years (42, 43). Allen at al.’s (44) study also investigated these effects. They found that lower HbA1c, intensive insulin therapy and better control were linked to more frequent hypoglycaemia. An association between SH and lower HbA1c was also found.

As mentioned previously, the prevalence of hypoglycaemia in the UK CYP population is under-reported. However, studies carried out in other countries also help to give an indication of the prevalence of hypoglycaemia for this particular group. One UK based study, carried out by Amin et al. (27) measured glucose levels in 28 under 12 year olds, over 3 days and 3 nights using the Continuous Glucose Monitoring System (CGMS). Hypoglycaemia was defined as glucose <60mg/dl for more than 15 minutes. Results of the study indicated that 10.1% of all readings from participants fell within the study’s defined range of hypoglycaemia. A comparison of conventional (twice daily injections) vs more
intensive regimens (not including pump therapy) suggested a high prevalence for those on conventional (twice daily injections) insulin regimens especially for nocturnal hypoglycaemia. Those on intensive regimens also presented with high prevalence, however, more during the morning hours. This study collected actual glucose levels for participants in order to identify those levels that typically indicate an episode of hypoglycaemia, which provides objective measurements of hypoglycaemia. The sample size is small however and age range does not account for all CYP (the youngest patient was 6.9 years old). Nevertheless, it does give a good indication regarding the problems that hypoglycaemia can present for CYP and their families.

Katz et al. (25) carried out an observational study with 255 CYP, aged between 9-15 years. They collected prospective data on the incidence of severe hypoglycaemia (incidences requiring assistance from another/with seizure/coma) at quarterly time points, over a median of 1.2 years. Overall, the incidence rate for severe hypoglycaemia in this CYP sample was reported as 37.6/100 patient-years (severe hypoglycaemia with seizure/coma: 9.6/100 patient-years). A limiting factor for this study was its observational design, but in order to collect data for a large cohort and over a lengthy period of time such a design was appropriate. In comparison to the study carried out by Amin et al. (27) reports of severe hypoglycaemia in Katz et al.’s (25) study are largely subjective and based on severe hypoglycaemia being defined as an episode requiring assistance from another or with a seizure/coma. While the latter part of the definition is clear, defining an episode of severe hypoglycaemia as an episode requiring assistance might not be as accurate for reporting severe hypoglycaemia. In CYP samples especially, and specifically for pre-adolescent participants, parents may regularly provide support for their child suffering from hypoglycaemia and this could be whether that episode is severe or not. Therefore reports of severe hypoglycaemia cannot always be trusted as accurate. This being said, however, this is the case for many studies using an observational approach to studying prevalence of hypoglycaemia/severe hypoglycaemia and until a more standard definition is agreed there will be grey areas in reports.
A more recent study of the prevalence of severe hypoglycaemia explored incidence rates of severe hypoglycaemia in Western Australia, from 2000-2011. Cooper et al. (26) used patient data collected from 1770 patients aged 0-17.8 years. Severe hypoglycaemia in this study was defined as an episode of coma or convulsion resulting from hypoglycaemia. Overall, researchers found that the incidence of severe hypoglycaemia varied over the 12 years. The incidence of severe hypoglycaemia peaked in 2002 at 21.8/100 patient-years before showing a reduction on a yearly basis and then stabilising in 2006. There was very little change from 2006 to 2011 where the incidence of severe hypoglycaemia was reported as 6.2/100 patient-years. Again this study employed observational methods however, it also had access to an extremely large dataset over an extended period of time. Of note is the fact almost all children attending the participating hospital took part in the study so the results are taken from a representative sample. Although cause and effect could not be determined from this observational study the authors conclude that there has been a decrease in the prevalence of hypoglycaemia over the past 12 years and there is also a weaker relationship between glycaemic control and risk of severe hypoglycaemia. Potential influencing factors are reported as an increase in pump therapy, improved education and increased glucose monitoring. It is as important as it interesting for the current study to try to identify the prevalence of hypoglycaemia and severe hypoglycaemia for a UK sample, to assess whether this is a problem for the T1DM CYP population here.

The long term consequences of hypoglycaemia have been studied widely in children and adults with T1DM. The most commonly reported lasting effects of suffering from hypoglycaemia include impaired awareness and cognitive dysfunction. These are discussed in more detail below with reference to relevant research studies.

1.2.3 Impaired awareness
Awareness of hypoglycaemia alters over time whereby the patient’s symptoms change or become weaker (45) due to experiencing frequent episodes of hypoglycaemia. This can also result in an individual being unable to recognise that the physiological changes they
are experiencing are due to a fall in blood glucose levels. Frequent experience of hypoglycaemia can eventually lead to hypoglycaemia unawareness meaning that a patient can lose the ability to detect the symptoms of low blood sugar. Losing the ability to detect the symptoms of hypoglycaemia can be dangerous. As well as the fact that the frequency of hypoglycaemia will likely increase, more worryingly, if an individual does not recognise the early signs of hypoglycaemia then that episode is likely to become more severe hence there will be an increased chance of severe hypoglycaemia. Hepburn et al. (46) questioned 302 T1DM patients about awareness of the onset of hypoglycaemia and the symptoms of hypoglycaemia. They found that loss of awareness of hypoglycaemia was associated with increased severe hypoglycaemia, suggesting a link between awareness and frequency of hypoglycaemia and consequently the occurrence of severe hypoglycaemia.

Impaired awareness of hypoglycaemia (IAH) was investigated by Gold et al. (47). They found that patients with IAH demonstrated a 6 fold increase in the frequency of severe hypoglycaemia. Later studies also found that patients with reduced awareness of hypoglycaemia suffer from more moderate and severe episodes of hypoglycaemia (48, 49). A longer duration of T1DM has also been found to change the symptoms of hypoglycaemia (50) with T1DM children and adolescents displaying reduced autonomic symptoms (palpitations, anxiety) and increased neuroglycopenic symptoms (fatigue, confusion, seizures). It seems that patients with impaired awareness of hypoglycaemia also report earlier onset of diabetes, are younger and have lower HbA1c (48). Therefore, it is important for those with IAH to be taught how to recognise the early warning signs of hypoglycaemia, in order to reduce the likelihood of the occurrence of severe hypoglycaemia. It should be noted, however, that where symptoms actually change or weaken these effects can be reversed by consistent avoidance of hypoglycaemia over a number of weeks (29).

Comparison of patients with and without hypoglycaemia unawareness has also revealed differences in cognitive dysfunction. Gold et al. (51) found those T1DM patients with hypoglycaemia unawareness displayed more abnormal cognitive function during an
episode of hypoglycaemia and following BG recovery than those without hypoglycaemia unawareness. They recommended that skilled tasks should not be carried out for at least 30-40 minutes following BG levels returning to normal. One explanation for Gold et al.’s (51) findings is that those who with IAH experienced a greater number of episodes of hypoglycaemia which therefore impacted on their cognitive functioning. Such evidence goes some way in explaining another long term consequence of hypoglycaemia; cognitive dysfunction.

1.2.4 Cognitive dysfunction
Many studies of T1DM report that hypoglycaemia can have a negative effect on cognitive functioning (41, 52-56). The human brain relies on a source of glucose in order to function optimally (52). Lack of glucose to the brain can lead to cognitive dysfunction, coma and seizures, as a result of hypoglycaemia. Reports suggest that the young are more susceptible to the symptoms of hypoglycaemia due to the fact that glucose deprivation in the brain (neuroglycopenia) may occur at higher glucose levels than in adults (57). Although there are no official reports highlighting what these levels are, studies do report a difference between age groups. Jones et al. (58) compared the glycaemic thresholds of hypoglycaemia symptom onset between adolescent T1DM patients and non-diabetic adults. Results showed that these glycaemic thresholds were much higher for younger participants (4.9mmol.l vs 3.1mmol/l) suggesting that there is a difference in the way that glucose deprivation is experienced by these two distinct groups. Research, however, has primarily been conducted with adolescent vs adults and does not explore the difference between younger and older children (48). The impact of hypoglycaemia on cognitive functioning in children with early onset T1DM can be especially concerning. This group inevitably experiences more severe hypoglycaemic events due to their reduced ability at recognising or communicating the symptoms of hypoglycaemia in order for swift treatment. The fact that those with early onset T1DM have also been diagnosed at an early age means that they are likely to have experienced a greater number of episodes of hypoglycaemia than those diagnosed later in life.
Conversely, the negative effects of hyperglycaemia on cognitive functioning have also been reported (53, 59, 60). Perantie et al. (53) studied the effects of both hypoglycaemia and hyperglycaemia on cognition. Their findings indicate that extreme BG levels (high or low) contribute to differing effects on cognitive functioning. Hyperglycaemia was found to affect verbal intelligence of CYP with T1DM whereas hypoglycaemia had an impact on spatial analysis and was linked with a delay in recall of learned information. This study will be discussed in more detail below. For the purposes of this study the focus will remain on the effects of hypoglycaemia on cognitive functions of CYP.

As previously mentioned, Perantie et al. (53) compared 117 T1DM children (aged 5-16 years) to their non-diabetic siblings (N=58) on cognitive performance. Children who had been diagnosed with diabetes before the age of five performed significantly worse on spatial relations than any other group. These children were also found to suffer more frequent episodes of hypoglycaemia, which highlighted how tight control can adversely affect a child’s cognitive development. The outcomes of this study should be treated cautiously, however, as the retrospective nature of the design does not allow any conclusions to be drawn regarding cause and effect. The sample used in this study was broken down into smaller sub groups which could have also had an impact on the analyses.

Conflicting evidence is reported by Strudwick et al. (61), who investigated the association of severe hypoglycaemia in young children with early onset T1DM with cognitive abnormalities. For this study, severe hypoglycaemia was defined as prior hypoglycaemia seizure/coma. The study compared three groups of diabetic children and adolescents who were diagnosed aged <6 years; one group had a history of severe hypoglycaemia at age<6 years; another group experienced their first severe hypoglycaemic episode after the age of 6 years; the last group was the T1DM control with no history of severe hypoglycaemia. Interestingly, no significant differences were detected between any of the groups on intellectual, memory or behavioural measures. Severe hypoglycaemia, in this study, was characterised only by episodes of seizures or coma and didn’t take into account severe hypoglycaemia without these events. Including a wider range of episodes of severe
hypoglycaemia might have made a difference to the strength of relationships however, researchers would then have had to rely on retrospective and subjective data. Additionally, the small sample size may have impacted on this study’s ability to detect any significant results, although the researchers of this study stress that similar studies have also used comparable sized samples.

Ho et al. (62) used a similarly matched sample of diabetic children (those with a history of SH vs those without a history of SH) diagnosed with diabetes <6 years. Again, severe hypoglycaemia here was defined as a seizure/coma resulting from severe hypoglycaemia. Magnetic resonance imaging (MRI) was used to compare structural differences in the brain, between groups. Although significant differences were not found between the groups, the results of this study indicated that early onset T1DM was associated with central nervous system (CNS) abnormalities. Specifically, mesial temporal sclerosis (MTS) was evident in the entire cohort. MTS is unusual in those without seizure disorders so its presence in itself was an interesting finding. The implications of MTS on the brain are damage to the hippocampus, leading to long term memory deficits and problems with cognitive functions. MRI in children can be problematic due to the fact that these tests require participants to lie very still, in a confined space, albeit for a short period of time. This may have impacted on the quality and usability of the MRI scans (63). However, the study did objectively examine the structural effects of severe hypoglycaemia on the brain of this sample of children.

In spite of research which has focused on the link between severe hypoglycaemia and cognitive dysfunction, the topic remains controversial. McNay and Cotero (52) carried out a mini-review of research specific to the impact of recurrent hypoglycaemia. Their review looked at both human and animal studies and concluded that recurrent hypoglycaemia seemed to induce a positive brain response whereby an increased supply of fuel was directed to the brain, so that cognitive functions were supported rather than impaired. The authors however, also acknowledged that whilst the brain seemed to protect against hypoglycaemia, previous experiences of hypoglycaemia can interfere with the body’s ability to deal with further episodes of hypoglycaemia. Paired with the fact that recurrent
hypoglycaemia also impacts on awareness of hypoglycaemia, there are still major implications of hypoglycaemia on those who are affected.

1.2.5 **Dead in bed**
One of the most worrying consequences of hypoglycaemia, although also the least common, is dead in bed syndrome (64). Before discussing dead in bed further, nocturnal hypoglycaemia and associated anxiety will be discussed.

Hypoglycaemia during sleeping hours can be a source of particular stress for both CYP with T1DM and also their parents because nocturnal hypoglycaemia can often go undetected by patients (32, 65). Previous studies suggest that the incidence of nocturnal hypoglycaemia is in excess of 40% (66, 67). Research has shown how episodes of hypoglycaemia and severe hypoglycaemia can impact on the daily lives of those with T1DM. However, the threat of experiencing hypoglycaemia when asleep and the potential implications can be extremely worrying. Parents and CYP are unlikely to know about the many potential contributors of nocturnal hypoglycaemia considering the fact that it is, arguably a different construct to hypoglycaemia experienced in the day (32). In her paper on nocturnal hypoglycaemia in children with T1DM, Matyka (32) suggests that daytime hypoglycaemia may differ from nocturnal hypoglycaemia due to a number of factors. Firstly, the period of sleep reflects the longest period of fasting for CYP, which will inevitably impact on their BG levels. The characteristics of nocturnal glucose homeostasis (32), physiological changes accompanying the stages of sleep (68) and changes in counter regulatory responses overnight (69), all contribute to how the body reacts to a fall in blood sugar and do so differently when we sleep. Paired with the difficulty of managing insulin delivery during the night suggests that there are differences between daytime and nocturnal hypoglycaemia. Anecdotal evidence suggests that nocturnal hypoglycaemia and associated worry of dead in bed syndrome are very real worries for CYP and parents.
Tattersall and Gill’s 1991 (64) study analysed the deaths of 50 diabetic patients and concluded that 22 out of the 50 had suffered what they coined as ‘dead in bed’ syndrome. These patients were found dead, in undisturbed beds having gone to bed feeling well. Similar reports have been reported for other unexplained nocturnal deaths of diabetic patients. Koltin and Daneman (70) report a case of a 14 year old girl with T1DM. This girl was relatively well, with fair glycaemic control and blood glucose levels within the target range the evening before she died. Although some brain pattern and glucose levels appeared to suggest hypoglycaemia, results were not conclusive and hypoglycaemia could not be given as the cause of death. This suggests that contrary to likely worries about nocturnal hypoglycaemia, these patients did not seem to have experienced a nocturnal hypoglycaemia related seizure. A number of contributory factors, other than hypoglycaemia have been suggested as possible causes of these unexplained deaths, for example, a cardiac event (caused by hypoglycaemia, rises in adrenaline and falls in potassium (resulting from hypoglycaemia) and autonomic neuropathy (whether severe or not) (71). It seems unlikely, given the fact that nocturnal hypoglycaemia can occur frequently, without a patient even realising, that hypoglycaemia alone is the sole reason for dead in bed syndrome. Incidence rates of dead in bed are not particularly high; accounting for between 2-6% of all T1DM deaths (71). However, this does not preclude hypoglycaemia from being a trigger to this unexplained phenomenon.

So, although rare, the ambiguity of the causes of dead in bed syndrome leave parents and CYP with a sense of doubt and therefore, fear of experiencing hypoglycaemia in the night. This fear however, isn’t confined to only nocturnal hypoglycaemia, as will be discussed next.
1.3 Fear of hypoglycaemia in children and young people (CYP) and parents

Considering that the symptoms and potential outcomes of hypoglycaemia can be extremely distressing, it is no wonder that patients can develop a fear of hypoglycaemia (FoH) and try to avoid this state by maintaining higher BG levels (72). Higher BG levels seem to have no immediate consequences but in the long term can lead to microvascular complications, leading to morbidity or mortality. Nordfelt and Ludvigsson (73) reported that SH with unconsciousness causes more fear in patients than does the development of possible later complications of diabetes mellitus, which suggests important implications for diabetes management. Despite the apparent need for further research into FoH in the paediatric population, studies are limited in number. Although there is some focus on research into FoH in adolescents and children (72, 74), much of the research on these age groups looks at parental FoH (72, 75-78). As with studies in adult diabetes patients, paediatric studies have shown that FoH is linked with past experiences of hypoglycaemia (72, 79, 80) and can have consequences for long term management of the condition.

1.3.1 The Hypoglycaemic Fear Survey

The Hypoglycaemic Fear Survey (HFS), adapted for use by children and parents (75), is commonly used to assess the presence of FoH in the paediatric population. Green et al. (79) evaluated the use of this measure in children and adolescents and reported good validity and internal consistency reliability. Importantly, this longitudinal study also identified the transient nature of FoH, which suggests that FoH actually changes over time and is not a stable construct. This significant finding suggests that potentially a number of factors could contribute to FoH, and any variation in contributory factors will impact on FoH in individuals. It is therefore important to identify stressors and try to reduce these, in order to try to reduce FoH and allow CYP to maintain optimum BG levels. Reviews of subsequent studies looking at the HFS as a measure of FoH (74, 81) showed that the measure was found to have good internal reliability, good validity and researchers were able to evaluate interventions aimed at reducing FoH by comparing HFS scores before and after the intervention.
The prevalence of FoH is difficult to determine, considering that it is a transient construct. However, FoH studies worldwide have been carried out in the paediatric population with a view to understand FoH, contributory factors, impact of FoH on CYP’s lives and interventions aimed at reducing FoH.

1.4 Predictors of fear of hypoglycaemia

Diabetes researchers have tried to identify whether or not fear of hypoglycaemia can be predicted. Implications for such findings could help to improve diabetes management in those affected.

1.4.1 Severe hypoglycaemia as a predictor of fear of hypoglycaemia

Irrefutably, the majority of studies investigating FoH regard previous experience of hypoglycaemia, specifically severe hypoglycaemia, to be a contributory factor. Irvine et al. (80) studied the impact of hypoglycaemia on fear in adult patients using the HFS. They found that scores on the HFS correlated positively with stress and previous experience of hypoglycaemia. This was reflected in similar studies which all highlighted the key relationship between FoH and previous experience of hypoglycaemia (82). Reports from studies focusing on the paediatric population also suggest that a history of hypoglycaemia is consistent with incidence of FoH (72, 74, 83). Gonder-Frederick et al. (72) investigated predictors of FoH in an adolescent group (and their parents). Researchers collected data on the experience of moderate and severe hypoglycaemia, FoH, anxiety and HbA1c. Results indicated that previous experience of severe hypoglycaemia significantly predicted higher FoH in this paediatric group, however, there were no significant links found between FoH and metabolic control. This conflicts with studies that suggest higher FoH levels can contribute to poor diabetes management (higher BG levels) and consequently impact on long-term health outcomes (76, 83, 84). Parental FoH for this sample was predicted by whether parents believed that their child carried emergency glucose with them. Again there was no significant relationship between adolescent HbA1c and parental
FoH. Gonder-Frederick et al’s (72) study was limited in that only 39 parent-child dyads took part in the study and only one of these was a father-child pair. Researchers suggested that a larger sample might find stronger relationships between the collected data.

As mentioned earlier, fear of hypoglycaemia in paediatric and adolescent diabetes is reported by patients’ parents. Studies show that parental FoH for their child can actually be greater than adult patients have for themselves. This was demonstrated in a study of mothers of children with T1DM by Clarke et al. (75) who found that mothers of children who had episodes of SH with unconsciousness scored highly on the HFS. Studies examining parental FoH in parents of adolescents have produced contrary results, to those in young children. Gonder-Frederick et al. (72) found that although adolescents with a history of SH with unconsciousness had higher HFS scores and higher HbA1c than those with no history, this did not translate over to their parents. The only predictor of parental FoH in this study was whether their child carried emergency glucose or not. This suggests that parents were less fearful if they believed their child was equipped to treat an episode of hypoglycaemia. It also indicates that parents of adolescents might be less fearful than parents of younger children because they might believe that their older children are more likely to be able to treat hypoglycaemia than younger children. This is supported by the work of Hawkes et al. (84) who reported that FoH was highest amongst parents of 6-11 year olds. However, Hawkes et al. (84) therefore, also reported that FoH in parents of 6-11 year olds was higher than younger age groups. This is surprising, however, with further thought it could be that parents of primary age children have a greater fear because they feel their child is not old enough to take complete responsibility for managing hypoglycaemia, but it is also at this age where parents potentially lose the control that they may have had before their child started school (85). Parents are most likely to be the main caretakers of children younger than primary age and therefore might feel less fear because their child is with them the majority of the time.

Although Gonder-Frederick et al.’s (72) study aimed to examine parental FoH, only one father participated, therefore results can only be applied to maternal FoH. In studies
comparing mother and father reports of FoH, however, mothers reported higher FoH than fathers (86). Overall, higher parental HFS worry scores were associated with higher HbA1c levels and a higher frequency of problematic hypoglycaemia. This illustrates that although mothers are likely to be the main caregivers (87) and therefore might report higher FoH levels than fathers, fathers also report FoH.

### 1.4.2 Anxiety as a predictor of fear of hypoglycaemia

Another variable commonly associated with FoH is anxiety, in both CYP and parents. Gonder-Frederick et al. (72) reported trait anxiety to be a predictor of FoH in adolescents, however, found no such relationship between parental trait anxiety and FoH. Herzer et al. (88) also reported a significant association between anxiety in adolescents and suboptimal management of diabetes, suggesting that anxiety may be linked to hypoglycaemia-avoidance behaviours (as measured by the HFS measure). Jaser et al. (89) reported significant links between maternal FoH and maternal state anxiety in mothers of children aged less than 8 years old and more recently Pate et al. (87) found significant links between maternal and paternal FoH and trait anxiety (in parents of children aged 7-17 years). These findings suggest that FoH may be influenced by how anxious an individual is, which could have implications for reducing FoH and diabetes management. However, as these studies are cross-sectional in design it is not possible to conclude what the cause and effect are.

### 1.5 Impact of fear of hypoglycaemia

The impact of FoH on diabetes management has already been mentioned. This will be discussed further. There are a number of other ways in which FoH can impact on both CYPs’ and their parents’ lives.

#### 1.5.1 Fear of hypoglycaemia and diabetes management

There has already been some discussion of the association between FoH and BG levels suggesting that those with higher FoH also report higher BG levels, potentially as a result
of trying to avoid hypoglycaemia (83, 84). Anecdotal reports suggest that patients (or parents) will try to avoid hypoglycaemia, as a result of their fear, by maintaining higher than optimal BG levels. In a case study reported by Matyka (90) diabetes management of a 12 year old girl with no history of severe hypoglycaemia was managed by her mother, who had witnessed severe hypoglycaemia in her ex-partner. This had led to anxiety and fear in the mother who consequently managed her daughter’s diabetes by maintaining higher BG levels, eventually resulting in the early stages of diabetic retinopathy. This case study goes some way in illustrating the impact that FoH can have on patients and their families.

Marrero et al. (91) wanted to address the impact of parental FoH on children and adolescents with diabetes. They referred to parents’ suboptimal management of their child’s diabetes i.e. maintaining high BG levels in order to avoid hypoglycaemia and reduce their own FoH, as an example of negative reinforcement (carrying out behaviour in order to reduce a particular outcome). This hypothesis was supported by the fact that children of parents with greater FoH had a greater percentage of self-monitored blood glucose (SMBG) values above the target range. Young children who had experienced a sudden loss of consciousness (SLC) due to a SH had significantly higher BG values than those with no SLC history. This is despite the fact that there were no significant differences in the percentage of SMBG results below the specified range. Results here suggest that parents might have been maintaining high BG levels in their children in order to avoid hypoglycaemia. Patton et al.’s (76) research supports this suggestion. They found that the HFS Behaviour scores of parents of young children treated with continuous subcutaneous insulin infusion (CSII) correlated positively with HbA1c 3 months after study enrolment. They also found a significant positive association between parent Worry scores and child’s daily BG control. These results show that higher parental HFS behaviour and worry scores indicate higher blood sugar levels, which could suggest that parents with higher FoH are those who also maintain higher BG levels in order to avoid hypoglycaemia in their child (78).
Similar reports were presented in studies looking at the analysis of cohorts of children and adolescents together (87, 92). Higher parental HFS worry scores were associated with higher HbA1c and higher frequency (≥7) of problematic hypoglycaemia in CYP aged 1-15 years (86). The perceived impact of FoH on diabetes management suggests there may be an impact on self-care behaviours. However there is a paucity of research looking at diabetes self-care and FoH.

Although the above reports indicate a link between FoH and HbA1c, these findings are inconsistent. A number of studies have been unable to find an association between FoH and HbA1c (75, 79). These inconsistencies may be explained by the fact that HbA1c is in itself is likely to be impacted by a number of variables such as hormones, puberty (during puberty, insulin action can decrease by 30%-50% therefore, an adolescent’s HbA1c may be affected by these changes (93) and even the weather (warmer months have been linked to lower HbA1c and vice versa (94). Therefore, it is difficult to conclude that even where significant relationships have been reported that there are no other attenuating factors impacting on this relationship.

Interestingly, Stallwood (95) found greater perceived diabetes related stress was related to better metabolic control. It seems then for some parents, trying to maintain optimum BG levels in their children can trigger stress which worryingly suggests that parents of children with T1DM suffer from anxiety and stress whether they are achieving tight control of diabetes management or not. The impact of diabetes on parents will be discussed further later in this chapter.

1.6 Detection of hypoglycaemia by parents

It is important to note that detection of an episode of hypoglycaemia in children, by their parents, is not always accurate. Therefore, parents could either mistakenly correct hypoglycaemia or not recognise the symptoms of low BG levels, leading to SH. Incorrect detection could lead to hyperglycaemia or an increased number of episodes of severe hypoglycaemia, which is a predictor of FoH. Bognetti et al. (38) interviewed patients and
parents about the occurrence of SH over a 3 year period. They found that the number of episodes of hypoglycaemia decreased significantly with increasing age. Therefore, it seems that the risk of severe hypoglycaemia was higher in young children than in adolescents. One explanation for this is that parents might not always have been successful at detecting hypoglycaemia in their younger children and so were unable to treat hypoglycaemia appropriately. In order to detect hypoglycaemia in younger children, who may not themselves be able to recognise the symptoms and inform their parents, parents need to be aware of physical symptoms of hypoglycaemia e.g. mood changes, sweating, shaking. Gonder-Frederick et al.’s (72) field study found that children aged 6-11 years failed to correctly identify hypoglycaemia a large proportion of the time. Such findings only add to the burden and stress on parents of CYP with T1DM.

1.7 Parental anxiety and diabetes

Parental anxiety is especially evident in mothers of young children with T1DM (89, 95). Jaser (89) reported that mothers of young children (aged less than 8 years old) with T1DM were found to have clinically significant levels of anxiety and depression. These symptoms were typically linked to feelings of being unable to cope with their child’s diagnosis and were related to maternal FoH, however, they were not associated with glycaemic control. Anxiety experienced by fathers of young children with T1DM does not appear to be as common (96). Paternal stress was correlated with fathers’ lower self-efficacy, high FoH and higher state anxiety. This suggests that for fathers there is a link between high FoH and high anxiety.

Although much of the research into parental anxiety concerns parents of young children with T1DM, maternal anxiety in mothers of adolescents with T1DM is also reported (92). Links between maternal trait anxiety and higher HbA1c were reported for mothers of younger adolescents. This suggests an association between high anxiety and CYP HbA1c. As stated previously, research looking at the link between parental FoH and CYP HbA1c is inconclusive; however, parental anxiety might also play a role in this association and should be investigated further. Moderate levels of anxiety and stress might actually
mediate the levels of FoH and be motivating factors in achieving good glycaemic control (95), however at some point excessive stress/anxiety might be maladaptive in diabetes management. Recent research supports the idea of FoH, anxiety and glycaemic control being related, for parents of CYP with T1DM (87). It will be interesting to investigate this relationship further.

1.8 Additional effects of T1DM on parents of CYP with T1DM

Aside from anxiety and FoH parents seem to suffer from additional psychological effects as a result of their CYPs’ diabetes. The effects of diabetes on parents are apparent from diagnosis (97). There is a huge impact from learning that your child has a chronic illness.

As a result of the often sudden onset of T1DM and resulting threat that the condition presents, studies report the presence of post-traumatic stress disorder (PTSD) in parents of young children newly diagnosed with T1DM. A pilot study by Landolt et al. (98) found that 24% mothers and 22% fathers met the full diagnostic criteria for current PTSD, using self-report measures. Based on the outcomes of the pilot study Landolt et al.’s (99) prospective study supported reports of PTSD for mother and fathers. Results also showed that the number and severity of parental PTSD decreased in the 12 months after the child’s diagnosis.

However, PTSD diagnoses should be made with caution, especially when using self-report measures. Using a structured clinical interview, Stoppelbein and Greening (100) found that only seven per cent of their sample of mothers of children diagnosed with T1DM met the criteria for PTSD. Researchers suggested that previous studies may have reflected acute stress symptoms rather than PTSD, given that others were assessed a month after their child’s diagnosis.
Following diagnosis, parents may experience further psychological difficulties in coping with their child’s illness. Considerable research has been conducted on the mothers, usually the primary caregivers, of CYP with T1DM and the impact that their child’s diagnosis has on them (92, 101-103). The burden of the responsibility of care for their child is often overwhelming for mothers and seems to continue from diagnosis and beyond (104). Bowes et al. (105) explored the long-term impact of CYPs’ diabetes diagnosis on parents. They found that even in the long-term mothers had not necessarily accepted their child’s diagnosis and still felt the emotions that they had felt when their child was first diagnosed, such as, grief and anger. Fathers too reported these feelings. Bowes et al. (105) confirmed the existence of chronic sorrow in parents of children with T1DM, an intermittent experience of grief, which highlights the impact of diabetes on parents. Similarly, in another qualitative study with mothers of children with T1DM, Sullivan-Bolyai et al. (101) reported that mothers had an overwhelming amount of responsibility for the care of their children and there was often no break from the constant diabetes care they had to provide.

The constant pressure and burden on parents of children with T1DM will naturally have implications for parents’ health and well-being; both physical and mental. This adds to the impact that T1DM can have on the families of children diagnosed with the condition.

1.9 CYP quality of life and diabetes
It is important to assess quality of life (QoL) and its association with T1DM. As a chronic disease, T1DM is likely to have a big impact on the day to day lives of patients. Assessing how the illness impacts on diabetic CYPs’ QoL may allow us to understand the psychological impact of living with diabetes. It could help to identify the best way of managing the illness in a way that QoL is not compromised or if it is then at least to a minimum.
Kalyva et al. (106) reported that CYP had lower general health-related QoL than matched healthy participants. Later onset, less hyperglycaemic episodes, lower HbA1c, older age and male gender were associated with better diabetes-specific health-related QoL. Parents reported diabetes had a greater effect on CYPs’ lives than CYP reported themselves suggesting that parents potentially worry more about the impact of diabetes and consequently attribute more weight to the impact of diabetes on their children. As previously reported, the impact of diabetes on parents is great and so might reflect on their impressions of their child’s QOL (101, 104).

The association between QoL and metabolic control has been explored in a number of paediatric studies however results have been largely inconclusive. It was the international, multi-centred HvidØre study group (107) who were able to explore this relationship on a large scale. Results indicated that better metabolic control was associated with better QoL in adolescents. Although the study cannot infer cause and effect it does have important implications for the management of diabetes for this age group. The findings were unprecedented on such a large scale and further exploration might clarify the role of QoL in diabetes management. Subsequent studies also supported reports of the link between QoL and metabolic control (108-110) which suggests that QoL is an important factor in living with diabetes.

Johnson et al. (83) explored the relationship between QoL and fear of hypoglycaemia. Results suggest that increased FoH relates to a lower QoL in CYP with T1DM. Interestingly, even parents with higher FoH reported lower QoL for their children. This is yet another aspect of the impact that diabetes can have on QoL. However, again cause and effect cannot be inferred from cross-sectional data, and largely research in this area is not designed to overcome this issue.
Interventions aimed at intermittently measuring QoL in CYP and addressing any issues, do show improvement in health-related QoL of CYP with diabetes (111). Similarly, adjustments to insulin regimen have also shown an improvement in the reported QoL of CYP (13, 112). Considering the impact that diabetes has on QoL in CYP (and potentially vice versa), it is important to acknowledge the ways in which it might be improved.

1.10 CYP self-care and diabetes
Although CYP self-care behaviours are vital to achieving optimal glycaemic control, there seems to be a lack of research in this area. This is reflected in Hood et al.’s (113) meta-analysis of studies looking at the association between adherence and glycaemic control in CYP with T1DM. Their findings showed that as adherence to diabetes-related self-care behaviours increases, HbA1c levels have been shown to decrease (across studies between 1950 and 2008).

Given the implications of increased adherence on glycaemic control, improving or sustaining adherence to self-care diabetes should be encouraged amongst CYP with T1DM. La Greca et al. (114) reported that increased adherence was related to support from friends and family for both practical and emotional aspects of diabetes management. Although supported by later studies which reported that parental monitoring of self-care behaviours also improved glycaemic control in adolescents (115), conflicting results have also been reported. Shroff Pendley et al.’s (116) research suggested that adolescent perceived support (from peers) did not correlate positively with metabolic control (as measured by HbA1c), suggesting that peer support in adolescence might not be conducive to adherence to diabetes-related self-care. Importantly, in the case of family support, increased diabetes conflict (areas of family conflict in diabetes management tasks) is a key predictor of poor metabolic control (117). Therefore, optimal self-care behaviours appear to be achieved by increased family/parental support and reduced familial (diabetes-related) conflict.
Links between the fear of hypoglycaemia and poor metabolic control suggest that FoH may have an impact on self-care behaviours (83, 84). A reduction in FoH was reported for those CYP who were able to manage their diabetes independently, albeit with social support, following repeated attendance at a diabetes camp (118). This suggests that there is an association between diabetes self-care and FoH.

1.11 Qualitative research

Qualitative research allows exploration of data at a deeper level. It can often provide richer information, which otherwise might be difficult to attain. Qualitative data for CYP with T1DM is limited however, it is supported by research with parents of CYP with T1DM. Often the primary caregivers, parents are able to report on CYPs’ experience of diabetes, as well as their own. Qualitative research for both CYP and parents has concentrated on various areas including living with diabetes (119-124), diabetes management (125-127), impact of diabetes (101, 104, 105), fear of hypoglycaemia (65) and insulin regimens (128-130).

Parents’ experiences of their child’s diabetes have been explored to clarify how the diagnosis of a chronic condition affects them. Research highlights the many issues parents seem to face as a result of their child’s diagnosis. Flynn’s paper on parental coping highlighted the issues that parents of CYP with T1DM face (104). A key issue was the responsibility parents have for their younger child’s diabetes care, which can often be an overwhelming prospect. As their child approaches adolescence there is then a need for a shift in responsibility to the young person so that they can approach their own care independently. This can be a source of anxiety for parents who might struggle in letting go of the responsibility of diabetes care for their child. Parents report feelings of anxiety, upset and distress (105) as well as being burdened with the responsibility for their child’s health (125). Bowes et al. (105) conducted in depth interviews with parents of CYP with T1DM. These parents reported feelings of grief and guilt up to 10 years after their child’s diagnosis with some parents becoming visibly distressed when recalling this period.
Bowes et al’s (105) findings highlight the profound long term effect that T1DM can have on parents and support the notion of ‘chronic sorrow’ in this group. ‘Chronic sorrow’ refers to recurring feelings of sadness, resurfacing amongst seemingly ‘normal’ and happy periods, with no endpoint. Triggers at certain timepoints caused parents to experience the sadness they had experienced when their child was initially diagnosed. Although this study included both mothers and fathers, researchers reported that fathers were less likely to talk about their emotions. The fundamental learning point was the lack of emotional support provided to parents who continue to experience these feelings of grief, years after their child is diagnosed. This highlights the need for ongoing emotional support for these mothers and fathers.

Smaldone et al. (125) investigated parental perspectives of a T1DM diagnosis in parents of children diagnosed aged 5 years or younger. Parents reported feeling overwhelmed with the responsibility of care as well as feeling isolated from friends and family who did not understand what they were going through. This aspect of feeling overwhelmed and being given responsibility for the daily medical care of your child reoccurred throughout many of the qualitative studies (101, 105, 128) which again highlights the impact of living with a child with T1DM, on their parents.

Studies focusing on parents and children as a family unit report interesting results. CYP and parents were reportedly affected to differing degrees by T1DM, three years after diagnosis. Wennick et al.’s (122) longitudinal study found that at three years post diagnosis, children and their parents felt that they had successfully integrated diabetes management into their day to day lives. Parents tried to encourage independent behaviour with regards diabetes management in their children, whereas CYP were quite happy for their parents to assume responsibility for their care. Other studies explored the conflict between parent and child in terms of autonomy and diabetes management (121, 123). Ivey et al. (121) found that parents reported worrying about future complications and did not want any regrets later in terms of how they or their child had managed their
Parents also seemed frustrated with the lack of optimal diabetes control that young people displayed whereas young people were similarly frustrated when their parents did not notice when they did do things well. On a similar note, Spencer et al. (123) found that when parents tried to ‘let go’ and give their children the responsibility of managing their diabetes, that this resulted in poor self-management. Conflicting priorities and feeling self-conscious were often blamed as reasons for less than optimal diabetes care. Using qualitative methods, researchers were able to further explore the feelings and emotions of CYP who were trying to move towards being more independent but whose parents’ diabetes-related fears made this difficult. Other studies report on the shared experiences of diabetes between families at different stages of living with diabetes; the fact that the condition has a significant impact on both parents and children (4-17 year olds) (124). For example, there were references to the effects of treatment on both the parent and the child. Both parent and child reported the difficulty associated with the painful injections with children reporting the pain they felt receiving them and parents reporting the pain they felt administering them. Although their lives had changed, both parents and children tried to make adjustments so that life was ‘normal.’ In their review of qualitative studies with adolescents, Spencer et al. (120) systematically evaluated all such research conducted between 1988 and 2008. By integrating the results of appropriate studies, four sets were identified. These indicated the most common findings and were made up of (i) independence and autonomy for diabetes management; (ii) living with T1DM; (iii) family relationships and (iv) diabetes care. Bearing in mind that the findings of the systematic review were limited to studies published in English and that there were gaps in some of the papers, authors concluded that, for adolescents, some of the key topics of concern were the struggle for autonomy and taking responsibility for diabetes management (120). These struggles were reduced somewhat through peer understanding, parental support and encouragement of autonomy. Qualitative research on the subject of the fear of hypoglycaemia is limited. Scott’s (65) doctoral thesis explored FoH in mothers of children aged 9-10 years. The clear message from mothers was that hypoglycaemia was indeed a large source of worry. They feared the worst and worried that their child would not wake up from an episode of hypoglycaemia. There were references to anxiety at being away from their child as well as feelings of guilt and
sadness. Although carried out with only four mothers, this in-depth account of FoH is key
in qualitative research as it is the first to address FoH in parents and inspires further
research to understand the true impact of FoH on families and CYP.

1.12 Current research study

Given that research in the T1DM paediatric population is relatively limited in the UK, this
study will focus on CYP and their parents in order to understand how living with diabetes
impacts on them.

The aims of the current study are to establish the prevalence of hypoglycaemia, and
consequently fear of hypoglycaemia in this UK sample. This is an exploratory,
observational, cross sectional study to allow us to further understand hypoglycaemia in a
paediatric population and explore the implications of this on our sample of diabetes
patients and their parents. Although similar studies have been conducted in other
western countries, namely the USA and Australia, the differences in healthcare provision
and diabetes management highlights this UK sample to be a distinct and appropriate
sample for further investigation.

Firstly, it is important to identify the prevalence of hypoglycaemia in this sample. This will
be achieved by collecting data on the frequency of hypoglycaemia and the experience of
episodes of severe hypoglycaemia. Although this data will be collected retrospectively,
which is not ideal, it will allow exploration of the prevalence of hypoglycaemia in a large
sample. This study appears to be the first UK study to investigate prevalence of
hypoglycaemia in a large cohort of children and adolescents with Type 1 diabetes.
Establishing whether hypoglycaemia is a problem for this sample will allow further
investigation of any links between the prevalence of hypoglycaemia and fear of
hypoglycaemia.
Hypoglycaemia awareness will also be assessed in adolescents in order to confirm whether they are experiencing the warning signs of hypoglycaemia. Lack of awareness of the warning signs could lead to adolescents being more likely to suffer from severe episodes of hypoglycaemia. This could be related to the prevalence of FOH. This is amongst the first UK studies to investigate hypoglycaemia awareness in adolescents.

Examining the fear of hypoglycaemia in this cohort of CYP and parents will help us to understand how much of a problem FoH is in this UK sample. Importantly, this study will look at how FoH might contribute to glycaemic control, as studies in other countries report conflicting data (75, 79, 83, 84). To my knowledge this will be the first study to examine fear of hypoglycaemia as a predictor of glycaemic control in UK children. This information will improve our understanding of the impact of FoH on glycaemic control and the possible barriers to appropriate diabetes self-care. It is likely that this will be an important factor to assess when considering children and families for intensification of insulin therapy. It is anticipated that using this information relevant and effective educational interventions may be designed to prevent / modify FoH that may become / be maladaptive. As there is little T1DM literature/research in the paediatric population the current study will contribute to FoH research that has mainly focused on adults.

Further to the prevalence of hypoglycaemia and FoH, this study will also collect data on psychosocial factors related to T1DM. Links between FoH and anxiety in adolescents have previously been reported (72). Therefore, it is sensible to explore anxiety in this sample as anxiety traits may underpin FoH.

Experience of hypoglycaemia and FoH is likely to impact on QoL and self-care behaviours in this cohort (74, 83). Investigating the links between these variables will help to understand these relationships and potentially understand their impact on diabetes.
management. Again, this is an area that has not been extensively researched in UK paediatric populations.

Further to studying UK children with T1DM, this study will also investigate parental FoH and associated anxiety. Previous research indicates that parents of CYP with T1DM report elevated FoH and anxiety (87) so it is important to establish whether this is true for a UK sample. Most research on parents in this area tends to focus on the mothers (75, 91) so this study will aim to collect data from both parents to add to the growing literature (86, 87) and give an insight into paternal experiences too.

In order to gain a more in depth understanding of the experience of hypoglycaemia and FoH in CYP and parents, qualitative interviews will be carried out. Previous qualitative research in this area tends to focus on parental views, although there are limited qualitative studies looking at CYP perspectives. Qualitative interviews specifically looking at hypoglycaemia and FoH are minimal. It appears that only one qualitative study focussing on FoH has been published (65). This particular study used interpretative phenomenological analysis techniques so only engaged a small sample (four participants) who were all mothers of CYP with T1DM. The current study will aim to get views from a larger sample of CYP as well as parents, specifically on the impact of hypoglycaemia and FoH, with a view to adding to published research in this area.

**Aims**

To collect data regarding:

1. The prevalence of episodes of hypoglycaemia in a large group of children and young people with diabetes attending the clinical services within the West Midlands;
2. The prevalence of FoH among children / adolescents and their parents and the relation to glycaemic control, previous experience of severe hypoglycaemia, diabetes related quality of life, trait anxiety and self-care;

3. The impact of episodes of hypoglycaemia on the family using qualitative interviewing in a subset of subjects from differing age groups: adolescent, primary school children.

It is anticipated that the outcomes of this research study will increase knowledge and contribute to existing findings into the prevalence of hypoglycaemia, FoH and possible related factors, by focusing on the paediatric population and their parents, in the UK, where diabetes management is different to that in the US or Europe and for which there is limited research. Implications of this research could lead to the development of a hypoglycaemia management programme for children, adolescents and their parents.
Chapter 2 Method

Phase 1: Quantitative research method

2.1 Design

A mixed-method cross-sectional design was used for this study. This is the first UK study, to my knowledge, looking at the fear of hypoglycaemia in both children and young people and their parents, in conjunction with potentially related biological and psychological factors, including frequency of hypoglycaemia. It is important to initially ascertain the prevalence of hypoglycaemia before investigating FoH in this sample. The study replicates aspects of extensive FoH research carried out in the U.S. by Gonder-Frederick et al. (72).

Questionnaires were used to collect quantitative data with regards to the fear of hypoglycaemia and living and coping with diabetes. Subsequently, the data were analysed using SPSS and factors needing further exploration were noted. The factors that were identified were those that had produced significant findings from the current study and previous studies looking at FoH. These key factors included FoH, knowledge of hypoglycaemia, strategies for coping with hypoglycaemia and potential strategies for improving support for young people with Type 1 diabetes, frequency of hypoglycaemia, and living with diabetes. They were used as a basis to form topics for discussion and subsequently to form questions for the semi-structured interviews. CYP and parents, who had previously completed the questionnaires, were invited to take part in the interviews.

2.2 Sample

Two hundred and ten children and adolescents (CYP) aged 3-17 years took part in the study. At least one parent was also invited to take part. Fifty-two fathers and 138 mothers participated in the research study. One hundred and sixty children had at least one parent complete the questionnaire, of these, 30 children had both parents complete questionnaires.
Patients were recruited from five Diabetes outpatient clinics in the Midlands, United Kingdom; University Hospitals Coventry and Warwickshire (UHCW) NHS Trust Coventry, UHCW NHS Trust Rugby, Heartlands Hospital Birmingham, George Eliot Hospital (GEH) Nuneaton and Leicester Royal Infirmary (LRI) Leicester.

In order to be eligible to take part in the research study CYP had to meet the following inclusion criteria:

- Be aged between 2-18 years
- Have had T1DM diabetes for at least 12 months
- Have no other co-morbidities that may influence responses i.e. diabetes with cystic fibrosis
- Have no specific conditions/learning disabilities which prevent them from understanding/completing the questionnaires i.e. autism.

For those CYP who were eligible to take part, reasons for non-participation included unwillingness to take part, language problems, reading difficulties, concerns/anxiety around answering some of the questions and the effect that this possibly may have on the CYP/parent, family problems, bereavement in the family.

The reasons for not returning the questionnaires included participants forgetting to return the questionnaires, not having the time to complete the questionnaires, and taking part in the study was not a priority so packs were not completed or returned. Reasons for not completing questionnaires when waiting in clinic were that participants ran out of time and also that they did not want to face potential parking charges by staying longer to complete the questionnaires.
Due to ethical reasons it was not possible to collect demographic data on those CYP/parents who refused to participate in the current study. Therefore, it is not possible to assess whether there were any significant differences between those who agreed to participate and those who declined.

2.3 Overview of recruitment issues

Between September 2008 to September 2009 data collection was completed at UHCW NHS Trust (Coventry) and Rugby Hospital. During the following months, those patients who had taken questionnaires away to complete at home but had not yet returned them were approached for a second time in order to identify whether they still wanted to take part in the study. Data collection was carried out at Heartlands Hospital between the end of February 2009 and end of October 2009. Patients at George Eliot Hospital (GEH) were invited to participate in the research study from August 2009 until October 2009. Data collection continued at GEH in February and March 2011, after I returned from maternity leave. Patients at Warwick Hospital were approached to take part in this study by their lead consultant who passed on the details of those who wished to take part. These patients agreed to complete questionnaires via post, in light of my maternity leave. Unfortunately as the lead consultant retired during the research study and no permanent replacement was identified it was agreed that it was best to exclude data from patients at Warwick hospital. Data collection was completed at Leicester Royal Infirmary between September 2010 and March 2011. Quantitative analysis of data commenced in May 2011. The majority of the interviews were also transcribed during this time. I then went on maternity leave from September 2012 until August 2013. Quantitative analysis continued in December 2013 and qualitative analysis commenced in September 2015. The final write up of the thesis was undertaken between December 2014 and September 2016.
2.4 Research with CYP

2.4.1 Conducting research with CYP

Conducting research with children and young people is not as straight-forward as research with adults. Not surprisingly, merely trying to get access to CYP in order to discuss the research comes with its own difficulties. There are often gatekeepers (e.g. parents, clinicians, teachers) whom the researcher will likely have to negotiate with in the first place (131). Once this has been achieved then CYP and their guardians must consent to taking part in the research to ensure that a child is not taken advantage of. The researcher must be as certain as possible that the child or adolescent is aware of what is being asked of them and fully understands their role in the research. The researcher must also be aware of the power difference between a child and adult and how this could influence consent to take part in the research (132, 133). Parents may also take the decision away from the child, deeming the research too sensitive or the child too young to take part without giving the child the option of participating in the research (133, 134). Once the guardian is happy for the researcher to approach the child the researcher must be sure that the child/adolescent is also happy to take part in the research before moving to the next stage.

2.4.2 Informed consent

A number of considerations must be taken into account when working with CYP, such as a child’s age, literacy and understanding amongst other things. CYP should be presented with information about the research they might potentially be involved in, in a way that they will be able to understand their involvement, their role, implications of taking part in the research and also their rights as participants (133, 135). Once CYP feel that they are happy with the information they have received and have asked any questions they need to they can then give their informed consent. Researchers need to ensure that CYP are happy to participate throughout the study (135). In addition to the differences between children and adults, those conducting research should be aware of the differences
between children and adolescents and even between age groups within these categories. The age groups targeted for research should inform the type of methods employed for the research study, where possible. Younger children are likely to benefit from a nurturing approach, whereby the researcher presents the research topics/questions in an informal way to try to reduce any power differences. Similarly, the power difference should also be taken into consideration with adolescent groups and the researcher should try to provide an inviting and non-judgemental setting for this research. However, adolescents might be more independent and forthcoming with their views, than younger children. It should be noted that not all CYP will fit the assumed level of understanding and autonomy for their age group so researchers must be aware of individual differences and adjust their methods accordingly.

2.4.3 Confidentiality & the right to withdraw

All participating parents and CYP should be assured of confidentiality when consenting to take part in the research study as well as the fact that confidentiality could be broken if the researcher believes the child to be at risk of harm. These steps were followed for the present research study. No patient identifiable data were present on any of the measures completed by participants. CYP were each assigned a unique code with a linked unique code for each associated parent that took part. Participant codes and associated participant details were stored on a password protected file. Consent forms were kept separately from completed measures, in a locked filing cabinet.

All participants were informed of their right to withdraw from the study without any impact on their medical care. I was required to undergo enhanced CRB checks and had honorary contracts in place at each of the NHS Trusts I recruited at to ensure the safety of participating CYP, especially since they are considered ‘vulnerable’ participants. Ensuring CYP were fully informed about all aspects of the consent process and their role as participant, ensured good ethical practice.
2.4.4 Research paradigms: mixed method approach

A mixed-methods approach was taken for this research study. In terms of research with CYP, this approach provided a varied method of data collection (132). Methods using questionnaires as a form of data collection often draw forced responses from CYP, whereas interview methods allow further exploration of the topic and allow CYP to elaborate, describe feelings and emotions and also give CYP the platform to tell their story. Other methods of data collection which can be helpful in research with children and young people are free responses to questionnaires (written), drawing pictures to help explain or describe opinions and feelings and taking photographs (132). This two-pronged approach gives CYP various mediums through which to express their opinions, in a way that they feel most comfortable and in a way that allows broad exploration of topics (136). For this study, starting with a self-report method of data collection was perhaps less daunting and gave CYP the opportunity to understand the topic of the research without feeling under pressure to provide their own thoughts or opinions. Those who then wished to talk about the topic further were given the chance to do so in a relaxed manner whereby the researcher tried to make the CYP feel more comfortable by presenting the interview less formally and more like having a chat.

2.5 Measures

Questionnaires were completed by CYP and their parent(s) whilst they waited to attend their regular clinic appointment. Questionnaire packs took approximately 30 minutes to complete. On occasion the questionnaires were taken home to complete and posted back to the researcher. Some families preferred to complete their questionnaires at home. Figure 1 below outlines the content of the questionnaire pack for each age group participating in the study. Questionnaires can be found in Appendices 1-9.
**Figure 1: Questionnaire packs by age group**

<table>
<thead>
<tr>
<th>13-18 years</th>
<th>11-12 years</th>
<th>8-10 years</th>
<th>5-7 years</th>
<th>2-4 years</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CHILD:</strong></td>
<td><strong>CHILD:</strong></td>
<td><strong>CHILD:</strong></td>
<td><strong>CHILD:</strong></td>
<td><strong>CHILD:</strong></td>
</tr>
<tr>
<td>PedsQL 13-18</td>
<td>PedsQL 8-12</td>
<td>PedsQL 8-12</td>
<td>PedsQL 5-7</td>
<td>None</td>
</tr>
<tr>
<td>Frequency of hypoglycaemia</td>
<td>Frequency of hypoglycaemia</td>
<td>Frequency of hypoglycaemia</td>
<td>None</td>
<td></td>
</tr>
<tr>
<td>Hypoglycaemia Fear Survey</td>
<td>Hypoglycaemia Fear Survey</td>
<td>Hypoglycaemia Fear Survey</td>
<td>None</td>
<td></td>
</tr>
<tr>
<td>State-Trait Adult Self-care inventory</td>
<td>State-Trait Child Self-care inventory</td>
<td>State-Trait Child</td>
<td>None</td>
<td></td>
</tr>
<tr>
<td>Awareness survey</td>
<td>Awareness survey</td>
<td>Information sheet 6-10</td>
<td>None</td>
<td></td>
</tr>
<tr>
<td>Information sheet 11-18</td>
<td>Consent 16-18</td>
<td>Assent U16</td>
<td>None</td>
<td></td>
</tr>
<tr>
<td>Consent 16-18</td>
<td>Consent 11-18</td>
<td>Consent 16-18</td>
<td>None</td>
<td></td>
</tr>
<tr>
<td>Assent U16</td>
<td>Assent U16</td>
<td>Assent U16</td>
<td>None</td>
<td></td>
</tr>
<tr>
<td><strong>PARENTS:</strong></td>
<td><strong>PARENTS:</strong></td>
<td><strong>PARENTS:</strong></td>
<td><strong>PARENTS:</strong></td>
<td><strong>PARENTS:</strong></td>
</tr>
<tr>
<td>Peds 11-18</td>
<td>Peds 8-12</td>
<td>Peds 8-12</td>
<td>Peds 2-4</td>
<td>None</td>
</tr>
<tr>
<td>Frequency of hypoglycaemia</td>
<td>Frequency of hypoglycaemia</td>
<td>Frequency of hypoglycaemia</td>
<td>Frequency of hypoglycaemia</td>
<td></td>
</tr>
<tr>
<td>Hypoglycaemia Fear Survey</td>
<td>Hypoglycaemia Fear Survey</td>
<td>Hypoglycaemia Fear Survey</td>
<td>Hypoglycaemia Fear Survey</td>
<td></td>
</tr>
<tr>
<td>State-Trait Adult Self-care inventory</td>
<td>State-Trait Adult Self-care inventory</td>
<td>State-Trait Adult Self-care inventory</td>
<td>State-Trait Adult Self-care inventory</td>
<td></td>
</tr>
<tr>
<td>Parent demographics</td>
<td>Parent demographics</td>
<td>Parent demographics</td>
<td>Parent demographics</td>
<td></td>
</tr>
<tr>
<td>Information sheet Parent 11-16</td>
<td>Information sheet Parent 11-16</td>
<td>Information sheet Parent 8-10</td>
<td>Information sheet Parent under 8s</td>
<td></td>
</tr>
<tr>
<td>Parent consent</td>
<td>Parent consent</td>
<td>Parent consent</td>
<td>Parent consent</td>
<td></td>
</tr>
<tr>
<td>Parent consent on behalf of child</td>
<td>Parent consent on behalf of child</td>
<td>Parent consent</td>
<td>Parent consent</td>
<td></td>
</tr>
<tr>
<td>Parent consent on behalf of child</td>
<td>Parent consent on behalf of child</td>
<td>Parent consent</td>
<td>Parent consent on behalf of child</td>
<td></td>
</tr>
</tbody>
</table>
2.5.1 Background information

The following information was collected from CYP and parents who took part in the study.

**Demographic data (CYP):** This was collected from hospital records but confirmed when participants were recruited to take part. Demographic data included age, date of birth, gender, ethnicity.

**Disease related information (CYP):**
- Date of diagnosis: taken from medical records but confirmed by patient/parent. This was generally given as the year of diagnosis, in some instances the month was also given.
- Duration of diabetes: again, information was obtained from medical records but confirmed by patient/parent. This was generally given as months and years (converted into years for analysis).

**Insulin regimen:** was obtained from medical records and later categorised either as conventional insulin therapy or intensive insulin therapy for analysis. Twice a day insulin therapy was categorised as conventional therapy and multiple injections and pump therapy were categorised as intensive therapy.

**HbA1c:** CYPs’ glycosylated haemoglobin (HbA1c) data from the past 12 months were collected from their medical records. All children and young people with diabetes have a three monthly assessment of HbA1c which is usually performed on capillary sampling. No additional tests were taken for the purposes of the study. Data were collected retrospectively from clinical records to document the most recent HbA1c as well as the average of the readings from the 12 months prior to the questionnaire assessments. All local laboratories used DCCT standardised assays.

**Demographic data (parents):**
This included height, weight, collar size, ethnicity, age, age when left full time education, where they were educated (UK or other), highest level of education received and occupation. This information was captured using the parent demographic document, designed specifically for this study.

2.5.2 Description of measures

Questionnaire data
The questionnaires used in this study are all validated measures.

2.5.2.1 Frequency of hypoglycaemia survey

This questionnaire was used to measure the frequency of hypoglycaemia and severe hypoglycaemia (47) (Appendix 1).

A retrospective assessment of frequency of episodes of both severe (needing assistance) and mild hypoglycaemia was made. This questionnaire has been produced by the Edinburgh group and has been used in a number of studies assessing hypoglycaemia frequency in patients with Type 1 diabetes. The measure includes a definition of hypoglycaemia and a severe hypoglycaemia episode to help patients distinguish between the two in their responses. Although retrospective assessment of the frequency of hypoglycaemia is generally inaccurate, the Frier group in Edinburgh developed a range of possible answers to obtain a measure of the frequency of exposure, which refers to both lifetime experience and to a particular time period, such as the preceding year, 2 years. For severe hypoglycaemia, the responses range from "never" to "1 - 2 events", "2 - 5 events", ">5 events" to obtain a measure of the total exposure. Mild hypoglycaemia is measured over time e.g. "weekly", "monthly", "annually". The measure includes both forced response (information on the frequency of both severe and non-severe episodes of hypoglycaemia) and free response (information on the frequency of episodes of severe hypoglycaemia over the past one and two years). The parent version of this measure is a proxy measure and asks parents about the frequency of their child’s hypoglycaemia.
2.5.2.2 Hypoglycaemia awareness survey

This measure was used to identify the presence of impaired awareness of hypoglycaemia (IAH) (47, 49) (Appendix 2).

The IAH measure is used to identify the presence of impaired awareness of hypoglycaemia. The Gold and Clarke (Edinburgh) methods were combined to assess IAH, as recommended by Geddes et al. (45). The two validated measures are made up of ten items which ask the respondent to identify whether they experience symptoms of hypoglycaemia when they have low blood sugar and the frequency of these experiences. The Clarke method (49) makes up items one to nine. Item nine on the measure looks at the likelihood of the presence of 17 potential symptoms a patient might experience (presented as a list) when having a hypoglycaemic episode, on a scale of one (not present) to seven (present a great deal). The final item, from Gold et al.’s (47) measure is an explicit question which asks the patient to rate whether they are aware they are experiencing hypoglycaemia. They are required to respond to this on a scale of one (always aware) to seven (never aware). For items one to eight a score of 4+ implies impaired awareness (max = 8). For item ten a score of 4+ implies impaired awareness of hypoglycaemia (max = 7). The awareness measure also collects details on insulin regimen, including insulin type and timings and amounts of insulin taken. The IAH is aimed at adolescent patients aged 11+ years. There is no parent version of the measure.

2.5.2.3 Self-care inventory (SCI)

The original SCI (137) was updated (SCI-R) and measures diabetes-related self-care behaviours (138) (Appendix 3).

The 15-item version of the self-care inventory revised (SCI-R) is specifically designed to assess the extent to which the respondent believes he or she follows diabetes-specific self-care behaviours, over the past 1-2 months. This measure is aimed at adolescents; for pre-adolescent children proxy reports are completed by their parents (139). When scoring the items it is advisable to look at categories within the measure rather than the total score.
The items can be categorised into the following groups: overall adherence (items 1,2,5,6,7,14,15), blood glucose regulation (items 1,2,15), insulin and food regulation (items 5,6,7), exercise (item 14) and emergency precautions (items 11 and 13) (138). Items are scored on a 5-point scale (1= Never, 2= Rarely, 3= Sometimes, 4= Usually, 5= Always). Scores were transformed to a 0-100 scale for analysis using the following formula: ((average raw score-minimum possible score)*100)/(maximum possible score-minimum possible score). Higher scores on the measure indicate better perceived diabetes self-care.

Reliability and validity for the SCI is evident from previous studies (138, 140, 141) using the SCI. Lewin et al. (141) reported internal consistency for the SCI when used with adolescents (α = 0.80) and with parents (α = 0.72). Similarly, Weinger et al. (138) found that their data showed high internal consistency (α = 0.87) for the SCI-R.

2.5.2.4 Quality of life assessment: Pediatric Quality of Life Inventory (PedsQL 3.0 Diabetes module)

This measure looks at health-related quality of life (HRQoL) in T1DM patients (Appendix 4).

The PedsQL 3.0 Diabetes Module is part of a larger Pediatric Quality of Life Inventory (142), which assesses quality of life (QoL) in children (healthy children and those with acute or chronic illnesses). The diabetes module is made up of 28 items looking at problems a child might have with his/her diabetes. The items are split into five groups: About my diabetes (diabetes symptoms; 11 items), Treatment I (treatment barriers; 4 items), Treatment II (treatment adherence; 7 items), Worry (3 items) and Communication (3 items). For this study, the PedsQL Diabetes 3.0 module was used to measure QoL in children with Type 1 diabetes aged between 5-18 years. Age-specific questionnaires were available for varying age groups (5-7 years, 8-12, 13-18 years).

For children aged less than 5 years, parent proxy measures were completed (Appendix 5). Parents of older children were also asked to complete parental reports in order to identify
how parents perceived their child’s QoL. Items were reverse scored and transformed from a 0-5 scale to a 0-100 scale for analysis (0= 100, 1= 75, 2= 50, 3= 25, 4= 0). For the 5-7 year group items were scored on a three point scale and reverse scored and transformed to a scale of 0-100 (0= 100, 2= 50, 4= 0). The total score for each subscale and for the overall scale were calculated as an average score (total score/ number of complete items). If more than 50% of the items were missing the scale/subscale score was not computed. Originally only subscale scores for the PedsQL modules were calculated however, later research using factor analysis suggests that a total PedsQL score is psychometrically appropriate for use (143). A high score on the PedsQL measure indicates higher quality of life.

Some of the items on the PedsQL Diabetes module included ‘US English’ words or terms. To ensure the participants of this study would understand the items clearly it was decided, with the approval of Mapi (distributors of PedsQL) that we could amend those words to ‘UK English.’ Details of the translation procedure are provided in section 2.7.2, below.

The PedsQL diabetes module has been tested and found to have internal consistency reliability and construct validity. The majority of parent and child reports for the diabetes module exceeded Cronbach’s alpha co-efficient of 0.70 (144-146). For the Diabetes module, Varni et al. (144) reported Cronbach’s alpha co-efficient of 0.71 for the child-report and 0.73 for the parent-report. Higher internal consistency for the Diabetes module of the PedsQL was reported by Kalyva et al. (106). For child-reports they found a Cronbach’s alpha of 0.81; although Cronbach’s alpha co-efficient did vary across age groups (5-7 years: α = 0.81; 8-12 years: α = 0.92 and; 13-18 years: α = 0.93).

2.5.2.5 Hypoglycaemia Fear Survey (HFS)

The HFS survey identifies the presence of the fear of hypoglycaemia. The current study utilised an adapted version of the original Cox et al. (147) HFS measure, which was adapted for use by children (CHFS) and parents (PHFS) (72, 74, 77) (Appendix 6 and 7).
**Child version**
The CHFS is made up of three parts. The first part of the survey includes 10 items which measure the presence of behaviours associated with hypoglycaemia, for example, “eating large snacks before bedtime.” This is also known as the behaviour sub-scale. The second part of the survey looks at 15 items on worries about hypoglycaemia, for example, “no one being around to help during a hypo” (worry subscale). The items on the ‘Worry’ and ‘Behaviour’ subscales are rated from 0 (never) to 4 (almost always). Part three of the CHFS is made up of yes/no questions about the situations in which a child has had hypoglycaemia (e.g. “is low blood sugar a big problem for you”).

Scores for the CHFS are calculated by adding up the ratings given for each item. Total scores are calculated for the Behaviour (max = 50) and Worry (max = 75) sections, with the total HFS (max = 125) score calculated by adding the Behaviour and Worry scores. Higher scores on the measure indicate higher fear of hypoglycaemia.

Gonder-Frederick et al. (74) report good internal consistency for the CHFS Total scores (0.84-0.87). The subscales also are reported to have reasonable Cronbach’s alpha coefficient, with the Behaviour subscale ranging from 0.59-0.78 and the Worry subscale with a higher coefficient ranging from 0.87-0.89.

**Parent Version**
The parent version of the HFS also looks at behaviour, worry and experience of hypoglycaemia. Ten items make up the behaviour section (e.g. “keep my child’s sugar higher when he/she will be alone for a while”), 15 items make up the worry section (e.g. “child having a hypo while asleep”) with an additional two items which ask the parent to rate their confidence in identifying and treating their child’s hypoglycaemia. The two additional items are used as independent assessors of parent’s confidence so the ratings for these two items should not be included in the scores for worry or the total PHFS score. The items on the ‘Worry’ and ‘Behaviour’ subscales are rated from 0 (never) to 4 (almost
always). The behaviour and worry subscales are followed by the third section which explores in more detail, the numbers and associated experiences of hypoglycaemia in various situations, for instance when asleep or at school (e.g. “has your child ever had a hypoglycaemic event at school”) and the availability of emergency glucose (e.g. “does your child carry emergency glucose with him at all times”).

Scores for the PHFS are calculated by adding up the ratings given for each item. Total scores are calculated for the Behaviour (max = 50) and Worry (max = 75) sections, with the total HFS (max = 125) score calculated by adding the Behaviour and Worry scores. Higher scores on the measure indicate higher fear of hypoglycaemia.

Previous reports of internal consistency for the PHFS range from 0.89-0.92 (74). Good internal consistency has also been reported for the Behaviour subscale (0.72-0.76) and the Worry subscale (0.88-0.91) (74).

2.5.2.6 State Trait Anxiety Inventory (STAI/STAIC)

Spielberger’s state trait anxiety inventory (STAI) is a well-validated measure used to identify the degree of a person’s state and trait anxiety. There are separate measures for children and older children/adults (148, 149) (Appendix 8).

The state trait anxiety inventory for children (148) (STAIC) (Appendix 9) is suitable for children aged 9-12 years old, although it can be used with younger children with at least average reading ability, and is made up of 40 items. The first 20 items ask how a child is feeling at this moment and measures state anxiety (e.g. ‘I feel very calm/calm/not calm’). Half of the questions in the state anxiety subscale reflect the presence of anxiety whilst the other half reflects the absence of anxiety (these items are reverse scored during scoring). The last 20 items ask the child about how they usually feel and measures trait anxiety (e.g. ‘I worry too much’). Each item has three possible responses which are scored from 1-3. The scores are totalled separately for trait and state anxiety with a highest total of 60 for each.
The internal consistency of the STAIC is good. For the state subscale, Cronbach’s alpha coefficient is reported to be between 0.82 and 0.87 and for the trait subscale between 0.78 and 0.81 (148).

The Spielberger trait personality Inventory (150) (STPI) was originally used in this study to identify trait anxiety scores (based on similar previous research carried out in FoH (72)) however, once data collection was underway, using the STPI, it was decided that the STAI/STAIC was actually a better and shorter measure of anxiety. As a result, the assessments were altered to include the STAI/STAIC instead of the STPI. As the STAI also offered a child version of the anxiety measure, this measure seemed to be more appropriate to use in this study. The anxiety measure was amended and ethics approval of this substantial amendment was given (Appendix 13). Although some of the items on the STPI corresponded with those on the STAI, it was decided that the completed STPI measures would be disregarded for ease, considering only a small number had been collected by the time the change of assessment was decided. This is reflected in the differing number of parents who completed the STAI in comparison with the rest of the battery of measures.

The state trait anxiety inventory for adults (149) (STAI) (revised version) is suitable for 13+year olds to adults and is made up of 40 items. As with the child version, 20 items measure trait anxiety (e.g. ‘I make decisions easily’) and 20 items measure state anxiety (e.g. ‘I feel at ease’). Each item is scored on a scale of 1-4 (not at all, somewhat, moderately so, very much so) with a total possible score of 80 for each subscale.

The STAI is a widely used measure of both state and trait anxiety (149). Cronbach’s alpha coefficients are reported as 0.92 for the state subscale and 0.90 for the trait subscale (149), indicating high internal reliability for this measure.
A higher score on both the adult and child measure indicates higher anxiety. As the items on the child and adult STAI differ the scores were converted to z-scores before analysis, to allow comparison between the two groups.

**Reliability of measures**

Cronbach’s alpha (151) is used to provide a method of measuring the internal reliability of a scale, that is, the degree to which the items within a scale are inter-related, and therefore, measuring the same thing. Acceptable levels of alpha range from 0.70 to 0.95 (152). Cronbach’s alpha co-efficient has already been reported in the descriptions of each of the measures used in this study. However, here Cronbach’s alpha will determine the internal reliability of the measures used, based on the current study data (Table 1).
Table 1: Cronbach’s alpha co-efficient

<table>
<thead>
<tr>
<th>Measure</th>
<th>Total CYP</th>
<th>U11</th>
<th>Adolescents</th>
<th>Mother</th>
<th>Father</th>
</tr>
</thead>
<tbody>
<tr>
<td>HFS Behaviour</td>
<td>0.68</td>
<td>0.71</td>
<td>0.68</td>
<td>0.76</td>
<td>0.75</td>
</tr>
<tr>
<td>HFS Worry</td>
<td>0.9</td>
<td>0.91</td>
<td>0.9</td>
<td>0.92</td>
<td>0.92</td>
</tr>
<tr>
<td>HFS Total</td>
<td>0.86</td>
<td>0.85</td>
<td>0.86</td>
<td>0.91</td>
<td>0.91</td>
</tr>
<tr>
<td>State Anxiety</td>
<td>N/A</td>
<td>0.89+</td>
<td>0.81-</td>
<td>0.90</td>
<td>0.93</td>
</tr>
<tr>
<td>Trait Anxiety</td>
<td>N/A</td>
<td>0.87+</td>
<td>0.91-</td>
<td>0.92</td>
<td>0.94</td>
</tr>
<tr>
<td>PedsQL Diabetes Module total score</td>
<td>13-18 years</td>
<td>0.9</td>
<td>N/A</td>
<td>N/A</td>
<td>0.93</td>
</tr>
<tr>
<td></td>
<td>8-12 years</td>
<td>0.86</td>
<td>N/A</td>
<td>N/A</td>
<td>0.91</td>
</tr>
<tr>
<td></td>
<td>5-7 years</td>
<td>0.88</td>
<td>N/A</td>
<td>N/A</td>
<td>0.88</td>
</tr>
<tr>
<td></td>
<td>2-4 years</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>0.91</td>
</tr>
<tr>
<td>Self-care</td>
<td>N/A</td>
<td>N/A</td>
<td>0.8</td>
<td>0.83</td>
<td>0.90</td>
</tr>
</tbody>
</table>

- 13-18 years
+ Under 13 years

Table 1 presents Cronbach’s alpha co-efficient for each of the measures used in the study and groups this data by respondent. The data indicate that internal consistency for the measures, across groups, is good. Cronbach’s alpha co-efficient only drops below 0.70 for CYP and adolescents reporting on the CHFS behaviour subscale ($\alpha = 0.68$ for both).
2.6 Advantages of using questionnaires

This study used a collection of validated structured questionnaires which participants were required to respond to during their clinic appointments. One of the advantages of using this method of data collection is that it allows large samples of participants to take part with little difficulty. This method also allows data to be analysed easily. Where questionnaires have been tested for validity and reliability researchers can feel confident in their data. Structured questionnaires, however, also have disadvantages. Respondents are not free to give their own views and are ‘forced’ to choose one of the pre-coded responses. This means that some of the data collected using this method may not be a true reflection of the respondent’s thoughts. Structured questionnaires can also be open to biases such as social desirability whereby the respondent will answer questions in a way that they think will show them in a positive light. This method also relies on the same questions and responses being presented to a wide sample with varying levels of knowledge. The assumption being that all respondents will understand the intended meaning of the questions in the same way. In this study we were able to overcome the shortcomings of using structured questionnaires by carrying out structured interviews.

2.7 Procedure

Prior to starting the study the following tasks were undertaken:

2.7.1 Ethics approval

The ethics application was completed using the NHS IRAS tool. Ethics approval for this multi-centre study was obtained from Oxfordshire Research Ethics Committee on 30\textsuperscript{th} November 2007 (Appendix 10).

All substantial amendments during the study were reported to the Ethics committee and approved (Appendix 11-14). The substantial amendments were in relation to minor amendments to the parent demographic form; amended letter of invitation; change from STPI to STAI as a measure of anxiety (discussed in more detail later in this chapter).
2.7.2 PedsQL translation of some items

A translation from US English to UK English on the PedsQL for Young Children, Parent report for Young Children and Parent report for toddlers was carried out. As there has already been a translation to UK English for the Teen, Parent report for Teens, Child and Parent report for Child it was agreed by Mapi Research that researchers could use the previously translated questionnaires as a guide to translating the remaining US English versions of the questionnaire. Researchers also felt that if two independent translators were used to carry out the forward and backward translations, the two new translators might translate the questionnaires differently to the way that they have been translated previously. Therefore, the translation might not be consistent across the age groups.

- A comparison of the US and UK English questionnaires was carried out for the Teen, Parent report for Teen, Child and Parent report for Child. Differences between the US and UK versions were noted and highlighted.
- Using the Teen/Child/Parent U.K. versions of the PedsQL questionnaire as a guide those areas that had been translated were highlighted on the U.S. versions of the Young Child/Toddler/Parent questionnaires.
- Next, the highlighted sections in the US English version of the questionnaires were translated into UK English using the translated UK English versions of the questionnaires.
- For the PedsQL for Young Children questionnaire the cover page was vastly different to the cover pages for the other age groups as this included an example, for children, of how to complete the questionnaire. The example refers to whether the young child can ‘snap’ his/her fingers. In UK English ‘snapping fingers’ is known as ‘clicking fingers’ so the researcher decided to make this amendment without having a similarly translated questionnaire to refer to.
- Figure 2 (below) highlights the phrases that were translated from US English to UK English can be found below. Although the Young Child, Parent of Young Child and Parent of Toddler reports differ slightly they all include the translations.

**Figure 2: Translation of phrases from US to UK English for the PedsQL measure**

<table>
<thead>
<tr>
<th>US English</th>
<th>UK English</th>
</tr>
</thead>
<tbody>
<tr>
<td>Having to go to the bathroom too often</td>
<td>Having to go to the toilet too often</td>
</tr>
<tr>
<td>Going “low”</td>
<td>Going “low” or “hypo”</td>
</tr>
<tr>
<td>Feeling tired or fatigued</td>
<td>Feeling tired</td>
</tr>
<tr>
<td>Having trouble sleeping</td>
<td>Having trouble sleeping at night</td>
</tr>
<tr>
<td>Getting irritable</td>
<td>Getting grumpy or annoyed</td>
</tr>
<tr>
<td>Needle sticks (i.e. injections/blood tests) causing him/her pain</td>
<td>Injections/blood tests causing him/her pain</td>
</tr>
<tr>
<td>Arguing with me or my spouse about diabetes care</td>
<td>Arguing with me or my partner about diabetes care</td>
</tr>
<tr>
<td>Sticking to his/her diabetes care plan</td>
<td>Sticking to his/her diabetes routine</td>
</tr>
<tr>
<td>It is hard for my child to take insulin shots</td>
<td>It is hard for my child to give himself insulin injections</td>
</tr>
<tr>
<td>It is hard for my child to track carbohydrates or exchanges</td>
<td>It is hard for my child to follow a healthy diet</td>
</tr>
<tr>
<td>It is hard for my child to wear his/her id bracelet</td>
<td>It is hard for my child to wear his/her id bracelet/necklace or carry a card</td>
</tr>
<tr>
<td>Question</td>
<td>Translation</td>
</tr>
<tr>
<td>-------------------------------------------------------------------------</td>
<td>-----------------------------------------------------------------------------</td>
</tr>
<tr>
<td>It is hard for my child to eat snacks</td>
<td>It is hard for my child to eat snacks between meals when they should</td>
</tr>
<tr>
<td>Worrying about “going low”</td>
<td>Worrying about “going low” or “hypo”</td>
</tr>
<tr>
<td>Worrying about long-term complications of diabetes</td>
<td>Worrying about long-term problems of diabetes</td>
</tr>
<tr>
<td>Is it hard for you to snap your fingers*</td>
<td>Is it hard for you to click your fingers*</td>
</tr>
<tr>
<td>Ask the child to demonstrate snapping his or her fingers*</td>
<td>Ask the child to demonstrate clicking his or her fingers*</td>
</tr>
</tbody>
</table>

*Statement is only present in the Young Child Report

### 2.7.3 Hypoglycaemia Fear Survey (measurement of FoH) translation

A translation from US English to UK English on the Hypoglycaemia Fear Survey for the Children and Parent report was carried out. One phrase in the questionnaire was amended; ‘Insulin reaction’ to ‘hypo’ because in the UK the term ‘insulin reaction’ is generally referred to as ‘hypo.’ The translation of this term was agreed to by developers of Hypoglycaemia Fear Survey without the need for testing and forward and backward translations.

### 2.8 Procedure in clinic

- Patient details (name, address, date of birth) and upcoming clinic lists were obtained from either the medical secretary (Heartlands, GEH, LRI) or hospital booking system (UHCW).
- Patients at LRI and UHCW were screened prior to being invited to take part in the study. This was not possible for patients at GEH or Heartlands Hospital so all CYP attending the Diabetes clinics here were invited to take part via an invitation letter by post.

- A letter of invitation was sent to parents and CYP two weeks prior to their upcoming clinic appointment with age appropriate information sheets for both parent and patient. Examples of these information sheets can be found in Appendix 15 and 16).

- Age-appropriate questionnaire packs (consisting of age-appropriate questionnaires and consent forms), extra questionnaire packs, crib sheet, extra information sheets and pens were taken to each clinic.

- At each clinic CYP and parents were approached to see if they had received and read the information sheets and whether they were interested in taking part in the study. Parents could not take part if CYP did not want to participate in the study. If only one parent was present they were given a set of questionnaires for the 2nd parent to complete at home and send back in the enclosed stamped addressed envelope, if they were happy to do so.

- Inclusion/exclusion criteria were confirmed by CYP and parent to ensure that the CYP had, had T1DM for at least 12 months, whether CYP had any co-morbidities and whether they had any conditions/learning disabilities preventing them from understanding/completing the questionnaires i.e. autism.

- Consent forms were completed by CYP aged 16+ years (Appendix 17). Assent forms were completed by all CYP aged under 16 years, to indicate their willingness to take part in the study (Appendix 18). For all those CYP aged under 16 years, parents (as the children’s guardians) also had to complete a consent form on
behalf of child’ (Appendix 19) to document that they agreed to their child participating.

- All parents who agreed to take part in the study were required to sign consent forms for themselves (Appendix 20)

- Even though 2-4 year olds were not required to complete questionnaires their parents still needed to sign an ‘on behalf of child’ consent form. This was to ensure that the researcher had permission to access to the child’s HbA1c data.

- Boxes on the consent forms had to have the participants’ initials, not a tick, to indicate they agreed to the each of the statements.

- CYP and parents were encouraged to complete the questionnaires during clinic waiting times. Younger children received assistance in completing the questionnaires by their parent or the researcher, if they wanted it. The researcher was also available to answer any questions or clarify any ambiguities whilst the questionnaires were completed.

- Consent forms were signed and retained by researcher, one copy for participants, one copy for the researcher (the participant to sign two copies of the same form).

- Each questionnaire was given a unique reference number (URN) which was written on the front of the questionnaire packs and on the crib sheet (a record of child URN, name, age, duration of diabetes/date of diagnosis). For the first parent who was present P1 was added to the code, for the second parent P2 was added to the code.
- HbA1c data were collected for those patients who consented to take part. These were obtained from hospital records or via the Diabetes Specialist Nurses.

All completed questionnaires were scored and a secure Microsoft ACCESS database was developed to store responses to items on all questionnaires.

### 2.9 Statistical analyses

Measures were scored by hand and the quantitative data were entered and analysed using SPSS version 19.0 (IBM Corp. Released 2010. IBM SPSS Statistics for Windows, Version 19.0. Armonk, NY: IBM Corp.). Missing data was minimal and steps to eliminate the impact were taken depending on the measure; guidelines for dealing with missing data were provided in scoring guidelines for each measure. The main outcome of this study was the prevalence hypoglycaemia and the prevalence of fear of hypoglycaemia (FoH) among CYP and parents, and its relation to glycaemic control, previous experience of severe hypoglycaemia, diabetes related quality of life, trait anxiety, and self-care as determined by the questionnaire data. Data were analysed according to CYP age-specific groups and parents.

Each measure was assessed to determine whether data were normally distributed. Non-parametric tests were used where data were concluded not to be normally distributed. Cronbach’s alpha co-efficient was calculated for all measures for which it was appropriate, in order to report the internal reliability of these measures for the current study sample.

The characteristics of the CYP and parents were described using basic descriptive statistics reporting frequencies, mean scores, standard deviation scores. Differences between groups were analysed using t-tests and chi-square analyses were used to explore associations between groups. Basic descriptive statistics were used to describe the
prevalence of the frequency of hypoglycaemia. Bar charts illustrated the differences in reports of hypoglycaemia and severe hypoglycaemia by age group. Chi-square analysis was conducted to identify any differences between groups in the frequency of hypoglycaemia and severe hypoglycaemia. Group differences in age, gender and insulin regimen were explored. Chi-square tests were also used to compare parents’ reports of hypoglycaemia and severe hypoglycaemia. Comparison between parents of children and parents of adolescents were also made. Correlation analyses were carried out between CYP and parental reports to assess the agreement on reports of the number of episodes of severe hypoglycaemia. Finally, the difference in HbA1c across the categories of frequency of hypoglycaemia and severe hypoglycaemia was explored using ANOVA and Mann Whitney. Frequency data was not normally distributed; however, there is no suitable non-parametric counterpart for ANOVA. Correlations between free response reports of severe hypoglycaemia in the past year and year before with HbA1c were also explored.

Continuing the analysis of the frequency of hypoglycaemia data it was also important to explore awareness of hypoglycaemia and its prevalence in this sample. Descriptive statistics are presented for awareness in the adolescent group only. Mann-Whitney tests were used to identify any differences in the frequency of hypoglycaemia and severe hypoglycaemia between adolescents with normal vs impaired awareness. Correlational analyses were used to identify any relationships between awareness and reports of hypoglycaemia and severe hypoglycaemia. Chi square analysis was then carried out to test the association between awareness of hypoglycaemia and the number of episodes of hypoglycaemia and severe hypoglycaemia experienced in an adolescent’s life.

Basic descriptive statistics were used to describe the FoH data for CYP and their parents, overall and by age-group. The prevalence of FoH was difficult to determine as the scale does not have a cut-off point indicating FoH in a person. Therefore, descriptive statistics were studied in relation to the minimum and maximum scores on the HFS scale and comparisons between groups were made to identify how group scores compared. T-tests
were used to examine any differences in HFS scores between age groups, insulin regimen and gender. T-test analyses were also used to compare HFS scores between CYP and their parents, to identify any differences in HFS scores between these groups. In order to compare CHFS scores based on CYP experience of severe hypoglycaemia, t-tests were carried out, by age group. Comparison of PHFS scores and SH was also carried out by age group. Correlation analyses were carried out to identify any relationship between HFS scores and HbA1c for both CYP and their parents.

Basic descriptive analyses were calculated for additional measures: anxiety, quality of life and self-care. Anxiety scores were converted to z-scores to allow comparison between adult and child anxiety measures. Mann-Whitney and t-test analyses were used to examine any differences in scores between groups. Correlational analyses were used to look at any relationship between the additional measures and HFS and HbA1c data.

Stepwise multiple regression analyses were used to examine the independent correlates of fear of hypoglycaemia. Emerging themes from the quantitative data informed the topics presented in the interviews.

2.10 CYP and parent participation: variations in completion of measures

The number of participants for each group varies from the total number of CYP and parents who completed the measures, for a number of reasons. The first reason is that the measures were distributed among varying age groups. So, for example although 210 CYP took part in the study only 203 CYP completed the HFS scale. This is due to the fact that younger CYP, aged 2-4 were not asked to complete any measures, however their demographic details and HbA1c data were recorded. For this young age group parents completed proxy measures on the children’s behalf. Some participants did not complete
measures fully, therefore where there were too many missing data for the measure these scores were not recorded. Following the scoring guidelines for each measure, I had to decide whether the amount of missing data constituted a decision to include or disregard that participant’s data. For the anxiety measure there was a difference in the number of parents that completed this measure in comparison to the total N=number of parents taking part in the study. The reason for this is that at the start of the study the State Trait Personality Inventory (150) was used to collect data regarding state/trait anxiety. This measure was initially used as it had been used in a previous, similar study. CYP were required to complete the State Trait Anxiety Inventory for Children (148), also based on previous research carried out in this area. However, on reflection, it was decided that it would be better to use a specific anxiety measure for parents. The State Trait Anxiety Inventory (149) is a shorter measure and as the study was already using the child version for CYP it was felt that this would be a better choice for collecting anxiety data. Having looked at the adult and child versions of the anxiety measure it was decided that parents and children aged 13+years would complete the adult version, with the younger age groups completing the child version. As a result of this change in measure the earlier completed STPI scores were disregarded, hence the difference in the number of parents completing the measure. A substantial amendment highlighting this change was sent to the Ethics REC and approved (Appendix 13).

Table 2 below highlights the issues associated with specific measures and corresponding response data.
### Table 2: Completion issues encountered with specific measures

<table>
<thead>
<tr>
<th>Measure</th>
<th>Number of respondents</th>
<th>CYP and parent respondents</th>
<th>Issue</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Frequency of hypoglycaemia</strong></td>
<td></td>
<td></td>
<td>Completed by children aged 8+ years. Parents completed proxy reports for younger children</td>
</tr>
<tr>
<td>CYP: 193</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CYP plus proxy reports: 206/210</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mothers: 133</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fathers: 51</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Hypoglycaemia Fear Survey</strong></td>
<td></td>
<td></td>
<td>For some subscales of the measures there was missing data for participants, which meant that a total score could not be calculated. However, in these instances, where some subscale scores could be calculated and missing data only accounted for one subscale, then these participants’ data was included in the analysis of the subscales even when data could not be used in the analysis of the measure as a whole. The 2-4 years old group did not complete this measure.</td>
</tr>
<tr>
<td>CYP: 197</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mothers: 138</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fathers: 52</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Peds Quality of Life Diabetes Module</strong></td>
<td>CYP (not including 2-4 year old reports. These are included in the parent response numbers): 200</td>
<td></td>
<td>Although children aged 2-4 years did not complete this measure, proxy reports were provided by parents.</td>
</tr>
<tr>
<td>CYP</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mothers: 136</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Measure</td>
<td>Participants</td>
<td>Notes</td>
<td></td>
</tr>
<tr>
<td>----------------------------------------------</td>
<td>--------------------------------------</td>
<td>----------------------------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td><strong>Self-Care Inventory</strong></td>
<td>Fathers: 52</td>
<td>This measure was completed by the adolescent group and parents only.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Adolescent: 150</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Mothers: 136</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Fathers: 52</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>State Trait Anxiety Inventory (STAI)</strong></td>
<td>CYP: 191 (State) 193 (Trait)</td>
<td>For the anxiety measure the age groups were slightly different for</td>
<td></td>
</tr>
<tr>
<td><strong>State Trait Anxiety Inventory for Children (STAIC)</strong></td>
<td>Under 13 years: 84 (S) 86 (T)</td>
<td>CYP; U11 group included all CYP aged under 13 years. They</td>
<td></td>
</tr>
<tr>
<td></td>
<td>13+ years: 107 (S) 107 (S)</td>
<td>completed the STAIC. The adolescent group included CYP aged 13</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Mothers: 116 (S) 116 (T)</td>
<td>years and older. They completed the adult version of the measure,</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Fathers: 48 (S) 46 (T)</td>
<td>as recommended by the STAI test administration guide (149).</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>The parent N for the anxiety measure differs to the total N for</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>parents as initially the study used the Spielberger Trait Personality</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Inventory (150) to collect data on anxiety. However, it was decided</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>that the STAI was a more efficient method of collecting this</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>information, therefore, STPI scores collected prior to this change</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>were discarded.</td>
<td></td>
</tr>
<tr>
<td><strong>Awareness Survey</strong></td>
<td>Adolescents: 144</td>
<td>Only CYP aged 11 years and above completed this measure as it is</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>not intended for younger children.</td>
<td></td>
</tr>
</tbody>
</table>
2.11 Practical issues
As discussed earlier in the chapter, research with children can be difficult for a number of reasons. Both consent and assent must be taken from child participants. This means that a parent must agree to their child participating in the study and the child themselves must fully understand their involvement in the study. In order to ensure that this was achieved the study had to be explained to potential participants in a way that would be understood by different age groups. The information sheets used for this study were aimed at different groups (e.g. parents and CYP) and age groups of participants to help ensure that the information that they received was clear and coherent to them.

Completing lengthy questionnaires can be difficult for children as it can be tiring and difficult for them to concentrate for long periods. However, in order to include large numbers of participants in the study with only one researcher, in quite a short period of time a questionnaire based study seemed the best way to proceed and the most efficient way to collect data concerning a variety of relevant areas. For this study the age groups of the participants were considered when compiling the questionnaire packs to ensure that the packs weren’t too demanding for each group. Appropriate questionnaire packs were aimed at 5-7 year olds, 8-10 year olds and 11+ year olds; the younger 2-4 year olds were represented through parent by proxy reports.

There were also some issues with recruitment to the study and again this could be related to the fact that children were being recruited. Parents were asked to give consent for their children as well as for themselves and then asked to complete the questionnaires during waiting times in clinics. At times there was sufficient time for the questionnaire packs to be completed but where parents and children might be required to stay longer than the appointment required, questionnaires were not always completed within the clinic and were taken home to complete. Once taken home questionnaires were often forgotten or overlooked, even with reminder prompts from the researcher. Parents and children often could not or were not prepared to spend additional time in clinic to
complete the questionnaires for a number of reasons. This included car parks charges, which were high at some clinics, and having to get back to school and work. Also some children become tired and did not feel like completing the questionnaires if they had had lengthy appointments, for example, with the nurse, consultant and perhaps also a dietician. To overcome such issues all potential participants were approached as soon as was possible in the clinic waiting area and encouraged to complete questionnaires in clinic where possible. Younger children received assistance from the researcher when completing questionnaires so that parents could concentrate on their own questionnaire packs.

**Phase two: Qualitative research method**

The aim of Phase two was to explore CYP’s views of living with diabetes in addition to their thoughts on hypoglycaemia. Parental views were also sought.

**2.12 Design**

A semi-structured interview design was used. The interview was designed to discuss living with T1DM, experience of hypoglycaemia, diabetes management and impact of diabetes. The semi-structured design allowed the process to remain flexible so that CYP and parents could talk about other diabetes-related factors.

**2.13 Sample**

Participants were recruited from the original group of CYP and parents who participated in Phase one of the study. All those who had taken part in Phase one and who had agreed to be approached for the second phase of the study were invited to take part in the interviews.
In order to address some of the shortcomings of the structured questionnaires in Phase one, Phase two of the study focused on collecting more in-depth data on themes arising from the quantitative analysis. Thirteen CYP and thirteen parents took part in semi-structured interviews to allow participants to talk more in detail about living with diabetes. Training in conducting focus groups and interview with young people was undertaken prior to Phase Two, at Warwick Medical School, UK. Semi-structured interviews have the advantage of allowing both the participant and the interviewer to discuss a particular topic in much more depth than structured questionnaires allow. A face to face interview also allows the interviewer to probe for further information to elicit richer data and enables the interviewer to clarify any ambiguities in a participant’s responses. This method is more individualised and can allow questions to be clarified for participants with varying levels of understanding. However, unlike structured questionnaires, the interview method is very time consuming and expensive. This means that only a small number of participants are able to take part. They can also be subject to interviewer bias where participants answer in a way they believe the interviewer wants them to respond. However, training in interview methods can help to avoid bias.

In terms of this study the data from interviews will add to the limited qualitative data on adolescents and children with Type 1 diabetes. In a systematic review of the qualitative studies of this type Spencer et al. (120) found limited studies in the UK and suggested measures should be taken to improve validity (i.e. triangulation) in order to provide better understanding of what it’s like for CYP to live with diabetes and to help to understand how they cope with it. There will be further focus on the issue of hypoglycaemia and overcoming problems associated with hypoglycaemia and living and coping with diabetes in general.

### 2.14 Qualitative measures

A set of questions relating to living with diabetes and experiencing hypoglycaemia, to be used during interviews with patients and their parents, was devised by the researcher. Interview questions were based on items from the questionnaires used in Phase one. The
The interview schedule began with asking CYP and their parents about living with diabetes and the circumstances surrounding diagnosis. The questions then focused on the experience of hypoglycaemia and feelings/behaviours associated with episodes of hypoglycaemia. The interview schedule was designed to allow the researcher to elicit more detailed accounts of parent and CYPs’ fear of hypoglycaemia, self-care behaviours and living with diabetes in general. Once the questions were put together the researcher together with two supervisors (consultant paediatrician in diabetes and senior lecturer in psychology) worked together to modify the questions to ensure that they were suitable for obtaining further details about living with diabetes in CYP and their parents. The interview questions for CYP and parents are presented below (Tables 3 and 4).

**Table 3: Interview schedule (CYP)**

<table>
<thead>
<tr>
<th>Interview Questions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Children/Adolescents</strong></td>
</tr>
<tr>
<td>1. How old were you when you first had diabetes?</td>
</tr>
<tr>
<td>2. How do you find living with diabetes? What’s it like having diabetes? Does it affect your daily life? If so, how?</td>
</tr>
<tr>
<td>3. What do you find difficult about having diabetes? (Do you think there’s anything good about having diabetes? Younger children)</td>
</tr>
<tr>
<td>4. Do you know what hypoglycaemia is? /What do you think hypoglycaemia is?</td>
</tr>
<tr>
<td>a. How would you describe hypoglycaemia?</td>
</tr>
<tr>
<td>5. Have you ever experienced hypoglycaemia?</td>
</tr>
<tr>
<td>a. How many times have you had a hypo in the past year?</td>
</tr>
<tr>
<td>b. Were you able to treat all of your hypos or did you need help?</td>
</tr>
</tbody>
</table>
c. Are you always aware that you are having a hypo?

d. What symptoms do you have when experiencing a hypo?

6. Do you tend to have hypos at specific times? Example: when you exercise?

7. Have you ever had a hypo at school, with friends, away from your parents, during the night?

8. Have you ever had a hypo while you’ve been asleep?
   a. Do you worry about having a hypo while you’re asleep?
   b. What in particular worries you about this?
   c. Does this affect how you sleep at night?
   d. In what way does this have an effect?

9. Do you think your diabetes or hypos affect your family life?
   a. In what way do they have an effect?

10. Do you think your diabetes or hypos affect your school life?
    a. In what way do they have an effect?

11. Do you worry about having hypos?
    a. What in particular do you worry about?
    b. How does having a hypo make you feel?

12. How do you cope with hypos?
    a. What do you do when you have a hypo?
    b. Do you try to avoid having hypos?
       i. How do you manage this?

13. Do you get any support in terms of your experience of hypos?
a. From family?

b. From other sources (e.g. clinics, DSN, etc.)

14. Would you like support from your Dr or DSNs in terms of dealing with your/your child’s diabetes?
   a. What kind of support do you think would be beneficial?
      For example, if they provided some training or teaching would it be better given one to one, in a group or maybe online
      
      Would e-learning be interesting if done in an age appropriate way?
      
      Would hypo alarms be any use (something that could be worn all the time or just at specific times of increased risk)?
      
      Do you have any ideas of what might be useful to you?

Thank you for taking part, do you have any questions?

Table 4: Interview schedule (parents)

<table>
<thead>
<tr>
<th>Interview Questions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Parents</strong></td>
</tr>
</tbody>
</table>
| 1. How old was your son/daughter when they were diagnosed with diabetes?  
   a. How do they cope with it generally?  
   2. How do they find living with diabetes? What do you think it is like for them having diabetes? Does it affect their daily life? If so, how? |
3. What do you think they find difficult about having diabetes?

4. Do you know what hypoglycaemia is? /What do you think hypoglycaemia is?
   a. How would you describe hypoglycaemia?

5. Has your child ever experienced hypoglycaemia?
   a. How many times has your child had a hypo in the past year?
   b. Was your child able to treat all of their hypos or did they need help?
   c. Is your child always aware that they are having a hypo?
   d. What symptoms does your child have when experiencing a hypo?

6. Has your child ever had a hypo while they’ve been asleep?
   a. Do you worry about your child having a hypo while they are asleep?
   b. What in particular worries you about this?
   c. Does this affect how your child sleeps at night?
   d. In what way does this have an effect?

7. Do you experience any problems with sleeping?
   a. If so, what problems do you have
   b. Why do you think you have problems with sleep
   c. Do you feel that your difficulties with sleep impact on your day to day functioning?
   d. If so, in what way?

8. Do you think your child’s diabetes or hypos affect their/your family life?
   a. In what way do they have an effect?
9. Do you think your child’s diabetes or hypos affect their school life?
   a. In what way do they have an effect?

10. Do you worry about your son/daughter having hypos?
    a. What in particular do you worry about?
    b. How does this make you feel?

11. How do you cope with your child’s hypos?
    a. What do you do when your child has a hypo?
    b. Do you try to avoid your child having hypos?
       i. How do you manage this?

12. Do you get any support in terms of your experience of hypos?
    a. From family?
    b. From other sources (e.g. clinics, DSN, etc.)

13. Would you like support from your Dr or DSNs in terms of dealing with your/your child’s diabetes?
    a. What kind of support do you think would be beneficial?
    b. For example, if they provided some training or teaching would it be better given one to one, in a group or maybe online

   Would e-learning be interesting if done in an age appropriate way?

   Would hypo alarms be any use (something that could be worn all the time or just at specific times of increased risk)?
2.15 Procedure

CYP and parents who took part in Phase One of the study were invited to take part in Phase two. The focus was on collecting qualitative data obtained via interviews with CYP and parents. CYP and their parents were invited to take part in Phase two via a letter which was sent to their home address with information sheets included. An example of this letter and information sheet can be found in Appendix 21 and 22. CYP and their parents were asked to return an expression of interest form, indicating on the form whether or not they wanted to take part in the second phase of the study. The researcher then contacted the parents who had expressed an interest in participating, by telephone, to arrange a time and place for the interview and to answer any questions they may have had. Phase two of the study involved interviewing children/adolescents and their parents attending diabetes clinics at UHCW, Coventry and LRI, Leicester.

The patients and parents who agreed to take part in the interview sessions met with the researcher either at their local clinic (UHCW and LRI) or at patients’ homes, where interviews were conducted between February 2011 and December 2011. Thirteen CYP and 13 parents took part in the semi-structured interviews.

CYP and parents were told what the study was about, why the study was being conducted and what the interview session would involve. Written consent was taken from both CYP and one parent (example in Appendix 23). The CYP were aged between 7-17 years and were interviewed separately from their parent, unless they requested otherwise. This was the case for two of the younger members of the group. Interviews were recorded using a
Marantz digital recorder and then transcribed. Interviews were recorded to ensure that the full concentration on the interview and without preoccupation with taking notes from the interview. However, some notes were taken when necessary to record any non-verbal actions made by participants, such as hesitation, crying. Recording the interview sessions also allowed full transcription of the interview and familiarisation with the exchange, which helped to contribute to the qualitative analysis. Audio recordings were listened to at least twice in full. Interviews were transcribed by listening back to recorded interviews and transcribing using Microsoft Word. No prior training was received in transcribing. However, in order to ensure quality control, initial transcriptions were checked by two of my PhD supervisors. This process also allowed both supervisors to monitor the way in which the interviews were conducted.

Throughout the interview process CYP and their parents were given the freedom to speak as much or as little as they felt comfortable with within a friendly, empathetic and non-judgmental forum.

2.16 Data analysis

2.16.1 Thematic analysis

The qualitative data was analysed using thematic analysis. The aim was to get richer data on the information that had already been collected during the quantitative phase of the study. Braun and Clarke’s (153) paper on thematic analysis was used as a step by step guide to analysing the data, as described below. This was deemed an acceptable method of carrying out the thematic analysis.

Step 1: Familiarise yourself with data
Transcribing the interviews involved listening to each recording of the interviews a number of times. This allowed familiarisation of the data. Once each of the interviews had been transcribed, a final listen through of the interview was completed in order to check that each of the interviews had been transcribed correctly. Familiarisation with the data contributed to data analysis as it allowed initial generation of codes. During this step potential themes and codes emerged but were not formally recorded.

**Step 2: Generating initial codes**

Once all interviews had been transcribed, NVivo qualitative data analysis Software (QSR International Pty Ltd. Version 10, 2012) was used to help code sections of each of the interviews. The codes were extracts of the interviews which contributed to the research question.

**Step 3: Searching for themes**

Once each interview had been coded, the coded extracts were analysed to identify how they might group together or where in fact they should remain distinct. Initial analysis led to development of the following themes: Impact, diabetes experience, fears (about diabetes), hypoglycaemia, fear of hypoglycaemia, coping with diabetes, diabetes management.

**Step 4: Reviewing themes**

Initial themes were reviewed and where themes seemed to have extracts that overlapped, these initial themes were merged. For example, ‘diabetes experience’ was made up of initial themes including ‘coping with diabetes’ and ‘diabetes management.’ Reviewing the themes was an ongoing process whereby themes were merged and emerged through revisiting each transcript to see whether any other themes/sub-themes/codes might be
identified. There was some discussion about the initial generation of themes and emerging themes with the three PhD supervisors. This enhanced the thematic analysis as I was challenged to defend the themes I had initially identified and so reviewed my themes a number of times before I felt comfortable that they reflected the essence of the interviews.

**Step 5: Defining and naming themes**

During this stage all the themes and sub-themes were reviewed. Where themes or sub-themes were similar, these were merged. Similarly in cases where the themes seemed too broad they were split into more distinct themes. Eventually, three distinct themes were identified. In the process of analysing these themes and writing up the analysis, sub-themes also emerged where there was a pattern within the extracts from all of the interviews.

**Step 6: Producing report**

The final step was producing analysis of the interviews with extracts from the data to illustrate the themes and sub-themes identified.

The relationship between the quantitative and qualitative data was examined in order to determine whether the data supported each other.

**2.16.2 Reflexivity**

Inevitably, when conducting qualitative research a researcher’s own experiences and feelings might impact on the way the way that they carry out interviews and influence the direction of the interview. Being a mother of two young children and also someone who has lived with a chronic condition for over a decade, some of the issues that were discussed during the interviews did have an impact on me personally. However, I tried to
ensure that I stuck to the topics that needed further exploration and this was helped by having a semi-structured interview schedule to follow. I certainly felt a lot of empathy towards mothers and the CYP and also admiration for the way that they coped with T1DM. I feel that this enhanced my data collection and also later my analysis. I could really empathise and tried to identify with their situation which helped me recognise the issues that really seemed to affect them and to what extent.
Chapter 3 Results: Recruitment, participation and descriptive statistics

This chapter will report on the recruitment and participation of eligible CYP and parents. Demographic data for the entire cohort of CYP, by age group and parents will also be presented. The chapter ends with a discussion regarding response rates and the differences in response rates for specific measures.

3.1 Participant recruitment

After initial screening of 647 children and young people, 121 were deemed not eligible to participate (because they had been diagnosed with diabetes for less than one year). Of the remaining 526 remaining eligible CYP, 117 (22%) did not attend their appointment, 46 (9%) were missed in clinic, and 70 (13%) declined to take part, giving an overall participation rate of 55.7% (293/526). Of these, 210 (71.7%) completed the study (Figure 3)

Figure 3: Participant recruitment
3.2 CYP demographics

Two hundred and ten children and adolescents completed the study. Table 5 shows the mean plus/minus standard deviation and minimum and maximum scores for demographics of the entire CYP cohort. The mean age of the sample was 12.40 ± 3.4 years with 49% females. HbA1c scores for the sample overall ranged from 43.5-149.6 mmol/mol (6.1% - 15.8%), with a mean score of 75.14±14.59. Both current and previous (in brackets) methods of reporting HbA1c are shown. The majority of the study sample was on an intensive (multiple daily injections) insulin regimen, with a small number of these using a pump. Almost equal numbers of males and females took part in the study. Adolescents represented almost three quarters of the whole study sample.
### Table 5: CYP demographics

<table>
<thead>
<tr>
<th>Variable</th>
<th>All CYP (3-18 years)</th>
<th>Under 11 (3-10 years)</th>
<th>Adolescents (11-18 years)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(n= 210)</td>
<td>(n= 59)</td>
<td>(n= 151)</td>
</tr>
<tr>
<td>Age (Mean ± SD)</td>
<td>12.40±3.4</td>
<td>8.15±1.97</td>
<td>14.05±2.06</td>
</tr>
<tr>
<td>Female Number (%)</td>
<td>102 (49%)</td>
<td>26 (44%)</td>
<td>76 (50%)</td>
</tr>
<tr>
<td>White ^ Number (%)</td>
<td>172 (82%)</td>
<td>46 (81%)</td>
<td>126 (83%)</td>
</tr>
<tr>
<td>HbA1c mmol/mol (HbA1c %)</td>
<td>75.14±14.59 (9.0±1.3)</td>
<td>70.23±10.62 (8.6±1.07)</td>
<td>77.06±15.49 (9.2±1.4)</td>
</tr>
<tr>
<td></td>
<td>43.53-149.55 (6.1-15.8)</td>
<td>44.26-105.46** (6.2-11.8)</td>
<td>43.53-149.55 (6.1-15.8)</td>
</tr>
<tr>
<td>Duration of diabetes, in years (Mean ± SD)</td>
<td>5.14 ± 3.37 1-17</td>
<td>3.55± 2.02 1-8.5</td>
<td>5.77± 3.58 1-17</td>
</tr>
<tr>
<td>Insulin regimen</td>
<td>Conventional 38</td>
<td>16</td>
<td>22</td>
</tr>
</tbody>
</table>

^includes White British, White Irish and Any other White ethnic groups

* p<0.05 adolescents vs under 11

** p<0.01 adolescent vs under 11

Children and adolescents were split into two groups for analysis. Fifty-nine (28%) under 11 year olds and 151 (72%) adolescents took part in the research. The ethnicity of the
majority of the study sample was identified as white (82%), whilst the remaining 18% of the sample was made up of African, Asian (Indian/Pakistani), Caribbean, mixed and other ethnic group. A similar breakdown of ethnicity was also found for the under 11 year old and adolescent groups and both male and female participants. The National Paediatric Diabetes Audit (NPDA) 2013-2014 (154) shows a population make up of 72% Type 1 Diabetes patients who were White, which suggests, in terms of the wider population, this sample is slightly over-representative of white ethnicity. Almost equal numbers of males and females took part in the study overall, which is representative of the overall paediatric Diabetes population.

3.3 CYP and HbA1c

The target HbA1c level for patients with diabetes is 48mmol/mol (6.5%) (36). However, this target is a general target and patients are advised of their ideal HbA1c by their local healthcare team.

The mean HbA1c value for the overall sample was 75.14 ± 14.59mmol/mol (9.0±1.3), which is higher than the recommended level for patients with T1DM.

3.3.1 Differences in HbA1c levels, by demographics.

Further analysis showed that there was a significant difference in HbA1c between the under 11 year old group and adolescents. Adolescent HbA1c values (M=77.06, SE=1.26) were significantly higher than the HbA1c values of under 11 year old children (M=70.23, SE=1.38); t=3.65, p= <0.001. This difference could be explained by the fact that those in the younger age group were likely to have had T1DM for a shorter period of time and potentially were in the ‘honeymoon’ period of their diagnosis (2) where blood sugar levels seem to settle and are relatively easy to manage. This is due to an increase in insulin production, a response to the insulin therapy a child is receiving. Once this honeymoon

80
period comes to an end blood glucose levels should be monitored and managed more
diligently.

Males had slightly higher HbA1c levels than females (M=76.69, SE=1.43 v M=73.51,
SE=1.41) although this did not reach statistical significance (p=0.115).

Although it was be expected that those aiming for tighter blood glucose control (intensive
regimens) would have a lower HbA1c, comparison of HbA1c levels between those on
conventional (twice daily injections) vs intensive (multiple daily injections/pump therapy)
insulin regimens (M=77.21, SE=13.6 vs M=74.69, SE=14.78) did not yield a statistically
significant result (p=0.335).

3.4 Insulin Regimen

The mean duration of diabetes for the total population sample was 5.14 ± 3.37 years. The
majority of CYP were on an intensive (multiple daily injection/pump therapy) insulin
regimen: 172 vs 38 on conventional (twice daily injections) insulin regimens. Twenty-seven
percent of under 11 year olds were on conventional (twice daily injections) insulin
regimens compared with 15% of adolescents.

There was a significant association between age group and type of insulin regimen (χ² (1) =
4.51, p=0.034) indicating that the adolescent group was significantly more likely to be on
an intensive insulin regimen (85.4%) than the under 11 age group (72.9%). This is to be
expected as, at the time of the study younger patients were generally started on the
conventional (twice daily injections) insulin regimen and then transitioned to the more
intensive regimen as they got older. This is not the case in current paediatric diabetes
practice; newly diagnosed patients are more likely to be started on intensive regimens.
An equal number of males and females reported being on intensive insulin regimen therefore no differences were found between the groups for either treatment regimen ($x^2 (1) = 0.78, p=0.38$).
3.5 Parent demographics

One hundred and ninety parents (73% mothers) also took part in the study (Table 6).

**Table 6: Parent demographic data**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Mothers (N=138)</th>
<th>Mothers of U11 (N=47)</th>
<th>Mothers of Adolescents (N=91)</th>
<th>Fathers (N=52)</th>
<th>Fathers of U11 (N=15)</th>
<th>Fathers of Adolescents (N=37)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age</strong> (Mean ± SD)</td>
<td>40.33±6.78</td>
<td>36.19±6.26</td>
<td>42.53±6</td>
<td>43.2±6.84*</td>
<td>37.27±6.35</td>
<td>45.74±5.43</td>
</tr>
<tr>
<td><strong>University educated</strong></td>
<td>32 (28%)</td>
<td>14 (35%)</td>
<td>18 (24%)</td>
<td>19 (41%)</td>
<td>6 (46%)</td>
<td>13 (39%)</td>
</tr>
<tr>
<td><strong>Senior level/Professional Occupation</strong></td>
<td>18 (13%)</td>
<td>6 (15%)</td>
<td>12 (16%)</td>
<td>21 (40%)</td>
<td>5 (36%)</td>
<td>16 (46%)</td>
</tr>
<tr>
<td><strong>CYP HbA1c mmol/mol (%)</strong> (Mean ± SD)</td>
<td>74.16±14.44</td>
<td>70.37±11.62</td>
<td>76.12±15.39</td>
<td>72.96±10.58</td>
<td>68.00±10.66</td>
<td>74.98±8.85</td>
</tr>
<tr>
<td></td>
<td>(8.94±1.32)</td>
<td>(8.59±1.06)</td>
<td>(9.12±1.41)</td>
<td>(8.83±0.97)</td>
<td>(8.37±0.81)</td>
<td>(9.01±0.98)</td>
</tr>
</tbody>
</table>
Table to show the mean scores plus/minus standard deviation, in addition to the minimum and maximum figures for each variable.

*Mothers vs Fathers p<0.05

The age range of parents was 24 – 59 years. The majority of mothers and fathers were identified as white (89% of mothers and 92% of fathers). Twenty-eight per cent of mothers and 41% of fathers were university educated. Thirty children and adolescents had both parents take part in the study.

3.6 Breakdown of parental occupation

The majority of mothers were employed in administrative (18.64%) and caring professions (18.64%). A large number of mothers also identified themselves as housewives (16.95%). In comparison, the majority of fathers worked in managerial (24.49%), professional (18.37) and associate professional (16.33%) occupations.

3.7 Response Rates

The number of participants completing each measure varied from the total number of CYP and parents who took part in the study, for a number of reasons. More detailed explanations and response rates can be found in the Methods chapter (section 2.10), however, in brief, the reasons for variation include the differing age requirements for the completion of measures; by proxy reporting by parents for young children; and a change in tool for the collection of anxiety data during the course of the study.

3.8 Summary of Chapter 3

This chapter outlines the demographic data of the children and adolescents who took part in the study. Participants were recruited from a number of paediatric diabetes clinics in in the West Midlands, UK.
Equal numbers of males and females took part in the study and, as expected, a larger proportion of the sample was made up of those aged eleven and over (adolescent group). The ethnicity of the sample reflected figures reported by the NPDA 2013-2014 (154), with a slightly higher majority identifying themselves as White. In terms of insulin regimen, the majority of CYP were on conventional (twice daily injections) insulin regimens, as was generally the norm at the time of the study. However, paediatric practice in diabetes care has changed more recently, with intensive (multiple daily injections/pump therapy) regimens preferred at the point of diagnosis (26).

Not surprisingly, the majority of the parent sample was made up of mothers. This is typical of studies with paediatric groups as mothers tend to be the main carers. It was refreshing to see that a number of fathers also participated in the study as paternal data tends to be limited.

Response rates for CYP and parents were good, but as is the case in questionnaire-based studies, there was some variation due to factors associated with the measures themselves. These factors are reported and discussed in Chapter 2, section 2.10.
Chapter 4 Results: Self-reported frequency of hypoglycaemia and relationship to awareness of hypoglycaemia and HbA1c

Managing diabetes in childhood is extremely important to help ensure that children remain healthy and to minimise the long-term complications associated with the condition. Hypoglycaemia is an unavoidable and unpleasant consequence of diabetes management however, studies have shown it to be quite common amongst those with Type 1 Diabetes Mellitus.

This chapter, therefore, focuses on the prevalence of hypoglycaemia in the study sample. The aim is to identify whether hypoglycaemia is evident in this UK sample of children and young people. Descriptive statistics and graphical representations are used to demonstrate the incidence of hypoglycaemia and severe hypoglycaemia.

4.1 Self-reported frequency of hypoglycaemia

4.1.1 Definition of hypoglycaemia:
Hypoglycaemia is defined as blood sugar levels lower than the normal 4-7mmol/L range (36). Please note HbA1c is measured in mmol/mol and blood glucose levels are measured by mmol/L (155).

The frequency of hypoglycaemia survey (47) was used to collected retrospective data on the experience of hypoglycaemia and severe hypoglycaemia over recent years and also over the course of the CYPs’ diabetes diagnosis.
Self-reported, retrospective data collection of the frequency of hypoglycaemia for the whole sample showed that only four per cent of the sample had never experienced hypoglycaemia. A large percentage of the population sample reported experiencing an episode of hypoglycaemia more than once a month (66% of the entire cohort).

In the following graphs, the under 11 year old responses include proxy reports from parents who responded for the under 8 year old participants as the measure is not suitable as a self-report measure for children aged under 8 years. Percentages are reported by age group rather than percentages of the whole cohort.

**Figure 4: Self-reported and parent proxy reported frequency of hypoglycaemia by age group**

![Graph showing frequency of hypoglycaemia by age group](image.png)

Figure 4 above shows that a higher percentage of the Under 11 group report more frequent episodes of hypoglycaemia than adolescents do (44.6% vs 26% experiencing hypoglycaemia more than once a week). There are a number of factors which could explain these data. Younger children (and their parents) might over-report hypoglycaemia as a result of being over cautious and potentially mistaking symptoms for an episode of...
hypoglycaemia. Conversely, adolescents might be under-reporting hypoglycaemia due to impaired awareness of hypoglycaemia (45). Impaired awareness refers to a state where repeated exposure to hypoglycaemia actually reduces a person’s ability to detect an episode of hypoglycaemia, therefore affecting reports of hypoglycaemia history (48, 49). This will be discussed in more detail later in the chapter.

Of course, the data could just be an accurate reflection of the experience of hypoglycaemia. It could be that younger children do experience more episodes of hypoglycaemia, resulting from an inability to recognise symptoms of low blood sugar or potentially due to a newly diagnosed child still getting used to managing his/her diabetes. In this case then adolescents may actually experience less hypoglycaemia as they may be better at managing their BG levels. It is also important to note that these data are retrospective and rely on participants accurately recalling hypoglycaemic events. Inevitably there will be some inaccuracies in the recalled responses.

4.2 Self-reported episodes of Severe Hypoglycaemia

4.2.1 Definition of severe hypoglycaemia:
It can be difficult to define severe hypoglycaemia, especially for a paediatric population. This is because in adult studies an episode of hypoglycaemia is often defined as severe if the patient requires assistance to be treated (156).

In paediatric groups, the likelihood that a child will need assistance in treating an episode of hypoglycaemia, is high, because often a parent will take responsibility for this. Some studies (25, 27, 40) use a stricter definition citing the presence of a coma/seizure to define an episode of severe hypoglycaemia. Nevertheless, as the measure for frequency of hypoglycaemia (47) defines an episode of SH as an episode requiring assistance for treatment, this is the definition that will be used for the present study.
Experience of severe hypoglycaemia for the whole sample showed that 48% of the entire CYP cohort had experienced more than 5 episodes of severe hypoglycaemia in their lives.

**Figure 5: Self-reported and parent proxy reported episodes of severe hypoglycaemia in CYP since diagnosis, by age group**

The data in the Figure 5, above, show that the majority of CYP, overall, have experienced at least one episode of severe hypoglycaemia, since diagnosis. Episodes of severe hypoglycaemia seem to be similar between under 11 year olds and adolescents. However, a higher percentage of adolescents reported experiencing 3-5 episodes of severe hypoglycaemia, whereas more of the younger group reported more than five episodes of severe hypoglycaemia in their lives. This indicates that, in general, both under 11 year olds and adolescents experience a high number of episodes of severe hypoglycaemia.

Grouping the higher frequency categories together (i.e. ‘3 to 5’ and ‘more than 5’ episodes) we can see that adolescents actually experience a greater number of episodes of severe hypoglycaemia than the under 11 group. This could be due to impaired awareness of hypoglycaemia (as mentioned earlier, this will be discussed later in the chapter). Having impaired awareness of hypoglycaemia means that a person might not experience or recognise the warning signs of hypoglycaemia until the episode becomes more serious and
requires assistance from another person. Having said that, the estimated number of episodes of severe hypoglycaemia is also high for the under 11 group. This could be explained by the fact that parents tend to have to assist their children in treating an episode of hypoglycaemia, so in this instance may report these episodes as severe hypoglycaemia. Another explanation is that younger children themselves might not recognise the symptoms associated with hypoglycaemia or might be unable to verbalise this to their parents, or their parents might not be able to recognise the signs of hypoglycaemia in their child (157), thus resulting in a more severe episode of hypoglycaemia.

Either way, hypoglycaemia and severe hypoglycaemia both seem a real problem for children and young people in this sample. Further analysis of self-reported frequency of hypoglycaemia and episodes of severe hypoglycaemia is reported below.

### 4.3 Group comparisons of self-reported frequency of hypoglycaemia and self-reported episodes of severe hypoglycaemia.

Self-reports of the frequency of hypoglycaemia and episodes of severe hypoglycaemia were explored further by age group and also insulin regimen group. The tables below show all CYP responses to the multiple choice options presented in the frequency of hypoglycaemia measure (47) (which can be found in Appendix 1).

Responses in the table below are shown for adolescents and 8-10 year olds. Parents completed a proxy report for under 8 year olds, results of which can be found in the parent frequency tables (Table 11-16).
Table 7: Self-reported frequency of hypoglycaemia (%) by age group

<table>
<thead>
<tr>
<th>Frequency of hypoglycaemia</th>
<th>CYP (N=193)</th>
<th>8-10 (^) (N=43)</th>
<th>11-18 (N=150)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Never</td>
<td>9 (5)</td>
<td>1 (2)</td>
<td>8 (5)</td>
</tr>
<tr>
<td>Less than once/year</td>
<td>5 (3)</td>
<td>0 (0)</td>
<td>5 (3)</td>
</tr>
<tr>
<td>1-3 times/year</td>
<td>18 (9)</td>
<td>3 (7)</td>
<td>15 (16)</td>
</tr>
<tr>
<td>4-12 times/year</td>
<td>37 (19)</td>
<td>6 (14)</td>
<td>31 (21)</td>
</tr>
<tr>
<td>More than once/month</td>
<td>67 (35)</td>
<td>15 (35)</td>
<td>52 (35)</td>
</tr>
<tr>
<td>More than once/week</td>
<td>57 (29)</td>
<td>18 (42)</td>
<td>39 (26)</td>
</tr>
</tbody>
</table>

The table shows the CYP responses to the frequency measure. The number in brackets indicates the percentage of CYP who responded in each category.

^ Children aged under 8 did not complete the self-report Frequency of Hypoglycaemia measure (however parents completed a proxy report for under 8 year olds, results of which can be seen in the parent frequency table, Table 11).

A chi-square test was carried out on the categorical frequency data in order to identify whether there were any significant differences in reported frequency of hypoglycaemia. There was no significant difference in reports of the frequency of hypoglycaemia and between age groups (p=0.288) or across gender (p=0.298). The categories were dichotomised into ‘less than once a week’ vs ‘more than once a week, to allow comparison of episodes of hypoglycaemia that were less disruptive vs extremely disruptive. Chi-square analysis here showed a significant difference between age groups, \( \chi^2(1) = 4.58, p=0.032 \), with more of the younger age group experiencing hypoglycaemia.
more frequently than adolescents (42% vs 26%). This difference in reports of hypoglycaemia could be attributed to the fact that younger children are more likely to be newly diagnosed or have had T1DM for a shorter period than their adolescent counterparts and therefore may not have quite managed to get their blood sugars under control.

**Table 8: Self-reported episodes of severe hypoglycaemia (%) by age group**

<table>
<thead>
<tr>
<th>Episodes of severe hypoglycaemia (in CYP’s life)</th>
<th>CYP N=193</th>
<th>8-10 ^ N=43</th>
<th>11-18 N=150</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>62 (32)</td>
<td>16 (37)</td>
<td>46 (31)</td>
</tr>
<tr>
<td>1 or 2</td>
<td>65 (34)</td>
<td>16 (37)</td>
<td>48 (32)</td>
</tr>
<tr>
<td>3-5</td>
<td>26 (13)</td>
<td>1 (2)</td>
<td>25 (17)</td>
</tr>
<tr>
<td>More than 5 times</td>
<td>40 (21)</td>
<td>10 (24)</td>
<td>30 (20)</td>
</tr>
</tbody>
</table>

*This table shows the CYP responses to the frequency measure. The number in brackets indicates the percentage of CYP who responded in each category.*

^ *Children aged under 8 did not complete the self-report Frequency of Hypoglycaemia measure* (however parents completed a proxy report for under 8 year olds, results of which can be seen in the parent frequency table, Table 11).
Chi-square analysis also showed no significant difference in reports of the number of episodes of severe hypoglycaemia between age groups (p=0.120) or across gender (p=0.509).

### Table 9: Self-reported frequency of hypoglycaemia (%) by insulin regimen

<table>
<thead>
<tr>
<th>Frequency of hypoglycaemia</th>
<th>Conventional insulin regimen N=37</th>
<th>Intensive insulin regimen N=156</th>
</tr>
</thead>
<tbody>
<tr>
<td>Never</td>
<td>6 (16)</td>
<td>3 (2)</td>
</tr>
<tr>
<td>Less than once/year</td>
<td>1 (3)</td>
<td>4 (3)</td>
</tr>
<tr>
<td>1-3 times/year</td>
<td>8 (22)</td>
<td>10 (6)</td>
</tr>
<tr>
<td>4-12 times/year</td>
<td>7 (19)</td>
<td>30 (19)</td>
</tr>
<tr>
<td>More than once/month</td>
<td>6 (16)</td>
<td>61 (39)</td>
</tr>
<tr>
<td>More than once/week</td>
<td>9 (24)</td>
<td>48 (31)</td>
</tr>
</tbody>
</table>

*The table shows the CYP responses to the frequency measure. The number in brackets indicates the percentage of CYP who responded in each category.*

*p<0.05 (overall significant difference between conventional and intensive insulin regimens).*

Chi-square analysis revealed significant differences between the insulin regimen groups where, not surprisingly, overall, CYP on intensive insulin regimens reported a higher frequency of hypoglycaemia than CYP on the conventional insulin regimen ($x^2 (5) = 25.46$, p= <0.001). Specifically, those on intensive insulin regimens reported a higher frequency
of hypoglycaemia (more than once per month) compared to those on conventional insulin therapy (70% vs. 40%; p = <0.001). These results were not unexpected. By trying to maintain optimum blood glucose levels, those CYP who managed their diabetes with intensive insulin regimes were potentially more likely to experience blood glucose levels that fell below the recommended 4-7 mmol/L and were therefore more likely to experience hypoglycaemia.

This finding suggests that when CYP intensively manage their T1DM then the frequency of hypoglycaemia is likely to be high. It is important to note the relevance of this finding in the management of T1DM today, because recommended diabetes regimens have changed since this study was carried out (26) and intensive regimes are more common-place than they were previously. More often than not CYP diagnosed with T1DM will be started on an intensive regimen straight away.

Table 10: Self-reported episodes of severe hypoglycaemia (%) by insulin regimen

<table>
<thead>
<tr>
<th>Episodes of severe hypoglycaemia (in CYP’s life)</th>
<th>Conventional insulin regimen</th>
<th>Intensive insulin regimen</th>
</tr>
</thead>
<tbody>
<tr>
<td>N=37</td>
<td>N=156</td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>20 (54)</td>
<td>42 (27)</td>
</tr>
<tr>
<td>1 or 2</td>
<td>9 (24)</td>
<td>55 (35)</td>
</tr>
<tr>
<td>3-5</td>
<td>3 (8)</td>
<td>23 (15)</td>
</tr>
<tr>
<td>More than 5 times</td>
<td>5 (14)</td>
<td>35 (23)</td>
</tr>
</tbody>
</table>
This table shows the CYP responses to the frequency measure. The number in brackets indicates the percentage of CYP who responded in each category.

**p<0.01** (overall significant difference between conventional and intensive insulin regimens).

Further chi-square analysis revealed significant differences between the insulin regimen groups where, again, not surprisingly, overall, CYP on intensive insulin regimens reported a higher number of episodes of severe hypoglycaemia than CYP on the conventional insulin regimen $\chi^2(3) =10.17$, $p=0.017$. Overall, those on intensive insulin regimens were also more likely to experience more episodes (more than 5) of severe hypoglycaemia than those on conventional regimens (23% vs. 14%, $p=0.017$). Again these results were expected. It seems that CYP who managed their diabetes with intensive insulin regimes were more likely to experience blood glucose levels that fell well below the recommended 4-7mmol/L and were therefore more likely to experience severe hypoglycaemia. The implications of this have already been discussed in relation to the relationship between insulin regimen and frequency of hypoglycaemia. However, it should be noted that in a review of data of Danish children with T1DM from 1998-2009, intensive insulin regimens (multiple daily injections and pump therapy) significantly reduced the risk of severe hypoglycaemia in these patients (39).

### 4.4 Parental reports of frequency of hypoglycaemia and episodes of severe hypoglycaemia
Table 11: Parent-reported frequency of hypoglycaemia (%), all CYP.

<table>
<thead>
<tr>
<th>Frequency of hypoglycaemia</th>
<th>Parents N= 184</th>
<th>Mother N= 133</th>
<th>Father N= 51</th>
</tr>
</thead>
<tbody>
<tr>
<td>Never</td>
<td>7 (4)</td>
<td>6 (5)</td>
<td>1 (2)</td>
</tr>
<tr>
<td>Less than once/year</td>
<td>4 (2)</td>
<td>0 (0)</td>
<td>4 (8)</td>
</tr>
<tr>
<td>1-3 times/year</td>
<td>11 (6)</td>
<td>9 (7)</td>
<td>2 (4)</td>
</tr>
<tr>
<td>4-12 times/year</td>
<td>31 (17)</td>
<td>25 (19)</td>
<td>6 (12)</td>
</tr>
<tr>
<td>More than once/month</td>
<td>62 (34)</td>
<td>48 (36)</td>
<td>14 (27)</td>
</tr>
<tr>
<td>More than once/week</td>
<td>69 (38)</td>
<td>45 (34)</td>
<td>24 (47)</td>
</tr>
</tbody>
</table>

The table shows parental responses to the frequency measure. The number in brackets indicates the percentage of parents who responded in each category.

*p<0.05

Overall, there was a significant difference between reports of hypoglycaemia between mothers and fathers ($\chi^2 (5) = 15.18, p=0.010$). Fathers reported a higher frequency (more than once a week) of hypoglycaemia for their children than mothers did (47% vs. 34%). This could be attributed to fathers potentially perceiving their child to have more episodes of hypoglycaemia than mothers (who are most likely to have a better idea of the number of episodes) and therefore over-reporting these episodes.
Table 12: Parent-reported episodes of severe hypoglycaemia (%), all CYP.

<table>
<thead>
<tr>
<th>Episodes of severe hypoglycaemia (in CYP’s life)</th>
<th>Parents N= 184</th>
<th>Mother N= 133</th>
<th>Father N= 51</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>60 (32)</td>
<td>44 (33)</td>
<td>16 (31)</td>
</tr>
<tr>
<td>1 or 2</td>
<td>54 (29)</td>
<td>43 (32)</td>
<td>11 (21)</td>
</tr>
<tr>
<td>3-5</td>
<td>23 (12)</td>
<td>11 (8)</td>
<td>12 (23)</td>
</tr>
<tr>
<td>More than 5 times</td>
<td>48 (26)</td>
<td>35 (26)</td>
<td>13 (25)</td>
</tr>
</tbody>
</table>

Table 12 shows parental responses to the frequency measure. The number in brackets indicates the percentage of parents who responded in each category.

*p<0.05

As with analysis of frequency of hypoglycaemia, there was a significant difference between reports of severe hypoglycaemia between mothers and fathers ($\chi^2 (3) = 8.28$, p=0.041).
Table 13: Parent-reported frequency of hypoglycaemia (%), under 11 group.

<table>
<thead>
<tr>
<th>Frequency of hypoglycaemia</th>
<th>Mother Under 11</th>
<th>Father Under 11</th>
</tr>
</thead>
<tbody>
<tr>
<td>Never</td>
<td>1 (2)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Less than once/year</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>1-3 times/year</td>
<td>4 (9)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>4-12 times/year</td>
<td>2 (4)</td>
<td>1 (7)</td>
</tr>
<tr>
<td>More than once/month</td>
<td>14 (31)</td>
<td>5 (33)</td>
</tr>
<tr>
<td>More than once/week</td>
<td>24 (53)</td>
<td>9 (60)</td>
</tr>
</tbody>
</table>

Table 13 shows the parental responses to the frequency measure. The number in brackets indicates the percentage of parents who responded in each category.

Looking at the mother and father reports of hypoglycaemia for the two age groups separately, results showed no significant differences between mother and father reports of hypoglycaemia for children aged under 11 (p=0.76). A difference might have been expected here as with mothers being the primary caregivers they are more likely to have an accurate idea of frequency of hypoglycaemia than fathers.
Table 14: Parent-reported episodes of severe hypoglycaemia (%), under 11 group.

<table>
<thead>
<tr>
<th></th>
<th>Mother Under 11</th>
<th>Father Under 11</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N= 45</td>
<td>N= 15</td>
</tr>
<tr>
<td>Episodes of severe</td>
<td></td>
<td></td>
</tr>
<tr>
<td>hypoglycaemia (in</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CYP’s life)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>12 (27)</td>
<td>7 (47)</td>
</tr>
<tr>
<td>1 or 2</td>
<td>15 (33)</td>
<td>1 (7)</td>
</tr>
<tr>
<td>3-5</td>
<td>3 (7)</td>
<td>4 (27)</td>
</tr>
<tr>
<td>More than 5 times</td>
<td>15 (33)</td>
<td>3 (20)</td>
</tr>
</tbody>
</table>

Table 14 shows the parental responses to the frequency measure. The number in brackets indicates the percentage of parents who responded in each category.

* p<0.05

Looking at the analysis of the parents of the under 11 age group for severe hypoglycaemia, chi-square tests showed there was a significant difference in reports of severe hypoglycaemia between mother and fathers ($x^2(3)=8.95$, p=0.030), with mothers reporting more episodes (more than 5 times) of severe hypoglycaemia for the under 11 group than fathers (33% vs 20%). This result may be the result of mothers being the primary caregivers and therefore being more aware of actual episodes of severe hypoglycaemia than fathers.
Table 15: Parent-reported frequency of hypoglycaemia (%), adolescent group.

<table>
<thead>
<tr>
<th></th>
<th>Mother Adolescent</th>
<th>Father Adolescent</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N= 88</td>
<td>N= 36</td>
</tr>
<tr>
<td>Frequency of</td>
<td>**</td>
<td></td>
</tr>
<tr>
<td>hypoglycaemia</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Never</td>
<td>5 (6)</td>
<td>1 (3)</td>
</tr>
<tr>
<td>Less than once/year</td>
<td>0 (0)</td>
<td>4 (11)</td>
</tr>
<tr>
<td>1-3 times/year</td>
<td>5 (6)</td>
<td>2 (6)</td>
</tr>
<tr>
<td>4-12 times/year</td>
<td>23 (26)</td>
<td>5 (14)</td>
</tr>
<tr>
<td>More than once/month</td>
<td>34 (39)</td>
<td>9 (3)</td>
</tr>
<tr>
<td>More than once/week</td>
<td>21 (24)</td>
<td>15 (42)</td>
</tr>
</tbody>
</table>

Table 15 shows the parental responses to the frequency measure. The number in brackets indicates the percentage of parents who responded in each category.

** p<0.01

Analysis of the parents of the adolescent group showed the opposite of the results produced for parents of the under 11 group. A significant difference was evident in reports of frequency of hypoglycaemia ($\chi^2(5) = 16.08, p=0.007$) between parents of the adolescent group. Mothers reported a higher frequency of hypoglycaemia (more than once a month) for the adolescent group than fathers did (63% vs 45%). This could be attributed to mothers being around the adolescent group more than fathers and
potentially having a better idea of the number of episodes of hypoglycaemia they tend to have.

Table 16: Parent-reported episodes of severe hypoglycaemia (%), adolescent group.

<table>
<thead>
<tr>
<th>Episodes of severe hypoglycaemia (in CYPs’ life)</th>
<th>Mother Adolescent N= 88</th>
<th>Father Adolescent N= 36</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>32 (36)</td>
<td>9 (24)</td>
</tr>
<tr>
<td>1 or 2</td>
<td>28 (32)</td>
<td>10 (27)</td>
</tr>
<tr>
<td>3-5</td>
<td>8 (9)</td>
<td>8 (22)</td>
</tr>
<tr>
<td>More than 5 times</td>
<td>20 (23)</td>
<td>10 (27)</td>
</tr>
</tbody>
</table>

The table shows the parental responses to the frequency measure. The number in brackets indicates the percentage of parents who responded in each category.

For the parents of the adolescent group there was no significant difference in reports of severe hypoglycaemia between mothers and fathers (p=0.192).
4.5 Comparison of episodes of reports of SH between CYP and parents

A comparison of CYPs’ and mothers’ and fathers’ free responses of self-reports of severe hypoglycaemia in the preceding year revealed a significant relationship between the responses of CYP and their mothers (r=0.65, p<0.001) and fathers (r=0.39, p<0.001). Similarly, responses to the number of episodes of severe hypoglycaemia experienced in the year before last also showed a significant relationship between CYP and mothers’ (r=0.52, p<0.001) and fathers’ (r=0.32, p=0.027) responses. So CYP and parents’ reports of hypoglycaemia and severe hypoglycaemia are similar and showed a positive linear trend.

As with the overall CYP group, mothers’ and fathers’ responses correlated positively with the responses provided by their children (with the exception of the fathers and U11 group) at, at least the 0.05 level of significance. Reports of hypoglycaemia were similar between parents and CYP, for both age groups, except for fathers and the under 11 group. Reasons for the difference in fathers’ responses and the response of the younger age group could be that fathers don’t tend to be the primary caregivers and so are less aware of the frequency with which their child is experiencing severe hypoglycaemia. Why is this different to fathers of adolescents then? The reason could be that reports of severe of hypoglycaemia are actually more likely to be severe in the adolescent group and therefore be relayed back to fathers whereas for the under 11 group a severe hypoglycaemia might be more likely just an episode which requires assistance from a parent but actually isn’t as severe in its nature, so therefore a lot of the time the fathers are unaware that they have occurred (because the event isn’t relayed back to them).

Free responses to Q3a and Q3b (Appendix 1) asking recall of the specific number of episodes of severe hypoglycaemia in the previous year and year before that, suggest that
parents and their children have a similar recollection of CYPs’ experience of severe hypoglycaemia.

4.6 The relationship between the frequency of hypoglycaemia and hypoglycaemia awareness

Reports of hypoglycaemia will no doubt be affected by CYPs’ awareness of an episode of hypoglycaemia and severe hypoglycaemia. Awareness of hypoglycaemia can be a factor in CYPs’ ability to report the frequency of hypoglycaemia as they may not always be aware that they are experiencing hypoglycaemia. Awareness can also play a part in whether CYP are able to respond to an episode of hypoglycaemia before it becomes too severe, again because of the delay in being aware of experiencing hypoglycaemia.

Hypoglycaemia awareness was measured using both the Gold (47) and Clarke (49) methods, across the adolescent group only, as it is not suitable for use by younger children. Adolescents were assigned to one of two groups (normal awareness and impaired awareness) depending on their total score on the measure. A score of 4+ indicates an impaired awareness of hypoglycaemia (IAH). Scores suggest that 25% (N=36) of adolescents have IAH.

Differences between adolescents with normal awareness vs impaired awareness were explored. The two groups did not differ significantly on age, gender, HbA1c levels or insulin regimen. Mann-Whitney tests showed that adolescents with IAH have a significantly longer duration of diabetes (Mdn = 6.5 years) than those with normal awareness (Mdn=5.0 years), U=1465.0, p=0.027. This is not unexpected as those with a longer duration of diabetes are likely to experience more episodes of hypoglycaemia, which itself is a contributor to impaired awareness.
Although there were no significant differences in awareness between adolescents on conventional vs intensive insulin regimens (p=0.683) here it might have been expected that those on intensive insulin regimens may be more likely to show signs of IAH than those on the conventional regimen due to those on intensive regimens potentially being more likely to experience hypoglycaemia due to tighter blood sugar control (156).

Figure 6 below shows a comparison of adolescent reports of the frequency of hypoglycaemia by awareness of hypoglycaemia.

**Figure 6: Comparison of frequency of hypoglycaemia between CYP with normal vs impaired awareness of hypoglycaemia.**

This figure shows that very few adolescents in either group reported hypoglycaemic episodes less than once per year. Those with IAH, however, were less likely to report hypoglycaemic episodes more than once a week. This could be a reflection of their impaired ability to detect hypoglycaemia.
Correlational analysis was carried out using the raw scores from the awareness measure. There was no significant correlation between hypoglycaemia awareness and reported frequency of hypoglycaemia ($r=-0.081$, $p=0.333$). When looking at awareness dichotomised into normal vs impaired awareness, chi-square analysis to observe the association between frequency of hypoglycaemia and hypoglycaemia awareness further, showed no significant relationship ($\chi^2(5)=9.06$, $p=0.107$). Based on the theoretical link between hypoglycaemia and IAH (49), a significant association was expected. More frequent episodes of hypoglycaemia might be expected to be associated with a higher incidence of impaired awareness of hypoglycaemia, considering research suggests increased exposure to hypoglycaemia can lead to IAH. It could, however, be that those with IAH simply under-reported frequency of hypoglycaemia as they did not recognise the symptoms of an episode.

4.7 The relationship between the episodes of severe hypoglycaemia and hypoglycaemia awareness.

Having discussed the relationship between frequency of hypoglycaemia and IAH, it is important to also look at any association between severe hypoglycaemia and IAH.

Figure 7 below shows the number of adolescents with normal and impaired awareness of hypoglycaemia, reporting on their experience of severe hypoglycaemia.
Figure 7: Comparison of episodes of severe hypoglycaemia between CYP with normal vs impaired awareness of hypoglycaemia.

For severe hypoglycaemia, the data in Figure 7 show a difference between those adolescents with normal awareness and those adolescents with impaired awareness of hypoglycaemia. Figure 7 shows that more adolescents with a normal awareness of hypoglycaemia report having had no or 1 or 2 severe hypoglycaemia in their lives whereas a higher proportion of those with an impaired awareness of hypoglycaemia (IAH) report a higher number of episodes of severe hypoglycaemia. This follows from the earlier observation that those in the impaired group reported a lower number of episodes of hypoglycaemia potentially due to the fact that they had IAH. Therefore the lack of awareness of hypoglycaemia could have led these adolescents to be more likely to experience severe hypoglycaemia as they might not have noticed or experienced the initial symptoms until their blood sugars dropped to extremely low levels.

There was a significant positive correlation between awareness of hypoglycaemia scores and the number of episodes of severe hypoglycaemia in an adolescent’s life ($r=0.391$, $p=0.000$), indicating that those with IAH experienced more frequent episodes of
hypoglycaemia. Similarly, awareness scores also produced significant positive correlations with reports of severe hypoglycaemia in the last year ($r=0.357$, $p<0.001$) and the year previous to last year ($r=0.287$, $p<0.001$). Again this indicates that those adolescents with IAH experienced more episodes of severe hypoglycaemia in preceding years, notwithstanding the fact that increased experiences of hypoglycaemia might have caused IAH in the first place. Table 17 outlines the reported data for episodes of SH in the last year and the year before last.

**Table 17: Self-reported number of episodes of severe hypoglycaemia in preceding years (median (range)).**

<table>
<thead>
<tr>
<th></th>
<th>CYP</th>
<th>U11</th>
<th>Adolescent</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>No. of episodes of SH in the last year</strong></td>
<td>0.0 (0-100) N=181</td>
<td>1.0 (0-100) N=43</td>
<td>0.0 (0-30) N=138</td>
</tr>
<tr>
<td><strong>No. of episodes of SH in the year before last</strong></td>
<td>0.0 (0-100) N=178</td>
<td>0.0 (0-100) N=43</td>
<td>0.0 (0-50) N=135</td>
</tr>
</tbody>
</table>

The association between awareness of hypoglycaemia and the number episodes of severe hypoglycaemia experienced in an adolescent’s life was explored further using chi-square analysis. A significant association between awareness and experience of severe hypoglycaemia was found $\chi^2 (3) = 11.32$, $p=0.010$. Reports of more than 5 episodes of severe hypoglycaemia were higher for those with impaired awareness when compared with CYP with normal awareness (33.3% vs 16.7%). This is not surprising considering that those with impaired awareness are less likely to experience the early signs of a hypoglycaemic episode (if at all), which in turn can become more severe if it hasn’t been treated.
4.8 Frequency of Hypoglycaemia and HbA1c

4.8.1 CYP
Overall, for all CYP there were no significant differences in HbA1c data across frequency of hypoglycaemia (F=0.92, p=0.47) and frequency of severe hypoglycaemia (F=0.30, p=0.83). No differences in HbA1c were found when comparing those CYP who had suffered from an episode of severe hypoglycaemia vs those who had not (U=4013.0, p=0.90). Correlations of free reports of severe hypoglycaemia in the past year and year before with HbA1c also returned no significant relationships (p=0.336 and p=0.601, respectively). This is surprising. It might have been expected that there was some link between frequency of hypoglycaemia/severe hypoglycaemia and HbA1c, perhaps a lower HbA1c to reflect more frequent episodes of hypoglycaemia. However, this was not the case. HbA1c can be affected by a number of external (and internal factors) which could have mediated any potential relationship.

4.9 Summary of Chapter 4
The incidence of hypoglycaemia and severe hypoglycaemia is high in both the under 11 age group and adolescent group. The data show that 60% of adolescents and 80.3% of under 11 year olds report experiencing hypoglycaemia more than once a month. This is in stark contrast to the percentage of under 11 year olds and adolescents reporting never having experienced hypoglycaemia (1.8%; 5.3%).

Reports of episodes of severe hypoglycaemia (requiring the assistance of another person in order to treat the episode) are also high. Almost 37% of adolescents report having suffered from severe hypoglycaemia more than 3 times in their lives, with almost 30% of under 11 year olds also reporting the same thing. The figures do cause for concern, however, they don’t tell us how severe the episodes of hypoglycaemia being reported here, are. Are they episodes leading to coma/seizures or are they just episodes that require assistance because the child or adolescent is too young or unprepared to treat the
episode themselves? A limitation of the data here may also impact the reports of severe hypoglycaemia. The interpretation of severe hypoglycaemia might vary across individuals in this age group so the data might not give a true reflection of the experience of severe hypoglycaemia. Self-report data also relies on participants being able to accurately recall events that may have happened a year or two previously.

Overall, there was no statistically significant difference for the frequency of hypoglycaemia or frequency of severe hypoglycaemia, either between age groups or across gender, although dichotomising the frequency responses showed otherwise. Significant differences were found, however, between the two insulin regimens. Not surprisingly, those on more intensive regimens reported a higher frequency of hypoglycaemia and severe hypoglycaemia than CYP on conventional insulin regimens.

Mothers and fathers were found to report significantly different frequencies of hypoglycaemia and severe hypoglycaemia. This could be related to the roles that they play in their child’s diabetes management. Reports of hypoglycaemia were similar, at, at least the 0.05 level of significance, between parents and their children across age groups, except for fathers and the under 11 year group.

Links between the frequency of hypoglycaemia and impaired awareness of hypoglycaemia were explored. Significant differences in the frequency of severe hypoglycaemia between adolescents with impaired vs normal awareness of hypoglycaemia were found. The results were not replicated for the frequency of hypoglycaemia.

Unexpectedly, no significant relationships were found between frequency of hypoglycaemia, frequency of severe hypoglycaemia and HbA1c.
Chapter 5 Results: Fear of Hypoglycaemia

Fear of hypoglycaemia (FoH) is an emotional/cognitive response to the experience of hypoglycaemic episodes. Experience of hypoglycaemia can be upsetting, embarrassing and even terrifying for people with diabetes and their carers. This can lead to a fear of experiencing an episode of hypoglycaemia and can lead to sub-optimal care for oneself or if caring for another, by keeping blood sugar levels higher (72, 78) than recommended by health professionals, in order to avoid the unpleasant symptoms associated with hypoglycaemia.

The scale used to measure FoH in the population sample of this study is the Hypoglycaemia Fear Survey (HFS) (147). This measure looks at behaviours and worry associated with hypoglycaemia, as well as a Total score, in order to quantify (to an extent) the fear of hypoglycaemia in an individual (see 2.5.2.5 for full description of HFS measure). The HFS scale has a version suitable for CYP (Child Hypoglycaemia Fear Survey; CHFS) and one aimed at parents of CYP with T1DM (Parental Hypoglycaemia Fear Survey; PHFS). The measure does not provide definitive scores or cut off points of whether a person has a fear of hypoglycaemia or not, but rather gives indication of FoH on a scale (0 - 125 scores); i.e. a higher score indicates a higher fear of hypoglycaemia.

5.1 Fear of hypoglycaemia in CYP

It is difficult to say conclusively whether CYP in this study have a fear of hypoglycaemia, considering there is no cut off score. However, the scores suggest that children and adolescents do experience a level of FoH, given that the scores are above zero. Table 17 highlights the mean and standard deviation for scores on the HFS measure for CYP.
Table 18: HFS Measure (Mean plus/minus SD and range)

<table>
<thead>
<tr>
<th></th>
<th>Total CYP</th>
<th>U11</th>
<th>Adolescents</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>HFS Behaviour</strong></td>
<td>19.68±6.82</td>
<td>20.54±7.65</td>
<td>19.38±6.51</td>
<td>N/S</td>
</tr>
<tr>
<td></td>
<td>(0-40) N=203</td>
<td>(4-36) N=52</td>
<td>(0-40) N=151</td>
<td></td>
</tr>
<tr>
<td><strong>HFS Worry</strong></td>
<td>17.49±11.92</td>
<td>18.96±13.79</td>
<td>16.99±11.21</td>
<td>N/S</td>
</tr>
<tr>
<td></td>
<td>(0-53) N=197</td>
<td>(0-52) N=50</td>
<td>(0-53) N=147</td>
<td></td>
</tr>
<tr>
<td><strong>HFS Total</strong></td>
<td>37.11±14.94</td>
<td>39.7±16.75</td>
<td>36.22±14.23</td>
<td>N/S</td>
</tr>
<tr>
<td></td>
<td>(0-82) N=197</td>
<td>(6-82) N=50</td>
<td>(0-75) N=147</td>
<td></td>
</tr>
</tbody>
</table>

5.2 *Difference in fear of hypoglycaemia between age groups*

Figure 8 below illustrates the difference in HFS scores between the under 11 group and adolescents.
Analysis looking at the differences between the CHFS scores for the age groups of CYP showed no significant differences between the under 11 group and adolescents. The under 11 group (M=20.54, SE=1.06) scored higher for HFS Behaviour than the adolescent group (M=19.38, SE=0.53). The difference, however, was not statistically significant, t=-1.05, p=0.293. For HFS Worry, again the under 11 group (M=18.96, SE=1.95) scored higher than the adolescent group (M=16.99, SE=0.93). There was not a significant difference between the scores for the two groups, t=-1.01, p=0.315. Finally, the two groups’ total CHFS scores were compared. The under 11 group (M=39.7, SE=2.37) scored higher than the adolescent group (M=36.22, SE=1.17). There was no significant difference between groups for total CHFS scores, t=-1.43, p=0.156. Although there were negative correlations between CHFS scores and age and diabetes duration, the correlations were not statistically significant. This indicates that FoH does not decrease as age and duration of diabetes increase.
5.3 Differences in fear of hypoglycaemia, by demographics

Figure 9 below shows the difference in HFS scores between those on conventional vs intensive insulin regimens.

Figure 9: Differences in fear of hypoglycaemia by insulin regimen

5.3.1 Fear of hypoglycaemia and insulin regimen

Differences in FoH scores between CYP on conventional and intensive insulin regimens were explored. T-test analysis revealed no significant differences in CHFS scores between CYP on conventional vs intensive insulin regimens, (M= 36.86, SE = 16.76) vs (M = 37.16, SE = 14.54), t=0.11, p=0.913. The results were surprising; it might be expected that those who are on intensive insulin regimens are more likely to experience a higher frequency of hypoglycaemia and severe hypoglycaemia. Therefore a higher frequency of hypoglycaemia and SH might be expected to contribute to a fear of hypoglycaemia (due to increased exposure to hypoglycaemia).
Looking at results for CHFS by insulin regimen, for each of the age groups, there was also no significant difference within the under 11 group between conventional vs intensive regimens (M=36.0, SE=4.48) vs (M=40.51, SE=2.72), p=0.470. A similar result is reported for differences in CHFS for adolescents between those on conventional vs intensive regimes (M=40.19, SE=2.83) vs (M=35.37, SE=1.28), p=0.117.

5.3.2 Fear of hypoglycaemia and gender
No differences between genders, for CHFS scores were found. Data not presented.

5.3.3 Fear of hypoglycaemia and HbA1c
Considering one of the key implications of FoH is the impact it may have on HbA1c levels it is important to explore whether there is a relationship between HbA1c and CHFS scores (Table 19).

Table 19: Relationship between fear of hypoglycaemia (Behaviour (B), Worry (W) and Total (T)) scores and HbA1c levels

<table>
<thead>
<tr>
<th>CYP</th>
<th>U11</th>
<th>Adolescent</th>
</tr>
</thead>
<tbody>
<tr>
<td>CHFS-B</td>
<td>CHFS-W</td>
<td>CHFS-T</td>
</tr>
<tr>
<td>-0.095</td>
<td>-0.001</td>
<td>-0.047</td>
</tr>
<tr>
<td>-0.122</td>
<td>0.181</td>
<td>0.091</td>
</tr>
<tr>
<td>-0.073</td>
<td>-0.030</td>
<td>-0.057</td>
</tr>
</tbody>
</table>

*Table above reports the correlation coefficients, illustrating the relationship between CHFS scores and HbA1c.*

Analyses of CHFS scores and HbA1c showed no statistically significant correlations between the two variables for all CYP or by age group. Considering that behaviour
associated with FoH might lead to those CYP with T1DM (or their parents) maintaining higher blood glucose levels, a positive correlation between CHFS scores and HbA1c might be expected. So as fear of hypoglycaemia increased blood glucose levels and consequently HbA1c levels would also increase (to reflect behaviours to avoid hypoglycaemia). However, as HbA1c can be affected by a number of factors (duration of diabetes, the weather, physical activity, body mass index) it could be that alone, FoH does not have a strong enough link with HbA1c levels. HbA1c is also a relatively short term measure and changes every three months so might not be a reliable indicator, however, for this study, where available, the average HbA1c over the past 12 months was recorded to counteract this.

Although these results reflect similar reports to other studies looking at HbA1c and FoH (72), other studies report an association between high CHFS scores and higher HbA1c levels, especially for adolescents (83).

### 5.4 Parental fear of hypoglycaemia

As mentioned previously, there is no cut off point to indicate whether or not a person has a fear of hypoglycaemia. Instead, the scores indicate the level of fear on a scale (higher scores indicate higher FoH). For parents of children and adolescents in this study, FoH is evident, however, statements cannot be made as to whether this fear is high or not. Comparisons of scores between groups however, will allow some conclusions to be drawn. Parental scores are shown below in Table 20.
Table 20: HFS measure parental scores (Mean plus/minus SD and range)

<table>
<thead>
<tr>
<th></th>
<th>Mother</th>
<th>Father</th>
<th>Mother U11</th>
<th>Mother Adolescent</th>
<th>Father U11</th>
<th>Father Adolescent</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>PHFS Total</strong></td>
<td>50.16±17.76 (3-89) N=137</td>
<td>45.15±17.96 (13-89) N=52</td>
<td>50.13±15.36 (22-77) N=47</td>
<td>50.18±18.97 (3-89) N=90</td>
<td>48.07±16.83 (21-83) N=15</td>
<td>44.14±18.60 (13-89) N=37</td>
</tr>
</tbody>
</table>
5.4.1 Comparison of parental HFS scores, by age group.
There were no significant differences between the two groups for CYP overall, although mothers’ scores were higher than fathers’ scores. A comparison of mothers’ and fathers’ PHFS scores revealed no significant differences across age groups for each of the subscales. Similarly, no significant differences were found between mothers’ and fathers’ PHFS scores, for the under 11 group and the adolescent group, although, mothers scored higher than fathers across all PHFS subgroups for adolescents.

PHFS scores of mothers of the two age groups and fathers of the two age groups were compared. No significant differences were found between PHFS scores for mothers of the under 11 age group and mothers of the adolescent group. Similarly, no significant differences were found between PHFS scores of fathers of the under 11 group and fathers of the adolescent group.

5.4.2 Comparison of parental HFS scores, by CYP’s insulin regimen
No significant differences in parental PHFS scores were found between mothers of CYP on conventional vs intensive insulin regimens. Similarly no significant differences in PHFS scores were found between fathers of CYP on conventional vs intensive insulin regimens. Data not shown.

5.5 Relationship between CYP and parental fear of hypoglycaemia
The relationship between CYP FoH and parental FoH was investigated by analysing CHFS and PHFS scores.
Table 21: Comparison of all CYP and Parent HFS scores (Mean plus/minus SD and range)

<table>
<thead>
<tr>
<th></th>
<th>Total CYP</th>
<th>Mother</th>
<th>Father</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>HFS Behaviour</strong></td>
<td>19.68±6.82 (0-40)</td>
<td>22±7.07 (2-38) **</td>
<td>21.06±7.17 (4-38)</td>
</tr>
<tr>
<td><strong>HFS Worry</strong></td>
<td>17.49±11.92 (0-53)</td>
<td>28.04±13.51 (0-56) ***</td>
<td>24.02±12.74(2-55) **</td>
</tr>
<tr>
<td><strong>HFS Total</strong></td>
<td>37.11±14.94 (0-82)</td>
<td>50.16±17.76 (3-89) ***</td>
<td>45.15±17.96 (13-89) **</td>
</tr>
</tbody>
</table>

**p<0.01 CYP vs Mothers/Fathers

***p<0.001 CYP vs Mothers

Table 21 shows a comparison of HFS scores between all CYP, mothers and fathers. T-test analyses of mothers’ and CYP HFS scores showed significant differences across all HFS categories. Mothers scored significantly higher than CYP for HFS Behaviour (t=-3.04, p=0.003), Worry (t=-7.36, p<0.001) and Total (t=-7.04, p<0.001) all at the 0.01 level of significance. These results suggest that mothers of CYP with T1DM actually present a higher FoH for their children than CYP do for themselves. As far as I am aware there have been no similar reports of comparisons between mothers’ and CYP HFS scores, however this outcome is not surprising. Clarke et al. (75) found that mothers have higher FoH than adult patients have for themselves. Haugstvedt et al. (86) looked at both mothers’ and fathers’ FoH and found that mothers report higher FoH than fathers do, as did Patton et al. (158) and more recently Pate et al. (87). These results show that in general, mothers do tend to report higher FoH than other groups do. This presents an important issue that could have a number of implications for mothers of children with T1DM in terms of their well-being and also their children’s diabetes management. This will be explored further in Discussion Chapter 7 and the qualitative results Chapter 8.
A comparison of CYP vs fathers’ HFS scores showed that fathers scored higher on all subscales for fear of hypoglycaemia than CYP did for themselves. Although scores were not significantly different for the HFS Behaviour subscale ($p=0.199$), fathers’ scores were significantly higher than CYP for the HFS Worry ($t=-3.46$, $p=0.001$) and Total ($t=-3.31$, $p=0.001$) subscales. Fathers also have a higher FoH than their children but this is more linked to worry about hypoglycaemia and not so much the behaviours associated with having a fear of hypoglycaemia. Again, this can have implications for fathers’ well-being.

### 5.5.1 Under 11 group vs parental HFS scores

A comparison of HFS scores across the age groups and respective parental age groups was also made (Table 22).

**Table 22: Comparison of U11 and parental HFS scores (Mean plus/minus SD and range)**

<table>
<thead>
<tr>
<th></th>
<th>Under 11</th>
<th>Mother U11</th>
<th>Father U11</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>HFS-Behaviour</strong></td>
<td>20.54±7.65 (4-36)</td>
<td>22.51±5.45 (8-33)</td>
<td>22.53±6.19 (12-35)</td>
</tr>
<tr>
<td><strong>HFS-Worry</strong></td>
<td>18.96±13.79 (0-52)</td>
<td>27.70±13.53 (4-51)</td>
<td>25.53±13.46 (9-55)</td>
</tr>
<tr>
<td><strong>HFS-Total</strong></td>
<td>39.7±16.75 (6-82)</td>
<td>50.13±15.36 (22-77)</td>
<td>48.07±16.83 (21-83)</td>
</tr>
</tbody>
</table>

* *p<0.01 U11 vs Mothers of U11

For the under 11 age group the only significant difference in HFS scores was evident between the under 11 group and mothers of under 11 year olds for the HFS Worry ($t=-3.15$, $p=0.002$) and Total ($t=-3.19$, $p=0.002$) subscale, with mothers of under 11s, again scoring higher. Although mothers of under 11s were also found to have a higher mean score than the under 11 groups for the HFS Behaviour subscale, this difference was not
significant (p=0.140). This again shows that mothers reported a higher FoH for their under 11 year olds, than this group did for themselves. Although behaviour scores did not significantly differ, mothers’ worry about hypoglycaemia exceeded that of their child. Again, this is not surprising given that previous research does suggest that mothers tend to report higher FoH than other groups (i.e. patients with T1DM, fathers) (75, 86, 87, 158).

Fathers of under 11 year olds also scored higher than the under 11 group across all HFS subscales, however, none of these comparisons were significantly different (p>0.05 across all HFS subscales).

5.5.2 Adolescent vs parental HFS scores
Looking at the adolescents’ HFS scores in comparison to the HFS scores of mothers and fathers of adolescents’, in the main, parents scored significantly higher than adolescents across all subscales (Table 23)

Table 23: Comparison of Adolescent and parental HFS scores (Mean plus/minus SD and range)

<table>
<thead>
<tr>
<th></th>
<th>Adolescents</th>
<th>Mother Adolescent</th>
<th>Father Adolescent</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>HFS Behaviour</strong></td>
<td>19.38±6.51 (0-40)</td>
<td>21.74±7.79 (3-38)</td>
<td>20.46±7.52 (4-38)</td>
</tr>
<tr>
<td></td>
<td>N=91 *</td>
<td>(3-38)</td>
<td>N=37</td>
</tr>
<tr>
<td><strong>HFS Worry</strong></td>
<td>16.99±11.21 (0-53)</td>
<td>28.21±13.57 (0-56)</td>
<td>23.57±12.71 (2-53)</td>
</tr>
<tr>
<td></td>
<td>N=90 ***</td>
<td>(0-56)</td>
<td>N=37 **</td>
</tr>
<tr>
<td><strong>HFS Total</strong></td>
<td>36.22±14.23 (0-75)</td>
<td>50.18±18.97 (3-89)</td>
<td>44.14±18.60 (13-89)</td>
</tr>
<tr>
<td></td>
<td>N=90 ***</td>
<td>(3-89)</td>
<td>N=37 *</td>
</tr>
</tbody>
</table>

*p<0.05 Adolescent vs Mother of Adolescent/Father of Adolescent

**p<0.01 Adolescent vs Mother of Adolescent/Father of Adolescent
***p<0.001 Adolescent vs Mother of Adolescent

Mothers of adolescents scored significantly higher than the adolescent group for HFS Behaviour (t=-2.53, p=0.012), Worry (t=-6.59, p= <0.001) and Total (t=-6.02, p= <0.001) scores. Similarly, fathers of adolescents scored significantly higher than adolescents on the HFS Worry (t=-3.10, p=0.002) and Total (t=-2.42, p=0.020) scores and although fathers scored higher than adolescents on the HFS Behaviour subscale, this was not a statistically significant difference (p=0.384). So, it seems that even when broken down by age groups, at least for the adolescent group, mothers and fathers actually reported a greater fear of hypoglycaemia than their children reported for themselves. Fathers reported higher worry scores whereas mothers reported both higher worry and behaviour scores associated with FoH. These results are unprecedented, at least in UK samples, to my knowledge, no studies have found a significant difference between parent and child HFS scores. This could have implications for both the well-being of mothers and fathers of CYP with T1DM and also for the management of diabetes for mothers of adolescent age groups.

5.6 CYP HbA1c and parental fear of hypoglycaemia

CYP HbA1c and parental FoH were explored to identify any relationship between the two (Table 24).

<table>
<thead>
<tr>
<th>Scale</th>
<th>Mothers</th>
<th>Fathers</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>HFS-T</td>
<td>HFS-B</td>
</tr>
<tr>
<td>CYP HbA1c</td>
<td>-0.0112</td>
<td>-0.049</td>
</tr>
</tbody>
</table>
Pearson’s correlation was carried out on the data. The table shows that there were no significant correlations between parental PHFS score and CYP HbA1c. This suggests that for this study sample, there is no relationship between HbA1c levels and parental HFS scores. This supports research by Johnson et al. (83) who also found no association between parental HFS scores and CYP HbA1c levels. Again a positive relationship might have been expected here as higher FoH might lead to behaviours associated with avoiding hypoglycaemia such as maintaining higher than recommended blood glucose levels. Hawkes et al. (84), report that parents of CYP with HbA1c levels lower than 7.5% had lower HFS scores than parents of those CYP with HbA1c levels over 7.5%. It should be noted however, that HbA1c can be affected by more than just blood glucose control so analyses of cross-sectional data might not pick up on the full impact of FoH.

5.7 Fear of hypoglycaemia and self-reported frequency of hypoglycaemia

Frequency of hypoglycaemia was not significantly related to either CHFS or PHFS scores in any group studied, which was surprising. A higher frequency might be likely to be linked with a higher FoH, since the experience of an episode of hypoglycaemia and accompanying symptoms might lead to a person with T1DM carrying out hypoglycaemia-avoidance behaviours.

5.8 Fear of hypoglycaemia and self-reported episodes of severe hypoglycaemia

5.8.1 CYP

Overall, there was a significant positive relationship between episodes of severe hypoglycaemia and CHFS-W scores ($r=0.16$, $p=0.025$) and CHFS-T ($r=0.20$, $p=0.005$). This suggests that those who experience a higher number of episodes of severe hypoglycaemia
are also more likely to worry about hypoglycaemia and consequently report higher levels of FoH.

CYP CHFS-T scores also seemed to differ between those who had no experience of severe hypoglycaemia vs those who had suffered at least one episode of severe hypoglycaemia (M= 32.34, SE=1.68) vs (M=39.14, SE=1.34), t(185)=3.04, p=0.003). Again, this shows that those with experience of severe hypoglycaemia also presented higher levels of FoH.

5.8.2 Under 11 years
Further analyses showed no significant correlations between under 11 CHFS scores and episodes of severe hypoglycaemia.

There was also no significant difference in CHFS scores between children in the under 11 year group who have experienced at least one episode of severe hypoglycaemia compared to those who have not (p>0.05 across all CHFS subscales).

For this younger age group then, there appears to be no difference in FoH between those who have experienced severe hypoglycaemia and those who have not. This could be explained by the fact that severe hypoglycaemia for this age group might represent more episodes where an adult has had to help the child to treat their hypoglycaemia, not necessarily because their symptoms were severe but more due to the young age of the child. Severe hypoglycaemia for this age group might not therefore, translate to a fear of hypoglycaemia. It will be interesting to look at adolescents’ results in comparison.
5.8.3 Adolescents
In contrast to the younger group, significant positive relationships were found between severe hypoglycaemia and all subscales of the HFS measure (HFS-B: r=0.162, p=0.047; HFS-W: r=0.175, p=0.035; HFS-T: 0.244, p=0.003) for the adolescent group. Again, this suggests a link between FoH and the number of episodes of severe hypoglycaemia.

For the adolescent group then, it is likely that the reports of severe hypoglycaemia are based on more severe symptoms of hypoglycaemia rather than just the fact that they required assistance to treat their episode of hypoglycaemia. Therefore, it is not surprising that those who have experienced severe hypoglycaemia have higher FoH than those who have not.

Adolescents who had never experienced severe hypoglycaemia in the past had significantly lower CYP CHFS scores compared to those who had, had at least one episode of severe hypoglycaemia in their lives (CHFS-B (M= 17.39, SE=0.86) vs (M= 20.34, SE=0.65), t=-2.61, p=0.010; CHFS-W (M= 12.78, SE=1.11) vs (M=18.84, SE=1.21), t=-3.68, p= <0.001; CHFS-T (M=30.17, SE=1.7) vs (M=38.99, SE=1.46), t=-3.61, p= <0.001) suggesting that prior experience of severe hypoglycaemia is an important contributor to fear of hypoglycaemia in this age group.

5.8.4 Parental HFS scores, all CYP
Differences in parental PHFS scores were evident between those whose CYP had experienced severe hypoglycaemia vs those whose CYP had not, for mothers (PHFS-W (M=30.15, SE=1.37) vs (M=24.8, SE=2.29), t=-2.11, p=0.037) and fathers (PHFS-T (M=48.94, SE=2.95) vs (36.57, SE=4.64), t=-2.24, p=0.300. This supports the idea that those parents whose children have suffered at least one episode of severe hypoglycaemia have a higher fear of hypoglycaemia (fathers) or at least worry about hypoglycaemia (mothers) more than those parents whose children have never experienced severe hypoglycaemia.
5.8.5 Parental HFS scores, under 11
Mothers of children who had suffered at least one episode of severe hypoglycaemia, in the under 11 group, scored higher on PHFS-W scores compared to mothers of under 11 year olds who had never experienced severe hypoglycaemia (M= 32.7, SE=2.52) vs (M=23.77, SE=3.66), respectively, t=-2.08, p=0.046. This suggests that for mothers, previous experience of severe hypoglycaemia for their children (aged less than 11 years) contributes to worry about hypoglycaemia, but not necessarily behaviours to avoid hypoglycaemia.

5.8.6 Parental HFS scores, adolescents
There was no relationship between mothers’ PHFS scores and their child’s history of severe hypoglycaemia in analysis of adolescents. However, fathers’ PHFS scores differed significantly between those fathers with adolescent children who had experienced severe hypoglycaemia compared with those that hadn’t (M=48.64, SE=3.57) vs (M=30.11, SE=2.57), t=-4.21, p<0.001. Interestingly here, it appears that fathers of adolescents with a history of severe hypoglycaemia have an increased fear of hypoglycaemia. It could be that being the main caretakers, mothers are more aware of and therefore more confident in their child’s ability to treat their own hypoglycaemia than fathers are.

5.9 Summary of Chapter 5
This sample of CYP and their parents do experience a level of fear of hypoglycaemia. However, as there is no definitive score to indicate the presence of FoH or not we cannot conclusively report whether participants had a high FoH.

There were no statistically significant differences between CHFS scores between under 11 year olds and adolescents, indicating that the level of FoH does not differ based on age...
group. Similarly, no differences were found across gender or insulin regimens. It might have been expected that those on intensive insulin regimens could experience more episodes of hypoglycaemia and severe hypoglycaemia and consequently have higher FoH.

Another surprising outcome was that there was no significant link between HbA1c and FoH. It might be expected that those with high FoH might engage in behaviours to avoid hypoglycaemia, such as, maintaining high blood glucose levels. However, this alone did not have as much of an effect as was expected.

Looking at parental fear of hypoglycaemia, the key finding was that parents do score higher on the HFS scale than CYP do for themselves. As reported, these findings have previously not been reported, to the best of my knowledge. This suggests that parents have a higher FoH than their children have. The problem of FoH, therefore, could be a bigger problem for the parents of CYP with T1DM rather than for the children and consequently could have an impact on parental well-being and quality of life. This will be explored further in the qualitative analysis.

Not surprisingly, looking at the whole cohort, parents of CYP who had suffered from at least one episode of severe hypoglycaemia had a higher fear of hypoglycaemia. Mothers of children in the under 11 group who had had at least one episode of severe hypoglycaemia had a higher FoH than mothers of under 11 year olds who had never experienced severe hypoglycaemia (this difference was not evident between fathers of the under 11 age group). However, for adolescents, the opposite result was found. There was no statistically significant relationship between mothers’ PHFS scores and their child’s history of severe hypoglycaemia. For fathers though, those fathers whose adolescent children had experienced severe hypoglycaemia at least once, had a higher FoH than those fathers of adolescents with no history of hypoglycaemia. Parental experience of their child’s severe hypoglycaemia therefore, is linked to parental fear of hypoglycaemia.
Chapter 6 Results: Secondary factors associated with fear of hypoglycaemia

In this results chapter I explore the secondary factors that are potentially associated with fear of hypoglycaemia for this population sample. It is important to look at these factors as potential contributors to FoH in CYP and their parents.

The State Trait Anxiety Inventory (STAI for adults) (149) and State Trait Anxiety Inventory Child (STAIC for children) (148) is used to identify anxiety levels in respondents at the time of completing the measure (state) as well as the levels of anxiety that tend to stay relatively stable over time (trait). High scores on the STAI(C) indicate high state anxiety and/or high trait anxiety.

A series of tables showing the mean state and trait anxiety scores of CYP and parents, as well as by age group, are presented below. The age groups for this measure were slightly different as the child version of the measure (STAIC) is aimed at those aged under 13 and the adult measure (STAI) is suitable for those aged 13 years and above. To allow for comparisons between the groups and to carry out analyses, scores were converted to z-scores before any analysis was carried out.
Table 25: State and trait anxiety scores for CYP and parents (Mean plus/minus SD and range)

<table>
<thead>
<tr>
<th>Measure</th>
<th>Total CYP</th>
<th>Mother</th>
<th>Father</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>State Anxiety^</td>
<td></td>
<td>39.16±10.82 (20-65)</td>
<td>37.02±11.42 (20-65)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>N=116</td>
<td>N=48</td>
</tr>
<tr>
<td>Trait Anxiety^</td>
<td></td>
<td>38.77±10.24 (20-62)</td>
<td>38.11±10.24 (20-56)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>N=116</td>
<td>N=46</td>
</tr>
</tbody>
</table>

^ Actual anxiety score are presented here. For analysis raw scores were converted to z-scores as the measures for children and older children/adults are different.

Table 26: State and trait anxiety scores for U11 and parents (Mean plus/minus SD and range)

<table>
<thead>
<tr>
<th>Measure</th>
<th>U11+</th>
<th>Mother U11</th>
<th>Father U11</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>State Anxiety^</td>
<td>28.85±6.42 (20-51)</td>
<td>42.69±10.91 (20-65)</td>
<td>35.77±14.82 (20-65)</td>
</tr>
<tr>
<td></td>
<td>N=84</td>
<td>N=39</td>
<td>N=13</td>
</tr>
<tr>
<td>Trait Anxiety^</td>
<td>30.66±6.64 (20-47)</td>
<td>41.13±10.53 (23-59)</td>
<td>35.36±10.83 (23-54)</td>
</tr>
<tr>
<td></td>
<td>N=86</td>
<td>N=39</td>
<td>N=11</td>
</tr>
</tbody>
</table>

^ Actual anxiety score are presented here. For analysis raw scores were converted to z-scores as the measures for children and older children/adults are different.

+ Under 13 years
Table 27: State and trait anxiety scores for adolescents and parents
(Mean plus/minus SD and range)

<table>
<thead>
<tr>
<th>Measure</th>
<th>AdolescentΔ</th>
<th>Mother Adolescent</th>
<th>Father Adolescent</th>
</tr>
</thead>
<tbody>
<tr>
<td>State Anxiety^</td>
<td>34.36±9.17 (20-62)</td>
<td>37.36±10.39 (20-60)</td>
<td>37.60±10.25 (20-56)</td>
</tr>
<tr>
<td></td>
<td>N=107</td>
<td>N=77</td>
<td>N=35</td>
</tr>
<tr>
<td>Trait Anxiety^</td>
<td>36.62±11.32 (20-67)</td>
<td>37.57±9.94 (20-62)</td>
<td>39.17±10.29 (20-56)</td>
</tr>
<tr>
<td></td>
<td>N=107</td>
<td>N=77</td>
<td>N=37</td>
</tr>
</tbody>
</table>

^ Actual anxiety score are presented here. For analysis raw scores were converted to z-scores as the measures for children and older children/adults are different.

Δ13-18 years

Trait and state anxiety are both important factors to consider when looking at FoH. Those individuals with evidence of higher trait anxiety, i.e. relatively stable levels of anxiety over a period of time, could arguably also be more likely to worry about things in general, including episodes of hypoglycaemia, which in turn could produce higher HFS scores.

6.1 CYP anxiety and HbA1c

HbA1c scores were correlated with state (r=0.107, p=0.142) and trait (r=0.028, p=0.696) anxiety scores, however no significant relationships were found. Therefore, for this sample there was no relationship between HbA1c and anxiety.

6.2 CYP anxiety and insulin regimen

Comparison of state and trait anxiety scores between insulin regimens showed a significant difference only for state anxiety scores, only (t=0.23, p=0.021). Those on intensive regimens reported higher state anxiety scores (M=0.76, SE=0.80) than those on
conventional regimens (M=-0.36, SE=0.15). Potentially those CYP on intensive insulin regimens might have found the insulin regimen more stressful (due to higher incidences of hypoglycaemia linked to intensive insulin regimens) and therefore scored higher on the state anxiety scale than those on conventional insulin regimens. Alternatively, more anxious people prefer to be on an intensive insulin regimen which might give them more flexibility in diabetes management.

No significant differences in state and trait anxiety scores were found between male and female CYP.

6.3 Relationship between anxiety and fear of hypoglycaemia

6.3.1 CYP (whole cohort)

State anxiety
CYP state anxiety scores correlated positively across CHFS-W (r=0.311, p= <0.001) and CHFS-T (r=0.263, p= <0.001) scores at the 0.01 level of significance. These findings suggest a relationship between anxiety and fear of hypoglycaemia. It is possible that one causes the other although causality cannot be confirmed.

Trait anxiety
CYP trait anxiety scores correlated across all CHFS scales at least the 0.05 level of significance (CHFS-B: r=0.144, p=0.045; CHFS-W: r=0.525, p= <0.001; CHFS-T: r=0.486, p= <0.001). Causality may be inferred here as trait anxiety is defined as being relatively stable and doesn’t tend to fluctuate. Therefore, those with higher trait anxiety might be more likely to worry in general and therefore could be more likely to worry about hypoglycaemia, resulting in higher FoH. These findings support previous research carried out in this area (72, 74).
6.3.2 Under 11

State anxiety
For state anxiety there was a significant correlation with CHFS-W (r=0.309, p=0.050) and CHFS-T (r=0.368, p=0.018). Again this suggests that as anxiety increases so does FoH, in this age group.

Trait anxiety
Trait anxiety scores for under 11 year olds significantly correlated (positively) across all CHFS scales at, at least the 0.05 level of significance (CHFS-B: r=0.330, p=0.031; CHFS-W: r=0.565, p= <0.001; CHFS-T: r=0.582, p= <0.001). So, higher trait anxiety scores are associated with higher FoH.

6.3.3 Adolescents

State and trait anxiety
Significant, positive correlations between adolescent anxiety scores (state and trait) and CHFS scores were found for CHFS-W (state: r=0.312, p= <0.001; trait: r=0.506, p= <0.001) and CHFS-T (state: r=0.223, p=0.007; trait: r=0.445, p= <0.001) scores. This suggests that higher anxiety is linked with higher FoH, in adolescents.

6.3.4 Parents

Under 11
A significant positive correlation was observed, between maternal trait anxiety and children’s (under 11 years) total CHFS (r=0.455, p=0.009) and CHFS-W (r=0.484, p=0.005) scores suggesting an influence of maternal anxiety on child fears, or vice versa. Again, considering this relationship is evident for trait (not state) anxiety, it seems appropriate to suggest that mothers’ trait anxiety might contribute to the FoH children have for themselves.
**Adolescents**

No significant correlations were found between maternal anxiety and adolescent CHFS scores. In mothers and fathers there was a strong positive correlation between total PHFS score and trait anxiety (mothers: $r=0.241$, $p=0.009$; fathers: $r=0.311$, $p=0.035$), as well as between PHFS-W scores and trait anxiety (mothers: $r=0.242$, $p=0.009$; fathers: $r=0.319$, $p=0.030$). It is fair to suggest that those parents who are more anxious have higher levels of fear of hypoglycaemia. Alternatively, fear of hypoglycaemia could lead to persistent anxiety (74, 77, 87, 89, 159).

**6.4 Quality of life and fear of hypoglycaemia**

The PedsQL Diabetes Module 3.0 (144) was used to measure quality of life (QoL) in CYP with type 1 diabetes mellitus. This is a self-report measure designed to be completed by the child themselves and also a parent version where the parent is required to report on their child’s quality of life; so CYP’s perceived quality of life as judged by their mother or father. High scores on the PedsQL Diabetes Module 3.0 indicate high health related quality of life either for self (reported by CYP) or perceived high quality of life of child (reported by mothers/fathers). A series of tables showing the mean and standard deviation scores for CYP and parents, by age group, is presented below.

**Table 28: Health-related quality of life scores for CYP and parents**

* (Mean plus/minus SD and range)

<table>
<thead>
<tr>
<th>Measure</th>
<th>Total CYP</th>
<th>Mothers</th>
<th>Fathers</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(Mean±SD)</td>
<td>(Mean±SD)</td>
<td>(Mean±SD)</td>
</tr>
<tr>
<td></td>
<td>(Range)</td>
<td>(Range)</td>
<td>(Range)</td>
</tr>
<tr>
<td>HRQoL</td>
<td>69.03±14.67</td>
<td>57.67±16.30</td>
<td>65.46±15.22</td>
</tr>
<tr>
<td></td>
<td>(29.09-99.54)</td>
<td>(7.48-99.09)</td>
<td>(7.48-92.46)</td>
</tr>
<tr>
<td></td>
<td>N=200</td>
<td>N=136</td>
<td>N=52</td>
</tr>
</tbody>
</table>
Table 29: Health-related quality of life scores for U11 and parents (Mean plus/minus SD and range)

<table>
<thead>
<tr>
<th>Measure</th>
<th>U11</th>
<th>Mothers U11</th>
<th>Fathers U11</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean ± SD</td>
<td>Mean ± SD</td>
<td>Mean ± SD</td>
</tr>
<tr>
<td>HRQoL</td>
<td>67.04±15.80</td>
<td>58.28±14.64</td>
<td>67.55±9.53</td>
</tr>
<tr>
<td></td>
<td>(39.15-99.54)</td>
<td>(29.63-87.39)</td>
<td>(52.9-83.91)</td>
</tr>
<tr>
<td></td>
<td>N=52</td>
<td>N=47</td>
<td>N=15</td>
</tr>
</tbody>
</table>

Table 30: Health-related quality of life scores for adolescents and parents (Mean plus/minus SD and range)

<table>
<thead>
<tr>
<th>Measure</th>
<th>Adolescent</th>
<th>Mothers Adolescent</th>
<th>Fathers Adolescent</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean ± SD</td>
<td>Mean ± SD</td>
<td>Mean ± SD</td>
</tr>
<tr>
<td>HRQoL</td>
<td>69.73±14.24</td>
<td>57.35±17.19</td>
<td>64.61±17.04</td>
</tr>
<tr>
<td></td>
<td>(29.09-99.28)</td>
<td>(7.48-99.09)</td>
<td>(7.48-92.86)</td>
</tr>
<tr>
<td></td>
<td>N=148</td>
<td>N=89</td>
<td>N=37</td>
</tr>
</tbody>
</table>

6.5 Relationship between quality of life and demographic data

6.5.1 CYP

There was a significant negative correlation between HbA1c and QoL ($r=-0.186$, $p=0.008$) as measured by Spearman’s rho, suggesting that those with high HbA1c levels report lower quality of life, and vice versa (Figure 10). This suggests that those with lower HbA1c levels and potentially better control of blood glucose, report a better quality of life.
Mann-Whitney tests revealed that there were no significant differences between QoL scores of males vs females, under 11 year olds vs adolescents and those on intensive insulin regimens vs conventional insulin regimens.

6.6 Relationship between quality of life and fear of hypoglycaemia

6.6.1 CYP
In CYP greater fear of hypoglycaemia correlated with poorer quality of life with significant negative correlations between all three HFS (Behaviour, Worry and Total) scales and the PedsQL ($r=-0.197$, $p=0.005$; $r=-0.585$, $p=0.000$; $r=-0.525$, $p= <0.001$). Investigating the relationship a little further by looking at each of the domains for the PedsQL also showed
significant negative relationships between each of the PedsQL domains and CHFS Worry and Total scores. This suggests that a greater fear of hypoglycaemia is associated with poorer quality of life in CYP.

6.6.2 Under 11
In the under 11 group a greater fear of hypoglycaemia correlated with poorer quality of life with significant negative correlations between CHFS-W and CHFS-T scales and PedsQL ($r=-0.679, p<0.001; r=-0.572, p<0.001$). There was a non-significant relationship between PedsQL and CHFS-B. This suggests that in children, a greater worry and overall fear of hypoglycaemia might lead to poorer quality of life (83), although causality cannot be inferred from cross-sectional data.

6.6.3 Adolescent
Greater fear of hypoglycaemia correlated with poorer quality of life in adolescents. There were significant negative correlations between all three HFS scales (Behaviour, Worry and Total) and PedsQL ($r=-0.241, p=0.003; r=-0.545, p<0.001; r=-0.507, p<0.001$). Significant negative correlations were also found between the each of the domains on the PedsQL and CHFS Worry and Total scores, in the adolescent group. Again, suggesting a link between fear of hypoglycaemia and quality of life, although causality cannot be inferred directly from correlational analyses (83).

6.6.4 Parents
All PHFS scores were negatively correlated with parents’ PedsQL scores. These data suggest that for parents, higher parental fear of hypoglycaemia is related to a lower perception of their child’s quality of life (83).
All analyses of the PedsQL scores with HFS scores for parents and children suggest a relationship between these two variables. This suggests that a greater fear of hypoglycaemia correlates with a lower quality of life/perceived quality of life, in CYP with T1DM. Fear of hypoglycaemia could be a predictor of poor quality of life in this population and further exploration of this might allow inferences about causality, to be made.

6.7 Self-care and fear of hypoglycaemia

The Self-Care Inventory (SCI-R) (138) was used to elicit scores on CYPs’ self-care behaviours in relation to their diabetes diagnosis. It can also be used to get parental views of their child’s self-care behaviours, so is a proxy measure for pre-adolescent children. High self-care scores indicate high levels of self-care behaviours specific to diabetes care. Self-care scores can be found below. Scores are presented for adolescents only as the self-care inventory is recommended for use with this age group.

Table 31: Self-Care scores for adolescents and parents (Mean plus/minus SD and range)

<table>
<thead>
<tr>
<th>Measure</th>
<th>Adolescent</th>
<th>Mother Adolescent</th>
<th>Father Adolescent</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>66.27±13.86 (18.3-96.7) N=150</td>
<td>66.08±17.37 (13.5-96.67) N=90</td>
<td>58.31±23.79 (13.30-91.67) N=37</td>
</tr>
</tbody>
</table>
Table 32: Parental proxy reports of self-care (Mean plus/minus SD and range)

<table>
<thead>
<tr>
<th>Self-care</th>
<th>Mother CYP</th>
<th>Father CYP</th>
<th>Mother U11</th>
<th>Father U11</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>69.64±15.84</td>
<td>62.05±21.76</td>
<td>76.61±9.03</td>
<td>71.29±11.87</td>
</tr>
<tr>
<td></td>
<td>(13.5-96.7)</td>
<td>(13.5-91.7)</td>
<td>(58.3-96.7)</td>
<td>(51.7-88.3)</td>
</tr>
<tr>
<td></td>
<td>N=136</td>
<td>N=52</td>
<td>N=46</td>
<td>N=15</td>
</tr>
</tbody>
</table>

6.8 Relationship between self-care and demographic data

Correlational analyses showed a significant negative relationship between HbA1c and self-care scores (r=−0.215, p=0.002) which, not surprisingly, suggests that those with lower HbA1c levels (and potentially better metabolic control) also report higher levels of self-care (Figure 11).
There were no significant differences in self-care scores between males and females, or between those on conventional vs intensive insulin regimens.

### 6.9 Relationship between self-care and fear of hypoglycaemia
Correlational analysis revealed that the relationship between CHFS scores and self-care for adolescents was not significant. This suggests that there is no link between fear of hypoglycaemia and self-care behaviours. It was expected that there might be some link between fear of hypoglycaemia and self-care, considering the CHFS-B subscale measures behaviours (some of which are linked to self-care). So potentially lower self-care behaviours could be evident in those with a higher FoH, to reflect behaviours that...
potentially help prevent hypoglycaemia, but might not be the best behaviours in terms of diabetes management.

A breakdown of parental proxy scores of self-care can be found in Appendix 26. The relationship between parental FoH and self-care (proxy reports) was also found not to be statistically significant. This suggests that there is no link between FoH and self-care behaviours.

### 6.10 Multivariate analysis of fear of hypoglycaemia

In order to understand fear of hypoglycaemia further, initial exploration, of significant relationships between CHFS scores and other investigated variables, was followed up with multivariate analyses. These analyses were carried out in order to identify whether any conclusions could be drawn regarding risk factors of or contributory factors to the presence of FoH in CYP and their parents.

For each age category, a step-wise multiple regression analysis was performed using two of the variables that showed a significant relationship with FoH. Trait anxiety and number of episodes of severe hypoglycaemia were entered as predictor variables, with HFS-T scores as the dependent variable. Previous research also suggests a significant relationship between trait anxiety and FoH and previous experience of severe hypoglycaemia and FoH (72, 74, 91).
### 6.11 Multivariate analysis of CHFS-Total in Under 11 group

Table 33: Regression analyses to identify significant predictors of FoH in Under 11 group (N=41)

<table>
<thead>
<tr>
<th>Significant variables</th>
<th>B</th>
<th>R²</th>
<th>Adjusted R²</th>
<th>β</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Step 1</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trait anxiety</td>
<td>9.662</td>
<td>0.366</td>
<td>0.349</td>
<td>0.605**</td>
</tr>
<tr>
<td><strong>Step 2</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trait anxiety</td>
<td>9.598</td>
<td>0.369</td>
<td>0.336</td>
<td>0.601**</td>
</tr>
<tr>
<td>Severe hypoglycaemia</td>
<td>0.804</td>
<td></td>
<td></td>
<td>0.057</td>
</tr>
</tbody>
</table>

Dependent variable: CHFS-T

**p<0.01

The table above shows that both trait anxiety and severe hypoglycaemia have a positive relationship with CHFS-T scores in the under 11 group. However, trait anxiety is the only variable which significantly predicts higher CHFS-T scores. Trait anxiety scores account for 36.6% variance in Under 11’s CHFS-T scores. Although the addition of severe hypoglycaemia increases the variance it does so very slightly ($\Delta R^2=0.003$). The addition of severe hypoglycaemia in Step 2 does not significantly contribute to the predictability of Model 1. It seems then for this group, trait anxiety is likely to be associated with a higher fear of hypoglycaemia. The number of episodes of severe hypoglycaemia, however, does not add to the model’s ability to predict FoH. It could be that in the younger group, children are less aware of the perceived danger of an episode of hypoglycaemia, and therefore having experienced severe hypoglycaemia in the past is less likely to impact on their fear of hypoglycaemia. For under 11 year olds, having high trait anxiety suggests a higher fear of hypoglycaemia. These results could have implications for the treatment and management of diabetes for this age group.
6.12 Multivariate analysis of CHFS-Total in adolescent group

Table 34: Regression analyses to identify significant predictors of FoH in adolescent group (N=145)

<table>
<thead>
<tr>
<th>Significant variables</th>
<th>B</th>
<th>R²</th>
<th>Adjusted R²</th>
<th>β</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Step 1</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trait anxiety</td>
<td>6.43</td>
<td>0.20</td>
<td>0.19</td>
<td>0.45**</td>
</tr>
<tr>
<td><strong>Step 2</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trait anxiety</td>
<td>6.08</td>
<td>0.23</td>
<td>0.22</td>
<td>0.42**</td>
</tr>
<tr>
<td>Severe hypoglycaemia</td>
<td>2.30</td>
<td></td>
<td></td>
<td>0.18*</td>
</tr>
</tbody>
</table>

Dependent variable: CHFS-T

**p<0.01
*p<0.05

Multivariate analysis of adolescent scores also show that Trait anxiety can significantly predict CHFS-T scores in this group (Table 34). Trait anxiety accounts for 20% of the variance in CHFS-T scores. The addition of severe hypoglycaemia at Step 2 increases this variance to 23% and for the adolescent group, the addition of this predictor variable significantly adds to the model’s ability to predict fear of hypoglycaemia. So even though the variance is small, it seems here that both trait anxiety and severe hypoglycaemia together make a significant contribution to the model. In adolescents, it seems that severe hypoglycaemia does impact on CHFS-T scores probably because this age group is more likely to be aware of the dangers associated with hypoglycaemia and also potentially have memories of their experience. Therefore, it is likely that adolescents with a history of severe hypoglycaemia and high trait anxiety scores are likely to have a high fear of hypoglycaemia. In practice, these results could have implications for paediatric diabetes clinicians, in supporting adolescents with diabetes management.
6.13 Multivariate analysis of PHFS-Total in mothers

Table 35: Regression analyses to identify significant predictors of FoH in mothers of CYP with T1DM

<table>
<thead>
<tr>
<th>Significant variables</th>
<th>B</th>
<th>$R^2$</th>
<th>Adjusted $R^2$</th>
<th>$\beta$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mothers of U11 (N=27)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Step 1</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trait anxiety</td>
<td>5.99</td>
<td>0.18</td>
<td>0.14</td>
<td>0.42*</td>
</tr>
<tr>
<td>Step 2</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trait anxiety</td>
<td>6.53</td>
<td>0.25</td>
<td>0.19</td>
<td>0.46*</td>
</tr>
<tr>
<td>Severe hypoglycaemia</td>
<td>3.78</td>
<td></td>
<td></td>
<td>0.27</td>
</tr>
<tr>
<td>Mothers of adolescents (N=76)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Step 1</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trait anxiety</td>
<td>4.63</td>
<td>0.06</td>
<td>0.04</td>
<td>0.24*</td>
</tr>
<tr>
<td>Step 2</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trait anxiety</td>
<td>5.08</td>
<td>0.09</td>
<td>0.07</td>
<td>0.26*</td>
</tr>
<tr>
<td>Severe hypoglycaemia</td>
<td>3.35</td>
<td></td>
<td></td>
<td>0.19</td>
</tr>
</tbody>
</table>

Dependent variable: PHFS-T

*p<0.05

In mothers of both the under 11 group and the adolescent group it seems that trait anxiety was the strongest predictor of FoH (Table 35). Although, as previously seen, severe hypoglycaemia did add to the variance in PHFS-T scores, the addition of this variable did not significantly add to the ability of the initial model to predict PHFS-T scores. This regression shows that mothers’ trait anxiety scores are significant predictors of FoH (accounting for 18% (under 11) and 6% (adolescent) of the variance) and the addition of previous severe hypoglycaemia does not significantly contribute to this relationship. In
order to identify mothers who are likely to have a fear of hypoglycaemia, looking at trait anxiety scores might give an indication to who these might be. The fact that trait anxiety potentially contributes to the level of FoH may have implications for reducing FoH by managing mothers’ anxiety.

6.14 Multivariate analysis of PHFS-T in fathers

Table 36: Regression analyses to identify significant predictors of FoH in fathers of adolescents with T1DM

<table>
<thead>
<tr>
<th>Significant variables</th>
<th>B</th>
<th>R²</th>
<th>Adjusted R²</th>
<th>β</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fathers of adolescents (N=35)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Step 1</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trait anxiety</td>
<td>6.70</td>
<td>0.13</td>
<td>0.11</td>
<td>0.36*</td>
</tr>
<tr>
<td>Step 2</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trait anxiety</td>
<td>5.97</td>
<td>0.30</td>
<td>0.26</td>
<td>0.32*</td>
</tr>
<tr>
<td>Severe hypoglycaemia</td>
<td>7.80</td>
<td>0.30</td>
<td>0.26</td>
<td>0.41**</td>
</tr>
</tbody>
</table>

Dependent variable: PHFS-T

*p<0.05

**p<0.01

Multivariate analyses were not carried out for fathers of under 11 year olds due to the small sample size. For fathers of the adolescent group (Table 36), however, trait anxiety accounted for 13% variance in their PHFS-T scores. However the addition of severe hypoglycaemia in Step 2 shows an increase in variance, to 30% (ΔR²=0.168), indicating that the addition of severe hypoglycaemia significantly increases the model’s ability to predict FoH in this group. It seems that fathers of adolescents are likely to have increased PHFS-T scores if they have higher trait anxiety and if their son/daughter has experienced severe hypoglycaemia. This finding slightly differs to that of the mothers of adolescents in that
for mothers, severe hypoglycaemia did not significantly add to the predictability of the original model (with only trait anxiety as a predictor variable) of PHFS-T scores. This difference could be explained by the fact that, in general, mothers are the main carers of CYP with T1DM and therefore have more experience of episodes of hypoglycaemia and severe hypoglycaemia. Previous experience of severe hypoglycaemia might not have as much impact on mothers as it might do on fathers, who potentially have less exposure to these episodes and therefore might have more of an influence on PHFS scores (and FoH levels). As with the under 11, adolescent and mother group analyses, these findings could help address FoH in fathers of adolescents by identifying those most at risk of high fear of hypoglycaemia.

6.15 Summary of Chapter 6
Fear of hypoglycaemia, for this sample of CYP and their parents, is significantly associated with factors such as state anxiety, trait anxiety and quality of life. Fear of hypoglycaemia correlated positively with both state anxiety and trait anxiety across all groups. This suggests that those with higher anxiety (including anxiety which remains relatively stable across time) are also likely to have higher fear of hypoglycaemia. Potentially, anxiety may contribute to a higher FoH or inversely, for state anxiety at least, FoH might be the contributing factor. For trait anxiety, however, it seems that those scoring higher on this scale also report higher CHFS scores (therefore higher FoH). Trait anxiety could, therefore, be a contributory factor to the presence of FoH (72, 74, 159). Potentially those individuals who have a tendency to worry might score higher on the Worry scale of the HFS and therefore are possibly likely to have higher FoH. Another explanation for the relationship between anxiety and FoH could be that the HFS is actually measuring diabetes-related anxiety. If this is the case then inevitably those CYP with higher anxiety levels are also likely to score higher on the HFS scale. It will be interesting to explore this relationship further through qualitative analysis.
Quality of life (QoL) of children and adolescents, participating in the study, was investigated. Statistically significant, negative correlations were found between the fear of hypoglycaemia and QoL. This suggests that lower reported QoL is linked to a higher FoH. So those under 11 year olds and adolescents analyses could be interpreted to suggest that higher fear of hypoglycaemia might lead to poorer quality of life. It could also be suggested that this association suggests that those personalities who report a lower QoL are also more likely to report a higher FoH.

Parents’ PedsQL scores reflected parents’ perception of their child’s quality of life. All PHFS scores had statistically significant, negative correlations with parental PedsQL scores. The data suggest that for parents, the higher parental fear of hypoglycaemia is, the lower the perception of their child’s quality of life is. Fear of hypoglycaemia and QoL are associated with one another. Although causality cannot be inferred from correlational data, fear of hypoglycaemia could potentially contribute to children and adolescents’ QoL and also parents’ perception of their son/daughters’ QoL.

Unexpectedly, self-care was not found to have a significant relationship with fear of hypoglycaemia for adolescents or their parents. Some relationship might have been expected considering that self-care behaviours reflect the HFS behaviour scales, to an extent.

Multivariate analyses of fear of hypoglycaemia showed that trait anxiety was a significant predictor for FoH for under 11 year olds, adolescents, mothers of under 11s, mothers of adolescents and fathers of adolescents. This suggests that those with higher trait anxiety are also likely to have higher fear of hypoglycaemia. This is probably due to the fact that individuals who are more likely to worry will also score higher on the Worry scale of the HFS and therefore have a higher FoH. The addition of severe hypoglycaemia to the model
added to the predictability of models for adolescents, and fathers of adolescents, suggesting that severe hypoglycaemia is a precursor to FoH in these groups.
Chapter 7: Discussion (Quantitative phase)

7.1 Prevalence of hypoglycaemia
Analysis of the data indicated that the prevalence of hypoglycaemia is high in this particular sample of CYP with Type 1 Diabetes Mellitus. Although this study appears to be one of only a few to report on the prevalence of hypoglycaemia in the U.K. (27), Ly and Jones’ (48) comprehensive article on hypoglycaemia in CYP highlights worldwide research on hypoglycaemia and reports that hypoglycaemia is an issue in diabetes management. For this UK sample, the majority of CYP reported experiencing hypoglycaemia at least once per month with only a small percentage of the group stating that they had never experienced an episode of hypoglycaemia (9/193).

Severe hypoglycaemia is defined as an episode of hypoglycaemia where the patient requires assistance of another person in order to treat the episode. Only 62 CYP out of the sample of 193 reported never experiencing an episode of severe hypoglycaemia, with the majority reporting that they had experienced this at least once in their lives. A number of studies reporting on the prevalence of severe hypoglycaemia in paediatric populations (26, 38), also indicate that this is a problem in diabetes management. Johansen et al. (39) carried out a large (n=3320) observational study of data collected for CYP in Denmark with diabetes between 1996 and 2009. Severe hypoglycaemia was defined as an event leading to loss of consciousness and/or seizure (34). Their results showed that despite advances in diabetes care during this time period the incidence of severe hypoglycaemia did not change (15.1 per 100 patient years). Authors concluded that severe hypoglycaemia was a problem for paediatric diabetes patients and further research to assess risk factors for severe hypoglycaemia are needed. In an earlier study Katz et al. (25) also carried out an observational study to establish prevalence rates of severe hypoglycaemia in CYP with T1DM, in the US. They used the DCCT definition (40) of severe hypoglycaemia which includes both a hypoglycaemic event requiring assistance from another; and an event with seizure/coma. Overall, the reported incidence of severe hypoglycaemia in Katz et al.’s (25) study was 37.6/100 patient years. This is much higher than reports from Johansen et al.’s
study, however, this could be due to the difference in the definition of severe hypoglycaemia between the two studies. Katz et al. (25) also refined reports of incident rates and found that the incidence of severe hypoglycaemia (as characterised by seizure/coma) was 9.6/100 patient years, which is comparable to Johansen et al.’s (39) findings. Although the reports of incidence of severe hypoglycaemia differ between reports from these two studies, authors concur that severe hypoglycaemia is a problem in paediatric groups. This may have implications for the management of diabetes and clinicians should be aware of the frequency of hypoglycaemia amongst their patients in order to help manage any difficulties they have controlling their diabetes.

Paternal participation in this type of research tends to be limited, so it was interesting to investigate fathers’ perceptions of their child’s diabetes and compare these to mothers’ perceptions. Parental reports of hypoglycaemia for their children showed significant differences in reports of frequency of hypoglycaemia and severe hypoglycaemia between mothers and fathers. Few studies have discussed parental reports of hypoglycaemia in their child per se, which could be due to the unreliability of parental reports. Studies are generally focused on parents’ abilities and accuracy in identifying hypoglycaemia in their child (157, 160, 161).

In the current study, fathers tended to report that their sons/daughters experienced more episodes of hypoglycaemia than the mothers did. This could be explained by the fact that mothers are often the primary carers of children with T1DM and so might have been more aware of the actual frequency of these episodes than fathers were. No differences were found in parental reports of severe hypoglycaemia and further analyses indicate reports of severe hypoglycaemia between parents and CYP were also consistent with one another. This suggests that parents seem to be able recognise when their child is experiencing hypoglycaemia however, this was not tested objectively in this study. Confirming parental recognition of hypoglycaemia would involve CYP checking their blood glucose at the time and proving that they were experiencing hypoglycaemia when parents suspected it (157).
Experience of hypoglycaemia can eventually lead to impaired awareness of hypoglycaemia, as reported by Geddes et al. (45). Impaired awareness of hypoglycaemia often occurs as a result of repeated episodes of hypoglycaemia and is characterised by a loss of warning symptoms usually associated with hypoglycaemia (45). Adolescents in the current study completed the hypoglycaemia unawareness measure, adding to limited awareness research in UK samples. Recently, Graveling et al. (161) attempted to measure IAH in children and adolescents in a UK study using both the Clarke (49) and Gold (47) methods (as was reported for the current study). Their findings suggested that the methods for assessing IAH in CYP are better placed for older children aged 9 or older which supports the procedures undertaken for the current study only investigating IAH in adolescents. Not surprisingly, adolescents with impaired awareness were shown to have a longer duration of T1DM than those with normal awareness. This supports the idea that awareness of hypoglycaemia can become impaired after experiencing frequent episodes of hypoglycaemia. Those adolescents with a longer duration of diabetes would have inevitably experienced a higher number of episodes of hypoglycaemia leading to impaired awareness. No other differences between groups were found for impaired awareness.

Impaired awareness of hypoglycaemia scores were correlated with free recall of severe hypoglycaemia in the past year and preceding year. Results showed a significant positive relationship between the two indicating that those likely to have impaired awareness (higher score) reported higher incidences of severe hypoglycaemia. This is in line with results of Gold et al.’s (47) study which reported a six-fold increase in the incidence of severe hypoglycaemia in those with impaired awareness, albeit in adult patients. Paediatric research in IAH revealed similar results. In Ly et al.’s (48) cohort study, 29% of 656 participating CYP reported IAH. The overall incidence of severe hypoglycaemia was significantly higher for CYP with impaired awareness (37.1 vs 19.3 per 100 patient years). This is in agreement with the results of the current study which revealed that reports of severe hypoglycaemia were higher for those with impaired awareness when compared to
those with normal awareness. This highlights the problem of IAH in diabetes care and could have further implications for those at risk, of a higher frequency of severe hypoglycaemia. These findings support the suggestion that awareness of hypoglycaemia can be impaired in those who report frequent episodes of hypoglycaemia or severe hypoglycaemia. This is an important factor to consider when supporting CYP in managing their BG levels. If CYP are unable to identify that they are experiencing hypoglycaemia this can lead to more frequent episodes of hypoglycaemia or severe hypoglycaemia. Adolescents might benefit from learning about and recognising all possible symptoms of hypoglycaemia that they might otherwise be unaware of in an attempt to identify the onset of an episode before it becomes more serious. It should be noted that the effects of IAH can be reversed by consistent avoidance of hypoglycaemia over several weeks (29), however, clinical support to achieve this is likely to be needed.

7.2 Fear of hypoglycaemia
Fear of hypoglycaemia (FoH) was evident in children, adolescents and their parents. This does not seem to have been reported previously for a UK sample, although limited studies overseas report the presence of FoH for paediatric samples (74, 81). The results of the Hypoglycaemia Fear survey (HFS) indicate that CYP and their parents do experience fear of hypoglycaemia to varying extents. Marrero et al. (91) investigated FoH in CYP and parents using the HFS. They reported that FoH was apparent in these groups, although the level of fear was dependent on factors such as previous experience of severe hypoglycaemia (discussed later). Later studies have investigated parental FoH further. Hawkes et al. (84) assessed FoH in 106 parents of CYP. Their results suggest that parents do experience FoH, however more so for younger children (aged 6 to 11 years) than other age groups. The current study revealed no such differences in FoH reports between parents of different age groups.

Previous research studies report conflicting data on the link between FoH and CYP HbA1c (86, 89, 92). Pate et al.’s (87) cross-sectional study looked at parental FoH again using the
HFS. They reported that higher FoH scores were associated with higher HbA1c levels in children, suggesting an impact of FoH on diabetes management. This is supported by previous research conducted by Patton et al. (76) who, although used reports of average daily blood glucose levels rather than HbA1c as indicators of glycaemic control, also found higher parental FoH was associated with higher blood glucose levels. Johnson et al. (83) found slightly different results. Although they reported no link between parental FoH and CYP HbA1c, they did report that CYP with higher FoH also had higher HbA1c levels. For the current study there was no significant link between FoH (parental or CYP) and HbA1c levels. Gonder-Frederick et al.’s 2006 (72) study, amongst others (80, 89, 162) supports this finding. Gonder-Frederick et al. (72) investigated predictors of FoH with 39 adolescent-parent pairs and found no relationship between FoH and HbA1c levels. The association between HbA1c and FoH is complex, especially in the CYP group, therefore subtle, yet significant links may go undetected. Changes in hormone levels and onset of puberty are just two factors which might impact and mediate the relationship between HbA1c and FoH. It is also important to note that the majority of studies that have previously reported a link seem to do so based on parental FoH rather than CYP FoH.

HFS scores were higher in parents, both mothers and fathers, than in either children or adolescents indicating that parents have higher FoH for their children, than CYP have for themselves. Specifically, comparison of scores across groups showed that mothers reported a greater fear of hypoglycaemia (all HFS subscales) for their children than their children did themselves. This was a statistically significant result and although is in keeping with previous studies which report that mothers of children with T1DM have higher FoH than adult patients have for themselves (75), does not appear to have been reported before in FoH research. Fathers were also found to report higher fear of hypoglycaemia than their children did for themselves, although the results were only statistically significant for the Worry scale and Total score, this again seems to be a unique finding in FoH research. Similar findings for mothers and fathers were reported when the CYP group was split into under 11 year olds and adolescent age groups, although fathers reported lower FoH for the adolescent group than mothers did. Haugstvedt et al. (86) also
found lower FoH in fathers (than mothers) but did not differentiate between parents of children and adolescents. This study appears to be the first study to highlight that parents report higher FoH than their children do. This could have implications for parental management of their child’s diabetes, as well as parental well-being. Mothers and fathers report a greater fear of hypoglycaemia (and often greater worry for their child) however, it is difficult to ascertain the best way to meet the needs of parents of children with T1DM who are often already burdened with the responsibility of caring for a child with a chronic illness and even more so for those individuals who are less likely to come to clinic appointments with their children (i.e. fathers). Assessing FoH in parents might alert clinicians of the fact that parents may be struggling with the diabetes care for their child however, there currently does not seem to be any useful intervention that could address FoH in these parents.

7.2.1 Fear of hypoglycaemia and severe hypoglycaemia
Data from previous studies across Europe, the US and Australia suggest a considerable level of fear among children with Type 1 diabetes and their families. Like others we found a link between prior experience of severe hypoglycaemia and FoH in adolescents (72, 76, 91). One study found that it was only those adolescents experiencing severe hypoglycaemia in the recent 12 months who reported greater fear of hypoglycaemia (91). These authors suggested that FoH might be a transitory event in the life of an adolescent as a response to a specific stimulus. Interestingly, we found no link with prior experience of severe hypoglycaemia and fear in younger children. This may be due to differences in developmental stage and perspectives on the frightening nature of severe episodes of hypoglycaemia. Johnson et al. (83) suggest that the nature of severe hypoglycaemia resulting in a seizure or loss of consciousness might mean that younger children have less recollections of the event and so may not worry about it as much as their parents who are likely to be witnesses. The absence of a significant link between severe hypoglycaemia and FoH in this younger group could also be related to younger children’s reliance on and trust in their parents’/adult carers’ ability to manage episodes of hypoglycaemia on their behalf. This may lead to a greater burden on parents, particularly mothers (primary caregivers),
with increased stress and anxiety which has been shown to impact on diabetes care (95, 97, 103, 163).

In line with previous studies parental fear was linked to prior experience of severe hypoglycaemia for mothers in younger children and fathers in adolescents (72, 91). Marrero et al. (91) explored the relationship between severe hypoglycaemia and FoH in parents and their children. They found that parents whose children had a history of severe hypoglycaemia (seizure or sudden loss of consciousness), had higher levels of FoH. Moreover, parents whose children had experienced an episode of severe hypoglycaemia in the past year exhibited the greatest levels of FoH. Looking at parents separately, Pate et al. (87) reported higher worry scores on the HFS for mothers, whilst highlighting higher behaviour scores (i.e. behaviours to avoid hypoglycaemia) for fathers of younger children.

The small number of fathers of under 11 year olds participating in the current study, might have had an impact on the analysis for this particular group. In the current study, mothers seemed to be more concerned about hypoglycaemia if their child was younger whereas fathers reported more worry for their adolescent children. This could suggest that mothers, who are usually the main caregivers, are aware of the difficulty in detecting hypoglycaemia in younger children who themselves might be slow to recognise or react to the symptoms, however they have more confidence in their older children to recognise and treat an episode of hypoglycaemia before it becomes severe. Fathers then may be less worried about their younger children, believing that they are under their mothers’ care (in most instances) and so may have more worries about whether their adolescent children can in fact treat an episode of severe hypoglycaemia independently. The findings suggest that for parents, their child’s experience of severe hypoglycaemia can contribute to their own fear of hypoglycaemia (91).

7.2.2 Fear of hypoglycaemia and anxiety
An increasing number of studies have examined the relationship between trait anxiety and FoH in adolescents and parents, (72, 87, 89). This is perhaps due to the fact that the HFS
measure includes a Worry subscale which could in fact reflect a person’s tendency to exhibit general anxiety. Therefore it is important to investigate any relationship between these two variables. Gonder-Frederick et al. (72) explored the link between FoH and trait anxiety in adolescents and their parents. Analyses of parent scores on both the HFS scale and trait anxiety measures indicated no relationship between parental FoH and trait anxiety. However analyses of adolescent scores showed a significant positive correlation between their HFS total scores and trait anxiety score, as well as between their HFS worry scores and trait anxiety scores. Considering that the HFS scale measures both worry and avoidance behaviour associated with hypoglycaemia it is possible that those with higher trait anxiety may be prone to generalised worry/anxiety and therefore have a tendency to report higher FoH levels than those with lower trait anxiety levels. Gonder-Frederick et al. (72) however, argued that there is ultimately a very real difference between trait anxiety (which may be predisposed according to genetics) and maternal diabetes-related worry (which varies according to the confidence mothers have in their child’s ability to manage their diabetes). Therefore the relationship between the two variables may not be so obvious and might benefit from further exploration.

Univariate analyses for the current study suggest that trait anxiety in all participants was independently associated with FoH in all groups. The association between high trait anxiety and high FoH may be a reflection of the higher hypoglycaemia worry scores for those with a tendency towards general anxiety. The worry scale on the HFS then may just be another measure of anxiety albeit with a diabetes slant. Nevertheless, increased FoH is evident in those with higher trait anxiety therefore attempts to relieve anxiety might also contribute to reducing FoH. A significant positive correlation between maternal trait anxiety and FoH in younger children was also observed, which may be bi-directional. This loosely supports the findings for Gonder-Frederick et al.’s (72) study which found a moderate positive correlation between parental trait anxiety and adolescent (rather than younger children’s) HFS worry scores. This could suggest that a more anxious mother contributes to more generalised worry in their child, particularly in relation to diabetes. It was not possible to examine the temporal relationship between anxiety and fear,
however, so it is difficult to report whether anxiety precipitates FoH or vice versa. Research is still limited in this area which might benefit from further investigation.

7.2.3 Fear of hypoglycaemia and CYP health-related quality of life
Fear of hypoglycaemia has been recognised as an issue for CYP (72, 81). Therefore it is possible that FoH will have an impact on CYPs’ lives. The impact of FoH on quality of life was reported by Johnson et al. (83) who concluded that FoH is associated with reduced CYP QoL as reported by both CYP and their parents. This is true for the current study. Higher fear scores were related to poorer health related quality of life in both children and adolescents, and were also related to parents’ poorer perception of their child’s quality of life. The data indicate that children and adolescents who have a greater FoH also have poorer diabetes-related quality of life. Although the direction of the relationship between FoH and QoL cannot be confirmed, managing and improving QoL in CYP with T1DM is vital. A review by Cameron (108) concluded that health-related quality of life was key to improving diabetes-related outcomes. Those parents who worry more about hypoglycaemia also perceive their offspring to have a poorer quality of life. These findings highlight the impact of T1DM not only on children but on their parents too. Parents’ FoH may impact their judgment of their child’s QoL and could potentially cause parents distress or further worry as a result. It would be interesting to explore the association between FoH and parental QoL, given the large role parents play in diabetes management.

7.2.4 Multivariate analysis of hypoglycaemia fear survey
Multivariate analyses were conducted in order to examine the significant independent correlates of fear of hypoglycaemia. Gonder-Frederick et al. (72) found that both trait anxiety and severe hypoglycaemia were important predictors of FoH in adolescents only. Results from the current study however, indicated that trait anxiety was associated with FoH in all groups except fathers of under 11 year olds (although this might be a reflection of the low number of fathers of under year 11 olds participating in the study). Those with higher trait anxiety were also likely to have higher FoH. This is not surprising considering
that it is probable that those with higher anxiety will tend to worry more as reflected in their worry scores on the HFS. Another explanation for this relationship is that the HFS worry subscale is actually a diabetes-related anxiety scale and so will inevitably be related to a measure exploring general anxiety. Previous experience of severe hypoglycaemia was also found to add to the predictability of FoH in adolescents and fathers of adolescents, which suggests that it is the combination of trait anxiety and previous experience of severe hypoglycaemia which is important. It would be interesting to understand the link between severe hypoglycaemia and trait anxiety to determine whether increased severe hypoglycaemia contributes to increased general anxiety. The reduction of severe hypoglycaemia in CYP and management of anxiety might be important factors in managing both fear of hypoglycaemia and quality of life. Due to the limited evidence base of this topic, in the target population, further investigation of the direction of causality between the aforementioned variables should be carried out in order to decide the best method of intervention.

7.3 Challenges in this research
Looking back at the study, a number of challenges in the research are apparent. A number of difficulties regarding research with children were encountered. However, research with children is important so solutions to these difficulties were sought. In order to obtain informed consent/assent from CYP the aims of the study had to be explained to potential participants in a way that would be understood by different age groups. The information sheets used for this study were aimed at different groups (e.g. parents and CYP) and age groups of participants to help ensure that the information that they received was clear and coherent to them.

In order to address the issue of completing lengthy questionnaires that can be tiring and difficult for young children, age appropriate questionnaire packs were produced for 5-7 year olds, 8-10 year olds and 11+year olds; the younger 2-4 year olds were represented through parent by proxy reports. Although for the older age groups there were a number
of questionnaires which needed to be completed, younger children were asked to complete a smaller battery of assessments. Using questionnaires was essential to allow data from a large number of participants to be collected with limited resources.

There are methodological limitations to the study which was cross sectional and included participants with a wide range of diabetes duration and experience of hypoglycaemia. The definition of hypoglycaemia and severe hypoglycaemia might have not been clear enough and interpreted differently amongst CYP and parents who took part in the study. The frequency measure included the DCCT definition (40) of severe hypoglycaemia which includes all episode requiring assistance for treatment, as well as those resulting in seizure or coma. In hindsight, this definition of severe hypoglycaemia in paediatric studies, is unsuitable. When this is taken in the context of younger children, the majority of episodes of hypoglycaemia could be interpreted as severe episodes, even when they are not because the child will require assistance. Participants in paediatric studies should be provided with a stricter definition of severe hypoglycaemia (an event resulting in loss of consciousness or seizure) as recommended by ISPAD (34). Retrospective assessment of the frequency of hypoglycaemia is generally inaccurate, and previous authors have found that asking patients about absolute numbers of severe events is only accurate for the preceding year (164). In adolescents, recall of the episodes of hypoglycaemia they experienced might also have been affected by impaired awareness. A more reliable way of reporting the prevalence of hypoglycaemia might be to wear a device measuring physiological changes in the body in order to detect and consequently record hypoglycaemia. However, this type of method would need to be done over a long period of time which might be difficult to achieve for a large cohort of CYP over an extended period. Therefore we have to accept that self-report, retrospective reports are the next best way of obtaining information relating to past episodes of hypoglycaemia in CYP participants, over a long period of time and in large cohort studies.
Participants in this study were a self-selected group who may either over-represent those who worry about hypoglycaemia and might be more interested in a study of this nature, or may have excluded those who were too anxious to participate. Unfortunately these shortcomings may be difficult to overcome, participants have to be willing to participate in research and cannot be compelled to take part. Those CYP or parents who were unable to participate in the study due to language/reading difficulties might also contribute to a potentially biased view, as reflected by the predominantly white sample of CYP and parents. The National Paediatric Diabetes Audit (NPDA) 2013-2014 (154) shows a population make up of 72% Type 1 Diabetes patients who were White, therefore this sample is over-representative of white ethnicity. Future research might utilise questionnaires in languages other than English to be more inclusive of participants. This study was able to report paternal data, which is otherwise limited in FoH research; however, the small numbers may have impacted the results and their generalisability.

7.4 Implications

The results of this study add to the growing body of quantitative literature on CYP with T1DM and their families. Understanding that there is an association between trait anxiety, severe hypoglycaemia and fear of hypoglycaemia may have clinical implications not only for diabetes management in this age group but patient-reported outcomes too (165). Managing and reducing severe hypoglycaemia may contribute to less anxiety/worry about experiencing hypoglycaemia. Similarly, managing the fear associated with hypoglycaemia could contribute to improving outcomes for CYP and their parents. Interventions aimed at reducing severe hypoglycaemia and/or managing anxiety might contribute to reducing FoH in CYP. Severe hypoglycaemia may be the result of impaired awareness of hypoglycaemia, for some CYP. Therefore, teaching CYP to recognise the early signs of hypoglycaemia could contribute to a reduction in overall severe hypoglycaemia. The relationship between FoH and quality of life provides further motive for reducing FoH in order to improve outcomes for CYP living with a chronic condition. Identifying ways to
reduce FoH may help CYP better manage their condition without it impacting too negatively on their lives.

Acknowledging the strength of parental FoH has implications for mothers and fathers of CYP with T1DM. Results of the current study show that parents experience higher FoH than CYP with T1DM do for themselves. This suggests a necessity to find ways to manage parental anxiety and worry in order to better help them cope with their child’s illness and potentially promote optimal diabetes management in their CYP. The data indicate that CYPs’ diabetes does have a negative effect on parents so it is important to try to find ways to support parents in their role as caregivers. Such interventions could also be extended to supporting CYP/parents in the management of other chronic conditions. These results encourage researchers and clinicians to think about and acknowledge the impact that CYPs’ diabetes has on parents. Although there is some focus on supporting parents/carers of children with long-term conditions within research, this does not translate into support available to them in practice. Parents often have little time, with conflicting responsibilities (166) therefore many interventions are not practical or suitable for them. Further investigation should be done to find out what parents think would work for them in terms of being supported in their role as carers, both practically and psychologically.

The data suggest that parental FoH is related to parental anxiety. In a review of parental FoH, Barnard et al. (77) concluded interventions to address anxiety in parents were needed in order to help parents optimally manage their child’s diabetes. The impact of FoH on parental quality of life has received some attention (167) however, the benefits of additional support for parents of children with T1DM, to manage anxiety should be explored further. For the current study, the qualitative analyses should clarify what parents think might help them to cope with the daily diabetes care they are required to provide to their child. This will be discussed in later chapters. Clinically significant FoH cut-off points might make it easier for clinicians to identify those CYP and parents who are struggling. However, in the absence of a cut-off score, clinicians should at least be aware
of FoH and its impact on both CYP and parents, especially in the UK where limited research has been published.

7.5 Future research

Further research into the lives of CYP with T1DM and their parents needs to be carried out in order to develop a greater understanding of these experiences. Phase two of this study aims to uncover the experience of living with diabetes at a deeper level. These results will be presented and discussed in the next two chapters. A longitudinal study examining FoH and anxiety in children, young people and their parents from diagnosis could provide more informative data about the emergence of fear of hypoglycaemia and related variables, such as the experience of hypoglycaemia/severe hypoglycaemia, which may underpin and explain its development.

Given that FoH is present in this cohort of CYP and parents, future research should address reducing this FoH, which, as previously suggested may impact on CYP QoL. There is a clear link between severe hypoglycaemia, anxiety and FoH, although the direction of this relationship cannot be inferred from this cross-sectional study. As the present study has highlighted that CYP and parents suffer from anxiety about hypoglycaemia, future research should concentrate on developing interventions that help reduce FoH, or at least anxiety and worry (which may contribute to FoH) in both CYP and their parents, in order to improve their well-being. The results confirm a link between severe hypoglycaemia and FoH which suggests that those with a history of episodes of severe hypoglycaemia present higher levels of FoH. Therefore, reducing the number of episodes of severe hypoglycaemia might help to reduce the associated fear and anxiety. Hermanns et al. (168) have already devised an education programme aimed at informing patients about the problem of recurrent hypoglycaemia, recognising symptoms of hypoglycaemia using a combination of methods and teaching them these techniques. Results for Hermanns et al.’s (168) study were promising and suggest that the HyPOS educational programme helps
to reduce severe hypoglycaemia. Researchers also reported improvements in anxiety and quality of life related variables, although these findings were not significant. The impact of HyPOS on the fear of hypoglycaemia, however, has not been investigated. It would be interesting to see whether the reduction in severe hypoglycaemia had an impact on FoH levels in CYP and their parents. A longitudinal study, using the HyPOS intervention could be conducted to assess the impact of this intervention on patient and carer FoH, which might also impact on QoL.

The development of an educational intervention aimed at reducing FoH in CYP and parents, could be another way of managing FoH. This might include education on diabetes management, hypoglycaemia, implications of hypoglycaemia/hyperglycaemia and the impact of hypoglycaemia avoidance, delivered in a group setting based in clinic. Educational programmes for adults (DAFNE; (169)) and children (KIC-kOFF; (170)) have reported improvements in glycaemic control and quality of life respectively, but did not address FoH. Recently, a pilot study testing a glucose management programme with a specific focus on FoH was carried out at University College London by Cai et al. (171). Although results have yet to be published, early analyses indicate a reduction in hypoglycaemic events with no increase in HbA1c. Those parents and CYP who attended the sessions reported enjoyment, increased confidence and feeling connected to others in the same situation. Unfortunately attendance at the clinic-based educational groups was not as good as hoped. Parents reported other commitments, unwillingness to miss school and transport issues as reasons for non-attendance. This may have impacted on the feasibility of this type of intervention.

Educational interventions aside, another way to help reduce FoH in CYP and parents might be to address anxiety levels in these groups. The burden of caring for a child with diabetes might also contribute to parents exhibiting depressive symptoms. Future research could further explore the impact of CYP T1DM on parental well-being by measuring anxiety, depression and stress in this group. The current study focused quality of life of CYP. Given
that parents reported higher levels of FoH, this fear could impact on parental QoL. Research investigating parental FoH and parental QoL is limited and therefore would benefit from further exploration. Future research focusing on parental QoL alongside parental anxiety, depression and stress could add to data regarding parental experience of living with a child with diabetes. Such a study could also add to the limited information regarding the psychosocial factors associated with this group.

Mindfulness is thought to help improve mental health and refers to paying attention to the present moment; being more aware of your present thoughts, feelings and the world around you (172). The principles of mindfulness were used to develop mindfulness-based stress reduction (MBSR) by Dr Kabat-Zinn (173). MBSR combines mindfulness meditation with Hatha yoga as methods to help individuals to pay attention to their thoughts but let them pass without judgment, thereby reducing the impact these thoughts may have. MBSR techniques have been used with patients living with long-term conditions including T1DM (174, 175), however research with paediatric groups is limited (176). Results indicate that MBSR techniques are successful in reducing depression, anxiety and distress, which in turn may improve management of long term conditions. However, many of the paediatric studies in this field have been disadvantaged by poor methodologies in addition to the difficulties in practicing mindfulness with younger age groups (177). Future research should take these factors into account to ensure collection of empirically sound data.

MBSR has also been used to reduce stress and distress in care-givers of chronic disease. Much of this research has been carried out in families of dementia patients. Whitebird et al. (178) compared an MBSR intervention with a standard education and support intervention aimed at family caregivers. Results indicated that MBSR was a much more effective at reducing stress and depression and improving mental health in caregivers than the educational intervention. Although both MBSR and the educational intervention were successful in improving anxiety, MBSR does seem to have more strength than educational interventions do. This supports the idea of using mindfulness as a method of reducing
stress and anxiety. A five-component intervention incorporating mindfulness was also used with hospital workers who provide continuous care to patients (179). This model helped to significantly reduce stress in participants compared to controls. The results of these studies are promising, and provide support for using MBSR on parental carers, despite the paucity of research looking at the impact of MBSR on parents of CYP with T1DM. As the results of the current study have shown, parents (both mothers and fathers) exhibit a higher fear of hypoglycaemia than their children do. Therefore it is as important to consider parental outcomes, as carers of CYP with T1DM and ways of improving these outcomes. An MBSR intervention aimed at parents of CYP with T1DM is needed to help address the FoH and anxiety reported by these parents. This would also address the lack of interventions aimed at this population. MBSR techniques might be more useful for those parents whose child has lived with diabetes for approximately one year, thus giving them some time to become accustomed to their child’s condition. The MBSR programme could then address the worries, fears and anxieties that emerge through caring for their child, via a short course of sessions.

As mentioned previously, research in MBSR programmes for CYP is relatively limited; however, future research could also look at developing MBSR programmes specifically for CYP, potentially by age group, in order to address fears and anxieties and potentially impact on self-management, care and QoL. As suggested for the parents of CYP, this intervention would be best prescribed once the child/young person has lived with the daily demands of T1DM in order to address emerging anxieties. Interventions incorporating mindfulness will add to existing research in both diabetes research and MBSR research. For this intervention to have value it should be properly developed to ensure data is collected robustly. Future studies should include both experimental and control groups in order to assess the impact of the intervention on the target group.
7.6 Summary of Chapter 7

In summary, FoH is a complex construct that may be impacted by both genetic disposition (trait anxiety) and external cues (episodes of severe hypoglycaemia). Both CYP and parental FoH were evident in this sample highlighting it as a problem in diabetes management. Although a link with glycaemic control was not found, the significant impact on the quality of life of the entire family is demonstrated (74) as well as the impact of trait anxiety and previous experience of severe hypoglycaemia on FoH.

Implications of the findings of the current study point towards increased awareness of the presence of and impact of FoH on CYP and their parents. There is a clear link between severe hypoglycaemia and FoH which indicates that managing these episodes of severe hypoglycaemia could help to manage the associated fear. Clinical staff should be aware of the FoH and its prevalence in CYP and parents. Beneficial interventions are needed to help CYP and parents to cope with the daily demands of diabetes management and to also improve outcomes for both of these groups.

Interventions should aim to manage and reduce FoH, although it is not clear what the best method to do this is. Reducing severe hypoglycaemia using educational programmes has shown to be successful however the impact of these programmes on FoH should also be explored. Interventions aimed at reducing the risk of hypoglycaemia may not be effective for all, given the contribution of personality factors such as trait anxiety. Instead interventions that consider the psychological well-being of patients and their families that provide strategies to reduce fear and anxiety need to be considered. MBSR has shown to be effective in reducing anxiety and having a positive impact on well-being. Incorporating the principles of MBSR and focusing them on CYP and perhaps more crucially on parents of CYP could contribute to managing anxiety and FoH in addition to other psychosocial outcomes.
Chapter 8: Qualitative analysis

This chapter will report on the qualitative analysis of Phase Two of the study, looking in more detail at living with diabetes through the eyes of children, young people and their mothers. The methods employed to analyse the qualitative data will be described briefly, as they have already been described fully in a previous chapter (Chapter 2, 2.12), followed by a description of the sample study population. The aim of this chapter is to describe the main themes arising from analysis of interviews conducted with children, young people and their mothers.

8.1 Summary of method

The aim of Phase Two of the study was to get more in depth, detailed accounts of living with diabetes, from the perspective of children and young people with Type 1 diabetes, and their mothers. Semi-structured interviews were conducted with a subset of participants who had already taken part in Phase one of the study. Thematic analysis was conducted on the interview transcripts and took a theoretical approach (153). Full details of the analysis can be found in (Chapter 2, 2.12 onwards)

8.2 Demographics

Children, young people and parents who had already taken part in Phase one of the study were invited, by letter, to take part in Phase two interviews. Thirteen children and young people aged 7-17 years took part in Phase two of the study. The sample was made up of three under 11 year olds and the rest of the sample was classed as adolescents, as in the quantitative phase of the study. The sample consisted of eight girls and five boys. Thirteen mothers also took part. The sample was predominantly white, with the exception of one mother and son pair who identified as Asian (Pakistani). Unfortunately no fathers took part in the qualitative phase of the study so the qualitative analysis refers to mothers of CYP with T1DM only, although some mothers did refer to the part that fathers play in their child’s care.
Interviews were semi-structured and followed a set of questions around living with diabetes, although there was flexibility to focus on certain topics if participants seemed to have more to say in those areas. Where appropriate children, young people and mothers were interviewed separately, however, all participants were given the option of being interviewed with their mother present. This was requested only by two of the younger members of the group. In total 24 interviews were conducted, ranging from 8 minutes, 46 seconds to 63 minutes, 3 seconds. Data collection for Phase two was completed at the point of data saturation where the interviews ceased to elicit any new topics. This is the point at which no new information seemed to emerge as the interviews were being conducted i.e. the responses did not add to data which had already been collected.

8.3 Results of thematic analysis

8.3.1 Burden
After familiarisation with the interview transcripts, various themes and sub-themes were considered. ‘Burden’ was identified as the overarching theme in this analysis. CYP and mothers, especially, referenced negative emotions associated with T1DM and the responsibility of living with diabetes. The themes ‘negative emotions’ and ‘living with diabetes’ emerged as key areas of the interviews. The majority of mothers and CYP relayed the ‘negative emotions’ they experienced as a result of living with T1DM. These emotions were examined in relation to topics including ‘feelings about T1DM’ and ‘fear of hypoglycaemia’; which were identified as sub-themes. ‘Living with diabetes’ was particularly prominent in discussions about the early years of adjusting to living with diabetes. However, changes and impact on life were also reported during later phases of CYPs’ and mother’s lives. The emergent sub-themes here were the ‘positive impact,’ ‘negative impact’ and ‘practical’ changes associated with CYP and mothers’ lives beyond diagnosis. Figure 12 below illustrates these themes and sub-themes for CYP and mothers.
Each theme and sub-theme will be discussed from the perspectives of both CYP and their mothers. Initially, it was assumed that separating the analysis for these two groups would lead to more clarity, however, crossover between CYPs’ and mothers’ accounts made it difficult to present the data in this way. The differences in the experience of diabetes between CYP and parents are apparent from the quantitative analysis. The qualitative analysis also highlighted differences between these groups, these will be discussed further.

### 8.3.2 Negative emotions

Both mothers and CYP reported negative emotions during interviews about living with diabetes. These emotions included feelings of distress, worry and guilt.

#### 8.3.2.1 Feelings about T1DM

Recollections of diagnosis evoked memories of distress, worry and fear from mothers and CYP. Children’s (and mothers’) accounts of diagnosis referred heavily to how they felt, emotionally, at the time. This included indications of extreme distress and disbelief:

> I thought I was gonna die cause it said diabetes so I was like crying my eyes out and then mum was trying to like explain to me what it was. (14 year old CYP)
Many CYP were fearful that diabetes was life-threatening. Often CYP had never heard of diabetes so this elicited fear in itself. Reactions were unsurprisingly emotional. This was CYPs’ first experience of living with diabetes, having been given an actual diagnosis. Even following diagnosis, however and knowing that something was wrong, children and young people did not immediately fully understand their diagnosis and how it would affect them:

She said “am I going to die?” and I said “no no you’re not going to die”. (Parent of 12 year old)

This extract highlights the lack of knowledge CYP had regarding a diagnosis of T1DM. This was to be expected considering that for most CYP, the point of diagnosis was usually a response to an unforeseen and urgent hospital admission. The time from identifying extremely high blood sugars to having emergency treatment was swift with no time to think or process what was happening. The first experiences of diabetes then were frightening for CYP. As the extracts from the interviews above indicate, the diabetes diagnosis revealed feelings of anxiety, uncertainty and confusion from children and young people.

Although CYP reported being fearful of being diagnosed with T1DM acknowledging that diabetes is a treatable condition and that it could be worse, helped them to reach some acceptance:

It’s like obviously it’s not the worst like thing you could have like when I think of people that have cancer and things. (14 year old CYP)

This extract was reflected by this young person’s mother too, or perhaps this is a reflection of the mother’s perspective of the diagnosis. Either way, being grateful that there were options for treatment and that diabetes is a manageable condition seemed to help CYP to accept their diagnosis and try to cope with it.
As many of the children and young people interviewed were diagnosed fairly early on in life, it was not surprising that their mothers would have a clearer recollection of diagnosis than the CYP themselves. Similar to CYP, mothers gave factual reports of events leading to diagnosis. However, in addition to this mothers also gave vivid and emotional descriptions of what happened prior to diagnosis:

> They said sit in the waiting room. I said I’ve got a poorly child. She was lying across my arms like a rag doll….She’d lost so much weight, and all of a sudden the room was full of doctors and they’d done the blood test and she was off scale. They couldn’t even measure her blood, it was too much. (Mother of 8 year old)

As this extract shows, descriptions of the events leading to diagnosis were often frantic, unexpected and met with a great deal of urgency by medical staff. For parents, this was a frightening experience and for most it was totally unexpected.

Maternal reports of diagnosis suggest an even more distressing reaction to their child’s diagnosis than children and young people had for themselves, “I was just a gibbering wreck crying most the time” (mother of 14 year old). Initial maternal responses included reports of tearfulness at what their child was going through, and being “in shock.” Mothers’ initial experiences of diabetes then were not dissimilar to those of their children. They too felt anxious, scared and unprepared for such a diagnosis. Perhaps, being responsible for their child’s healthcare it is likely that mothers were more aware than CYP of the implications diabetes would have and therefore the diagnosis potentially impacted them a lot harder than it did their children. There was also an element of guilt that mothers had not noticed that their child was unwell:

> It’s like Oh my God, how did I not notice. But you just don’t because you’re with them all day every day. (Mother of 8 year old)

This added to the distress mothers experienced. In hindsight mothers could see the signs were there but had not noticed them before diagnosis. Mothers felt guilty about not spotting the early symptoms and reported anxiety about what might have happened had
they not have got their child the medical attention they had needed, sooner. So the guilt
resulting from their child’s diagnosis was apparent in mothers very early on.

In comparison to CYP, many mothers’ accounts of diagnosis were extremely poignant.
They seemed to understand the wider implications of having a lifelong condition, whereas
perhaps CYP were more focussed on the present:

I just thought our world had ended you know and I just thought she’s ill. (Mother of 9 year
old)

For their child to be diagnosed with a lifelong chronic condition was devastating for
parents; what they once knew had changed forever. It was almost in the same way a
death might have an impact, it was like a period of bereavement. One parent described
the diagnosis as a real loss, and referred to her young daughter’s life being cut short as a
result of the diagnosis:

I think I supposedly went through a period of bereavement...she was diagnosed umm on
my son’s 1st birthday so that I think was quite hard because I’ll remember the date until
the day I die...so I suppose I did find it quite hard I did, because my perfect daughter now
had 10 years wiped off her life. (Mother of 11 year old)

The references to death here illustrate the strong reactions mothers, unsurprisingly, had
towards the diagnosis given to their child. It seems that the diagnosis of diabetes signalled
the end of the life they knew. There was also acknowledgement that this diagnosis could
impact on the lifespan of their child. No parent wants to think that their child will not live
a long and healthy life and when faced with such a revelation, mothers were
understandably distraught.

Following the comparison of the diagnosis to death, mothers also reported initial feelings
of denial:
We came home and drove to the Leicester Royal and even that point I was thinking no it’s not going to be and even doing my job [paramedic] I was thinking no, no, no. It was at the point where they actually injected her with insulin and it was at that point where I had to leave the room and I thought oh God yes she is. (Mother of 12 year old)

Again, this links back to the experience of something ending, and in this case it was a life without diabetes. Life had changed for CYP and their parents after being given a diagnosis. Initial reports of denial certainly were apparent for mothers, but not for CYP in this sample, who, although distressed by the diagnosis did not refute the fact that they had diabetes.

 Mothers expressed a real sense of regret for their child, in response to their diagnosis:

    And why did it happen and why did it happen to him...Why was it [child], my youngest, and my baby. (Mother of 15 year old)

 The feeling of injustice and guilt about why their child was suffering was common amongst many of the mothers:

    You feel guilty a lot of the time. (Mother of 15 year old)

 They did not want their child to have to go through life with an illness, for the illness to impact on them every day and to potentially lead to future complications and possibly a shorter lifespan. Interestingly, none of the CYP interviewed for this study reported feeling this way which may or may not be a true reflection of how they felt at the time. It is possible that mothers were more open in terms of discussing their feelings than CYP were. Although mothers experienced a high level of distress and upset they had to remain strong for their child’s sake and so outwardly presented a very different response to the diagnosis in comparison to how they actually reported feeling inside.
For mothers especially then, the impact of diagnosis was great and it stirred many emotional reactions: denial, fear, distress and heartbreak, perhaps greater than children expressed for themselves. In some cases the diagnosis of diabetes took over:

A friend of mine said that it, it probably took me about 3 years to stop talking about it [diagnosis]. (Mother of 11 year old)

The diagnosis had a real impact on the lives of not only CYP but their parents and families too.

Following discussions about diagnosis, the interview transcripts returned more reports of negative experiences of diabetes, than positive ones. This could be due to the fact that especially for the more extreme events, mothers and CYP found these episodes difficult to forget:

She umm was fine talking she walked down the stairs and just collapsed and fitted at the bottom of the stairs. (Mother of 14 year old)

Witnessing your child experience a seizure, especially unexpectedly is likely to have been a key memory for mothers of CYP with diabetes. Perhaps, more so for mothers than their children as they would be more likely to remember details of the event than CYP themselves.

Diabetes regimen was often difficult for CYP but mothers also felt their child’s pain:

Some days she cries a lot cos her fingers hurt, that’s the big thing at the moment. (Mother of 11 year old)

Mothers found it hard to watch their children go through the constant regimen of blood testing and insulin injections. It is not surprising then that mothers reported that CYP struggled with the constant demands of dealing with diabetes:

We do get tears and she doesn’t wanna be diabetic anymore and that makes me sad. (Mother of 9 year old)
This mother expressed both sadness and helplessness at her daughter’s situation. The CYP’s obvious sadness was reflected by her mother.

Although mothers reported having faith that their child could treat hypoglycaemia if they needed to, one area of concern was whether or not their child was able actually able to recognise an episode of hypoglycaemia. While rare, there were some maternal reports of CYP suffering from impaired awareness of hypoglycaemia:

We went through a phase when he was losing his awareness, quite often, I mean even now I’m not sure it’s great. (Mother of 15 year old)

A lack of awareness meant that it would be difficult for a child to detect and treat hypoglycaemia quickly enough, which increased the likelihood of an episode of severe hypoglycaemia. This also contributed to mothers’ anxiety about whether or not CYP were able to manage their diabetes on a daily basis.

Evidently, there was a great impact of diabetes on mothers however mothers also described the impact it had on CYP’s fathers, which gives a little more insight to fathers’ experiences of having a child with diabetes:

Her dad found it more distressing...her dad was worried about day to day. (Mother of 12 year old)

Some fathers might not have coped with their child’s diagnosis as well as mothers who tended to be the main caregivers, although later sections highlight the supportive role fathers take in caring for their child. This is interesting in terms of learning more about paternal roles in the care of children with T1DM.

It seems that both CYP and mothers reported fear and worry about living with T1DM. However, mothers reported many more negative emotions than their children did. They
experienced periods of denial, following diagnosis; regret for their child and also reported feeling bereaved. Interestingly, these feelings were not reported by CYP which suggests that the impact of diabetes could be greater for mothers than it is for their children. CYP seemed to report negative emotions associated with immediate consequences of their diagnosis and did not talk about worries of or fears about the future, whereas mothers reported fear, grief and worry about the diagnosis, coping with diabetes and also the long term implications. This will be discussed further in subsequent themes.

Negative emotions stemming from the overarching theme of burden were reflected in interviews in various ways. Considering diabetes management does impact on everyday life to a large extent, with checking blood sugars and having to inject insulin, it is not surprising that, over time, CYP reported that they did not want to be seen as different from their peers and at times tried to hide the fact that they had diabetes, especially as they got older. This highlights the ongoing impact diabetes has on CYP’s lives. Even those CYP who had moved to pump therapy had issues about their condition being too obvious:

Though she’s got the pump, having something and having to carry something, you know, is a bit of a bind. (Mother of 16 year old)

The fact that the pump was something that CYP would have to wear most of the time did actually discourage some CYP from agreeing to move to this intensive therapy. It was almost like having the pump attached was a constant reminder of having diabetes and for many CYP, they already had plenty of reminders of their condition:

It’s just having it in my mind whole time. (15 year old CYP)

The endless management and daily treatment meant that CYP became tired and reported feeling like they needed a break from their diabetes. There was often little respite from the condition.
CYP difficulties in managing diabetes in the long-term were acknowledged by mothers. One mother spoke about how her 9 year old daughter coped with diabetes:

She does want more things, she does want what her friends have got, she does want to eat what they’re eating….She really broke down the last time we was at the hospital…she’d said she’d love just for one day not to have any injections and to be like everybody else.
(Mother of 9 year old)

It seems that for some CYP, as they got older and started to notice how they differed from other children their age, they experienced feeling unhappy about their condition. Mothers reported where CYP might have accepted their diagnosis and embraced diabetes management routines in the short-term, as they entered new phases and became more independent they became more aware of the impact diabetes had on their lives. One young person’s report of breaking away from her diabetes routine was verified by her mother’s account, which highlighted the CYPs’ mental health in relation to coping with her illness:

[My child] had told this [other] child that she had considered it [self-harming] because of her diabetes. (Mother of 12 year old)

As CYP approach adolescence and conflicting demands and pressures are placed upon them, it is no wonder that the constant management of diabetes might become more burdensome than it previously had. The constant demands of managing diabetes certainly impacted on how well CYP were able to cope with living with diabetes. One young person reported breaking away from the recommended treatment, indicating problems in coping with her condition:

After a while I got really annoyed with it cos at one point I stopped doing my injections and stuff. (12 year old CYP)

This illustrates the issues that some CYP have with coping with chronic illness, especially when there is a constant need to monitor and manage it. It is not only the physical impact of living with diabetes but also the mental and psychological effect it can have on CYP (this is reflected in the maternal reports of this young person’s ability to cope with her condition). During adolescence, when there are already many changes that a young
person might be experiencing, even for those CYP who have previously managed their condition well, living with a lifelong condition can become burdensome and CYP might rebel against their daily regimen. Girls (and some boys) during this time are also becoming more aware of their body and may experience issues with body image. Having to inject insulin then, which can cause weight gain, might be at odds with trying to portray the ‘perfect’ body (180). Although there were no reports of eating disorders from CYP, changes in motivation to manage their diabetes could stem from psychological issues.

CYP reported feeling more self-conscious about their diabetes as they got older, often as they entered high school or period of adolescence:

I think it’s that move to high school. A lot of her friends she’s made at High School, don’t know she’s diabetic. She hasn’t told them. (Mother of 12 year old)

Some CYP reports indicated that having to manage their diabetes at times made them feel like they were different and they did not want to feel this way all of the time.

CYP found other people’s perception of diabetes frustrating. Even after having lived with diabetes in the long-term often other children did not believe that the child had diabetes because there were no obvious signs of illness. This was upsetting:

I don’t like having diabetes because people come up to me and say “you don’t have diabetes” and I say “yes I do” and they say “how come I can’t see it” because most things you can see. (8 year old CYP)

The fact that diabetes is an ‘invisible’ illness can put additional pressure on those CYP who are trying to manage their diabetes whilst not showing signs of being ill.

Interestingly, one child reported the guilt she felt and the impact she felt her diabetes had on the rest of her family:
like Taybarns [restaurant], like even though they’re having a good time and I act like I am and I think in a way deep down they’re thinking ‘I bet [child’s name] would’ve been having a good time without diabetes.’ (9 year old CYP)

It’s thought-provoking to learn that CYP with diabetes report feelings of guilt about the impact their illness has had on their parents and rest of the family. This guilt could impact on CYP well-being and quality of life. CYP guilt has otherwise received very little attention in previous research and highlights a problem that previously does not appear to have been reported in this group.

Although CYP reported the burden of diabetes management there were mixed feeling with regards to additional support, outside of the family unit, with most CYP saying they had enough support:

Too much support, stops being support. That’s being over the top. I think what we’ve got is good. (15 year old CYP)

Most CYP felt that they knew how to manage their condition, what they needed to do to control blood sugars and how to deal with episodes of hypoglycaemia.

The burden that CYP felt as a result of living with diabetes was evident from the interview transcripts. The constant management and diabetes regimen were reported to impact on CYP over time and especially, as they approached adolescence, already a time of many changes. Most CYP reported that familial support helped to relieve the burden of their condition.

There were many references to the responsibility mothers felt for their child. This included the day to day responsibility of diabetes care and the responsibility of avoiding long-term health problems. As well as coming to terms with their child’s diagnosis, mothers reported feeling that there was a lot to learn about the practicalities of living with
diabetes and how stressful and overwhelming it was. There was also the feeling of having a lot of responsibility on their shoulders, for their child and their child’s well-being.

That responsibility was overwhelming. (Mother of 12 year old)

Mothers spoke about how they would check on their children throughout the night to make sure that their blood sugars were not too low. This was another added responsibility and pressure on mothers (and fathers) in the management of their child’s diabetes.

As well as struggles to grasp the new demands that the diabetes diagnosis brought there were also maternal reports of feeling unsure and unsupported by clinical staff about how to manage their child’s diabetes. Mothers felt conflicted at times between what the doctors and nurses were advising and what they felt was best for their child. This type of struggle was often difficult for mothers (and fathers) who were already going through a stressful period and no doubt added to any anxiety they were already experiencing.

Mothers reported being made to feel guilty by some clinical staff, which added to the pressure placed on them:

> Sometimes, they do have a way of making you feel as though you’re not trying hard. You’re not doing enough… I actually had a doctor that told me that when [child] went on the multiple injections, he said that perhaps it would be an idea, if I looked for a job that meant I could be around [child’s] school at lunch time. I said I can’t afford to leave my job! He said you got to decide what and I thought, I’m very respectful of people, but I was getting more and more irate and sometimes the doctors don’t get their heads out of the book and you sort of say right, come and live my life, for one week. (Mother of 12 year old)

So for mothers then, the pressure and responsibility of supporting and looking after a child with diabetes was enormous but eventually became a part of their daily lives. By accepting the fact that they/their child now had to live with diabetes, CYP and their mothers could now focus their energy on managing the condition and adjusting their lives to living with diabetes.
Mothers were helpless in relieving their children of the one thing that they wanted. This resulted in mothers harbouring feelings of guilt and dismay and feeling redundant in their role as protector:

I get quite tearful with it really really cos I say to her I’d love to take it away from you and sometimes I feel guilty because I didn’t have [child] ‘til I was 31. (Mother of 9 year old)

Mothers hoped they were doing the right thing and there was a lot of guilt about the things they could not do (however unrealistic), including making it so their child didn’t have diabetes.

Unsurprisingly there were a number of references to the pressure that mothers felt under:

It’s just a constant battle I, I, I just never know what I’m doing. (Mother of 14 year old)

Mothers felt that there was no break from the regimen and they were unsure of whether they were doing all they could to help their child. The constant burden of their child’s illness was described by many of the mothers interviewed:

It’s like, it’s like being a gerbil on a cage. (Mother of 16 year old)

Having a child with diabetes meant that mothers had to provide never-ending support and care often with no respite. Although they tried to be strong and “go with the flow” (mother of 14 year old), mothers reported feeling like “a complete failure” (mother of 14 year old).

There were references to other family members as a source of support and coping. Mothers spoke about the support and help fathers and siblings provided in caring for their children:

We all know dad’s brilliant I’ll quite happily come to work or do a night shift or whatever and he just she goes and wakes him up and he knows and even big sister brilliant. (Mother of 14 year old)
This seemed to help ease the pressure that a lot of mothers felt they were under. When mothers couldn’t cope with certain aspects of their child’s condition having a supportive partner helped to relieve some anxiety:

I suppose being a nurse I should have been [able] felt better about doing her injections but out of the two of us my husband was better. (Mother of 11 year old)

Where mothers felt they had shortcomings in the management of their child’s diabetes, they reported the ways in which CYPs’ fathers provided help. These reports add to small body of research with fathers of CYP with diabetes. They also help to illustrate how fathers are involved in helping CYP (and mothers) cope with the day to day management of diabetes. Ultimately, the primary care of CYP was the responsibility of mothers.

Considering all the pressure mothers felt under and the responsibility of providing optimum care for their children there were reflections about the lack of support made available to parents to help them and their children cope with the chronic condition:

There was never an opportunity or never a question asked to see how we were coping mentally or psychologically and whether we needed support. (Mother of 16 year old)

The constant management, stress and responsibility of managing diabetes had an impact on mothers, psychologically. Struggles in coping may benefit from psychological support for parents, to help them deal with the day to day stresses. Thinking about additional support in the long term, some mothers reported that they did not feel comfortable going to diabetes parents groups to talk about diabetes, as they might hear stories about the frightening things that could happen to their child. These parents preferred the support of the family unit, close friends and CYPs’ clinicians, suggesting that there are different types of support that parents benefit from.

Those parents who did feel additional support might be beneficial however, suggested that parent groups would be helpful, in addition to knowing about what the more serious
consequences were from the beginning so that if they did experience them they would already have an inclination that this could possibly happen:

That you know it will be alright you may they may I know it’s frightening to say they may have a fit or whatever but you know it is part of it. (Mother of 14 year old)

This refers to feeling confident and prepared for certain eventualities associated with having a child with diabetes, so that mothers did not feel unprepared in the event of, for example, an episode of severe hypoglycaemia leading to a seizure.

Mothers reported enormous pressure and responsibility for their child’s day to day diabetes care and also for their long-term health. This was often overwhelming and incessant, putting pressure on mothers and impacting on their quality of life. Mothers benefitted from support from their partners in managing their child’s diabetes but ultimately were the primary caregivers and assumed the majority of responsibility of care.

8.3.2.2 Fear of hypoglycaemia

Fear of hypoglycaemia was evident in CYP and maternal reports of living with diabetes. CYP reported feeling scared and worried about severe hypoglycaemia. CYP fears also extended to having an episode of hypoglycaemia in their sleep. One young person reported actively avoiding nocturnal hypoglycaemia as a reaction to a period of night-time episodes of hypoglycaemia. She was so afraid about having an episode of severe hypoglycaemia in her sleep, she stopped taking her insulin injections:

There was a period where I tried not to have any injections but I got seriously told off for that. (12 year old CYP)

Fear of hypoglycaemia for this young person had serious implications for her diabetes care. Children worried that they might go into a coma as a result of severe hypoglycaemia:

I think that I can go into a coma. (9 year old CYP)
It was something that they were genuinely scared and worried about at least for one of the CYP interviewed, impacted adversely on their motivation to achieve optimum glycaemic control.

CYP also reported keeping blood sugar levels a little higher, during exam times, where having an episode of hypoglycaemia might impact on their performance:

> It’s just like the last exam I had, I didn’t have, I had, I didn’t have as much insulin just in case. (14 year old CYP)

The worry about the impact of hypoglycaemia on performance in an exam contributed to hypoglycaemia avoidance behaviours, although reports of intentional avoidance were not common practice. It seems that CYP really tried to manage blood sugars as well as they could.

Fear of hypoglycaemia was apparent in this group of mothers. Mothers were not only worried about CYP having an episode of hypoglycaemia on their own; they also worried about the symptoms of hypoglycaemia and severe hypoglycaemia, in general:

> When they were little and she used to go it’s frightening for anybody to watch. (Mother of 14 year old)

Mothers feared the worst for their child in terms of severe hypoglycaemia and the implications of a severe episode.

> I’ve got that orange thing [glucagon injection] in my fridge and I just dread that, panic really. (Mother of 14 year old)

A number of parents spoke of their fear of administering a glucagon injection in an emergency, although no-one reported having to use it (with only one parent reporting that the paramedics had used it during one incident) and most being assured by the nurses that very often they wouldn’t have to. Nevertheless, the fact that it was a possibility was a
distressing prospect for mothers. This reflects another negative emotion as a result of T1DM.

Experience of severe hypoglycaemia was traumatic and episodes were obviously distressing and frightening for mothers. CYP did not report on these incidents in as much detail as their mothers did, perhaps because they did not remember as vividly/were not aware of the episode:

   They were bad hypos where she’d she wouldn’t even let you give her a drink she would refuse to swallow so I’d have to put the gel in her cheeks and rub and we’d pin her down cos she’d fight and become really angry. (Mother of 12 year old)

Mothers described genuine difficulties in treating their child’s episodes of severe hypoglycaemia. One account was obviously extremely upsetting for a mother but highlights why perhaps parents and CYP struggle with the prospect of severe hypoglycaemia and develop related fears and anxieties:

   That was our worst hypo, she did {starts to get upset} uh, ... he [father] just poured orange juice down ... I went ‘she’s dead!’ and she was by all attempts and purposes she’d got the thick skin, she’d got blue lips umm she just slumped forward yeh so being, being a nurse I just smacked her [to stop child choking] ... her behaviour was just outrageous, I said just call 999 I can’t deal with this. (Mother of 11 year old)

There were more than a few reports of cases where severe hypoglycaemia had led to emergency treatment, which in itself is an ordeal for both parent and child. It is no wonder then that mothers reported worry and fear of hypoglycaemia, especially severe hypoglycaemia.

Not surprisingly mothers described worries about their child having an episode of hypoglycaemia whilst asleep:

   I did not sleep particularly well for probably the first 4 months because I was terrified she’d have a hypo during the night and not wake up ... I just couldn’t sleep I had to go in and
keep checking on her and my, my husband was not as bad as me but he was you know he’d go in, we, we were performing blood tests on her while she was asleep. (Mother of 12 year old)

The fear of nocturnal hypoglycaemia compelled mothers (and fathers) to monitor blood sugar levels throughout the night. For some families this process continued long after their child had been diagnosed. Mothers reported that CYP would inform them if their sugars were low during the night however, the majority continued to carry out their own nightly checks, often supported by CYPs’ fathers:

What we do, do as well, religiously, is we do check her through the night...so between 2.30 and 3am ... we do a check... you know once you start ... my husband and I, he’s very good, he works and I don’t and he still alternates. Yay! (Mother of 16 year old)

This mother (and father) had been carrying out nightly checks since their daughter was diagnosed at 18 months old. This highlights the impact of diabetes on parents’ lives. Most of the references to sleep reflected the impact on parental sleep rather than on CYP sleep. CYP seemed to allow their (usually) mothers take responsibility for monitoring them after experiencing hypoglycaemia in the night. This maternal responsibility will be discussed further. One of the main reasons for mothers’ worry regarding nocturnal hypoglycaemia was that their child might not wake up to alert them or treat themselves, which could have devastating consequences:

As a parent that's our biggest fear would be that she doesn’t wake up so yeh it is always there... yeh your hypo's your biggest enemy and constant highs are you biggest enemy but hypos will cause death, instantly. (Mother of 16 year old)

Many of the mothers reported fears that their child would not wake up following a drop in blood sugars while they slept. However, it is worth noting here that hyperglycaemia (dangerously high blood sugars), while typically more insidious, is more likely than hypoglycaemia to result in serious harm to the child, including coma and death, so these reports reflect that mothers do not completely understand and perhaps overestimate the dangers of nocturnal hypoglycaemia. When CYP had low blood sugar during the night
mothers reported keeping their child with them for the remainder of the night and so often had disturbed periods of sleep:

I do go in and check on her then to make sure nothing has happened you know if she’s gone into the deep sleep coma or anything like that cos I do panic. (Mother of 9 year old)

The impact of diabetes was not only during the waking hours, for some mothers it really was incessant. The constant diabetes-related fear and anxiety and impact on parental sleep for some of the mothers interviewed suggest a major impact on mothers’ (and fathers’) lives, as well as on their quality of life. This reflects findings reported on the link between fear of hypoglycaemia and anxiety for the quantitative data, although the link with parental quality of life could be explored further in future studies.

Fear of hypoglycaemia was evident in both CYP and mothers. This fear stemmed from negative experiences associated with hypoglycaemia and severe hypoglycaemia. The trauma seemed to be greater for mothers who often witnessed episodes of severe hypoglycaemia. Mothers and CYP also expressed fear of nocturnal hypoglycaemia, however, it was mothers (and fathers) who seemed most affected by this. Maternal reports of nocturnal hypoglycaemia indicated that mothers regularly monitored their child’s blood sugar levels throughout the night to make sure their child’s BG levels had not suddenly dropped. Mothers’ accounts also highlighted issues with regards their understanding of the dangers of hypoglycaemia.

Hypoglycaemia-avoidance behaviours were reported by both CYP and mothers, only in specific situations. However, neither group admitted to deliberately maintaining high BG levels on a regular basis which suggests that CYP and their mothers do try to achieve good glycaemic control.
8.3.2.3 Summary of ‘Negative emotions’ theme

Mothers and CYP used a number of negative emotions to report their experience of diabetes. This included fear, anxiety, distress and guilt. Both CYP and mothers reported distress and worry at diagnosis. However, it was mothers who seemed to continue to feel anxious about their child’s diabetes, both in terms of day to day management and future impact of the illness.

Guilt was apparent in CYP and mothers, but for different reasons. Mothers reported feeling guilty that they had not recognised the symptoms their child had exhibited prior to diagnosis. Mothers also felt guilty that their child had to live with a long-term condition and that they could do nothing to help them. One child reported the guilt she felt regarding the impact diabetes had on her family, highlighting yet another example of the effect diabetes can have on CYP and their families.

The responsibility and burden of managing diabetes was evident from CYP and maternal reports. CYP reported that self-care could be relentless and mothers were overwhelmed by the daily management. Mothers tried to support their children with day to day diabetes care and although they themselves benefitted from the support provided to them by their partners, they felt that they had ultimate responsibility for their children’s care.

Reports of hypoglycaemia and severe hypoglycaemia revealed associated anxiety and fear, especially from mothers. Although there were few reports of maintaining high BG levels to avoid hypoglycaemia, mothers did report monitoring their child’s BG levels through the night because they worried about nocturnal hypoglycaemia.
8.3.3 Living with diabetes

Inevitably, a diagnosis of T1DM meant that there would be changes to both CYP and their mothers’ lives. The majority of reports on living with diabetes from both CYP and mothers were negative although some did try to acknowledge the positives. CYP and parents also acknowledged the practical changes associated with a T1DM diagnosis.

8.3.3.1 Negative impact

CYP reported the initial difficulties of diabetes management:

I mean the thought of injecting was, was really hard. (16 year old CYP)

CYP mentioned that certain things had to change as a result of their diagnosis, such as the types of food they could eat, being prepared for episodes of hypoglycaemia, being organised at school and remembering to check blood sugar levels regularly. Although CYP seemed to adapt well in the early days to the new routine and responsibility their diagnosis brought, the regimen of daily injections, checking blood sugars and monitoring meals were difficult to accept.

Generally, the effects of trying to manage diabetes and maintain optimum blood sugar levels resulted in embarrassing and sometimes distressing experiences for CYP. This was due in part to CYP-reported symptoms associated with hypoglycaemia: feeling “wobbly,” “dizziness” and “feeling sick,” but also the experience of severe hypoglycaemia. As hypoglycaemia was often flagged as a problem for CYP, they appeared to be very well prepared when it came to treating hypoglycaemia. In general, CYP reported having access to glucose tablets, Lucozade or chocolate to counteract hypoglycaemia.

Although some CYP reported that coping with diabetes was, “Just routine” (14 year old CYP) and wanted to try to resume life as normal to make it easier to cope with, others reported
the difficulties in everyday management of diabetes. CYP found injections and blood sugar testing painful and unpleasant:

It’s just that it’s not very fun sticking needles in yourself. (12 year old CYP)

Not surprisingly then, day to day management of diabetes was often flagged as a negative experience by CYP.

Mothers were aware that a diabetes diagnosis was the beginning of a lot of changes to the way to life as they knew it:

Because we’d always been quite relaxed about eating, what they wanted when they wanted. To then, not to do, we never had a regimen with our lifestyle at all. That was quite hard. (Mother of 17 year old)

So, in addition to adjusting to the diagnosis mothers reported struggling to help manage their child’s diabetes. The impact of diabetes was not just on care for their child, but everyday tasks such as shopping, cooking meals; essentially most aspects of their lives.

Mothers reported the impact their child’s diabetes had on their marital relationships. Mothers often being the primary caregiver had a lot of responsibility and pressure placed on them. It is hardly surprising that there might be some disagreements in how best to manage CYPs’ diagnosis:

I suppose it put pressure on our marriage for a while... there were slight differences where I was happy to let her go to birthday parties and sleepover and my husband was ‘oh no, no, no.’ (Mother of 12 year old)

The constant management of their child’s diabetes did seem to put additional pressures on parents’ marriages. Parents expectedly had disagreements about the best way to manage the diabetes and about how much independence to afford their child.
In addition to the more frightening aspects of managing diabetes, there were also reports of CYP feeling self-conscious as a result of their diagnosis:

He’s shy to do his injections in from of people so he always finds another room wherever we are. (Mother of 15 year old)

However, as CYP tended to be quite young at point of diagnosis (primary school age) this meant that the diagnosis was perhaps more visible to others, because their age meant that adult caregivers often had to take some responsibility for their diabetes care. Many CYP then reported that in the early days/years, their diabetes was not a secret and friends and family were all aware of the condition and what it meant for the child.

The reports of impact on school and learning were mixed. Some mothers reported that there was minimal impact of diabetes on learning. Others suggested that there was an impact:

I think it did affect her in primary school I think there are chunks of learning that she’s not got. (Mother of 11 year old)

Clearly some parents did feel there was a negative impact of diabetes on learning, whether that was due to living with diabetes itself or due to poor attendance at school.

Mothers hoped that their care and support of their child’s diabetes management meant that CYP would see diabetes as being part of everyday life. Depending on the age of the child it seems that at some point the daily management of diabetes wasn’t constantly seen as a negative, rather a way of life. However, the period of adolescence often resulted in a shift in diabetes experience, whether that be the social impact or the impact puberty had on managing blood glucose levels. Mothers had to deal with these changes and help CYP accept their condition again.

But first probably, six months, she didn’t inject herself at school. We had all sorts of problems. I was just keeping on at her. We made an appointment at the hospital and I said
right, and I said right, we’re going to tell the doctor. And I sent Tina [diabetes nurse] up and Tina came and basically sort of said, ‘you’ve got to sort it out.’ (Mother of 12 year old)

This mother reported that her daughter’s transition to high school resulted in a shift in diabetes management. Her daughter, who previously had been very open about her condition, now felt self-conscious and didn’t want her peers to know about her diabetes. Clinically this could have had serious implications for her health.

For mothers, there were obvious anxieties about their child’s future, living with diabetes. Mothers’ concerns related to the long-term impact of suboptimal diabetes care, on their child’s health in the future:

It’s if you don’t look after yourself and do it all properly and you know as a parent I, I dread the future really. (Mother of 14 year old)

In order to manage their child’s diabetes, mothers had to control blood sugars enough so that CYP were not constantly experiencing hypoglycaemia, but also so that their blood sugars didn’t run too high for fear of the consequences. It was a real balancing act:

So learning about the implications on her healthcare now having on her body in later life as far as, you know, her internal organs and her eyesight and you know all of those things was hideously scary to know that you are responsible for practic- that she in 20 years’ time could turn around and just say ‘well the pair of you didn’t do a very good job did you.’ (Mother of 12 year old)

This highlights the anxiety mothers felt for the future health of their children and the responsibility they carried. No doubt this kind of constant worry is likely to impact on maternal well-being and illustrates how mothers not only worried about the present impact of diabetes but also what it meant for their child in the future.

A couple of mothers had real life experience of the risk diabetes posed to their child, both in the short and long-term:
I had a friend, growing up, who completely abused his diabetes and went blind so that was a, that was a thought…and also my sister-in-law umm at 19, her daughter died, of a diabetic coma. (Mother of 16 year old)

Having had such negative first hand experiences of diabetes seemed to add to the worry that this mother felt for her daughter. This mother expressed her worry at her daughter getting older and becoming more independent and being responsible for making critical decisions, such as drinking alcohol.

A number of mothers reported feeling worried about their child’s increasing independence and were aware that they, themselves, needed to trust their child to be able to manage their own condition. Mothers made more references to their worries about their children’s diabetes than children and young people did themselves. Many fears and anxieties reflected separation anxiety mothers felt being away from their children and the lack of control they had over their child’s diabetes management. They especially worried about how their child would cope with hypoglycaemia without a parent present:

You know when she’s off out with her friends, even when she’s at school, you know I’m still kind of a little bit on alert. (Mother of 12 year old)

There was also worry about the impact diabetes might have on other aspects of the young person’s life, for example at school or later in life:

Yes something I think of all the time. How he’ll manage when he leaves home. (Mother of 15 year old)

Mothers worried about the reduced control they had as their children moved from primary to secondary school, college, university and beyond. This meant that having accepted their child’s diagnosis and being in a position to feel confident in their own and in their child’s abilities to manage diabetes (to an extent) now mothers were again experiencing anxiety and doubts about their child’s ability to manage their condition completely independently.
The negative impact of diabetes on day to day life revolved mainly around diabetes management, from the tasks associated with diabetes care to feeling self-conscious about carrying out self-care behaviours. Mothers also reported the impact diabetes had on otherwise normal day to day tasks, such as shopping and cooking for CYP and their families. They discussed the impact on their marital relationships and spoke about their worries about the future.

8.3.3.2 Positive impact
In spite of such a life changing diagnosis there were some positive responses. CYP and mothers reported that CYP felt special as they were given special attention as a result of their diagnosis, which in some ways, at times, helped to compensate for the fact that they now had to live with this chronic illness:

Well when she was first diagnosed it was umm she didn’t mind it was almost like star status at school because she was having this extra sort of care. (Mother of 14 year old)

Mothers acknowledged the extra care that they and others gave to their child after a diagnosis of T1DM, which seemed to help accept the diagnosis; that their child would at least receive special attention and care. There was also a sense of relief from mothers that the diagnosis was treatable and that things could be worse:

Also I’m relieved it’s something that can be treated because there are so many horrible things when you get down you have to sort of think thank goodness it is that and nothing worse. (Mother of 14 year old)

This mother had the view that she and her child should count themselves lucky, although the diagnosis was initially seen as a negative she tried to see the positive side of things. This could be a seen as a move to acceptance of the diagnosis.
Other instances of special attention at home and at school included being allowed to treat hypoglycaemia with sugar, “I can have sweeties” (7 year old CYP) and at school being able to, “get out of lessons when you’re ill” (12 year old CYP). It should be noted here that positive experiences in the short-term were reported by younger children, older CYP tended to report on more of the negatives or else were reported diabetes as neither positive nor negative, but just something that they had to live with.

Some mothers reported relief that there seemed to be an explanation for particular behaviours and phases that children had gone through such as bed wetting and mood changes. Thinking about the diabetes diagnosis differently helped to almost bring a sense of acceptance following the initial distress and anxiety.

Another positive reflection made by CYP was that they felt that having the T1DM diagnosis made them more aware of the lifestyle choices they made:

   I kind of like it, because I don’t eat all the sugary stuff which makes me fat and I don’t eat chocolate which has sugar in it. (8 year old CYP)

In some cases the diagnosis seemed to motivate CYP to be healthier which in turn helped them to feel better about living with diabetes.

Some mothers were full of praise for their children’s coping skills:

   He never cried for an injection. He never cried when we tested him. Not once has he ever! And I think that made it a lot more easier. Yes it’s a blessing really. He’s been brilliant. (Mother of 15 year old, son diagnosed at age 3)

They were proud of their children’s ability to adjust, manage and cope with their illness as well as all the responsibility it brought, for their child.
One parent also reported how the family benefitted on a trip to Disneyland:

In Disneyland we got fast passes, that was brilliant so 'yay' so it's the one thing that's beneficial. That was good so we all appreciated that. (Mother of 16 year old)

So despite the many difficulties and constant pressure of living with diabetes, mothers (and CYP) did try to see the positives where they could, which might have helped them to accept that T1DM was now a part of all of their lives.

8.3.3.3 Practical changes
Mothers spoke about their practical reactions to diagnosis:

We [parents] went to Sainsbury's we were in there for two hours reading absolutely everything [both laugh] because you're looking for sugar content within that and keeping it within certain, you know the, the percentages of everything you’re looking at. (Mother of 12 year old)

Mothers reported receiving copious amounts of information at diagnosis which they felt was overwhelming and also signalled the changes to the way that families would now have to function in order to manage their child’s diabetes. Mothers’ initial responses seemed to be a reflection of their lack of knowledge and understanding about living with diabetes.

As CYP had been diagnosed at quite a young age, they were able to adapt and accept the new demands of having diabetes. They ‘never knew any different’ (mother of 15 year old) and so were better able to deal with the practical changes to daily life. Nevertheless, mothers reported initially trying to help CYP accept their diabetes and focus on managing their condition, rather than dwelling on the negatives:

You just need to accept it and, and get on so that was our attitude and it seems to have worked. And we made a big point immediately as well of having her do everything publicly... we didn’t ever want it to be something that caused embarrassment or shame. (Mother of 12 year old)
Mothers hoped that by encouraging their child to be open about their diabetes would help them to accept their diagnosis and feel comfortable and confident managing their condition. For some families, especially in the first few years, this way of thinking continued once diabetes had been established and was reported as a positive coping strategy.

In order to manage the burden of T1DM mothers had to feel confident that their CYP knew how and were able to treat an episode of hypoglycaemia:

If he’s low he knows he needs to go and get Lucozade and a biscuit and he, he near enough does it all himself. (Mother of 7 year old)

This gave mothers the assurance that their child could manage their diabetes, and perhaps took some of the responsibility and burden away from themselves. This is a key development from the time of diagnosis to a point where mothers had adjusted to their child living with diabetes. School staff were generally reported to know how to treat/recognise hypoglycaemia which again helped mothers to feel able to let go a little in terms of their child’s diabetes management.

Siblings often were given extra responsibilities and had to help with household chores and do more than their share if CYP had an episode of hypoglycaemia or if CYP had to have their injections. In the main, however, mothers reported that siblings did look out for their siblings and contributed to managing CYP diabetes:

In the beginning we relied on the boys a lot more to look out for signs, whether we were in or out. You can’t constantly be in the same room. He’s got to play with his friends, he’s got to play with his brothers. You got to let go. They’ve had a huge role. (Mother of 15 year old)

The impact of diabetes and changes to family life were evident in the role siblings took, who provided an extra source of support for parents and CYP. Day to day support in
diabetes management seemed necessary in order to manage the demands of the condition.

Considering the impact of hypoglycaemia it is not surprising that there were some reports of avoiding hypoglycaemia. Mothers made it clear that this avoidance was not to make life in the short term easier but more for peace of mind if CYP were going to be away from parents overnight, for example (for practical reasons):

I’d rather him be a little bit higher than a little bit lower just because it’s somebody else’s house. (Mother of 7 year old)

Maintaining higher than optimum blood sugar levels allowed mothers to give their child the freedom they might have ordinarily not had to think twice about. In the main, however, mothers did not engage in hypoglycaemia-avoidance behaviours to avoid low blood sugar. Mothers were determined to help CYP manage their diabetes the best they could.

Mothers made references to the way in which diabetes affected leisure time/activities for CYP but in the main they were about adjustments CYP had to make rather than missing out as such:

For [child] it’s that she can’t just go out for the day with her friends and not have to plan it in advance. (Mother of 12 year old)

This was a promising outcome in terms of the impact diabetes had on CYP’s leisure time.

CYP reported that in time, management of diabetes became routine:

Well it’s kind of normal for me now, like I don’t know any different. (16 year old CYP)
This report came from a 16 year old girl who had lived with diabetes all her life (from 18 months old) who had experienced feeling frustrated about her condition during early adolescence but had now come to accept it again. This is encouraging and reflects the fact that managing diabetes over time does get easier. There were also positive and hopeful comments about diabetes management:

We thought that it [the pump] would give best control of blood sugars, I suppose so diabetes didn’t control me. (15 year old CYP)

CYP wanted to be in control of their condition, to feel that they had a grasp on their illness. They were optimistic that they were at a point where they felt in control of their diabetes and could manage it in a way that did not impact on day to day life as much as it might have previously.

The practical impact and changes T1DM brought were evident for CYP, mothers and their families. CYP had to adjust to the daily regimen of diabetes care and had to be vigilant with regards to treating hypoglycaemia and being prepared for such a situation every time they left the house. This was reflected by mothers’ reports too which described the practicalities of giving their child the freedom to do the things that other children their age were able to do, such as leisure activities and sleepovers.

### 8.3.3.4 Summary of ‘Living with diabetes’ theme

This theme highlighted the numerous examples of the negative impact of diabetes. This included injecting insulin, experiencing hypoglycaemia and the change in lifestyle. Impact was also discussed with regards to the effect diabetes had on school and learning, moving towards independence (CYP) and marital relationship (mothers). Mothers also spoke at some length, about the future impact of diabetes on their child’s health and worried about relinquishing the responsibility they had for their child’s care, as their child became more independent.
There were some references to the positive impact of a diabetes diagnosis. CYP and parents spoke about the special care and attention they/their child received as a result of the diagnosis. CYP also mentioned the positive impact that diabetes had on the lifestyle choices they made.

The practical changes had a noticeable impact on CYP and their mothers. CYP and their mothers had to adjust to the daily management of T1DM and ensure that they were prepared to treat episodes of hypoglycaemia. Over time, these changes became a way of life and both CYP and parents seemed to accept this.

8.4 Summary of Chapter 8

Thematic analysis of interviews carried out with CYP and their mothers illustrates the experience of living with diabetes and the emotions and pressure associated with this. Not surprisingly, a diabetes diagnosis was met by fear, uncertainty and worry in both mothers and CYP. Mothers felt the added pressure and burden of helping their child to adjust to the diagnosis as well as taking charge of diabetes management, at least in the early days, if not beyond. Mothers reported more distress regarding their child’s diagnosis than children did themselves. CYP burden was highlighted in interviews and emphasises the difficulties they faced as a result of their diabetes. CYP guilt also emerged as an impact of diabetes management, which had not been explored previously.

Hypoglycaemia and severe hypoglycaemia were reported as the most negative aspect of having diabetes. The symptoms of hypoglycaemia made CYP feel unwell, however, severe hypoglycaemia was often extremely frightening for CYP and mothers. There were reports of events that led to emergency treatment. Mothers exhibited much worry about their child having an episode of severe hypoglycaemia and were especially fearful of their child
experiencing nocturnal hypoglycaemia. As a result, many mothers reported night time BG monitoring which also reflected the constant management of their child’s condition. The reported impact on mothers’ lives then seemed to be as great if not greater than impact on CYP.

Long-term effects of diabetes were also a source of worry for mothers. They worried about future complications and grieved for their child’s shortened lifespan. Mothers also reported the added burden of trying to manage their child’s blood sugars at the optimum levels to prevent long term health problems but also to try to control hypoglycaemia.

Impact of diabetes was evident in multiple areas, from marital relationships and family life to leisure time and school. Promisingly, the impact of diabetes seemed to be controlled by adjustments to insulin and regular routines and being prepared. The main impact seemed to be on making preparations when going out or before exams, for example, which might not have been necessary if CYP were not diabetic. Throughout the interviews however, it is obvious that diabetes has a genuine impact on the quality of life of both CYP and mothers considering the reports of fear, worry and pressure.

Mothers described the practical changes they had to make to accommodate the diabetes diagnosis. CYP spoke about the daily demands of diabetes management from injections to monitoring blood sugar levels. The majority of mothers and CYP said that eventually they managed to get into a routine so that diabetes management just became part of life.

The interviews gave a richer and deeper insight into life with diabetes. This allowed further understanding of the similarities and differences in CYP and mothers’ experience of living with diabetes and the kind of impact this has on their lives.
Chapter 9: Discussion (Qualitative phase)

Qualitative research allows a deeper understanding of health-related topics which otherwise might not be so accessible when using structured questionnaires. Qualitative data also allow researchers to delve further into the experiences of participants in order to get a richer insight into their emotions, experiences and stories.

For the current study, results of the qualitative analysis add to the small body of research (65, 104, 120, 123, 124) carried out with CYP (not just adolescents) with T1DM and their families. This phase also allowed the researcher to gain further understanding of the findings that emerged from the quantitative analyses. The interviews and subsequent analysis addressed one of the key aims of this study; to collect data on the impact of episodes of hypoglycaemia. They also allowed further understanding of living with diabetes and the impact that that has on CYP and their mothers.

Thematic analyses conducted on the interview data with both CYP and their mothers (no fathers consented to take part in this phase of the study) led to the emergence of two main themes: negative emotions and living with diabetes. Sub-themes were also apparent for each of these themes after further analysis of the interview transcripts. Negative emotions were described with reference to ‘feelings about T1DM’ and ‘fear of hypoglycaemia.’ Living with diabetes was made up of three sub-themes: ‘negative impact,’ ‘positive impact’ and ‘practical changes.’ ‘Burden’ was identified as an overarching theme and was evident in each of the interviews with CYP and their mothers. Mothers and CYP discussed the impact of diabetes on their lives with reference to the constant management and responsibility of the necessary daily care.
9.1 Burden
Type 1 diabetes mellitus places much pressure and responsibility on CYP to manage their condition but more so on mothers of these children and young people. Several subthemes emerged within the overarching theme of ‘Burden,’ exploring the negative emotions associated with diabetes and the impact of living with diabetes. Mothers took responsibility for helping their children firstly accept their diabetes diagnosis, learn how to manage their condition and also took responsibility for supporting that management to varying degrees throughout CYPs’ lives. Mothers expressed the burden they felt, of the worry of the long term health implications resulting from diabetes which lead to considerable anguish and fear for their child’s future.

Worry, anxiety and feelings of burden were some of the key topics that emerged regarding living with diabetes. Interviews illustrated the ways in which diabetes impacted on CYP and mothers’ lives, and potentially their quality of life too (105, 167). This supports the findings of the quantitative analysis which identified links between anxiety, fear of hypoglycaemia and quality of life. The qualitative data allow further understanding of the ways in which anxiety presents itself and the impact that it has on CYP and mothers. CYPs’ and mothers’ accounts of the impact that hypoglycaemia, diabetes management and thoughts about the future can have, help to explain why there is a prevalence of fear and anxiety and also how that might impact on the quality of life in these individuals. Both CYPs’ and mothers’ accounts of living with diabetes suggested that diabetes is a burden (101, 122, 124, 125).

9.2 Negative emotions
Discussions about T1DM evoked negative emotions in both CYP and their mothers. The way in which this group spoke about their experience of diabetes is particularly poignant, especially in terms of mothers’ reports. Although the CYP did demonstrate distress and worry about living with diabetes and also indicated anxieties concerned with fear of hypoglycaemia, mothers seemed to experience these emotions to a greater extent.
In the days and months following diagnosis especially, mothers went through a period similar to bereavement and expressed feelings of grief in response to their child’s diagnosis. This goes some way in showing the magnitude of the impact this diagnosis had on mothers. In their qualitative study of living with diabetes, Marshall et al. (124) found that parents especially, spoke about ‘loss’ in terms of their child’s diagnosis. They also reported that parents went through a grieving process in response to the diagnosis. These reports, in addition to maternal reports for the current study, show how deeply parents are affected by T1DM in their child, from the point of diagnosis. This seems to be more evident in parents than it does in CYP themselves. Bowes et al. (105) also support the idea that parents of CYP diagnosed with T1DM go through a period of grief. They go further by suggesting that these parents experience ‘chronic sorrow’ (181) which reflects the ongoing, although not constant, sadness felt by parents when their child is diagnosed with a lifelong condition. Certain triggers can cause a resurgence of these feelings of grief such as an episode of severe hypoglycaemia or recollection of previous events such as diagnosis. Indeed mothers interviewed for the current study showed instances of distress when talking about their child’s diagnosis. These reports are vital in understanding the huge impact that caring for a child with a lifelong condition can have.

Distress, fear and worry were the initial key emotions experienced by CYP and their mothers at diagnosis. This is similar to other qualitative studies exploring living with diabetes within similar groups. Spencer et al. (123) conducted interviews with adolescents and parents in order to discover more about their experiences of diabetes. As with the current study, they found distress and worry to be part of the initial experience of diabetes. Researchers reported that mothers often had a better recollection of events around diagnosis and that many did not attribute the symptoms their child was experiencing to T1DM. The worry and anxiety experienced by CYP and their mothers was obvious from the point of diagnosis to present day, albeit varying in nature. The CYP who were old enough to remember reported that initial diagnosis was distressing and they
worried about the implications of diabetes. Similarly mothers also reported feelings of upset, worry and sorrow that this was happening to their child (104, 124), possibly to a greater extent than children felt, although this may reflect reporting differences.

Whilst coming to terms with their child’s diagnosis, mothers, simultaneously, tried to support their children by keeping life as normal as possible and incorporating diabetes care, as well as they could, into everyday life. Privately though, mothers struggled to accept the diagnosis that their child had been given. Although the impact of diagnosis was difficult for CYP, it seemed to have a profound effect on mothers’ lives. The diabetes care was constant, often with no break. Although the majority of mothers benefitted from support from fathers of the CYP, mothers bore most of the burden. Smaldone et al. (125) found that parents of CYP diagnosed at an early age felt completely overwhelmed at diagnosis. They worried that they would not be able to provide the care that their child needed. Feeling overwhelmed was also reflected in the accounts of parents interviewed by Spencer et al. (123). Their study investigated the experiences of adolescents with T1DM and their parents. Parents felt that they had a lot of responsibility to bear and again this was reflected in the current study by mothers.

Mothers reported feeling the pressure of having to care for a child with diabetes. This is a common finding as reported in Sullivan-Bolyai et al.’s (101) paper on constant vigilance. They found that mothers of CYP with T1DM expressed the constant care they had to provide their child in managing diabetes. This included day to day responsibilities, managing hypoglycaemia and worrying about future complications. The current study also highlighted that the care that mothers provided was constant and often there was little respite. As mentioned previously, mothers even continued to provide care throughout the night and this is reflected in previous research (65, 128). It is likely that this type of responsibility and never-ending care could result in negative health outcomes for mothers of children with T1DM. Although, like other reports, mothers in this study benefited from spousal support (101, 125) other mothers spoke of the pressure it put on marital
relationships often due to disagreements about diabetes management. Smaldone et al.’s (125) study reflects both of these findings. They found that fathers could be a source of great support for mothers, if they were able to work as a team. When this was not possible, however, the pressure of their child’s condition had a negative impact on their relationship with one another.

Guilt was evidently experienced by mothers and to a lesser extent, though not less significantly, by CYP. Mothers’ distress was exacerbated by their guilt at not noticing the symptoms of T1DM pre-diagnosis, often leading to a distressing series of events before diagnosis. Their guilt also resulted from worry that they were somehow to blame for their child’s condition. For example one mother felt that perhaps the diagnosis was due to her having her daughter later in life. This feeling of guilt was not uncommon. Mothers taking part in Spencer et al.’s study (123) also reported factors linked to pregnancy such as diet and pre-eclampsia, as possible reasons that their child had developed diabetes. These mothers blamed themselves and in doing so demonstrated that they took responsibility for their child’s illness, adding further to the burden they experienced.

It was affecting to note the guilt that one child expressed about the impact she felt that her diabetes had on her family. Her revelations seemed to reflect thoughts about her condition that she perhaps had not discussed before as her mother made no reference to this in her interview (which was conducted separately from her daughter). CYP guilt in this study seems to be a unique finding. This child felt guilty that her family could not enjoy themselves when they all went out for a meal because they would be worrying about her. This finding may be important in understanding the way in which diabetes can impact on CYPs’ psychological outcomes such as well-being and quality of life. Further exploration is needed.
As CYP approached adolescence, even for those who had lived with T1DM since they were toddlers, the diagnosis seemed to become a source of embarrassment. CYP were reluctant for their condition to be revealed and were selective in who they disclosed this information to. To keep a large part of themselves hidden from others is likely to have been difficult and burdensome. This again demonstrates the negative emotions associated with T1DM. A review of qualitative studies in adolescents with T1DM (120) highlighted the move towards adolescence, for some CYP, becoming a barrier to self-management. As highlighted in the current study, some CYP seemed to struggle with diabetes during adolescence as it was usually a time when many changes were taking place, such as moving to secondary school where inevitably new friendships would be formed. Whereas, it is likely that many friends and teachers would have been aware of CYPs’ diabetes in primary school (where perhaps teachers may have had some responsibility for supporting diabetes care) secondary school provided a new start therefore, CYP may not have been comfortable about revealing the condition they were living with. One mother in Spencer et al.’s (123) study revealed that her son avoided certain social situations if they clashed with his diabetes care, although he did not tell his friends that this was the reason and seemed to hide the fact from them. However, other reports from the same paper suggest that friends can play an important role in supporting CYP with their diabetes management. This was also reflected in the current research study. Clinicians should be aware of the changes in motivation and self-care that the period of adolescence may bring in order to ensure CYP are managing their condition optimally.

Considering the burden and responsibility placed on mothers of CYP with T1DM, there was a distinct lack of psychological support offered to mothers. Mothers in the current study were surprised by the lack of psychological/emotional support for carers, considering that having a child with diabetes was overwhelming. Although other types of support were available (support groups), albeit to varying degrees, mothers felt that specific psychological support would have been beneficial to help them to cope with the daily demands of diabetes care. Bowes et al. (105) reported a genuine need for psychological
support as expressed by parents of CYP with T1DM. They felt that as parents, they were often overlooked and perceived to be coping when in fact they were struggling. There were differences regarding when parents felt psychological support would be most appropriate, varying from at the time of diagnosis, a later time point and also the suggestions that support should be ongoing. Future studies may benefit from exploring the most effective method of delivering such support. Parents in Rankin et al.’s (128) study also conveyed the need for psychological support. They felt that although clinical staff empathised with their situation they did not fully understand the impact it had. These parents also worried that if they voiced their true feelings then the doctors and nurses might judge them negatively and perhaps assume that they were not coping. The current study, as supported by previous findings, supports the need for psychological support for mothers of CYP T1DM in order to better help them cope with the daily burden and stresses.

Fear of hypoglycaemia was identified as a subtheme due to CYPs’ and mothers’ associated worries. Hypoglycaemia and severe hypoglycaemia were reported as amongst the most negative experiences of living with diabetes by the majority of CYP and mothers interviewed. Although prevalence of hypoglycaemia cannot be inferred from the small sample, these reports do indicate that hypoglycaemia and severe hypoglycaemia are a problem for this group. This supports findings of the quantitative phase of this study which also highlighted that hypoglycaemia was an issue for CYP and their parents. Mothers tended to report the most distress regarding severe hypoglycaemia because they had witnessed these frightening events, and their accounts indicated that their memories of the events were vivid and evoked emotions such as sadness and distress. CYP reports of fear of hypoglycaemia were mainly related to nocturnal hypoglycaemia with one report of avoiding night-time hypoglycaemia by missing insulin injections. This shows that some CYP were more concerned with the more immediate impact of severe hypoglycaemia than the long-term problems that chronic hyperglycaemia might lead to.
Both mothers and CYP reported anxieties about hypoglycaemia, severe hypoglycaemia and nocturnal hypoglycaemia (65, 120, 123, 128). Mothers were equally, if not more, concerned about nocturnal hypoglycaemia. Although they did not report avoiding hypoglycaemia by maintaining higher blood glucose levels, possibly due to anxiety regarding future health complications, there were many reports of night-time monitoring of CYPs’ blood glucose levels. Using Interpretative Phenomenological Analysis, Scott (65) reported that mothers described the constant worry that they felt in terms of hypoglycaemia. Mothers were worried for their children day and night and feared that they might find their child unconscious. Mothers in the current study similarly reported a fear of nocturnal hypoglycaemia and reported diabetes fear-related behaviours such as checking their child’s blood sugar levels throughout the night. Rankin et al.’s (128) study also found that parents of children with T1DM struggled to sleep amid fears that they would have an episode of hypoglycaemia during the night, although most reports reflected that this was most common in the early days after diagnosis. The current study however, highlighted how such practices may continue for years after diagnosis with one parent still checking their child’s night-time blood glucose levels 16 years later.

These reports add to research which is focussed on the worries and fears associated with hypoglycaemia. Interestingly, CYPs’ fears of nocturnal hypoglycaemia do not seem to have been reported in the majority of previous studies. For parents, however, this topic is evident time and time again. These data also reflect the higher maternal fear of hypoglycaemia levels reported in the quantitative analysis, reinforcing the idea that mothers’ anxieties and fear of hypoglycaemia for their child are often greater than their child experiences themselves. These findings have clinical implications for the management of psychosocial factors in mothers.

9.3 Living with diabetes
This theme explored how living with diabetes impacted on the lives of CYP and their mothers, in terms of the negative impact, positive impact and practical changes.
The negative impact, as with the negative emotions discussed earlier, was great. CYP struggled with the diabetes regimen, especially the daily injections required to manage their blood glucose levels. Many of the CYPs’ worries were related to diabetes management, namely, injections and blood glucose testing (and hypoglycaemia, as previously mentioned). CYPs’ worries ranged from worry about the pain of diabetes management, to worry about peer reactions, especially as they got older and approached adolescence (as discussed earlier in this chapter) (120, 126). Some CYP experienced periods of wishing that they did not have diabetes and described wanting a break from the daily diabetes management. Wennick et al. (122) reported the difficulties some CYP had managing the daily regimen; eating properly, taking insulin and always being prepared. This responsibility was often difficult for CYP whose peers did not have the same amount of duty placed on them.

Mothers illustrated that diabetes not only contributed to the pressure they felt as caregivers, but also added to the difficulties in carrying out daily tasks, such as shopping and cooking. The pressure of looking after a child with T1DM also had a detrimental effect on some marital relationships, which added to maternal struggles.

Anxiety and worry about the future were again mainly reported by mothers. The responsibility they felt around their child’s care was reflected in their anxieties about long-term diabetes complications. Parents in Ivey et al.’s (121) study communicated the fear they had of future complications if they did not support their child with their diabetes care. Mothers in the current study also worried that if they did not manage their child’s diabetes properly now then their child might develop additional health problems later on. This was again common across previous research, for both mothers and fathers. Bowes et al. (105) reported that parents worried about the future implications of diabetes. It was something that parents were concerned about and was upsetting. Similarly, Spencer et al.
(123) reported the fear of future health complications which made it difficult for one mother to give up the responsibility she had taken on for the management of her son’s diabetes. These interviews highlighted why mothers experienced so much worry and anxiety in relation to their child’s diabetes whether their child was recently diagnosed or whether they had lived with diabetes over a number of years. Day to day, the anxieties revolved around diabetes care and management but there were also worries about what the future might bring.

Not surprisingly, given the numerous references to the negative implications of diabetes, there were very few reports on the positive impact of diabetes from CYP and mothers. CYP reported the ‘star status’ they experienced as a result of their diagnosis, citing the special attention they received. There was also mention of the diabetes regimen leading to CYP making healthy choices, which they thought was a good thing.

Mothers were thankful that diabetes was treatable and tried to see the positive in that. However, in essence, CYP and mothers struggled to identify the positive impact diabetes had on their lives, which supports the idea that living with diabetes is a struggle for CYP and their mothers.

The practical challenges of living with diabetes were initially described as overwhelming, however, promisingly, both CYP and mothers reported that the practical changes became routine over time and so the impact was less significant than it had previously been.

9.4 Challenges in this research
There were some limitations identified with conducting qualitative research, especially with CYP. To ensure that younger children felt confident and understood what they were being asked to do, pictures and gestures were used within the information sheet.
Interviews with CYP may not always be productive and elicit as much information as required. CYP might not feel confident in giving their views fully, and this is often due to the issue of power and dynamics of an adult/child interview setting (132, 133). There was potentially some experience of this with one particular interview with a 14 year old lasting only 8 minutes, 46 seconds. However, the researcher appreciated that this CYP had taken their time and wanted to give their views, whether or not they were able to articulate those views fully. For this particular young person, one extract was included in the analysis, so even though the interview was short, it still contributed to the overall findings. Although difficult, qualitative research with CYP can help researchers to understand the stories of these individuals at a more in depth level, which might afford a more useful analysis of the data.

In terms of the data, another limiting factor was that fathers did not consent to participate in this phase of the study. There is paucity of qualitative research with fathers of CYP with T1DM and it would have been interesting to get a more in depth view of their feelings and the impact their child’s condition has on them. Quantitative data already highlighted that fathers have a higher fear of hypoglycaemia than their children have for themselves, so this could have been an area for further exploration. Mothers were, however, able to give some indication of how fathers reacted/dealt with their child’s diabetes, so their accounts provided some indirect detail of what fathers’ perspectives may be.

With the exception of one mother and son pair (Pakistani), participants in Phase Two were white. Results might not be generalisable as ethnic minorities might have reported different experiences of diabetes although, previous qualitative research suggests CYP and families with experience of T1DM have similar experiences of living with diabetes despite differences in background culture (124).
9.5 Implications
The findings of the qualitative phase allow deeper understanding of the ways in which T1DM impacts on both CYP and their mothers. The data also add to the limited but growing amount of qualitative research looking at the impact of diabetes on CYP and their mothers. These data acknowledge the impact that diabetes has. It is therefore important to try to formulate ways to overcome any negative impact of T1DM on CYP and mothers. As with the quantitative findings, it seems that worry (anxiety) and fear, as well as burden, are key issues and play a big role in living with diabetes.

Acknowledging the pressure on both CYP and mothers is important. CYP report negative feelings associated with daily management of diabetes. However, it seems that mothers often support their children both emotionally and practically. Therefore, importance should be placed on developing supportive/psychological interventions for mothers. Mothers in this study have already expressed a need for psychological support. In previous studies there were often worries, however, that asking for this support might suggest that they were not able to cope with their child’s illness. Often this was not the case however, psychological support could help mothers cope more effectively and not to the detriment of their own mental health and well-being. It is well documented that caring for a child with a chronic illness can often trigger anxiety or depressive symptoms in parents (182), therefore, more needs to be done to support these parents. Clinicians should be aware that mothers might be struggling to cope even if they do not admit to it. Mothers may be managing their child’s diabetes optimally, however, this does not necessarily mean that the constant management is not having a negative effect on these mothers. Mothers would benefit from a non-judgemental, supportive arena where they felt comfortable discussing their worries or concerns. This may or may not be directly linked to their child’s diabetes care provider. Providing techniques to reduce this worry might help mothers cope better with diabetes and could potentially impact on well-being by helping to manage the stress and anxiety that they experience.
As children approach adolescence it is important that clinical staff are aware of the negative impact this stage in life might have on diabetes management and should incorporate techniques that might alleviate these new found worries, into regular clinic appointments. This could help to manage any difficulties with diabetes care as CYP move through new phases of their lives and towards independence.

### 9.6 Future research

A key area of future research would be to conduct qualitative research with fathers of CYP with T1DM to explore and understand the impact their child’s diabetes has on them. Previous research which suggests that fathers might encourage optimal diabetes management, in comparison to mothers \(^1\) could be investigated further to identify if there are any differences and if so, how and why. This would also add to the limited research with this group.

Further research could also explore CYP guilt. As discussed, maternal guilt was evident in more than one interview transcript. CYP guilt, however, was a more unique finding and could be an area worth exploring further to identify whether it is something that other CYP experience. This would allow further understanding of the impact of diabetes on CYP.

Additionally, whilst many CYP and mothers did not necessarily feel that they would benefit from additional help, they did report that psychological support might be useful. The qualitative data indicate that CYP and mothers do struggle with diabetes, both in the short-term and in the long-term. There are reports of guilt, worry, stress, responsibility and being different. The current study highlights the need to address the worry/anxiety experienced by CYP and perhaps more so, their mothers. Methods to manage these emotions on a daily basis might be beneficial to the well-being of both CYP and their mothers. Therefore, development of a programme of care to address these concerns could help to improve the quality of life of these individuals.
Mothers could benefit from psychological support to address their anxieties and fears with regards their child’s condition. They might also benefit from incorporating coping strategies to help them to deal with the multiple demands placed on them. Future research should look at implementing a pilot counselling service to address mothers’ worries and give them a safe forum to talk about their concerns. This should be a non-judgemental setting with a trained counsellor or psychologist and can be separate from the diabetes service. A programme of counselling sessions could be offered to mothers/parents of children potentially at various time-points from diagnosis and beyond in order to judge when the intervention might be most effective. During these sessions researchers could evaluate mothers’ psychological state at the first session and then again at the last session to see whether the counselling sessions have helped and whether the time of delivery is also a factor in the intervention’s effectiveness. Results of this study could provide evidence to support the provision of psychological support for parents who report a need for it.

As previously mentioned (Chapter 7, section 7.5) using a mobile application to address stress and worry, through mindfulness, might be an efficient and effective way of addressing some of the difficulties living with diabetes involves, especially as parents/CYP expressed more of a need for psychological support compared to the traditional diabetes education and support groups. With parents and their children already burdened with hospital appointments, running educational interventions in clinic, in a group setting, might not be practical or realistic for CYP or their parents. With the advent of mindfulness (173) to reduce anxiety, and constantly evolving technology, an intervention which combines the two might be more appropriate; a mindfulness mobile application aimed specifically at CYP with T1DM and their parents. This type of mobile app would give users access to ‘mindful’ exercises and deliver ‘mindful’ and ‘positive’ quotes on a daily basis to participants’ mobile phones. These short exercises and ‘messages’ remind CYP and mothers to be attentive to the present and could provide an easily accessible way of
practicing the principles of mindfulness without investing a large amount of time. If effective, this could be an accessible, economical and convenient method to manage stress and anxiety.

9.7 Summary of Chapter 9
The qualitative analysis provided a richer set of data regarding living with diabetes for this cohort of CYP and mothers. Thematic analysis reflected findings from the quantitative data and allowed further understanding of the issues that impact CYP living with diabetes and their families. This research adds to the limited T1DM qualitative data for CYP and mothers and illustrates the experience of living with diabetes and the impact that it can have. The key areas linking qualitative with quantitative data were anxiety, fear of hypoglycaemia, quality of life and experience of hypoglycaemia.

CYP and their mothers expressed the worry, anxiety, fear and burden of T1DM. CYPs’ motivations to manage their diabetes changed with age and as they approached adolescence. As with the quantitative results, the impact on mothers seemed to be greater than the impact on CYP. Mothers took on much of the responsibility of diabetes care for their children in order to manage the burden and pressure for them. However, support for mothers was limited. Although fathers were reported to help with diabetes care, the main caregivers were mothers. Constant worry about hypoglycaemia (severe and nocturnal) and worries about future implications of diabetes on their child’s health had a genuine impact on mothers. There was also evidence of chronic sorrow in their reports of living with diabetes.

The implications of these results suggest that clinical staff should be aware of the psychological impact diabetes can have on their paediatric patients and parents. As CYP move towards adolescence, clinicians should be aware of possible changes in diabetes management. Clinical staff also need to mindful of how mothers are coping with the daily
demands of managing their child’s diabetes. Optimal management might not be an indicator that a parent is coping well. Therefore, targeted psychological support for mothers should be offered in order to help them to manage and cope in their role as caregivers.

Recommendations for future research relate to providing additional support to help CYP and mothers cope with living with diabetes. This could be either be via a structured programme of psychological support or a more convenient, accessible way of managing stress.
10. Conclusions
Research regarding the prevalence of hypoglycaemia and the fear of hypoglycaemia is relatively limited, especially for paediatric cohorts in the UK. This study aimed to address this by collecting quantitative data in relation to the prevalence of hypoglycaemia, severe hypoglycaemia, hypoglycaemia unawareness and fear of hypoglycaemia amongst children, young people and their parents attending paediatric diabetes clinics in the West Midlands, UK. The relationship between the aforementioned variables and psychosocial variables, such as anxiety, quality of life and self-care was also of interest to the researcher. This study also aimed to explore the impact that living with diabetes had on this cohort by conducting semi-structured interviews.

To conclude, this study reports some interesting and important findings. The prevalence of hypoglycaemia, severe hypoglycaemia and fear of hypoglycaemia are all evident in this UK paediatric cohort and their parents. Parental FoH was reported to be higher than the FoH CYP had for themselves. This does not appear to have been reported in FoH studies, previously. The qualitative data further supports higher reports of fear in parents, with mothers reporting a fear of nocturnal hypoglycaemia and admitting to monitoring their child’s blood glucose levels throughout the night. These findings introduce more questions about the impact that T1DM has on parents of CYP. Although this impact has been identified in past research, the current study recognises that parents may benefit from additional support to help them to cope with and support their children with managing their diabetes. The current study also adds to the growing literature on FoH in CYP and parents.

The links between FoH and anxiety illustrate the worry that many CYP and parents experience in relation to diabetes management. This link could potentially be explained by the fact that the HFS Worry subscale is simply another measure of anxiety, with a diabetes slant. Nevertheless, it seems that those individuals with a tendency to worry also exhibit higher FoH. Therefore, reducing or managing anxiety may go some way to manage
FoH in CYP and parents. Although anxiety and FoH were not shown to be linked to higher HbA1c this does not necessarily indicate that CYP and parents are coping with managing T1DM. Those who appear to be managing their diabetes optimally could also be the group of patients/carers that are struggling with anxiety and FoH (as a result of the pressure of managing optimum BG levels). When considering interventions to manage anxiety it is important not to restrict these to those with poor diabetes control.

Higher FoH was associated with lower CYP/perceived CYP QoL, which again demonstrates the impact of T1DM on the psychosocial aspects of CYP and parents’ lives. The qualitative reports also highlight the struggle of living with T1DM for both CYP and mothers. The often negative impact of T1DM was reported by CYP and their mothers, which could be a reflection of their perception of their/their child’s QoL. Again, this has previously received some attention in past research and the current study adds to this.

Multivariate analyses suggest that higher trait anxiety adds to the predictability of FoH in all groups. One of the key findings emerging from this study highlights anxiety as a predictor of FoH in CYP and parents. Although clinically it is important to try to improve T1DM treatment to avoid hypoglycaemia, this study highlights the impact of T1DM on the psychological well-being of CYP and parents. Future research should explore this impact further to help identify methods to help manage symptoms of anxiety and FoH. Increased understanding of predictability of FoH could allow clinicians/CYP/parents to manage these predictors and consequently manage levels of FoH.

Overall, the findings of the current study highlight the issues that both CYP and parents face when living with diabetes. In addition to original findings regarding parental FoH, the current study also supports previous studies in this area. The gaps in addressing these issues, however, remain. Therefore, the outcomes of this study have important implications for clinical practice. Although clinicians will undoubtedly be aware of the
impact of diabetes on CYP and their parents, they should appreciate how this impact can affect these families’ lives. Further thought should be given to offering/providing psychosocial support to all CYP and parents who have to manage diabetes care on a daily basis; even if the family seem to be coping. Further research should investigate the predictors of FoH by conducting a more rigorous, longitudinal study. This could be achieved by having a more robust method of collecting hypoglycaemia incidence data. As we know, retrospective reports of hypoglycaemia are often inaccurate, however, in the absence of real time reports, are the next best way of obtaining such information. With mobile applications evermore popular and more advanced blood monitoring technology it would be much easier to collect actual data on blood glucose levels over a specified period. This would allow more accurate reporting on the frequency of hypoglycaemia and episodes of severe hypoglycaemia in CYP. FoH and anxiety data could be collected at intervals to see whether any changes were linked to fluctuations in daily BG levels, for example in the previous 4 week period, rather than relying on HbA1c data, which is a more crude measure of blood glucose.

Future research should also be carried out to test interventions that might reduce the stress and anxiety experienced by mothers (parents) of children with T1DM, and potentially help to manage FoH too. As previously mentioned in both the quantitative and qualitative discussion chapters, MBSR has been found to be an effective method of reducing anxiety in both patients of long-term illnesses and their carers (174, 178). MBSR might also be useful in reducing FoH, which itself incorporates a scale of worry (anxiety) about hypoglycaemia, especially in parents of children with T1DM, who seem to experience higher FoH than their children do. A pilot study could be developed to test the impact that MBSR has when delivered to parents face to face or via mobile technology (mobile based applications) compared to no intervention. The change in anxiety and FoH could be measured by comparing scores on the STAI state subscale (148, 149) and the HFS (72, 74, 147) at baseline and then 6 weeks later (after 6 sessions of MBSR have been delivered). The pilot study could also include a debrief qualitative session to understand
how parents felt about using MBSR and whether they felt any differently after the 6 session course.

CYP with T1DM and the parents who care for them face many anxieties, responsibilities and pressures to manage the condition on a daily basis. The results of this study have highlighted that hypoglycaemia and the fear of hypoglycaemia are a problem for paediatric diabetes patients and their parents, in the UK. These groups should be supported not only in their pursuit of optimal glycaemic control, but also to improve their psychosocial outcomes so that the stress and anxiety that they report do not become problems in themselves. By targeting FoH and anxiety (potentially by further education or reduction in the experience of hypoglycaemia) might help to improve QoL for CYP and reduce the burden experienced by mothers (parents). This study contributes the wider body of research on FoH worldwide but also provides specific recommendations for the UK population for which there is limited research.
References

64. Tattersall RBaG, G.V., Unexplained Deaths of Type 1 Diabetic Patients Diabetic Medicine. 1991;8:49-58.


174. Rosenzweig SR, DK; Greeson, JM; Edman, JS; Jasser, SA; McMearty, KD; Goldstein, BJ Mindfulness-based stress reduction is associated with improved glycemic control in type 2 diabetes mellitus: A pilot study. Alternative Therapies. 2007;13(5).

230
Appendices

*Appendix 1 – Frequency of hypoglycaemia survey*

<table>
<thead>
<tr>
<th>Patient details:</th>
<th>Sex</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name</td>
<td>Duration of diabetes</td>
</tr>
<tr>
<td>DoB</td>
<td>Occupation</td>
</tr>
<tr>
<td>Hospital number</td>
<td></td>
</tr>
</tbody>
</table>

To be completed by patient:

This question is about frequency of hypoglycaemia. This is not restricted to severe episodes, but includes any occasion when you feel that your blood sugar is low (or you get a low measurement) and take action to correct it, e.g. having a snack or an early meal.

1. How often do you experience hypoglycaemia? Please tick as appropriate:

   - Never
   - Less than once per year
   - 1 to 3 times per year
   - 4 to 12 times per year
   - More than once a month
   - More than once a week

The following questions are about sev*er*e hypoglycaemia. A severe episode is any occasion when you needed assistance to recover from a hypo. Assistance may be
medical (e.g. hospital admission, or treatment from an ambulance crew) or non-medical (e.g. being given sweets by a relative or member of the public)

2. How many episodes of severe hypoglycaemia have you had in your life?

   None ☐
   1 or 2 ☐
   3 to 5 ☐
   More than 5 ☐

3a. How many episodes of severe hypoglycaemia have you had in the last year?

   Estimate number _________

3b. How many episodes of severe hypoglycaemia did you have in the year before last?

   Estimate number _________
Appendix 2 – Hypoglycaemia awareness survey

Name………………………………

DOB……………………………

Address…………………………

Address…………………………

Address…………………………

Telephone number………………

Year of diagnosis of Diabetes (approximately)………………

Insulin types 1……………………… 2…………………………

Timing of insulin injections (please tick and fill in how many units of insulin you use):

☐ Before breakfast Units of insulin……………………

☐ Before lunch Units of insulin……………………

☐ Before evening meal Units of insulin………………

☐ Bedtime Units of insulin………………

Other medications (i.e. tablets etc)……………………
1) Tick the category that best describes you (tick one only)

I always have symptoms when my blood sugar is low       
I sometimes have symptoms when my blood sugar is low        
I no longer have symptoms when my blood sugar is low

2) Have you lost some of the symptoms that used to occur when your blood sugar was low?

Yes                  
No

3) In the past six months how often have you had moderate hypoglycaemia episodes? (episodes where you might feel confused, disorientated, or lethargic and were unable to treat yourself)

Never
Once or twice
Every other month
Once a month
More than once a month

4) How often in the past year how often have you had severe hypoglycaemic episodes? (episodes where you were unconscious or had a seizure and needed glucagons or intravenous glucose)

Never
1 time
4 times
6 times
9 times
10 times
5) How often in the last month have you had readings less than 3.9mmol/L with symptoms?

- Never  □
- 2 to 3 times/week  □
- 1 time/week  □
- Almost daily  □

6) How often in the last month have you had readings less than 3.9mmol/L without any symptoms?

- Never  □
- 2 to 3 times/week  □
- 1 time/week  □
- Almost daily  □

7) How low does your blood sugar need to go before you feel symptoms?

- 3.3-3.8 mmol/L  □
- 2.2-2.7 mmol/L  □
- 2.8-3.3 mmol/L  □
- <2.2 mmol/L  □

8) To what extent can you tell by your symptoms that your blood sugar is low?

- Never  □
- Often  □
- Rarely  □
- Always  □
- Sometime  □
9) Please score the extent to which you experience the following symptoms during a typical daytime hypoglycaemic episode (circle a number for each symptom)

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Not present</th>
<th>Present a great deal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Confusion</td>
<td>1 2 3 4 5 6 7</td>
<td></td>
</tr>
<tr>
<td>Sweating</td>
<td>1 2 3 4 5 6 7</td>
<td></td>
</tr>
<tr>
<td>Drowsiness</td>
<td>1 2 3 4 5 6 7</td>
<td></td>
</tr>
<tr>
<td>Weakness</td>
<td>1 2 3 4 5 6 7</td>
<td></td>
</tr>
<tr>
<td>Dizziness</td>
<td>1 2 3 4 5 6 7</td>
<td></td>
</tr>
<tr>
<td>Warmth</td>
<td>1 2 3 4 5 6 7</td>
<td></td>
</tr>
<tr>
<td>Difficulty Speaking</td>
<td>1 2 3 4 5 6 7</td>
<td></td>
</tr>
<tr>
<td>Pounding heart</td>
<td>1 2 3 4 5 6 7</td>
<td></td>
</tr>
<tr>
<td>Inability to concentrate</td>
<td>1 2 3 4 5 6 7</td>
<td></td>
</tr>
<tr>
<td>Blurred vision</td>
<td>1 2 3 4 5 6 7</td>
<td></td>
</tr>
<tr>
<td>Hunger</td>
<td>1 2 3 4 5 6 7</td>
<td></td>
</tr>
<tr>
<td>Nausea</td>
<td>1 2 3 4 5 6 7</td>
<td></td>
</tr>
<tr>
<td>Anxiety</td>
<td>1 2 3 4 5 6 7</td>
<td></td>
</tr>
<tr>
<td>Tiredness</td>
<td>1 2 3 4 5 6 7</td>
<td></td>
</tr>
<tr>
<td>Tingling lips</td>
<td>1 2 3 4 5 6 7</td>
<td></td>
</tr>
<tr>
<td>Trembling</td>
<td>1 2 3 4 5 6 7</td>
<td></td>
</tr>
<tr>
<td>Headache</td>
<td>1 2 3 4 5 6 7</td>
<td></td>
</tr>
</tbody>
</table>
10. Do you know when your hypos are commencing? Please circle a number:

<table>
<thead>
<tr>
<th></th>
<th>Always aware</th>
<th>Never aware</th>
</tr>
</thead>
<tbody>
<tr>
<td>Awareness</td>
<td>1  2  3  4</td>
<td>5  6  7</td>
</tr>
</tbody>
</table>
Appendix 3 – Self-care inventory (revised)

ID#________                        Date:
Month___Day___Year_____

Self-Care Inventory

Part 2 – Children’s Form

This survey measures what you actually do, not what you are advised to do. How have you followed your diabetes treatment plan in the past 1-2 months?

<table>
<thead>
<tr>
<th>1. Check blood glucose with a monitor</th>
<th>Never</th>
<th>Rarely</th>
<th>Sometimes</th>
<th>Usually</th>
<th>Always</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. Record blood glucose results</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Check ketones when glucose level is high</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Take the correct dose of insulin</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Take insulin at the right time</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. Eat the correct food portions</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. Eat meals/snacks on time</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8. Keep food records</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9. Read food labels</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Never  Rarely  Sometimes  Usually  Always
<table>
<thead>
<tr>
<th>10. Treat low blood glucose with just the recommended amount of carbohydrate</th>
<th>1  2  3  4  5</th>
<th>Never had low blood glucose</th>
</tr>
</thead>
<tbody>
<tr>
<td>11. Carry quick acting sugar to treat low blood glucose</td>
<td>1  2  3  4  5</td>
<td></td>
</tr>
<tr>
<td>12. Come in for clinic appointments</td>
<td>1  2  3  4  5</td>
<td></td>
</tr>
<tr>
<td>13. Wear a Medic Alert ID</td>
<td>1  2  3  4  5</td>
<td></td>
</tr>
<tr>
<td>14. Exercise</td>
<td>1  2  3  4  5</td>
<td></td>
</tr>
<tr>
<td>15. Adjust insulin dosage based on glucose values, food, and exercise</td>
<td>1  2  3  4  5</td>
<td></td>
</tr>
</tbody>
</table>
Appendix 4 – Pediatric quality of life inventory (CYP) - example

ID#
Date:

PedSQL™
Diabetes Module
Version 3.0

TEENAGERS REPORT (ages 13-18)

DIRECTIONS
Teenagers with diabetes sometimes have special problems. Please tell us how much of a problem each one has been for you during the past ONE month by circling:

0 if it is never a problem
1 if it is almost never a problem
2 if it is sometimes a problem
3 if it is often a problem
4 if it is almost always a problem

There are no right or wrong answers.
If you do not understand a question, please ask for help.
In the past ONE month, how much of a problem has this been for you?

<table>
<thead>
<tr>
<th>ABOUT MY DIABETES (problems with...)</th>
<th>Never</th>
<th>Almost Never</th>
<th>Sometimes</th>
<th>Often</th>
<th>Almost Always</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. I feel hungry</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>2. I feel thirsty</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>3. I have to go to the toilet too often</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>4. I have stomachaches</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>5. I have headaches</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>6. I go &quot;low&quot; or &quot;hypo&quot;</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>7. I feel tired</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>8. I get shaky</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>9. I get sweaty</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>10. I have trouble sleeping at night</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>11. I get grumpy or annoyed</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>TREATMENT - I (problems with...)</th>
<th>Never</th>
<th>Almost Never</th>
<th>Sometimes</th>
<th>Often</th>
<th>Almost Always</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. It hurts to prick my finger or give myself insulin injections</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>2. I am embarrassed about having diabetes</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>3. My parents and I argue about my diabetes care</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>4. It is hard for me to stick to my diabetes routine</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

Whether you do these things on your own or with the help of your parents, please answer how hard these things were to do in the past ONE month.

<table>
<thead>
<tr>
<th>TREATMENT II (problems with...)</th>
<th>Never</th>
<th>Almost Never</th>
<th>Sometimes</th>
<th>Often</th>
<th>Almost Always</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. It is hard for me to do blood glucose tests</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>2. It is hard for me to give myself insulin injections</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>3. It is hard for me to exercise</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>4. It is hard for me to follow a healthy diet</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>5. It is hard for me to wear my id bracelet/necklace or carry a card</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>6. It is hard for me to carry a fast-acting carbohydrate</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>7. It is hard for me to eat snacks between meals when I should</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>WORRY (problems with...)</th>
<th>Never</th>
<th>Almost Never</th>
<th>Sometimes</th>
<th>Often</th>
<th>Almost Always</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. I worry about &quot;going low&quot; or &quot;hypo&quot;</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>2. I worry about whether or not my medical treatments are working</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>3. I worry about long-term problems from diabetes</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

In the past ONE month, how much of a problem has this been for you?

<table>
<thead>
<tr>
<th>COMMUNICATION (problems with...)</th>
<th>Never</th>
<th>Almost Never</th>
<th>Sometimes</th>
<th>Often</th>
<th>Almost Always</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. It is hard for me to tell the doctors and nurses how I feel</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>2. It is hard for me to ask the doctors and nurses questions</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>3. It is hard for me to explain my illness to other people</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>
Appendix 5 - Pediatric quality of life inventory (Parent) - example

ID#  
Date:  

**PedsQL™**  
Diabetes Module (UK)  
Version 3.0  

**PARENT REPORT for TEENAGERS** (ages 13-18)  

**DIRECTIONS**  
Teenagers with diabetes sometimes have special problems. On the following page is a list of things that might be a problem for your teenager. Please tell us how much of a problem each one has been for your teenager during the past ONE month by circling:  

0 if it is never a problem  
1 if it is almost never a problem  
2 if it is sometimes a problem  
3 if it is often a problem  
4 if it is almost always a problem  

There are no right or wrong answers.  
If you do not understand a question, please ask for help.
In the past ONE month, how much of a problem has your teenager had with

**DIABETES (problems with...)**

<table>
<thead>
<tr>
<th>Feeling hungry</th>
<th>Never</th>
<th>Almost</th>
<th>Never</th>
<th>Some-</th>
<th>Often</th>
<th>Almost</th>
<th>Always</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Feeling thirsty</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Having to go to the toilet too often</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Having stomachaches</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Having headaches</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Going “low” or “hypo”</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Feeling tired</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Getting shaky</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Getting sweaty</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Having trouble sleeping at night</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Getting grumpy or annoyed</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**TREATMENT - I (problems with...)**

<table>
<thead>
<tr>
<th>Injections/blood tests causing him/her pain</th>
<th>Never</th>
<th>Almost</th>
<th>Never</th>
<th>Some-</th>
<th>Often</th>
<th>Almost</th>
<th>Always</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Getting embarrassed about having diabetes</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Arguing with me or my partner about diabetes care</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sticking to his/her diabetes routine</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Whether your teenager does these things independently or with your help, please answer how difficult these things were to do in the past ONE month. (Note: This section is not asking about your teenager’s independence in these areas, just how hard they were to do.)

**TREATMENT - II (problems with...)**

<table>
<thead>
<tr>
<th>It is hard for my teenager to do blood glucose tests</th>
<th>Never</th>
<th>Almost</th>
<th>Never</th>
<th>Some-</th>
<th>Often</th>
<th>Almost</th>
<th>Always</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>It is hard for my teenager to give him/her insulin shots</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>It is hard for my teenager to exercise</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>It is hard for my teenager to follow a healthy diet</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>It is hard for my teenager to wear his/her id bracelet/necklace or carry a card</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>It is hard for my teenager to carry a fast-acting carbohydrate</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>It is hard for my teenager to eat snacks between meals when they should</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**WORRY (problems with...)**

<table>
<thead>
<tr>
<th>Worrying about “going low” or “hypo”</th>
<th>Never</th>
<th>Almost</th>
<th>Never</th>
<th>Some-</th>
<th>Often</th>
<th>Almost</th>
<th>Always</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Worrying about whether or not medical treatments are working</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Worrying about long-term problems of diabetes</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

In the past ONE month, how much of a problem has your teen had with

**COMMUNICATION (problems with...)**

<table>
<thead>
<tr>
<th>Telling the doctors and nurses how he/she feels</th>
<th>Never</th>
<th>Almost</th>
<th>Never</th>
<th>Some-</th>
<th>Often</th>
<th>Almost</th>
<th>Always</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Asking the doctors or nurses questions</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Explaining his/her illness to other people</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Appendix 6 - Hypoglycemia Fear Survey (CYP)

Today’s Date: __________

Subject # ONLY (please do not put your name) __________

University of Virginia
Children’s Low Blood Sugar Survey

We want to find out more about what low blood sugar makes children feel and do. Please answer the questions below as honestly as you can.

I. Behavior: Below is a list of things children with diabetes sometimes DO TO KEEP FROM HAVING LOW BLOOD SUGAR. Circle the number that best describes YOU. 0=NEVER 1=RARELY 2=SOMETIMES 3=OFTEN 4= ALMOST ALWAYS

1. Eat large snacks at bedtime
2. Try not to be by myself when my sugar is likely to be low
3. Keep blood sugars a little high to be on the safe side
4. Keep blood sugar higher when I will be alone for a while
5. Eat something as soon as I feel the first sign of low blood sugar
6. Take less insulin when I think my blood sugar might get too low
7. Keep my blood sugar higher when I am going to be away from my parents
8. Carry some kind of sugar, drink, or food with me
9. Try not to do a lot of exercise when I think my sugar is low
10. Check my blood sugar often when I go away from home

II. Worry: Below is a list of worries children with diabetes sometimes have about low blood sugar. Circle the number that best describes YOU. 0=NEVER 1=RARELY 2=SOMETIMES 3=OFTEN 4= ALMOST ALWAYS

11. Not recognizing that my blood sugar is low
12. Not having food, fruit, or juice with me when my blood sugar gets low
13. Feeling dizzy or passing out in public because of low blood sugar
14. Having a hypo while asleep
15. Embarrassing myself because of low blood sugar
16. Having a hypo while I am by myself
17. Looking “stupid” or clumsy in front of other people 0 1 2 3 4
18. Losing control because of low blood sugar 0 1 2 3 4
19. No one being around to help me during a hypo 0 1 2 3 4
20. Making a mistake or having an accident at school 0 1 2 3 4
21. Getting in trouble at school because of something that happened when my sugar is low 0 1 2 3 4
22. Having seizures 0 1 2 3 4
23. Getting long term complications from low blood sugar 0 1 2 3 4
24. Feeling dizzy or woozy when my blood sugar is low 0 1 2 3 4
25. Having a hypo 0 1 2 3 4

Low Blood Sugar Survey – Part II

26. How often in the last 12 months have you had trouble with hypoglycemic (low blood sugar) episodes?
   ____ Never  ____ 7-11 times
   ____ 1-2 times  ____ 12 or more times
   ____ 3-6 times

27. Is low blood sugar a big problem for you?
   ____ YES  ____ NO

28. Have you ever passed out with low blood sugar?
   ____ YES  ____ NO

29. Have you ever had a hypo while asleep?
   ____ YES  ____ NO

30. Have you ever had a hypo while you were awake but by yourself?
   ____ YES  ____ NO

31. Have you ever had a hypo in front of friends or strangers?
   ____ YES  ____ NO

32. Have you ever had a hypo when you were at school?
   ____ YES  ____ NO
Appendix 7 – Hypoglycemia Fear Survey (Parent)

This survey is intended to find out more about how low blood sugar makes people feel and behave. Please answer the following questions as frankly as possible.

I. Behavior: Below is a list of things people with diabetes sometimes DO IN ORDER TO AVOID LOW BLOOD SUGAR. Read each item carefully. Circle one of the numbers that best describes YOUR ACTIVITY.

0 = NEVER  1 = RARELY  2 = SOMETIMES  3 = OFTEN  4 = ALMOST ALWAYS

1. Have my child eat large snacks at bedtime. 0 1 2 3 4
2. Avoid having my child being alone when his/her sugar is likely to be low. 0 1 2 3 4
3. Allow my child’s blood sugar to be a little high to be on the safe side. 0 1 2 3 4
4. Keep my child’s sugar higher when he/she will be alone for a while. 0 1 2 3 4
5. Have my child eat something as soon as he/she feels the first sign of low blood sugar. 0 1 2 3 4
6. Reduce my child’s insulin when I think his/her sugar is too low. 0 1 2 3 4
7. Keep my child’s blood sugar higher when he/she plans to be away from me for awhile. 0 1 2 3 4
8. Have my child carry fast-sugar. 0 1 2 3 4
9. Have my child avoid a lot of exercise when I think his/her sugar is low. 0 1 2 3 4
10. Check my child’s sugar often when he/she plans to go on an outing. 0 1 2 3 4
II Worry: Below is a list of concerns parents of children with diabetes sometimes have. Read each item carefully. Circle one of the numbers that best describes HOW OFTEN YOU WORRY ABOUT EACH ITEM.

<table>
<thead>
<tr>
<th>Item</th>
<th>Description</th>
<th>0 = NEVER</th>
<th>1 = RARELY</th>
<th>2 = SOMETIMES</th>
<th>3 = OFTEN</th>
<th>4 = ALMOST ALWAYS</th>
</tr>
</thead>
<tbody>
<tr>
<td>11</td>
<td>Child not recognizing/realizing that he/she is having a hypo.</td>
<td></td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>12</td>
<td>Child not having food, fruit, or juice with him/her.</td>
<td></td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>13</td>
<td>Child feeling dizzy or passing out in public.</td>
<td></td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>14</td>
<td>Child having a hypo while asleep.</td>
<td></td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>15</td>
<td>Child embarrassing self or friends/family in a social situation.</td>
<td></td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>16</td>
<td>Child having a hypo while alone.</td>
<td></td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>17</td>
<td>Child appearing to be “stupid” or clumsy.</td>
<td></td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>18</td>
<td>Child losing control.</td>
<td></td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>19</td>
<td>No one being around to help child during a hypo.</td>
<td></td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>20</td>
<td>Child making a mistake or having an accident at school.</td>
<td></td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>21</td>
<td>Child getting a bad evaluation at school because of something that happens when his her sugar is low.</td>
<td></td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>22</td>
<td>Child having seizures or convulsions.</td>
<td></td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>23</td>
<td>Child developing long term complications from frequent low blood sugar.</td>
<td></td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>24</td>
<td>Child feeling light-headed or faint.</td>
<td></td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>25</td>
<td>Child having a hypo</td>
<td></td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>26</td>
<td>Rate how often you are confident in your ability to recognize your child’s low blood sugar.</td>
<td></td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>27</td>
<td>Rate how often you are confident in your ability to treat your child’s low blood sugar.</td>
<td></td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>
Low Blood Sugar Survey – Part II

28. How often in the last 12 months has your child had trouble with hypoglycemia (low blood sugar) episodes?
   _____ Never _____ 1-2 times _____ 3-6 times _____ 7-11 times _____ 12 or more times

29. Do you see low blood sugar as a serious problem for your child?
   _____ YES _____ NO

30. Has your child ever “passed out” with hypoglycemia?
   _____ YES _____ NO

31. Has your child ever had a hypoglycemic episode while asleep?
   _____ YES _____ NO

32. How many hypoglycemia episodes has your child had while ASLEEP in the past 12 months?
   _____ How distressing was the worst such experience?
   1 not at all 2 3 4 5 extremely distressing

33. Has your child ever had a hypoglycemic episode while awake, but ALONE?
   _____ YES _____ NO

34. How many hypoglycemic episodes has your child had while AWAKE in the past 12 months?
   _____ How distressing was the worst such experience?
   1 not at all 2 3 4 5 extremely distressing

35. Has your child ever had a hypoglycemic episode while in a SOCIAL SITUATION or in public?
   _____ YES _____ NO

36. How many hypoglycemic episodes has your child had while in a SOCIAL SITUATION (parties, with friends, etc.) in the past 12 months?
   _____ How distressing was the worst such experience?
   1 not at all 2 3 4 5 extremely distressing

37. Has your child ever had a hypoglycemic episode while at SCHOOL?
   _____ YES _____ NO

38. Has your child ever had a hypoglycemic episode and been unable to treat it because there was no food, fruit, or beverage around?
   _____ YES _____ NO

39. Has your child ever had a hypoglycemic episode that resulted in any kind of accident?
   _____ YES _____ NO

40. Does your child carry an emergency glucose with him at all time?
    If yes, what does he/she carry?

41. Do you have Glucagon available in the home?
## Appendix 8 – STAI

**SELF-EVALUATION QUESTIONNAIRE STAI Form Y-1**

Please provide the following information:

<table>
<thead>
<tr>
<th>Name</th>
<th>Date</th>
<th>S</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Age</th>
<th>Gender (Circle)</th>
<th>M</th>
<th>F</th>
<th>T</th>
</tr>
</thead>
</table>

**DIRECTIONS:**

A number of statements which people have used to describe themselves are given below. Read each statement and then circle the appropriate number to the right of the statement to indicate how you feel right now, that is, at this moment. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which seems to describe your present feelings best.

1. I feel calm .......................................................... 1 2 3 4
2. I feel secure .......................................................... 1 2 3 4
3. I am tense ............................................................. 1 2 3 4
4. I feel strained ....................................................... 1 2 3 4
5. I feel at ease ......................................................... 1 2 3 4
6. I feel upset .......................................................... 1 2 3 4
7. I am presently worrying over possible misfortunes ....... 1 2 3 4
8. I feel satisfied ....................................................... 1 2 3 4
9. I feel frightened ..................................................... 1 2 3 4
10. I feel comfortable .................................................. 1 2 3 4
11. I feel self-confident .............................................. 1 2 3 4
12. I feel nervous ...................................................... 1 2 3 4
13. I am jittery .......................................................... 1 2 3 4
14. I feel indecisive ................................................... 1 2 3 4
15. I am relaxed ........................................................ 1 2 3 4
16. I feel content ...................................................... 1 2 3 4
17. I am worried ........................................................ 1 2 3 4
18. I feel confused .................................................... 1 2 3 4
19. I feel steady ........................................................ 1 2 3 4
20. I feel pleasant ...................................................... 1 2 3 4

250
SELF-EVALUATION QUESTIONNAIRE
STAI Form Y-2

Name_______________________________________ Date_______

DIRECTIONS
A number of statements which people have used to describe themselves are given below. Read each statement and then circle the appropriate number to the right of the statement to indicate how you generally feel.

21. I feel pleasant............................................................................................................ 1 2 3 4
22. I feel nervous and restless........................................................................................... 1 2 3 4
23. I feel satisfied with myself........................................................................................... 1 2 3 4
24. I wish I could be as happy as others seem to be....................................................... 1 2 3 4
25. I feel like a failure......................................................................................................... 1 2 3 4
26. I feel rested .................................................................................................................. 1 2 3 4
27. I am “calm, cool, and collected”................................................................................ 1 2 3 4
28. I feel that difficulties are piling up so that I cannot overcome them...................... 1 2 3 4
29. I worry too much over something that really doesn’t matter..................................... 1 2 3 4
30. I am happy .................................................................................................................. 1 2 3 4
31. I have disturbing thoughts .......................................................................................... 1 2 3 4
32. I lack self-confidence ................................................................................................. 1 2 3 4
33. I feel secure ................................................................................................................ 1 2 3 4
34. I make decisions easily............................................................................................... 1 2 3 4
35. I feel inadequate ......................................................................................................... 1 2 3 4
36. I am content ................................................................................................................ 1 2 3 4
37. Some unimportant thought runs through my mind and bothers me...................... 1 2 3 4
38. I take disappointments so keenly that I can’t put them out of my mind................ 1 2 3 4
39. I am a steady person................................................................................................... 1 2 3 4
40. I get in a state of tension or turmoil as I think over my recent concerns and interests... 1 2 3 4
Appendix 9 – STAICH

HOW-I-FEEL QUESTIONNAIRE
Developed by C.D. Spielberger, C.D. Edwards, J. Montuori, and R. Lushene
STAIC Form C-1

Name: __________________________________________________________________________ Age: _________ Date: __________

DIRECTIONS: A number of statements which boys and girls use to describe themselves are given below. Read each statement carefully and decide how you feel right now. Then put an X in the box in front of the word or phrase which best describes how you feel. There are no right or wrong answers. Don’t spend too much time on any one statement. Remember, find the word or phrase which best describes how you feel right now, at this very moment.

1. I feel........................................... □ very calm □ calm □ not calm
2. I feel........................................... □ very upset □ upset □ not upset
3. I feel........................................... □ very pleasant □ pleasant □ not pleasant
4. I feel........................................... □ very nervous □ nervous □ not nervous
5. I feel........................................... □ very jittery □ jittery □ not jittery
6. I feel........................................... □ very rested □ rested □ not rested
7. I feel........................................... □ very scared □ scared □ not scared
8. I feel........................................... □ very relaxed □ relaxed □ not relaxed
9. I feel........................................... □ very worried □ worried □ not worried
10. I feel......................................... □ very satisfied □ satisfied □ not satisfied
11. I feel......................................... □ very frightened □ frightened □ not frightened
12. I feel......................................... □ very happy □ happy □ not happy
13. I feel......................................... □ very sure □ sure □ not sure
14. I feel......................................... □ very good □ good □ not good
15. I feel......................................... □ very troubled □ troubled □ not troubled
16. I feel......................................... □ very bothered □ bothered □ not bothered
17. I feel......................................... □ very nice □ nice □ not nice
18. I feel......................................... □ very terrified □ terrified □ not terrified
19. I feel......................................... □ very mixed-up □ mixed-up □ not mixed-up
20. I feel......................................... □ very cheerful □ cheerful □ not cheerful
HOW-I-FEEL QUESTIONNAIRE

Name: ___________________________________ Age: _________ Date: __________

DIRECTIONS: A number of statements which boys and girls use to describe themselves are given below. Read each statement carefully and decide if it is hardly-ever, or sometimes, or often true for you. Then for each statement, put an X in the box in front of the word that seems to describe you best. There are no right or wrong answers. Don’t spend too much time on any one statement. Remember, choose the word which seems to describe how you usually feel.

1. I worry about making mistakes ........................................... □ hardly-ever □ sometimes □ often
2. I feel like crying ............................................................... □ hardly-ever □ sometimes □ often
3. I feel unhappy ................................................................. □ hardly-ever □ sometimes □ often
4. I have trouble making up my mind ..................................... □ hardly-ever □ sometimes □ often
5. It is difficult for me to face my problems ............................ □ hardly-ever □ sometimes □ often
6. I worry too much ............................................................. □ hardly-ever □ sometimes □ often
7. I get upset at home ......................................................... □ hardly-ever □ sometimes □ often
8. I am shy ........................................................................ □ hardly-ever □ sometimes □ often
9. I feel troubled ................................................................. □ hardly-ever □ sometimes □ often
10. Unimportant thoughts run through my mind and bother me ....................................................................... □ hardly-ever □ sometimes □ often
11. I worry about school .......................................................... □ hardly-ever □ sometimes □ often
12. I have trouble deciding what to do .................................. □ hardly-ever □ sometimes □ often
13. I notice my heart beats fast ............................................... □ hardly-ever □ sometimes □ often
14. I am secretly afraid .......................................................... □ hardly-ever □ sometimes □ often
15. I worry about my parents ................................................... □ hardly-ever □ sometimes □ often
16. My hands get sweaty ....................................................... □ hardly-ever □ sometimes □ often
17. I worry about things that may happen .............................. □ hardly-ever □ sometimes □ often
18. It is hard for me to fall asleep at night ............................... □ hardly-ever □ sometimes □ often
19. I get a funny feeling in my stomach ................................ □ hardly-ever □ sometimes □ often
20. I worry about what others think of me ............................... □ hardly-ever □ sometimes □ often
Appendix 10 – Ethics approval

30 November 2007

Dr Krystyna Matyka
Senior Lecturer in Paediatrics
University of Warwick Medical School
Clinical Sciences Research Institute, Clinical Sciences Building,
University Hospital Warstock Road
Clifford Bridge Road,
Coventry
CV2 2DX

Dear Dr Matyka

Full title of study: Fear of hypoglycaemia in childhood diabetes
REC reference number: 07/H0604/108

Thank you for your letter of 26 November 2007, responding to the Committee’s request for further information on the above research.

The further information has been considered on behalf of the Committee by the Chair.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised.

Ethical review of research sites

The Committee has designated this study as exempt from site-specific assessment (SSA). There is no requirement for [other] Local Research Ethics Committees to be informed or for site-specific assessment to be carried out at each site.

Conditions of approval

The favourable opinion is given provided that you comply with the conditions set out in the attached document. You are advised to study the conditions carefully.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

<table>
<thead>
<tr>
<th>Document</th>
<th>Version</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application</td>
<td></td>
<td>31 August 2007</td>
</tr>
<tr>
<td>Investigator CV</td>
<td>Dr K Matyka</td>
<td></td>
</tr>
<tr>
<td>Protocol</td>
<td>24 August 2007</td>
<td></td>
</tr>
<tr>
<td>----------------------------------------------</td>
<td>----------------</td>
<td></td>
</tr>
<tr>
<td>Covering Letter</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Peer Review</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Interview Schedules/Topic Guides</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Questionnaire: self care inventory</td>
<td>13-18yrs</td>
<td></td>
</tr>
<tr>
<td>Questionnaire: hypoglycaemia</td>
<td>13-18yrs</td>
<td></td>
</tr>
<tr>
<td>Questionnaire: symptoms</td>
<td>13-18yrs</td>
<td></td>
</tr>
<tr>
<td>Questionnaire: Children's low blood sugar survey</td>
<td>13-18 yrs</td>
<td></td>
</tr>
<tr>
<td>Questionnaire: PedsQL (13-18yrs)</td>
<td>3.0</td>
<td></td>
</tr>
<tr>
<td>Questionnaire: How I feel C-1</td>
<td>13-18yrs</td>
<td></td>
</tr>
<tr>
<td>Questionnaire: how I feel C-2</td>
<td>13-18yrs</td>
<td></td>
</tr>
<tr>
<td>Questionnaire: Self care inventory children</td>
<td>11-13yrs</td>
<td></td>
</tr>
<tr>
<td>Questionnaire: hypoglycaemia</td>
<td>11-13yrs</td>
<td></td>
</tr>
<tr>
<td>Questionnaire: symptoms</td>
<td>11-13yrs</td>
<td></td>
</tr>
<tr>
<td>Questionnaire: Children's low blood sugar survey</td>
<td>11-13yrs</td>
<td></td>
</tr>
<tr>
<td>Questionnaire: PedsQL</td>
<td>11-13yrs v3.0</td>
<td></td>
</tr>
<tr>
<td>Questionnaire: symptoms</td>
<td>8-11yrs</td>
<td></td>
</tr>
<tr>
<td>Questionnaire: Children's low blood sugar survey</td>
<td>8-11yrs</td>
<td></td>
</tr>
<tr>
<td>Questionnaire: PedsQL v3.0</td>
<td>8-11yrs v3.0</td>
<td></td>
</tr>
<tr>
<td>Questionnaire: How I feel C-1</td>
<td>11-13yrs</td>
<td></td>
</tr>
<tr>
<td>Questionnaire: How I feel C-2</td>
<td>11-13yrs</td>
<td></td>
</tr>
<tr>
<td>Questionnaire: children's low blood sugar survey</td>
<td>5-7yrs</td>
<td></td>
</tr>
<tr>
<td>Questionnaire: PedsQL v3.0</td>
<td>5-7yrs v3.0</td>
<td></td>
</tr>
<tr>
<td>Questionnaire: Self care inventory children</td>
<td>8-11yrs</td>
<td></td>
</tr>
<tr>
<td>Questionnaire: PedsQL</td>
<td>8-11yrs</td>
<td></td>
</tr>
<tr>
<td>Questionnaire: How I feel C-1</td>
<td>8-11yrs</td>
<td></td>
</tr>
<tr>
<td>Questionnaire: How I feel C-2</td>
<td>8-11yrs</td>
<td></td>
</tr>
<tr>
<td>Questionnaire: parents low blood sugar survey</td>
<td>parents 13-18yrs</td>
<td></td>
</tr>
<tr>
<td>Questionnaire: PedsQL</td>
<td>parents 13-18yrs</td>
<td></td>
</tr>
<tr>
<td>Questionnaire: Self care inventory children</td>
<td>5-7yrs</td>
<td></td>
</tr>
<tr>
<td>Questionnaire: Parent questionnaire</td>
<td>parents 8-12yrs</td>
<td></td>
</tr>
<tr>
<td>Questionnaire: Parents low blood sugar survey</td>
<td>Parents 8-12yrs</td>
<td></td>
</tr>
<tr>
<td>Questionnaire: PedsQL v3.0</td>
<td>Parents 8-12yrs</td>
<td></td>
</tr>
<tr>
<td>Questionnaire: Pittsburgh Sleep Quality Index</td>
<td>Parents 13-18yrs</td>
<td></td>
</tr>
<tr>
<td>Questionnaire: Self care inventory parents</td>
<td>Parents 13-18yrs</td>
<td></td>
</tr>
<tr>
<td>Questionnaire: Parents of low blood sugar survey</td>
<td>parents 5-7yrs</td>
<td></td>
</tr>
<tr>
<td>Questionnaire: PedsQL</td>
<td>parents 5-7yrs</td>
<td></td>
</tr>
<tr>
<td>Questionnaire: Pittsburgh sleep quality index</td>
<td>parents 8-12yrs</td>
<td></td>
</tr>
<tr>
<td>Questionnaire: Self care inventory parents</td>
<td>parents 8-12yrs</td>
<td></td>
</tr>
<tr>
<td>Questionnaire: Self analysis questionnaire</td>
<td>Parents 8-12yrs</td>
<td></td>
</tr>
<tr>
<td>Questionnaire: PedaQL</td>
<td>parents 2-4yrs</td>
<td></td>
</tr>
<tr>
<td>Questionnaire: Pittsburgh Sleep quality index</td>
<td>parents 5-7yrs</td>
<td></td>
</tr>
<tr>
<td>Questionnaire: self-care inventory parents</td>
<td>parents 5-7yrs</td>
<td></td>
</tr>
<tr>
<td>Questionnaire: self-analysis questionnaire</td>
<td>parents 5-7yrs</td>
<td></td>
</tr>
<tr>
<td>Questionnaire: Parent questionnaire</td>
<td>Parents 5-7yrs</td>
<td></td>
</tr>
<tr>
<td>Questionnaire: Pittsburgh sleep quality index</td>
<td>parents 2-4yrs</td>
<td></td>
</tr>
<tr>
<td>Questionnaire: self analysis questionnaire</td>
<td>parents 2-4yrs</td>
<td></td>
</tr>
<tr>
<td>Questionnaire: self-care inventory parents</td>
<td>parents 2-4yrs</td>
<td></td>
</tr>
<tr>
<td>Questionnaire: Parent questionnaire</td>
<td>parents 2-4yrs</td>
<td></td>
</tr>
<tr>
<td>Questionnaire: Parents low blood sugar survey</td>
<td>parents 2-4yrs</td>
<td></td>
</tr>
<tr>
<td>GP/Consultant Information Sheets</td>
<td>1 (questionnaire study)</td>
<td></td>
</tr>
<tr>
<td>Participant Information Sheet</td>
<td>11-18yrs, v2</td>
<td>10 July 2007</td>
</tr>
<tr>
<td>Participant Information Sheet</td>
<td>6-10yrs, v2</td>
<td>12 November 2007</td>
</tr>
<tr>
<td>Participant Information Sheet</td>
<td>Parent 11-16yrs, v2</td>
<td>12 November 2007</td>
</tr>
<tr>
<td>Participant Information Sheet</td>
<td>Parent 8-10yrs, v2</td>
<td>12 November 2007</td>
</tr>
<tr>
<td>Participant Information Sheet</td>
<td>Parent &lt; 8yrs, v2</td>
<td>12 November 2007</td>
</tr>
<tr>
<td>Participant Information Sheet: Parents (focus groups/interviews)</td>
<td>2</td>
<td>13 November 2007</td>
</tr>
<tr>
<td>Participant Information Sheet: &lt;6yrs (focus groups/interviews)</td>
<td>1</td>
<td>16 July 2007</td>
</tr>
<tr>
<td>Participant Information Sheet: 6-10yrs (focus groups/interviews)</td>
<td>2</td>
<td>13 November 2007</td>
</tr>
<tr>
<td>Participant Information Sheet: 11-15yrs (focus groups/interviews)</td>
<td>2</td>
<td>13 November 2007</td>
</tr>
<tr>
<td>Participant Information Sheet: Adults (focus groups/interviews)</td>
<td>2</td>
<td>13 November 2007</td>
</tr>
<tr>
<td>Participant Consent Form: Parent on behalf of child (questionnaire)</td>
<td>2</td>
<td>13 November 2007</td>
</tr>
<tr>
<td>Participant Consent Form: Parent taking part (questionnaire)</td>
<td>2</td>
<td>13 November 2007</td>
</tr>
<tr>
<td>Participant Consent Form: 16-18yrs (questionnaire)</td>
<td>2</td>
<td>13 November 2007</td>
</tr>
<tr>
<td>Participant Consent Form: Assent Form: &lt;16yrs (questionnaire)</td>
<td>2</td>
<td>13 November 2007</td>
</tr>
<tr>
<td>Participant Consent Form: parent on behalf of child (focus group)</td>
<td>2</td>
<td>12 November 2007</td>
</tr>
<tr>
<td>Participant Consent Form: Parent taking part (focus group)</td>
<td>2</td>
<td>13 November 2007</td>
</tr>
<tr>
<td>Participant Consent Form: 16-18yrs (focus group)</td>
<td>2</td>
<td>13 November 2007</td>
</tr>
<tr>
<td>Participant Consent Form: Assent Form &lt;16yrs (focus group)</td>
<td>2</td>
<td>13 November 2007</td>
</tr>
<tr>
<td>Participant Consent Form: Adult - Questionnaire study</td>
<td>1</td>
<td>16 July 2007</td>
</tr>
<tr>
<td>Participant Consent Form: Questionnaire study (children)</td>
<td>1</td>
<td>16 July 2007</td>
</tr>
<tr>
<td>Response to Request for Further Information</td>
<td>26 November 2007</td>
<td></td>
</tr>
<tr>
<td>Letter from Funder</td>
<td>18 May 2007</td>
<td></td>
</tr>
</tbody>
</table>
R&D approval

All researchers and research collaborators who will be participating in the research at NHS sites should apply for R&D approval from the relevant care organisation if they have not yet done so. R&D approval is required, whether or not the study is exempt from SSA. You should advise researchers and local collaborators accordingly.


Statement of compliance

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

After ethical review

Now that you have completed the application process please visit the National Research Ethics Website > After Review

Here you will find links to the following

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

b) Progress Reports. Please refer to the attached Standard conditions of approval by Research Ethics Committees.

c) Safety Reports. Please refer to the attached Standard conditions of approval by Research Ethics Committees.

d) Amendments. Please refer to the attached Standard conditions of approval by Research Ethics Committees.

e) End of Study/Project. Please refer to the attached Standard conditions of approval by Research Ethics Committees.

We would also like to inform you that we consult regularly with stakeholders to improve our service. If you would like to join our Reference Group please email referencegroup@nationalres.org.uk.

07/H0604/108 Please quote this number on all correspondence

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

Yours sincerely,

Dr Brian Shine
Chair

Enclosures: Standard approval conditions

This Research Ethics Committee is an advisory committee to South Central Strategic Health Authority
The National Research Ethics Service (NRES) represents the NRES Directorate within the National Patient Safety Agency and Research Ethics Committees in England.
Appendix 11 – Substantial amendment number 1

National Research Ethics Service

Oxfordshire REC A
2nd Floor, Astral House
Chaucer Business Park
Granville Way
Bicester
OX26 4JT

Tel: 01869 604077
Fax: 01869 604055

21 July 2008

Dr Krystyna Matyka
Senior Lecturer in Paediatrics
University of Warwick Medical School
Clinical Sciences Research Institute
Clinical Sciences Building
Walsgrave Hospital
Clifford Bridge Road
Coventry, CV2 2DX

Dear Dr Matyka

Study title: Fear of hypoglycaemia in childhood diabetes
REC reference: 07/H0604/108
Amendment number: No. 1
Amendment date: 03 June 2008

The above amendment was reviewed at the meeting of the Sub-Committee of the REC held on 18 July 2008.

Ethical opinion

The members of the Committee present gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

<table>
<thead>
<tr>
<th>Document</th>
<th>Version</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Questionnaire: Demographics form</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Questionnaire: Sleep diary</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Questionnaire: Epworth Sleepiness Scale</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Questionnaire: Functional Outcomes Sleep Questionnaire</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Participant Information Sheet: Parent - children 11-16</td>
<td>3</td>
<td>10 June 2008</td>
</tr>
<tr>
<td>Participant Information Sheet: Prent - children 8-10</td>
<td>3</td>
<td>10 June 2008</td>
</tr>
<tr>
<td>Participant Information Sheet: Parent - children less than 8</td>
<td>3</td>
<td>10 June 2008</td>
</tr>
<tr>
<td>Participant Consent Form: Parent on behalf of child</td>
<td>3</td>
<td>10 June 2008</td>
</tr>
<tr>
<td>Participant Consent Form: Parent</td>
<td>3</td>
<td>10 June 2008</td>
</tr>
<tr>
<td>Notice of Substantial Amendment (non-CTIMPs)</td>
<td>No. 1</td>
<td>03 June 2008</td>
</tr>
</tbody>
</table>

This Research Ethics Committee is an advisory committee to South Central Strategic Health Authority
The National Research Ethics Service (NRES) represents the NRES Directorate within the National Patient Safety Agency and Research Ethics Committees in England.
Membership of the Committee

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

R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

Statement of compliance

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

07/H0604/108: Please quote this number on all correspondence

Yours sincerely

Mr Gordon Riddell
Committee Co-ordinator

E-mail: scsha.OxfordRECA@nhs.net

Enclosures

List of names and professions of members who were present at the meeting and those who submitted written comments

Copy to:

Ms Kate Hughes, University of Warwick
Appendix 12 – Substantial amendment number 2

National Research Ethics Service
Oxfordshire REC A
2nd Floor, Astral House
Chaucer Business Park
Granville Way
Bicester
OX26 4JT
Tel: 01869 600077
Fax: 01869 604055

21 July 2008
Dr Krystyna Matyka
Senior Lecturer in Paediatrics
University of Warwick Medical School
Clinical Sciences Research Institute
Clinical Sciences Building
Walsgrave Hospital
Clifford Bridge Road
Coventry, CV2 2DX

Dear Dr Matyka

Study title: Fear of hypoglycaemia in childhood diabetes
REC reference: 07/H0604/168
Amendment number: No. 2
Amendment date: 10 June 2008

The above amendment was reviewed at the meeting of the Sub-Committee of the REC held on 18 July 2008.

Ethical opinion

The members of the Committee present gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

<table>
<thead>
<tr>
<th>Document</th>
<th>Version</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Notice of Substantial Amendment (non-CTIMPs)</td>
<td>No. 2</td>
<td>10 June 2008</td>
</tr>
<tr>
<td>Letter of invitation to participant</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Covering Letter</td>
<td></td>
<td>19 June 2008</td>
</tr>
</tbody>
</table>

Membership of the Committee

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

R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

This Research Ethics Committee is an advisory committee to South Central Strategic Health Authority.
The National Research Ethics Service (NRES) represents the NRES Directorate within the National Patient Safety Agency and Research Ethics Committees in England.
Statement of compliance

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

07/H0604/108: Please quote this number on all correspondence

Yours sincerely

[Signature]

Mr Gordon Riddell
Committee Co-ordinator

E-mail: scsha.OxfordRECA@nhs.net

Enclosures

List of names and professions of members who were present at the meeting and those who submitted written comments

Copy to:

Ms Kate Hughes, Warwick Medical School
Appendix 13 – Substantial amendment number 3

NHS
National Research Ethics Service
Oxfordshire REC A
2nd Floor, Astral House
Chaucer Business Park
Granville Way
Bicester
OX26 4JT
Tel: 01869 604077
Fax: 01869 604055

14 May 2009

Dr Krystyna Matyka
Senior Lecturer in Paediatrics
Clinical Sciences Research Institute
Clinical Sciences Building
University Hospital - Walsgrave Campus,
Clifford Bridge Road
Coventry
CV2 2DX

Dear Dr Matyka

Study title: Fear of hypoglycaemia in childhood diabetes
REC reference: 07/H0604/108
Amendment number: No. 3
Amendment date: 31 March 2009

The above amendment was reviewed at the meeting of the Sub-Committee of the REC held on 27 April 2009.

Ethical opinion

The members of the Committee present gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Please note: the favourable ethical opinion does not cover any use of this Questionnaire prior to the date of this letter. If you have used the Questionnaire in this study prior to gaining ethical approval you should report this separately to the Committee as a Protocol Violation and detail the violation and how you intend to rectify it, e.g. by destroying unethically collected data.

Approved documents

The documents reviewed and approved at the meeting were:

<table>
<thead>
<tr>
<th>Document</th>
<th>Version</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Questionnaire</td>
<td>State-Trait Anxiety Inventory (Adults)</td>
<td></td>
</tr>
<tr>
<td>Notice of Substantial Amendment (non-CTIMPs)</td>
<td>No. 3</td>
<td>31 March 2009</td>
</tr>
<tr>
<td>Covering Letter</td>
<td></td>
<td>08 April 2009</td>
</tr>
</tbody>
</table>

Membership of the Committee

This Research Ethics Committee is an advisory committee to South Central Strategic Health Authority. The National Research Ethics Service (NRES) represents the NRES Directorate within the National Patient Safety Agency and Research Ethics Committees in England.
The members of the Committee who were present at the meeting are listed on the attached sheet.

R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

Statement of compliance

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

07/H0604/108: Please quote this number on all correspondence

Yours sincerely

Mr Gordon Riddell
Committee Co-ordinator

E-mail: scsha.OxfordRECA@nhs.net

Enclosures List of names and professions of members who were present at the meeting and those who submitted written comments

Copy to: Ms Kate Hughes, University of Warwick
Appendix 14 – Substantial amendment number 4

National Research Ethics Service
Oxfordshire REC A
Room 302
TEDCO Business Centre
Rolling Mill Road
Jarrow
NE32 3DT
Tel: 0191 428 3561
Fax: 0191 428 3432

04 January 2011

Dr Krystyna Matyka
Senior Lecturer in Paediatrics
University of Warwick Medical School
Clinical Sciences Research Institute
Clinical Sciences Building
University Hospital – Walsgrave Campus
Clifford Bridge Road
Coventry
CV2 2DX

Dear Dr Matyka

Study title: Fear of hypoglycaemia in childhood diabetes
REC reference: 07/H0604/108
Amendment number: No. 4, 3rd December 2010
Amendment date: 03 December 2010

The above amendment was reviewed by the Sub-Committee in correspondence.

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

<table>
<thead>
<tr>
<th>Document</th>
<th>Version</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Letter of Invitation - Parents of adolescents aged 16-18</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Letter of Invitation - Adolescents 16-18 years old</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Letter of Invitation - Children aged 8-15 years and their parents</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Letter of Invitation - children under 8 years old and their parents</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Notice of Substantial Amendment (non-CTIMPs)</td>
<td>No. 4, 3rd December 2010</td>
<td>03 December 2010</td>
</tr>
<tr>
<td>Covering Letter</td>
<td>Priya Tah, Warwick Medical School</td>
<td>03 December 2010</td>
</tr>
</tbody>
</table>

This Research Ethics Committee is an advisory committee to South Central Strategic Health Authority
The National Research Ethics Service (NRES) represents the NRES Directorates within
the National Patient Safety Agency and Research Ethics Committees in England.
Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

Statement of compliance

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

07/H0604/108: Please quote this number on all correspondence

Yours sincerely

Ms Anne Taylor
Committee Co-ordinator

E-mail: anne.taylor7@nhs.net

Enclosures: List of names and professions of members who took part in the review

Copy to: Ms Kate Hughes
Research & Support Services
The University of Warwick
Coventry
CV4 7AL
Appendix 15 – Information sheet (CYP)

FEAR OF HYPOGLYCAEMIA STUDY
QUESTIONNAIRE STUDY – ADOLESCENT INFORMATION
(11-18 YEARS OF AGE)

This letter is an invitation to you to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you would like to. Please ask us if there is anything that is not clear or if you would like more information. Our contact details are at the end of this sheet. Take time to decide whether or not you would like to take part.

What is the purpose of the study?

We know that many young people with diabetes have problems getting good control of their diabetes. We know from other research and from talking to young people in clinic hypos can be quite worrying. We want to see how much of a problem fear of hypos really is in a big group of young people coming to the diabetes clinics in the Midlands and Leicestershire. We also want to see how common hypos are and how much they may affect people’s quality of life. The study involves a number of questionnaires. With this information we hope that we may be able to develop ways of helping people deal with hypos in a better way. There will be a second part to the study where we would like to talk to you in a bit more detail so if you think you might be interested in this please let us know. This study is part of an education project which will lead to a higher degree for the research associate.

Why have you been chosen to take part in this study?

We are asking all young people attending the diabetes clinic at this hospital to take part in the study. We would like as many families to take part as possible so that we can get as much information about peoples concerns as possible. We are also working with five other hospitals in the Midlands and hope to get information from up to 700 families.

Clinical Biostatistics Research Institute
Clinical Sciences Building
University Hospitals – Walsgrave Campus
Clifford Bridge Road
Coventry CV1 2DX, United Kingdom
Tel: +44 (0) 24 7696 8682
Fax: +44 (0) 24 7696 8653
www.warwick.ac.uk/clinbiost
Do I have to take part?

No. It is up to you to decide whether to take part. If you wanted to take part you would still be able to pull out at any time without having to give a reason. If you decide not to take part or want to pull out at any time this would not affect the standard of your medical care in any way.

What would happen if I agreed to take part?

*Questionnaires*

We would like you to fill in six questionnaires.

1) Frequency of Hypoglycaemia Survey. This is a questionnaire that looks at the number of hypos you may be having.
2) Quality of life assessment. This questionnaire looks at aspects of your quality of life. This questionnaire has been specially designed for young people with diabetes.
3) Fear of Hypoglycaemia Survey. This is a questionnaire that looks particularly at people’s fears about hypos and how they may influence their diabetes management.
4) State-Trait Anxiety Scale. This questionnaire looks at the kind of person you are in terms of how anxious you normally are.
5) Hypoglycaemia awareness survey. This questionnaire will look at the kind of symptoms you get when you are having a hypo and asks if you ever get hypos without warning.
6) Self care inventory. This asks questions on what kind of things you do to manage your diabetes on a day to day basis.

*Other information*

We would also like to collect some information on your diabetes from your hospital records. We would like to know how old you were when you were diagnosed, which insulin treatment you are on and also some information on your diabetes control. We would like to collect data of the HbA1c readings from the last 12 months.

What are the possible disadvantages and risks of taking part?

We know that some people find hypos very worrying and talking about hypos may make them more worried. If this should happen to you we would make sure that you would be able to talk to a member of the diabetes team to discuss any concerns.

What are the possible benefits of taking part?

This is a research study that will increase our knowledge about fear of hypoglycaemia and how it affects people’s lives and how they manage to look after their diabetes. It is unlikely to make a big difference to you if you decide to take part in the study but we hope that with the information from a big group of young people and parents we may be able to work out ways of helping people with the problem of hypos.
What if something goes wrong?

If you wish to complain or have any concerns about how you have been approached or treated during the study the University of Warwick Complaints Pathway is open to you. The contact details are:

Ms Cathy Charlton
University Secretary
University of Warwick University House
Kirby Corner Road
Coventry
CV4 8UW
Tel: (024) 765 22713

Will my taking part in this study be kept confidential?

All information which is collected will be completely confidential. All data will be kept on computers at the University of Warwick and the only people who will have access to this will be the people who run the study. All the data will have your name and address removed and all that will be on the computer is a study number which you will be given.

What will happen to the results of the research study?

When the study is completed the study team will look at the information from all the families who have taken part. The results will then be presented at scientific meetings and written up in medical journals.

We also plan to give presentations at each of the clinics that will take part in this study as well as writing a summary of the findings and sending it to all families who took part.

Who is organising and funding the research?

The research is being organised by Dr Krystyna Matyka at Warwick University, Dr Cathy Lloyd at the Open University, Dr Linda Gonder-Frederick at the University of Virginia, USA, Dr Michelle Miller at Warwick University and Professor Franco Cappuccio at Warwick University.

The research is being funded by Diabetes UK. The researchers do not receive payment for including you in the study.

Who has reviewed the study?

This study has been reviewed by the Oxford Research Ethics Committee A.

Contact for further information.
If you have any questions about the study please contact members of the research team:

Dr Krystyna Matyka  024 7696 8586
Division of Clinical Sciences
Clinical Sciences Research Institute
UHCW
Clifford Bridge Road
CV2 2DX

Priya Tah  024 7696 8595
Research Associate
Clinical Sciences Research Institute
UHCW
Clifford Bridge Road
CV2 2DX

Thank you for your time.
Appendix 16 – Information sheet (Parent)

10 June 2008/ Version 3

FEAR OF HYPOGLYCAEMIA STUDY
QUESTIONNAIRE STUDY – YOUNG PEOPLE AGED 11-16 YEARS
Parent information

This letter is an invitation to you and your child to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you would like to. Please ask us if there is anything that is not clear or if you would like more information. Our contact details are at the end of this sheet. Take time to decide whether or not you would like to take part.

What is the purpose of the study?

We know that many young people with diabetes have problems getting good control of their diabetes. We know from other research and from talking to families in clinic that people, both parents and children, are worried about hypoglycaemia, or ‘hypos’, if the blood sugar levels run quite low. We want to see how much of a problem fear of hypos really is in a big group of families coming to the children’s diabetes clinics in the Midlands and Leicestershire. We also want to see how common hypos are and how much they may affect people’s quality of life. The study involves a number of questionnaires both for you and your child. With this information we hope that we may be able to develop ways of helping people deal with hypos in a better way. There will be a second part to the study where we would like to talk to you in a bit more detail so if you think you might be interested in this please let us know. This study is part of an education project which will lead to a higher degree for the research associate.

Why have you been chosen to take part in this study?

We are asking all children attending the diabetes clinic at this hospital to take part in the study. We would like as many families to take part as possible so that we can get as much information about peoples concerns as possible. We are also working with five other hospitals in the Midlands and hope to get information from up to 700 families.
Do we have to take part?

No. It is up to you and your child to decide whether to take part. If you wanted to take part you would still be able to pull out at any time without having to give a reason. If you decide not to take part or want to pull out at any time this would not affect the standard of your child’s medical care in any way.

What would happen if we agreed to take part?

Questionnaires

We would like your child to fill in six questionnaires.

1) Frequency of Hypoglycaemia Survey. This is a questionnaire that looks at the number of hypos your child may be having.
2) Quality of Life assessment. This questionnaire looks at aspects of your child’s quality of life. This questionnaire has been specially designed for children with diabetes.
3) Fear of Hypoglycaemia Survey. This is a questionnaire that looks particularly at people’s fears about hypos and how they may influence their diabetes management.
4) State-Trait Anxiety Scale. This questionnaire looks at the kind of person your child is in terms of how anxious they normally are.
5) Hypoglycaemia awareness survey. This questionnaire will look at the kind of symptoms your child gets when they are having a hypo and see if they ever get hypos without warning.
6) Self care inventory. This asks questions on what kind of things your child does to manage their diabetes on a day to day basis.

We would like you to fill in the same questionnaires, apart from the one about symptoms of hypos, and we would also like you to fill in 3 extra questionnaires and a diary about the quality of your sleep and outcomes of this.

1) Frequency of Hypoglycaemia Survey. This is a questionnaire that looks at the number of hypos you feel your child may be having.
2) Quality of life assessment. This questionnaire looks at aspects of your quality of life. This questionnaire has been specially designed for families of children with diabetes.
3) Fear of Hypoglycaemia Survey. This is a questionnaire that looks particularly at people’s fears about hypos and how they may influence their diabetes management.
4) State-Trait Anxiety Scale. This questionnaire looks at the kind of person you are in terms of how anxious you normally are.
5) Self care inventory. This asks questions on what kind of things you do to manage your child’s diabetes on a day to day basis.
6) Sleep quality questionnaire. We would like to know how well you sleep given that your child has diabetes.
7) Epworth Sleepiness Scale. We would like to know if you experience sleepiness during the day.
8) Functional outcomes of sleep questionnaire. We would like to know how lack of sleep affects your day to day activities.
9) Sleep Diary. This will be used to record the number of hours you sleep over a period of one week.
*Other information*

We would also like to collect some information on your child’s diabetes from their hospital records. We would like to know how old your child was when they were diagnosed, which insulin treatment they are on and also some information on their diabetes control. We would like to collect data of the HbA1c readings from the last 12 months.

- **What are the possible disadvantages and risks of taking part?**

We know that some people find hypos very worrying and talking about hypos may make them more worried. If this should happen to either you or your child we would make sure that you would be able to talk to a member of the diabetes team to discuss any concerns.

- **What are the possible benefits of taking part?**

This is a research study that will increase our knowledge about fear of hypoglycaemia and how it affects people’s lives and how they manage to look after their diabetes. It is unlikely to make a big difference to you or your child if you decide to take part in the study but we hope that with the information from a big group of children and parents we may be able to work out ways of helping people with the problem of hypos.

- **What if something goes wrong?**

If you wish to complain or have any concerns about how you have been approached or treated during the study the University of Warwick Complaints Pathway is open to you. The contact details are:

Ms Cathy Charlton  
University Secretary  
University of Warwick University House  
Kirby Corner Road  
Coventry  
CV4 8UW  
Tel: (024) 765 22713

- **Will my taking part in this study be kept confidential?**

All information which is collected will be completely confidential. All data will be kept on computers at the University of Warwick and the only people who will have access to this will be the people who run the study. All the data will have the name and address of your child removed and all that will be on the computer is a study number which your child will be given.

- **What will happen to the results of the research study?**
When the study is completed the study team will look at the information from all the families who have taken part. The results will then be presented at scientific meetings and written up in medical journals.

We also plan to give presentations at each of the clinics that will take part in this study as well as writing a summary of the findings and sending it to all families who took part.

Who is organising and funding the research?

The research is being organised by Dr Krystyna Matyka at Warwick University, Dr Cathy Lloyd at the Open University, Dr Linda Gonder-Frederick at the University of Virginia, USA, Dr Michelle Miller at Warwick University and Professor Franco Cappuccio at Warwick University.

The research is being funded by Diabetes UK. The researchers do not receive payment for including you in the study.

Who has reviewed the study?

This study has been reviewed by the Oxford Research Ethics Committee A.

Contact for further information.

If you have any questions about the study please contact members of the research team:

Name of Research nurse to be appended here as well as telephone number

Dr Krystyna Matyka 024 7696 8586
Division of Clinical Sciences
Clinical Sciences Research Institute
UHCW
Clifford Bridge Road
CV2 2DX

Priya Tah 024 7696 8595
Research Associate
Clinical Sciences Research Institute
UHCW
Clifford Bridge Road
CV2 2DX

Thank you for your time.
Appendix 17 – Consent form CYP aged 16+

CONSENT FORM
Questionnaire study
Adolescent (16-18 years) consent

13 November 2007 – Version 2

Title of Project: Fear of Hypoglycaemia in children and young people with diabetes

Name of Researcher: Dr Krystyna Matyka

1. I confirm that I have read and understand the information sheet dated 12th November 2007 (version 2) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

2. 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.

3. I agree to data being collected regarding my HbA1c.

4. I agree to my data from the study being stored on Warwick Medical School computers.

5. I agree to take part in the above study.

Name of Patient ________________  ________________ Date  Signature

Name of Person taking consent  ________________ Date  Signature

When completed, 1 for patient file, 2 for researcher file; 1 (original) to be kept in medical notes.
Appendix 18 – Assent form

ASSENT FORM
For participants under the age of 16 years
Questionnaire study

To be completed by the child/young person and their parent/guardian.

Title of Project: Fear of hypos in young people with diabetes

Please indicate by putting a circle around either yes or no for all the following points:

Have you read (or had read to you) about this project? Yes/No
Has somebody else explained this project to you? Yes/No
Do you understand what this project is about? Yes/No
Have you asked all the questions you want? Yes/No
Have you had your questions answered in a way you understand? Yes/No
Do you understand it’s OK to stop taking part at any time? Yes/No
Are you happy to take part? Yes/No

If any answers are ‘no’ or you don’t want to take part, don’t sign your name!
If you do want to take part, you can write your name below

Your name ________________________________
Date ________________________________

The person who explained this project to you needs to sign too:

Print Name ________________________________
Sign ________________________________
Date ________________________________

Thank you for your help.
Appendix 19 – Parent consent on behalf of child

CONSENT FORM
Questionnaire study
Parent consent on behalf of their child

10 June 2008 – Version 3

Title of Project: Fear of Hypoglycaemia in children and young people with diabetes

Name of Researcher: Dr Krystyna Matyka

1. I confirm that I have read and understand the information sheet dated 10th June 2008 (version 3) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

2. 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.

3. I agree to data being collected regarding my child’s HbA1c.

4. I agree to my child’s data being stored on Warwick Medical School computers.

5. I agree to take part in the above study.

Name of Parent ___________________________ Date ___________ Signature ___________________________

Name of Person taking consent ___________________________ Date ___________ Signature ___________________________

When completed, 1 for patient; 1 for researcher file; 1(original) to be kept in medical notes
Appendix 20 – Parent consent form

CONSENT FORM
Questionnaire study
Parent consent

10 June 2008 – Version 3

Title of Project: Fear of Hypoglycaemia in children and young people with diabetes

Name of Researcher: Dr Krystyna Matyka

1. I confirm that I have read and understand the information sheet dated 10th June 2008 (version 3) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

2. 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.

3. I agree to my data from the study being stored on Warwick Medical School computers.

4. I agree to take part in the above study.

Name of Parent: ___________________________ Date: _____________ Signature: ___________________________

Name of Person taking consent: ___________________________ Date: _____________ Signature: ___________________________

When completed, 1 for patient, 2 for researcher file; 1 (original) to be kept in medical notes
Appendix 21 – Letter of invitation (interview)

Letter of Invitation (Children aged 8-15 years and their parents)

Date

Dear Parent

You may remember taking part in a questionnaire study a while ago, with your son/daughter looking at people’s experiences of hypoglycaemia. We would now like to get a more detailed account of you and your child’s experience of hypoglycaemia. We would like to invite you both to take part in a group discussion: one for parents and one for children. We would also like to invite you to a one to one interview session. Separate interviews would be conducted for you and your child. These sessions would take place at LRI/UHCW/BHH on:

Date
Time
Location

All your travel expenses will be paid and we will provide refreshments.

Please find enclosed an information sheet about the study. We would also be more than happy to answer any questions you may have.

If you and your child are happy to take part, please complete and return the attached slip in the envelope provided.

Thank you for considering being a part of this discussion. If you have any questions, please feel free to contact me on 02476 988935 or 07814024309

I look forward to seeing you

Priya Tah
Research Associate

Dr Krystyna Matyka
Senior Lecturer in Paediatrics

---

Priya Tah
Research Associate
Clinical Sciences Research Institute
Clinical Sciences Building
Warwick Hospital
Coventry CV2 2DX
United Kingdom
Tel: +44 (0) 24 7696 8635
Fax: +44 (0) 24 7696 8653
Email: p.tah@warwick.ac.uk

Dr Krystyna Matyka
Associate Clinical Professor
Clinical Sciences Research Institute
Clinical Sciences Building
Warwick Hospital
Coventry CV2 2DX
United Kingdom
Tel: +44 (0) 24 7696 8658
Fax: +44 (0) 24 7696 8653
Email: k.matyka@warwick.ac.uk
Fear of Hypoglycemia Focus Group

Name: ___________________________  Name of child: ___________________________

Contact number: ___________________________

___ Yes, we would like to participate in the discussion group and interview session on (date, time at, location)

___ Yes, we would like to participate in the discussion group only on (date, time at, location)

___ Yes, we would like to take part in the one to one interview session only, on (date, time at, location)

___ No, we cannot participate in this session. Please let me know if you have any other dates and times available

___ No, we are not interested in participating in the discussion group or interview session
Appendix 22 – Participant information sheet (interview)

PATIENT INFORMATION SHEET -
For young people aged 11-15 years
Interviews and focus groups

Study Title: Fear of hypos in young people with diabetes.

This letter is an invitation to you to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you would like to. Please ask us if there is anything that is not clear or if you would like more information. Our contact details are at the end of this sheet. Take time to decide whether or not you would like to take part.

Why are we doing this research?

We know that many young people with diabetes have problems getting good control of their diabetes. We know from other research and from talking to young people in clinic that hypos can be quite worrying. We want to see how much of a problem fear of hypos really is in young people. We also want to see how common hypos are and how much they affect people's quality of life. The study involves firstly taking part in a confidential interview, and secondly joining a focus group discussion with 4 other young people. By listening to what young people have to say about hypos we hope that we may be able to develop ways of helping people deal with hypos in a better way.

This study is part of an education project which will lead to a higher degree for the research associate.

Why have I been chosen to take part in this study?

We are asking all young people attending the diabetes clinic at this hospital and at five other hospitals in the Midlands, to take part in the study. By asking as many young people as we can to tell us about their experiences we can gather as much information as possible which will help us to improve care. A small number of you are also being asked to take part in an interview and focus group so that we can collect more detailed information about the experience of hypos.

Do I have to take part?

No. It is up to you to decide whether to take part. If you do, you will be given a copy of this information sheet and you will be asked to sign a consent form saying that you are happy to take part. If you do want to take part you would still be able to pull out at any time without having to
give a reason. If you decide not to take part or you want to pull out at any time this will not affect your medical care in any way.

What will happen to me if I take part?

Interview

We would arrange for you to be interviewed by a researcher, at a time and place of your choosing. The interview would be tape-recorded and last about one hour and would be completely confidential. You would not be identified on the audio-tape in any way. A written record of the interview will be made but you will not be identified on that written record. The audio-tape would be locked away in a filing cabinet during the period of study and would be destroyed once the study has finished. The interview would include discussing topics such as fear of hypos, knowledge of hypos, strategies you have for avoiding or coping with hypos, and possible ways we can improve support for young people with diabetes. Your travel expenses will be paid and we will provide refreshments.

Focus group

We would also like to invite you to attend a focus group meeting. This meeting will include up to five young people with Type 1 diabetes and will involve discussing the experience of hypos, strategies for avoiding or coping with hypos, and ways of improving support for young people with Type 1 diabetes. The focus group meeting will be audio-recorded and a written record of the discussion on the audio tape will be made later. The meeting with be completely confidential: no person will be able to be identified from either the audio or the written recordings. Each focus group meeting will last about 90 minutes and will take place at Warwick Medical School.

You will be reimbursed any travel expenses for study only visits.

Is there anything else to be worried about if I take part?

We know that some people find hypos very worrying and talking about hypos may make them more worried. If this should happen to you we would make sure that you would be able to talk to a member of the diabetes team to discuss any concerns in confidence.

What are the possible benefits of taking part?

We cannot promise the study will help you but we hope that with the information from a big group of young people and parents, we may be able to work out ways of helping people with the problem of hypos. We hope that this study will give you an opportunity to voice your opinions about your experience of diabetes and that you will feel supported in the interview and focus group to do so.

What if there is a problem or something goes wrong?

If something does go wrong then you can complain to the person at the hospital who is in charge of complaints. Your parent(s) or carers have been given more information on what to do if something goes wrong and who they can complain to.

Will anyone else know I'm taking part in this study?
All information which is collected about you during the course of the research will be kept strictly confidential and the only people who will have access to this will be the people who run the study. Any information about you will have your name and address removed so that you cannot be recognised from it.

What will happen when the research project stops?

When you have stopped taking part in this research you just carry on with caring for your diabetes as usual. When the study is finished the study team will look at the information from all the families who have taken part and write a report. We also plan to give talks at each of the clinics where we have done this research, as well as sending information about what we find to all the families who took part.

Who is organising and funding the research?

The research is being organised by Dr Krystyna Matyka at Warwick University, Dr Cathy Lloyd at The Open University, Dr Linda Gonder-Frederick at the University of Virginia, USA, Dr Michelle Miller at Warwick University, and Professor Franco Cappuccio at Warwick University.

The research is being funded by the Diabetes UK. The researchers do not receive payment for including you in the study.

Who has reviewed the study?

Before any research goes ahead it has to be checked by a Research Ethics Committee. They make sure that the research is fair. Your project has been checked by the Oxford Research Ethics Committee A.

Contact for further information.

Thank you for reading this – please ask any questions if you need to. You can also contact other members of the research team:

Dr Krystyna Matyka 024 7696 8586
Division of Clinical Sciences
Clinical Sciences Research Institute
UHCW
Clifford Bridge Road
CV2 2DX

Priya Tah 024 7696 8635
Research Associate
Clinical Sciences Research Institute
UHCW
Clifford Bridge Road
CV2 2DX

Dr Cathy Lloyd 01908 274066
Faculty of Health & Social Care
The Open University
Milton Keynes
MK7 6AA

Thank you for your time.
Appendix 23 – Consent form CYP aged 16+ (interviews)

CONSENT FORM
Focus group study
Adolescent (16-18 years) consent

13 November 2007 – Version 2

Title of Project: Fear of Hypoglycaemia in children and young people with diabetes

Name of Researcher: Dr Krystyna Matyka

Please initial box

1. I confirm that I have read and understand the information sheet dated 13th November 2007 (version 2) for the above study. I have had the opportunity to consider the information, ask questions and have these answered satisfactorily.

2. 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.

3. I agree to my data from the study to be stored on Warwick Medical School computers.

4. I agree for the interviews to be audiotaped.

5. I agree that anonymised quotes from the interviews can be used.

4. I agree to take part in the above study.

Name of Patient ___________________ Date ___________ Signature _____________

Name of Person taking consent ___________________ Date ___________ Signature _____________

When completed, 1 for patient copy for researcher file; 1 (original) to be kept in medical notes.
Appendix 24 – Participant information sheet for younger children (interviews)

16th July 2007 / Version 1

PATIENT INFORMATION - Children under the age of 6
Interviews and focus groups

To be shown/read to the child by the parent/guardian.

My name is Priya

I would like to talk to you and your (mummy/daddy/carer’s name) about your diabetes.

It’s OK if you don’t want to talk to us, but it would be good if you can.

If you want to stop talking to us at any time that’s OK too.