

NOT1CE – the Nocturnal Type 1 Caregiving Experience:

A mixed-methods exploration of the nocturnal burden of care
experienced by parent caregivers for juveniles with Type 1 Diabetes

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Declaration

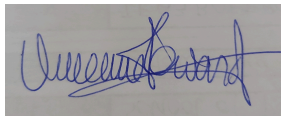
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Summary

This dissertation comprises six interrelated, mixed-methods observational studies, designed to explore the experience of parental nocturnal caregiving practice for juveniles with Type 1 Diabetes and enquire into related issues by investigating 1) the prevalence of nocturnal caregiving, 2) the drivers, characteristics and impacts of nocturnal caregiving on caregivers, 3) the effects, if any, of diabetes assistive technologies on nocturnal care and finally, 4) caregiver requirements for support. Throughout the research, the adoption of a participatory research approach was facilitated by the active engagement of a public and patient (PPI) panel. This PPI collaboration influenced the research agenda at each stage, contributed to the design of research materials and provided feedback on findings -- interpreting them through the lens of the lived-experience. The final study (study 6) details the process of operationalising a research collaboration between a group of five researchers and an arts practitioner, with the objective of enhancing the dissemination of qualitative findings. This dissertation is structured using 11 chapters, these are outlined below.

Chapter 1 describes diabetes and presents a brief history of the illness and the development of its treatment, differentiates between Type 1 Diabetes (T1D) and Type 2 Diabetes Mellitus (T2D), discusses prevalence rates for T1D and describes key aspects of managing the condition; tools. This chapter also reports on the clinical care provisions available to support families of juveniles with T1D in Ireland, while literature on parental caregiving is explored with an emphasis on nocturnal caregiving practice. Finally, chapter 1 articulates the overall research objective for this research and the corresponding research questions.

Chapter 2 presents an overview of the methodology that was employed for undertaking the series of six studies that are described in this dissertation. It begins by describing the philosophical paradigm that was adhered to, and follows with a discussion on engaged and participatory research, outlining how this approach was implemented

across this group of studies. The following chapters describe the empirical studies in this dissertation.

Chapter 3 describes Study 1, which comprised a mixed-methods systematic literature review (SLR) of peer-reviewed articles reporting findings on nocturnal caregiving for juveniles with T1D. A total of 31 articles met inclusion criteria representing 3,547 caregiver participants. This study provides a comprehensive, structured and methodologically transparent synthesis of all the evidence available on the date the database search was carried out, which acted as a foundational study that informed all the succeeding studies.

Chapter 4 reports on a collaborative engagement with a PPI panel that was designed to explore the SLR findings by carrying out a secondary analysis from the perspective of caregivers for juveniles with T1D. This was undertaken in collaboration with the PPI panel of caregivers, in a workshop setting. This qualitative study reported findings on aspects of the SLR results that were perceived as unexpected, questionable, or incomplete by individuals with lived experience. The panel also made recommendations for future research based on gaps they noted in the body of literature. For example, the panel agreed that the construct ‘Fear of Hypoglycaemia’ (FoH) was highly problematic and that further research into this construct and the most commonly used measurement tool, the Hypoglycaemia Fear Survey (HFS), was warranted. In collaboration with the PPI panel, it was agreed that tools to measure ‘knowledge seeking’ and ‘engagement with illness management’ in T1D would be beneficial to facilitate the exploration but that novel tools were required.

Chapter 5 presents Study 2, which describes the process of developing these novel tools (‘knowledge seeking’ and ‘engagement with illness management’) in collaboration with a PPI panel and establishing the validity of the novel tools using an online survey and quantitative analyses.

In **Chapter 6**, Study 3 is presented, which is a mixed-methods study designed to evaluate the construct FoH and the HFS tool. This two-phase study used a survey methodology in phase one and individual semi-structured interviews in phase two. Its overarching objective was to discern whether the tool and construct were deemed a good fit for the lived experience by this sample of caregivers who were surveyed (n=123) and caregivers who participated in individual semi-structured interviews (n=9).

Chapter 7 reports on study 4, a cross-sectional, mixed-methods study built on findings from the SLR (study 1) and study 2 (PPI secondary analysis of the SLR findings). It uses an online survey to enquire whether those finding would be replicated in an Irish sample (n=234) recruited from the diabetes clinic in a large, urban children's hospital. It investigated whether the prevalence rates of nocturnal caregiving practice found in study 1 would be replicated, despite high take-up in this sample of diabetes assistive technologies, and what other drivers of the behaviours might be. In addition, and in response to findings from the PPI consultation (chapter 4), it sought to document the previously under-explored granular detail of nocturnal caregiving activities and their frequencies, as well as the role of gender. This study also explored the experience of sleep disruption among this sample and where it occurred, its impacts.

Chapter 8 presents study 5, a qualitative study that builds on findings from studies 1 and 4, designed to facilitate a more comprehensive examination of this population's unmet need for recognition and support with nocturnal care. It was also interested in gathering evidence to support the future development of an intervention to support this highly burdened cohort with their nocturnal care burden, for use in clinical settings.

Chapter 9 details study 6, which represents a departure from traditional research such as that described in the other chapters of the dissertation. This reports on an innovative collaboration between this researcher, a group of four other PhD social science

researchers and an arts practitioner, exploring how creative practice can enhance and enrich the dissemination of traditional qualitative research findings.

In **chapter 10**, the academic and societal impacts of this research are outlined for the reader and finally, **chapter 11** integrates the findings from this series of studies and discusses the broader implications, highlighting the need to address this issue and spotlighting the often invisible but very significant burden that is carried by this cohort of caregivers. The final chapter also utilises the ‘assessing community engagement conceptual model’ framework to evaluate the impact that a high level of PPI input had on the research and its outcomes. The limitations of the research were discussed and directions for future research suggested. Finally, the conclusions of the dissertation are presented.

List of Abbreviations

CSII – Continuous Subcutaneous Insulin Infusion
DCCT – Diabetes Complications and Control Trial
DKA – Diabetic Ketoacidosis
FoH – Fear of Hypoglycaemia
HbA1c – Haemoglobin A1c
HCL – Hybrid Closed Loop
HFS – Hypoglycaemia Fear Survey
HFS-P – Hypoglycaemia Fear Survey (Parents)
MDI – Multiple Daily Injections
NCP – Nocturnal Caregiving Practice
T1DM – Type 1 Diabetes Mellitus
T2DM – Type 2 Diabetes Mellitus

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Chapter 1. Nocturnal caregiving for juveniles with Type 1 Diabetes

1.1 Introduction

Type 1 Diabetes is a high burden illness. This PhD dissertation focuses specifically on the burden associated with parental delivery of nocturnal care to juveniles with Type 1 Diabetes (T1D). The research was inspired by the lived experience of the author, who, having experienced nocturnal caregiving for a young child with T1D, found that minimal recognition of the associated caregiver burden and its impacts were provided in the clinical care setting and that few supports were made available. Furthermore, the author found that a notable gap existed around this issue in the literature and in guidance documents for clinical care provision. In response, this research was conceived with the intention of addressing this gap by documenting the lived experience of parental delivery of nocturnal care in T1D and exploring caregiver requirements for support. In the following sections, an overview of T1D will be provided, followed by a discussion on the available treatments for T1D and related illness management issues. The subsequent sections will address the provision of care for T1D in the Irish context, parent caregiving for juveniles with T1D and nocturnal care delivery. Finally, a statement of the research objective and the corresponding research questions is presented.

1.2 Diabetes Mellitus

Diabetes Mellitus, commonly referred to as diabetes, is a serious, chronic, metabolic disease that occurs when blood glucose levels are raised as a result of defects in insulin secretion, insulin action or both (American Diabetes Association, 2014). Insulin is an essential hormone produced in the pancreas that facilitates the absorption of glucose (carbohydrate) into the body's cells to be converted into energy that is required for normal functioning of the muscles and tissue of the brain and body, it is also required for the

metabolism of protein and fat. In the absence of insulin, blood glucose levels will rise, resulting in hyperglycaemia (high blood glucose), which is the clinical indicator of diabetes (Magliano et al., 2021). If an insulin deficit is left unchecked, in the short term it can lead to acute diabetic ketoacidosis (DKA), which is potentially fatal. Over the longer term, chronic hyperglycaemia can result in multiple serious or life-threatening health conditions such as cardiovascular disease, nephropathy (kidney damage), neuropathy (nerve damage), lower limb amputations, sight loss or blindness (The Diabetes Control and Complications Trial Research Group, 1993).

1.3 Historical perspective on Diabetes

The term Diabetes Mellitus is derived from the Greek word ‘diabetes’, which means ‘flowing through’, and the Latin word ‘mellitus’, meaning sweet like honey. This illustrates a historical understanding of diabetes which is accurately characterised by excessive urination or polyuria, and the sweetness associated with glucose in the urine. Ancient texts from Egypt record observations of these characteristics as early as 1550BC. Ancient texts from India documented how ants were attracted to the sweet urine of diabetic patients and for many centuries, the sweetened taste of urine was key to diagnosing the condition (Dean & McEntyre, 2004). For much of this time there was no known treatment, patients would waste away while passing increasing amounts of urine, the Greek physician Aretaeus noted that it was as though patients suffered “liquefaction of flesh and bones into urine”. A variety of therapies were offered over the centuries, from restrictive or ‘fad’ diets to blood-letting or use of opium. In 1889, German physicians Mering and Minkowski connected the illness to the pancreas, but it was 1921 before a Canadian doctor, Frederick Banting, isolated the internal secretions of animal pancreases. Then, in 1922 the first human patient, a 14-year-old boy who was near death, was treated successfully with injections of insulin secretions from the pancreas of a cow (Dean & McEntyre, 2004). The

process was refined and insulin was harvested from cow and pig pancreases to treat diabetes. In 1978, with the development of recombinant DNA technology, the first synthetic human insulin was developed, becoming available for clinical use in 1982. Over the following two decades, more sophisticated analogue insulins were developed that made insulin dosing more flexible and significantly improved quality of life for insulin-dependent diabetics. In subsequent years, the most significant developments have been technology based, falling into three categories of diabetes assistive technologies: (1) automated insulin delivery, (2) automated blood glucose monitoring and (3) artificial pancreas systems. These are discussed in further detail below, in section 1.6.1.

1.4 Diabetes types

There are sub-variants of diabetes, but generally three different classifications of diabetes are recognised: Type 1 Diabetes (T1D), Type 2 Diabetes (T2D) and Gestational Diabetes (GD). T1D is an autoimmune disease, where the body's immune system destroys the insulin producing beta cells in the pancreas leading to an absolute deficiency of insulin (Song et al., 2025). T1D is commonly diagnosed in children and young adults, patients present with excessive thirst (polydipsia), frequent urination (polyuria), fatigue and sometimes weight-loss. The causes are not yet understood but it is believed that some combination of genetic vulnerability and environmental trigger are usually at fault. Patients with T1D require daily injections of exogenous insulin to survive. In contrast, T2D is not an autoimmune condition, resulting instead from a combination of resistance to insulin action and an inadequate compensatory insulin secretory response (Galicia-Garcia et al., 2020). T2D is the most prevalent form of diabetes, accounting for 90-95% of diagnoses worldwide (Galicia-Garcia et al., 2020). While its causes are not deeply understood, they are commonly regarded to be a combination of genetic, environmental and lifestyle factors, such as poor diet and inadequate physical inactivity. Symptoms in T2D are similar to those

in T1D but are significantly less dramatic and, in some cases, will not be present at all. The International Diabetes Federation estimates that over 40% of cases remain undiagnosed (IDF, 2025). Complications can develop over prolonged periods without treatment, which can sometimes be the impetus for a diagnosis. Treatment approaches for improving blood glucose control range from the implementation of recommended lifestyle changes to support healthy living to anti-diabetic medication or insulin treatment in more severe or recalcitrant cases (Magliano et al., 2021). Gestational or pregnancy related Diabetes (GD) occurs during pregnancy as a transient disorder and resolves with the delivery of the infant. Women with GD have an increased risk of birth complications. The incidence of GD globally varies by region, ranging between 6% and 14% of pregnancies (La Verde et al., 2022; Sweeting et al., 2024). Risk factors include maternal older age, overweight or obesity, habitual smoking or family history of diabetes, it has higher prevalence in certain ethnic groups (e.g., south Asian). With GD, the risk of subsequently developing T2D becomes elevated (Yuen & Wong., 2015).

1.5 Incidence and prevalence of T1D

The International Diabetes Federation in their Diabetes Atlas (11th ed., 2025) estimate that more than 1.9 million children and adolescents under the age of 20 have been diagnosed with T1D worldwide. Traditionally, T1D has been regarded as a disease of childhood or adolescence but interestingly, the IDF Diabetes Atlas reports that in 2024, 56.5% of new cases across all regions were diagnosed in adults. Globally, Europe has the highest regional number of T1D cases among individuals under 20 years of age (419,000) and of all age groups together (2.7 million). A systematic review and meta-analysis carried by Hormazábal-Aguayo et al. (2024) pooled estimates of T1D incidence across 55 countries and concluded that the average global incidence of T1D in children and adolescents under 20 years of age was 14.07 per 100,000 between 2000 and 2022, though

regional disparities were significant with incidence rates varying widely, Finland and North America had the highest incidence rates; 56.8 and 28.8 per 100,000 respectively, while Mali had the lowest; 0.66 per 100,000. In Ireland, the incidence of T1D among children and young people is one of the highest in Europe, with rates in the top 25% worldwide (Noca.ie, 2022). There are 25,659 individuals living in Ireland with T1D (IDF, 2025), an incidence rate of 32 per 100,000 persons has been reported (Gajewska, 2020a). Furthermore, incidence rates are increasing, pooled data from across Europe have shown a 3.4% year-on-year rise (Patterson, 2019a), meaningful increases are expected globally also, the projected global T1D population for 2040 is estimated to be 14.7 million (Ogle et al., 2025). In 2024, there were an estimated 168,000 premature deaths due to T1D, among which 34,000 were in Europe (IDF, 2025).

1.6 Treatment for T1D

With T1D, the body is unable to produce the insulin necessary to control blood glucose levels. Currently, the only treatment available is the daily administration of exogenous insulin, which also requires regular self-monitoring of blood glucose levels. The treatment goal is to maintain blood glucose levels within or as close as possible to a prescribed range, which mimics that of non-diabetic individuals (i.e., 4 – 8 mmol/L). The standard regimen for insulin therapy involves multiple daily injections of insulin (MDI) (Danne et al., 2014), which commonly involves a combination of different insulins with varied action profiles, i.e., short-acting insulin to match each carbohydrate intake from meals or snacks and long-acting insulin to maintain adequate background insulin coverage, usually taken at 12hr intervals. Blood glucose testing is also required to allow for the identification of hypoglycaemia (below range blood glucose) and hyperglycaemia (above range blood glucose), so that strategies to prevent and treat these events can be implemented. Frequent testing is recommended, at a minimum before each dose of insulin

is administered but optimum care could require 10+ checks per day (Haller et al., 2004). The third element of blood glucose control involves nutritional management, which ensures that carbohydrate intake is balanced by the correct amount of fast-acting insulin. To achieve this, carbohydrate counting is employed, whereby the quantity of carbohydrate in all foods consumed is calculated and that figure is entered into the dosing algorithm (HSE.ie, 2023).

Glycated haemoglobin, usually referred to as HbA1c, is a blood test that is used to indicate the level of blood glucose control that has been achieved over a 3-month period. Higher HbA1c scores are indicative of poorer control, or higher blood glucose levels over the preceding 3 months. This test is normally carried out at each clinic visit; it is used as a proxy measure for adherence because of its direct association with blood glucose levels. However, this is known to have limitations. For example, a study by Wilson et al. (2011) showed that blood glucose levels for 252 patients over a three-month period had high individual variability with HbA1c values, implying that HbA1c measure should generally be interpreted with caution. As a result, it is increasingly common for other factors to be considered, such as ‘time in range’ and number of hypoglycaemic events, when ascertaining levels of adherence to illness management protocols (Chehregosha et al., 2019).

1.6.1 Illness management – tools

Over the last decade, diabetes management tools have evolved considerably, with new technologies becoming established as the ‘gold standard’ for T1D care. Previously, insulin administration was carried out using disposable syringes to draw insulin from vials, these have been largely replaced by insulin pens, which offer a more acceptable method of insulin delivery because they provide more dosing flexibility (smaller doses are available), are more subtle for use in public spaces, are more easily used as the insulin is contained, do

not need to be drawn from a vial and importantly, are less painful to use. Later iterations, or ‘smart’ pens, track insulin doses. Subsequently, technology delivered the most significant innovation for insulin delivery: the continuous subcutaneous insulin infusion (CSII) system, often referred to as an ‘insulin pump’. This is a medical device that is worn by the patient. A canula is inserted into the body and is attached to an infusion set contained within the insulin pump, which acts to some degree as an external (manual) pancreas. The system provides a constant, programmed supply of background insulin as well as manual insulin dosing capabilities for use when carbohydrates are consumed or when supplementary insulin doses are required (NHS.uk, 2024; Thriveabetes.ie, 2025).

Blood glucose monitoring was originally achieved using finger-prick blood testing, which was painful and laborious. Sensor technologies have emerged in the last decade, these take various forms but generally involve the placing of a sub-cutaneous sensing filament into the body, which then delivers continuous blood glucose readings to a receiving device. This innovation makes frequent blood glucose monitoring achievable and also provides added treatment efficacy and security because the user interface provides data on blood glucose trends, offering the patient invaluable information to support decision making on dosing and behaviour as well as longer term dosage adjustments. Finger pricks are still required to support the technology, but to a much lesser degree. However, these technologies are expensive; there is the initial outlay for the device and there are ongoing costs involved for consumables, e.g., the cannula needs to be replaced every 2-3 days. From the perspective of clinical care provision, there are also significant costs involved in providing the expertise to support patients in adopting and maintaining technology use. Accordingly, access to these technologies is cost prohibitive and a digital divide exists between global regions and, as noted in the section above, within localised regions (Gajewska et al., 2021; Addala et al., 2025).

1.6.2 Illness management – daily challenges

T1D illness management is complex, requiring patients to juggle the competing risks of hyperglycaemia and hypoglycaemia. This necessitates constant attention, adjusting insulin dosing to match nutritional intake, activity and other variables as well as remaining aware of fluctuations in individual insulin sensitivity, which determines the dosing ratio (Choudhary & Amiel, 2018). The difficulties involved in managing T1D are not well understood in the general population but it is regarded as a high burden condition in healthcare (Fornasini et al., 2020).

Insulin doses are not fixed, they vary throughout the day and each dose is calculated using complex individual algorithms that take into account a number of factors including insulin sensitivity, current blood glucose, the nutritional profile of a meal, activity levels, emotional state etc. These factors are variable and will change in response to any change in circumstances such as the presence of a virus or the time of day. Based on conversations with experts, peer reviewed research and personal lived experience, Brown (2022), in a highly cited article published by the international diabetes advocacy organisation, DiaTribe.org, identified 42 individual factors, such as fat intake or illness, that moderate the relationship between insulin and blood glucose. Navigating these factors presents an ongoing and unrelenting lifelong challenge for those affected (see Figure 1.1).

Figure 1.1. The 42 factors that affect blood glucose (DiaTribe.org)



Lastly, illness self-management behaviour plays a critical role in T1D care. It is imperative that the individual with T1D has fast-acting glucose available to them at all times to treat hypoglycaemia. Hypoglycaemic events can deteriorate very quickly and mental confusion can ensue, making it difficult to obtain the required treatment. In addition, documenting and record keeping are key to adjusting insulin ratios in response to various factors, which can be onerous (Wolpert et al., 2021). The diagnosis also necessitates regular attendance at a diabetes clinic, where HbA1c tests are carried out to

provide feedback on the level of success with blood glucose control that is being achieved. Where issues arise, patients and clinicians collaborate to develop strategies to address shortcomings in illness management. Research has shown that regular clinic attendance is linked to better T1D outcomes (Fisher et al., 2018). Lastly, on this non-exhaustive list, illness management requires constant access to supplies, keeping stocks maintained is critical and represents another behavioural challenge that is onerous and enduring.

1.6.3 Illness management - complications

Maintaining ‘optimal’ blood glucose control is a demanding task that the majority of individuals living with T1D struggle to achieve. However, managing the delicate balancing act between hypo- and hyper-glycaemia is crucial for positive health outcomes. Hyperglycaemia arises from an insulin deficiency. Treatments vary according to the severity of the episode but generally require the administration of insulin (American Diabetes Association, 2025). As detailed above in section 1.6.2, chronic hyperglycaemia (above range blood glucose) can lead to serious long-term complications but, in addition to this, the shorter term consequences from acute hyperglycaemia are also considerable. These can include nausea, fatigue, irritability, confusion, increased thirst and frequency of urination. When acute hyperglycaemia goes un-treated, it can, in a matter of hours, escalate into Diabetic Ketoacidosis (DKA). This is a potentially life threatening emergency and requires immediate hospitalisation (Dhatariya et al., 2025). DKA is most common at diagnosis, incidence rates are highly variable; a systematic review by Usher-Smith et al. (2012) looked at data from 31 countries and found that the frequencies of DKA at diagnosis ranged from 12.8% to 80%, with the highest frequencies found in the United Arab Emirates and Saudi Arabia and the lowest in Sweden and Canada. A large study from the US by Li et al. (2021) found a 5.6% incidence rate for hospital admissions with DKA among adults with T1D, which was almost doubled for children under 18 years, at 11%.

Furthermore, epidemiologic studies conducted in the US and Europe over the past decade have revealed a concerning rise in the rate of hyperglycaemic emergencies and hospitalisations among adults with T1DM (Dhatariya et al., 2025),

At the opposite end, hypoglycaemia occurs when blood glucose levels drop below range. This is a side-effect of insulin therapy and results from either taking too much insulin, not enough carbohydrate, or engaging in levels of physical activity that were not anticipated when taking insulin or not compensated for with carbohydrate intake.

Hypoglycaemia symptoms include shakiness, sweating, anxiety and confusion, it is treated with the administration of fast-acting carbohydrate, such as a high glucose drink, to rapidly raise blood glucose. It is not well recognised that insulin can be a substantially dangerous substance, though there are many documented cases of it being used as a weapon (Marks & Richmond, 2007; Tong et al., 2017). Severe Hypoglycaemia can occur relatively quickly (over minutes or hours) and can cause coma or even death, being responsible for approximately 100,000 visits to hospital emergency departments per year in the US (Geller et al., 2014) and 10% of deaths in Norwegian young adults with T1D, which was considered by the researchers to be an underestimation (Skrivarhaug et al., 2006).

Nonetheless, hypoglycaemia is a common, often daily occurrence experienced by most individuals with T1D (Kaur & Seaquist, 2023; Rzepczyk et al., 2022). The long-term risks of repeated hypoglycaemia events include increased cardiovascular events, cognitive decline and impaired awareness of hypoglycaemia, which further increases the risk of additional or more severe episodes of hypoglycaemic (Kaur & Seaquist, 2023). Severe hypoglycaemia is said to occur when the patient requires the help of another person or hospitalisation, and for each individual the threshold for the onset of severe hypoglycaemia is different (Rzepczyk et al., 2022). A large Australian survey found that 20% of adults with T1D reported at least one severe hypoglycaemic episode in the previous six months (Speight et al., 2011). While rates among children have declined since the introduction of

assistive technologies, a systematic review (Cherubini et al., 2019) found that the incidence of severe hypoglycaemia across 35 studies varied between 1.2 and 30 per 100 patients over 1 year.

1.6.4 Psychological impacts from living with T1D

Evidence has accumulated to indicate that the psychological impacts of T1D can be considerable for children and adolescents. In the first instance it is recognised that T1D impacts on many aspects of family life, from emotional functioning to the need to adapt family routines to the requirements of illness management (Fornasini et al., 2020). Moreover, children and adolescents living with T1D exhibit elevated levels of anxiety and depression (Buchberger et al., 2016; Missambou Mandilou et al., 2021), with the high levels of depressive symptoms recorded by patients adapting to new diagnoses (DeCosta et al., 2020). Furthermore, health related quality of life was diminished for some samples, with longer diabetes duration having a negative effect (Gadallah et al., 2017; Bekele et al., 2022). Among adolescents, higher rates of eating disorders, behavioural disorders and substance abuse have been evidenced (Bombaci et al., 2024). These findings align with those reported by Van Duinkerken et al. (2020) who carried out a narrative review of the literature on psychological effects of living with T1D, determining that across the lifespan T1D is related to a higher prevalence of depression, anxiety and distress, as well as a lower quality of life among patients.

1.7 Provision of clinical care for juveniles with T1D in Ireland

The Health Service Executive (HSE) is Ireland's national public health and social care service, providing hospital-based diabetes services, free of charge, through a network of public hospitals around the country. Seventy-six percent of adults and 96% of paediatric patients with T1D in Ireland attend for their care at these publicly funded, hospital-based

diabetes clinics (Diabetes.ie, 2023). The national paediatric health service is overseen by Children's Health Ireland (CHI), with the diabetes service including 19 centres organised over three regional levels: Firstly, the national hub is located in the capital city, Dublin, and provides tertiary diabetes care across three large hospital sites. Secondly, in smaller cities, regional hubs are situated within local hospitals such as Cork University Hospital. Finally, in smaller population centres, units operate from smaller local hospitals linked together in shared-care arrangements.

The HSE offers a robust and evolving system of care that is multi-disciplinary and grounded in clinical best-practice, specialist-led care, technology integration and patient education (HSE.ie, 2020). The HSE's National Clinical Programme for Paediatric Diabetes has developed multiple evidence-based clinical guidelines to standardise care for children and young people with Type 1 diabetes. The key documents were developed through multidisciplinary collaboration in consultation with patients, their families and the diabetes advocacy charity, Diabetes Ireland. They provide a model of care for all children and young people with T1D, as well as the national clinical guidelines for newly diagnosed children with and without diabetic ketoacidosis, guidelines for the treatment of sub-optimally managed T1D and co-morbidity screening (HSE.ie, 2015; HSE.ie, 2024a; HSE.ie, 2024b; HSE.ie, 2025a; HSE.ie, 2025b).

From diagnosis, children receive ongoing support from a specialist children's diabetes team, comprising endocrinologists, diabetes nurse specialists and dieticians, with some clinics providing families with access to a psychologist or social worker for counselling support. The team will supply education on insulin administration, blood glucose monitoring and carbohydrate counting. Care teams also liaise with schools and childcare settings to support diabetes management. In addition, families are provided with essential clinical supplies such as glucose and ketone meters, lancets, sharps bin, insulin pens, and test strips. Initially, families can expect very frequent contacts with the clinic,

often by phone or email. As confidence and self-management skills grow, routine check-ups continue at approximately 4-months intervals, where blood glucose control will be reviewed and adjustments or education provided as needed. Some clinics provide opportunities to avail of structured education programmes such as DAFNE (dose adjustment for normal eating), teaching patients and parents how to count carbohydrates and adjust insulin doses accordingly. The HSE supports integrated diabetes technology, insulin pumps, sensors and smart pens are prescribed in the clinics and supplied by the diabetes teams. Associated consumables as well as other diabetes supplies are available with prescription through community pharmacies and are supported by the Long-Term Illness card, a public scheme that covers most illness-related expenses.

Although the HSE/CHI strive to provide the highest level of service to all, discrepancies exist between centres, particularly with regard to smaller regional centres, where poor staffing levels are known to impact on care delivery and multidisciplinary teams are not resourced to the model of care standard (midland103.com, 2024; Dockery et al., 2023). These discrepancies are meaningful, leading to capacity issues that result in some patients experiencing long delays between appointments, or a lack of out-of-hours support, both of which contravene national care guidelines. In addition, roll out of diabetes assistive technologies has been severely hindered by a lack of suitably trained staff in many regional locations. A recent national analysis (2019–2023) compiled from HSE parliamentary replies shows marked variation in pump uptake across regions, among public-hospital patients. The uptake among 0–18-year-olds showed particular variation (Flynn, 2024). Overall, 14% of Ireland’s estimated T1D population were pump users, well below some European comparators (e.g., Germany), suggesting both regional disparities and national under-utilisation relative to potential need, according to Flynn (2024). The author supports moves toward a national audit of diabetes technology use, stating that it would be helpful for identifying underserved regions and reducing disparities. In addition,

a survey by the national diabetes charity for diabetes advocacy and education, Diabetes Ireland, found that 19% of people with T1D from outside Dublin pay privately for their care, which compares with 10% of those in Dublin. Complications and co-morbidities also had a significantly higher incidence rate outside of the Dublin region (41% vs 35%), again pointing to a care disparity (Diabetes.ie, 2023). A feasibility study for a national diabetes audit was carried out, with the report, published in May 2022, drawing the same conclusion, finding significant variation between diabetes centres in Ireland in terms of multidisciplinary team resourcing and expertise (Noca.ie, 2022). Here, the recommendation was that a national audit of paediatric T1D is feasible and also necessary for Ireland, as they observed a notable lack of reliable national data, which, they concluded, negatively impacts on healthcare practitioners' ability to identify and address disparities in the provision of paediatric care and to make informed decisions that would drive quality improvements (Noca.ie, 2022).

Use of diabetes assistive technologies has been consistently linked to better blood glucose control (Dicembrini et al., 2021; Pickup, 2019). In the Irish context, a study by Dockery et al. (2023) looked at adolescent patients categorised as high risk for complications due to their ongoing poor blood glucose control, finding that only 40% were using sensor technologies and only 10% were using insulin pumps, compared to the standard cohort who had greater uptake of sensor and insulin pump technologies, at 80% and 37% respectively. The diabetes audit feasibility study found insufficient multidisciplinary staffing levels to support the required education to initiate children onto the technologies, resulting in extensive waiting lists for children who would benefit from these interventions. Furthermore, the report stated that children currently using the devices are not receiving adequate support to ensure their optimal use (Noca.ie. 2022).

In spite of these shortcomings however, a recent survey of diabetes patients by Diabetes Ireland (Diabetes.ie, 2023) found that 83% of parents were happy with the care

their children were receiving and 47% of these parents thought it was excellent.

Furthermore, 54% of parents felt more confident managing their child's T1D after their most recent clinic appointment.

1.8 Parental caregiving for juveniles with T1D

Given the material contained in the sections above, it is clear that children with T1D will rely heavily on their parental caregiver for illness management. The degree to which the parent drives care is primarily determined by the age of the child. With younger children who do not have the cognitive capacity to manage the responsibility, the onus falls on the parents entirely. Older children will gradually begin to share illness management responsibilities with their parents and by degrees develop the necessary skills and absorb the required information, however the timing and rate of transfer to this co-managing stage varies greatly from family to family, depending on the dynamics of the relationships, parenting style and the personalities involved (Aalders et al., 2025). Ultimately the goal is for the young person to become autonomous, being fully accountable for their illness-management responsibilities.

Nevertheless, this transfer of responsibility can be a complex matter. Wysocki and Greco (2006) carried out a review of the literature on the role of family support in children and adolescents with T1D, concluding that earlier withdrawal of parental involvement in illness-management was associated with poorer diabetes outcomes while ongoing parental involvement was associated with better T1D outcomes for adolescents. Meanwhile, at the other extreme, it has been observed that transferring responsibility too late can lead to a loss of learning opportunities and hamper the development of independence; T1D related and in the broader developmental context also (Reed-Knight et al., 2014).

Many parents struggle to determine the correct timing for transferring care tasks to their children (Akre & Suris, 2014). Aalders et al. (2021) looked at the factors that

determine the successful transfer of T1D care responsibilities and concluded that child factors, such as illness awareness, age at diagnosis and cognitive abilities, all played a part but more nebulous factors such as willingness to assume responsibility and motivation were more predictive. Child and parent temperament were also influential; child anxiety and shame or parental tendency to be over-protective were not helpful, while parental values that prioritised normal child development over illness management were helpful. In terms of implementable strategies, Aalders et al. (2021) state that ‘teaching in small steps’ and ‘parental monitoring’ have consistently been observed to be helpful.

Scholars have highlighted the fact that managing T1D in children and adolescents presents significantly greater difficulty than in adults (Chetty et al., 2019; Chowdhury et al., 2015), due to the fluctuating presence of growth hormones in children as well as unpredictable activity levels and nutritional intake (Chetty et al., 2019). Furthermore, adolescence is associated with boundary testing, inconsistent behaviour and emotional lability, none of which sits comfortably with the rigors of effective diabetes management (Cox & Hunt, 2015). Hormones related to this developmental stage also add difficulty as they are understood to be linked to insulin resistance (Dockery et al., 2023), which impacts on insulin dosing and effectiveness.

A target range for HbA1c levels has been established that supports better illness outcomes among children, however research has shown that the majority of juveniles do not attain these levels, a study by Foster et al. (2019) found that only 17 % of juveniles who were included in a US national diabetes registry between 2016 and 2018, achieved these targets. It is widely recognised that blood glucose control in young people with T1D deteriorates during adolescence. Analysis of data from a national diabetes audit in the UK revealed that pooled median HbA1c values showed a steady rise from 9 years of age (7.65%), peaking at 19 years (8.8%) before falling to 8.3% for 30-year-olds. Furthermore, prevalence of one or more annual DKA hospital admission rose from a mean of 1.7% at 6

years old to a mean of 10.3% at 18/19 years before falling to a mean of 4.9% at 30 years (Holman et al., 2023).

Research recognises the substantial degree of extra parenting burden involved with caring for a young person with T1D (Saßmann et al., 2022; Moghadam et al., 2022), as well as the large degree of financial, emotional and social impact on the family unit (Rankin et al., 2018). Studies have shown that parents of children with T1D experienced increased anxiety, depression and stress related to their T1D caregiving role (Bassi et al., 2021), as well as perceiving a significant extra emotional burden in their families, and experiencing stress related to a lack of respite opportunities as well as a lack of educational and informational supports from their care providers (Commissariat et al., 2020). It has also been established that parental stress is predictive of poorer blood glucose management in children, as indicated by HbA1c values, while more effective control is linked to higher parental self-efficacy, mediated by higher levels of monitoring and adherence (Bassi et al., 2021). Furthermore, parental emotional wellbeing can support positive communication about illness management with adolescents (Rawdon et al., 2024), which is important for illness management and psychosocial wellbeing (Benson et al., 2024). Research has established that better health outcomes for juveniles can be dependent on quality of caregiving (Schunk, 2015). The link between the quality of parental support for positive illness outcomes in juveniles with T1D was explored in a review by Young et al. (2014). They observed inconsistent findings around parenting styles. In response they proposed two categories of parental engagement with their children's T1D; 'good cop' and 'bad cop'. Their analysis suggested that 'good cop' parental involvement enables collaborative engagement and is characterised by open communication, emotional support and regard for the youths' growing independence. This was linked to better outcomes. 'Bad cop' however, was characterised by intrusive support and controlling or critical parenting behaviours that drive conflict and undermine the child's self-efficacy. These behaviours predicted lower

adherence, poorer blood glucose control and lower health-related quality of life. Their conclusion was that parenting style can be protective or can present a risk for children with T1D.

1.8.1 Nocturnal caregiving in T1D

T1D can require 24-hour illness management practice for adult patients, and this is even more the case for juveniles (Patience et al., 2023; Streisand & Monaghan, 2014). The practice of nocturnal illness management encompasses both physical activities (e.g., insulin administration, finger-prick blood glucose testing, administration of carbohydrate treatments for low blood glucose), as well as less tangible cognitive and emotional activities such as the interpretation of physiological data, calculation of insulin dosages, decision-making in response to alarms, the burden of sustained vigilance and responding to the patient's symptom-related distress. The American Diabetes Association in their 'Standards of Care Statement' recognizes this, stating that caregiving in T1D "involves round the clock vigilance and active interventions, which commonly involve night-time wakings, often multiple times". It also notes that "there may be levels of extra stress related to managing illness, which may also contribute to sleep disruption" (American Diabetes Association, 2018). Nevertheless, nocturnal caregiving burden is commonly unrecognised in healthcare settings and anecdotal evidence suggests that this is not routinely addressed in clinical care. This is not surprising as care guidelines make very little reference to it.

The International Society for Paediatric and Adolescent Diabetes (ISPAD) published their Clinical Practice Consensus Guidelines (ISPAD.org, 2024), covering all aspects of Type 1 Diabetes. In the chapter addressing psychosocial care in T1D (De Wit et al., 2022) the requirement to acknowledge distress in parent caregivers and provide support was recognized as an important aspect of promoting better diabetes management, but no

explicit reference to nocturnal care burden or need for psychosocial support around that issue is found, despite the acknowledgement elsewhere in the guidelines that nocturnal hypoglycaemia is a significant risk and commonly presents as asymptomatic, with overnight blood glucose monitoring the recommended caregiver practice (Abraham et al., 2018). In the Irish context, the HSE 'paediatric model of care for children and adolescents with T1D' document (HSE.ie, 2025) declares an intention to address improved quality of life and reduction of family burden as a primary objective, but nowhere in this document is night-time caregiving or the associated burden addressed. Neither set of documents provides guidance on managing overnight hyperglycaemia or its associated burden.

This is not surprising, as nocturnal caregiving has received little attention in the research literature to date (Feeley et al., 2019), with topics related to nocturnal caregiver burden and caregiver need for support significantly underexplored (Ji et al., 2021). It is recognised that unmet support needs among caregivers for patients of all ages with a variety of conditions are underexplored in the literature and challenges experienced by this often-invisible cohort are given low priority in clinical care settings (Kuluski, 2018). However, in the last five years, attributable to the advent of novel blood glucose monitoring technologies, evidence has accumulated that supports this necessity. A study by González-Vidal et al., (2025) used glucose sensors to monitor overnight blood glucose and found that among 755 patients, 77% experienced nocturnal hypoglycaemic episodes over the 14-day observation period, with hypoglycaemic episodes recorded for 19.5% of the total nights observed. Other studies, particularly those with qualitative aspects, have found that many caregivers regularly monitor and treat their children's blood glucose through the night, with marked negative impacts for caregiver wellbeing (Bilgehan & Uludaşdemir, 2024; Macaulay et al., 2020).

1.9 Research objective and corresponding research questions

Nocturnal parental caregiving is an important element of illness management for juveniles with T1D (Feeley et al., 2019), but many aspects have been understudied in the research to date. Data on the prevalence of nocturnal care delivery is sparse and combines caregivers using different treatment regimens, often not accounting for technology use. There is limited research on the psychosocial impacts for caregivers and none on the impacts from sleep disruption on caregiver physical health. Furthermore, there is a paucity of research elucidating the factors influencing individual differences in the frequency of nocturnal caregiving behaviour or establishing the effectiveness of nocturnal care delivery in improving T1D outcomes or specifying the granular detail of nocturnal care behaviours. What literature does exist is inadequate to establish the thorough understanding of the practice that is necessary to direct policy for clinical care and drive further research toward the goal of identifying and implementing targeted, supportive interventions for use in T1D clinical settings. A robust, high-quality piece of observational research is needed to confirm the limited findings from previous studies and firmly establish the prevalence of nocturnal caregiving and sleep disturbance among caregivers for T1D. Research is also needed that responds to recent changes in the treatment landscape by looking at the role played by technology in nocturnal caregiving practice. Lastly, caregiver requirements for support must be detailed so that interventions to address the gaps can be developed using co-design principles and so that caregivers can ultimately be supported with their burden.

This dissertation aims to address this critical gap by exploring nocturnal caregiving practice in T1D, investigating its relationship with parental burden, inquiring into the related impacts and critically, examining caregiver experiences to determine the support needs of caregiving parents. It asks the following research questions:

RQ 1 What is the prevalence of nocturnal parental caregiving practice in an Irish sample?

RQ 2 What factors drive caregivers to provide nocturnal care, and what are the associated impacts for caregivers?

RQ 3 To what extent does the use of technology moderate the practice of nocturnal caregiving or impact on the associated burden?

RQ 4 What strategies or interventions can be implemented to better support caregivers in nocturnal caregiving?

The following chapter presents an overview of the methodology that was employed for undertaking the series of seven studies that were carried out to address these questions and are described in this dissertation.

Chapter 2. Research Methods and Design: An Overview

2.1 Overview of research design

A multi-phased, mixed-methods design was adopted to explore the research objectives. Central to the research was the adoption of participatory research methodologies, leveraging the researcher's lived-experience as well as public and patient involvement (PPI) to drive a patient-centred research process. A series of 6 studies utilised a variety of different methodological approaches, including surveys, individual semi-structured interviews and a focus group.

2.2 Philosophical paradigm

The overarching philosophical framework adopted was pragmatism. This was considered the most appropriate choice as it offers a flexible, problem-centred approach that prioritizes practical solutions over rigid adherence to particular assumptions about knowledge and truth. Unlike paradigms that emphasize either purely objective reality (positivism) or purely subjective interpretation (interpretivism), pragmatism acknowledges that knowledge can be both constructed and discovered, depending on the context (Brierley, 2017). This is especially useful for exploratory studies that deal with complex, real-world problems, where multiple perspectives and methods are necessary to capture the full picture. Methodological pluralism ensured that the research was both empirically grounded and contextually rich (Allemang et al., 2022). In addition, this choice allowed the research to maintain intellectual openness, draw from diverse sources of evidence – both quantitative and qualitative, and produce findings that are not only academically rigorous but also meaningful and useful for practice. Furthermore, pragmatism aligns with applied fields such as education, healthcare, and social policy, where stakeholders often seek actionable recommendations rather than purely theoretical insights (Cornish & Gillespie,

2009). Further detail on the particular epistemological and ontological choices made at each step of the research process will be included in the relevant chapters.

2.3 Reasoning strategy

In keeping with its pragmatist philosophy, this research utilised deductive, inductive and abductive modes of inference. A cycle of inductive, deductive and, where appropriate, abductive reasoning supported the research's iterative approach to exploring its core themes. Deductive logic moves from the general to the specific, inductive takes the opposite approach, from specific observations to broader understandings. Abductive reasoning employs an approach that integrates both in that it explores both the theory and the data to generate plausible hypotheses (Kovács & Spens, 2005). Using this strategy, data collection was employed to “explore a phenomenon, identify themes and patterns, locate these in a conceptual framework and test this through subsequent data collection and so forth” (Dudovskiy, 2016 , p. 66). This is accepted practice, scholars make the case that pragmatism supports the use of mixed research methods as well as a variety of data sources and modes of analysis combined with a cycle of abductive reasoning (Feilzer, 2010).

2.4 Engaged and participatory research

As noted, this research is grounded in lived experience. From its inception, key choices and decisions have been guided by this perspective. In addition, collaboration with a panel of experts with lived experience provided insights that had a significant impact on the research at all stages, locating this project at the deepest end of the engaged and participatory spectrums.

Engaged research describes a wide range of research approaches and methodologies that share a common high-level goal of collaborative engagement with communities of interest, practitioners, policy makers, and stakeholder organisations

(Research Ireland, 2017). Its broad remit is to improve, understand, or investigate any issue of public interest and its aim is to embed the engagement of citizens, public, patients and end users of research across the entire research process (Holliman, 2017). It also supports the development of public engagement with research, to strengthen links between the research and related agendas, such as promoting activities that impact research culture, research integrity, open education, and public or citizen engagement with research findings (Irish Universities Association, 2022). Participatory research is one form of engaged research.

Participatory research (PR) is an umbrella term that draws together research approaches that share a core philosophy of inclusivity and that recognise the value of engaging those who will be beneficiaries in the research process rather than viewing them as ‘subjects’. It includes terms such as community based participatory research, participatory action research, community-partnered research, cooperative enquiry, dialectical inquiry and others (Cargo & Mercer, 2008). PR has its origins in social action research and political movements that envisaged social liberation for disenfranchised groups as achievable through community empowerment. Working in the UK and US in the 1940s, Kurt Lewin, a social psychologist, proposed a ‘cycle of continuous inquiry, action and evaluation, undertaken *with or by*—as opposed to *on or for*—society’s marginalized peoples’ (Macaulay, 2017). Similarly, in the 1970s, a Brazilian philosophy scholar, Paulo Freire, stated that individuals should not be seen as objects of inquiry but as full participants, able to determine their own needs (Macaulay, 2017). In health research, commentators have opined that the practice of PR presents a significant opportunity for bridging academic work into practice and enabling people to gain increased control over the determinants of their health (Cargo & Mercer, 2008).

Systematic enquiry with PR requires operationalising the following core principles; full partnership with researchers that necessitates co-ownership of the work with co-

decision making and distributed power at every stage of the research process. Increasingly, PR has been understood as an ‘approach’, rather than simply a ‘method’ (Israel et al., 1998; Andersson, 2018). Indeed, some authors have even suggested that it is more of an ‘attitude’ than a method (Cornwall and Jewkes, 1995). In support of this position and in response to the finding that in practice, researchers were unaware of the complexities inherent in PR and that ‘true partnerships’ were less common, with ‘add-on’ community consultation being more the norm, guidelines have developed to evaluate the level of PR achieved by research in health-related studies (Bourke, 2009; Frankish et al., 1995; Mercer et al., 2008). The first of these guidelines (Frankish et al., 1995) were developed to align with the ‘Assessing Community Engagement Conceptual Model’ (Aguilar-Gaxiola et al., 2022) (see Figure 2.1 below). This research approach was able to demonstrate strong alignment with almost all of the guideline criteria (see Appendix 2.1 for the completed table). A second set of guidelines by Mercer et al. (2008) covered similar themes but utilised a more simplified framework. They were developed by synthesising over 400 PR articles and distilling the key concepts and processes. Again, this research approach rated as very highly aligned with PR principles using these guidelines also (see Appendix 2.2 for the completed checklist). Neither checklist employs a rating scale, evaluation depends on the level of response and alignment with PR statements. The Mercer checklist has demonstrated reliability (Mercer et al., 2008) and is offered as a tool to facilitate evaluation of research proposals by funding bodies.

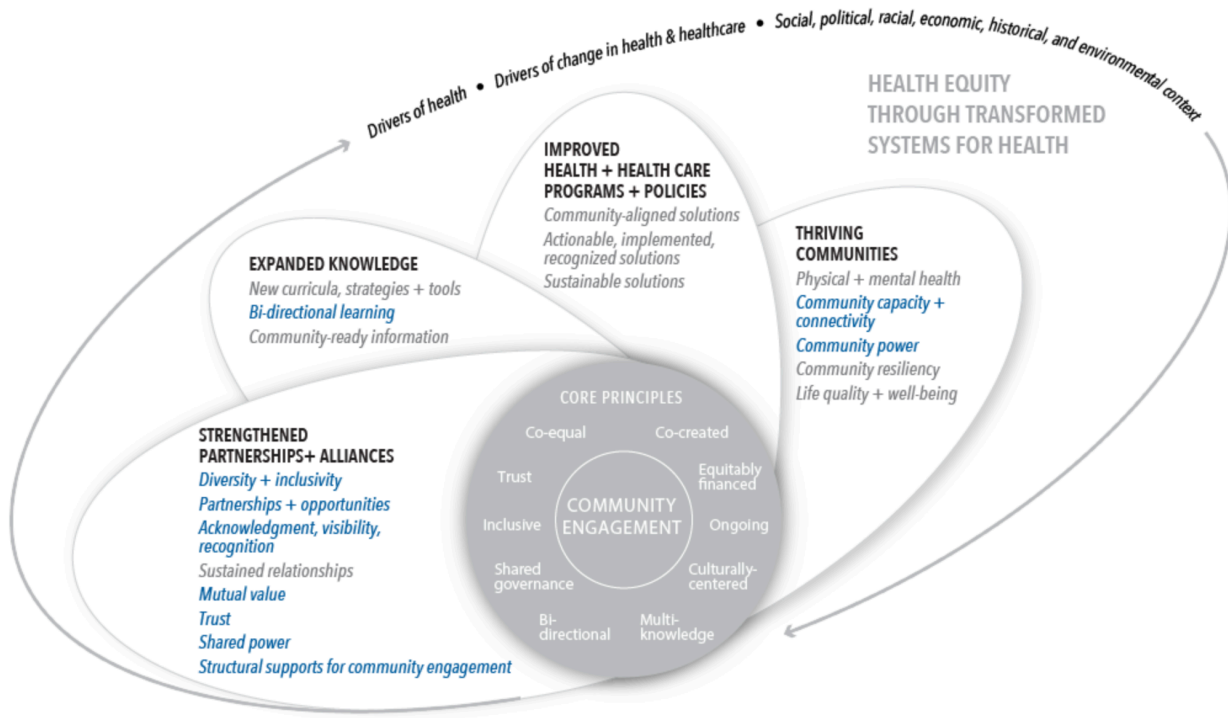
2.5 Assessing community engagement

Evaluating the benefits of utilising PR is critical for highlighting its value and promoting a culture shift toward greater engagement with the approach. Jagosh et al. (2012) analysed reports from 23 PR partnerships across 276 peer-reviewed and non-peer-reviewed publications to investigate what criteria could be applicable. They were able to

identify seven distinct benefits to adopting this approach: (1) culturally and logistically sound research, (2) enhanced recruitment capacity, (3) improved stakeholder capacity and competence, (4) generated stakeholder disagreements and negotiations that had positive and negative outcomes, (5) increased quality of outputs, (6) increased sustainability of project goals and (7) system changes as well as new unanticipated projects and activities. Subsequently, the Assessing Community Engagement Conceptual Model (Aguilar-Gaxiola et al., 2022) was developed as a framework for understanding and measuring the level of meaningful engagement and impact achieved by a study. The seven benefits defined by Jagosh et al. (2012) are embedded within the four assessment domains of this model. The model assumes a level of community engagement that is not about a single event but a continuous, complex engagement that responds and adapts to change. Foundational to this model are the core values of trust, bi-directional influence, authenticity and inclusivity. The first assessment domain is ‘strengthened partnerships and alliances’, this refers to whether the partners emerge from the engagement with improved, stronger relationships that can be sustained. The second assessment domain is ‘expanded knowledge’, which refers to the creation of new insights, stories and evidence as well as a novel appreciation for community ways of knowing that are unrecognised. The third domain is ‘improved health, healthcare programs and policies’, which is the stated goal of many partnerships, but in the context of this model required to be determined by community need and priorities, while representing the aligned interests of service providers and users, solutions must be ‘fit for purpose’. The fourth and final domain is ‘thriving communities’, this represents a wholistic view of health where a shared understanding includes the mental and physical aspects, which are understood to act symbiotically and are determined by health self-efficacy and shared decision making in treatment situations, leading to higher levels of community resiliency.

These benefits represent outcomes that were relevant and desirable for this research, this is discussed further in chapter 11.

Figure 2.1. Assessing Community Engagement Conceptual Model (Aguilar-Gaxiola et al., 2022)



2.6 Operationalising the participatory research approach

For this project the PR approach was operationalised using two strategies, (1) Involvement of a lived-experience researcher, and (2) collaboration with a public and patient involvement (PPI) panel through all stages of the research process.

2.6.1 Lived-experience researcher

The primary author of this dissertation is a parental caregiver for a juvenile with T1D. The presence of a lived-experience researcher in a key role was critical for shaping the work. However, it brought some challenges, including the difficulty of managing a dual identity. Identity is how we understand ourselves and others through personal

characteristics, social roles or groups that we are linked to (Howard, 2000). Lived-experience researchers can have a dual identity, occupying two positions within their work environment; experts in the practice of research and experts by lived experience of the topic they are investigating. Negotiating the complexities of integrating personal and professional experience is challenging. On one side there are significant benefits available from the researcher's ability to draw on their lived experience to develop research agendas, design studies and materials, and interpret data. However, it is commonly the case that with high visibility of their lived experience, the credibility of their research output may be called into doubt (Gupta et al., 2023). On the one hand the potential for bias will be noted by the research community, while on the other hand bias of a different sort, or possibly apprehension, may be encountered in their lived-experience community, where issues around allegiance and hierarchy may emerge (Fricker, 2007). This research was carried out with full appreciation of this dilemma and the matter of researcher positionality. Efforts were made to mitigate against the difficulty at each stage, which are documented throughout this dissertation in the empirical chapters.

2.6.2 Public and patient involvement

The motivation to democratise health research has its roots in the WHO conference on public health of 1978, where delegates issued the 'Alma Alta Declaration' (World Health Organisation, 1978), which stated that people have the 'right and duty to participate individually and collectively in the planning and implementation of their healthcare'. Public and Patient Involvement (PPI) in health research operationalises this principle, it refers to the active partnership between researchers, patients, carers, and members of the public in shaping and conducting studies, ensuring that research reflects the needs, priorities, and lived experiences of those it ultimately seeks to benefit. Rather than positioning patients and the public as passive subjects of research, PPI emphasizes their

role as co-creators of knowledge, contributing to the identification of research questions, the design of study methodologies, the interpretation of findings, and the dissemination of results (Lang et al., 2022). This approach not only enhances the relevance and applicability of health research but also strengthens its ethical foundation by recognizing the value of experiential knowledge alongside scientific expertise (Biggane et al., 2019). PPI is increasingly viewed as a marker of high-quality research, as it fosters transparency, accountability, and trust between the scientific community and the wider public. Furthermore, meaningful involvement can improve recruitment, retention, and acceptability of studies by ensuring that research materials and processes are accessible and appropriate for diverse populations (Lang et al., 2022). However, the implementation of PPI also presents challenges, including the need for adequate resources, training, and cultural change within research institutions to support genuine collaboration rather than tokenistic engagement (Jackson et al., 2020). Overall, PPI embodies a shift towards a more democratic model of health research, aligning scientific inquiry with societal values and promoting outcomes that are both scientifically robust and socially meaningful.

PPI has been endorsed and is increasingly required by public and other health research funding bodies. For example, in Ireland, the Health Research Board asks that research proposals describe PPI involvement through the research cycle. Some academic publishers are developing similar initiatives; the British Medical Journal (BMJ) group now require authors to submit a PPI statement with their research, indicating how patients or the public were involved and if they were not involved, why not. A number of organisations have emerged internationally that support PPI activities with training and opportunities to forge relationships with patient groups and representatives. In Ireland, two organisations have made a significant impact in health and social care research and policy development; PPI Ignite is nationwide network, situated across seven universities with numerous stakeholder partners, funded by the Health Research Board/Research Ireland. It is oriented

toward researchers and promotes high-quality PPI engagement and innovation by providing training and a range of dedicated resources such as a ‘Planning Canvas’, which is designed to assist researchers and contributors develop PPI strategies for each stage of the research cycle or the ‘Ethical Collaboration with Children and Young People in Research’, a toolkit providing guidance and support for involving minors in research. The Irish Platform for Patients' Organisations, Science & Industry (IPPOSI) is another organisation that often works alongside PPI Ignite. IPPOSI is a charity with a mission to promote patient involvement in the treatment and decision-making processes that affect healthcare in Ireland, providing a platform to facilitate engagement between patient groups, clinician groups and researchers. The aim is to place ‘the patient voice at the centre of policy, research and innovation’, it is open to all groups with an interest in healthcare. In 2021, IPPOSI published a ‘Strategic Plan’, outlining their proposals for facilitating ongoing partnerships across stakeholder groups, detailing their intention to develop further training and educational activities, and plans regarding the continued development of an ‘involvement agenda’ for patients in the health system (IPPOSI.ie, 2021). Furthermore, the HSE launched a PPI initiative in 2024 with the publication of their ‘Patient and Service User Partnership Plan’ which proposes a multi-level patient and service user partnership with the Health Regions Program, whereby a patient representatives would be formally embedded across the 6 HSE health regions. This proposal recognises PPI as “an essential element of a functioning health system, democratically facilitating and representing all voices across all disease areas from community and acute hospitals” (HSE.ie, 2024c).

2.6.3 Recruiting and collaborating with the PPI panel

Given the involvement of a lived-experience researcher, establishing a PPI panel to provide guidance was critical for mitigating biases throughout the research. The panel was recruited using convenience and snowball methods. Attention was paid to diversity in

demographic characteristics and T1D experiential backgrounds and perspectives, to ensure that, to the degree it was possible, the panel adequately reflected the broader population of caregiving parents in T1D. Potential contributors were approached in person or by email, they were provided with high-level details on the project, an explanation of the purpose of the panel and the anticipated time commitment. All of those who were approached (n=6) accepted the invitation to join the panel (see section 2.6.3 for further information). Funding was provided by Research Ireland to enable a degree of financial compensation for each member; this took the form of one 'one4all voucher', which was delivered to each participant when they had completed their engagement with the research. Notably, some members of the panel declined that offer. Panel members engaged to differing degrees at different stages of the project. Collaboration took a hybrid form, with some individuals meeting in-person and others only available for online video conferences. At some stages the collaboration was carried out using email exchanges. Throughout the process, the researcher remained flexible and responsive to the requirements of the individual's circumstances. One individual stopped responding entirely, it is difficult to know what the circumstances might have been that gave rise to this situation. All the other panel members remained engaged with the research until the end (n=5). Further detail on the role of the PPI panel in each study is provided in the relevant chapters.

2.7 Reflexivity

As qualitative methods have gradually been absorbed into the mainstream in Psychology, there has been an increasing expectation that researchers engage in reflexive practice as part of the research process (Shaw, 2010; Lazard & McAvoy, 2020). This can be challenging for researchers, particularly those who have a background in quantitative research and find the vague and nebulous objectives difficult to assimilate (Lazard & McAvoy, 2020). In 1988, the feminist Psychologist Sue Wilkinson defined reflexivity as

the process of “engaging in self-reflection about who we are as researchers, how our subjectivities and biases guide and inform the research process, and how our worldview is shaped by the research we do and vice versa”. Also in 1988, Steve Woolgar, a sociologist, in his book on reflexivity and knowledge, differentiated reflexivity from reflection by placing them both on a continuum. The continuum stretches from ‘radical constitutive reflexivity’ at one end to benign introspection or ‘reflection’ at the other. In this understanding, reflection represents general thoughts but in the research context they are concerned largely with process and verification, ensuring representational accuracy, which is underpinned by a positivist ontology. While radical constitutive reflexivity is born from an interpretivist ontology, which assumes a reality that is constructed in the ‘dialogic relationships’ between people or the co-construction of meaning within a social context. This necessitates the practice of reflexivity or ‘reflecting your thinking back to yourself’, addressing the implications of the research scenario to ensure empirical rigour (Shaw, 2010). According to Jamieson et al. (2023), reflexivity refers to the conscious, active acknowledgement of one's own belief, bias, and judgement systems before, during, and after the actual research process, while Lazard and McAvoy (2017) have stated that the point of reflexivity is to “scaffold critical thinking in order to make visible some of the connections between research questions and research conclusions, and open the way to critically different interpretations”. Although some criticise reflexivity, calling it narcissistic or self-indulgent, a distraction from the subject (Finlay, 2002), most recognise it as a powerful tool.

2.7.1 Reflexivity in practice

Throughout the research journey, reflexive attentiveness to researcher positionality was practiced. In the main, this involved introspective strategies, a reflexive journal was maintained for the duration of the research, where pertinent thoughts and emotional

responses were documented and decision-making processes scrutinised. In addition, a diversity of opinion was sought out to create opportunities for challenging assumptions and beliefs. For instance, care was taken to recruit PPI panel members that were widely representative and to include individuals with diverging experiences - one member of the PPI panel was in receipt of T1D care through the UK national health system (NHS). Engaging in these self-scrutinising activities was helpful for maintaining self-awareness and transparency when carrying out the work. Ethical dimensions that may be specific to this situation were sometimes highlighted by the reflexive work, including sensitive issues such as, assuring anonymity within the community for participants or managing the difficulties involved in challenging a system that the researcher was a beneficiary of, or even, asking peers for access using common difficulties as a connection point. Matters related to positionality were discussed in supervision and also, where possible, guidelines and frameworks were utilised to structure data analysis procedures and optimise accountability. Regarding researcher positionality as a responsibility and maintaining a practice of critical reflection enhanced the integrity of this project.

The first strategy employed to address the concern of bias involved conducting a foundational validation exercise, see below for details.

2.7.2 Validation exercise

As discussed in the sections above, it was recognised that significant challenges to the robustness of the research project exist as a result of its origins in the researcher's lived experience. Cognisant of this, prior to commencement of the project, a foundational validation exercise was undertaken to establish the validity of the underlying assumption driving the project; that the nocturnal caregiving burden of caring for a child or young person with T1D was a genuine concern for a significant number of caregiver parents. The objective was to establish the robustness of this proposition and confirm that the author's

experience was neither exceptional nor anomalous. In order to achieve this, it was decided to carry out an analysis of ‘humorous memes’ posted to an online T1D caregiver peer support group. This decision was based on a growing body of literature that examines memes as cultural artifacts that encode group experiences and attitudes. One of the central scholars in meme research, Shifman, argues that internet memes function as units of cultural expression that reflect and encode shared social meanings, identities and concerns (2013). For example, collective anxieties or frustrations such as from the experience of Covid-19 pandemic (Akram et al., 2021). Researchers commonly analyse these memes using content or thematic analysis (Malik & Zahra, 2022). While not directly evidential of population attitudes by themselves, they are treated as ‘signals’ of collective narratives (Shifman, 2012; Howard & Adan, 2022).

Background: A national online peer support group for parents of children and teens living with T1D offers a forum for parents to access support, share information and request advice at any time. This is a very active group which currently has 3,866 members, the author is also a member.

Method: In March 2020, this group had 2,325 members. The study involved accessing the media file of images uploaded to the group. These images included photographs of children with T1D, nutritional information on food packaging, food portions in restaurants requesting approximation of carbohydrate content from other members, images of T1D data outputs – for advice, and many other categories of images. From among these, the researcher chose to isolate the humorous memes. These were reviewed to determine their thematic content and to allocate them to thematic categories.

Results: There were 6,216 images shared to the group. Of these, there were 205 humorous memes posted that referenced caregiving or living with T1D. Theme categories comprised; hypoglycaemia (9%), calculating insulin doses (4%), counting carbohydrates (8%), using diabetes technology (23%), emotional distress from T1D (18%). The study

identified a total of 78 memes (38%) that specifically addressed ‘nocturnal caregiving’.

This was the most frequent theme, in Figure 2.2 some examples are presented.

Conclusion: Given the range and number of concerns that a T1D caregiver has to grapple with on a daily basis, this was a noteworthy finding and supports the assumption that nocturnal care is a prominent concern among many caregivers.

Figure 2.2. Examples of memes from scoping study

Mememes with various themes



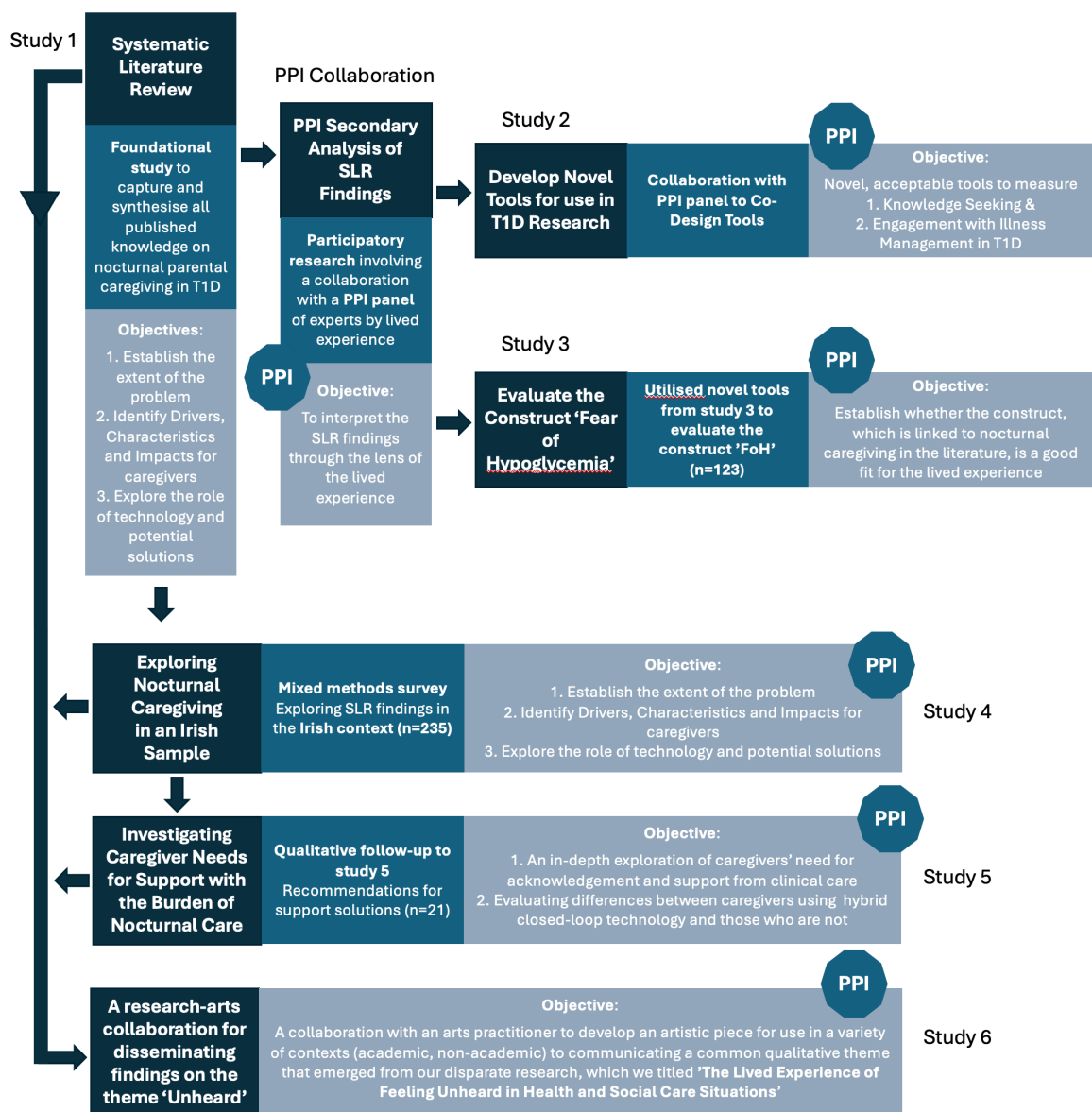
Nocturnal caregiving memes



2.8 Overview of the studies presented in this dissertation

To explore the topic of interest and address the research questions outlined in chapter 1, a series of six studies were carried out, as outlined in the summary provided above (p. iii). Each study was designed in response to findings from the previous study or studies. The schematic below provides a visual overview of the studies, which are described in the following chapters (see Figure 2.3).

Figure 2.3. Study overview schematic



2.9 Data collection and analysis overview by study

In line with the pragmatic approach, each study utilised methodologies that were suitable to meet the objectives of the individual stage of the research. These varied from study to study. The methods employed for data collection and data analysis are detailed within the individual chapters of this dissertation. For reference however, they are summarised below in Table 2.1.

Table 2.1. Data collection and analysis overview by paper

	Study 1 (SLR)	<i>PPI feedback on SLR</i>	Study 2 (Develop Tools)	Study 3 (Fear of Hypogly.)	Study 4 (Nocturnal caregiving Irish Context)	Study 5 (Desired solution)
	Chap. 3	Chap. 4	Chap. 5	Chap. 6	Chap. 7	Chap. 8
Data Collection						
PPI		X	X	X	X	X
Database search	X					
Mixed-Methods Survey		X	X	X	X	
Interviews				X		X
Focus Group						X
Data Analysis						
PPI	X	X	X	X	X	X
Descriptive/ Summary statistics	X	X	X	X	X	X
Associational and Correlational analyses	X			X	X	
Regression analyses				X	X	
Thematic analysis	X					
Content analysis				X		
Interpretive phenomenological analysis					X	
Directed content analysis						X

Building on the methods outlined in this chapter, the following chapter details study 1, a SLR that was undertaken to provide a comprehensive understanding of the current

state of knowledge on the topic of nocturnal caregiving in T1D. This systematic review serves as a foundational study that informs and guides the subsequent stages of the research presented in this dissertation.

Chapter 3: Study 1: Systematic Literature Review. Around-the-clock: Caregiving at night for juveniles living with Type 1 Diabetes

This chapter has been adapted from Howard, V., Maguire, R., De Bruin, E., Deane-King, J., Duda, N., & Corrigan, S. (2025). Around-the-clock: Caregiving at night for juveniles living with type 1 diabetes—a systematic review. *Psychology, Health & Medicine*, 1-22. <https://doi.org/10.1080/13548506.2025.2468529>

3.1 Abstract

Caring for children with T1D can require around-the-clock attention but there is little acknowledgment of the impact that nocturnal caregiving can have on caregivers in clinical care provision. This systematic review aimed to (1) explicate nocturnal caregiving practice (NCP) by identifying and synthesising peer-reviewed research to establish the prevalence and nature of NCP, (2) explore the impacts of NCP for caregivers, (3) evaluate the perceived value of technology for supporting NCP, and (4) examine potential solutions for mitigating NCP burden. In January, 2022, the databases CINAHL, MEDLINE, Web of Science, PsycINFO, Scopus and EMBASE were searched to identify peer-reviewed studies, published in English since 1997, which addressed NCP for juveniles with T1D. Quantitative, qualitative and mixed-methods studies were included. Risk of bias analysis was carried out using the Quality Assessment with Diverse Studies (QuADS) tool. Where possible, quantitative data were aggregated. Qualitative data was subjected to a narrative synthesis, using thematic analysis. Thirty-one studies met inclusion criteria, comprising 3,547 caregivers. 88% of caregivers engaged in NCP, though frequency was variable. Over 50% of participants (19-80%) failed to get adequate sleep and 54% reported poor sleep quality. Qualitative testimony detailed adverse impacts of NCP; exhaustion, difficulty making illness-management decisions, negative impacts on mood and physical health.

Benefits from technology were equivocal. Evidence regarding predictors and associations for NCP, such as patient age, was contradictory. 83% of authors recommended that sleep be routinely addressed in clinic, which is not current practice. This review provides clear evidence that NCP in T1D is pervasive with significant negative impacts on caregivers. These secondary impacts of juvenile T1D need to be acknowledged so that care guidelines can be modified and psychosocial supports can be developed for use in clinical treatment environments.

Keywords: Juvenile Type 1 Diabetes; nocturnal caregiving; parent caregivers; sleep disruption; caregiver burden; systematic review

3.2 Introduction

As the first stage of this series of studies, a systematic literature review SLR was undertaken (study 1). An SLR serves several important scholarly purposes as it employs explicit, transparent and replicable procedures that are defined a priori, for identifying, evaluating and synthesising existing evidence on a given topic. These purposes include ensuring research replicability and minimising bias as well as ensuring that the highest quality evidence is made accessible to inform policy and practice, linking academic pursuit to the practical application of knowledge (Perestelo-Pérez, 2013). The process is iterative and complex, it includes the development of a clearly defined search strategy, a set of inclusion and exclusion criteria, and pre-determined analytic procedures to identify, select, appraise, analyse and summarise previous empirical studies.

The objective of study 1 was to identify peer-reviewed articles, published within the previous 25 years (1996-2021), that reported quantitative and/or qualitative findings that focused on any aspect of the topic ‘nocturnal caregiving for juveniles with T1D’. This approach was particularly pertinent as a characteristic of this topic was that it was underrepresented in the academic literature to date. Indeed, the literature search found that

evidence or information on the topic was often embedded in studies on other themes such as family burden, fear of hypoglycaemia or technology use (Abitol & Palmert, 2021; Bahadur et al., 2022; Burckhardt et al., 2018; Cobry et al., 2021). The value of combining this evidence to justify and direct the succeeding research was critical. To this author's knowledge, no previous SLR had been conducted on the topic so the approach was deemed to be a key foundation step for the subsequent series of studies on nocturnal caregiving in T1D. The SLR protocol enabled the investigation to span diverse theoretical frameworks, methodologies and contexts to identify patterns and distil knowledge across a spectrum of studies. Subsequently, the SLR provided a rigorous and unbiased account of the research landscape around the theme as well as providing instructive insights on research approaches that had hitherto been utilised for uncovering related knowledge. Lastly, using a rigorous systematic approach to the literature review at the start of the study series also minimised the risk of selective reporting that could arise from high levels of participatory engagement and the author's own lived experience.

3.3 Background

T1D prevalence rates are increasing, particularly among children under 5 (Patterson et al., 2019b). Currently, one in 400-600 children globally will receive this diagnosis (Mobasseri et al., 2020). As mentioned in Chapter 1, juvenile T1D puts an enormous strain on families (Jaser et al., 2009) with management in children more difficult than in adults [Herbert et al., 2015; O'Hara et al., 2016]. The difficulties of maintaining stable blood glucose and the consequences of not achieving this control are well documented (Kahanovitz et al., 2017; Diabetes Control and Complications Trial, 1993; Fullerton et al., 2014).

Successful illness management and better health outcomes for juveniles can be dependent on quality of caregiving (Schunk et al., 2015), which is a 24-hour responsibility

(Streisand & Monaghan, 2014). In delivering round-the-clock care, parent caregivers can experience multiple night-time wakings, while illness-related stress may also contribute to sleep disturbance (American Diabetes Association, 2018). Current international clinical care guidelines do not address night-time caregiving or illness monitoring specifically (Silverstein et al., 2005). For example, the updated Clinical Practice Consensus Guidelines from the International Society for Paediatric and Adolescent Diabetes (ISPAD.org, 2018) acknowledges distress in parent caregivers, emphasising the need to provide support to promote better diabetes management, though no reference is made to potential impacts of nocturnal caregiving. This is not surprising, as nocturnal caregiving has received very little attention in the research literature to date (Ji et al., 2021).

As described in section 1.6.1, use of Diabetes illness-management technology has significantly changed the treatment landscape for T1D in recent years, with clear benefits for overall illness management (Naranjo et al., 2016). However, while continuous glucose monitors (CGM) and closed-loop technologies are promoted to reduce nocturnal care burden, the degree to which technologies in their present form moderate or mitigate nocturnal caregiving challenges is uncertain (Cobry et al., 2022). In addition, significant variance in technology uptake has been observed; this appears to be due to cost and availability as well as personal choice (Naranjo et al., 2016).

3.4 Objectives

Study 1 aimed to identify and synthesise research on nocturnal parental caregiving for juveniles with T1D in the home setting, with five research questions:

- (1) What is the prevalence of nocturnal caregiving practice (NCP) among parent caregivers?
- (2) What is the lived experience of NCP among parent caregivers?

- (3) What are the impacts of NCP on parent caregivers and on diabetes-related health outcomes for juveniles?
- (4) What is the efficacy, impact and perceived value of technological innovations for reducing the burden of nocturnal caregiving?
- (5) What are the potential solutions for supporting caregivers in managing this burden?

3.5 Methods

3.5.1 Review protocol

The review protocol was registered with PROSPERO in January 2022 (CRD42022298562). Reporting follows PRISMA 2020 (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines (Page et al., 2021; see Appendix 3.1 for the completed PRISMA checklist).

3.5.2 Eligibility criteria

Inclusion and exclusion criteria were developed using the SPIDER framework (Cooke et al., 2012): The *sample* of concern was parent caregivers for juvenile patients diagnosed with T1D (0-18 years), excluding parents of children with co-morbid conditions or samples with undifferentiated type 2 populations. The *phenomenon of interest* was nocturnal illness management activities, classified as any action that would not occur without the existence of a diagnosis of T1D, taking place after the juvenile has gone to bed and before both parties (caregiver/patient) would normally rise in the morning. There were no restrictions placed on research *design*. Research *evaluation* of any caregiver physical or mental health outcomes or any patient diabetes-related physical health outcomes were considered, but not specialist endocrinologic or other bio-medical endpoints. Quantitative, qualitative and mixed-methods *research*, published in the English language, in peer

reviewed journals, since 1997 was considered. See Table 3.1 for further detail on inclusion and exclusion criteria.

Table 3.1. Inclusion and Exclusion Criteria utilising SPIDER framework (Cooke et al., 2012)

	Include	Exclude
Sample	Parent caregivers for juvenile patients dx with Type 1 Diabetes (0-18 years)	- Caregivers for patients with co-morbid conditions - Aggregated illness groups - Undifferentiated Type 2 population
Phenomenon of Interest	Any data collected on nocturnal illness management activities, practices, behaviours, impacts or supports, with and without technological support	- Diabetes self-care in adult patient - Diabetes caregiving for juveniles that does not explicitly refer to nocturnal activities.
Design	- Any theoretical framework - Cross-sectional, prospective, and retrospective studies - Survey, questionnaire, focus group, interview, self-report tools, validated measures	
Evaluation	- Any caregiver physical or mental health outcomes - Any patient diabetes-related physical health outcomes	Specialist endocrinologic or metabolic biochemical and medical endpoints
Research	- Qualitative - Quantitative - Mixed-Methods - English language publication - Published within the last 25 years - There will be no restrictions on study timeframes or sample sizes	- Literature published in languages other than English - Literature published before 1997
Comparators (Where found)		
	- Healthy population - Other illness groups - Self-care groups	- Aggregated illness groups - Undifferentiated Type 2 population

3.5.3 Information sources and search strategy

The following databases were searched in January 2022: MEDLINE (Ovid), Web of Science (Clarivate), CINAHL and PsycINFO (EBSCOhost), Scopus and EMBASE. Reference lists of key publications were reviewed to confirm that all relevant data was captured. The search strategy was developed in collaboration with a specialist subject librarian using related terms harvested from literature published in the area (specifically, terms relating to Type 1 Diabetes AND paediatric OR juvenile AND caregiver OR parent AND nocturnal OR sleep). A sample database search is included in Appendix 3.2.

3.5.4 Selection process, data collection process and data items

Retrieved records were uploaded to Endnote (version 20). The literature was screened digitally in Endnote for duplicates and checked by the primary researcher, deletions were made where appropriate. All screening of remaining titles, abstracts and texts was carried out by two researchers working independently. Initially, titles and abstracts were screened to establish whether the publications met eligibility requirements. Some deletions were made. Following this, the full texts of remaining publications were screened for eligibility. Where opinions did not align, researchers discussed discrepancies until they were resolved. Thirty-one studies were deemed eligible to be included in the review.

A data extraction form was developed and piloted on a randomly selected subset of eligible publications. Data was then extracted from all eligible publications in duplicate, ensuring that all data points were captured. Data extraction categories included: Demographic and illness-related variables (patient – age/Haemoglobin A1c [biochemical marker for blood glucose control]/duration of diagnosis; participant – gender/SES/relation to patient); illness management regimen (use of technology, multiple daily injections); methods and methodologies (quantitative, qualitative, mixed methods, data collection

tools); any reported findings relating to nocturnal caregiving activities (sleep quantity and quality, impacts, drivers and characteristics of the behaviours); researchers' conclusions and recommendations.

3.5.5 Study risk of bias and reporting bias assessment

The Quality Assessment with Diverse Studies (QuADS) tool was selected to assess study quality because it facilitates quality assessments across mixed study reviews and places equal emphasis on methodology and reporting domains (Harrison et al., 2021). Inter-rater reliability was established as substantial ($k = 0.67-0.91$), as was face and content validity in health research contexts (Harrison et al., 2021). The tool rates each paper across 13 criteria with each scored between 0-3, the range of potential total scores is 0-39. The tool does not provide indicative score categories and scores are interpreted in relation to the overall body of scores (studies). The review was carried out by two reviewers, working independently.

3.5.6 Synthesis methods

This research utilised a narrative synthesis methodology, following guidance by Popay et al. (2006). Due to the complex nature of the phenomenon being explored by a heterogeneous group of studies, individual research questions were addressed by utilising a variety of analytic techniques associated with the narrative synthesis methodology, and which were deemed appropriate for achieving the research objectives. Techniques included; aggregating descriptive statistics and scores for similar measured variables across studies (e.g., actigraphy studies), clustering studies by theme to aggregate findings, interpreting data using narrative text, calculating weighted frequencies (vote-counting) and weighted means where possible, tabulating heterogeneous data by theme (e.g., sleep disruption) for comparative analysis. Qualitative data was synthesised using thematic

analysis, whereby data was aggregated to create higher-order categories of overarching themes. Data were tabulated and presented with illustrative quotes. Sub-group analyses (e.g., technology use; moderating variables) used aggregated descriptive statistics and narrative syntheses where relevant to the review aims. Due to the heterogeneous nature of the subject field, a variety of measurement modalities were employed, these were included or excluded from the synthesis as appropriate. Outlying or ill-fitting data was summarised and placed within the context of the field of knowledge. A more detailed outline of the six phrases involved in the narrative synthesis process is provided below.

3.5.7 Outline of Narrative Synthesising Process

Phase 1. The five research questions outlined in the introduction were developed based on a review of the background literature and in consultation with the PPI panel of caregivers for juveniles with T1D (as described in chapter 2, section 2.6.3), who were purposively recruited using convenience sampling (n=4). Due to the broad, heterogeneous nature of the enquiry and data captured by the search, researchers selected a ‘narrative synthesis’ approach as the best-fitting option for keeping the data synthesis focused and for facilitating a predominantly textual approach to interpreting the data.

Phase 2. Articles resulting from the database search and screening process were read multiple times so that researchers could familiarize themselves with the key concepts, constructs and approaches employed for data gathering/interpretation.

Phase 3. A preliminary map of the evidence, as it pertained to each of the research questions, was developed. Potential lines of evidence-based argument were explored.

Phase 4. Researchers considered the relationships between findings (contradictory or complementary) and studies were clustered to address the individual research objectives. A plan for syntheses that were deemed appropriate for pooled quantitative and qualitative data was devised iteratively (details above).

Phase 5. A framework was developed to guide the process of reporting the narrative synthesis, this comprised a series of themes, linking data to research questions, bridging quantitative and qualitative findings and driving interpretations.

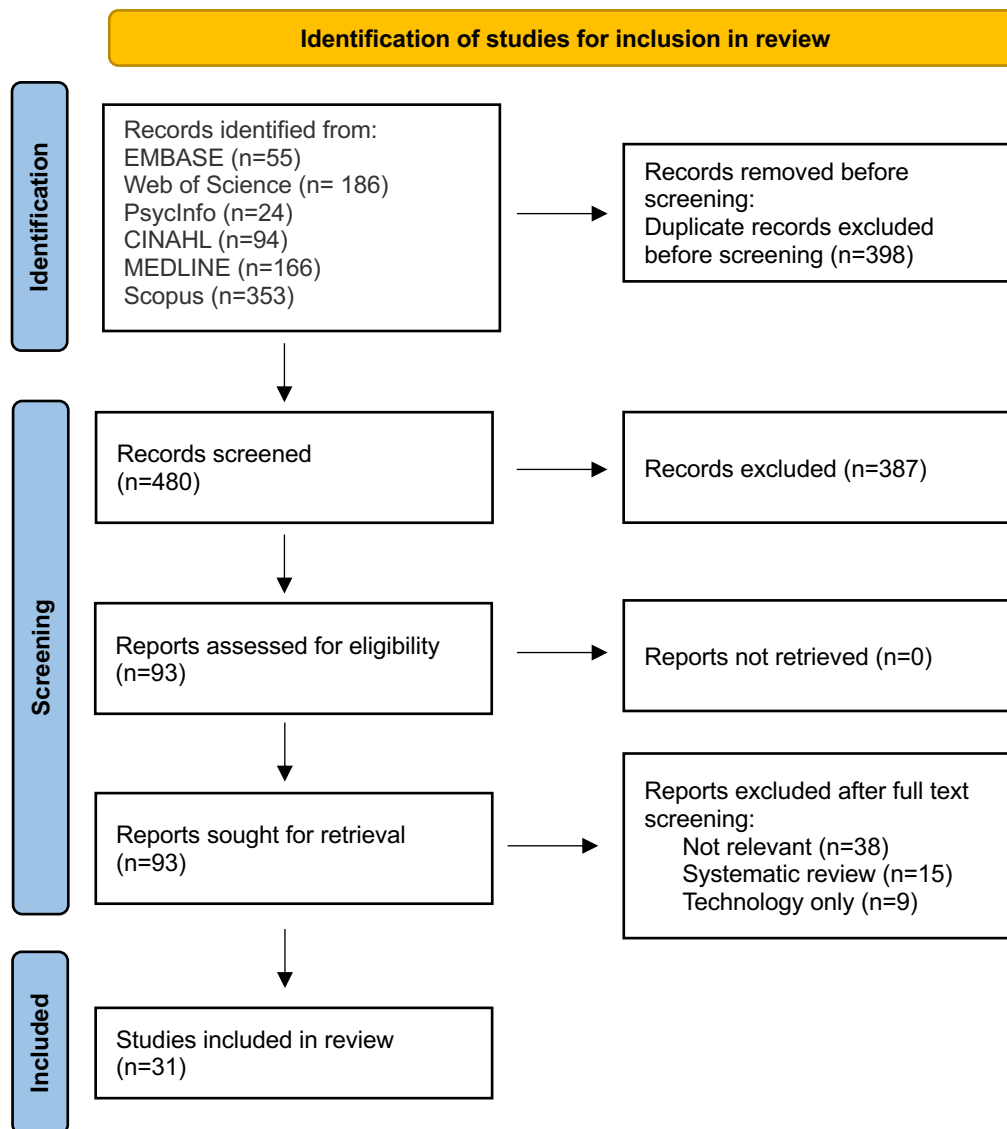
Phase 6. Robustness of the synthesis was supported by consultation with the PPI panel (n=4).

3.6 Results

3.6.1 Study Selection

A total of 878 studies were found following the database search. Following duplicate removal, the titles and abstracts of 480 records were screened. Of these, the full texts of 93 articles were assessed. This led to 31 studies being included in the review (see Figure 3.1).

Figure 3.1. PRISMA 2020 flow chart



3.6.2 Summary of selected studies

Studies comprised a total of 3,547 caregivers. Twenty-one studies were quantitative in design, 7 qualitative and 3 mixed methods. Six studies utilised actigraphy technology to gather objective data on sleep. Six reported purposively recruiting primary caregivers and one study recruited maternal caregivers only. Female gender was reported by 77-100% of caregiver participants. A summary of study characteristics is included in Appendix 3.3.

3.6.3 Quality assessment: Study risk of bias and reporting bias

QuADS scores ranged between 24-37 (mean 30.7), adhering to a normal distribution with no strong outliers (see Appendix 3.4). None of the studies were assigned a zero mark for any criteria. Studies performed well when considered in relation to the high-level research design criteria, e.g., ‘clarity around key concepts’, and also in relation to higher-level reporting, e.g., ‘sufficient detail in statement of aims’. Scores were more variable for detailed criteria in methodological domains such as ‘provision of recruitment data’. In some instances, reporting on criteria, e.g., ‘rationale for choice of data collection tool/s’, tended toward the descriptive rather than provision of a rationale. In the context of this analysis, it is notable that the poorest ratings were given for criteria 12; ‘evidence that research stakeholders have been considered in research design or conduct’, with only 10% of studies scoring 2 or above. Though none of the studies was ranked at a level that would cause concern and require the exclusion of data, a moderate risk of selection bias cannot be discounted, and broader generalizability of some findings are potentially equivocal.

3.6.4 Prevalence of Nocturnal Caregiving Practice (NCP)

To establish a foundation for understanding the importance of this research topic the SLR’s primary aim was to explore the prevalence to which NCP was a feature of caregiving for juveniles with T1D. Fourteen studies, comprising 1,635 participants, as well as 5,000 downloads of data from a diabetes blood glucose monitoring databank, provided information on this (see Table 3.2 below). Eleven studies reported the percentage of parents engaged in NCP, with a weighted aggregate percentage mean of 88.3% (n=1,301). However, there was notable variation in frequency of practice. Significant numbers of participants engaged in NCP nightly, with some documenting multiple daily NCP events. For example, Barnard et al. (2016) in study 1, found that 33% of participants engaged in NCP every night, with 27% doing so more than once per night. Moderate levels of NCP

were reported in some studies; utilising a very large sample of downloaded data (n=4990) in study 2, Barnard et al. (2016) found that 24% of participants were engaging in NCP 3-6 nights a week, while Sinisterra et al. (2020) found that 63% of participants engaged in NCP 3+ times per week. Other studies reported significantly lower frequencies; in Haugstvedt et al. (2011), only 27% engaged in NCP ≥ 1 per week, though in this sample cohort, mothers and fathers were equally represented, and the primary caregiver was not identified.

Table 3.2. Prevalence of Nocturnal Caregiving Practice

Study	Sample n=	Mean age	% Engaging in NCP	Frequency of NCP
Abitol	264	12y	71%	• 48% <2 week • 44% 2-7 week • 8% ≥ 2 per night
Barnard (study 1)	4990	n/a	99%	• 24% 3-6 nights p/w • 15% at least 50% of nights
Barnard (study 2)	258	n/a	97.3%	• 18.2% 2-3 times p/w • 14.3% 4-5 times p/w • 33% Every night • 26.7% > once a night
Feeley 2019	22	12.2y	86%	
Feeley 2021	18	9.6y	83%	
Haugstvedt	200	10.6y		• 27% ≥ 1p/w
Herbert	134	5.3y		• Mean 3.42p/w • 34% daily
Jaser, 2016	10	4.1y	100% (glucometer)	• Downloads show mean of 1.7p/n (range 0.6-4.1)
Jaser, 2017	515	9y	97%	• 69% always or often
Monaghan, 2009	71	4.5y	68%	• 35% Sometimes • 32% Always
Monaghan, 2012	24	4.1y	92%	• 42% most nights • 17% few nights p/w • 33% only if low at bedtime
Burckhardt, 2019	60	13.3y	70%	• Mean 3 nights p/w
Elbalshy	12	n/a		• 2-5 p/n
Landau	13	9.3y	77%	• 1 p/n (range 0-2.3)
Sinisterra	46	4.7y	95.7%	• 30% every night • 63% 3+ p/w
Aggregate	1,301		88.3%	

3.6.5 Understanding the lived experience of NCP

Synthesis of data from 16 studies that investigated some aspect of the lived experience of NCP led to the identification of three themes; characteristics of NCP, drivers of NCP, predictors of NCP (see Table 3.3).

3.6.5.1 Theme 1: Characteristics of NCP. At a high-level, NCP is understood as; ‘caregivers monitoring and/or responding to overnight blood-glucose excursions’. Seven studies provided detail on the practice; postponing caregiver bedtime in response to low or high blood glucose readings (Bergner et al., 2018), waking early to facilitate a pre-bolus of insulin to cover their child’s breakfast (Carreon et al., 2021), setting alarms to carry out NCP tasks and/or responding to prompts or alarms from technology (Bergner et al., 2018; Feeley et al., 2019). Nonetheless, there was a paucity of data overall on the granular detail of NCP. A single study, Barnard et al. (2016), surveyed NCP prompts (n=251 approx.), finding that 35% woke to monitor blood glucose; 22% woke in response to an alarm; 15% in response to a hypoglycaemic event; and 2% in response to a hyperglycaemic event. In each scenario, illness management was required (children woken to consume fast-acting carbohydrates or administration of insulin, follow up monitoring).

3.6.5.2 Theme 2: Drivers of NCP. Among data on ‘drivers for practice of NCP’ found in seven studies, the most prevalent theme was ‘hypoglycaemia mitigation’; participants were aware of the significant harms that could result when blood glucose levels drop below target levels; some participants feared seizures at night and even death, while others had previous experiences that drove their concerns or had children who they felt were hypo-unaware (didn’t wake when glucose level dropped precipitously). The second sub-theme expands on the first and speaks to participants’ experience of ‘anxiety’, which encompasses fear of hypoglycaemia, as well as generalized worry and nocturnal rumination. Some

participants felt that worries were experienced most strongly after diagnosis or when transitioning to a new treatment regimen, while for others the worry changed in nature but was nevertheless persistent through the duration of caregiving experience. In the third sub-theme ‘hyperglycaemia mitigation’, participants were driven to engage in NCP in order to administer insulin as mitigation against long-term impacts of high blood glucose. The desire to ‘optimise’ blood glucose control by engaging with it 24 hours a day emerged as a driver also, though this was not a prominent concern, as illustrated in Barnard et al. (2016); where researchers found 17% of participants were driven by fear of hypoglycaemia and only 0.5% reported concerns related to hyperglycaemia. In the final sub-theme ‘variable mediating factors’, participants identified variable personal factors, recognised to impact on stability of patient blood glucose levels, which drove NCP for some. Examples included day-to-day variations in diet and exercise and impacts of hormonal changes associated with developmental stage.

Table 3.3. Characteristics and Drivers of NCP with illustrative quotes

Theme 1: Characteristics of NCP
‘If she’s low before she goes to bed...we have to eat, drink, do something in order to get her sugar back up and I have to keep her awake and I have to stay awake in order to recheck it’ (Bergner et al., 2019)
‘Morning time, I have to get him up earlier just to make sure he’s got medicine in him and snack before we leave’ (Carreon et al., 2021)
‘I am sometimes up every 2 hours to correct the highs and lows’ (Feeley et al., 2019) ‘...try to stay awake because if I fall asleep I might not hear my alarm to test again’ (Feeley et al., 2019)
‘Higher numbers for my boys to ensure sleep for myself is sometimes a necessary trade off, but never a comfortable one’ (Oser et al., 2017)
‘Normal alarm settings for years now include two-night checks then @ 6.30am, normal life still begins’ (Walker et al., 2016)
‘Waking up to check lows requires waiting to make sure the BS are coming up. I have a hard time falling back to sleep’ (Feeley et al., 2019)
‘I’ll probably stay up a couple of hours to make sure he moves [glucose rise/fall]....I

would say per week I probably lose about 7 hours, maybe more' (Bispham et al., 2021)	
Theme 2: Drivers for NCP	
Sub-Themes	Quotes
Anxiety	'Well, I feel worried every time she goes to sleep.' (Carreon et al., 2021) 'I don't want to wake up in the morning and go to wake her up and she's dead, basically' (Macaulay et al., 2020) 'I have this image of a ship going through a very narrow strait with very high sharp rocks on either side...at night-time you never really know what is going to hit' (Sullivan-Bolyai et al., 2003)
Hypoglycaemia Mitigation	'I'd rather be tired than my son going into a coma because blood dropped too low' (Barnard et al., 2016) 'Sometimes I have trouble waking him when [he's] low and it is stressful' (Feeley et al., 2019) 'My sleep is broken into 2 to 3 hours at a time to check him if he's low' (Feeley et al., 2019)
Hyperglycaemia Mitigation	'...we just try to minimise damage from [high] sugars overnight' (Macaulay et al., 2020)
Variable Mediating Factors	'...if she's sick I set my alarm to make sure I'm up every 4 hours to check her sugar around the clock.' (Bergner et al., 2018) '...we don't eat our normal diet and then her blood sugars are very volatile' (Macaulay et al., 2020) '...there'll be a huge rise and then a huge drop if she's been exercising, it's just a bit more chaotic' (Macaulay et al., 2020) '...how much insulin he has on board is important, and...how recently he ate matters too' (Bispham et al., 2021)
Theme 3: Predictors and Associations for NCP	
Sub-Themes	Findings
Duration of Illness	Conflicted (Macaulay et al., 2020; Feeley et al., 2019; Monaghan et al., 2009; Lindstrom et al., 2011)
Patient's Age	No relationship found (Feeley et al., 2021; Harrington et al., 2017; Macaulay et al., 2020)
Fear of Hypoglycaemia	Higher FoH was associated with poorer sleep (Herbert et al., 2015; Jaser et al., 2017; Abitol & Palmert, 2021)

3.6.5.3 Theme 3: Predictors and Associations for NCP. Limited, sometimes contradictory, findings on predictors or associations for NCP were found:

Duration of illness. Macaulay et al., (2020) found that sleep disruption reduced with duration of diagnosis, other findings indicated that sleep duration actually increased with longer duration of diagnoses (Feeley et al., 2019; Monaghan et al., 2009). Feeley et al. (2021) found no significant relationship between the two and relatedly, Lindstrom et al. (2011), found no association between caregiver burnout and duration of illness.

Patient's age. Studies explored the association between child age and caregiver sleep (or NCP), with concordant findings. In Feeley et al. (2021) no significant relationship between age and parent sleep was found and in Harrington et al. (2017), age was not a predictor of perceived burden (including sleep interference) in three patient age cohorts. In Macaulay et al. (2020) authors stated that though NCP evolves over time, it endures irrespective of age.

Fear of hypoglycaemia (FoH). FoH was associated with sleep in a number of studies; in Herbert et al. (2015), parents experiencing greater hypoglycaemia worry reported greater sleep disruption through NCP, while in Jaser et al. (2017), greater FoH was linked to higher NCP and sleep deficits, although NCP frequency was not associated with parent sleep quality. Similarly, associations between higher FoH and more frequent overnight check as well as diminished sleep quality and daytime fatigue were found in Abitol & Palmert (2021).

3.6.6 Impacts of NCP on parent caregivers and diabetes-related health outcomes for patients

3.6.6.1 Impacts on Caregiver Sleep. Thirteen studies measured sleep quantity achieved by caregivers. Studies used a variety of approaches, including self-report sleep duration, objective sleep-duration data collected using actigraphy technology, and the percentage of

participants who reported sleep disruptions linked to NCP (see Table 3.4 for the tabulated results).

Table 3.4. Impacts of NCP on Caregiver Sleep Quantity

Reference	Sample n=	Patient Age	Achieving <7h Sleep *Self-report **Actigraph	Duration: Self-report	% experienced sleep disrupted by NCP
Bahadur	75	8.8	49.3%*		
Feeley, 2019	22	12.2		5.8h	64%
Feeley, 2021	18	9.6	72%**		
Harrington	597	5.2			59%
Herbert	134	5.3		6.19h	58%
Jaser, 2016	10	4.1	80%*	6.2h (5-8)	
Jaser, 2017	515	9	51%*	6.5h	
Lindstrom	142 (mothers) 109 (fathers)	n/a			37.5% of Burnout sub- group (63.9% mothers; 37.8% fathers)
Macaulay	10 (mothers) 10 (fathers)	8.7	19%**		
Monaghan, 2012	24	4.1		6.57h	79%
Morrow	40	8.1	56%**		
Burckhardt, 2019	60	13.3			NBGM impact on parent sleep; median score 5 (0=never; 7=always)
Sinisterra	46	4.7			78%

Aggregated Findings

% of Sample Achieving <7h Sleep		Total Nightly Sleep Duration
Self-report (n=600)	Actigraph (n=78)	(n=705)
51.27%	50.21%	6.42h

3.6.6.2 Self-report and objective data on sleep quantity. High variability in self-reported sleep quantity was found, with percentages of participants falling below the threshold for adequate sleep ranging between 19-80%. Moreover, aggregated self-report data on total nightly sleep duration found a mean sleep duration of 6.42h, which falls short of the recommended 7-9hrs. Data from actigraphy studies (presented below in Table 3.5) was aggregated to show a mean ‘Total Sleep Time’ of 6.85h (n=106). In adults, sleep efficiency

(SE) of 95% is indicative of a good night's sleep. For the aggregate group, SE was 87.49%, which indicates a moderately poor night's sleep. The 'Wake after Sleep Onset' (WASO) score for the aggregate group (n=66) was 37.26m (9.1%). Normal adult scores are below 10% or 42 minutes of a 7h sleep. Finally, across 98% of self-report data, 51.3% of participants were not reaching recommended sleep duration. Notably, aggregated actigraphy data on sleep duration returned a similar weighted mean of 50.21% sleeping <7h.

Table 3.5. Actigraph Data on Sleep Duration for Caregivers

Study	Sample n=	Patient Age	Total Sleep Time in hours	Sleep Efficiency in %*	Wake After Sleep Onset in minutes**
Feeley, 2021	18	9.6yr	7.6h	88.16%	32.98m
Macaulay	16 (mother 7; father 9)	8.7yr	7.2h	93.1%	34m
Morrow	40	8.1yr	6.7h	87.0%	
Cobry, 2020	19	13.9yr	6.47h	84.8%	40.6m
Landau	13	9.3yr	6.36h	85.1%	42.4m
Aggregated Findings	TST; SE n=106 WASO n=66	9.6yr	6.85h	87.49%	37.26m (9.1%)

*In adults, 95% sleep efficiency indicates a good night's sleep; less than 80% indicates a bad night's sleep.

**The value considered normal in adults is <10% of total sleep minutes or 42 minutes for a person who sleeps 7h/night (420 mins) (Berger et al., 2007).

3.6.6.3 Sleep quality. Eleven studies deployed the Pittsburgh Sleep Quality Index (PSQI) to explore caregiver sleep quality (see Table 3.6 below). With a global score range of 0-21, a score of >5 is an indicator of a clinically significant level of poor sleep (Buysse et al., 1989). Fifty-four percent of 663 parent caregivers returned scores >5, while the mean global score was 7.06 (n=404), Macaulay et al. (2020) found a notable difference between maternal and paternal scores (8.7 and 5.7 respectively). Five studies reported on the

percentage of caregivers (n=790) who agreed that NCP disrupted their sleep, with a mean of 59.9% (range 58-79%). In addition, Burckhardt et al. (2019) asked 60 participants to rate the impact of NCP on sleep on a 7-point scale (0=never; 7=always); the median recorded score was 5, suggesting significant impact. In Lindstrom et al. (2011), of participants scoring over a threshold for clinical burnout, 64% of mothers and 38% of fathers reported NCP driven sleep disruption. Finally, a study of maternal caregivers (n=75) found 49.3% slept less than the required 7h, in comparison to 26.5% of controls (n=49) (Bahadur et al., 2022).

Table 3.6. Caregiver Sleep Quality utilising Pittsburgh Sleep Quality Index (PSQI) (Buysse et al., 1989)

Study	Sample n=	% global score >5 (indicating poor sleep quality)	Mean global score
Bahadur	75	46.6%	
Feeley, 2021	18		8.1
Herbert	134		7.07 (1-15)
Jaser, 2017	515	53%	
Macaulay	20 (10/10)	90% mothers 49% fathers	8.7 mothers 5.7 fathers
Morrow	40	76%	7.97
Bisio	13		10.15
Burckhardt, 2018	49		7.7
Cobry, 2020	24		7.41
Cobry, 2021	93		5.9
Landau	13	46.2%	4.9
Aggregated Findings	663	54.02%	
Aggregated Findings	404		7.06

3.6.6.4 Other Impacts for Caregivers from NCP. Barnard et al. (2016) documented other reported impacts of NCP; exhaustion (60%), poor concentration and lack of focus (28%), next day poorer performance (22%), bad mood and impatience (17%), anxiety and depression (16%). Similarly, Macaulay et al. (2020), found that sleep disturbance affected cognitive, emotional and physical health to varying degrees; fatigue (85%), mood and

stress (50%), work performance (40%), cognitive function (40%), exercise (30%), relationships (25%), and lastly, impacting on diabetes management (20%).

Six studies contained relevant qualitative data, several referred to the experience of ‘sleep problems’ resulting from NCP; reduced ability to fall asleep (Bergner et al., 2018) or to return to sleep after NCP (Feeley et al., 2019). Analysis of qualitative data identified 3 novel themes; ‘Physical Impacts’, ‘Social and Emotional Impacts’ and ‘Impacts on illness management’ (see Table 3.7). Physical consequences from sleep disruption were extensive and included exhaustion, poor concentration, poor performance at work, daytime dysfunction, cognitive deficits, stress, weight gain, poor lifestyle choices, migraines, difficulties driving, low energy and health problems. Social and emotional impacts included poor mood, anxiety, depression, feeling isolated, emotional distress, worry, reduced wellbeing, low patience, irritability and negative impacts on relationships. In addition, across studies, some participants spoke about the effects of sleep disturbance on T1D illness management.

Table 3.7. Impacts from NCP: Themes and Quotes

Themes	Quotes
Physical and Cognitive Impacts	‘Exhaustion. It is torture’ (Barnard et al., 2016) ‘...some nights the exhaustion holds me like a straight-jacket...’ (Oser et al., 2017) ‘Well, it definitely makes me tired. During the day I feel like you’re back in the stage where you have a new-born and you’re up all the time’ (Carreon et al., 2021) ‘I can’t even function and focus on what I need to be doing at work’ (Macaulay et al., 2020)
Emotional and Social Impacts	‘...affects relationships with family and friends as not enough energy. One of my friends said ‘it has lost a part of me’’ (Barnard et al., 2016) ‘...every 2 hours waking up is hard. I mean, it makes me really cranky the next day’ (Bergner et al., 2018) ‘...moods probably, stress levels go up when you’re tired too because you’ve less of an ability to handle something’ (Macaulay et al., 2020) ‘...when we haven’t had any sleep, in the way that we all interact with each other and the happiness that flows around the house’ (Macaulay et al., 2020)

Impacts on Illness Management	‘...it’s hard to make good decisions when you are exhausted’ (Barnard et al., 2016) ‘I have bloused her...in the middle of the night out of habit...she should only be getting a correction’ (Barnard et al., 2016) ‘When I reach the point of utter exhaustion, I will let high numbers go uncorrected if it means I get a few more minutes of sleep’ (Barnard et al., 2016) ‘...if the brain’s not working all that well then at night you might not make the most logical decisions...’ (Macaulay et al., 2020) ‘...I’ll wake up and wonder why I did that...things like forgetting to bolus...or turning off basal for two hours instead of one and she wakes up high’ (Macaulay et al., 2020)

3.6.6.5 Impact on Health-Related Outcomes for Patients. In Monaghan et al. (2012), researchers looked to establish whether frequency of NCP could have a positive impact on illness outcomes, utilising A1c as a proxy for illness management, no relationship was found. Similarly, in De Beaufort et al. (2021), researchers found no association between parental sleepiness and A1c and in Monaghan et al. (2009), no differences were found in A1c between those who engaged in NCP rarely/never, sometimes or often/always. Furthermore, findings from other studies suggest that parents of children with higher A1c scores (suggesting poorer blood glucose management) had worse sleep (Feeley et al., 2021; Herbert et al., 2015; Morrow et al., 2022).

3.6.7 Value of Technology for Reducing Nocturnal Burden

Three studies utilised actigraphy to measure the effect that use of illness-management technology (CGM; closed loop) had on caregiver sleep quantity (Bisio et al., 2021; Cobry et al., 2020; Landau et al., 2014). Participant testimony enhanced these findings with qualitative data.

3.6.7.1 Quantifying the impact of technology on caregiver sleep. Aggregated actigraphy findings from the technology group showed a total sleep time of 6.51hr, sleep efficiency of 88.3% and WASO of 37.5min (see Table 3.8). Two studies reported pre- and post-

technology intervention actigraphy data; with aggregate total sleep times of 6.43h and 6.27h respectively, indicating that no benefits for sleep were found for these cohorts (see Table 3.9).

Table 3.8. Actigraph Data for Caregivers using Technology for Illness Management Support

Study	N=	Mean Age in years	Total Sleep Time in hours	Sleep Efficiency* in %	Wake after Sleep Onset** In mins
Bisio (a)	13	9.1	6.51	93.04	30.57
Landau	13	9.3	6.12	84.7	48.3
Bisio (b)	13	9.1	7.06	92.85	33.17
Cobry, 2020	19	13.9	6.38	84.4	37.8
Aggregate	58	10.7	6.51	88.3	37.5m (9.6%)

*In adults, 95% sleep efficiency indicates a good night's sleep; less than 80% indicates a bad night's sleep.

**The value considered normal in adults is <10% of total sleep minutes or 42 minutes for a person who sleeps 7h/night (420 mins) (Berger et al., 2007).

Table 3.9. Actigraph Data: Pre- and Post-Technology Intervention

Study	N=	Mean Age (years)	Total Sleep Time (hours)	Sleep Efficiency (%)	Wake after Sleep Onset (min)
Cobry, 2020; Landau Baseline	32	12.03	6.43	84.92	41.3m (10.7%)
Cobry, 2020; Landau Post-intervention	32	12.03	6.27	84.5	42.13m (11.2%)

3.6.7.2 Caregiver experience of technology and sleep. Eight studies gathered qualitative data on nocturnal caregiving while exploring the effectiveness of technology-based interventions for illness management (total n=194; see Table 3.10). Themes have been given representative frequencies (x/8), presented as percentages. Two overarching themes were identified: 'Benefits' and 'Costs & Barriers', with a number of sub-themes in each.

Table 3.10. Themes and Sub-Themes for Perceived Value of Technology for Reducing Burden of NCP

Theme 1: Benefits of Technology	
Subtheme (%)	Caregiver Quotes
Improved Sleep (100%)	‘I started to feel human again, rejuvenated, could tackle the world, I was getting sleep’. (Feeley et al., 2019) ‘I sleep better, I am calmer’ (Monaghan et al., 2009) ‘First time we as parents were able to sleep the night straight since diagnosis’ (Lindström et al., 2011)
Reduced Anxiety (88%)	‘We were sleeping better because we had that safety and more comfort’ (Haugstvedt et al., 2011) ‘I can go to sleep as it will go off if she has a low’ (Feeley et al., 2019)
Positive Impact on NCP (50%)	‘Not sort of either having to check on her every 2h’ (Feeley et al., 2019) ‘I can just roll over have a quick look and go back to sleep. So you’re getting up less, possibly waking more’ (Haugstvedt et al., 2011) ‘...not having to drag yourself out of bed testing at 2 or 3 o’clock in the morning...’ (Abitbol & Palmert, 2021)
Reduced Nocturnal Hypos (38%)	‘...less hypoglycaemia because at night time we would have that alarm to stop it from happening...’ (Haugstvedt et al., 2011)
Better Control (38%)	‘The whole next day her blood sugar would be great’ (Barnard et al., 2016) ‘Numbers were perfect’/ ‘Didn’t want to give it back’ (Abitbol & Palmert, 2021)
Sharing of Burden (38%)	‘...it made him [partner] more present and more able to have a role in the care’ (Feeley et al., 2019)
Theme 2: Costs & Barriers	
Technology Issues (63%)	‘Sometimes we just find it’s disconnected, and we don’t really know why’ (Haugstvedt et al., 2011) ‘Sometimes in the middle of the night the signal is lost...the CGM won’t beep’ (Herbert et al., 2015)
Trust and Accuracy (38%)	‘...I check the blood...those differences scare us’ (Jaser et al., 2016)
Alarms as mixed blessing (38%)	‘...it wasn’t giving accurate readings and it was alerting the whole house a thousand times’ (Herbert et al., 2015) ‘...we had a problem...it was alarming all the time’ (Abitbol & Palmert, 2021) ‘Somewhere, a CGM alarmed and into the story enters Diabetes as a main antagonist’ (Oser, 2017)

Constant Flow of Data (25%)	‘...too much information’ / ‘It fed into the fact that I was so anxious about it. It kinda wasn’t worth it for me’ (Herbert et al., 2015)
Physical Discomfort (25%)	‘The insertion system I think is horrific. It’s a big needle. It’s gonna hurt’ (Herbert et al., 2015) ‘...she’d to wear this great big sensor, the pumps and then this great big computer’ (Barnard et al., 2016)

The strongest finding present as a theme in all eight studies, was that sleep improved through use of technology. In the main, participants found that requirements to engage with NCP were reduced or made more manageable. For instance, in Elbalshy et al. (2020) participants reported that easy access to blood glucose levels and information on trends, as well as alarms, reduced disease burden and improved sleep quality. However, significant numbers of participants found that technology increased their nocturnal burden of care by prompting increased night-time vigilance through availability of data and alarms (where research alarm settings were reported there was wide variation (Burckhardt et al., 2018)). Lastly, in Cobry et al. (2020), 17% of participants left the study as they experienced the technology as disruptive.

3.6.8 Solutions and recommendations

Data across all the studies in the review was analysed in order to generate recommendations for potential interventions and approaches to mitigate or moderate nocturnal caregiver burden. This was achieved by examining both the participant caregiver perspective and the conclusions drawn by the studies’ authors.

3.6.8.1 Solutions from the caregivers’ perspective. With the exception of Macaulay et al. (2020), generating qualitative data on potential solutions or approaches to address NCP burden was not a stated aim of any of the studies. Nonetheless, considerable data was identified to address this. Analysis revealed two dominant sub-themes. Firstly, a desire

among participants for ‘access to technology’; ‘He has a glucose monitor that will alarm of [sic] he goes too low or too high so there have been nights that I’ve slept all the way through’ (Carreon et al., 2021). Indeed, 50% of participants in Macaulay et al. (2020) were optimistic about the potential for technologically supported, blood-glucose measuring and remote monitoring to relieve nocturnal burden, although authors’ note that ‘some [participants] were unaware that this technology existed’. In addition, there is some evidence that parents with greater ‘fear of hypoglycaemia’ utilised more technology, the direction of this relationship is uncertain (Van Name et al., 2018). The second sub-theme was ‘support’, which was also seen as key to burden relief, for example, caregiver advocacy blogs and online peer support were experienced as helpful; ‘[Peer support] knowing there are others out there going through the same things helps other people so much’ (Oser et al., 2017). Overall, shared responsibility for primary caregiving as well as respite opportunities were considered to be the most helpful options. Furthermore, participants felt that clearer guidance from the diabetes clinic would be beneficial. In Sullivan-Bolyai et al. (2003), some caregivers felt that this aspect of caregiving was not recognised in clinical care settings, and it was found that mothers with the least support resources (internal and external) experienced more anger and overwhelm.

3.6.8.2 Solutions from the researchers’ perspective. Across 23 relevant papers within the review, conclusion sections and recommendations were analysed thematically to explore the proposed changes that authors felt could potentially reduce NCP burden or increase benefits for this caregiving cohort (see Table 3.11 below). Themes and sub-themes are given representative frequencies (x/22) to deepen interpretation, these are presented as percentages.

Table 3.11. Author Conclusions and Recommendations

Theme 1: Address Nocturnal Caregiving Routinely in Clinic 83%	
Sub-Themes	Quotes
Ask about it 70%	‘Given how common sleep disturbances are in this population, diabetes care providers should ask about sleep as part of routine clinical practice...’ (Morrow et al., 2022) ‘Partnership with the family is key to providing parents with the support and recognition that they deserve, considering the care they are providing’ (Sullivan-Bolyai et al., 2003)
Offer support or behavioural interventions 44%	‘...intervention for sleep and mental health can increase the quality of life of both the children with T1DM and their parents’ (Bahadur et al., 2022) ‘...family-based interventions, aimed to support parents in managing their child’s diabetes have had positive effects on glycaemic control as well as parent-child relationships’ (de Beaufort et al., 2021)
Promote realistic view of technology 22%	‘...families should be aware of the potential for such [tech] devices to also contribute to sleep disruption.’ (Macaulay et al., 2020) ‘...mixed blessing of frequent information about BF levels and increased opportunities for fine-tuning management’ (Monaghan et al., 2009)
Sleep Education 26% and Caregiving Guidelines 17%	‘Health-care providers are in a unique and important position to reinforce the importance of sleep’ (Feeley et al., 2021) ‘Parents would likely benefit from guidelines regarding night-time T1D management’ (Herbert et al., 2015)
Encourage sharing of burden 9%	‘Paediatric diabetes teams...encourage shared nocturnal care between caregivers/parents’ (Macaulay et al., 2020)
Theme 2: Research and Innovation 57%	
Sub-Themes	Quotes
Predictors and associations for NCP 44%	‘...analyse associations between...[A1c] and treatment-related variables’ (Haugstvedt et al., 2011) ‘[explore] factors causing sleep disruption’ (Bispham et al., 2021) ‘...understand how poor sleep affects the health outcomes of parents’ (Bispham et al., 2021)
Value of technology to ease nocturnal burden 26%	‘...fully investigate the effect of new diabetes devices such as CGM and insulin pump on sleep and behaviour’ (Bahadur et al., 2022) ‘...impact of these devices on parental sleep warrants further evaluation...’ (Cobry et al., 2021)
Actigraphy 22%	‘It is recommended that objective measures of sleep, such as actigraphy, be incorporated in study designs...’ (Herbert et al., 2015)

The first theme; ‘Addressing Nocturnal Caregiving Routinely in Clinic’ was prevalent in 70% of studies. Among the subthemes, ‘ask about it’ had strongest representation. Offering non-specified support or intervention in clinic was also strongly represented as a sub-theme, while more specified intervention suggestions included sleep education, improved guidelines for nocturnal care, promoting shared care duties and a more nuanced approach to education on the benefits of technology. A second theme ‘Research and Innovation’ had two dominant subthemes; ‘predictors and associations for NCP’, where research to explore modifiable characteristics was envisaged, and ‘value of technology’, where further and more detailed exploration of the potential for technology to ease the burden was proposed. Lastly, it was proposed that future research would benefit from the inclusion of objective data collection on sleep using actigraphy technology.

3.7 Discussion

Study 1 has firmly established NCP as a common feature of caregiving for juveniles with T1D among a large sample of caregivers (n=3,547), echoing the concerns voiced by researchers working with smaller sample populations that T1D is “a disease that requires 24-hr vigilance” (Feeley et al., 2019; n=22). It has shown that NCP generates a sustained and significant burden for caregivers that has real-life impacts, which are in line with those experienced by caregivers for children with other chronic diseases; “depression and anxiety...elevated rates of negative daytime functioning” (Meltzer & Moore, 2008). This is particularly unwelcome when considered in light of the knowledge that poor caregiver wellbeing can also impact negatively on children’s physical and mental health outcomes (Pierce et al., 2017; Pena-Shaff et al., 2023), and that poor parental sleep quality has been associated with lower self-efficacy for diabetes management (Herbert et al., 2015).

The review found significant levels of variability in NCP among the studies (Abitol & Palmert, 2021; Barnard et al., 2016; Monaghan et al., 2012). Establishing the aggregated mean across this large sample group was valuable. For international care guidelines to acknowledge this aspect of the caregiver experience, a clear picture of behaviour patterns is required. A reasonable summary of this evidence proposes that approximately a third of caregivers engage in NCP infrequently or never (Monaghan et al., 2012), a third with moderate frequency (Burckhardt et al., 2019) and a third frequently (always or multiple times nightly) (Herbert et al., 2015). This was the case despite the inclusion of secondary caregivers in some larger study cohorts (Haugstvedt et al., 2011; Lindstrom et al., 2011). This aligns with the limited studies in the area, which do “consistently demonstrate that parents of children with T1D experience poor sleep quality” (Perez, 2018). Nevertheless, the scale of the issue is striking, particularly when considered in the context of the findings on impacts for caregivers that are reflected in the qualitative evidence, e.g., “It’s 24/7. There’s never a break. There’s never a vacation” (Carreon et al., 2021).

Overall, findings indicated that NCP was rarely addressed by healthcare professionals (HCPs) in clinical care provision (Macaulay et al., 2020; Sullivan-Bolyai et al., 2003; Feeley et al., 2021) and that the consequences for caregivers are often underappreciated by HCPs (Barnard et al., 2016). A number of authors in the studies reviewed speculated on the cause; Feeley et al. (2019) felt that clinicians had a large amount of information to impart and therefore NCP may be overlooked, Macaulay et al. (2020) felt that recommendations for NCP were deliberately vague to accommodate individual differences, while Haugstvedt et al. (2011) argued that it was challenging for HCPs to find a balance between delivering realistic information regarding risk without potentially stimulating fear and anxiety in parent caregivers. It is likely that all the arguments provide valid explanations of contributory factors. Furthermore, several authors in the review agreed with Silverstein et al. (2005), noting that globally, clinical care

guidelines do not address nocturnal caregiving or provide recommendations (Bergner et al., 2018; Carreon et al., 2021; Herbert et al., 2015; Jaser et al., 2017; Monaghan et al., 2012). In addition, 29% of the articles made explicit reference to the lack of supporting literature, describing NCP as ‘overlooked’ and ‘understudied’ (Carreon et al., 2021; Feeley et al., 2019; Bispham et al., 2021; Macaulay et al., 2020; Abitbol & Palmert, 2021).

Enquiry into variables that may moderate or predict the behaviours did not appear to identify any substantially influential factors, with studies reporting contradictory findings. For example; the lowest proportions of participant caregivers engaging in NCP (68%) utilised one of the youngest sample patient cohorts in the review (mean 4.5 years of age) (Monaghan et al., 2009), but in Jaser et al. (2016), with a patient sample of similar age profile (mean 4.1 years), 100% of the caregivers reported engaging in NCP. These findings are indicative of the complexity of the issues at play. We know that a deep understanding of behavioural determinants is key for the development of behavioural and psycho-social interventions in the health domain (Bauman et al., 2002). This review clearly indicates that more, high-quality research is needed to explore the causal relationships.

Arguably, the most important body of data to emerge from study 1 relates to the impacts from NCP. Unsurprisingly, the most direct impact from NCP is on caregiver sleep. Interestingly, in Carreon et al.’s (2021) study, no questions on sleep were posed but nevertheless, 68% of parent-caregiver participants mentioned it in their responses. At a higher-level, it is notable that in the review sample overall, more than half of participants were not achieving the recommended sleep duration of 7-9 hours. To appreciate the significance of this finding it is important to recognise that 7 hours is the *minimum* requirement for sleep (Hirshkowitz et al., 2015). This research provides a cross-sectional analysis of what is, in actuality, an ongoing experience that may potentially endure for years (Sousa et al., 2023). In Feeley et al. (2019), participants reported that they required 8.5 hours sleep per night to feel their best.

As far back as 2003, authors Sullivan-Bolyai et al., stated that a particularly important finding from their study was the health problems that caregiving mothers attributed to the burden of providing of around-the-clock care to their child. Although Feeley et al. (2019) noted that ‘meaningful questions’ need to be asked about the health of sleep-deprived caregivers and Macaulay et al., (2020) reported some physical health impacts from sleep disturbance, surprisingly little data was gathered in the intervening years on caregiver personal physical health and its association with chronic sleep disturbance.

Prevalence levels of NCP appear to remain consistent whether technology (CGM. CSII) is utilised or not, which aligns with emerging literature (Macaulay et al., 2020; Aouchiche et al., 2024). Furthermore, this time aligning with evidence on the value of technology for beneficial non-medical outcomes in T1D (Jaser et al., 2017; Bahadur et al., 2022; Perez et al., 2018), the review found contradictory evidence on the impact of technology on caregiver sleep, which interestingly did not appear to translate into a negative user experience. Indeed, Landau et al. (2014) reported that although nocturnal awakenings increased with use of CGM, self-perception of sleep quality remained unchanged. Qualitative data on the perceived value of technology was also conflicted (Abitol & Palmert, 2021; Haugstvedt et al., 2011) but it suggested that a powerful mechanism for improved caregiver sleep (and tolerance for physical burden associated with technologies) may be located in the psychological benefits of reduced anxiety found with automated blood glucose monitoring, bolusing and alarms (Haugstvedt et al., 2011; Abitol & Palmert, 2021; Feeley et al., 2019). Indeed, across the studies, the majority of participants were willing to sustain some increased burdens (sleep or other) in order to achieve reduced anxiety or illness benefits for the patient (Landau et al., 2014; Carreon, 2021). This is an important insight, given the significant levels of associated burden documented here, and in the literature (Tanenbaum & Commissariat, 2023). Finally,

growing evidence on the closed-loop system (combining the technologies) strongly suggests that it is “a promising device” for addressing the NCP burden and improving caregiver sleep (Perez, 2018). While more positive developments are anticipated, it is important to remember that a digital divide exists here as elsewhere. Research must be cognisant that significant numbers of caregivers/patient dyads will not have access and that not all children will choose or will tolerate the technologies (Gajewska et al., 2021; Gajewska, 2022).

3.8 Limitations

Due to heterogeneous nature of data collection methods among included studies, it was not possible to carry out overarching meta-analyses. Also, variations in eligibility criteria across studies may have impacted on the data. The quality assessment highlighted a lack of stakeholder involvement in the research (only 10% of studies scoring 2 or above). With caregiver lived experience the focus of many enquiries, it is likely that patient experts could have offered useful insights to drive research design. In addition, few of the studies reported purposive recruitment of primary caregivers, hence findings may to some degree represent the amalgamated experience of primary and secondary caregivers. Lastly, mean HbA1cs of patient samples, in many studies, were not representative of the general population of juveniles with T1D.

3.9 Conclusion

It is clear that the findings from study 1 provide powerful evidence that issues related to NCP are pervasive and significant negative impacts are endured. Nineteen studies (83%) proposed that addressing NCP routinely in clinical care was key to supporting this community of caregivers. Information to direct stakeholders on approaches

to alleviating this burden are contained in this group of studies, further work is needed that responds to this evidence.

The following chapter describes a PPI collaborative engagement that builds on Study 1 employing a novel participatory approach by engaging a PPI panel to conduct a secondary analysis of the findings from this SLR, identifying key themes and issues of concern from the lived-experience perspective.

Chapter 4. The Lived Experience Perspective on Nocturnal Caregiving in T1D

Literature: A secondary analysis

4.1 Abstract

The nocturnal caregiving burden for parents of juveniles with T1D is significant but underexplored in research to date. To address this, study 1, a systematic literature review (SLR), was carried out to capture and aggregate relevant data. This chapter describes a secondary analysis of the 31 publications identified by this SLR, utilising a ‘participatory research’ approach, whereby a lived-experience researcher carried out the analysis in collaborations with a panel of experts by lived experience (n=4). The aim was to respond to the research, interpret the findings and identify issues, through the lens of personal, lived experience. Using reflexive thematic analysis as a tool for systematic expert synthesis, five high-level themes were identified: (1) Distributed knowledge; (2) Maternal burden; (3) Are these conclusions relevant for me? (4) What about the confounders? and (5) Outstanding questions. These findings should be considered for future research designs in juvenile T1D to facilitate study outcomes that more accurately reflect the concerns and interests of parent caregivers and their children. This PPI collaboration has demonstrated the value of patient participation in every stage of the health research process.

4.2 Introduction

As discussed previously, throughout the research journey the primary researcher engaged in a variety of reflexive activities that were designed to uncover and address issues related to bias and positionality, as they arose. In the course of carrying out these reflexive activities and conducting the analytic process for the SLR, the researcher noted a number of issues within the body of literature, which it was believed would not have been evident to individuals without personal lived experience of the phenomenon of interest.

The researcher had recently established a public and personal Involvement (PPI) panel to collaborate on the project and concluded that carrying out a secondary review of the SLR findings, in collaboration with the PPI panel, may reveal novel insights that would be valuable for informing the subsequent stages of this research.

4.3 Background

As previously discussed, T1D is a chronic autoimmune disease, typically diagnosed in childhood. Prevalence rates vary globally, but approximately 1 in 400-600 will receive a diagnosis (Mobasseri et al., 2020). Caring for children with T1D requires around-the-clock care, but little attention has been given to the impact that nocturnal caregiving practice (NCP) has on families. The systematic literature review (SLR) described in Chapter 3 was conducted to explicate nocturnal parental caregiving for juveniles with T1D. The SLR aimed to establish the prevalence of NCP, explore associations and predictors, impacts and the role of technology (Howard et al., 2025). The purpose of this follow-up study was to carry out a secondary analysis of the findings from the SLR, interpreting the findings from the perspective of a panel of experts by lived experience. The objective was to evaluate the findings and identify issues or aspects of the evidence that were notable and evident to individuals with the perspective of close personal experience of the condition but not highlighted by the research. The SLR included thirty-one peer-reviewed papers (21 quantitative, 7 qualitative, 3 mixed-methods; n = 3,547 parent caregiver participants).

4.4 Methods

4.4.1 Design

This collaboration employed a qualitative PPI consultation design in line with HSE guidance on public and patient engagement in health research (Minogue, 2021). The **PPI** consultation framed caregivers as active collaborators, contributing perspectives to shape

the development of forthcoming studies on this PhD project. As this was a PPI activity rather than primary research, ethics approval was not required. Nonetheless, principles of consent, respect, transparency, and reciprocity were adhered to and confidentiality of discussions were upheld. This collaboration adopted a constructivist standpoint, emphasising the co-construction of knowledge and the subjective experiences of panel contributors. Braun and Clarke's (2023) Reflexive Thematic Analysis (RTA) framework was utilised as a tool for systematic expert synthesis and move toward consensus. It was chosen as it offers a flexible approach to identifying, analysing, and interpreting patterns of meaning within qualitative data. Critically, this method emphasises the researcher's active role in theme development and encourages reflexivity throughout the analytic process, making it particularly suitable for exploring complex, context-dependent data (Byrne, 2022).

4.4.2 Recruiting the PPI panel

As outlined in Chapter 2, the PPI panel was recruited to support the research activities of this PhD research. Panel members with lived experience of the health condition under consideration were recruited through personal and support group networks using a combination of convenience and purposive sampling methodologies. Efforts were made to ensure diversity, inclusion and representation. Six panel members were recruited, of these, four chose to engage with this PPI collaboration. Here, panel members included two fathers and two mothers of juveniles with T1D. One individual was also living with T1D themselves, three used technology and all had children who had been living with this diagnosis for 1+ years.

4.4.3 Procedure

Over the course of a month, collaborative consultations were conducted via two formats: Four group workshops were facilitated by the researcher and held either in-person (twice) or online (once), depending on contributor preference. One contributor who was unable to attend the group sessions was accommodated by three one-to-one consultations. Workshop sessions followed a semi-structured agenda (introduction, open discussion, loosely defined outcome objectives), designed to balance information-sharing with open dialogue. This was replicated in the one-to-one sessions.

4.4.4 Data recording and analysis

Detailed field notes were taken during all workshops and consultations. Summaries were returned to contributors to ensure their views had been represented fairly. The process of carrying out the secondary analysis was multi-staged and iterative. Feedback was analysed using RTA, which takes an inductive approach. Specifically, there were seven stages as follows:

Stage 1: The researcher carried out the incipient SLR analysis.

Stage 2. Initial findings were summarised and presented to the expert panel of caregivers and feedback was elicited in the first consultation (workshop and one-to-one discussion).

Stage 3: The feedback was compiled and consolidated by the researcher.

Stage 4: The consolidated feedback was presented to the panel in the second consultation, further discussion ensued.

Stage 5: The researcher carried out a thematic analysis on the collaboratively generated data from both consultations.

Stage 6: An initial, speculative theme map with findings was presented to the panel in consultation 3. A process of iterative questioning, summarising and discussion was carried out until a consensus understanding on the themes was achieved.

Stage 7: A refined theme map was developed and presented at a final workshop/one-to-one discussion, this facilitated discussions leading to the development of five final themes with subthemes. A high level of convergence was sought for each included theme. Only themes that reached 80% consensus among the participatory contributor group were included.

4.4.5 Reflexivity

The researcher maintained a reflexive stance throughout, acknowledging that their dual positionality may have shaped the consultation process. To mitigate potential power imbalances, the value of experiential knowledge was emphasised and SLR findings were provided in accessible language to support understanding.

4.5 Results

4.5.1 Theme 1: Distributed knowledge

Given the collaborative nature of T1D care (patient/caregiver with HCP), as well as the active role required of the patient/caregiver, it was surprising that only two out of 31 studies referenced stakeholder input in the methodology. Quality assessment found only 10% of the studies were deemed to be of moderately high quality or above for the item that identifies; ‘evidence that stakeholders have been considered in the design or conduct’. One study developed a questionnaire with a multi-disciplinary team including individuals with T1D, while another developed research materials with a team of experts, but no patient involvement (Barnard et al., 2016; Bergner et al., 2018, Howard et al., 2025).

4.5.2 Theme 2: Maternal burden in nocturnal caregiving

Across studies reporting caregiver participant gender, 77-100% were female. Interestingly, samples including more fathers appeared to capture a different profile of caregiving behaviour. In Haugstvedt et al. (2011, cited in Howard et al., 2025), utilising a sample that was 48.5% male, only 27% of all the participants engaged in NCP ≥ 1 per week - the lowest rate found in the studies reviewed. Given that few caregivers report sharing night-time duties and that more equal division of burden with greater appreciation of a partner's efforts decreased maternal emotional distress (Feeley et al., 2019; Haugstvedt et al., 2011, cited in Howard et al., 2025), highlighting issues related to gender and caregiving roles is necessary to support the identification and prioritisation of targets for intervention and to discern requirements for support.

4.5.3 Theme 3: Are these conclusions relevant for me?

The review included 23 studies that reported mean sample HbA1cs ($n=2,889$). Only one study, Jaser (2017, cited in Howard et al., 2025), used a sample from a clinic and reported both the sample mean A1c and the full, clinic-wide mean A1c (7.8% and 8.4% respectively). The clinic mean serves as a good reference for comparison across the other studies; two studies reported sample means of 8.4%, two reported means above 8.4% and most ($n=19$) reported mean A1cs below 8.4% (lowest = 7.2%). These are significant variations, as shown by the EDIC (epidemiology of diabetes interventions and complications) observational study where a 1% HbA1c increase was shown to be equivalent to an increased risk of T1D complications, which was found to be equivalent to 5.6 - 18 additional years of living with T1D (Bebu et al., 2020).

4.5.4 Theme 4: What about the confounders?

Analysis of studies, revealed a number of issues or confounding factors, challenging the credibility of some findings for patient-researchers. Lived experience suggests that the variables identified below would have almost certainly influenced study outcomes if they were not controlled for.

4.5.4.1 *Treatment regimens.* Many caregivers have experience of a variety of treatment regimens, syringes, insulin pens or pumps for dosing insulin, finger stick blood glucose testing, flash or continuous glucose monitors. Each scenario brings different burdens and challenges. These data were undifferentiated in the majority of studies, making it difficult to find the resulting conclusions convincing.

4.5.4.2 *Alarm settings and target ranges.* Few studies reported the settings used on assistive technologies. For example, Buckhardt et al. (2018, cited in Howard et al., 2025) found that among 49 participants; “most chose a low [blood glucose] alert setting between 3.1 and 5.3 mmol/L, and high alert between 8.0 and 20.0 mmol/L”. Where programmed settings on illness-management tools are not explicitly referenced or vary to this degree, it’s difficult to draw meaning from some of the research outcomes.

4.5.4.3 *Honeymoon period.* The ‘honeymoon period’ is the time it takes for the diseased pancreas to stop producing insulin entirely. During this time illness management can be significantly easier as endogenous insulin is still being produced. It is commonly regarded that a honeymoon period can last up to one year (Sokołowska, Chobot, & Jarosz-Chobot, 2016). While most of the studies referenced a minimum required length of time since diagnosis in their recruitment criteria, these varied significantly (3–12 months), weakening the evidence as the inclusion of ‘honeymooning’ data may obscure and/or dilute findings.

4.5.5 Theme 5: Outstanding questions of particular interest to caregivers

This theme includes topics that were identified as being of specific interest from the lived experience perspective.

4.5.5.1 Effectiveness of NCP. Important questions for parents are whether NCP benefits their child's health and, if it does, what are the optimum levels for balancing burdens with benefits. Only two authors addressed the first question (Monaghan, 2012, 2009; De Beaufort et al., 2021, cited in Howard et al., 2025), with none addressing the second question. No relationship between caregiver sleep and better patient health outcomes was found, however this does not align with lived experience or with evidence across the SLR studies as a whole, where high levels of NCP were found (88% across participants) and, as detailed above, the patient group reported significantly better health outcomes (as measured by A1c) than clinic means.

4.5.5.2 Hyperglycaemia. Hyperglycaemia management and mitigation is almost never mentioned in the NCP literature. Feeley et al., (2019, cited in Howard et al., 2025), uses the labels 'anxiety about blood glucose levels' and 'anxiety about hypoglycaemia' interchangeably, even though these are not in effect the same thing because 'blood glucose levels' could be low (hypoglycaemic) or high (hyperglycaemic). For some parents, the benefits of tight management of hyperglycaemia during the night means that day-time management can afford to be slightly less restrictive for the child. Not all parents can engage at this level. It was felt that it would be critical to have the benefits of this facet of NCP justified and validated by this research.

4.5.5.3 *Myth of overnight blood glucose stability.* Throughout the literature reviewed, there was a marked absence of discussion on overnight blood glucose instability. Evidence is growing, through use of new glucose monitoring technologies that supports what many caregivers have known from their own experience, which is that much greater nocturnal fluctuations in blood glucose occur overnight than previously thought (Gardner et al., 2025). Research is required that responds to these findings.

4.5.5.4 *Secondary harms for caregivers.* In Sullivan-Bolyai et al. (2003), authors commented on caregiving mothers reporting health problems that they attributed to the impact from caregiving burden. Only three of the other studies identified by the review, from the following 20 years of research, acknowledged this issue and the majority of data referenced by them was only captured when caregivers incidentally reported impacts from NCP.

4.5.5.5 *Is the construct ‘Fear of Hypoglycaemia’ fit for purpose?* This final sub-theme emerged from the consultation as possibly the panel’s foremost area of concern with this body of literature, where the researcher and the PPI panel agreed strongly that the characterisation of parental concern over nocturnal hypoglycaemia as ‘maladaptive’, leading to poor illness management (Abitol and Palmert, 2021; Burckhardt et al, 2019) was not acceptable and felt that a deeper exploration of the topic was required. Studies 2 and 3, described in the following two chapters, addressed these concerns.

4.6 Discussion and Conclusion

This novel approach to participatory research found that the body of literature on nocturnal caregiving for juveniles with T1D uncovered in Study 1 contains unintentional biases and confounders that somewhat limit its generalisability and utility. By spotlighting

details in the research that were apparent to them but had not been emphasised in the literature, such as the lack of acknowledgement of nocturnal hyperglycaemia and its role in nocturnal care, the panel provided valuable insights that could enhance the relevance and completeness of future research in the area, as well as the real-world applicability of their conclusions. The panel also identified aspects of the findings that did not align with their lived experience (e.g., unmanaged confounding variables such as technology settings), which are factors that are likely to impact on the validity of findings. Furthermore, they made recommendations for future research based on gaps they noted in the body of literature, such as exploring the effectiveness of NCP on illness outcomes like HbA1c.

With regards to this PhD research, all of the themes that emerged from the PPI consultation impacted, to some degree, on the PhD research agenda as well as on the design of data collection instruments, as illustrated by the following examples: Firstly, where possible, research was designed to manage the highlighted confounding factors, for example, in studies 3 & 4, data were stratified by 'treatment regimen' in order that relevant sub-group analyses could be conducted and treatment regimen outcomes could be differentiated. Secondly, high-level issues that emerged, such as 'gender bias in caregiving', were given careful consideration. In the case of gender bias, purposive recruiting of 'fathers' was pursued for the PPI panel, as well as for studies 4 & 5, to moderate this bias. Thirdly, topics of particular interest to the PPI panel but not evidenced in the literature, such as the impact of NCP on T1D illness outcomes, were incorporated into the research plan and data was collected to enable these investigations. Similarly, in response to the characterisation in the literature of 'Fear of Hypoglycaemia' as maladaptive, an extra study (study 3) was conceived to explore whether this interpretation was justified.

Overall, The findings support the proposition that health-related research benefits significantly from designing study protocols that incorporate the highest level of patient

involvement (driving and directing the work), which will then be more acutely attuned to the specifics of the lived experience, thereby building a more robust evidence base, leading to interventions that have greater acceptability and effectiveness for the target population.

The following chapters, 5 and 6, will report on two studies (study 2 and study 3) that were designed in response to the PPI panels' findings from their analysis of the SLR results, which were represented by the subtheme '*Is the construct 'Fear of Hypoglycaemia' fit for purpose?*'. As noted above, a consensus emerged within the panel indicating that further investigation of this topic was warranted. The first of these studies, study 2, is described in the next chapter and involves using a participatory research partnership to develop two questionnaires: one to capture caregiver 'knowledge-seeking' and the second to quantify 'levels of engagement with illness management' in paediatric T1D. Both of these variables were deemed key for exploring the Fear of Hypoglycaemia construct but no acceptable tools to capture them were identified by the researcher from the literature.

Chapter 5. Study 2: Participatory Research Partnership for Developing Questionnaires on Caregiver Knowledge-Seeking and Engagement in Juvenile Type 1 Diabetes Management

5.1 Abstract

Background: T1D is a high-burden condition, typically diagnosed in childhood. Parent-caregivers vary considerably in their level of knowledge-seeking and engagement with illness management; however available measurement tools may not reflect lived experience. Enabling researchers to better quantify illness-management practices would support caregivers and drive better health outcomes. *Objective:* Using a participatory research approach, involving a research partnership with a public and patient involvement (PPI) panel of experts by lived experience, this study aimed to capture community knowledge and co-design two novel caregiver self-report questionnaires to quantify 1) ‘knowledge-seeking’ and 2) ‘engagement’ in T1D parent-caregivers. *Methods:* The research collaboration was multi-staged and iterative. An expert PPI panel (n=6) was formed to review existing tools. Following identification of a long-list of candidate items, an iterative process was used to finalise the selection of items for inclusion. Questionnaires were deployed using an online survey with T1D parental caregivers (n=123). *Results:* The research partnership effectively embedded lived-experience expertise to optimise the development of two robust questionnaires that met patient expectations. Exploratory factor analyses and Cronbach’s alpha established reliability and validity for both questionnaires. *Conclusion:* This study illustrates the value of meaningful, community-based, participatory research for delivering robust questionnaires that are closely aligned to lived experience.

5.2 Background

As stated in previous chapters, T1D is a chronic autoimmune disease, typically diagnosed in childhood. The difficulties of maintaining stable blood glucose are well documented (Fullerton, 2014) and the consequences of not achieving control can result in significant complications impacting on; sight, kidney function, cardio-vascular health and neurological systems. T1D is considered one of the most psychologically and behaviourally demanding of all chronic medical illnesses (Guo, 2011). Effective illness management requires a complex and demanding daily regimen (Carcone, 2012), putting an enormous strain on families (Jaser, 2009). Management in children is usually more difficult than in adults (Herbert, 2015). Better health outcomes for juveniles can be dependent on quality of caregiving (Schunk, 2015).

On diagnosis, parent-caregivers face a steep learning curve as illness management requires a significant level of T1D-related knowledge to inform complex decision making throughout the day and night. The majority of illness management is carried out in the home setting, independent of clinical health providers. Patients and caregivers receive Diabetes self-management education (DSME) and are only discharged from hospital when clinicians feel that they have reached a good level of competence (Tong, 2021). The American Diabetes Association and WHO recommend ongoing DSME for people living with diabetes (American Diabetes Association, 2015; Powers et al., 2020), but pressure on health system resources can make this goal difficult to achieve (Hurley et al., 2017). As a result, motivation to seek out further knowledge and more nuanced information is commonly decided at the individual level, naturally, there is significant variance in the level of ongoing DSME that caregivers will pursue and consequently, difficulties can arise around care delivery.

Higher caregiver knowledge is associated with better health outcomes for children with T1D (Stallwood, 2006; Owusu et al., 2023). It is reasonable to assert that more

effective metabolic control will be associated with higher levels of ‘knowledge seeking’ and higher levels of knowledge application or ‘engagement with illness management practice’. Enabling researchers to quantify these aspects of the caregiver experience is key for identifying targets for intervention, which is desirable for reducing stress and anxiety in this highly burdened cohort, ultimately supporting better health outcomes in children. The researcher carried out a review of questionnaires currently available in the literature and concluded that, to their knowledge, no tool exists that captures ‘knowledge seeking’. Among those tools that captured ‘engagement with illness management’, none appeared adequately aligned with the lived experience of parental caregivers. It is increasingly recognised that PPI in every aspect of health research adds valuable insights that benefit patient outcomes and delivers interventions and tools that are more highly attuned to community expectations and needs (Arumugam et al., 2023).

5.2.1 Objective

In line with the approach taken previously, the research objective was to engage in a partnership with a panel of experts by lived experience to 1) confirm the researcher’s position, and 2) address the community-identified issue by co-designing two novel caregiver self-report questionnaires, deemed acceptable by the subject group and aligned with their lived experience. This approach enabled the researcher to gather valuable data on ‘knowledge seeking’ and the level of ‘engagement’ with illness management among parent caregivers of juveniles with Type 1 Diabetes (T1D). By ensuring the development of robust tools that accurately reflect caregiver experiences, this research will ultimately benefit both patients and caregivers by facilitating the exploration of research questions that address real-world challenges faced by the T1D community, leading to improved support, resources, and care strategies for managing the condition.

5.3 Method

5.3.1 Research design

The research objectives were achieved by creating a meaningful collaboration between a PPI panel of experts by lived experience (n=6) and the researcher. This participatory research (PR) method utilised engaged co-design principles to optimise the development of novel questionnaires. The co-design process, outlined below, was multi-staged and iterative. It adopted a constructivist framework, which emphasises the co-construction of meaning between researcher and participants, acknowledging multiple realities shaped by individual experience (Creswell & Poth, 2016). This was supported by the use of an interpretive phenomenological approach, emphasising the subjective lived experience (Burns, 2022).

5.3.2 Procedure

An iterative, multi-staged procedure was utilised.

Stage 1: Using Google Scholar, a narrative review of the literature was carried out by the researcher, using relevant terms and phrases (i.e., quantifying illness management in T1D; diabetes care regimen adherence; parent caregiving and metabolic control in juveniles with T1D; ongoing knowledge acquisition in T1D). The resulting literature was reviewed by the lived-experience researcher to identify questionnaires, scales and single-item measures that had relevance to the themes ‘knowledge seeking’ and ‘level of engagement’ in illness management for parent caregivers of juveniles with T1D. As noted above, specific tools that speak to the theme of ‘knowledge seeking’ in T1D do not appear to exist. Multiple tools that measure the ‘effectiveness of illness self-management in diabetes’ do however exist and were deemed to be the closest approximation for an ‘engagement’ scale. Six of these tools were accessible, relevant for a T1D population and reasonably current (Wysocki

et al, 2012; Markus et al., 2022; Lewin et al., 2009; Toobert et al., 2000; Hou et al., 2021; Holmes et al., 2006)

Stage 2: An expert PPI panel (n=6) was formed following a call for expressions of interest among T1D caregiver groups and personal networks. Individuals who self-reported high levels of engagement with good domain knowledge and also had experience of each available illness-management regimen (multiple daily injections, finger prick blood glucose reading, continuous subcutaneous insulin infusion and sensor blood glucose monitoring) were included. The panel comprised 3 parent caregivers, 2 parent caregivers who were also self-caring adults with T1D and 1 individual with T1D who had been diagnosed as a juvenile. See Table 5.1 for panel characteristics.

Table 5.1: Expert PPI panel member characteristics

Expert Panel Member	Age	Gender	Current Age of Juvenile	Years Since Juvenile Dx	Years Since Self Dx	T1D Experience
#1	43	F	14	8		Self-managing T1D & Caregiver for JT1D*
#2	52	F	9	6		Caregiver for JT1D
#3	45	F	13	10		Caregiver for JT1D
#4	52	M	17	14		Self-managing T1D & Caregiver for JT1D
#5	24	F	n/a	n/a	7	Self-managing T1D
#6	58	M	13	10		Caregiver for JT1D

*Juvenile with T1D

Stage 3: In October 2023, an online workshop using a remote online platform (Zoom) was conducted, this included the 6 PPI panel members and was facilitated by the researcher, it lasted approximately 1.5 hours. A summary of six ‘effectiveness of illness self-management’ questionnaires identified by the researcher at stage 1, was presented. Panel members were invited to respond to each questionnaire. The workshop followed a flexible

structure, but the researcher ensured that all members contributed by using prompts (e.g., “Can I check if you all agree with that point?”). The panel discussed the merits of the questionnaires and how useful they were for capturing data on the variable ‘level of engagement’. Questionnaires had positive elements, such as well constructed questions or appropriate response formats, however no single questionnaire was suitable for the purpose of capturing ‘engagement with T1D management’ as either they were found to be uncomprehensive, did not adequately reflect the lived experience, did not address communication with healthcare providers or problem solving or did not anticipate the behavioural adaptations that have occurred with technological developments. The panel also found onerous questionnaires and those that conflated Type 1 and Type 2 Diabetes to be unacceptable. Lastly, none of the questionnaires specifically addressed caregiver concerns. Table 2 includes some examples of items from the various questionnaires as well as PPI panel feedback. The panel agreed with the research position that two novel questionnaires were required to capture caregiver ‘knowledge seeking’ and ‘engagement with illness management’ in juvenile T1D.

Table 5.2: Sample feedback from expert PPI panel on items from established questionnaires

Measure	Item	PPI panel feedback
Self-Care Inventory – Revised (SCI-R) Lewin, 2009	<i>Take diabetes pills or insulin at the right time</i>	Too vague, don't understand the question; refers to Type 2 Diabetes
	<i>Eat the correct food portions</i>	Food portions not relevant in current approach
	<i>Eat meals/snacks on time</i>	Not relevant with current treatment approach
	<i>Keep food records</i>	Is not in line with how we are taught to think about Type 1 Diabetes; emphasis on food found unacceptable
Diabetes Self-Management Questionnaire - Revised (DSMQ-R) Markus, 2022; Schmitt, 2022	<i>I avoid physical activity although it would be good for my diabetes.</i>	Is not in line with how we are taught to think about Type 1 Diabetes
	<i>Sometimes I have real 'food binges' (not triggered by hypoglycemia).</i>	Tone of the question is unacceptable
	<i>I eat without regard to my diabetes.</i>	Tone problematic and is not in line with how we are taught to think about Type 1 Diabetes
	<i>I occasionally eat large amounts of sweets or other foods rich in carbohydrates.</i>	Tone problematic and is not in line with how we are taught to think about Type 1 Diabetes
The diabetes self-management profile-self report (DSMP-SR) Wysocki, 2012	<i>I follow the current dietary recommendations for people with diabetes (e.g. given to me diabetes specialist).</i>	More relevant to Type 2 Diabetes, which is alienating
	<i>In the past 3 months, how often have you eaten "fast foods" or "junk foods" such as sweets, cookies, cakes, ice cream, chips, pizza, french fries, hot dogs, or others?</i>	Tone problematic and is not in line with how we are taught to think about Type 1 Diabetes
	<i>In the past 3 months, how often have you gotten exercise such as running, bike riding, swimming, skating, or playing team sports for at least 20 minutes?</i>	Is not in line with how we are taught to think about Type 1 Diabetes; more relevant to Type 2 Diabetes, which is alienating
	<i>If you think you are having a low blood sugar, how often do you check your blood sugar before treating?</i>	Question doesn't make sense to the lived experience
	<i>I do not check my glucose levels frequently enough for achieving good blood glucose control</i>	Tone and framing of the question found unacceptable

Stage 4: The co-design process (stages 4-7) took place in October-November 2023.

Following the panel review of 6 existing questionnaires, the PPI panel members, working individually, identified potential themes or question topics from the aforementioned questionnaires to be considered for inclusion in the novel ‘engagement’ questionnaire, they also generated novel items for potential inclusion. In addition, potential novel items were generated for the ‘knowledge seeking’ questionnaire. Finally, two comprehensive long-lists of candidate items were produced by each member, one each for ‘knowledge seeking’ and ‘engagement’.

Stage 5: All the lists were pooled, and this pooled list was circulated to each panel member. Working individually, each member reviewed the pooled list of candidate items, commented on each item (see Table 5.3) and made recommendations for deletion, based on their own experience.

Table 5.3: Sample comments from the panel long-list review of candidate questionnaire items

Sample PPI panel comments on long-list candidate items for the ‘engagement’ questionnaire	
• Very relevant to my experience	• Captures more than one behaviour
• Not relevant to my experience	• Wording confusing
• More information required, I don’t understand it fully	• Unclear terminology
• Framing of question too negative	• The tone is judgemental
	• Doesn’t represent caregiver experience

Stage 6: Working independently the expert PPI panel moved gradually toward consensus on selecting the questionnaire items for inclusion; 1) candidate items were prioritised (given a relevance rating of 1-3) by each panel member and 2) further deletions were made (lower rated items), 3) two short-lists of candidate items were circulated and the items here were given relevance ratings of 1-3, as before, 4) lower rated items were deleted. The final

‘knowledge seeking’ questionnaire contained 5 items (see Table 5.4) and the final ‘engagement’ questionnaire contained 14 items (see Table 5.5).

Stage 7: Finally, both questionnaires were subjected to close analysis by three members of the PPI panel who were available, working remotely on a shared document, to refine the wording of the text, increase accessibility for caregiver participants and limit socially desirable responding.

Table 5.4. Knowledge Seeking Questionnaire

Below are some statements about looking for information to help with managing your child's T1D. Please indicate on the scale how much you disagree or agree with each statement (**1. Strongly Disagree - 5. Strongly Agree**).

1.	My level of T1D knowledge is very good
2.	I always try to learn more about diabetes management
3.	I follow diabetes discussion groups, blogs and advocacy groups to get more information
4.	I try to find reliable online sources of information on managing T1D
5.	I like to talk to and learn from other people living with T1D (family, friends, wider community)

Table 5.5. Engagement with Illness Management in Juvenile T1D Questionnaire

Please read the statements below and indicate on the scale the degree to which you feel that the statement applies to you (**1. Does not apply to me – 5. Very strongly applies to me**)

1	My child's glucose levels are checked before each meal.
2	My child's insulin doses are adjusted to the carbohydrate content of their meals.
3	My child always boluses before they eat
4	Insulin boluses are timed according to whether my child is eating fast or slow acting carbohydrates
5	My child's insulin doses are adjusted according to their current glucose levels and any planned physical activities
6	My child's high glucose levels are corrected whenever necessary
7	Fast acting carbohydrates to enable quick treatment of low blood glucose are always available

8	When my child has low blood glucose, the amounts of carbohydrates needed are calculated to avoid causing rebound high blood glucose
9	My child's blood glucose sensor is changed on schedule
10	My child's injection or pump canula insertion site is varied consistently
11	Records, food diaries, sensor or pump reports are used to help with diabetes management planning
12	My child's insulin sensitivity/correction factor is always known
13	My child's insulin sensitivity/correction factor is regularly checked for accuracy
14	We regularly check that my child's insulin ratios are correct (basal, bolus)

Stage 8: The questionnaires were deployed in study 4, using a survey that was posted to an online peer-support group for caregivers for juveniles with T1D (see Appendix 3.1 for the full survey and chapter 6 for details on that study).

Stage 9: The survey results were subjected to quantitative analyses (exploratory factor analyses; Cronbach's alpha) to determine the psychometric parameters of the novel questionnaires. One hundred and twenty-three parent caregivers completed the survey. This number of survey respondents was sufficient to ensure adequate statistical power to carry out the desired analyses as established by an a priori power analysis conducted using G*Power 3.1 ($\geq .80$) to detect medium-sized effects (Faul et al., 2009).

5.4 Results

5.4.1 Exploratory factor analyses

Exploratory factor analyses (EFA) were carried out. The first EFA looked at the 5 items in the 'Knowledge Seeking' questionnaire after the Keiser-Meyer-Olkin test verified the sampling adequacy for the analysis ($KMO = .672$) and Bartlett's test of sphericity was found to be significant ($86.865, p < .001$), indicating that the correlation structure was adequate for factor analysis. The principle-component factor analysis with varimax rotation yielded a two-factor solution as the best fit for the data, accounting for 65.25% of the variance, with items 3, 4 & 5, loading onto factor 1 (action: 0.712-0.812) (42.68%) and

items 1 & 2 loading onto factor 2 (attitude: 0.776-0.895, 22.57%). A second EFA looked at the 14-item 'Engagement' questionnaire. Again, the Keiser-Meyer-Olkin test verified the sampling adequacy for the analysis (KMO = .888) and Bartlett's test of sphericity was significant (803.96, $p < .001$), indicating that the correlation structure was adequate for factor analysis. A principle-component factor analysis with varimax rotation yielded a three-factor solution as the best fit for the data, accounting for 65.59% of the variance, with items 1, 2, 4, 5, & 6 loading onto factor 1 (Insulin administration, 0.444-0.848), items 8,11,12,13,14 loading onto factor 2 (Information management, 0.460-0.835), and items 3, 7, 9 & 10 loading onto factor 3 (planning, 0.544 -0.753).

5.4.2 Reliability and validity

Reliability was established using Cronbach's alpha, which was computed for each questionnaire: Cronbach's alpha for the 5-item 'Knowledge Seeking' questionnaire was 0.656, which is very good, as achieving an alpha >0.5 for a <10 -item questionnaire is difficult (Pallant, 2013). Cronbach's alpha for the 14-item 'Engagement' questionnaire was 0.913.

Content validity was established during the process of developing the questionnaires. As described above, the expert PPI panel reached consensus on selecting and drafting the final items that were included in the questionnaires. The process was driven by the lived experience and resulted in tools that were deemed by the panel to be comprehensively representative of current, real-world illness management requirements. The process was enhanced by the use of a Delphi-method procedure, which provided assurance that the questionnaires represented all aspects of the constructs being operationalised and do not include any irrelevant factors.

Quantitative analysis of the survey results showed a moderate positive correlation between 'Knowledge Seeking' and 'Engagement' ($r = .334$, $p = <.001$), which is regarded

as a positive finding when considered within the context of these complex and multi-dimensional behavioural constructs. Furthermore, a linear regression analysis showed that ‘Knowledge Seeking’ significantly predicted higher levels of ‘Engagement’, ($F(1,106) = 13.35, p = < .001$). The R^2 was .112, indicating that ‘Knowledge Seeking’ predicted approximately 11.2% of the variance in engagement. In turn, ‘Engagement’ significantly predicted better illness management (as indicated by a Glycated Haemoglobin blood test or HbA1c), ($F(1, 103) = 6.59, p = < .012$). The R^2 was .06, indicating that ‘Engagement’ explained approximately 6% of the variance in HbA1c levels.

5.5 Discussion

A participatory research partnership with a PPI panel enabled the caregiver perspective to be successfully embedded in a co-design process that proved highly successful for developing two novel, reliable and valid tools. This research found participatory research methodologies valuable for first, highlighting the gaps in the available research tools for quantifying caregiver ‘knowledge seeking’ and ‘engagement with illness management’ in T1D, and second for addressing these gaps by developing novel research tools, thereby demonstrating the importance of meaningful engagement with communities in healthcare research and supporting the strong body of evidence on this value of this approach (Brett et al., 2014; Arnstein et al., 2020). Application of an academic-participatory partnership was found to be beneficial to the co-development of questionnaires that have been shown to be robustly designed, while deemed accessible and intuitive by the end-using cohort. These questionnaires will facilitate the gathering of reliable and valid data on these variables, enabling the researcher to gain deeper insights into the drivers of variability in caregiving practice among parent-caregivers in T1D. This research will facilitate the development of interventions to support care delivery in the home setting, potentially relieving caregiver anxiety and depression (George et al., 2020;

Hansen et al., 2022) and supporting caregiver mediated improvements in health outcomes for juveniles living with T1D (Fiest et al., 2018).

The research partnership benefitted from the following aspects of the process: (1) Collaboration with the expert PPI panel was greatly facilitated by recognition of the time-burden commitment for panel members, which aligns with previous evidence suggesting that supporting PPI contributors is associated with higher-quality involvement (Blackburn et al., 2018; Saini et al., 2021). To manage this, meetings were kept to a minimum, and panel members worked independently to generate candidate item lists, which reduced the time commitment while allowing members to respond at their convenience. (2) Independent consultation activities were also helpful for neutralising the effect of stronger voices, which can act as opinion leaders and make it difficult to capture a wider range of views. Previous research has shown that managing power dynamics in community consultations can be a challenge (Andress et al., 2020). (3) Using interpretive phenomenology to frame the research was very helpful for encouraging the panel to focus on their subjective personal experience and resist the impulse to respond to queries with the idea that there could be right and wrong answers. It was also helpful for supporting the panel in recognising the legitimacy of their knowledge contribution (Burns, 2022). This case study presents as an instructive example of the value of deeper engagement with communities, to drive research priorities and direct the work toward outcomes that align with the lived experience. It supports the case for greater investment of resources into high-quality community engagements in the research context, and the value of developing methodologies to amplify the community voice. Lastly, the co-design methodology devised for this research is an approach that is transferrable to other problems in other research domains.

5.6 Limitations

This research used a degree of convenience and snowball sampling to form the expert PPI panel. This may have resulted in a degree of homogeneity among the panel members, which may have impacted on the study's ability to capture a broad spectrum of opinion. In addition, the self-report tools were piloted using a closed online, peer-support group. Due to the nature of the group, it is likely that the respondents were more knowledgeable and engaged than would be expected in the broader population of caregivers for T1D.

5.7 Conclusion

The determinants of parental caregiver illness-management behaviours are multifactorial, but two aspects are understood to be key in effective caregiving; knowledge and engagement (Stallwood et al., 2006; Guo et al., 2011). A partnership between the researcher and a panel of experts by lived experience was leveraged to optimise the development of two novel caregiver self-report questionnaires that capture these variables in a manner that was deemed acceptable and relevant to the expert panel, where established questionnaires were not. Meaningful PPI and community knowledge shaped the process at every stage. Reliability and validity analyses from deployment of the questionnaires demonstrate that the resulting tools are robust, underscoring the effectiveness of 'participatory' methodologies. This approach has the potential to enhance healthcare outcomes by producing tools that better address the real needs and experiences of patients and caregivers.

The two tools developed through this process, quantifying 'knowledge seeking' and 'engagement with illness management' in T1D are expected to provide significant value for researchers seeking to capture nuanced aspects of the lived experience of individuals

with T1D. By enabling a more comprehensive and contextually grounded understanding of daily life with T1D, these tools will generate rich data that can inform and facilitate the investigation of issues most relevant to patients. In doing so, they hold the potential to enhance patient-centred research and contribute to the development of interventions that more closely align with the priorities and challenges identified by those directly affected. As an example of this, study 3 was based on a finding from the PPI consultation, where the PPI panel proposed that the construct ‘Fear of Hypoglycaemia’ was not ‘fit for purpose’ as it did not align with their lived experience. Study 3, presented in the following chapter, investigates this proposition, utilising these novel questionnaires to capture aspects of the lived experience deemed by the PPI panel to be key for this discussion.

Chapter 6. Study 3: The parent-caregiver perspective on ‘Fear of Hypoglycaemia’ in Type 1 Diabetes: A mixed methods study

6.1 Abstract

Background: Fear of hypoglycaemia (FoH) is a construct that captures the psychological and behavioural impacts of hypoglycaemia threat for patients with T1D. The Hypoglycaemia Fear Scale (parents) (HFS-P) is commonly used for quantifying the construct in parent-caregivers. High FoH has been characterised as an anxiety disorder that adversely effects T1D outcomes. The objective of this study was to investigate the perceived value of the FoH construct among parent-caregivers and the perceived utility of the HFS-P tool. *Method:* Assuming a relativist, constructivist position, a two-phase, mixed-methods, cross-sectional study was co-designed with a PPI panel (n=6). In phase 1, parent-caregivers (n=123) completed an online survey, which measured demographic and illness-related factors, T1D ‘knowledge-seeking’ and ‘engagement’ in T1D management, and FoH (using the HFS-P). Open-text questions asked about the FoH construct, its perceived relevance and assumptions about score interpretations. In phase 2, a qualitative protocol analysis methodology was utilised to examine the subjective experience of completing the HFS-P (n=9), data was analysed using interpretive phenomenological analysis (IPA). *Results:* In phase 1, higher FoH was associated with better illness management as measured by HbA1c values. No associations between FoH and child age, T1D duration, technology use, or T1D knowledge seeking and engagement were found. Content analysis of open-text responses identified 4 themes: Hypoglycaemia burden and FoH relevance; Reflecting on the HFS-P; Drivers of FoH; and Speculating on scores. In phase 2, IPA identified 5 themes: Universal daily concerns; Drivers of Hypo Distress; Hypos in real life; and HFS-P scepticism; FoH as a construct. *Conclusion:* Findings linked higher FoH to better health outcomes, challenging common beliefs. Qualitative evidence indicated that

FoH is highly dependent on day-to-day contextual factors such as activity levels or whether the child will be alone. The study suggests that the FoH construct may not be well attuned to the lived experience of T1D parental-caregivers and thereby has limited utility and the potential to impact negatively on a highly burdened population by mischaracterising their experience as maladaptive. The research proposes a more judicious use of the construct and highlights the value of PPI consultation for developing research tools.

6.2 Background

This study was designed in response to a strong theme that emerged from the PPI secondary review of the findings from the SLR (chapter 4), the theme was titled ‘Fear of Hypoglycaemia; is this construct fit for purpose?’. The panel agreed that this theme warranted further investigation, concluding that PPI involvement would be key to such an investigation because it was believed that the nuance involved in an in-depth exploration of the construct could only really be appreciated through the lens of the ‘lived experience’.

Hypoglycaemia is a common but dangerous side effect of insulin treatment for T1D, occurring when an individual’s blood glucose (BG) drops below the healthy range (<3.9 mmol/L). Symptoms include anxiety, tremulousness, palpitation, sweating, weakness, confusion and nausea, more severe episodes can lead to seizures, loss of consciousness, coma and even death (Guettier & Gorden, 2006; Nishihama et al., 2021; Yale et al., 2018). Recurrent hypoglycaemia commonly results in hypoglycaemia unawareness, where the patient does not consciously experience the symptoms, resulting in more frequent and prolonged episodes with increased negative consequences for health (Vignesh et al., 2004).

With advances in BG monitoring technology, evidence has emerged to show that Hypoglycaemia occurs more often in T1D than previously appreciated (Heinemann et al.,

2018). For example, Khunti et al. (2016) found that across 24 countries, patients with T1D experienced an average of 73 episodes of hypoglycaemia per year, including 11 nocturnal episodes and five severe episodes. Among children living with T1D, frequencies of hypoglycaemia tend to be significantly higher than in adults: Abitol & Palmert (2021) found that 22% (57/264) of children with T1D reported loss of consciousness, seizure or administration of *glucagon* (a treatment for hypoglycaemia). In addition, Gagnum et al. (2017) found that, in Norway, 31.7% of deaths (n=20/65) in persons aged 0-41 years with T1D were attributed to hypoglycaemia.

Perhaps unsurprisingly, anxiety about potential hypoglycaemia and its mitigation is a feature of diabetes care: 'Fear of Hypoglycaemia' (FoH) is a construct that has emerged to capture the experience of living with this challenge (Wild et al., 2007). FoH is defined as "a specific and extreme fear evoked by the risk and/or occurrence of low blood glucose levels" (Diabetes.org.uk, 2024). Depending on its intensity, FoH is understood as adaptive or maladaptive (Przezak et al., 2022). Higher FoH is commonly characterised as an anxiety disorder (Driscoll et al., 2016). According to the literature, maladaptive FoH leads to overly vigilant BG monitoring, deliberate maintenance of inappropriately elevated BG levels and overtreating hypoglycaemia (Abitol and Palmert, 2021). It is thought to limit the achievement of good glycaemic control (Burckhardt et al, 2019), leading to an increased risk of long-term complications (Barnard et al., 2010; Burckhardt et al., 2018). It has also been suggested that lower FoH can be indicative of an underappreciation of, or possibly disregard for, the risks of hypoglycaemia, which can also manifest as poorer illness management (Przezak et al., 2022). However, there are no published guidelines on thresholds or cut-off points to differentiate between low, moderate and high levels, which is problematic as it creates the potential for some parent-caregiving behaviour to be mischaracterised as maladaptive.

Research that has focused on the impact of parent-caregiver FoH on children's clinical outcomes has produced inconsistent results, with some studies finding an association between higher levels of FoH and poorer diabetes control (Barnard et al., 2010; Wild et al., 2007) and others finding no relationship (De Beaufort et al., 2021; Amburgey et al., 2020). Other research on the drivers for caregiver FoH suggests that higher FoH is associated with higher frequency or severity of previous hypoglycaemic episodes (Shepard et al., 2014; Monaghan et al., 2009), that FoH is experienced more intensely at night (Gjerløw et al., 2014), is higher in mothers than fathers (Barnard et al., 2010; Amiri, 2018) and higher amongst those with higher levels of education (Monaghan et al., 2009). With the development of diabetes assistive technologies (detailed in chapter 1, section 1.6.1), research has emerged that shows benefits for FoH from their use, for example, De Beaufort et al. (2022) found improved caregiver wellbeing and reduced FoH among caregivers using closed-loop systems. However, findings related to child's age or T1D duration as drivers of caregiver FoH were inconsistent across 43 studies (Fernando & Patel, 2021). Lastly, higher FoH 'worry' has been found in parent-caregivers who check BG ≥ 6 times per day (Van Name et al., 2018). While such behaviour was interpreted negatively, it is noted that guidelines recommend 4-10 checks daily as appropriate for adults (mayoclinic.org, 2024) and 5-7 for children (HSE.ie, 2024), suggesting that checking BG ≥ 6 was perhaps an informed decision.

The most widely used tool to quantify FoH is the Hypoglycaemia Fear Survey (HFS) (Shepard et al., 2014). The HFS was originally developed by Cox et al. (1987), with adapted versions for juveniles and parents of children with T1D (Clarke et al., 1998; Gonder-Frederick et al., 2011). The questionnaire includes both psychological and behavioural dimensions (worry/behaviour subscales). While the HFS is widely used, a significant shortcoming is that no thresholds are identified and no 'normative range' for FoH has been defined. Across studies, mean scores vary significantly (e.g., 71 in Patton et

al., 2017 and 50.2 in Burckhardt et al., 2019) and any comparisons that are made are often simply baseline versus post-intervention. Typically, the objective for any intervention with a HFS endpoint is simply to *reduce* scores (Burckhardt et al., 2019).

Given the absence of validated guidelines or clarity on critical cut-off scores for FoH, along with conflicted research findings on driver and moderator variables, it can be argued that FoH as a construct oversimplifies the experience of hypoglycaemia management that accompanies insulin-dependent blood-glucose control. While the American Diabetes Association's (2025) statement on psychosocial care recommends screening for FoH using standardized and validated tools and referring adults with FoH to mental health providers (Young-Hyman et al., 2017), such practices may incorrectly pathologize the experience of managing a recognised high-burden illness.

6.3 Objective

FoH is a matter of concern for healthcare professionals and caregivers supporting patients with Type 1 Diabetes (T1D), however, as described previously, a review of the SLR findings, conducted in collaboration with a patient and public involvement (PPI) panel, highlighted several issues with the existing 'FoH' construct. Concerns were raised also about the most commonly cited measurement tool and the characterization of high-scoring individuals as maladapted.

To the researcher's knowledge, no research to date has investigated the utility and validity of the FoH construct from the parent-caregiver perspective. Guided by insights from the PPI panel, this study evaluated the perceived value of the FoH construct among parent-caregivers for juveniles with T1D and the utility of the HFS-P tool for quantifying FoH in individuals. It was hypothesised that FoH as a construct is not adequately attuned to the lived experience of caregivers and that the HFS-P is not a reliable tool to measure it.

6.4 Method

This was an exploratory, two-phased, mixed-methods, cross-sectional study. The research assumed a relativist, constructivist position and was guided by PPI. Ethical approval for the research was obtained from The School of Psychology Research Ethics Committee (SPREC), Trinity College Dublin in September 2023, see Appendix 1.

6.4.1 Preliminary PPI scoping activity

As described in chapter 2, section 2.6.3, a panel of parent-caregiver experts by lived experience (n=6) was recruited using the researcher's personal network and an online, peer support group. Using an online focus group (n=4) and online individual interviews (n=2), panel members were invited to complete the HFS-P. The researcher gave a brief overview of the construct, its relevance and its treatment in the literature. The panel were provided with their scores and score interpretations and asked to comment/reflect on these and their overall views regarding the FoH construct. The group scored a mean of 79.8 (range 60 – 89), which represents scores on the higher end of the scale indicating high FoH. There was consensus that the construct FoH somewhat misrepresented their experience of managing hypoglycaemia and that the scale did not capture the complexity of their lived experience. They were uncomfortable with the terms 'phobic' and 'maladaptive', which were used to designate high HFS-P scores in the literature (Kamps et al., 2005; Abitol & Palmert, 2021). The succeeding 2-phase study was guided by the feedback.

6.4.2 Reflexivity

As discussed in chapter 2, section 2.6.1, the researcher had personal experience of T1D caregiving. While this provided valuable insider perspective, the researcher also understood the challenges of a dual role and the potential for bias. To address this the

researcher employed reflexive strategies such as maintaining a research journal, engaging in peer debriefing and external validation as well as carrying out continual reflection and self-awareness to ensure transparency and rigor.

6.4.3 Phase 1. Research design

The first phase involved an online mixed-methods survey that was hosted on Survey Monkey over the course of 10 days in November 2023. It took 20-30 minutes to complete. The survey contained items which gathered demographics and T1D-related data, measured FoH, knowledge-seeking/engagement with illness management, using the questionnaires developed in study 2, and included some open-text response items to address the following hypotheses and questions:

1. Higher FoH scores will be positively associated with better illness management as represented by HbA1c.
2. Higher levels of knowledge seeking and engagement with illness management will predict higher FoH scores.
3. Technology use will have a moderating effect on FoH but patient age and T1D duration do not.

Qualitative research questions were designed to explore the personal relevance of FoH and elicit feedback on HFS-P questionnaire items and scoring interpretations.

The STROBE cross-sectional study checklist was adhered to (see Appendix 6.1).

6.4.4 Phase 1 - Participants

Participants for phase 1 were recruited using an advertisement posted on a closed, national, online, peer-support group for parents of juveniles with T1D. The post invited parents to complete a survey that was ‘interested in the experience of caregiving’. No information regarding the specific topic of interest (FoH) was included and there were no

specified exclusion criteria. As reported in study 2, 123 individuals completed the survey, deemed adequate by power calculations to detect meaningful effect.

6.4.5 Phase 1 - Survey measures

Demographics. Information on parent-caregiver demographics was collected with questions on; gender, level of education achieved, employment status and ease/difficulty making ends meet. Patient demographics and illness-related variables were also gathered; Age, T1D duration, technology use (closed loop, insulin pump with and without sensor, multiple daily injections with and without sensor); most recent HbA1c value (measure of blood-glucose control achieved).

Caregiver Knowledge Seeking in T1D. Caregiver knowledge-seeking was measured using a researcher-devised tool that was developed with PPI input in study 2, as described in chapter 5. This measure included 5 items (e.g., ‘I try to find reliable online sources of information on managing T1D’) scored on a 5-point Likert scale (strongly disagree – strongly agree), scores range from 5 to 25, with higher scores indicating higher levels of T1D knowledge seeking . Internal consistency was established with an alpha of 0.656, which is very good as achieving an alpha >0.5 for a <10-item questionnaire is difficult (Pallant, 2013).

Caregiver Engagement with illness management in T1D. Caregiver engagement was measured using a researcher-devised tool, also developed with PPI input in study 2 and described in chapter 5. The measure included 14 items (e.g., ‘My child’s glucose levels are checked before each meal; My child always boluses before they eat’) and was scored on a 5-point Likert scale (does not apply to me – very strongly applies to me), scores range from 14 to 70, with higher scores indicating higher levels of engagement with T1D illness management . Cronbach’s alpha established strong reliability for the tool (0.913).

Hypoglycaemic Fear Survey – Parents (HFS-P). The HFS-P was designed for use with caregivers for children 8+ years of age (Clarke et al., 1998). It comprises 10 items on the behaviour subscale (e.g., '[do you] Have your child eat large snacks at bedtime?') and 15 items on the worry subscale (e.g., '[How often do you worry about your] Child not having carbohydrate with him/her?'). These are measured on a 5-point Likert scale, with total scores ranging from 25 to 125. Good reliability for the HFS-P has been reported by several studies, with Cronbach's alphas ranging from 0.72 to 0.76 for the behaviour subscale and 0.88 to 0.91 for the worry subscale (Gonder-Frederick et al., 2011).

Open-ended qualitative questions. The following qualitative questions were posed:

What do you think of the concept 'fear of hypoglycaemia'? Do you think it applies to you? Can you describe how it does or doesn't apply to you? What do you think a higher score on the questionnaire would represent? What do you think a lower score on the questionnaire would represent? What other thoughts about the questionnaire do you have?

6.4.6 Phase 1 - Analysis of survey data

Quantitative data were analysed using SPSS (version 29) software. Descriptive statistics, including means and frequencies, were computed for all variables. Pearson correlation coefficients were calculated to examine bivariate relationships between selected continuous variables (FoH and HbA1c). Regression analyses were conducted to assess the predictive power of independent variables (age, time since diagnosis, knowledge seeking and engagement) on the dependent variable (FoH). One-way analysis of variance (ANOVA) was used to compare the FoH means across different levels of target variables (technology use, age). Assumptions for parametric tests were met; extreme values were excluded, and missing data were managed using listwise deletion.

Data from the open text responses were analysed using qualitative content analysis (QCA) (Erlingsson and Brysiewicz, 2017). This methodology was selected as the best fit

for the qualitative data elicited using the survey, as it required interpretation at the manifest level and systematic transformation into a concise representation of key information. The QCA was carried out following a 6-step procedure. 1) Familiarity with the text was achieved. 2) Taking an inductive approach, a coding system was developed that best captured the data. 3) Units of text were systematically coded for meaning at the semantic level. 4) Codes were organised into broad themes and categories. 5) Relationships between codes, themes, and categories were considered in relation to the research objectives. An audit trail was maintained to ensure rigor. 6) Themes were reviewed and refined to create a model that represents the dataset comprehensively and coherently addresses the objectives of the research.

6.4.7 Phase 2 – Research design

This qualitative phase of the study was designed to supplement phase 1, using a protocol analysis methodology to closely examine the individual experience of completing the HFS-P and to ascertain whether it reliably captures the construct it purports to capture. The SRQR qualitative study checklist was adhered to (see Appendix 6.2).

6.4.8 Phase 2 - Participants

Parent-caregiver participants for individual semi-structured interviews were purposively recruited for maximum variance on child's age, technology use and T1D duration. The sample was recruited from a list of phase 1 survey participants who registered their interest in further engagement with the research, an advertisement on a closed, online peer-support group and convenience sampling. Eight caregivers (some also self-caring T1Ds) and one young adult wT1D took part in the interviews. Information provided to participants stated that the parental-caregiving experience was being explored.

6.4.9 Phase 2 - Procedure

Online, one-to-one, semi-structured interviews were scheduled at the participants' convenience. Two participants requested the HFS-P in advance, this was furnished close to the scheduled interview time and did not impact on their decision to participate. Consent was obtained verbally at the beginning of the interview. Following this, the participant was instructed on how to carry out the protocol analysis; they were asked to complete the HFS-P questionnaire out loud, sharing each item score with the researcher and attempting to vocalise or narrate their internal process, their associations to each item, any issues they noted, any relevant personal experiences and any questions they had. The researcher had a number of prompts, to stimulate participant commentary, which were used sparingly, such as, 'could you say a little more?' or 'could you explain what you mean?'. The name of the questionnaire (HFS-P) was revealed to the participants when it was completed, along with a brief explanation of the FoH construct. Audio recordings were made of the interviews, which were transcribed verbatim at the semantic level and then deleted. Interviews lasted between 35 and 55 minutes. After 9 interviews, it was deemed that data saturation had been achieved.

6.4.10 Phase 2 – Data analysis

Data from semi-structured interviews was analysed using Interpretive Phenomenological Analysis (IPA) (Larkin et al., 2021). This methodology was selected as the most appropriate choice as it is an emerging tool in qualitative research in health psychology (Biggerstaff & Thompson, 2008) and it is found particularly useful for achieving deeper understanding of internal patient experience, in addition, it is suited to interpreting data gathered when engaging in a focused, specified task (Smith, 2011).

Following recommendations (Pietkiewicz and Smith, 2014; Alase, 2017), a 6-step process of analysis was initiated: (1) Data transcribed and familiarity with text achieved.

(2) Key words identified. (3) Short segments coded with phrases or words. (4) Broadly descriptive groupings developed. (5) Meaningful relationships identified and clustered by theme. (6) Themes without a strong evidential base deleted and a model of themes, subthemes and subordinate themes finalised. Illustrative quotes that best captured the participants' narrated 'lived experience' of completing the HFS-P were selected. Qualitative data and audit trail were managed using NVivo 14.

6.5 Results

6.5.1 Phase 1 – sample characteristics

Table 6.1 and 6.2 display the demographic and T1D-related characteristics of the sample captured by the online survey.

Table 6.1 Survey sample demographics and T1D characteristics, categorical variables

Categorical Variables	Mean/Percentage (n=123)
Gender	97% Female (n=116)
Education	62% attained 3 rd level degree or higher (n=73)*
Household Income	56.5% easily met monthly expenses (n=67) 43.8% met monthly expenses with difficulty (n=52)
Technology Use	Closed loop insulin pump and sensor 46% (n=54) Non-looping insulin pump with/without sensor 29% (n=34) Multiple daily injections (MDI) with/without sensor 25% (n=30) Participants without sensor 5% (n=6)

**% of General population with 3rd level degree or higher in 2022, 34% (CSO.ie, 2024)*

Table 6.2 Survey sample demographics and T1D characteristics, continuous variables

Continuous Variables	Mean/Percentage (n=123)
Child's Age	Mean: 12 yrs (n=114; range 4-19 yrs; SD 4.2 yrs)
T1D Duration	Mean: 4.3 yrs (n=114; range <1-15 yrs; SD 3.66 yrs)

HbA1c	Mean: 7.4% (n=111; range 5.4%-11%; SD 0.92%)*

*HbA1c target for paediatric patients <7.5% (Diabetes.ie, 2024)

6.5.2 Phase 1 - Quantitative findings

6.5.2.1 Hypothesis 1. A Pearson's correlation coefficient assessed associations between FoH (as represented by HFS-P scores) and success in illness management (as represented by HbA1c scores). A significant, negative correlation of low-moderate strength was found, $r(104) = -.24, p = .031$. This indicates that higher FoH was associated with better illness management.

6.5.2.2 Hypothesis 2. A regression analysis was carried out to establish whether Knowledge seeking and engagement (KSE; n=111) would predict Fear of Hypoglycaemia (HFS-P scores). Results of the linear regression indicated that there was no significant effect ($F(1, 85) = 2.665, p = .106, R^2 = .03$), see Table 6.3.

Table 6.3. Linear regression predicting Fear of Hypoglycaemia total score from Knowledge Seeking and Engagement in T1D

Predictor	B	SE B	β	t	p	95% CI for B
Constant	62.60	8.21	—	7.63	< .001	[46.28, 78.91]
KSE	0.23	0.14	.17	1.63	.106	[-0.05, 0.50]

6.5.2.3 Hypothesis 3.

Technology use: A one-way ANOVA revealed that there was no significant difference in HFS-P scores between the three technology groups (Closed loop; Non-looping insulin

pump with/without sensor; MDI with/without sensor), ($F(2, 85) = 0.497, p = 0.61$). This indicates that use of technology is not a moderating factor on HFS-P scores.

Patient age: Patients were divided into three sub-groups based on a tertile split by age, with each group representing approximately 33% of the patients to capture the youngest, middle, and oldest cohorts. A one-way ANOVA found no significant difference in mean HFS-P scores between the three age groups (≤ 9 ; 9.1-14; 14.1+), ($F(2, 85) = 0.033, p = 0.968$), suggesting that patient age does not have an effect on HFS-P scores.

T1D duration: Patients were divided into two groups, according to the length of time since they received their diagnoses; below the median of 4.6 years ($n=46$) and above the median ($n=42$). An independent samples t-test was conducted to determine if there was a difference between the means of the two groups. No significant difference was detected between the mean HFS-P scores for both conditions; shorter time since diagnosis ($M = 73.8, SD = 15.15$) and longer time since diagnosis ($M = 77.43, SD = 16.19$); $t(86) = -1.085, p = 0.281$, indicating that time since diagnosis is not a significant predictor of HFS-P scores.

6.5.3 Phase 1 - Qualitative Findings

A QCA of data related to the research questions on the topics of the FoH construct and the HFS-P scale, resulted in the emergence of meaningful data clusters around the following 4 topic threads:

6.5.3.1 Thread 1: Hypoglycaemia burden and FoH relevance. A considerable amount of data was focused on the participants' experience of burden with T1D, a condition that they experience as "omni-present", causing "constant- or intense- worry" and "struggle", with lives that were "profoundly affected". Many negatively valenced emotional words were

used to describe their experience of hypoglycaemia, such as “terrifying”, “panic”, “fright”, “burnout”, “beyond stressful” and “overwhelming”. Typically, the burden experienced intensified during the night, with some parents waking multiple times to manage BG; “There are nights I set alarms to keep an eye on her readings”, “For years I didn't sleep well as I was terrified she'd go low overnight”, “[Blood sugar] levels are checked every night, sometimes 2 or 3 times”.

Participants were asked if they thought FoH applied to them, 68.2% felt that it did, 12.5% responded that it did not and 19.3% were not sure. When asked what they thought about the FoH construct, 66% of those who responded (n=67) said that they felt that FoH is a normal response; “Fear of hypos is real and justified and we should never be complacent”, “It's a legitimate fear as a bad hypo can be fatal”. Some expressed unease with the use of the word ‘fear’ in this context; “I'm not ‘afraid’ of hypos. I want to avoid them as they make her feel unwell”, “It's a *real* worry though so I don't like the word fear being used, makes it sound a bit like I'm over-reacting and I'm absolutely not, these are all justified fears”. As another caregiver put it; “...that fear in the back of your head that you don't catch a low and the worst happens”, this was reflected in others' comments; “I fear in case he might go into a coma”.

6.5.3.2 Thread 2: Reflecting on the HFS-P. Some caregivers responded positively to the questionnaire, they felt that the questions were “appropriate”, “relevant” and “real”, “[The questions] are lists of normal things I have to be careful about every day”. One respondent commented that they were “Very realistic questions due to 24/7 illness” reflecting “what happens on a day-to-day basis”.

Other caregivers valued the questionnaire as a “good reminder of all we do”, “I felt a validation of my concerns...nurses can be quite flippant about my concerns as they are knowledgeable, friends can also be quite flippant as they don't understand the severity or

dangers of the condition” and some parents found it enlightening; “...knowing I worry, but not realising how much until I see the answers I picked”. But, the tone of the questionnaire was not appreciated by others; “I don't like that it sounds a bit judgy”, “I thought the tone was a bit off”, “I didn't like those question they seem a bit insensitive”, “I feel like some of the questions were a bit silly, like worrying about child embarrassing self, that's just flippant beside the very real worries we have of our child dying during the night”. One parent felt that the questions were “strange”; ‘of course I worry, v. dangerous”. A number of participants noted that the questions had limited application for patients using technology; “A lot not relevant when child on pump and CGM”.

6.5.3.3 Thread 3: Drivers of FoH. Amongst those who commented, it was almost universally considered that scores on the HFS-P would be transient and/or circumstantial, i.e., related to fluctuating child variables, situational variables or illness variables. Participants felt that FoH may be heightened when their child is at play, during the night, shorter T1D duration, previous severe hypo/hyperglycaemic episodes or where the child was ‘hypo-unaware’. Participants thought that FoH may also be increased when caregivers live with T1D themselves and know how it feels to experience hypoglycaemia; “I don't want my child to feel like that”.

The most prevalent circumstantial factor identified by the participants (45% of those who commented) was being away from their child; “a severe hypo is a scary thing and the worry it could happen when I'm not around him...”. Caregivers reported difficulty trusting that others will have the understanding or knowledge to manage a hypo effectively; “...maybe unaware of how serious hypos can be or not understanding T1 management properly”. Younger age was also considered to be a significant precipitating factor for some, but other participants commented that as the child ages the worries are

changed rather than resolved, citing puberty, independence, school pressure and alcohol as factors. As one mother put it; “worries will leave, others will replace”.

6.5.3.4 Thread 4: Speculating on scores. Fifty-seven individuals commented on what a low score on the HFS-P might represent. 33.3% equated lower scores with poorer illness management, some felt this could be due to “someone unaware of the risks”, “Being *too* laid back and relax[ed] (sic)”, or “Not enough knowledge”. 21% of participants felt that a lower score represented a positive attitude to illness management; “More balanced view of hypos”, “More relaxed approach” 21% felt that it represented well controlled BG linked to greater understanding or more experience; “a parent of a T1 child for a long time” and access to technology; “Maybe better tech”, while 17.5% didn’t know what the score might mean. One respondent commented that a low score was “Superhuman?”.

A similar number of participants (n=52) speculated on what a higher score on the scale might represent. The largest group (34.6%) felt that a higher score indicated an overly anxious approach to illness management; “Hypervigilance”, “Over thinking”. A subgroup (5.7%) opined that this might be the result of experiencing severe hypoglycaemic episodes in the past. Twenty-two percent felt that higher scores equated to better illness management; “Maybe better understanding of the risks?”, and 11% felt that it represented poorer quality illness-management: “Someone struggling to deal with the enormity of the condition”, “Not in control of diabetes”. Finally, 20.4% did not know.

6.5.4 Phase 2 – Sample characteristics

The phase 2 sample included 8 caregiving parents (6 mothers/2 fathers) and 1 self-caring young adult diagnosed in childhood. One mother was caring for two children with T1D. Participants were purposively recruited to include a variety of children’s ages (8-18yrs), variable T1D duration (1.5-11yrs) and experience with/without technology use;

50% were using closed-loop technology and 50% were using MDI with sensor. All nine participants completed the HFS-P; mean behaviour score was 36.4 (range 30-49; SD 6.34), mean worry score was 46.7 (range 34-65; SD 9.87), the mean total score was 83.1 (range 72-114; SD 14.13).

6.5.5 Phase 2 – Findings

An IPA was carried out on the interview data, which was notably homogeneous in terms of the themes it generated with highly convergent views. Where percentages have been included, they serve to indicate that participants were in full consensus on that theme. Five themes with subthemes were identified (see table 6.4 below).

Table 6.4: Phase 2 Qualitative themes, subthemes and quotes

Theme	Subtheme	Quotes
1. Universal Daily Concerns (100%)	Child alone	• Yeh, so we don't allow him to be on his own. That's the honest answer here... so I would say a 10 if you could go higher...I think I speak for every parent when I say that (P5) • His sugars were [low], we called him and called him and of course his phone was on silent. I called my daughter to wake her up and go to the house (P4)
	Hypos at night	• That's the biggest worry, because it's the longest period unsupervised... where they're asleep they're less likely to feel symptoms that could protect them (P3) • I do worry about this, I sleep though alarms, the technology fails (P1)
	Access to fast acting carbs (FAC)	• The ultimate panic...We did get stuck on the M50 for 2.5 hours last year [with no FAC], I have never been so panicked in my life... (P5) • Yeh, 5, all the time... it's better to be prepared...you're risking going into a coma or death or even just you want to avoid the feeling of going low...it's very bad, it's not pleasant (P2)
2. Drivers of Hypo Distress	Experience	• We had two big serious [hypos] and it's very frightening for her and for us...you're on constant alert.... (P9) • Waking up to my mother screaming oh my god, somethings happened... you're running in to find your dad out cold (P5)
	Not feeling seen in clinic	• Do they [HCPs] know how families really feel? The constant panic, the constant sleeping with one eye open...how can you [sleep] when you're constantly listening for an alarm to go off... and there's this panic of OMG I hope he woke up.... I'd better check if he's breathing (P5) • When HCPs make parents feel that they're to blame for the child's fluctuating blood sugars, it just makes them feel anxious and less confident in figuring out managing the illness (P3)
	Technology	• ...but it's not a perfect solution, the tech fails in loads of ways, I sleep though alarms, the phone might run out of charge or the pump or the sensor might run out in the middle of the night etc... (P1)

		because the sensors taking it from interstitial fluid, the blood sugar can be 10-15 minutes behind the finger prick. And, sometimes that 10-15 really counts (P7)
3. Hypos in Real Life	FAC, exercise, running BG high	- You've got so many factors that you can control as much as you can but then everything else, life, the weather, feelings and emotions, everything has an impact (P9) ...if he doesn't have something [FAC] he'd go low, even with the pump (P6) - You can't be exercising unless you've got stable blood sugars and glucose in reserve, because of the speed with which your sugars would drop (P3) [run BG high] For sure! I often do because away from home or school I know he'll be easily distracted and that people minding him won't be as easily available or know what to do quickly (P1)
	Protective layer	- I feel there's many steps of protection or catches in place before a serious hypo would happen, if all the above steps are taken it [losing consciousness] would virtually never happen (P3) - I put all these mitigations (feed, run slightly high, FAC) in place to minimise the risk (P1)
	Training & empowerment	[Training] You get your kit... but really that doesn't... the written word doesn't... I think through lived experience you learn (P9) - A lot of the learning...I've found with D it's scenario based, it's not about following rules... so for example before exercise ... you have to look at the scenario; what was the child doing before the exercise, and will do afterwards...with sport, it took us a year to work out (P4)
4. HFS Scepticism	Answers are context specific (100%)	[Q. give carb before bed?] So, every single time, it would depend on the circumstances, how the bloods are, previous meal, amount of activity during the day, trending arrows on the cgm, there's a whole pile of variables...actually all of it [questions] are very much dependent on the situation (P3)
	Social questions (100%)	- Hahaha. Really how that's related to Diabetes, I don't know, it doesn't make sense because those things don't happen... (P2) - I, yeh, no that wouldn't cross my mind, it's not a worry, you've far bigger things on the worry scales (P7)
	Tone and wording	I don't like the random questions about embarrassment or losing control. (P2)

		Some of it I feel is slightly insensitive, I think, like there's words like child appearing stupid or clumsy, it just seems like the person who wrote that question doesn't understand what D is or something. (P3)
	Confusing questions	[dizzy/pass out] I've never actually done that, it doesn't sound like a hypo (P2) [feeling light-headed] I don't understand, I don't worry about that (P4)
5. FoH as a Construct	Higher Scores (100%)	[scores] I would say that I am neurotic about this and I make no apologies for it....This is his life and if we can't get it right for him now, he's going to suffer later on (P5) - Disappointed that there's a tool that would interpret my parental worry and care as 'too much' or not normal, particularly as there's lot of those questions where I feel I am actually too loose (P3)
	Reflections on FOH	- The fear I think comes from the necessity of managing so many imponderables such as, tiredness or stress, failing technology, alarm fatigue, errors in carb counting or estimated activity-levels. The fear will have some irrational aspects that influence behaviours but it's from understanding (P1) - Avoiding lows is our primary goal. That's the first thing the doctor will tell you 'you need to avoid lows' and the first thing they look for is the amount of lows you've had (P3) - No. I think it's [fear] sensible. because it's a scary thing. I don't think anything related to lows is overreacting, cos as I've said before it's the most dangerous part about being a diabetic... (P2)

6.5.5.1 Theme 1: ‘*Universal Daily Concerns*’ links data that speak to worries and related behaviours scored ‘often’ or ‘very often’ by all 9 participants. The subthemes identify three highly concerning issues, each of which came up repeatedly in response to various questionnaire items.

1.1 Child alone: All participants, regardless of their child’s age, were uncomfortable with their child being left alone and all had measures in place to ensure this was kept to a minimum, i.e., networks of support personnel; “there's either my daughters here or one of us or a family member” (P5). With older children, where this was not practical, extra arrangements were made; “we went on holiday recently...so even though he's 18, my husband insisted that he stayed at his grandparents, because he didn't want him to be alone at night” (P4).

1.2 Hypos at night: All participants found nocturnal illness management around hypoglycaemic events and mitigations to be the most difficult aspect of caregiving. Many detailed their worries and the impacts on their sleep; [do you worry about your child going low while asleep?] “Yeh, that would be a 5. I don't think I've slept since diagnosis properly...” (P5). Interestingly, half of the participants using closed-loop technology still had high levels of overnight anxiety and were losing significant amounts of sleep; “Even though my phone will scream at me if he goes low [alarm], I still check his sugars every time I wake or turn during the night” (P8).

Fast acting carbs (FAC). Access to FAC was regarded by all as a fundamental requirement for T1D care, all endorsed ‘very often’ or ‘always’ on the related items: “I check this every morning, no matter what” (P1).

6.5.5.2 Theme 2: ‘*Drivers of Hypo Distress*’. This theme captured key determinants of participants’ hypoglycaemia distress.

2.1 Experience: Most participant narratives touched on how their personal experiences have influenced their T1D related behaviours and worries. Two participants felt that their professional and educational backgrounds provided a good foundation for managing the complexities of T1D. Concerningly, five out of the 9 participants had first- or second-hand knowledge of individuals who had died or suffered severe consequences as a result of hypoglycaemia: “[A person we knew] had T1 and he died in his sleep one night and another lady we knew of in [another country] crashed the car and she died [as a result of a low], and it sticks with me” (P4)

2.2 Not feeling seen in clinic: While most participants explained that they felt very well supported by their clinical teams, some used the opportunity to express frustration with the lack of acknowledgment in clinic appointments of their difficulties managing hypoglycaemia: “It’s really difficult to get it all across in clinic, all the tiny things that have influenced caregiving decisions, sometimes it’s overwhelming and you feel they don’t have the time to listen” (P9)

2.3 Technology: 50% of the children were using closed-loop technology. There was great appreciation for the benefits, but also a clear signal that technology was not a panacea and that in certain instances the technology could exacerbate FoH; “I don't know if there's something called Dexcom anxiety, you know, you're constantly looking at it and saying is he ok, is he ok. Because the alarms don't always work and I was finding it was waking me up and I couldn't go back to sleep then. Overload of data” (P4).

6.5.5.3 Theme 3: ‘*Hypos in Real Life*’. This theme details daily management behaviours that are intended to mitigate hypoglycaemia. It highlights the complexities involved and illustrates the importance of context for determining illness-management behaviours, challenging the questionnaire items as potentially over-simplistic.

3.1 '*FAC, exercise and running BG high*': All participants emphasised the variable nature of illness management decisions; "it's like a science experiment every single day" (P9). They explained that under specific circumstances, feeding FAC to their child could be required to avert a hypo; "certainly, food to prevent a low later on in the night would often be part of it..." (P3). In addition, all concurred that they would always delay exercise when a child is trending low "that's common sense...cos a lot of the time exercise causes lows so. Yep." (P2). Lastly, 80% of participants reported that keeping children 'slightly' high was sometimes warranted; "We would sooner see it run a little bit on the higher side, but a little bit... something that would benefit them to be very slightly high than go low" (P8).

3.2 '*Protective layer*': 55% of the participants noted that the behaviours and worries explored by the questionnaire are to varying degrees, keys to building a system of 'protective strategies' to manage the ever-present threat of hypos; "...I think when you've covered all your eventualities and you're prepared in advance... you're never going to get to a 3 [mmol/hypo]" (P5).

3.3 '*Training & empowerment*': This subtheme emphasises the requirement to be well informed on the complex issues at play in managing T1D safely in the home setting. Most of the participants paid tribute to the healthcare professionals who trained them. "they're an amazing team and very supportive" (P5). Many emphasised the significant amount of information required to keep their children safe; "There is a huge amount of knowledge and learning" (P4), and also the value of active learning; "I remember them saying in the hospital, stop checking his numbers so often...I just said to him, do you have a T1 in your house, he said no and I said well you work it and I live it, it's completely different. Like looking at a movie and reading a textbook" (P5). Participants also spoke about the importance of feeling capable of making treatment adjustments themselves; "I feel like it's like reacting rather than going by data, which we are doing. We do feel confident to do that, (our clinic) has given us that (P8)".

6.5.5.4 Theme 4: ‘HFS Scepticism’. Participants queried item topics or the framing of questions.

4.1 Answers are context specific (100%): In this subtheme (linking to theme 3) all of the participants made the point that the questions did not take into account the many variables that determine how they would endorse items: “Asking about the ‘right’ amount is not taking in context. Right amount. There is none” (P1). The most representative of these variables was the child’s age, with participants suggesting that behaviours and worries about hypoglycaemia vary significantly depending on the age of the child: “So ‘often’, not anymore, but when he was younger, absolutely yes” (P4); “I guess in a way they're [the questions] all age dependent in some sense” (P3). Also, use of technology as a contextual factor was highly represented, all expressed the opinion, often multiple times, that their responses would have been completely different before adopting the illness-management technology, all expected substantially higher scores: “I would think that without the technology everything would have been a 5, very often” (P5).

4.2 Social questions: Four questions (#s 13,15,17,20) were interpreted by the participants as enquiring into the social consequences of hypoglycaemia (e.g., ‘[do you worry about your] Child appearing stupid or clumsy?’), these were deemed to be inappropriate by 90% of the participants. Few of the questions were endorsed at levels higher than never (1) or rarely (2) by the majority of participants; “...compared to all the other stuff these questions are trivial” (P1).

4.3 Tone and wording: The tone of some questions was felt to be alienating. 50% of participants queried why one question asked if they gave their child a ‘large’ snack at bedtime, this felt like an unnecessary qualification that seemed to suggest uninformed caregiving and wasn’t appreciated; ‘feels like a trick question’ (P1). Some participants found other questions to be poorly worded, questioning whether it was necessary to label

hypo behaviour as ‘stupid or clumsy’, which didn’t represent their experience; ‘that’s just not how we think about it’ (P3).

4.4 Confusing questions: Three questions (18,22,24) created confusion (e.g., [do you worry about your] Child losing control?): “I don’t know what this means? Are we talking about their D or in general” (P5). Aggregated scores for all three items were notably low for 67% of the participants (totals; 3,4,4,5,5,6).

6.5.5.5 Theme 5: ‘FoH as a Construct’. On completion of the questionnaire, participants were given their scores and asked what they would expect that score to represent, they were then prompted to explore their ideas further.

5.1 ‘Higher scores’ (100%): Interestingly, all of the participants felt that a higher score indicated that they were carrying out their caregiving capably, in an engaged and informed manner: “I will definitely answer high [on questionnaire] because it’s what we parents do to be engaged in good diabetes management for our children” (P1). Some noted that lower scores would be concerning for patient safety: “It’s an undeniable truth that insulin is extremely dangerous and with children involved, I feel I would not be a good parent if I scored any lower” (P3). It was noted by two participants that higher scores may be indicative of overly anxious caregiving, but this was qualified by; “these are all valid concerns, I can’t see how you’d call it a problem” (P4).

5.2 ‘Reflections on FoH’: None of these participants felt that their beliefs around hypoglycaemia were creating problems; “There’s a lot of questions that all mean ‘are you scared of lows?’, and the answer is, yes” (P1). Hypoglycaemia was understood as a serious, unavoidable consequence of insulin treatment and hypoglycaemia-mitigation was regarded by all as key to managing their child’s illness and keeping them safe; “you’re doing the work of an organ, and that’s a biggie” (P9).

6.6 Discussion

The objective of this study was to evaluate the construct FoH from the perspective of T1D parent-caregivers and to explore whether the HFS-P corresponds to the lived experience of parental caregivers and credibly captures FoH, this was achieved through two distinct study phases, phase 1 involved an online survey and phase 2 utilised individual interviews.

A key finding from Phase 1 of study was that that higher FoH levels were associated with better health outcomes (HbA1c), which contradicts both the commonly held belief that higher FoH drives poorer illness management (Burckhardt et al., 2018; Abitol and Palmert, 2021) and other research that found no relationship (De Beaufort et al., 2021; Amburgey et al., 2020). This finding illustrates that it may be misleading to designate all caregivers with higher FoH scores as engaging in maladaptive caregiving behaviours and suggests that highly motivated and informed illness management is captured by high FoH scores and can be mischaracterised as ‘fear’. While no clear association was found between knowledge seeking/level of engagement and FoH in the quantitative analysis, responses from the qualitative analysis suggests these factors may have played a role. Some researchers have proposed that more fear can stimulate greater vigilance and motivate more effective BG control (Hanna et al., 2014; Molęda et al., 2017), but there is an outstanding question of whether the fear is ‘rational’ or ‘irrational’. Qualitative evidence detailing the parent’s perspective suggests that almost all of the sample considered FoH to be rational and justified by the constant threat of serious hypoglycaemia, which is understood as a high jeopardy issue with potentially very serious consequences for their children (Yale et al., 2018).

The study also looked at FoH drivers, finding none of the demographic or care factors associated with the level of FoH experienced. This implies that any parental caregiver (regardless of child age etc.), could have this experience. In contrast to the

hypothesis, the use of technology was not associated with lower FoH scores. This was explained by qualitative data, which suggested that although the technology was welcomed, it often brought challenges that heightened FoH, for example, the constant flow of data was experienced by some as a FoH driver. This echoes recent findings in the literature (Abitol and Palmert, 2021).

Key findings from phase 2 included participants' descriptions of the difficulties they experienced responding to the HFS-P questionnaire. Participants felt that their responses on many of the items related to caregiving tasks, such as giving FAC or running BG high, would always be variable and context related, taking situational factors such as child being alone, nighttime or exercise into account. The majority of participants emphasised that care delivery needed to be adaptive, reflecting the highest standards of care and aligning with previous research (Tong et al., 2021). However, from the parent-caregiver perspective, this was not reflected by the construct, the HFS-P scale, or indeed much of the research on the topic. For example, the safety and efficacy of insulin therapy is closely related to glucose monitoring and insulin dose adjustments made by the individual with diabetes (Holt, 2021). However, in one study on FoH in parent-caregivers, authors included questions on how often participants were 'non-compliant in administering insulin according to recommendations from the clinical team (due to FoH)' (Abitol and Palmert, 2021). The framing of these questions suggests that the clinical team know better, which does not align with the dynamic and collaborative nature of modern illness management.

The absence of 'normative ranges' for FoH was noted above. In this regard, it was instructive to note that the FoH-P mean total score for phase 1 was 75.5 and 83 for phase 2. For comparison, six studies included in the systematic review (study 1) looking at general nocturnal caregiving, that reported HFS scores for their samples, reported means ranging from 43.2 (Jaser et al., 2017) to 68.5 (De Beaufort et al., 2021). Interestingly, in the phase 2 sample, the range of scores was very broad (63-114) but not well aligned with those from

the systematic review. At the highest point was an individual who reported high awareness and understanding around hypoglycaemia, attributing this to their partner's experience as a healthcare practitioner. Notably, this person's child was also living with the diagnosis, the longest of the group. One could argue that more information/experience led to higher fear, but it was also the case that the lowest scoring participant in the sample, who reported a comparable T1D duration, recalled very traumatic experiences related to a relative with T1D having numerous life-threatening events. This presents a contradiction that may in part relate to the limitations inherent in Likert scales, as documented by Ogden and Lo (2012), who showed that frame of reference and expectations impact significantly on how questionnaire items are rated, casting further doubt on the value of the HFS scoring system.

Across both phases, the qualitative data revealed considerable challenges encountered by individuals in their efforts to manage hypoglycaemia, the negative emotional language that was almost universally used painted a powerful picture. Given this common experience it was interesting that some individuals queried use of the word 'fear' in FoH, suggesting that 'anxiety' may be a more appropriate descriptor. This could be explained by the finding that 66% felt their FoH was entirely justified as a rational response to a situation carrying significant potential harm, while the word 'fear' has more pathological connotations, as evidenced by the characterisation of FoH as maladaptive and phobic (Abitol and Palmert, 2021; Kamps et al., 2005). In addition, when asked if the construct applied to themselves, 68.2% felt that it did, which would be unlikely if the construct was recognised as undesirable. Furthermore, it is instructive that confusion was generated around the participants' interpretation of lower and higher scores; 21% correctly identified the meaning of a low score and 34.6% a high score. This is a construct that purports to capture their own experience, again, it seems unlikely that such a large portion of the subject population would not be able to interpret its meaning. Taken together, these

analyses support the argument that FoH is a construct that potentially oversimplifies a complex experience.

Lastly, much of the feedback on the questionnaire itself was consistent across phase 1 and 2, with the tone of some questions experienced by many participants as alienating and other questions causing confusion or difficulty in comprehending the relevance. Furthermore, some question topics were deemed inappropriate, resulting in some participants stating that they felt the questionnaire was not very well attuned to the experience of managing this condition. This finding spotlights the emergent understanding that consultation with patient experts to integrate community knowledge into research is critical for developing tools and interventions that are of genuine benefit, deemed acceptable by the subject cohort and empowered to deliver improved research quality and impact (Luger et al., 2020; Whitesell et al., 2018).

6.7 Limitations

Methods used to recruit for this study may have resulted in a relatively informed/engaged sample that may not adequately reflect the general population, for example, as noted in Table 6.1, this population had a significantly higher level of education than population norms. In addition, poor response rates among male caregivers resulted in a significant gender bias and limited the capacity to carryout gender analyses, which could have been informative.

6.8 Conclusion

Findings show that the HFS-P operationalises the assumptions underpinning the FoH construct, however neither appears to map onto the lived experience convincingly from the parent-caregiver perspective. This creates doubt around the reliability and validity of the HFS-P as a scale for isolating and capturing FoH. The issues are exacerbated by the

lack of defined cut-off points. In the definition included above ‘extreme’ levels of FoH were regarded as problematic, but this is not how this construct is treated in the literature. Understanding the implications for caregivers of having their experience pathologised based on a dubious construct is important as it may not be helpful long-term for supporting this already highly burdened population and empowering them to deliver high quality illness-management support to their children. This study does not propose that the construct/scale have no value but recommends more judicious use that challenges assumptions and continues to explore findings critically.

The following chapter reports on study 4, a cross-sectional, mixed methods study that builds on findings from the SLR (study 1), by using an online survey methodology to investigate whether those findings would be replicated in an Irish sample (n=239) recruited from the diabetes clinic in a large, urban children’s hospital.

Chapter 7. Study 4: Nocturnal caregiving practice among caregiver parents of juveniles with T1D in Ireland– a mixed methods study

7.1 Abstract

Introduction: Delivery of nocturnal care can be a feature of parenting juveniles with T1D.

Objectives: To explore nocturnal caregiving practice among caregiver parents attending for their children's T1D care at Ireland's largest children's hospital. *Methods:* Mixed-methods, cross-sectional study co-designed with a PPI panel (n=4), utilising survey methodology.

Participants (n=235; 71% female) were recruited from a clinic waiting room between January - April 2024. The survey comprised a mixture of researcher-devised questions, a validated scale and open-text response questions. Descriptive statistics addressed nocturnal caregiving prevalence, t-tests and a logistic regression explored impacts and predictors.

Results: Caregivers of 60% of clinic patients participated. Among these, 76% reported sleep disruption and reduced sleep quality due to nocturnal caregiving practice, with 43% engaging in nocturnal caregiving 3-7 nights per week and 32% waking twice a night, 2-5 nights per week. No significant impact on HbA1c from NCP was found. 41% reported related sleep problems, with 42% scoring for fatigue on the Iowa Fatigue Scale and 11% scoring for exhaustion. In addition, 37.5% felt that sleep disruption from nocturnal caregiving had negatively affected their health. 73% had not discussed caregiver burdens in their clinics. A logistic regression explained 45% of the variance in nocturnal caregiving practice but only two factors made a unique, statistically significant contribution to the model: The 'pump and sensor' treatment regimen ($B = 2.31, p = .010$), OR = 10.077, and 'difficulty making ends meet' ($B = -2.11, p = .013$), OR = .121. *Conclusion:* Nocturnal caregiving presents a considerable burden for caregivers, impacting significantly on wellbeing. Despite this, it is not routinely addressed in clinical settings or in research. This

work highlights a need for more comprehensive support systems and proactive clinical dialogue to address caregiver burden in T1D care.

7.2 Background

Prevalence of T1D in Ireland is at the higher end of global rates, with approximately 37 per 100,000 children under 15 years diagnosed in 2021 (Roche et al., 2023). Illness management is complex and high burden, requiring constant vigilance to manage insulin therapy and control blood glucose. Poor blood glucose management (sustained hyperglycaemia) can result in serious long-term complications, while the more immediate threat of hypoglycaemia, a side-effect of insulin therapy, can result in coma and even death (Amiel, 2021).

Juvenile T1D can put a significant strain on families (Jaser et al., 2009) as stable blood glucose (BG) is harder to achieve in juveniles than in adults (American Diabetes Association, 2018). Successful illness management and better health outcomes are often dependent on engaged parental caregiving (Schunk et al., 2015). For some families, T1D care is a 24hr responsibility (Streisand & Monaghan, 2014), though the topic of nocturnal caregiving has received very little attention in the literature to date (Ji et al., 2021) and current international care guidelines do not address nocturnal care specifically (ISPAD.org, 2018). In Ireland, while the current model of care recognises the overall burden T1D places on families, it fails to address the specific challenges of nighttime care (HSE, 2015).

Recent technological advances in continuous glucose monitoring have shown that nocturnal BG fluctuations are more common than previously understood (Heinemann et al., 2018). To manage these fluctuations, caregiver parents may postpone bedtimes, wake multiple times per night and/or wake earlier than normal to monitor BG and treat as required with insulin or carbohydrate (Bergner et al., 2018; Carreon et al., 2021; American Diabetes Association, 2018). The prevalence of nocturnal caregiving practice is

surprisingly high. Study 1 reported that 88% of caregivers (n=1,301) engaged in nocturnal caregiving practice (Howard et al., 2025), however there was a large degree of variance in the frequency of practice. The review found that nocturnal caregiving behaviour was motivated by both hypoglycaemia and hyperglycaemia mitigation, diabetes related anxiety and variable factors like diet, exercise and hormonal changes. Many parents institute nighttime care routines to optimise juveniles' T1D outcomes, but there is a notable paucity of comprehensive research on the effectiveness of nocturnal caregiving practice on overall illness management (as represented by A1c blood test value). Counterintuitively, the few studies that do address this question, found no relationship (Howard et al., 2025). However, higher caregiver 'Fear of Hypoglycaemia' has been linked to increased nocturnal caregiving as well as poorer illness outcomes (Howard et al., 2025; Schierloh et al., 2024; Macaulay et al., 2020; Andreopoulou et al., 2024), suggesting that Fear of Hypoglycaemia could be acting as a confounding factor in research exploring the effectiveness of nocturnal care delivery. Meanwhile, evidence on the influence of patient factors on nocturnal caregiving has been inconsistent, with diabetes duration and patient age showing low predictive value (Howard et al., 2025). Furthermore, caregiver gender differences in nocturnal caregiving were apparent, with 77-100% of caregiver participants identifying as female among the studies reviewed as part of the SLR (Howard et al., 2025). This aligns with findings from previous research, for example, Kobos and Imiela (2015) purposively recruited primary caregivers for their study sample (n=112) and observed that all the caregivers endorsed female gender, reflecting the reality that mothers typically carry primary caregiving responsibility in T1D (Toledano-Toledano & Luna, 2020).

Nocturnal caregiving has obvious implications for caregiver sleep. It is well established that sufficient, good quality sleep is necessary for good cognitive and emotional functioning (Satterfield & Killgore, 2019; Toschi et al., 2021). It is known that impairments in these domains can have implications for T1D caregiving dyads; complex

treatment decision-making requires cognitive competence (Rustad et al., 2013) and parents' emotional response to T1D burden will influence that of their children (Willemen et al., 2022). Caregiver's general functioning can also be impacted by a lack of sufficient sleep and fatigue that puts carers at higher risk of the negative consequences, for physical and psychological health, associated with lack of sleep (Martínez et al., 2022; Peng et al., 2020).

A positive outlook for T1D care has emerged because of the advances in medical assistive technology, which have changed the T1D treatment landscape significantly in recent years, offering considerable potential for supporting nocturnal caregiving burden (Charleer et al., 2018; Triki et al., 2021; Roos et al., 2024). Currently available treatment regimens provide varying degrees of automation; manual insulin dosing and BG monitoring, automated insulin delivery via an insulin pump, automated BG monitoring via a sensor and, most recently, a closed-loop system that links sensors to pumps with an algorithm that calculates and delivers insulin doses automatically. Such diabetes assistive technologies can link to smart phones offering many benefits to caregivers, allowing them to monitor their children's BG in real time, therefore reducing worry (Burckhardt et al., 2018; Lawton et al., 2018). These advanced technologies are costly however, so access is a significant issue due to limitations on resources. Many individuals (in Ireland and globally) will only have manual treatment options available to them (Gajewska et al., 2022; Ng et al., 2024). Technology driven improvements in glycaemic control and illness management burden are well documented (Prahalad et al., 2018), though there is conflicting evidence on whether these devices universally improve caregiver sleep, with many caregivers citing device failures, alarms and the continuous flow of data as actually increasing their nocturnal care burden (Cobry et al., 2022b; Macaulay et al., 2020).

The burden of care associated with parenting a child with T1D is often unrecognised or underestimated, leaving caregivers feeling unsupported and lonely

(Symons et al., 2015). Caregivers report feeling isolated because friends and family do not understand how difficult it is for them “on a physical, daily, everyday thing” (Rifshana et al., 2017). Friends and family often have poor diabetes knowledge (Kimbell, 2021) and can be unwilling to learn (Azimi et al., 2024). One study found that, although medical staff and diabetes teams were considered important sources of support, parents felt that they too did not fully understand the struggle of caring for a child with T1D on a day-to-day basis (Azimi, 2024), or “appreciate the complex and dynamic nature of managing diabetes at home” (Kimbell, 2021). Lindström et al., (2017) reported that clinicians sometimes failed to acknowledge how some parents may be struggling to cope with the burden of diabetes care within the context of the family. Regarding nocturnal care, Bowen (2024) found the majority of caregivers had no recollection of discussing sleep with their clinical care providers, the minority who had been engaged by clinicians on these topics, noted that the conversations were superficial.

Limited research has attempted to identify potential supports for nocturnal care beyond those offered by technological solutions. Among studies that have been carried out, findings can be grouped into the following themes; connecting with peers (Azimi et al., 2024; Oser et al., 2017), shared responsibility for nocturnal caregiving within the home, respite opportunities and additional guidance from diabetes healthcare teams (Macaulay et al., 2020), sleep education (Feeley et al., 2021), diabetes education, information support and flexible working hours (Saßmann et al., 2022). Morrow et al. (2022) highlighted the importance of diabetes healthcare teams addressing parent sleep during check-ups. This was supported by findings from Howard et al. (2025), who reported that across 23 relevant papers, 83% of the authors recommended that the issue of nocturnal care be routinely addressed in T1D clinics, which is not current practice.

7.3 Objectives

Building on the outcomes of study 1 (SLR), this study aimed to carry out an in-depth exploration of nocturnal caregiving practice among caregiver parents attending for their children's care at a large, paediatric diabetes clinic in Ireland. The overarching aim was to establish whether the patterns of nocturnal caregiving practice, identified in the systematic literature review, would be replicated in an Irish context.

For the purposes of the current study, nocturnal caregiving refers to any T1D related activity that occurs after the child has gone to bed at night and before the child and parent would normally rise in the morning. The study used a mixed-methods approach and was designed in collaboration with a public and patient involvement (PPI) panel of experts by lived experience, specific aims were to:

- (1) Establish nocturnal caregiving prevalence in a clinic that is highly supportive of assistive technology.
- (2) Explore the impacts from nocturnal caregiving practice on parent caregivers.
- (3) Enquire into the relationship between gender and nocturnal caregiving burden.
- (4) Investigate the moderating impact of diabetes assistive technologies on nocturnal caregiving burden.
- (5) Establish what demographic and patient illness-related factors predict nocturnal caregiving practice among parents.
- (6) Explore what aspects of care provision are more effective for supporting caregivers in managing the burden associated with nocturnal caregiving.

7.4 Method

7.4.1 Reporting

The STROBE cross-sectional study checklist was adhered to (Von Elm et al., 2007) as well as the Standards for Reporting Qualitative Research (SRQR) checklist (O'Brien et al., 2014)

7.4.2 Research design

This mixed-methods, observational study utilised a survey methodology. The study was designed by the researcher in collaboration with a public and patient involvement (PPI) panel (n=4). Ethical approval was granted the School of Psychology Research Ethics Committee (SPREC) from Trinity College Dublin in September 2023 and Children's Health Ireland research ethics committee in November 2023. See Appendix 1.

7.4.3 PPI involvement

As discussed in chapter 2, section 2.5.3, a PPI panel was recruited to support the research activities of this series of studies. For this study, a sub-group of four caregiving parents for juveniles with T1D were available to engage with the research over the timeframe required, they included 3 mothers and 1 father. One individual also had a diagnosis of T1D themselves. Three cared for children who used hybrid closed-loop technology, but two also had prior experience of manual illness management. All the panel members had children who had been living with this diagnosis for over 1 year. Collaborative consultations took place over a series of three in-person and online meetings as well as email exchanges. The topics addressed were the following: 1) The research agenda was agreed in response to findings from the previous studies. 2) Panel members proposed novel themes/items for inclusion. 3) Iterative work was carried out to co-develop more complex survey items, for example, two questions were required to capture

comprehensive data on nocturnal caregiving frequencies, the PPI collaboration identified the most efficient and accessible approach for achieving this. 3) The survey structure was co-designed with panel members, who gave feedback on the section topics and the order they were presented in. 5) Finally, 2 panel members pre-piloted the survey, very minor changes resulted.

7.4.4 Research paradigm

The study adopted a pragmatic philosophical approach, which is suitable for a mixed-methods survey that integrates both quantitative and qualitative items. Pragmatism prioritises the research question as the central driver of research decision making and acknowledges that both objective and subjective realities can offer valuable insights, supporting the use of multiple data sources and analytical strategies to gain a more comprehensive understanding of the phenomenon under study (Morgan, 2014; Allemang, 2022). The use of a survey methodology reflects this pluralistic stance, combining quantitative items aimed at identifying patterns and generalizable trends, with open-ended, qualitative responses that allow participants to articulate personal experiences and perspectives, enabling the study to capture both the measurable dimensions of a behaviour and the contextual elements that underpins them. Furthermore, while the quantitative components of the study are informed by a post-positivist orientation, which recognizes that knowledge can be approximated through observation and measurement, the qualitative elements are grounded in interpretivist principles, acknowledging the co-construction of meaning between participants and researcher (Elliott & Timulak, 2005).

7.4.5 Participants

The survey inclusion criteria were ‘parents of a juvenile with a diagnosis of T1D’ and ‘conversant with English language’. No other criteria were applied. Participants were recruited in the waiting room of a hospital-based diabetes clinic.

7.4.6 Procedure

The researcher was granted access to attend the paediatric T1D clinic at a large, urban children’s hospital in a major city. The clinics were scheduled once or twice weekly. The researcher attended for a full cycle of appointments (January-April 2024). Parent-caregiver participants were approached when they arrived in the clinic waiting room. Each potential participant was asked if they were caregivers for a child with T1D (CCT1D), while some were waiting on a different clinic, the vast majority indicated that they were CCT1D. The researcher gave a high-level description of the research (without referencing nocturnal care) and offered them a research device (tablet) to access the information sheet and consent form for the survey. Those who consented then proceeded to the anonymous online survey (hosted on Survey Monkey). They were also offered the option to use a QR code to access the survey using their own device, in their own time. The survey took between 20-30 minutes to complete. Some patients were called for appointments while they were completing the survey, most returned to complete it.

7.4.7 Measures for data collection

The survey comprised a mixture of demographic and illness-related questions, a validated scale and open-text response questions (see Appendix 7.1 for full survey). It included the following sections:

Demographics: Questions on parent-caregiver demographics included gender, education level achieved, employment status, domestic partnership status and financial status, which

was captured using an item that asked about ‘ease of making ends meet’ (6-point scale, very easily-with great difficulty). Participant health status was reported using a 5-point self-rating scale. Patient demographics included current age and age at diagnosis.

Illness related variables: These included ‘what treatment regimen are you currently using?’ (injections, insulin pump, sensor, closed loop technology), ‘what was your child’s most recent HbA1c?’ (measuring level of blood-glucose control achieved), ‘do you have any family history of T1D?’, ‘have you had any episodes of severe hypoglycaemia/hyperglycaemia, and if so, how many?’

Nocturnal caregiving practice: Nocturnal caregiving frequencies were gathered using 2 questions; ‘how often do you wake to take care of your child’s diabetes?’ and ‘how often do you wake to take care of your child’s diabetes?’, 3 questions addressed nocturnal care behaviours, such as, ‘does your child sleep in the bed with you?’. Specifics regarding the characteristics of nighttime care activities were captured using a question with 15 items, allowing individuals to endorse the activities they engaged in, for example, at night, ‘do you test blood glucose with a finger prick?’; ‘do you feed carbohydrates to treat a low?’.

Sleep experience: Sleep data was captured by asking whether caregivers experienced sleep disruption due to their caring activities, whether their sleep quality was affected, how many hours of sleep they typically achieved and how many they required to feel rested. A final question asked whether they have experienced sleep problems as a result of their disrupted sleep.

Impacts: Fatigue was measured using the Iowa Fatigue Scale (IFS). This is an 11-item instrument, utilising a 5-point scale (not at all - extremely) to respond to questions such as ‘I feel worn out’. Scores fall between 11 and 55, with scores between 30-39 indicating fatigue and 40+ indicating severe fatigue. This scale has an overall Cronbach’s alpha coefficient of .90 (Hartz et al., 2003), the alpha for this sample was .87. An ‘Other Impacts’ scale was developed with PPI input, based on findings from a systematic literature review

by Howard et al., (2025). This was a 10-item questionnaire, utilising a 5-point scale (no impact – very significant impact) to respond to items such ‘Does nocturnal caregiving impact on your levels of stress?’. A reliability analysis found the Cronbach’s alpha for the scale was .94, indicating excellent internal consistency. While high internal consistency is desirable, values above .90 may suggest item redundancy. PPI consultation on the matter led to the conclusion that in this instance, the items were adequately different to be included.

Qualitative data was gathered using 2 open-text questions; ‘Could you describe any other impacts that you have experienced?’ and a series of 3 questions asked about the caregivers’ own health, ‘do you feel that your health has been affected by your disrupted sleep?’.

Potential solutions: A series of 5 qualitative questions such as ‘do you discuss nocturnal caregiving with your doctor?’ or ‘what do you find helpful with nocturnal caregiving?’, were included to elicit data that would provide some insight on potential moderators for nocturnal caregiving burden and requirements for support.

7.4.8 Pilot of online survey

A pilot of the online survey was conducted with a small group consisting of 3 researchers and 2 caregivers known to the researcher, to assess the clarity, usability, and overall flow of the questionnaire. Feedback indicated that while the survey was generally easy to navigate, a few areas for improvement were identified. Researchers noted that some questions contained technical terms (i.e., HbA1c, low bloods, hypoglycaemia) that could be simplified or defined for non-specialist respondents, it was decided that this was not likely to be an issue for the target population and no change was made. Additionally, a researcher suggested reordering the questions in the ‘sleep experience’ section to improve the logical progression, this change was carried out. Caregivers recommended shortening the length of the survey to increase the completion rate, a small number of items were

deleted i.e., ‘how long has your child lived with this diagnosis?’ (this information could be ascertained by subtracting child’s age at diagnosis from current age). Minor technical issues were also identified, such as unclear instructions for skipping non-applicable items or submitting the completed survey. Lastly, a modest amount of question wording was thought to be confusing. In response to this feedback, adjustments were made to some instructional text and some questions’ wording, these changes were made to enhance accessibility and support higher levels of engagement with the research.

7.4.9 Data Analysis

An a-priori power analysis was conducted using G*Power 3.1 (Faul et al., 2007), using an estimated medium effect size of 0.3, 0.8 power, and 0.05 error. The analysis confirmed that the sample was adequately powered to carry out the desired analyses. A research assistant supported this stage of the study. Quantitative data were analysed using SPSS (version 29) software. Descriptive statistics, including means, frequencies and standard deviations were computed for all variables to address prevalence, impacts and gender questions. Inferential analyses included; independent samples t-tests to address the impacts from nocturnal caregiving practice on self-rated health as well as addressing questions related to gender, ANOVAs addressed questions related to treatment regimens and impacts from nocturnal caregiving, a Chi-Square test addressed sleep disturbance from nocturnal caregiving, and a multiple logistic regression was carried out to assess the predictive power of patient and caregiver independent variables (i.e., child’s age, time since diagnosis, treatment regimen, HbA1c, parent’s gender, domestic partnership status, educational level achieve, ease making ends meet), on the target variable nocturnal caregiving.

Qualitative data were analysed using NVivo (version 14). Inductive qualitative content analysis was considered an appropriate choice, as the research was interested in

taking an inductive approach to uncovering underlying patterns, categories and themes in the open-response text, interpreting the comments at the explicit level (Forman & Damschroder, 2007). The following steps were followed: (1) Preliminary coding of the text at sentence level. (2) Based on the preliminary codes, a codebook was developed and a second round of coding was carried out to implement the framework. (3) Codes were categorised and frequencies calculated. (4.) Patterns were identified and inferences made. (5) Codes were organised into themes and subthemes so that a coherent map of the data could be presented. (6) Illustrative quotes were selected to accompany each subtheme. All stages of the analysis were reviewed by the research assistant, where disagreements arose, they were discussed until they were resolved and the theme map was adjusted to reflect any changes.

7.4.10 Reflexivity

As noted, the researcher had personal experience of T1D caregiving. While this provided a valuable insider perspective, the researcher also understood the challenges of a dual role and the potential for bias. To address this the author employed reflexive strategies such as maintaining a research journal, engaging in peer debriefing and external validation to ensure transparency and rigor, as well as maintaining a practice of continual reflection and self-awareness.

7.5 Results

7.5.1 Sample Characteristics

In total, 235 caregivers responded to the survey. 71% identified as female (n=165) and 88% ranged in age between 35–54 years (n=205). The sample reported higher levels of education, with 60% (n=139) holding a graduate or post-graduate degree. 61% agreed that they were able to make ends meet (n=142) and 82% were living in a domestic partnership

(n=191). Almost half (49%, n=113) were in full-time employment and 22% (n=50) were working part-time. Notably, 71 (30%) had changed their employment status as a result of their T1D caregiving responsibilities. 5% of the sample had more than one child diagnosed with T1D. High levels of chronic disease were present in this sample (n=206); 27% reported living with chronic conditions, (autoimmune, blood pressure, chronic pain), some with multiple conditions. On participant health status, 24% reported very good or excellent health, 46% reported good health and 30% poor or fair. Table 7.1 displays the demographic and T1D-related data in further detail.

Table 7.1. Demographic and illness-related variables

Caregiving parents (N= 235)	Patient with T1D
Gender (n=234)	Age (yrs) (n=230)
F: 71%	M=11.74; SD=3.79
M: 28%	<6=7.3%
Prefer not to say:1%	6-11=33.6%
	12+=59.1%
Education (n=233)	Age Dx (yrs) (n=231)
Primary School 1%	M=6.765; SD=3.928
Secondary School 22%	Range=0-16yrs
Apprentice/Diploma 18%	
University Graduate 31%	
Post-Graduate 29%	
Marital Status (n=233)	Dx duration (yrs) (n=230)
Single 10%	M=4.99yrs; SD=3.826
Married/Domestic partnership 82%	Range 0-15yrs
Separated/Divorced 7%	
Widowed 2%	
Occupation Status (n=233)	HbA1c (mmol) (n=206)
Employed full time 49%	M=7.2; SD=.754
Employed part time 22%	Range 4.6-10.0
Working in the home 24%	
Not working (illness/disability) 2%	
Other 4%	
Income: Is your household able to make ends meet? (233)	Treatment Regimen N=231
Very easily 8%	Injection + sensor 28%
Easily 19%	Pump + sensor 24%
Fairly easily 35%	Closed loop 32%
With some difficulty 29%	No sensor 17%
With difficulty 7%	
With great difficulty 3%	
More than one child with T1D (n=234)	Family history of T1D (n=231)
Yes: 5%	Yes: 26%
No: 95%	No: 74%
Severe Hypoglycaemic event (n=230)	Episode of Diabetic Ketoacidosis (n=231)
10%	38%

7.5.2 Prevalence of nocturnal caregiving

7.5.2.1 Frequencies.

On average, participants personally contributed 68% of *general* caregiving duties (n=235) and 73% of *nocturnal* caregiving duties (n=230). Responses to the question ‘how many nights in an average week do you wake to take care of your child’s diabetes’ are presented in Table 7.2. This illustrates how almost two thirds (65%) of the sample engaged in nocturnal caregiving at least once a week, with almost a fifth (17%) engaging every night. Participants were also asked about their experience of multiple wakings per night (see Table 7.3), almost a third (32%) report waking twice a night on 2-5 nights a week.

Table 7.2. Nocturnal caregiving frequencies per *week* (n=231)

High to moderate frequency		Lower frequency	
Every night	17%	2-3 nights a month	18%
5-6 nights a week	11%	1 night a month	4%
3-4 nights a week	15%	<1 night a month	10%
1-2 nights a week	22%	Never	5%

Table 7.3. Nocturnal caregiving frequencies per *night*

Wakings per night	Frequencies in an average week
One waking a night (n=182)	20.3% wake once a night between 4 and 7 nights a week
Two wakings a night (n=168)	32% reported that this occurs between 2 and 5 nights a week
Three wakings a night (n=156)	35% reported that this occurred between 1 and 3 times a week
Four wakings a night (n=130)	22.4% endorsed this experience, 5% reported that this occurs 5-7 nights a week

7.5.2.2 Qualitative comments on nocturnal caregiving frequencies

Participants were asked to comment further on their nocturnal caregiving using open-text responses. Eighty-six participants commented, responses were categorised into five themes: (1) *Technology*. The vast majority of participants identified benefits for nocturnal caregiving from technology use, though a minority noted that technology use can

have drawbacks. (2) *Nocturnal caregiving activities*. 22% of the responses referenced specific activities that were a feature of nocturnal caregiving for them (e.g., responding to alarms). (3) *Unpredictable*. Some participants highlighted their experience of variability in the necessity for nocturnal caregiving (4) *Exhaustion*. Individuals referenced the fatigue associated with nocturnal caregiving burden and (5) *No longer required*. Participants referenced factors (child’s age, family support, running BG high) that had reduced the necessity for nocturnal caregiving for them. See Table 7.4 for illustrative quotes for each of the themes.

Table 7.4. Additional comments on nocturnal caregiving frequencies

Theme	Quotes
Technology (32%)	<i>“New pump with guardian sensor means I can now sleep. Prior to this, 7 years of interrupted sleep, waking every 3 or 4 hours”; “Often the anticipation of hearing pump alarms keeps me awake”</i>
Nocturnal Caregiving Activities (22%)	<i>“I set alarm to go off twice to go into [child] to make sure her sugar levels are ok”, “Both highs and lows can cause anxiety and nightmares on top of tending to the actual lows/highs and this can mean additional disturbances”; “Sports as older child has big impact by overnight”</i>
Unpredictable (19%)	<i>“I could only get up once in a week or 3 times a night for a week”</i>
Exhaustion (15%)	<i>“It’s exhausting and impacts the whole family”.</i>
No Longer Required (12%)	<i>“It has lessened as he has gotten older”.</i>

7.5.3 Nocturnal Caregiving – Activities

Participants reported that 68% of nocturnal caregiving tasks require them to get out of bed, while 36.4% reported setting alarms to monitor their child’s BG during the night and 32% always/often/sometimes have their child sleep in bed with them to facilitate nocturnal caregiving. Nocturnal care tasks were reported as follows, in descending order of frequency (see Table 7.5).

Table 7.5. Percent of caregivers who endorsed each category of nocturnal caregiving activity as being representative of their experience (n=207)

Activity	Frequency	Activity	Frequency
Test blood glucose with a finger prick	73%	Check for compression lows	27.57%
Feed child carbohydrates in response to low	70%	Check glucose trend data on child's phone	24%
Wake in response to an alarm	68%	Refill insulin cartridge on pump	16%
Check glucose readings from a CGM	51%	Set a temporary basal	14.9%
Check blood glucose and wait up to recheck	50%	Set pump to suspend	13.5%
Bolus insulin to correct high	49%	Charge pump or CGM receiver	9%
Check glucose trend data on own phone (i.e., follow app)	49%	Check glucose readings using a flash monitoring (libra)	3%
Replace sensor	28%		
Other activity suggestions from open text responses:		Silence unnecessary alarm, wake child, inject insulin, phone hospital, correct with pen, replace sensor that falls out or fails, signal loss from technology, encourage toilet use when hyperglycaemic, comfort child.	

7.5.4 Impacts from Nocturnal Caregiving

7.5.4.1 Blood glucose management (HbA1c)

An independent-samples t-tests was conducted to compare HbA1c scores in children of caregivers who engage in nocturnal caregiving and those who do not. No significant difference was found, $t(171) = [-1.529]$, $p = [.128]$, $[-.512, -.065]$, suggesting that nocturnal caregiving does not impact on blood glucose management outcomes.

7.5.4.2 Caregiver sleep experience

Among 210 caregivers, 76% reported that they experience sleep disruption as a result of their nocturnal caregiving activities, 76% of 206 felt that the quality of their sleep had been affected by their nocturnal caregiving activities and 41% of 207 reported experiencing sleep problems (e.g., getting back to sleep) as a result, with 17.4% unsure. Of 197 caregivers, 54% reported achieving ≤ 4 hours of un-broken sleep in an average night, and 50% of 135 caregivers estimate that in an average week they lose ≥ 5.5 hours of sleep.

133 participants further described how their sleep quality was affected using open-text responses. Of these, 53% sleep lightly due to anxiety about alarms and general vigilance regarding child's wellbeing; "*Much lighter sleeper now, have to be alert to hear Dexcom alarms*", 27% highlighted their experience of broken sleep or short sleeping, sometimes over protracted periods, often resulting in exhaustion on waking; "*Continuous broken sleep over extended periods of time eventually affects function of every aspect of daily life*". Seventeen percent reported impacts on sleep behaviour; "*I wake easily to alarms and then could take up to 2 hrs to go back asleep*". The introduction of technology or a technology upgrade had greatly reduced the burden or eradicated the need for nocturnal caregiving for 11% of those who responded, "*Rarely get a full night of sleep but the pump has been amazing and improved things*".

Forty-one percent of 207 participants endorsed experiencing sleep issues as a result of nocturnal caregiving. The majority reported difficulty falling back to sleep after administering care (50%), while 18% reported anxiety driven sleep disturbance, 12% reported difficulty achieving deep sleep and 9% had problems initiating sleep. Other participants reported short sleep and exhaustion.

7.5.4.3 Caregiver health

Of 203 participants, 37.5% felt that sleep disruption from nocturnal caregiving had negatively affected their health, while 25% answered that they were unsure. Forty-seven individuals provided more detail on the symptoms they were experiencing that they linked to sleep disruption; chronic fatigue, lack of motivation, anxiety, weight gain and lack of ability to exercise, stress, pain, depleted cognitive function and problems achieving or maintaining sleep. A number of participants identified a perceived threat to their future wellness as a result of short sleeping and stress.

7.5.4.4 Iowa Fatigue Scale (IFS)

213 caregivers completed the IFS, the mean score was 30 (SD 9.9; range 0-51). 42.3% scored between 30 and 39 (fatigue), and 10.8% scored ≥ 40 (severe fatigue).

7.5.4.5 Other caregiver impacts from nocturnal caregiving scale

Over 90% of 204 participants reported experiencing additional impacts that they associated with nocturnal caregiving. The most impacted domain of life was psychological wellbeing, with ‘stress’ and ‘anxiety’, endorsed at the significant and very significant levels by 44% and 36% respectively. Family wellbeing and relationships were the second most impacted domains, with 31% and 30% endorsing significant and very significant impacts. Mood, motivation and focus also showed significant to very significant impact (21%, 20% and 17%), see Figure 7.1. Some participants provided additional insights in open text comments (Table 7.6).

Figure 7.1. Percentages endorsing other impacts from nocturnal caregiving at their level of personal significance

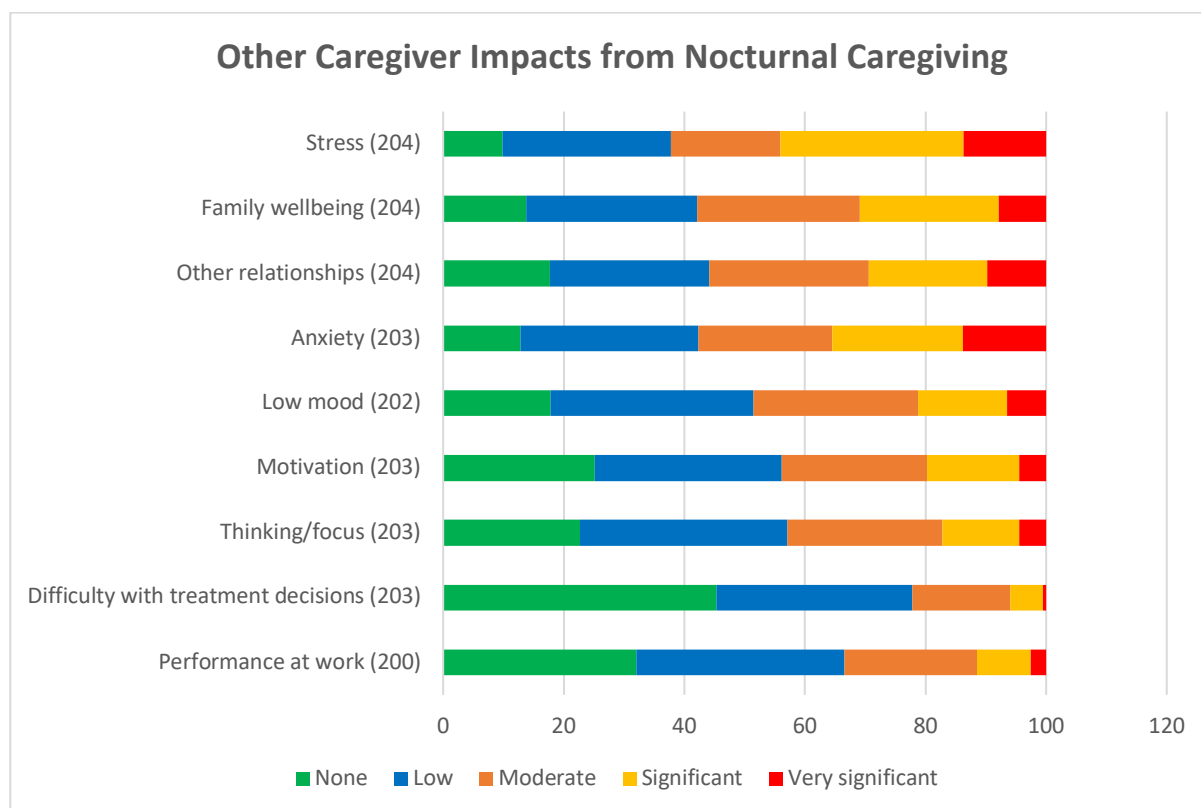


Table 7.6. Open text responses to ‘other impacts from nocturnal caregiving’

Open text responses (n=35)	Quotes
• Worry	<i>“It’s just a constant worry”; “constantly in hyper-alert”</i>
• Loneliness	<i>“Lack of appreciation for what we’re going through”,</i>
• Family disruption	<i>“it’s completely consuming for the whole family”; “relationship with TI very strained”</i>
• Emotional fallout	<i>“I feel inadequate...it reflects how good or bad a mother I am”</i>

7.5.4.6 Outcome differences between those who engage in nocturnal caregiving and those who do not

Further analyses were carried out to explore the findings on impacts from nocturnal caregiving on *Sleep problems, IFS, Other Impacts and Health Self-Rating scores.*

Sleep problems. A Pearson chi-square was carried out to establish whether there was an association between nocturnal caregiving and the self-reported experience of sleep problems. This was significant, $\chi^2 (2, n=192) = 34.39, p < .001$, *Cramer’s V* = .423 (medium to large effect size). Specifically, those who engaged in nocturnal caregiving were significantly more likely to report sleep problems.

Iowa Fatigue Scale, Other Impacts and Health Self-Rating Scale. Independent-samples t-tests were conducted to compare scores between caregivers who engage in nocturnal caregiving and caregivers who do not on IFS scores, Other Impacts scores and Health Self-Rating scores. Statistically significant differences were found between mean scores on the IFS; nocturnal caregiving (M=32.75, SD 7.49) and do not engage in nocturnal caregiving (M=22.1, SD 8.75; $t (193) = 7.4, p < .001$, two-tailed). The magnitude of the difference in the means (mean difference = 10.66, 95% CI: 7.82-13.51) was large (Eta squared = .22). A statistically significant difference was also found between mean scores on the Other Impacts scale: nocturnal caregiving (M=27.33, SD 8.74) and do not engage in nocturnal caregiving (M=16.23, SD 5.31; $t (66.6) = 9.42, p < .001$, two-tailed). The magnitude of the difference in the means (mean difference = 11.1, 95% CI: 8.75-13.46) was very large (Eta

squared = .32). Lastly, a statistically significant difference was found between mean scores on the Health Self-Rating scale; nocturnal caregiving ($M=2.9$, $SD .82$) and those who do not ($M=3.3$, $SD .79$; $t(191) = -2.55$, $p < .05$, two-tailed). The magnitude of the difference in the means (mean difference = -0.39 , 95% CI: $-0.69 - 0.09$) was small (Eta squared = .032).

7.5.5 Relationship between gender and nocturnal caregiving burden

7.5.5.1. *Caregiving contributions by gender*

An independent-samples t-test was conducted to compare the mean percentage of *general* caregiving they personally contribute by males and females. A statistically significant difference was found between female participants ($M= 76.26$, $SD = 21.39$) and male participants ($M=55.79$, $SD = 22.979$; $t(222) = 6.59$, $p < .001$, two-tailed). The magnitude of the difference in the means (mean difference = 20.47 , 95% CI: $14.349-26.59$) was large (Eta squared = .16). A second independent-samples t-test was conducted to compare mean percentages recorded by females and males, when asked what percentage of *nocturnal* caregiving they personally contribute. A statistically significant difference was found between female participants ($M= 82.6$, $SD = 23.48$) and male participants ($M=56.64$, $SD = 27.653$; $t(219) = 7.267$, $p < .001$, two-tailed). The magnitude of the difference in the means (mean difference = 24.69 , 95% CI: $17.5 - 31.9$) was very large (Eta squared = .19).

7.5.5.2 *Nocturnal caregiving burden and impacts by gender*

A sub-analysis was carried out to explore gender differences in the burden associated with nocturnal caregiving, see Table 7.7.

Table 7.7. Gender: frequencies and impacts

Question (n=F/M)		Female %	Male %	
1	How often do you wake at night to take care of your child's Diabetes? (n=148/61)	Every night	20	13
		5-6 nights a week	11	9.5
		3-4 nights a week	16	15
		1-2 nights a week	23	25
		2-3 nights a month	19	16
		1 night a month	1	12
		< 1 night a month	10	9.5
2	Does taking care of your child's diabetes interfere with your sleep? (n=147/60)	Yes 80.3% Unsure 4.8%	Yes 70% Unsure 8.3%	
3	Do you think that the quality of your sleep has been affected by night-time caregiving? (n=144/59)	Yes 82% Unsure 9%	Yes 62% Unsure 14%	
4	Have you experienced any sleep problems that you think might have developed as a result of taking care of your child at night? (n=145/59)	Yes 49% Unsure 15%	Yes 23.7% Unsure 22%	
5	How many hours of sleep do you lose per week because of your night-time caregiving activities? (n=96/39)	7.22	6.86	
6	How many hours of unbroken sleep do you get per night (on average)? (n=137/57)	4.07	4.59	

7.5.6 Treatment regimen: Impact on nocturnal caregiving and level of burden

7.5.6.1 Treatment regimen and success in blood glucose management as represented by HbA1c scores

A one-way analysis of variance (ANOVA) was conducted to gauge the impact of treatment regimen on HbA1c scores. The results indicated that the impact of treatment regimen was not statistically significant, $F(3, 185) = 1.724$, $p = .164$, $\eta^2 = .027$. The mean A1c scores were 7.16 (SD = .842) for injection + sensor; 7.23 (SD = .556) for pump + sensor; 7.12 (SD = .645) for closed loop and 7.5 (SD = 1.103) for the no sensor group. These results suggest that treatment regimen did not significantly influence HbA1c scores for this sample.

7.5.6.2 Treatment regimen and nocturnal caregiving

A Chi-Square analysis was carried out to explore whether there is a relationship between treatment regimen and engagement in nocturnal caregiving practice. The test indicated that there was a significant association between treatment regimen and nocturnal

caregiving, $X^2(3, n=213) = 14.435, p=.002$, *Cramer's V* = .260 (medium effect size). The highest levels of nocturnal caregiving were found among those using a pump and sensor treatment regimen (90.9%). (See Table 7.8).

Table 7.8. Proportion of caregivers in each treatment regimen group engaging in nocturnal caregiving

	No Nocturnal Caregiving (%)	Yes Nocturnal Caregiving (%)
Injection + Sensor (n=54)	24.1	75.9
Pump + Sensor (n=55)	9.1	90.9
Closed Loop (n=69)	20.3	79.7
No Sensor (n=35)	42.9	57.1
Total (all regimens) (n=213)	22.1	77.9

7.5.6.3. Treatment regimen and level of nocturnal caregiving

A Chi-Square analysis was carried out to investigate whether there is a relationship between treatment regimen and level of nocturnal caregiving engaged in. As the analysis violated the 'minimum expected cell frequency' assumption (31.3%), the Likelihood Ratio test was used for this interpretation. This test indicated that there was a significant association between treatment regimen and the degree to which the respondent reported engaging in nocturnal caregiving. $X^2(21, n=230) = 39.595, p=.008$, *Cramer's V* = .233 (medium effect size). The highest levels of nocturnal caregiving were found among those using a pump and sensor treatment regimen and the no sensor group had the greatest proportion not engaging in nocturnal caregiving (60% and 15.4% respectively, see Table 7.9).

Table 7.9. Level of nocturnal caregiving reported by caregivers in each treatment regimen group

	High Nocturnal Caregiving (%)	Moderate Nocturnal Caregiving (%)	Low Nocturnal Caregiving (%)	Never Nocturnal Caregiving (%)
Injection + Sensor (n=63)	36.5	46	15.8	1.7
Pump + Sensor (n=55)	60	32.8	1.8	5.4
Closed Loop (n=73)	37	41	19.2	2.8
Injection/Pump No Sensor (n=39)	33.3	35.9	15.4	15.4
Total (all regimens; n=230)	41.7	39.5	13.5	5.3

7.5.6.4 Effect of treatment regimen on Fatigue (IFS) and on ‘Other Impacts from nocturnal caregiving’

One-way analyses of variance (ANOVAs) were conducted to examine the impact of treatment regimen on IFS scores and Other Impacts scores. Results indicated that the effect of treatment regimen was not statistically significant on IFS scores; $F(3, 208) = 2.14, p = .097, \eta^2 = .03$, with mean IFS scores of 28 (SD = 10.49) for injection + sensor; 32.2 (SD = 7.73) for pump + sensor; 30.35 (SD = 10.01) for closed loop and 27.88 (SD = 11.3) for the no sensor group. In addition, results indicated that the effect of treatment regimen was not statistically significant on Other Impacts scores; $F(3, 198) = 1.784, p = .152, \eta^2 = .026$. The mean ‘Other Impacts’ scores were 23.25 (SD = 9.819) for injection + sensor; 27.29 (SD = 9.447) for pump + sensor; 25.42 (SD = 8.355) for closed loop and 24.73 (SD = 8.855) for the no sensor group. These results suggest that treatment regimen did not significantly influence Fatigue (IFS) or scores on the ‘Other Impacts’ scale.

7.5.7 Predictors of nocturnal caregiving

A logistic regression was carried out to determine the sociodemographic and health-related predictors for caregivers engaging in nocturnal caregiving and/or sleep disruption due to nocturnal caregiving. The model contained 1 child demographic and 3

illness-related factors as independent variables; child age group (<6, 6-11, 12+), diagnosis duration, HbA1c and treatment regimen (injection + sensor, pump + sensor, closed-loop, injection/pump no sensor). The model also contained 4 parent-caregiver demographic factors as independent variables; gender, educational achievement (no 3rd level, 3rd level), ability to meet financial obligations (with difficulty, with ease), domestic partnership status (partner, no partner), all assumptions were met.

The full model containing all 8 predictors was statistically significant, $X^2 (12, N = 172) = 76.02, p < .001$, indicating that the model was able to distinguish between caregiver participants who reported engaging in nocturnal caregiving and those who did not. The model as a whole explained between 27.4% (Cox and Snell R square) and 44.9% (Nagelkerke R squared) of the variance in nocturnal caregiving, and correctly classified 88.4% of cases, an improvement of 6.4% on the null model. As shown in table 7.10, only two of the variables made a unique, statistically significant contribution to the model. The ‘pump and sensor’ treatment regimen ($B = 2.31, p = .010$), $OR = 10.077$, indicating that the likelihood of engaging in nocturnal caregiving was over ten times greater for those using this treatment regimen. In addition, individuals who reported greater ‘ease making ends meet’ were significantly less likely to engage in nocturnal caregiving ($B = -2.11, p = .013$), $OR = .121$. Other variables, such as child’s age, HbA1c, Diabetes Duration, Education and Gender, showed non-significant results ($p > .05$), suggesting they did not independently predict the outcome in this model.

Table 7.10. Logistic Regression Predicting the Outcome Variable Nocturnal Caregiving Practice

Predictor	B	SE	Wald	df	Sig.	Odds Ratio (Exp(B))	95% CI for OR
Child Age 0-6			4.753	2	.093		
Child Age 6-11	1.414	1.358	1.084	1	.298	4.112	[0.287, 58.898]
Child Age 12+	0.022	1.307	0.000	1	.986	1.023	[0.079, 13.247]
HbA1c	0.578	0.367	2.480	1	.115	1.783	[0.868, 3.661]
Diabetes Duration	-0.093	0.071	1.714	1	.190	0.911	[0.793, 1.047]
Regimen			6.855	3	.077		
Regimen (pump+sensor)	2.310	0.892	6.715	1	.010*	10.077	[1.756, 57.838]
Regimen (closed loop)	0.490	0.601	0.665	1	.415	1.633	[0.502, 5.304]
No sensor	0.455	0.935	0.237	1	.627	1.576	[0.252, 9.851]
Gender			1.055	2	.590		
Gender (male)	-0.518	0.504	1.055	1	.304	0.596	[0.222, 1.600]
Education (3 rd level)	0.692	0.569	1.480	1	.224	1.998	[0.655, 6.089]
Domestic Partner	-19.281	6446.628	0.000	1	.998	0.000	[0.000, -]
Ease making ends meet	-2.110	0.851	6.149	1	.013*	0.121	[0.023, 0.643]
Constant	17.561	6446.629	0.000	1	.998	42318352.9	

* Significance at the .05 level.

Note. OR = Odds Ratio; CI = Confidence Interval; SE = Standard Error. Dependent variable: Nocturnal caregiving practice

7.5.8 Exploring solutions

7.5.8.1 Caregiver requirements for reducing nocturnal caregiving burden

178 participants (87%) agreed that technology was or would be helpful with nocturnal care; “2 words - *Game Changer*”. When asked what else might help, 112 caregivers responded; the largest group (31%) didn’t know or felt that nothing could help, 25% felt that support and/or understanding would be beneficial; “*Someone to share the work*”, “*Respite for carers especially people on their own as diabetes never sleeps*”, “*just someone recognising my problems and trying to understand*”. Another 12% stated that information, education and improved planning could support nocturnal care by promoting stable blood glucose levels, while 11.5% suggested that further research and technological

innovation could deliver new tools that would have a positive impact and 10% believed that ‘a cure’ was the only option for alleviating nocturnal burden. Other participants proposed older patient age, reduced work pressure and ‘rest’ as factors that would make the nocturnal care burden more manageable.

When asked what their Diabetes team could do to support them with nocturnal caregiving, 29% replied that they didn’t know, 14% that they didn’t think there was anything the team could offer and 5% felt that it wasn’t relevant for them. A significant number of carers felt that their team was already providing great support (12%); *“Our team is amazing they couldn't do more”*. Among those who had suggestions, 27% felt that they would benefit from greater support from their team, for some this would take the form of emotional support (11%); *“Listen. Ask about it”, “reassurance”*, for others, informational support (8.5%); *“...offering advice as needed”, “Continuing education and seminars”*. Nine percent of carers proposed tangible ideas for interventions, of these, the majority envisaged 24-hr access to support; *“Maybe a 24-hour phone line”*, others proposed the creation of a peer support network and some desired instructional support; *“Easy to read step-by-step guide to follow when a bit sleep deprived”*.

7.5.8.2 Nocturnal caregiving: Helpful and unhelpful factors

Finally, participants were asked to identify factors that had either helped or hindered them in the practice of delivering nocturnal care. Findings were organised into categorical themes and are presented below (Table 7.11). Technology was recognised as a strong support by many, some expressed a desire for technological improvements, while others felt that the issue was improved access to technology (e.g., closed loop). The majority of participants felt that sharing the care burden was key and that informed planning around BG management (e.g., managing nutritional intake after sports) provides important benefits for nocturnal BG stability. Some caregivers reported that self-care had

beneficial impacts on burden management, however others reported feeling overwhelmed, highlighting personal factors such as ‘work-related stress’ and child factors like ‘lack of co-operation’ that amplified their experience of nocturnal caregiving burden.

Table 7.11. Nocturnal caregiving: Helpful and unhelpful factors

Question	Themes	Quotes
What is/would be <i>helpful</i> with nocturnal caregiving? (n=97)	More and better technology (39%)	<i>"I think what did people do in 1960 - 1990 when the technology wasn't there"</i> <i>"More stable sensor on first night of insertion"</i> <i>"Maybe fitted with a pump asap"</i>
	Sharing the load (28%)	<i>"Taking turns to look after the alarms"</i> <i>"When my son takes more care of himself"</i>
	Achieving stable blood glucose (20%)	<i>"Type of food eaten in the evening"</i> <i>"Keeping sugar levels in range 1 - 2 hours before bed time"</i>
	Positive caregiver factors (13%)	<i>"I walk and read that helps me"</i> <i>"I take most of the care burden because the care is often tech driven and requires a certain analytical mindset"</i> <i>"Trust in devices"</i> <i>"If I am off for a few days it helps"</i>
What is <i>unhelpful</i> for nocturnal caregiving? (n=87)	Negative caregiver factors (40%)	<i>"Tiredness, the more tired the worse it feels"</i> <i>"The relentless of it all"</i> <i>"Other life stresses, dealing with other family members (waking other kids), trying to hold down high stress full time job on less sleep"</i>
	Technology challenges (18%)	<i>"Sensor updating and failing"</i> <i>"Failed sensors and pump sets is a big factor for us"</i> <i>"Not having closed loop"</i>
	Unstable blood glucose (17%)	<i>"If insulin given before last meal wasn't calculated correctly"</i> <i>"High blood sugars, fear of correcting at bedtime"</i>
	Child factors (14%)	<i>"When my teenage son ignores what he should be doing"</i> <i>"Child with other issues. Anxiety. Asd. Pick your battles"</i>
	Managing alone (11%)	<i>"Just being on my own"</i> <i>"When my husband travels with work"</i>

7.5.8.3 Discussing nocturnal caregiving with HCPs in Diabetes clinic

The survey asked caregivers whether they had discussed nocturnal caregiving with their Diabetes nurse or Endocrinologist (see Figures 7.2 and 7.3).

Figure 7.2. Caregivers who discussed nocturnal caregiving with their **nurse**

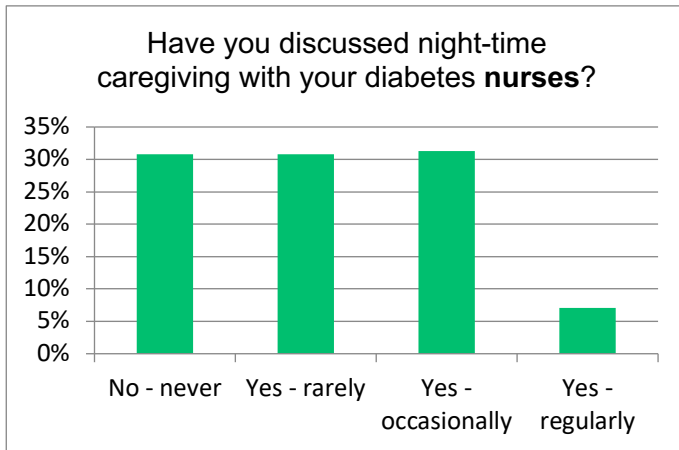
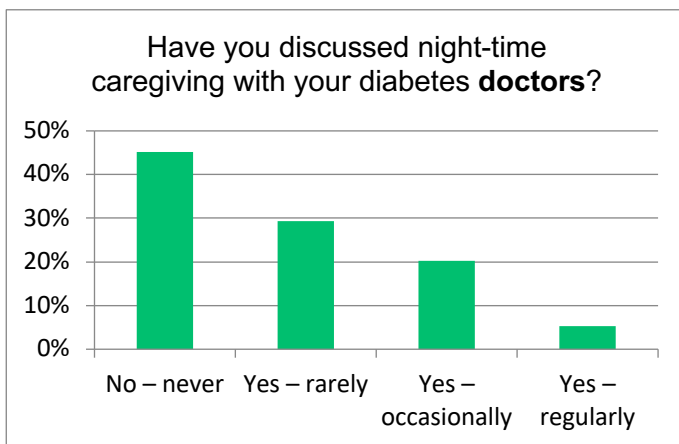


Figure 7.3. Caregivers who discussed nocturnal caregiving with their **doctor**



Participants who had *not* engaged in these conversations were asked why not.

Among 91 participants who commented on why they had not discussed nocturnal caregiving with *either* their endocrinologist or Diabetes nurse, 25% felt that there was no necessity for that conversation, 21% felt that there is nothing HCPs can offer as nocturnal caregiving is ‘par for the course’ with T1D, 14% reported that they were not asked about nocturnal caregiving and 7.5% said they had other priorities. Other participants said they were newly diagnosed, that technology had provided relief from the burden or that nocturnal caregiving was only an occasional issue. Of 45 caregivers who commented on why they had not discussed nocturnal caregiving with their Endocrinologist specifically,

25% explained that discussions with the Diabetes nurse had been sufficiently helpful and there was no requirement for further discussion with the Endocrinologist (see Figures 7.4 and 7.5).

Participants who had these conversations were asked what it was about the conversation that they found helpful. Among 90 comments on this topic, the majority of participants said that helpful discussions generally centred around education on T1D management; *“When is suitable to change insulin ratios to prevent the lows”* or tips and advice on nocturnal management; *“Having snacks on hand to prevent going downstairs”*. In addition, 12% of participants referenced benefiting from psychosocial support; *“Reassurance is sometimes all that is required”*. Lastly, a few participants highlighted the significance of individual factors; *“While all the advice overall is helpful sometimes it’s trial and error and whatever works for your own child”* and a minority reported negative experiences; *“Don’t always think they get how difficult it is to manage this 365 days a week plus manage this and full-time job and family and long-term impact sleep deprivation has on family”*.

Figure 7.4. Caregivers who found the discussions with their **nurse** helpful

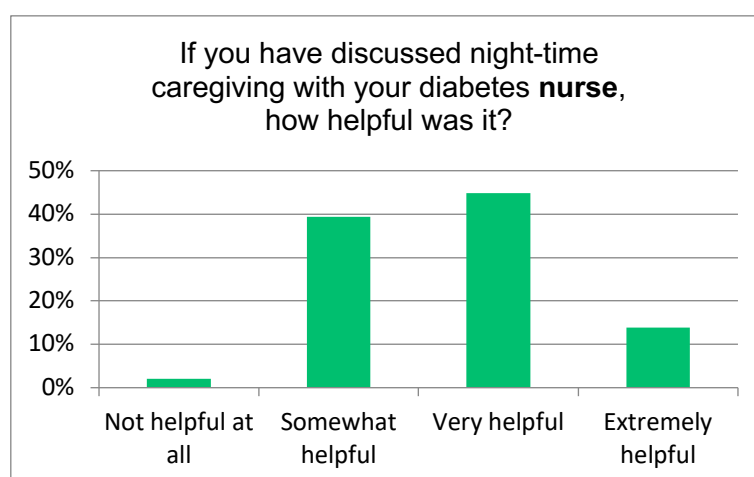
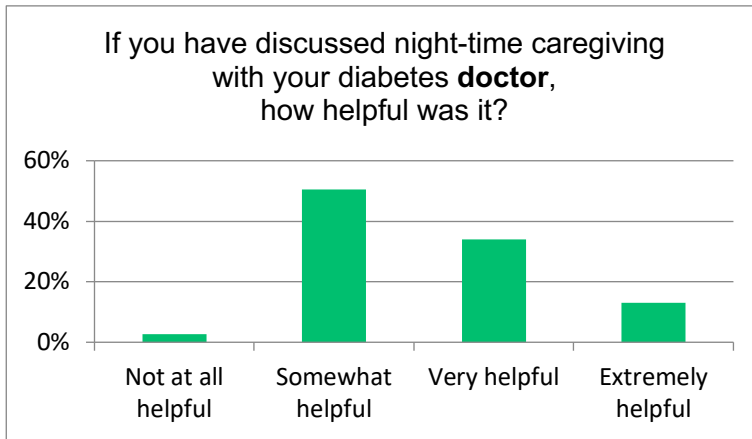


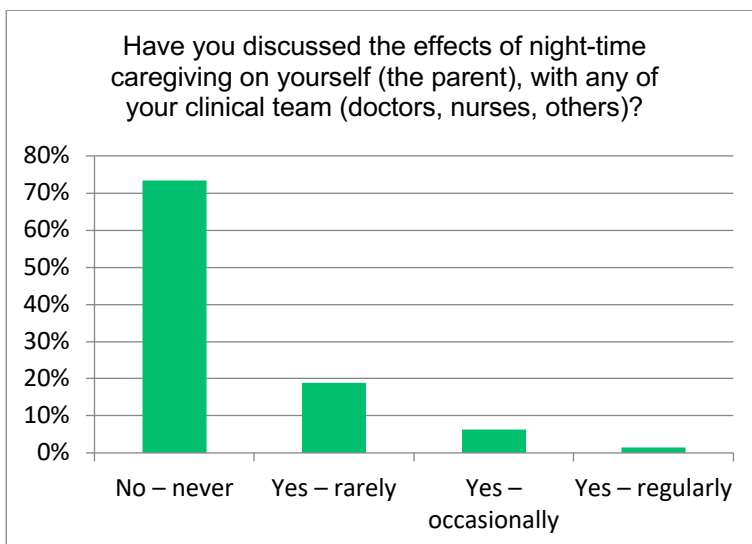
Figure 7.5. Caregivers who found the discussions with their **doctor** helpful



7.5.8.4 *Discussing caregiver burden with HCPs in Diabetes clinic*

Caregivers were asked if they had discussed nocturnal caregiving associated burden, that they personally experienced with any of their clinical team. Of those who responded, 73% said that they had not (see Figure 7.6).

Figure 7.6. Caregivers who have discussed the impacts from nocturnal care on themselves



One hundred and six caregivers commented on why they had not discussed their personal experience of nocturnal caregiving burden with HCPs in the clinic. The largest group (27%) said that they had not been asked about nocturnal caregiving, didn't know that

they could discuss it or felt that there was nothing that clinicians could offer that would help; *“Because it never came up”, “I know there is little or nothing that can be done”*. 23% reported that they *“just manage”* the burden, or *“get on with it”* as it *“goes with the territory”*, while 19% felt that the child was the priority in clinic appointments; *“Visits to hospital are about my daughters diabetes care and my needs are irrelevant”*, 17% felt that they had no need for a discussion; *“[nocturnal caregiving is] not a regular issue”*, and lastly, 5.5% felt that it was an awkward or inappropriate topic for clinic appointments; *“Never really found the doctors very approachable to discuss issues like this”*.

7.6 Discussion

This study aimed to explore the prevalence, impacts and predictors of nocturnal caregiving among caregivers attending for their child’s T1D care at a large urban paediatric T1D clinic in Ireland. It also explored the relationship between gender and nocturnal burden as well as the moderating influence of assistive technology on nocturnal caregiving. Lastly, it investigated caregiver unmet need for support from clinicians with the burden of delivering nocturnal care.

Analysis of the prevalence of nocturnal caregiving within this sample indicated that only 15% of caregivers reported rarely or never engaging in nocturnal caregiving, while 28% of participants engaged in nocturnal caregiving 5-7 nights a week and 37% engaged 1-3 nights a week. These levels are broadly in line with those reported in the systematic review described in study 1 (Howard et al., 2025). This is notable as the introduction of assistive diabetes technology has changed the treatment landscape significantly in very recent years, while studies included in the systematic review dated from 2003. Furthermore, this research also collected data regarding the frequency of multiple wakings per night, this supplementary detail provides more information on this behaviour, with a significant proportion of the sample waking multiple times per night. This level of

specificity has not, to the researchers' knowledge, been published previously, but echoes findings such as those in Kimbell et al. (2021) who found evidence of 'Hypervigilance' through the night, this level of detailed information is helpful for establishing the extent of the burden experienced by some caregivers.

As noted previously, the few studies that enquire into the benefits for overall BG management (A1c levels) from nocturnal caregiving found no association (Howard et al., 2025). For this sample also, no relationship was found. This counters a growing body of evidence that reveals benefits for A1cs from the 24-hour treatment offered by closed-loop technology, which credits overnight BG adjustments as an important factor (Prahalad et al., 2018). A possible interpretation of this contradiction is that most nocturnal interventions are reactive, typically responding to the hypoglycaemia rather than proactively responding to hyperglycaemia with insulin adjustments that would have more impact on overall BG or A1c. This position is supported by Barnard et al. (2016), who found that 17% of caregiver participants were motivated to engage in nocturnal caregiving by hypoglycaemia, while hyperglycaemia drove only 0.5% of these behaviours. Similarly, in a review by Azimi et al. (2024), studies consistently found that hypoglycaemia mitigation was the strongest driver of nocturnal caregiving, authors stated that "[hypoglycaemia] fear leads to a lack of sleep, stress, exhaustion, and anxious or interrupted sleeping patterns", which also aligns with this study's findings.

The considerable extent of the impacts from nocturnal caregiving on caregiver sleep is clearly evident in this study. Recommended sleep duration is 7-9 hours per night, with an optimum of 8 hours firmly established in the literature (Hirshkowitz et al., 2015); implications for health and wellbeing from short sleeping are also evidenced (Medic et al., 2017). It is important to remember that the T1D caregiver experience of disrupted sleep commonly endures, potentially for years, and typically without respite. 76% of participants reported experiencing sleep disruption and experiencing negative impacts on their sleep

quality, with 41% reporting chronic sleep issues, perceived to be a direct result of nocturnal caregiving. Comparative analyses between participants who do not engage in nocturnal caregiving and those who do, found statistically significant differences in fatigue, stress, anxiety, relationships, mood and self-rated health, which were reinforced by qualitative reports. This replicates findings from other studies, such as Barnard et al. (2016) and Macaulay et al. (2020) who found that caregiver sleep disturbance and associated fatigue resulted in irritability, anxiety and depression, reduced ability to exercise, poor dietary choices, difficulty making decisions, poor work performance and reduced capacity for diabetes management among caregivers for JT1D, it also led to reduced relationship satisfaction and worsened home environments (Azimi et al., 2024).

To the researchers' knowledge, no previous evidence on fatigue has been gathered for this population using the IFS, 42% of this sample scored for moderate fatigue and almost 11% for severe fatigue. A study by Yoon et al. (2023), looked at fatigue in a general, global population using the IFS, they found that 14.6% reported moderate fatigue and 6.1% severe fatigue. The 'Other Impacts' tool was developed in collaboration with the PPI panel, it quantifies other burdens in some detail. This information is useful for establishing future research priorities and selecting the most impactful use of limited resources for supports or interventions.

Interestingly, 38% of caregivers felt that nocturnal caregiving related sleep disruption had negatively affected their health. Questions on health status supported this; in the Irish 2022 census, 83% of the population rated their health status as good or very good (CSO.ie, 2023b). In this sample, 70% rated their health status as good/very good/excellent, it is also notable that 94% of the sample were under the age of 54 years and the CSO data would represent a cross-section of the whole population, with older adults are more likely to experience poorer health status. Lastly, 27% reported living with chronic health condition(s), this is in line with the national average (28%) (Department of Health

(Ireland), 2021), although again, the age profile is important as significantly higher rates of chronic illness occur in older adults (65+). Taken together these findings suggest that secondary harms from T1D may be experienced in caregiver health.

A substantial body of evidence indicates that mothers predominantly assume the role of primary caregiver for children with chronic illnesses (Toledano-Toledano & Luna, 2020; Baysal & Çorabay, 2024). This study, however, finds that a small shift toward greater sharing of burden in T1D is evidenced. Studies in the area commonly have a strong participant gender skew, Bowen (2024) is typical; mothers represented 85% of the sample and fathers 15%. For this study sample, 71% of participants were female, with 28% of the children accompanied to their clinic appointment by their father. This could be interpreted as evidence of a higher degree of paternal engagement with T1D caregiving in this sample. Nevertheless, a gender discrepancy around nocturnal caregiving was clear. Differences by gender (F/M) in self-report contributions to general caregiving and to nocturnal caregiving were large (20%) and very large (26%) respectively. Significantly higher levels of sleep disturbance and resulting sleep problems were reported by females. Obviously, these are not objective reports but nonetheless, it's clear that females carry a higher level of burden, though plausibly to a slightly smaller extent than in the past. This aligns with findings from Azimi's review (2024), where mothers reported being mostly responsible for nighttime caregiving duties and expressed more sleep deprivation when compared to fathers. In a review by Kimbell (2021) a recommendation was put forward that T1D clinics set an expectation that both parents attend clinic consultations and, where possible, have full involvement in their child's diabetes management.

Assistive technology is a critical topic in nocturnal illness management for T1D. There is no doubt that assistive technologies have had an enormously beneficial impact on illness management burden and T1D outcomes (Charleer et al., 2018; Triki et al., 2021; Roos et al., 2024). Nonetheless, it is important to recognise that these technologies have

their limitations and that a digital divide exists, where significant numbers of caregiver/patient dyads will not have access to these expensive technologies and that many children will not choose or will not tolerate the assistive technologies (Gajewska et al., 2021; Gajewska, 2022; Addala et al., 2021). In this study, participant comments on nocturnal caregiving behaviours were consistently weighted in favour of acknowledging the value of assistive technology for moderating nocturnal caregiving (e.g., 32% acknowledged its value when providing additional comments on nocturnal caregiving frequencies). Many had experienced caregiving without assistive technology and were very positive about the improvements it provided for sleep. However, this finding was not replicated in the quantitative data, which found no significant differences in nocturnal caregiving between parents using assistive technologies and those who did not. Furthermore, a notable subgroup of technology users drew attention to the negative impacts of the technology, such as the experience of having the overnight burden exacerbated by the constant flow of data. This reflects similar findings from Rose (2023) and Bowen et al. (2024) who reported that assistive technologies benefit disease management but often with the additional burden of interrupted sleep. It's essential to recognise that, despite these additional burdens, the vast majority of parents in this sample would not opt to return to manual treatment regimens, choosing to accept the technology-related challenges in order to secure the associated illness outcome benefits for their child. These contradictory findings support the assertion that the variables at play and the nature of the associations are complex and more nuanced at the individual level than some statistical analyses can capture. This insight has value for informing the clinical approach, highlighting a need for a bespoke approach at the individual case level.

. This study aimed to examine individual patterns of nocturnal caregiving and to model how various parent and illness factors might predict the extent of participants' engagement in these behaviours. While the overall model was significant, the variance

accounted for was relatively small at 6%. Interestingly, six of the eight variables showed no significant individual influence on nocturnal caregiving, aligning with findings from Azimi (2024), who concluded that caregiver sleep disruption continues irrespective of the child's age and development, and Macauley et al., (2020) who found that against expectations, sleep disruption actually increased with duration of diagnosis. Relatedly, Howard et al. (2025) concluded in their systematic review that a notable lack of substantially influential factors had emerged from their synthesised data. Regarding parent factors, only 'ease of making ends meet' significantly influenced nocturnal caregiving, decreasing the likelihood of caregivers engaging in the behaviour. It is possible that this finding could have been influenced by the significant number of caregivers (30%) who had changed their work status in response to their caregiving responsibilities, thereby limiting their earning capacity and financial resources. Again, this evidence supports an understanding of the phenomenon that recognises nocturnal caregiving behaviours and their predeterminants as complex and nuanced, underscoring the need to meet individual caregivers where they are situated.

This research was also interested in identifying caregiver unmet support needs and potential solutions for addressing nocturnal caregiving burden. It is generally acknowledged that feeling supported and having struggles acknowledged can be important for caregiver wellbeing, which in turn impacts on patient wellbeing (Thomas et al., 2024) but, interestingly, when participants were asked what, other than access to technology, could be helpful with the nocturnal burden they were experiencing, it was clear that many were not comfortable bringing the focus onto themselves, feeling that the child should be the priority. Moreover, many felt that there was no point in having a discussion as the clinics do not have anything to offer. Although research on the topic is sparse, both themes reflect previous findings (Bowen et al., 2024). Furthermore, qualitative accounts of their experience aligned with work by Azimi et al., (2024) and Kimbell et al., (2021), where

caregivers expressed the sense that clinics didn't fully appreciate the dynamic and unpredictable nature of managing BG in daily life. In this study, 62% of participants said that they rarely or never discussed nocturnal caregiving with the diabetes specialist nurses and 75% rarely or never discussed it with their doctors. Moreover, 92% had rarely or never discussed the burden they personally experience from nocturnal caregiving with any healthcare professional in the clinic, reflecting findings in Symons et al. (2015) who found caregiver burden to be underacknowledged in clinical care situations, leaving caregivers feeling isolated. When asked why they didn't discuss it, some responded that they hadn't been asked, here echoing previous findings from Lindström et al., (2017). Among those who had suggestions for ways the clinic could assist with nocturnal care, the majority asked for support; informational, instrumental and emotional. This evidence aligns with findings from the systematic review (Howard et al., 2025), discussed above, where 19 out of 23 articles recommended that parent caregivers should be asked about nocturnal caregiving routinely during clinic appointments and given an opportunity to discuss its impacts on sleep. Such an intervention would help caregivers feel validated and create the opportunity for discussions on appropriate supportive measures to assist caregivers with the nighttime routines that they feel provide optimal care for their children.

7.7 Future Research

Future research should aim to develop a more nuanced understanding of the relationship between A1c levels and nocturnal caregiving. This could be achieved by distinguishing between proactive and reactive forms of nocturnal caregiving, which may have differing impacts on glycaemic outcomes and caregiver burden. Further investigation is also warranted into the use of closed-loop technologies, particularly their effects on overnight care, in order to better assess their potential to alleviate burden. Additionally, research on psychosocial supports would be helpful, particularly when guided by the needs

articulated by parents in this and other related studies. Caregiver priorities could be addressed, these include feeling listened to, having choices to engage in nocturnal caregiving validated, improved access to support services, and increased collaborative engagement with healthcare providers. Involving caregivers in the design and implementation of support interventions is especially critical to ensure relevance and effectiveness.

7.8 Strengths and Limitations

A key strength of this study was that it was the first study of its kind in an Irish context. The study was strengthened by its robust sample size, while the direct involvement of the researcher in clinic-based data collection was particularly beneficial for interpreting the findings. In addition, the inclusive recruitment strategy, whereby all parents attending for their children's diabetes care at the largest children's hospital in Ireland were invited to participate, benefitted the reliability of its findings. Considering the time commitment required to complete the 30-minute survey, the achieved participation rate of 60% is notable and suggests strong engagement with the research. PPI contributors played an integral role in shaping the research, from the formulation of research objectives and the development of study materials to the interpretation of findings, thereby enhancing the relevance, quality, and contextual sensitivity of the study outcomes. In terms of limitations, it is noted that the sample was biased toward higher parental educational achievement (60% holding a third level qualification, while nationally, the proportion of the population educated to third level was 48% (CSO.ie, 2023a) and children with predominantly well-controlled diabetes. As such, the experiences presented in this synthesis may not be reflective of parents' experiences of different demographic and socioeconomic circumstances. In addition, this study included children who had been diagnosed with type 1 diabetes for less than six months, a period during which many remain in the 'honeymoon

phase' and continue to produce some endogenous insulin. This may have influenced caregiving experiences and glycaemic management patterns, potentially limiting comparability with families of children further post-diagnosis. As a self-report survey, the study is inherently subject to reporting bias and the limitations of subjective perception. The inclusion of objective measures, such as actigraphy, to assess sleep disruption would have strengthened the validity of the findings. Lastly, the number of caregivers for children under six years of age was relatively small (7.3%). While this may partially reflect the lower incidence of diagnosis in this age group, approximately 80% of children are diagnosed between the ages of 5 and 14 (Roche et al., 2023), it is also likely also to be a reflection of the difficulties of recruiting parents of younger children in the clinic waiting room, where parenting demands were significant as they kept their children occupied.

7.9 Conclusion

Overall, findings from this study illustrate the complex and deeply personal nature of nocturnal caregiving practice. While statistical trends offer valuable insights, they often obscure the individual variability revealed through qualitative analysis. These findings emphasize the need for personalised, clinically embedded interventions, including access to supportive technologies as well as tailored emotional and educational support. In light of the finding that caregiver participants perceived a lack of clinician availability to provide support around nocturnal caregiving, the development of a simple tool containing relevant questions for healthcare practitioners to enquire into nocturnal caregiving practice would be helpful to initiate conversations and open the door to meaningful support. The consistency of these findings with previous research further reinforces the imperative for a more nuanced and compassionate approach to supporting caregivers with nocturnal care delivery.

Building on this work, the following chapter reports on study 5, which evolved out of this study and was designed to facilitate a more comprehensive examination of this population's unmet need for acknowledgement and support with nocturnal care. It looked to confirm the findings on desired or recommended interventions from this study and those from study 1, exploring the topic from the perspective of caregivers who are utilising closed-loop assistive technology as well as the perspective of those who are not utilising closed-loop.

Chapter 8. Study 5: Caregivers' needs for acknowledgement and support in managing nocturnal care for juveniles with T1D

8.1 Abstract

Background: Delivery of nocturnal care can be a feature of parenting juveniles with T1D. Previous studies have identified an unmet need for acknowledgement and support with the associated burden of sleep disruption and its impacts. *Aim:* The objective for this study was to investigate caregiving parents' requirements for recognition and support for the burden of nocturnal caregiving, during routine clinical contacts. *Method:* A qualitative study design was used, with PPI consultation throughout. Data collection was carried out using focus groups, interviews and open-text response questionnaire methodologies. Data analysis took a 'deductive' approach utilising a 'directed content analysis' methodology, which was guided by a pre-existing framework. *Results:* 21 parent caregivers for juveniles with T1D participated (FG n=2; interviews n= 7, open-text questionnaire n=12), whose children had a mean age of 11.7 years and a mean diagnosis duration of 3.8 years. Analysis resulted in 4 overarching categories of response being identified. (1) 'Role of Technology'; participants using hybrid closed loop technology reported significant benefits for nocturnal care burden, however associated challenges and issues with access were noted. (2) 'Nocturnal Burden of Care'; all participants reported sleep interference from caregiving, impacts covered a broad spectrum from physical to emotional, with the word 'exhausted' recorded 18 times across the dataset. (3) 'Addressing Nocturnal Care in Clinic'; only 2 participants reported being asked about nocturnal care delivery in clinic, 15 participants would like the topic to be raised, with the majority preferring to have this conversation with the diabetes nurse specialist. (4) 'Other Potential Solutions'; participants suggested that 24-hour phone support would make a significant difference to their nocturnal burden of care. *Conclusion:* This research makes the case that engaging with parent caregivers

about nocturnal care and acknowledging their burden by simply asking about it, regularly, during routine clinic appointments could be an effective and simple intervention for addressing this issue.

8.2 Background

T1D is a chronic autoimmune condition for which there is currently no cure. Incidence rates show significant variation across geographical regions, ranging between 23 and 54 diagnoses per 100,000 persons, per year (Gajewska, 2020a). In Ireland an incidence rate of 32 per 100,000 persons per year has been reported (Gajewska, 2020a). Incidence rates have been increasing worldwide, pooled data from across Europe have shown a 3.4% rise per year (Patterson, 2019a), with the largest relative increases in the under 5s (Gomez-Lopera et al., 2019).

Diabetes illness management is complex, requiring constant vigilance to manage insulin therapy and maintain blood glucose within the desirable range (Kahanovitz et al., 2017). Sustained hyperglycaemia (above range blood glucose) can result in serious long-term complications while hypoglycaemia (below range blood glucose), a side-effect of insulin therapy, is a common, often daily occurrence that requires an immediate response as it can result in coma and even death (Frier, 2008). T1D care is a 24hr responsibility (Streisand & Monaghan, 2014), however the topic of nocturnal caregiving has received very little attention in the literature to date (Ji et al., 2021) and current care guidelines do not address the topic specifically (ISPAD.org, 2018). As an example, the current model of care in Ireland recognises the burden T1D places on the family but it fails to address the specific challenges related to nighttime care (HSE.ie, 2015). Recent advances in assistive diabetes technologies, i.e., sensors providing continuous glucose monitoring, have shown that nocturnal blood glucose fluctuations are more common than previously understood (Heinemann et al., 2018). For parents who engage in nocturnal caregiving practice,

activities may include postponing bedtimes, waking multiple times per night and/or waking up earlier than normal to monitor blood glucose, treat as required with insulin or carbohydrate and follow up with further monitoring (Bergner et al., 2018; Carreon et al., 2021; American Diabetes Association, 2018).

There is evidence mounting that the use of diabetes assistive technologies, particularly hybrid closed-loop (HCL) pumps, significantly reduces the nocturnal burden of care for parents and self-caring adults alike (Cobry, 2022a). However, in Ireland, only 10% of people with T1D were reportedly using HCL technology in 2020 (Gajewska, 2020b). By 2022, the proportion of all patients using HCL technology had risen to 15% (Flynn, 2023), the proportion in paediatric care is significantly larger, with uptake in children three-fold that of adults (34.7% vs 10%) (Gajewska, 2020b), but this is still low in comparison with other countries (Gajewska et al., 2020b). According to Gajewska, barriers to uptake in the adult population fall into two broad categories; (1) Individual; patient awareness of benefits and personal preference as well as HCP attitudes, interest and clinical experience, and (2) resources; lack of access due to limitations on service resources and regional variations. Among 19 paediatric diabetes clinics in Ireland (Hawkes, 2014), only 13 offer insulin pump therapy (Flynn, 2023).

Previous qualitative research has explored areas of caregiver experience such as adapting to new diagnoses, living with the condition or managing transitions from paediatric to adult services (Rankin et al, 2016; Iversen et al, 2018; Butalia et al, 2020), but, to our knowledge, no research has enquired into the parent's experience of seeking support for the nocturnal caregiving burden. The objective for this study was to investigate caregiving parents' requirements for recognition and support for the burden of providing nocturnal care for their children with T1D, during routine clinical contacts.

8.3 Methods

8.3.1 Reporting

The Standards for Reporting Qualitative Research (SRQR) checklist was adhered to (O'Brien et al., 2014). See Appendix 8.1 for the completed checklist.

8.3.2 Design

This study was designed to investigate caregiver requirements for an acceptable approach to acknowledging and supporting nocturnal caregiving practice in the clinical setting. The study was intended to be an addendum to study 4, addressing the topic with a subset of that study's sample. It was found however that the experience and perspective of that participant sample, recruited from a clinic that was relatively well resourced and highly supportive of assistive technology, tended to be somewhat homogenous; highly engaged with high technology access and uptake. The decision was made to broaden the scope of the research by deliberately recruiting additional participants with a different experience by using an online support group to purposively recruit caregivers who, for a variety of reasons, are not using the 'state of the art' diabetes assistive technology.

This qualitative study utilised online focus groups, online individual semi-structured interviews and open text response questionnaires to gather data on the issues being addressed. The sample was comprised of individuals from two distinct groups, the first being parents of children using HCL technology and the second group being parents of children who only used sensor technology.

8.3.3 Ethics

Ethical approval was granted the School of Psychology Research Ethics Committee (SPREC) from Trinity College Dublin in September 2023 and Children's Health Ireland research ethics committee in November 2023.

8.3.4 Research Paradigm

This research took a pragmatic stance, which was chosen as a fit for the study as it adopted a utilitarian focus on real world, problem-solving for a specific context. Pragmatism also supported a pluralistic methodology, and this study used a variety of methods to gather data, in response to the needs of the participants. Furthermore, Pragmatism recognises the researcher as an active agent in the research process, which was consistent with PPI involvement and the involvement of a researcher with lived experience (Morgan, 2014; Allemang, 2022).

The study employed a deductive approach that was grounded in previous research, with the foundational exploratory work completed previously, this study began with predefined categories such as ‘desired supports’, which were operationalised in the question map. The deductive method allowed researchers to assess the presence of anticipated constructs within participants' experiences while also facilitating the identification of novel insights regarding caregiver need for support with nocturnal caregiving. The data were analysed using directed content analysis, which was guided by a pre-existing framework (Assarroudi, 2018).

8.3.5 PPI and reflexivity

The agenda for this study was established in consultation with a public and patient involvement (PPI) panel (n=4), who were recruited as contributors to study 4 (described in chapter 7). The panel included 3 mothers and 1 father. One individual also had a diagnosis of T1D themselves. The panel discussed this study in one online meeting and reviewed the questionnaire by email exchange.

In addition, and as noted in chapter 2, section 2.5.1, the lead researcher has lived experience of the phenomenon of interest. While this provided a valuable perspective, it

also presented challenges and the potential for bias in addressing this topic. The researcher addressed this by employing reflexive strategies such as maintaining a research journal, debriefing in supervision, and continual reflection and self-awareness.

8.3.6 Sampling strategy and recruiting

There were no inclusion criteria other than being a caregiving parent of a child with T1D in Ireland. Purposive sampling was employed to select individuals for diversity with respect to sex, child's age, diagnosis duration and use of technology. The caregivers were drawn from two sources. (1) The *HCL* group was recruited from participants who completed the online survey as part of study 4, which took place in the waiting room of a paediatric diabetes clinic in a large, urban children's hospital. The survey included a link to a form where participants who were interested in engaging with further research could leave their contact information, of 32 participants who provided details and were contacted 14 months later, only 10 (31%) accepted the invitation to engage with this study. This clinic offers high levels of access to diabetes assistive technologies, and all of these participants were HCL users. (2) The *Sensor Only* group were purposively recruited using an online peer support Facebook group for parents of children and teens living with T1D. An invitation to engage with the research was posted by a researcher, asking caregivers who attended for their children's care at clinics that do not have the resources to offer access to the HCL technologies or who have chosen not to take up the HCL technology or who are on a waiting list to gain access to the technology, to provide their contact details if they were interested in participating.

8.3.7 Data collection

Data collection was carried out using a questionnaire that had been developed by the researchers in collaboration with the PPI panel and were based on findings from study

4. The questionnaire comprised 5 sections: 1) Background information, e.g., what is their child's age and what technology do they use. 2) Opening questions, e.g., do you take care of your child's diabetes in the nighttime? 3) Intermediate questions, e.g., what could others do to make it easier for you? 4) Concluding questions, e.g., is there anything your medical team could do to help with night-time care? and 5) Final question, is there anything else that you would like to add? (please see Appendix 8.2 for the full questionnaire).

Three key approaches to data collection were employed (focus group; interviews; open text response questionnaires), initially it was intended to carry out data collection using focus groups, but they were proving difficult to organise and three participants did not keep their arrangements. In addition, in the first focus group it became quickly apparent that a dominant voice emerged, which was impacting on the nature of the data being captured around 'sensitive' topics such as the individual's experiences of clinicians. In order to facilitate contributions from individuals who had limited availability and in response to the threat of dominant participant bias, the choice was made to pivot to individual interviews. However, in the interviews (n=7), some participants enjoyed the 'therapeutic' value of expressing their frustrations and sometimes went off topic, generating extraneous data. The researchers were concerned that the situation may have been somewhat misleading for some participants, who may have had different expectations regarding the research even though they had reviewed the participant information leaflet and signed the consent form. The deductive nature of this study meant that accommodation could not be made for the additional testimony, and the choice was made to carry out all further data collection using open text questionnaire (n=12). In all three scenarios (FG, interviews, open-text questionnaire) the same, aforementioned questionnaire was utilised, with questions posed in a consistent order, using the same wording.

These data were combined for analysis; the analytic process took account of any resulting inequities by consciously managing data from over- and underrepresented

individual cases by coding the transcripts to give equal weight to shorter and longer answers. This was not challenging as the analysis was deductive. There are precedents for this hybrid methodology (Lambert & Loisel, 2008), for example, in Wigham et al. (2022) researchers looked at primary care access for people with learning disabilities, gathering stakeholder perspectives using focus group, interview and open text response questionnaire and combining the data for analysis.

8.3.8 Data collection procedure

Focus groups and individual semi-structured interviews were scheduled by email exchange, the participant information sheet and consent form were also emailed, when they were completed and returned to the researcher a link was forwarded. They were conducted by the researcher using an online platform (Zoom). Participants confirmed that they had read the study information sheet and whether they consented to have the conversation audio recorded. The focus groups lasted between 50 and 60 minutes, and interviews between 25 and 45 minutes. Participants were thanked and reminded that they were welcome to make contact if they had any further questions or concerns.

The open text response questionnaire was deployed using the SurveyMonkey platform, it included a preliminary section with the participant information and the consent form. A link was emailed to participants who had responded to the recruitment post (detailed above). All data collection activities took place between May and August 2025.

8.3.9 Data processing

Audio recorded interviews were transcribed verbatim, which was carried out by the researcher within a week of the recordings being made. Transcriptions were cross-checked against the recordings to ensure accuracy and completeness. To maintain confidentiality, all names and identifying details in the transcripts were removed and pseudonyms were

assigned to participants. The original recordings were subsequently destroyed. All qualitative data were managed using Microsoft Word (version 16.1), which facilitated the systematic organisation and analysis of the transcripts.

8.3.10 Data analysis

Directed content analysis, using a protocol adapted from the 16-step method outlined in Assarroudi (2018) was used. This method was selected because it takes a *deductive* approach that utilises pre-determined frameworks, based on theory or previous research, to interpret the raw data and guide the analysis (Hsieh, 2005). The procedure followed the following steps, *preparation phase*: (1) Develop the interview guide; open-ended directed questions based on previous research. (2) Data collection. (3) Data immersion and familiarisation. *Organisational phase*: (4) Develop a categorisation matrix and determine abstraction level to establish the main categories (based on the research aims and previous research) as well as potential generic categories (based on an inductive interpretation of the raw data). (5) Theoretically define the main categories and subcategories. (6) Determine the coding rules for main categories to ensure that they are clear and distinct. (7) Pre-test the categorisation matrix and modify as required. (8) Choose and specify the anchor samples for each main category. (9) Perform main data analysis; identify meaning units related to category matrix. Assign preliminary codes. (10) Inductively abstract the main categories and generic categories from the preliminary codes. (11) Establish links between main categories and generic categories by applying constant comparison to develop a conceptual and logical relationship. Nest generic categories into main categories. A colleague PhD co-researcher independently coded a subset (25%) of transcripts to ensure consistency and reliability in the coding process. Any discrepancies were discussed and resolved through consensus, and the revised coding scheme was then

applied to the full data set. Memos and annotations were used throughout the process to capture analytic insights.

8.3.11 Enhancing trustworthiness

This research utilised a variety of methods to ensure trustworthiness. Firstly, it aimed to capture as broad an experience as possible, within both groupings, to support robust findings with highly generalisable recommendations. Secondly, data saturation was aimed for and achieved (Saunders et al., 2018), this required the inclusion of an extra participant in the ‘sensor only’ group. Thirdly, the research was driven by consultation with a PPI panel, who assured researchers that the questions were suitable within the context of the research and advised on the significance of potential results (Yardley, 2000). Lastly, as noted above, a co-researcher collaborated on the process of developing and testing the coding framework and its application until excellent inter-coder reliability was achieved.

8.4 Results

8.4.1 Sample

This sample included 21 caregiver parents for juveniles with T1D. Of these, 19 reported female gender. Their children were aged between 2.5 and 17 yrs, with a mean age of 11.7 yrs. They had been living with their diagnosis between 0.5 and 13 yrs, with a mean diagnosis duration of 3.8 yrs, see Table 8.1.

Table 8.1: Sample characteristics

	Data Collection Method	Child mean age. Yrs (range)	Mean Dx Duration. Yrs (range)	Wait for sensor. range	Wait for HCL. range
Sensor only Group (n=11)	OTRQ 11	11.3 (2.5-15)	2.6 (0.5-9)	Dx – 4 yrs	
HCL group (n=10)	FG 2 II 7 OTRQ 1	12.1 (8-17)	4.9 (1-13)	Dx - 3 mo.	10 mo. – 11 yrs

OTRQ = open text response questionnaire; FG = focus group; II – individual interview.

8.4.2 Diabetes Assistive Technology

There were three treatment journeys represented by the experiences of this sample, as follows: (1) Some parents began their T1D caregiving experience with no diabetes assistive technology support. In these cases, blood glucose was measured using finger prick blood tests and insulin doses were delivered manually, using syringes or preloaded insulin pens. Some parents reported leaving the hospital post-diagnosis with blood glucose sensors, but others reported waiting between 3 weeks and 4 years to gain access to sensor technology support. (2) Some caregiving parents have only used sensor technology (sensor only group). This can be as a result of personal choice but more often it is because of access limitations. As noted above, 6 of the 19 paediatric T1D clinics do not support the technology and in those that do support it, resources and routes to access are variable. (3) Some caregiving parents were using sensors to monitor blood glucose continuously and they used hybrid closed loop (HCL) pump technology, whereby the sensor and pump are communicating, and the pump responds to blood glucose level with automatic insulin infusions that are regulated by an algorithm. Parents in this sample report that they waited between 9 months and 11 years to get access to closed-loop pump technology. Ten of the children were using closed loop technology (scenario 3) and eleven were using continuous glucose monitoring only (scenario 2), (see Table 8.1 for a detailed outline of participant characteristics).

8.4.3 Findings

Findings are presented according to the categories derived from the application of a directed content analysis approach. There are three main categories reflecting the initial coding framework (see Appendix 8.3), followed by a fourth category containing additional themes that emerged inductively from the data. Table 8.2 supplements these discussions with illustrative quotes.

8.4.4 Category 1: The Role of Diabetes Assistive Technology

The key determinant in level of nocturnal burden was almost universally recognised to be use of diabetes assistive technology.

8.4.4.1 Benefits for nocturnal care

All of the participants were using sensor technologies for blood glucose testing. Many noted that it was an improvement from finger-prick testing but those who were using HCL technology highlighted the very notable reduction in nocturnal care burden that accompanied the adoption of that technology; “If I didn’t have the closed-loop we would be in trouble” (P2).

8.4.4.2 Access to technology

It was evident that many participants in the HCL group were not aware that HCL technology was not universal standard care, only three acknowledged this gap; “I read things there [FB peer support group] and was shocked, I’m going OMG” (P1). Among those who were ‘not looping’, there was variable understanding of the potential burden reduction associated with the technology and the possibility of gaining access; “I’m not sure but I heard the pump is helpful [at night] ...but waiting lists are long” (P17). Furthermore, 7 participants appeared to be unfamiliar with the fact that the ‘closed-loop’

pump differs from a traditional pump, failing to recognise the terminology ‘closed-loop’; “do you mean the pump?” (P10).

8.4.4.3 Adapting to technology

A number of participants highlighted their experience of adapting to the technologies; “I was worried about ‘was it working...does the pump actually work’” (P5). Often, the challenge was most pronounced during the night; “the nighttime thing when it goes wrong it is quite scary, when you really feel like you don’t know what you are doing” (P5). Trusting the technology to deliver overnight care was quite challenging for many; “Each time it’s learn to trust the tech., that it’ll step in or alarm, that’s a big part” (P10).

8.4.4.4 Limits of the technology

A strong line of evidence came from participants with experience of using HCL, who felt that the technology was not a perfect solution; “Maybe less frequent now but she’s 9 and spends all day running around, even the loop isn’t a catch all” (P4). “He didn’t realise that it wasn’t connected properly, it was leaking [insulin] so that was why it was going high” (P5). Among the limitations noted were; “[The pump] is not 100% though, it’s like with Diabetes, no two days...it’s no two hours are the same” (P8), “I’ll go down and get into bed with her, there’s no point in alarms keeping my husband awake” (P7). However, it was clear from the data that although the burden of nocturnal care continued it was significantly reduced.

8.4.5 Category 2: The Nocturnal Care Burden

Eight of the participants, independently, across focus group, interview and questionnaire contexts, made a comparison between caring for a child with T1D and parenting a newborn, often adding that the difference is that with T1D it will be ongoing,

indefinitely. In one case the participant spoke of her child as her “*forever newborn*”. This was highly indicative of the tone of many participant contributions. All twenty-one participants reported sleep interference from caregiving. Many of the participants were quite emphatic about experiencing sleep interference; “very much so” (P12), “Always” (P15), “Absolutely” (P18). All ten HCL participants acknowledged significant improvements since acquiring the pump; “the first year was a blur, since she went on the pump it has made big differences” (P8),

8.4.5.1 NCP prevalence

There was a very clear difference between the ‘sensor only’ and HCL cohorts with respect to their engagement levels with nocturnal care delivery. Among HCL participants, the majority reported 2-3 wakings per month, while 73% of ‘sensor only’ participants reported waking between 5-7 nights a week and 27% waking 2-3 nights a week to deliver care to their child, many noted that they often wake multiple times a night; “sometimes every night, sometimes every second night, also sometimes a few times during the night” (P17).

8.4.5.2 Impacts for caregivers

The impacts on daily life from delivering nocturnal care were broad, some participants experienced emotional difficulties; “I am always tired and it affects my mood” (P12) and for some the impacts described were more pragmatic: “The thing was I was actually planning to go back [work] and it did kind of effect that decision if I’m honest” (P5). Ultimately, the burden from sleep interruption was pervasive and significant; “...you’d be bleary eyed trying to look to see what the numbers were, then you’d fall asleep and you’d go, did I give the insulin, oh God” (P7); “I never switch off, never, you can’t. I’ll reach over and check her number, there’s a curiosity. It’s sleeping with one eye open” (P6).

Throughout the dataset it was notable how frequently the word ‘exhausted’ was used (n=18).

8.4.5.3 Support from friends and family

Many participants reported that their extended families and social circles had very little understanding of Type 1 Diabetes or the level of burden required to support their children toward positive T1D health outcomes; “Nobody without a T1 kid really gets it.” (P4). In many cases this was experienced as hurtful and isolating; “I must’ve balled crying to my mum saying that the others don’t understand...maybe it took me saying to them could you just mind him for a few hours” (P9). Instrumental support was also lacking for the majority of participants; “Obviously a break would be great but I don’t have that kind of support system” (P11). In some cases, a more equitable distribution of nocturnal caregiving responsibilities with partners was desired, although where partners had more demanding work commitments, this was not regarded as feasible; “I feel that I have more capacity to be tired so I do all the night care” (P11). Lastly, a number of partners had distanced themselves from the caregiving by choosing not to educate themselves on diabetes management; “he’d say to me, he’s not...my husband just doesn’t...I’m the one who’s kind of got my head around it” (P5).

8.4.6 Category 3: Addressing Nocturnal Care Burden in Clinic

Participants were asked to discuss their previous experiences of addressing the nocturnal burden of care at their clinic appointments. They were also asked whether this might be helpful and how they might envisage it occurring in the future.

8.4.6.1 Previous experience in clinic on nocturnal care

Only two participants said they had been asked about nocturnal care (9%), thirteen (62%) said they'd never been asked and six participants stated that they had opened the discussion themselves but that the conversations had not been satisfactory; "I was told to increase the basal, but this doesn't work for us, I give corrections instead [requiring wakings]" (P14). Many offered rationales for why this discussion didn't happen: "No, hmmm, you know, I think there's so much else to do that probably gets forgotten about" (P6)

8.4.6.2 Looking for help with nocturnal burden

One participant had a positive experience, reporting simply; "They listened" (P15). Others were unsatisfied; "They said do this, I'll try it, then something changes or it doesn't work or...you're always chasing something" (P6)

8.4.6.3 Address routinely in clinic?

Although there were some participants who didn't desire nocturnal caregiving to be discussed in clinic; "I would feel that there is not much the clinic could offer us to help us as the bad nights are not predictable" (P13). 73% of all participants felt that it was a topic that should be addressed routinely at clinic appointments; "It would be nice if the clinic asked how we were coping with daytime *and* nighttime, I feel it's something I really can't ask them about" (P13). Many were quick to qualify this; "I realise they don't have resources to offer support, but it would be a huge relief to speak with someone who gets it..." (P11), "I think that's nice, it's wholistic, it would be lovely but do they have the capacity, I doubt it" (P6). Some participants felt that there was no substantial intervention that clinicians would be able to offer: "I would feel that there is not much the clinic could offer us to help us as the bad nights are not predictable" (P13), "I don't really know how

the HSE would cater for adults when we're there to look after the child" (P9), "I really believe they should acknowledge the overnight care, I fully understand there's nothing they can do about it" (P11), nonetheless, they would like the topic to be raised. In fact, multiple participants expressed the same need; "Acknowledgement of the burden would be supportive" (P1), "I think maybe even to have it acknowledged" (P7), "Although, having it acknowledged would be good" (P6), "Acknowledgement of the problem would be a start and we could take it from there" (P4). Some participants noted that they found participating in this study helpful; "Even that you're looking into this subject is helpful, it tells me somebody knows this is a big problem for some people" (P11), "[Talking about] This is very therapeutic isn't it" (P9).

8.4.6.4 Managed discussions in clinic

Asked how this conversation might be managed within the clinic, 52% of participants said they would prefer to have this discussion with a diabetes nurse specialist; "I think the nurses to be honest....I find them easier to deal with and to get access to" (P8), "Oh a nurse...doctors just go by numbers" (P7), and 39% would like to have it with doctors, nurses or both; "any of the team" (P20). A number of participants indicated that they would not like their child to be present for this conversation; "...and preferably not in front of the child" (P5).

8.4.6.5 Acceptable approaches to addressing the topic

The strongest evidence in this category was that participants would like to be asked directly about nighttime care: "As plainly as possible so that there is no confusion" (P3), using language that is sensitive to the associated stress and emotional impact, suggested questions were; "I know it's huge, how are you finding it?" (P7), "How are you coping?" (P8).

8.4.6.6 Information gaps to be addressed

These fell into two categories, firstly, practical information, participants remarked on the importance of nocturnal care for securing better T1D outcomes for their child; “If you can get the nighttime right that’s golden because you’ve got that time in range, you’ve got half the day” (P6), but a number expressed the view that they were poorly prepared for nocturnal care; “I think a full training on this area...on nighttime care, what happens to bloods during sleep” (P21). Secondly, participants indicated that informational support to mitigate distress would be welcome; “It would have been good to have been given the heads-up as to what was facing us” (P4), “acknowledgement that it’s going to get easier” (P10).

8.4.7 Category 4: Proposing Other Potential Solutions

Some participants warmed to the topic of ‘possible solutions to meet needs for support’ and grappled with other possibilities for providing support for nighttime care; “It’s more stressful when something goes wrong at night...you probably worry a lot more in the dark” (P5). The strongest evidence proposed the idea that 24-hr phone support would be helpful.

8.4.7.1 Diabetes specialist nurse phone support 24/7

A number of participants suggested that 24-hr phone support would make tangible and significant difference to the nocturnal care burden. Multiple participants differentiated between routine nocturnal care and difficulties that can be encountered when issues arise and expert guidance would be helpful; “the nighttime thing when it goes wrong is quite scary, when you really feel like you don’t know what you’re doing, it would be lovely to pick up the phone to nurses because they know...the worry just seems to be an awful lot bigger because there’s no one there to talk to....” (P5). When difficulties arise, most

participants have recourse to expert support during work hours but there is nothing at night, when arguably it would more valued.

8.4.7.2 Advice to parents with new diagnoses

Participants were asked what they would advise parents of newly diagnosed children regarding nocturnal care, some said they wouldn't have any because every case is different; "people have different personalities" (P6), of those who responded the advice varied, from minding themselves; "Look after your own health" (P1) to tips for nocturnal illness management; "keep pens and glucose by the bed" (P14).

Table 8.2: Directed content analysis: Categories and subcategories with illustrative quotes

Category	Subcategory	Illustrative Quotes
1. Role of HCL technology	Benefits for nocturnal care	<i>"I don't know where we'd be without the technology" (P8)</i> <i>"[pump], the nocturnal, it changed our lives, oh my god, we were exhausted, that was two years ago but we still are a bit, you've got to be so careful" (P6)</i> <i>"on injections, you didn't really get a night's sleep" (P8)</i> <i>"pre-pump we were definitely up a lot more, cos it's harder to be accurate with the injections so it's harder...it's almost impossible not to be high or low". (P9)</i> <i>"We were giving her a big injection of insulin and we were blissfully unaware what it was doing for about 3 hours...looking back now that was quite dangerous" (P6)</i> <i>"It's definitely more comforting when they're on the pump at night...the low thing won't happen anything near as frequently" (P5)</i>
	Access	<i>"I think it's [access] better in the Dublin area" (P10)</i> <i>"If I could afford it and was living outside Dublin, I would pay...I mean it's that life changing". (P9)</i> <i>"there'd be say 12 mums on a panel and so you get a sense of different experienced, what they have maybe down the country type of thing, or people from other countries, and the age as well..." (P6)</i>
	Adapting to tech.	<i>"The first couple of months of being on the pump I was exhausted because I wasn't, I wouldn't trust the thing almost..." (P5)</i> <i>"Worried about having something visible hanging off him, you don't want them to look different...and then the learning curve...but Jesus it was worth it". (P9)</i> <i>"...they don't want all the stuff [technology] now, they've just gotten used to it [manual care]". (P6)</i>

Loop not a “catch all”	<i>“He’d taken a shower and he came back, plugged himself back in but forgot to start the insulin...that was really scary because he didn’t hear the alarm and got really sick” (P5)</i> <i>“I found with the pump is it is correcting her, not immediately, I’d still like her not to be high for 2 or 3 hours overnight...the fact is she’s still high for 6 hours” (P6)</i> <i>“I’ll be up the night her sensor needs changing and the next night...it gives false readings...that could happen twice during the night and the next night” (P8)</i> <i>“Sometimes it’s just too much information, my child gets anxious, ‘I’m going to be in trouble, I haven’t been in range for a month’” (P7)</i> <i>“...because of the child’s activities during the day sometimes the loop system isn’t enough to catch the lows completely, also she gets highs from certain foods” (P4)</i> <i>“The pump alarms for various reasons, highs, lows, low battery, low insulin, new sensor needed, auto alarm if you don’t respond to an alarm, alarms if you haven’t bloused in 12 hours...etc...” (P4)</i> <i>“...with closed loop I was told night time care should reduce dramatically. It has, but continues to be required every week.” (P1)</i> <i>“Sometimes you’re so deep asleep that it’s hard to hear it [alarm]” (P9)</i>
2. Nocturnal Care Burden	Prevalence + burden <i>“Four nights a week I’d say my sleep is disturbed, I’m up twice maybe two of those nights” (P11)</i> <i>“...on [sensor] it’s multiple times a night, multiple times a week.... On the pump it’s totally calmed down...only once or twice in ten days...” (P8)</i> <i>“For eight years before the closed loop sometimes I was awake every 2 hours until sugars settled” (P2)</i> <i>“When we got the sensor it was multiple times nightly but I could check without leaving the bed but if there was any intervention needed I had to get up. This could be highs or lows or tech difficulties or just alarms.” (P4)</i> <i>“In our case we have alarm clock set up every 2 hours during nights just to check if everything going well” (P17)</i> <i>“If you’re giving somebody insulin in the middle of the night you’ve got to be awake...you wait an hour then you’re looking at the phone to see how did that work” (P6).</i> <i>“With the sensor, even moderate rises cause alarms, depending on where you set your ranges, ours isn’t very tight but we always want the best outcome for our child so it’s tight enough...if the bloods are going down it could mean almost zero deep sleep in a night” (P4)</i> <i>“I’ve met parents who don’t get up to check at night and that’s totally fine” (P11)</i>

Impacts for caregivers	<i>"It's like having a newborn baby again, you won't sleep properly for a long time" (P19)</i> <i>"I had to give [the job] up in August, I just couldn't take the stress anymore". (P7)</i> <i>"The hardest bit is going back to sleep, you're wide awake to sort everything...it's like your body's decided oh it's morning time again." (P5)</i> <i>"It's completely changed my life, not overnight but bit by bit as I got gradually more exhausted and had to make changes in my life to accommodate that" (P11)</i> <i>"We find we are exhausted at work" (P13)</i> <i>"We are all so tired physically" (P17)</i> <i>"It is difficult to concentrate." (P18)</i> <i>"General tiredness...feelings of frustration when it's been a long night of out of range sugars" (P16)</i> <i>"I have more anxiety than I probably would have if I was rested" (P11)</i> <i>"I also think it affects siblings as you are so exhausted you have less time for them and can be cranky" (P15)</i> <i>"Families take a severe hit from diabetes" (P12)</i> <i>"Sleep disturbance is one of the most frustrating things about type 1, similar to a newborn baby...you never know when you will have to wake again" (P18)</i> <i>"It's very very hard when you're in the midst of it, and you've alarms ringing everywhere and you're bleary eyed...you just can't see straight, it's...you just can't describe it" (P7)</i> <i>"I'm not sure how much longer I can work and provide care. This has broken my soul" (P3)</i>
Support - Friends & Family	<i>"No one understands unless you have a type 1 child" (P15)</i> <i>"...you're constantly in education mode for the first... forever!" (P9)</i> <i>"You just have to make your circle smaller I think" (P6)</i> <i>"Because of the relentless nature of it, a strong bond with a co-carer is really great to have" (P12)</i> <i>"[it would help] If people understood, they say you don't need to be doing all that but now these are people who don't know a thing about it all" (P11)</i> <i>"It's a burden that parents really have to carry on their own because of the jeopardy involved with insulin...the risks of carers not taking it too seriously are too great...there's a tendency for people not to believe how dangerous insulin is" (P4).</i> <i>"I have to be blunt [with friends] and say, if you give her that now [treat], I won't sleep tonight" (P6).</i>

3. Addressing the Burden of Nocturnal Care in Clinic	Previous clinic experience on nocturnal care	<i>"...no, when you go into clinics that's not the discussion. The discussion is height and weight, what her numbers are..." (P8)</i> <i>"Not particularly, they'd kind of just ask how many lows you'd get a week..." (P5)</i> <i>"I think in their head, their concern is the child and the child is your child and it's up to you to take care of the child no matter what" (P8)</i> <i>"No, nobody's ever asked about the night, ever. Maybe I haven't brought it up either" (P9)</i>
	Looking for help with nocturnal burden	<i>"I remember sitting in my car trying to ring the nurses for help as I thought this just can't go on, I dialled them over 50 times, eventually I got through, she was very nice but she just told me the same old line 'adjust her basal...it should be fine" (P11)</i> <i>"They suggested other places he could put his Dexcom but he won't change" (P18)</i> <i>"Changed Lantus [basal] but there are too many factors to take not consideration to fix it and it can't be fixed indefinitely" (P19)</i> <i>"I feel all the clinic staff does just suggest changes via text book and they don't live with it. Very different" (P14)</i> <i>"...in life everything is different and what is working for one it doesn't mean will work for another...sometimes if you are asking something and always they have the same answer" (P17)</i> <i>"The nurses are great but again, sometimes I feel like this stuff is like a purple unicorn, like they say if you do this and do that then you'll get it right, we've never, that never..." (P6)</i> <i>"If feels like they were dismissive of me when I try to bring up the waking" (P4)</i> <i>"When my son was small, I recall asking when I might expect the night time care to reduce. I was told that it would not reduce, it would always be needed" (P1)</i>
	Address routinely in clinic?	<i>"Just so I could share the burden of it with someone who would understand" (P4)</i> <i>"It's a huge amount of work, I wish they'd just recognise that. It would go a long way to making it bearable" (P11)</i> <i>"If mammy is coping better it's going to be better all round for the child" (P7)</i> <i>"Being heard is good" (P6)</i> <i>"Even an acknowledgement that it is tough" (P13)</i>

	<i>"There may not be any obvious solutions but even talking about it without inhibition would be comforting" (P12)</i> <i>"You shouldn't be in that situation where you're fatigued and struggling to get through the day, all that impacts on family life and will impact on the child" (P8)</i> <i>"[With HCL] it's still an issue, particularly the technical glitches, batteries, sensors, it would be good to be able to discuss options from that point of view" (P4)</i>
Managed discussions in clinic	<i>"The nurses are more in touch with the actual 'living with' the illness" (P11)</i> <i>"It has to be the whole team....it has to be everybody" (P6)</i> <i>"I don't think I'd be comfortable in front of my child, I wouldn't want him to know that I'm worried" (P9)</i> <i>"It would be a difficult thing to bring up with the child in the room, whether they could be elsewhere, I'm not sure how it could be done" (P10)</i>
Acceptable approaches to addressing the topic	<i>"...asking 'and the night time', as a separate question" (P13)</i> <i>"Tell us about the night time, specifically call it out" (P11)</i> <i>"I think just asking out straight" (P19)</i> <i>"Directly asking and looking at record of nighttime inputs" (P1)</i> <i>"Asking how we are managing at night" (P20)</i> <i>"Suggest a plan for night time and make both parents responsible" (P3)</i> <i>"How are you getting on a scale of 1-10?" (P9)</i> <i>"I think any question would be seen as support, because it's almost like someone cares" (P7)</i> <i>"In a way that acknowledges the problem as real and pressing" (P12)</i>
Information gaps to be addressed	<i>"...nobody really explains the science...but yeah, there should be something there about the night and how to address it" (P8)</i> <i>"Insulin seems way less effective at night...spikes that just appear out of nowhere and that's just part and parcel of it all" (P16)</i> <i>"I think if somebody had said to me at the start, maybe get some relief at night time, like a baby...with a newborn people say get rest in the day.... But then you don't want to frighten people either" (P6)</i>

		<i>"I do think up front, early on...maybe it's like you're going to be really overwhelmed and there's a massive learning curve, and no sleep, but there's a light at the end of the tunnel" (P9)</i> <i>"let them know it's hard" (P4)</i> <i>"I'd like someone to have warned me as it [tiredness] just creeps up on you and suddenly you're so deep in" (P11)</i>
4. Alternative Supports for Nocturnal Care	24/7 diabetes nurse specialist phone support	<i>"I think the ideal would be from parents pov, if you could ring them 24/7...ringing the ED, you get to someone who isn't a specialist...." (P5)</i> <i>"We were exhausted, you've got to be so careful...and then you can't ring during the night" (P6)</i> <i>"Maybe if the first weeks there was a [phone] line you could sign up to" (P9)</i> <i>"Reply to the emails they could be faster, not after 3 or 4 days" (P17)</i>
	Advice to parents with new dx...	<i>"Make sure alarms are set slightly higher as to wake you early enough from hypo" (P21)</i> <i>"The desire and expectation that our children are attempting to get the best possible outcome...is completely reasonable and should be supported" (P4)</i> <i>"Finding a pattern, not waiting 3-4 nights, at that stage you're exhausted, you're not thinking correctly" (P8)</i> <i>"Parent to parent support...like a mentor" (P10)</i> <i>"I'd also be like don't try and be so militant keeping them in range...going to bed" (P9)</i> <i>"Don't do it all" (P3)</i>

8.5 Discussion

This qualitative study explored the nocturnal caregiving experiences of 21 parents of children with T1D with the objective of identifying an actionable approach to easing or addressing their burden. Participant accounts of their experience of nocturnal caregiving and their desire for support exhibited considerable concordance, which tells a clear story:

Firstly, the majority of parent caregivers represented by this sample were highly engaged with nocturnal caregiving. This aligns with findings from study 1, the systematic literature review (Howard et al., 2025), which found that 83% of caregivers engaged in nocturnal care activities, though frequencies were highly variable. For this sample, frequencies of nocturnal caregiving were less variable, in the sensor-only group, the majority reported high frequencies with a minority reporting moderate frequencies. In the HCL group, 70% of participants reported low or very low frequencies, supplementing previous research literature on the benefits of HCL technology by highlighting the considerable drop in nocturnal caregiving activities that accompanied the adoption of HCL diabetes assistive technology in this sample.

In addition, the burden and associated impacts from nocturnal care were substantial. Use of 'sensor only' technology helped somewhat, but only in comparison with the enormous burden associated with finger-prick blood glucose monitoring. The adoption of HCL systems has, as noted, provided considerable benefits for nocturnal caregiving burden. It is important however to note that the use of HCL technology has not eradicated the need for nocturnal care but has reduced the burden to a relatively manageable level (Cobry et al., 2022a). Again, these accounts add to the growing body of literature around the adoption of diabetes assistive technologies. Finally, we know that in Ireland, access to pumps is not universal and there is greater take-up of sensors than pumps (Gajewska et al., 2020; 2020b; 2021). It is likely that this digital divide is mirrored in other regions of the

world; therefore, viewing the issue of nocturnal care as largely managed substantially misrepresents the reality faced by many overburdened caregivers.

Almost none of the participants had been asked about nighttime care specifically in clinic, although the majority of participants in both the ‘sensor only’ and HCL groups would like to have the opportunity to discuss nocturnal care routinely at clinic appointments. This aligns with findings from the systematic review by Howard et al., (2025) who reported that 83% of study authors included in the review (n=22) recommended that nocturnal care be routinely addressed in clinic. This study adds to that literature by confirming how the caregiver’s perspective aligns with the position taken by other scholars (e.g., Morrow et al., 2022; Bahadur et al., 2022). Furthermore, the majority of participants recognised that, in the Irish context, considerable limitations on health service resources exist and there was a clear understanding that an increased provision of structured interventions for caregivers is unlikely. However, a large number of participants highlighted the desirability and value of simply having their burden acknowledged by the clinicians and of opening a space for high-level discussion on this topic. This aligns with recent research that highlights the value of ‘feeling heard’ for positive interpersonal relations (Roos et al., 2023), with ‘feeling unheard’ most prevalent where ‘unequal status’ and a subordinate position was experienced (Roos et al., 2023), as may be the case in a healthcare environment. A growing body of healthcare literature has addressed the role of ‘feeling heard’ in clinical contexts, regarding this as a key element of ‘person-centred’, high-quality healthcare, (Langberg et al., 2019). Increasingly, this has been recognised as helpful for moderating health related burden in a variety of chronic illness contexts (Bradshaw et al., 2022), while it has been observed that listening and engaging with distress in clinical healthcare settings can be highly impactful (Street et al., 2009; Bivins et al., 2017; Silverthorne et al., 2023) and where limited resources prohibit the inclusion of

expert psychological support, adoption of a psychologically informed approach can be beneficial (Silverthorne et al., 2023).

Critically, from the point of view of this research, caregiver requirements for engagements with clinicians on this topic were clear, they would like to be asked about nocturnal care directly and routinely, the majority envisage these conversations occurring with diabetes nurse specialists. In terms of specific support requirements, participants were divided between a desire for instrumental, informational or emotional support. This reflects the literature on caregiver support, which emphasises the importance of matching support to the individual and recognising that support needs are likely to vary, according to changes in circumstances (Kwame & Petrucka, 2021; Becqué et al., 2021; Lopez-Hartmann et al., 2012). Children's Health Ireland, in their national clinical guidelines, clearly indicate their intention to provide psychosocial support to parents and families struggling with the burden of T1D (Children's Health Ireland, 2019). In addition, a clear signal emerged from the data indicating that where help with the nocturnal care burden had been sought previously, the resulting exchanges with the experts were unsatisfactory. For example, in many cases, participants were told that an adjustment to basal insulin would alleviate the problem, it did not. This approach to supporting nocturnal care is not adequate, one participant stated that they felt 'gaslit' (P11). Research is needed that highlights the fact that Type 1 Diabetes does not 'pause' for the night (Perlmutter et al., 2008; Feeley et al., 2019) and that enquires into novel approaches or protocols for integrating nocturnal and daytime care effectively are overdue. Participants themselves argued that the clinics are for the children, but it is understood from the literature that supporting parental caregivers leads to better health outcomes for their children (Pierce et al., 2017; Pena-Shaff et al., 2023).

Relatedly and echoing findings from Streisand & Monaghan (2014) which highlighted the 24-hour nature of T1D caregiving responsibilities, caregivers provided

other suggestions for nocturnal care support interventions, the strongest evidence coalesced around the request for a 24/7 diabetes nurse phone support. While the value of this intervention would be more meaningful for unusual difficulties or crises rather than for routine care issues, it addressed a support gap that many identified.

Lastly, this study noted a possible gap in T1D education; some caregivers were unfamiliar with the terminology and the variety of technologies available. For example, when the research purposively recruited ‘non-looping’ participants, a number of ‘looping’ participants accepted the invitation to engage with the research. This was encountered previously in study 4 (chapter 6) and presents as an issue because it impacts on caregivers’ ability to advocate for themselves and it leaves them out of the conversation in the peer support environment, which many participants highlighted as a critical element of their support system.

8.6 Limitations

This study provides novel information on an understudied aspect of the experience of caring for juvenile T1D patients, following the application of a robust methodology that was coherent with its research objectives. The study’s main limitation is that the sample comprised self-selecting parent caregivers who may potentially be more highly engaged in their children’s T1D care than others. This might have introduced a bias that skewed findings somewhat. Furthermore, this study was carried out within the context of a healthcare system that is specific to Ireland. Possibly impacting further on the findings’ generalisability and applicability to other contexts. Lastly, the use of varied data collection methods may have impacted on the richness of the data collected, particularly with respect to the ‘sensor only’ group, where open text response questionnaire was used exclusively.

8.7 Conclusion

This study has cast light on an issue that has been underexplored, misunderstood and somewhat excluded from routine clinical care. Nocturnal care provision can have a huge impact on caregivers' day-to-day lives; they can find themselves exhausted and feeling isolated. This research makes the case that engaging with parent caregivers about nocturnal care and acknowledging their burden by simply asking about it, regularly, during routine clinic appointments could be an effective and simple intervention for addressing this issue.

This study completes a series of 5 studies that explored nocturnal parental caregiving burden in T1D. Across this group of studies, a strong qualitative theme emerged, this theme was named 'the lived experience of feeling unheard'. Study 6 addresses this finding, it is presented in the following chapter and represents a departure from traditional research such as that described in the other chapters in the dissertation. Study 6 reports on the process of operationalising a collaboration between this researcher, four other PhD researchers working on topics in health or social care that had similar findings on 'feeling unheard', and an arts practitioner. The objective was to develop a novel method of communicating our findings on this theme, using a non-traditional medium, to enable broader dissemination opportunities.

Chapter 9. Study 6: Communicating the lived experience of feeling unheard in health and social care settings: An arts collaboration

9.1 Introduction

This researcher-artist collaboration came about as the result of a series of conversations that took place over a number of years. The first of these was at a conference on Psychology, Health and Medicine, where a colleague and I noted that many of the poster presentations could be gathered under an overarching theme titled “poor communication between patient and clinician”. Later, in my own research I found this emerged as a key theme in my qualitative data and noted how difficult it was to communicate the full depth of the lived experience that spoke to this theme. I discovered that conventional methods of disseminating these findings make it quite easy to ignore the message. Through exposure to other researchers’ work, such as that of Prof. O’Neill of UCC who used theatre to convey the lived experience of women struggling within the criminal justice system (O’Neill, 2022; Grace et al., 2022), it became apparent that there were other avenues to explore with regard to disseminating these findings. Exploring other options was deemed important because decisions that impact on patients’ and caregivers’ lives are often made without their voice and also, because the experience of being ‘heard’ or feeling ‘seen’ can be highly impactful for relieving distress and supporting positive physical and mental health outcomes.

I am carrying out my PhD within the Research Ireland funded ADVANCE Centre for Research Training programme. This centre actively encourages and supports transdisciplinary collaboration opportunities. I approached the programme manager with a proposal to explore the possibility of initiating a collaboration with an arts practitioner to facilitate the development of a novel method of research dissemination. I proposed reaching out to other PhD researchers on the programme that I was aware of whose work

may have generated data that spoke to the overarching theme and may have been interested in getting involved, and the programme manager, who is familiar with the work of all the PhD candidates on the programme, produced an additional list of other potentially suitable project/PhD researchers to approach. In total, we approached 18 PhD researchers with the proposal; 14 responded, all with very positive feedback. Of those, 4 were in a position to engage with the collaboration. Others stated that they did not have data that spoke to this theme, that they had not yet collected data or that personal circumstances precluded their engagement.

This chapter reports on the process of operationalising the collaboration, detailing the procedure and discussing issues that arose. Chapter 10 will provide further information on dissemination process and the impact that the collaboration achieved.

9.2 Abstract

Background: While research has documented caregiver and patient experiences of living with chronic illness, traditional forms of qualitative research dissemination often fail to communicate the depth and power of some research findings. This paper reports on a methodology employed to implement an alternative approach to disseminating qualitative research findings using an arts collaboration. The objective of this project was to explore a novel, more effective method for communicating the lived experience of ‘feeling unheard’ in health and social care. *Method:* To achieve this objective, the research group chose to pursue a trans-disciplinary collaboration with a spoken-word artist. Thirty-eight spoken word artists responded to the ‘call out’ (advertisement for arts opportunities). The selection process was guided by the artists’ engagement with the dataset and their alignment with the overarching theme of *Unheard Voices*. The selected artist engaged individually with each researcher to gain a deeper understanding of their respective contributions to the composite dataset and to explore any personal responses to the material. *Result/Output:* Drawing on

these discussions, the artist developed a spoken-word poem and devised a performance in response to the dataset. A performance of the spoken-word poem was recorded by a videographer, resulting in a novel tool for communicating this high-level message across multiple contexts. *Conclusion:* The ‘artifact’ created is a powerful tool for facilitating this communication and supporting a perspective shift in researchers and clinicians, while also acknowledging the distress experienced by carers and care recipients, and hopefully delivering some sense of being ‘heard’.

9.3 Background

Qualitative research has its roots in the colonial ethnographic observational practices of the 17th-19th centuries (Vidich and Lyman, 1994). While the term ‘qualitative research’ is present in scientific literature from the early 20th century, this was only the case for the natural sciences, with 1970 the take off point for qualitative research in the social sciences (Karpatschhof, 2010). The exponential growth of qualitative methods from that point onwards was driven by a mix of new political and philosophical discussions, such as those in hermeneutics, phenomenology and pragmatism, as well as from the emergence of post-modernity, which heralded a new dynamic of social complexity that could not easily be captured with the use of quantitative research (Brinkmann et al., 2014).

Scholars have speculated on the ‘nature’ of qualitative enquiry. Jovanovic (2011) wrote that “qualitative research is more than just a method, it’s a ‘worldview’, an understanding of human experience that is fundamentally different from a quantitative view”. According to Lune (2017), quality refers to the what, how, when, where, and why of a thing—its essence and ambience. Thus, qualitative research refers to the meanings, concepts, definitions, characteristics, metaphors, symbols, and descriptions of things (Lune, 2017). O’Brien (2014) defines its objective as follows; “to understand the perspectives/experiences of individuals or groups and the contexts in which these

perspectives or experiences are situated”. Given this, qualitative research is valued in health and social care literature (O’Brien, 2014).

Ongoing and continuous work has been carried out to formalise methodological approaches and develop frameworks and tools that support the validity and rigour of this method, the landmark work by Braun and Clarke (2006) being a notable example. Conventional methodologies for analysing qualitative data generally involve grouping and categorising data into named themes, illustrating the categories with descriptive quotes and mapping them according to relationships. The emphasis is on clarity, coherence and structure (Goldberg and Allen, 2015). However, while quotes exemplify the descriptions and add richness to the interpretation, analytic text dominates (Goldberg and Allen, 2015). In addition, journal guidelines on word count can have a significant impact on the selection of quotes for inclusion, which can also have implications for communicating the power of some findings.

Research is incomplete until it is disseminated and shared with stakeholder communities to inform policy and practice (Williamson et al., 2018). Standard dissemination formats include journal and conference papers, book chapters, reports and grey literature (Williamson et al., 2018). Various authors have written on the topic of communicating qualitative findings (Braun and Clarke, 2006; Goldberg and Allen, 2015) and a small number of reporting guidelines exist, such as the Consolidated Criteria for Reporting Qualitative Research (COREQ) checklist for reporting qualitative health research (Tong et al., 2007) that offer guidance on communicating rigorous methods, salient inferences and coherent reporting for academic publishing. However, the limits of these conventions, such as an inability to account for the full breath of potential approaches and an implicit definition of ‘what research is’, have been occasionally addressed in the literature (Reid & Gough, 2000).

Traditional methods of presenting qualitative research, such as thematic summaries and structured reports, have been criticised for their tendency to oversimplify and sanitise rich data, with scholars arguing that the reduction of nuanced narratives into categorical themes can strip away complexity and emotional resonance (MacLure, 2013; Sandelowski, 1998). Others argue that the process can marginalize participants' voices, privileging the researcher's interpretations over lived experiences (Frank, 2005; Riessman, 2008). Furthermore, standard academic formats are frequently inaccessible to non-specialist audiences, limiting the broader impact of qualitative research in community and policy contexts (Bochner & Ellis, 2016; Tracy, 2010).

Some scholars argue that current qualitative research is 'scientistic', being overly concerned with validity, generalizability and objectivity, leading to an overemphasis on standardized methodologies and reporting conventions (Steiner, 2002). Others argue for a qualitative enquiry that takes the opposite approach, envisaging qualitative research as a form of activism, based on the values of community, which supports social justice (Leavy, 2015). They propose that researchers utilise aesthetic methods adapted from the visual and dramatic arts as well as from literature to communicate findings, often highlighting the value of exploring non-standardised formats (e.g., theatre, poetry) as means of dissemination (Brinkmann et al., 2014; Wood, 2020).

In response, alternative practices that involve arts-based methodologies and collaborations have emerged, initiatives that aim to authentically capture and communicate qualitative insights (Leavy, 2015; Wood, 2020). This is unsurprising as the arts are commonly regarded as one of the most powerful modes of communication, highly valued by most people and often used to communicate messages that are not easily articulated; sadness, grief, love (Fraser & al Sayah, 2011). Arts informed research, in essence, draws on the creative arts to enhance understanding of the human experience and to make academic scholarship more accessible to academic and non-academic communities alike

(Cole, 2008). One author, Boydell (2012) finds many common factors between qualitative research and the arts, most significantly, ‘valuing the subjective nature of human experience’.

In health and social care, the arts have historically been primarily valued as therapeutic tools, e.g., in music or art therapy (Bird, 2022). In research, arts-based methods fall into two broad categories, knowledge production and knowledge translation (Fraser & al Sayah, 2011). The use of arts-based approaches to knowledge transfer/translation is a growing field, with the majority of studies using performance-based mediums. In a systematic review, Fraser and al Sayah (2011) identified seven studies using arts-based methods to disseminate findings, all of which employed theatre as their medium; for example, Mitchell et al. (2006) used theatre to disseminate findings on the experience of living with dementia. It was noted that studies utilising arts practice for knowledge transfer, commonly focused on populations living with serious or life-threatening conditions. They postulate that these methodologies are most useful in situations where experiences are not easily conveyed using everyday language, also suggesting that the addition of an aesthetic dimension raises the quality of the communication significantly. This aligns with Jones (2006) who spoke of arts-based knowledge representations as “the collective elaboration of meaning...to increase understanding”. In a scoping review of arts-based health research, Boydell (2012) found that the most commonly used mediums for explicating an illness experience were photography and theatre, while only three out of a total of 71 studies used poetry.

9.4 Objective

This research aims to chart the contours of the experience of everyday caregiving and patient life, with respect to the theme; ‘feeling unheard’. It came about when a group of PhD researchers, working on a variety of topics in health- and social-care (T1D,

caregiver wellbeing in multiple sclerosis, physical activity support in serious mental illness and assistive technologies for autonomous aging or visual impairment), found a common theme in the qualitative data from their very diverse work that was named '*the lived experience of feeling unheard in health- and social-care situations*'. The researchers found that it was very difficult to effectively communicate the depth and power of their findings using conventional methods of reporting qualitative research. They decided to aggregate their data and adopt a transdisciplinary approach, using a collaboration with a creative artist to explore a novel method of knowledge exposition. The researchers concluded that '*we cannot tell everyone's story but we can remind people to listen*'. This paper aims to describe the process of establishing and executing a transdisciplinary project that had the objective of disseminating the cross-project findings on this qualitative theme in a manner that would enrich communication with varied audiences, enhance engagement and improve accessibility.

9.5 Epistemology and Ontology

This work took a constructivist hermeneutic approach, recognising that knowledge is shaped by individual perspectives and regarding understanding as a dynamic, interpretive practice, mediated by the interpreter's personal history and beliefs as well as contextual factors such as social environment (Peck & Mummery, 2018). Constructivist hermeneutics commonly utilises narrative techniques that combine the data, contextual information and the researcher's perspective. This allows for a much richer engagement, promoting a deeper and more powerful communication. The approach has been previously utilised to explore the individual experience of health and social care research (Chivers, 2005; Bytheway, 2011).

9.6 Method

With high-level agreement on the project's objective established, individual institutional ethical approvals deemed appropriate for this activity and funding secured from ADVANCE, Research Ireland, the researchers found that there was a notable lack of formal guidance or established frameworks available to direct the process of executing a transdisciplinary arts collaboration. For this reason, a significant level of discussion was required to carefully plan the procedure, to identify gaps in researchers' knowledge and experience and to identify individuals for consultation. This report has been prepared to make this methodological approach explicit and available to guide other researchers with similar objectives to pursue arts collaborations.

9.6.1 Step 1 – Amalgamate data

A protocol was developed, whereby each individual researcher was asked to identify quotes from their qualitative data sets that had been collected as part of their own qualitative or mixed-methods studies using focus groups, co-design activities, interviews or open-text response items in surveys, which spoke to the common theme; *'the lived experience of Feeling Unheard in health- and social-care situations'*. Each prepared a list of anonymised quotes of varying lengths (approx. 6-10 quotes) that were representative of their sample's experience. A single-page summary of the objectives of each individual's research project, their population of interest, and their key findings was created to provide context for the quotes.

9.6.2 Step 2 – Address key questions

Before initiating the process of developing a transdisciplinary collaboration with an arts practitioner, the researchers agreed that the following *'key questions'* needed to be

addressed. In a series of in-person and online meetings, the team of researchers made decisions on each high-level point in question:

- **What was the objective?** The team identified multiple objectives: (1) To connect with the audience emotionally rather than intellectually. (2) To capture attention. (3) To stand out in the academic setting. (4) To challenge norms.
- **What medium to engage with?** The team recognised that the performance arts have an “empathetic power and dimension” which cannot be found in traditional qualitative research dissemination approaches (Cole & Knowles, 2008) and were aware that some have been introduced into qualitative health research in order to extend research findings beyond the discipline and make it more accessible to a variety of audiences (Gray et al., 2000; McIntyre & Cole, 2008). As such, the team decided that the performance arts were uniquely suited to meeting our objectives. The initial aim was to develop a theatre collaboration, but it was quickly recognised that limitations on funding resources would exclude this option, as multiple individuals would be involved and it would be costly to re-stage. The final choice was to pursue a collaboration with a spoken-word artist because the spoken-word art-form is a means of expression that gives voice to personal and collective experiences and as such can bridge the gap between the personal and political, making it a powerful tool for change (Reynolds, 2024). Spoken-word is an oral poetic performance art that combines written language with oral delivery and dramatic performance. It is usual for a single individual to write and perform an original piece.
- **Who was the target audience?** The original intention was to create a piece to share with academics, researchers and clinicians in conference settings. However, it quickly became clear that patient advocacy and support organisations, as well as

caregiver and patient peer support forums, would offer opportunities to connect the piece with individuals who might see themselves in the work.

- **What would be the intended output?** Many options were discussed (i.e., pop-up theatre performances, performance art installations). It became clear however, that the costs involved in such scenarios would be prohibitive and that a final piece would be more cost effective if it could be recorded for multiple uses. It was decided that the performance should be captured on video, using a digital format that would enable it to be made available on multiple platforms and forums.

9.6.3 Step 3 – Consultation with experts

With the key decisions made, it was clear that knowledge gaps would require consultation with external expertise from individuals with experience of producing creative and artistic artifacts. The researchers agree that this was the most important step in ensuring the success of the project. Experts consulted included the editor of a spoken-word journal; arts administrators; funding managers; the director of literary festival; a writer; a video artist; a film maker; a composer and other arts practitioners. Advice was sought on matters such as; establishing artists' likely requirements for a collaboration; refining and wording an outline of the proposed collaboration and the proposed process of engagement; framing and presenting the collaboration as a commission and developing the 'call-out'; information on suitable platforms and forums for reaching into spoken-word communities to advertise the commission with the call-out; guidance on remuneration and working conditions; guidance on systems for remuneration; guidance on appropriate recruitment and interview processes; potential approaches for representing the performance visually.

9.6.4 Step 4 - Recruitment process

The call-out for the commission was finalized and distributed to various relevant organisations (e.g., Poetry Ireland; The Irish Writers Centre) for dissemination through their website, newsletters or commission alert email lists. Thirty-eight artists responded, expressing their interest in collaborating by providing biographical details, a personal response to the theme and video samples of previous work. We agreed that a three-person panel would review submissions. In two sittings, these submissions were read and/or viewed by three of the PhD researchers. Submissions that did not include a CV and/or a link to former work were not accessed. The panel independently scored each submission out of five, and the average score was taken. In the first stage of screening, six artists scored four or higher and were invited to interview. In the second stage, the three-person panel conducted interviews either in-person or online. The interviews explored four key issues: (1) the artist's background and potential connection or resonance with the call, (2) the artist's proposed approach to the topic and willingness to collaborate iteratively with the researchers and respond to feedback, (3) their ability to deliver an output within the timeline and work with the expected video artefact production process, and (4) their approach to live performance in various contexts. Artists were independently scored across these criteria by each interviewer as a basis for further discussion. The panel subsequently engaged in extensive deliberations to determine who among the top scoring candidates was the most suitable choice. The artist selected was finally chosen because his approach was based on storytelling, which it was believed might be relatable to a broad audience. Furthermore, the panel believed that this artist was likely to be amenable to a degree of iterative input from the researchers, each representing the interests of their own research populations.

9.6.5 Step 5 -- Collaborative process

The commissioned artist met each researcher individually, either virtually (over Microsoft Teams) or in-person. Researchers had the opportunity to describe the overarching meaning of their work, explain selected quotes from their research, and share other relevant materials, as well as their ideas on what the poem might achieve. In turn, the artist posed questions and took notes from each encounter. The artist followed up with further questions and clarifications via email, until satisfied that a deep understanding of the material had been achieved. Crucially, it was made clear that the artist had free reign to interpret the material however their creative process dictated. Within an agreed timeframe, the artist delivered the first draft. Two rounds of feedback from the researchers followed, which the artist responded to with minor alterations to the second and third drafts. At this point there was unanimous agreement among the researchers that the piece was highly engaging and that it perfectly captured the tone and emotional resonance the research group had envisaged. The result was a written and audio rendition of a spoken-word poem titled 'Unheard'.

9.6.6 Step 6 – Create video recording

Three video artists were consulted. It was decided to engage the artist whose vision for the piece was most closely aligned with the message. They proposed a simple and direct recording of the performance, with the spoken-word recitation at its centre. The lighting and setting would convey the tone of the message, and no supplementary visual elements would be incorporated. A moderate sized professional theatre space was hired so that full control of light and sound could be achieved. The recording took five hours, which included considerable experimentation with lighting set ups and backgrounds. The editing process was complex. Initially, the video artist included a number of edits and cuts, that captured the poet from a variety of angles and were designed to emphasise certain points in

the poem. After much consideration, it was decided to cut the video as though it were a live, face-on performance. This approach was selected as the most powerful option in terms of conveying meaning, and also the most likely to connect emotionally with an audience, be that academic or other.

9.7 Result/Output – spoken word video

The output is an eight-and-a-half minute video of a spoken-word performance of a poem named 'Unheard'. The 1,704-word poem was also performed by the spoken-word artist. The poem spotlighted hypothetical characters and their experiences, including: (1) the nocturnal caregiving experiences of a mother named Aisling; (2) John, Aisling's son living with type-1 diabetes; (3) Maria, who lives with multiple sclerosis; (4) Her partner, Darragh, who is experiencing some challenges in providing care and support; (5) Aisha, living with visual impairment; and (6) Wojtek, living with serious mental illness and grappling with assistive technology to support him in becoming physically active.

Please use the QR code below to access the video.



9.8 Discussion

Arts-based methodologies are relatively new and certainly not common practice. As a result, comprehensive methodological guidelines and protocols are limited, with the majority focusing on arts 'practice as research' (PaR), where the arts engagement is the

primary method of addressing a research question (Nelson, 2013), used for education (Trott et al., 2020) or is high-level and conceptual (Fortier & Coulter, 2021). To address this gap in a way that was relevant for this project, exhaustive exploratory discussions were carried out within the research team to identify the required steps and brain-storm potential pitfalls. It was recognised at an early stage that consultation with experts in the production of creative artistic endeavours would be key. The result of these discussions was a clear, step-by-step procedure that successfully delivered the project output in a timely and structured manner. The experience of carrying out this project leads the researchers to agree with scholars who queried the value of a ‘scientistic’ approach to qualitative research (Denzin & Lincoln, 2011; Smith & Hodgkinson, 2009). They conclude that standardised guidelines may not be the way forward as traditional research methodologies that follow specified procedures do not align with the ‘creative’ impulse that drives an arts collaboration. Instead, reviewing reports of other project’s experiences, outlining bespoke processes that highlight important considerations and key pitfalls is the preferred and recommended approach.

Careful consideration was given to the ethical dimensions of this project. Central to these discussions were questions around protecting the integrity of individual researchers’ institutional ethics approvals, the authenticity of participant voices and the anonymity of the individuals whose experiences were represented by the quotes selected for inclusion. As noted in the literature, the interpretive and often public nature of an artwork raises complex ethical considerations regarding anonymity and informed consent (Pavarini et al. 2021; Yassi et al., 2016). Further research should be undertaken to explore the unique ethical challenges for this growing and diverse practice.

Undertaking developmental work on the theoretical aspects and procedural frameworks for arts collaborations may be warranted to ensure rigorous scholarship. In the context of this research initiative, the researchers contemplated this recommendation and

asked; is rigorous scholarship an issue for a collaboration such as this one? If it is, what are the appropriate delineations or boundaries? Scholars have written on the challenge of bridging the transdisciplinary divide (Black et al., 2023; Lawrence et al., 2022), arguably, this divide is most evident between the sciences and the arts. In the experience of this research team, academic rigour was integral in each researcher's individual study; design, data collection and analytic approach, but it was felt that once the research documents, which included the amalgamated qualitative data (quotes) and contextual texts, had been completed, the academic framework shifted. When these documents had been passed to the artist, the collaborative process became, to some degree, 'organic'. That is not to say that it was unstructured, but that the structure of the process was flexible and driven by the artist's requirements and creative process. The artist had a background in journalism, which was highly relevant as this training and skill set facilitated a rich exchange of information with each researcher, until each was satisfied that their data was fully explored and understood and until the artist was satisfied that he had acquired the depth of understanding that would drive his creative process. This was a significant challenge as the project comprised findings from five diverse research topics.

It is recognised that this unconventional dissemination format challenges standard evaluative criteria, requiring the adoption of alternative notions of rigor such as resonance, coherence, and aesthetic merit (Hannes, 2023). In addition, the aesthetic quality and interpretive clarity of a project such as this one are influenced by the artist's subjective lens and creative skillset. As a result, the researchers had to reflect carefully on their expectations and their own criteria for evaluating the spoken-word piece and reaching a point in the collaboration, where no further work was required from the artist on the piece. Interestingly, this was achieved with far less trepidation than had been anticipated. At each of the three evaluation points, the researchers quickly reached agreement on the feedback for the artist. In turn, the artist was responsive and appeared to understand said feedback

and effectively implement it. The researchers postulate that this ease resulted from the substantive time investment from all parties into the initial knowledge exchange and collaborative processes, as well as from the early recognition from receipt of the first draft, that the artist had created an emotionally powerful and aesthetically coherent interpretation of the data, which resonated strongly with the high-level goals for the project that were reflected in the arguments of Jones et al. (2006) who opined that arts collaborations evoking emotional responses and constructing alternative forms of representation will promote dialogue and shared storytelling.

The research team can confidently assert that the impact significantly exceeded that which would have been expected from traditional presentations of their data. The piece has been shared and re-shared multiple times, reaching an audience of stakeholders far beyond expectations (see chapter 10 for details). Certain related difficulties were encountered, firstly, questions about the intellectual property (IP) arose. For this project we had defaulted to the academic standard for IP management, regarding the video as a research output, encouraging open dissemination with all involved parties suitably credited. At a certain point, the video was utilised as a training tool by a for-profit enterprise, this gave rise to considerations that were not anticipated, such as whether the artist should enjoy residual financial benefits in these scenarios by retaining some IP. A second unforeseen difficulty was encountered after the first presentation at an academic conference. Conference delegates requested access to the video, this was granted but mapping the dissemination became unfeasible. This was slightly regrettable as it would be interesting to have an idea of the reach of the piece. Nonetheless, access continued to be granted as maximising exposure of the piece was considered to be of primary importance.

The researchers concur with authors who write that balancing the artistic and scientific components of a researcher-artist collaboration is difficult (Rossiter et al., 2008). It is acknowledged that in the making of this project some blurring of the lines between

researcher, researched, and interpreter has occurred. While this was not felt to have negatively impacted the output, it is our opinion that this reality necessitates the incorporation of strong, iterative reflexive elements as part of the process, which we would pursue more formally in the future. Our preference would be for an 'Action-reflection cycle' (Koch, 2005), where reflective pauses are built into the process of operationalising an arts collaboration.

Parsons and Boydell (2012) have discussed the value of arts collaboration for reaching diverse audiences with health-related research, inspiring dialogue on needs for change as well as empowering and enhancing democracy. As noted above, this work was originally meant for academic environments but there has been valuable feedback from caregivers and patients, supporting the idea that there is benefit for the individuals who see themselves in the work, to have their lived experience communicated positively and empathetically. Some individuals responded that they felt validated and 'seen' or 'heard'. The researchers felt that this was helpful for influencing public understanding of diverse health issues as well as potentially impacting health policy and future practice (Boydell, 2012), while supporting the use of an arts collaboration as a legitimate way of disseminating knowledge from the health and social sciences.

9.9 Limitations

While subjectivity is embraced as a strength in arts-based research, it is acknowledged that it may limit the generalisability of findings or lead to multiple, potentially conflicting, interpretations of the output. The findings represented in this piece are context-specific and not intended to be generalisable. Nonetheless, it was considered that they may offer transferable insights or emotional resonance for 'similar' contexts in health- and social care settings. Equally, it is recognised that the format of this dissemination piece may be less accessible or persuasive to academic audiences

accustomed to conventional empirical reporting. Lastly, the majority of dissemination opportunities are limited by conventional academic publishing norms, which may not accommodate performative outputs, thereby to some degree restricting the reach of this project.

9.10 Conclusion

This arts collaboration is a powerful, effective and accessible method for communicating qualitative findings around a common theme found in five disparate research studies. The researchers believe that the output facilitated a deeper understanding of the subjective experience ‘*of feeling unheard in health and social care situations*’ among those individuals who were exposed to the final spoken-word piece. The methodology developed and outlined above was successful in delivering this novel output, which aimed to deliver a knowledge transfer vehicle that elucidated the somewhat ineffable experiences of patients and carers that often can be extremely difficult to convey using standard academic formats.

In the following chapter, an outline of the academic and societal impacts of this research is provided, a variety of dissemination approaches are described, and some feedback is included.

Chapter 10. Sharing Knowledge, Shaping Practice: Academic and Societal Impact of the Research

10.1 Introduction

A core component of any research activity is the dissemination of its findings. Dissemination in health research is essential for enhancing knowledge and translating investments in research into benefits for patients (Minogue et al., 2022). According to Kerner et al. (2005), passive diffusion of research findings is rarely effective for influencing healthcare practice, however, dissemination research has been a burgeoning area over the previous two decades (Purtle et al., 2020) and evidence from this body of work suggests that there are specific approaches that have been shown to optimise its success. Firstly, utilising the community-based participatory research model, to which this research is closely aligned, has been proposed as an effective framework for information diffusion through the collaborative development of dissemination strategies with the population on interest (Purtle et al., 2020). In addition, Purtle et al. (2020) proposed that integrating theory from the field of communications research can be highly effective for guiding dissemination practice, as well as deploying knowledge from implementation science theory, related to the designing of ‘persuasive’ communication (e.g., messages must be clear and compelling). The authors also recommend that researchers think of dissemination practice as a knowledge translation system, requiring co-ordinated activities and the investment of time and resources.

The potential impacts from disseminating the findings from this research include its immediate academic contribution, shaping both theoretical understanding of burdens experienced by caregivers and informing clinical practice and treatment guidelines for juveniles with T1D. In addition, by disseminating findings related to critical gaps in knowledge about nocturnal caregiving, this project aims to contribute to advancing

understanding of conceptual frameworks such as the key construct ‘Fear of Hypoglycaemia’, as well as contributing to the conversation about refining methodological approaches to health research by evidencing the value of participatory methods. Lastly, through knowledge exchange and non-academic dissemination, the project also aims to engage non-academic audiences, ensuring that findings are accessible and meaningful to patients, practitioners, policymakers, and the wider public, while also creating opportunities to connect with other lived-experience researchers, in order to share learnings and benefit from peer support.

This chapter reports on these activities. The first section outlines the academic impact the research has achieved to date and highlights how it will continue to be disseminated. The second section concerns strategies that take alternative approaches to delivering accessible and impactful dissemination activities in a variety of contexts. There were four key areas of dissemination and impact:

- Educational and Public Engagement (EPE), and ‘knowledge exchange’ activities.
- An initiative designed by the researcher in collaboration with a researcher from another academic discipline to initiate cross-disciplinary collaboration within the Research Ireland’s ADVANCE Centre for Research Training.
- An initiative that was funded within TCD and was conceived to create a forum for lived-experience researchers (LERs) to connect, to share experiences and to offer the opportunity for LERs to discuss with peers the extra challenges they experience as an LER, within a supportive environment.
- Disseminating findings on the theme ‘the lived-experience of feeling unheard in health and social care situations’ utilising a researcher-arts practitioner collaboration, this was discussed in detail in chapter 9.

10.2 Academic & Scientific Dissemination

10.2.1 Publications

- Howard, V., Maguire, R., De Bruin, E., Deane-King, J., Duda, N., & Corrigan, S. (2025). Around-the-clock: Caregiving at night for juveniles living with type 1 diabetes—a systematic review. *Psychology, Health & Medicine*, 1-22.
- Howard, V., Maguire, R., Corrigan, S. Secondary analysis of a systematic literature review on nocturnal caregiving for juveniles with Type 1 Diabetes – From the perspective of the lived experience. *Psychological Applications and Trends* 2024, 465-467. <https://doi.org/10.36315/2024inpact110>
- Howard, V., Corrigan, S., & Maguire, R. (2022). Nocturnal caregiving practice among parent caregivers for juveniles with Type 1 Diabetes: A systematic review protocol. PROSPERO 2022CRD42022298562. https://www.crd.york.ac.uk/prospero/display_record.php?ID=CRD42022298562

10.2.2 Articles currently under peer review

- Study 2: ‘*Engaged Research Partnership for Developing Questionnaires on Caregiver Knowledge-Seeking and Engagement in Juvenile Type 1 Diabetes Management*’, submitted to the journal ‘Research4All’ in October 2024.
- Study 3: ‘*A novel perspective on ‘Fear of Hypoglycaemia’ among parent-caregivers for Juveniles with Type 1 Diabetes: A mixed methods study*’, submitted to the journal ‘Paediatric Diabetes’ in February, 2025.
- Study 6: ‘*Communicating the lived experience of feeling unheard in health and social care settings: An arts collaboration*’, submitted to the ‘International Journal of Qualitative Methods’, in November, 2025.

Articles for studies 4 and 5 are currently in preparation for submission to academic journals, target journals will include, Journal of Paediatric Endocrinology and Diabetes (Scientific Scholar), Paediatric Diabetes (Wiley), Diabetes Care (American Diabetes Association) and Diabetologia (Springer Nature).

10.2.3 Conferences

- European Health Psychology Society (EHPS) conference, September 2023, Germany.
Oral presentation on study 1: *‘Around the clock: Nocturnal caregiving for juveniles with Type 1 Diabetes – a systematic review’*.
- International Psychological Applications Conference and Trends (InPact) 2024, Portugal.
Poster and oral presentation on the PPI collaboration on SLR findings: *‘Secondary analysis of a systematic literature review on nocturnal caregiving for juveniles with Type 1 Diabetes: From the perspective of the lived experience’*.
- Psychology Health & Medicine conference 2024 (Psychological Society of Ireland), Galway. Oral presentation on study 2: *‘An engaged research approach for optimising the development of tools to assess caregiver ‘knowledge-seeking’ and ‘engagement’ in illness management for juveniles with Type 1 Diabetes’*.
- Irish Human Factors and Ergonomics Society (IHFES) Conference 2024, Dublin.
Poster on study 2: *A Human Factors approach for optimizing the development of tools to assess caregiver ‘knowledge-seeking’ and ‘engagement’ in illness management for juveniles with Type 1 Diabetes’*.
- Healthcare Systems, Ergonomics and Patient Safety (HEPS) conference, 2025, Dublin
Poster on study 3: *‘Exploring parent-caregivers’ experiences and perspectives on ‘Fear of Hypoglycaemia’ in Type 1 Diabetes: A mixed methods study’*.

- International Society for Paediatric and Adolescent Diabetes (ISPAD) conference, 2025, Canada. Oral and poster presentation on study 4: *‘Nocturnal caregiving practice among caregiver parents of juveniles with T1D; prevalence, impacts and predictors’*.
- Healthcare Systems, Ergonomics and Patient Safety (HEPS) conference, 2025, Dublin. Oral presentation on study 6: *‘Listening to Lived Experience: An Arts Collaboration’*.
- Irish Association of Directors of Nursing and Midwifery (IADNAM) conference, 2025, Dundalk (invited guest speakers). Oral presentation on study 6: *‘Communicating the Lived Experience of ‘Feeling Unheard’ - an arts-based collaboration bridging research, healthcare, and patient voices’*.

10.3 Non-academic dissemination activities

10.3.1 Educational and public engagement (EPE) & Knowledge exchange activities

- Thriveabetes annual conference, 2024: Presentation titled: *‘Looking after Kids with T1 at Night -- PhD research to explore the caregiver experience and amplify the parent voice’*.

Invited by this national Type 1 Diabetes advocacy group to participate in their ‘Engaging with Research’ event, by presenting on the research as a whole at an interactive poster event.

- Children’s Health Ireland, Crumlin. Diabetes Clinic. 2024. Invited to present to a group of clinician stakeholders from the Diabetes clinic at Crumlin children’s hospital. The objective was to inform stakeholders about the research project and the data collection activities that would be taking place over 3 months in the clinic, also to stimulate interest and to establish support for the project going forward.
- LaunchBox incubator project, TCD. 2023. A presentation was made to leaders from a healthcare technology start-up company that is taking part in the TCD LaunchBox incubator project, which supports students to turn ideas into real world businesses.

Discussions were held to explore possibilities for collaboration as well as to exchange insights and perspectives on developing interventions for healthcare utilising engaged methodologies.

- ‘Multidisciplinary research teams from the perspective of a research student: Experiences from Finland’, TCD. The event was facilitated by Maija Take from Aalto University, Finland and attended by approximately 40 PhD and early career researchers from across a variety of academic departments in TCD. Prof Taka facilitated a series of time-bound, one-to-one interactions between researchers, to create opportunities for researchers to discuss their work and exchange ideas and find commonalities with researchers from other disciplines.
- Research Ireland ADVANCE CRT knowledge exchange events. Every year ADVANCE hosted events to showcase research being carried out by the students. These included posters and presentations and social events. Over 4 years, ADVANCE CRT scholars were given opportunities to exchange learnings and findings from their PhD research with other PhD candidates on the programme who are carrying out research on varied topics, many in STEM disciplines.

10.3.2 Initiative to promote cross-discipline collaboration within the ADVANCE CRT programme

When carrying out the foundational research for this PhD project it became evident that diabetes assistive technology was a factor that would play a central role in the work. The timing was such that significant changes in the assistive technology landscape were having an impact on the phenomenon of interest. This research was carried out within the ADVANCE CRT programme, which included a significant number of PhD scholars who were computer scientists. The author was interested in pursuing the opportunity to engage in cross-disciplinary collaboration for this research within the research group, to potentially

engage with a student from a computer science department or faculty with the aim of investigating whether there was a possibility of recording the frequencies of nocturnal caregiving activities using existing diabetes technologies or with a small adaptation to existing diabetes technologies. Informal PPI consultations had confirmed that the benefits of such an adaptation would be significant for the community and two members of the PPI panel for study 2 made the point that it should have been included in the original design (field notes, study 2).

Working with a colleague in the programme, we developed a proposal for an initiative to facilitate cross-discipline engagement and a marketplace to support this activity for the longer term. With support from the programme executive and two additional student colleagues, we developed a two-day residential colloquium with workshops, keynote speakers and activities that operationalised this goal. It was attended by 70 PhD researchers. The key elements are listed below, see supplementary materials for the full research colloquium schedule.

Research colloquium. Wednesday 8th March 2023 – The Connacht Hotel, Galway

1.) *1st Keynote speaker – Multidisciplinary, Interdisciplinary and transdisciplinary definition and cultural barriers by Dr Orla Murphy*, Head of the Department of Digital Humanities, School of English and Digital Humanities, University College Cork.

2.) *Workshop – Storytelling - Engage with others (I) by Malcolm Love*, science communication expert

3.) *Workshop – Storytelling – Finding a common language (II) by Malcolm Love*, science communication expert

Thursday 9th March 2023 – The Connacht Hotel, Galway

1.) *Abstract Pitching Session (Supported by Malcolm Love)*

Separated into groups of 10 PhD researchers, each made a 3-minute presentation on their own research to a multi-disciplinary group of 10 colleagues. Participants delivered the presentation without the use of visual aids such as PowerPoint, Keynote etc. Feedback was provided by other members of the group and supervisors.

2.) Matchmaking and marketplace

- Introduce the matchmaking process. Using a randomized system, pairings between students were organised. Eight pairings of 10 minutes were facilitated; halfway through the pairing a bell was rung to give each researcher an equal opportunity to speak about their own project.
- Students were asked to reflect and fill out a high-level survey which was utilised to create a marketplace database, this information was gathered for use to create a platform to facilitate future collaborations and to facilitate researchers accessing a skills or experience market.

3.) 2nd Keynote speaker – Multidisciplinary, Interdisciplinary and transdisciplinary research experiences. Dr Anne Cody - Head of Investigator-Led Grants, Research Careers and Enablers at Health Research Board (HRB) - To support research that improves people's health, promotes evidence-informed care and creates solutions to societal challenges.

This author was not able to attend the event for personal reasons and chose not to pursue this avenue of investigation for this PhD project. Interestingly, feedback from the researchers on the research exchange event was very positive but to this researcher's knowledge, while individual researcher responses were enthusiastic, no collaboration teams were formed. This chimes with previous work in the area, such as that presented by Maija Take from Aalto University, Finland, at the event discussed in section 10.3.1 above, which finds extremely low take-up rates for cross- or inter-discipline collaboration

promoting initiatives. The reasons for this can be unclear as they are likely to be context specific, however it is recognised that rates of engagement vary by discipline (Li & Yu, 2024) and that female scientists are more likely to engage in interdisciplinary collaboration (Van Rijnsoever & Hessels, 2011). Barriers often involve perceived variability in the methods employed to ‘handle complexities’, differences between researchers’ expectations, the demands of the individual researcher’s contexts and a lack of adequate resourcing to meet these challenges. Critically, researchers cite the importance of institutional support, possibly in the form of rewards and reinforcement (Culhane et al., 2024) and skills in project management and trust building as desirable to support these types of activities (Nyström et al., 2018).

10.3.3 Networking event for ‘lived experience’ researchers

In January 2025, I applied for a TCD Equality, Diversity and Inclusion (EDI) grant to support an initiative to create a networking and support opportunity for ‘lived experience’ researchers. The application was successful; the proposed event was titled: ‘Supporting the Wellbeing of Early-Career Researchers with Lived Experience’.

10.3.3.1 Objective

The objective was to create a forum to support the wellbeing of student/early-career researchers, working in areas that align closely with their personal lives. In many cases, involvement in the research area was driven by their lived experience, this connection with their topic can be highly motivating and provide extraordinary insights but it also carries a level of burden that is not commonly recognised. The objective of the forum was to create an opportunity for lived-experience researchers to share their stories with understanding peers and provide each other with support, while also offering an opportunity to discuss ideas, share novel methodologies and explore potential collaborations.

10.3.3.2 Participants

The project targeted student/early-career, lived-experience researchers.

In the main, lived-experience researchers are working with and are representative of populations that are considered vulnerable or disadvantaged. These would include a variety of marginalised populations, a variety of illness groups, populations living with physical, mental, developmental or intellectual disability and caregivers for individuals in any of these categories.

10.3.3.3 Rationale

Research Ireland policy states that a core objective of the organisation's approach to EDI is to 'recognise and champion' evidence that diverse and inclusive research systems generate. Lived-experience researchers play a significant role in supporting this objective.

Lived-experience researchers are often mature, and some have been out of education or the workplace for a prolonged period. Many have significant extra burdens. This is a population, without visibility, who contribute significantly but often struggle, being situated between their subject population and their research community. An initiative that benefits the welfare of lived-experience researchers and recognises their difficulties and contribution, supports TCD's EDI objectives by promoting awareness, fostering an inclusive and equitable research environment and nurturing this valuable resource toward reaching their full potential. In addition, it could support this community to build resilience by connecting with each other.

EDI research policies in Ireland (based on Equal Status Acts) are founded on the recognition that research systems and working environments need to support researchers to enjoy a sense of belonging and are empowered to achieve their full potential. This project aligns with that vision as it recognises that lived-experience researchers have extra challenges in these regards and envisions a way to address that.

10.3.3.4 Networking event: *Connecting lunch, with invited speaker*

The event was chaired by a TCD research fellow whose work is informed by their personal lived experience. It was attended by 12 early career researchers, working on a variety of research topics, the majority within the social sciences. The event was held within the TCD campus and lasted 2.5 hours.

- 1.) Coffee and tea were provided on arrival to create an opportunity for participants to introduce themselves to each other and become orientated.
- 2.) A round-table discussion was initiated and facilitated by the chairperson, researchers were invited to make short, informal presentations on themselves and their work. The chairperson led the succeeding conversation around relevant topics.
- 3.) Lunch was provided to create an opportunity for informal networking.
- 4.) The invited speaker was Dr Maguire, from the Department of Psychology, Maynooth University, who is also one of my PhD supervisors. Dr Maguire made a presentation on her experience as a lived-experience researcher and led a deeper discussion around lived-experience researcher positionality.
- 5.) The chairperson summarised the key topics discussed, gathered final words from participants and enabled the collection of contact details to facilitate further networking opportunities for those who may be interested.

Below are quotes from participants commenting on the value of engaging with other researchers who have lived experience of the topic they are studying:

“Good to find others who understand that it’s incredibly frustrating when that emotional connection is seen as a methodological weakness or reason for suspicion”

“Realising and valuing contributions to research from outside of the ivory tower”

“Being open about the emotional labour that comes with this work”

“Suspicion and feeling that your work is undervalued [because of dual positionality] – the question is how to reframe that your research is actually going to benefit your participants in the end?”

10.3.4 Researcher-arts collaboration; interpreting data on the theme ‘Unheard’

As discussed in chapter 9, a collaboration with a creative artist was pursued in order to explore a novel approach to communicating qualitative findings from this and four other colleagues’ PhD projects, which spoke to the theme ‘the lived experience of feeling *unheard* in health and social care situations’. The output from this collaboration was an 8.6-minute video recording of a performance of a spoken word piece by its author, Cormac Fitzgerald.

This video was uploaded and the link shared by this author through a patient support group and in response to requests from individuals who were exposed to it at a recent conference in Dublin. It has been viewed 350 times to date, which does not include the number of downloads. In addition, each individual author has shared the video through their own networks and contact groups and through a variety of platforms and blogs that they considered relevant. Due to the nature of the video, it is difficult to map its dissemination and impact, but as an example the following details the response after it was presented at the Healthcare Systems, Ergonomics and Patient Safety (HEPS) 2025 conference in Dublin: The presentation was received positively. A number of individuals made contact afterwards. A representative from a medical school in the USA asked for access, he intends to show it to their medical students, he said *“In my opinion it should be a global teaching tool for medical students”*. A number of representatives from the HSE

asked for access, one was interested in including it in the curriculum for all the HSE post-grad trainings in nursing. A representative from a pharmaceutical company who develops medical technologies asked for access so that they could show it to their engineering teams. Most recently, the Irish Association of Directors of Nursing and Midwifery invited us to present the piece at their annual conference, where it was very well received. The director of community nursing for North Dublin has asked for access, to present it to her nursing and support staff at their next annual gathering (16 health centres).

10.3.4.1 A selection of quotes responding to the piece

“I am a parent of a young child with type 1 diabetes. I just watched the video Unheard and I am in tears. You have hit the nail on the head and I just wanted to say thank you. You and your team have captured the caring role so perfectly, and it means so much that you went to the trouble to.” (response to inclusion of video in patient ‘advocacy and support group’ newsletter)

“I thought it was a very powerful poem and presentation; I would like to follow up within the HSE to see if it can be shared more widely” (HSE manager)

“I was hoping to be able to share it with our Patient Safety committee as a really excellent example of co-production and better understanding our service users’ needs. Would that be possible at all please?” (Human Factors specialist, NHS trust, UK)

“I really loved the piece and would very much like to know more about the methodology you used to develop it” (Professor of Health Sciences, USA)

“I would like to access the video please, and would like to share with anyone and everyone who would like or should, see it! (Professor of Bioengineering, USA)

“I loved the piece, it makes a good point about technology not fixing things. I think health care professionals avoid the 'how are you question' sadly! I hope that the piece gets heard widely, congratulations on a great project.” (Patient)

“I just wanted to let you know that I brought this lovely piece to the team meeting last week, and it got fantastic feedback from the counsellors.” (Carer support organisation)

“We have both watched the video and it is so powerful” (Director of Nursing, HSE)

“We would like to close the session by showing the film of the very powerful poem ‘unheard’” (invitation to present the piece as a guest speaker at the IADNAM conference)

“It was amazing and really is powerful. I've actually gone back and watched it a couple of times I loved it so much.” (Founder of Patient support group)

“Strong and inspiring”, “Such a powerful video” (Senior Researcher)

“Strong messaging in there...Well done on this- the arts are an important vehicle for change and should be used more”. (Leader from patient organisation)

“That is really great, really powerful, and gets across some really important issues faced by carers. The challenges of technology are particularly well highlighted”. (Lecturer in health)

“Very emotional, comforting to have my experiences reflected back to me in this short film and encouraging that our difficulties are being taken seriously” (Patient)

“You could have presented 50 pages of data and it wouldn’t have pulled me in like this did, it just hooked me right in, the use of storytelling drove the message straight home” (HSE clinician support service manager)

Chapter 10 highlighted the impact this research has achieved by adding to scientific knowledge through publications in academic journals and conference presentations. The chapter also details dissemination activities that have reached wider societal audiences, through the initiative to create of a novel forum for lived experience researchers to connect, an arts collaboration that serves as a medium for communicating findings across disciplinary and academic boundaries, and knowledge exchange and public engagement activities. These undertakings have had a meaningful impact in academic, practitioner and patient environments, which is a key objective of effective research practice.

The following and final chapter (11) integrates findings from the series of 5 empirical studies on nocturnal caregiving practice in T1D described in this dissertation and discusses the broader implications of these insights. It highlights the need to address this issue by focusing on the often invisible but very significant burden that is carried by this cohort of caregivers. The chapter also utilises the ‘assessing community engagement conceptual model’ framework to evaluate the impact that a high level of PPI input had on the research and its outcomes. The limitations of the research are discussed and directions for future research suggested.

Chapter 11. Discussion

11.1 Introduction

The objective for this dissertation was to explore and describe the experience of nocturnal caregiving among parental caregivers of juveniles with T1D. This was achieved through a series of studies investigating nocturnal caregiving practice in this population. These studies were guided by collaboration with a Public and Patient Involvement (PPI) panel, which was embedded in every stage of the research process.

This chapter is structured over two broad parts. In part 1, sections 11.2 and 11.3 present an overview of the research questions and the studies conducted, synthesising the key findings from each and integrating them into a coherent interpretation of the overall results. The aggregated findings are examined in relation to one another and critically discussed within the context of existing academic literature. In part 2, section 11.4 focuses on the impact, benefits and learnings from utilising a participatory approach, summarising insights gleaned from the project's collaboration with experts by lived experience and proposing strategies that operationalise this novel knowledge. It also presents learnings from the experience of implementing participatory research methods and examines how the project as a whole maps onto the 'assessing community engagement conceptual model' framework, identifying strengths and weaknesses of the project from the 'community engagement' perspective, which was key.

Limitations of the research are also addressed and finally, the chapter presents suggestions for future research that are based on findings from these studies and offer the potential to build on this project's conclusions and guide the development of further supportive interventions.

11.2 Addressing the research questions

At the outset of the research, there were 4 key research questions, which were as follows:

RQ 1. What is the prevalence of nocturnal parental caregiving practice in an Irish sample?

RQ 2. What factors drive caregivers to provide nocturnal care, and what are the associated impacts for caregivers?

RQ 3. To what extent does the use of technology moderate the practice of nocturnal caregiving or impact on the associated burden?

RQ 4. What strategies or interventions can be implemented to better support caregivers in nocturnal caregiving?

To address these research questions, a series of studies were carried out. *Study 1* was the foundational study, a mixed-methods systematic literature review of 31 peer reviewed publications that included data on nocturnal parental caregiving in T1D, this study addressed all of the RQs. *Following this, an* exploration of the SLR findings from the caregivers' perspective was carried out by instituting a secondary analysis of the findings, which was conducted in collaboration with a PPI panel of caregivers. This PPI consultation informed the approach to the succeeding studies, in particular, driving the agenda for study 3. *Study 2* reports on the process of developing and statistically evaluating novel tools to measure 'knowledge seeking' and 'engagement with illness management' in T1D, to facilitate study 3. *Study 3* was a mixed-methods online survey, designed in response to a PPI finding. This study's aim was to evaluate the construct 'Fear of Hypoglycaemia' (FoH) and the 'Hypoglycaemia Fear Survey' (HFS) measurement tool, from the perspective of caregivers in T1D, the objective was to establish whether they align with the lived experience. *Study 4* was also a mixed-methods online survey, this study was interested in whether findings from the SLR (study 1) on nocturnal caregiving practice, would be replicated with an Irish sample recruited from a clinic that supports high

levels of diabetes technology use. This study gathered evidence on all the RQs. *Study 5* aimed to respond to findings from studies 1 & 4 that addressed RQ4, it was designed to facilitate a more comprehensive examination of this population's unmet need for acknowledgement and support with the burden of nocturnal care. *Study 6* represents a departure from traditional research; it describes a collaboration with an arts practitioner to explore the development of a novel tool to disseminate findings on the qualitative theme 'feeling 'unheard' in health and social care situations'.

11.3 Key findings

The sections below present the key findings from studies 1, 3, 4, & 5, which are organised according to the research questions. The PPI consultation and studies 2 & 6 are excluded from this analysis as they did not directly respond to the research questions, contributing instead to guiding the research process (PPI consultation), the development of materials to facilitate the research objective of study 3 (study 2) and the development of a novel tool to facilitate the dissemination of a qualitative theme (study 6).

11.3.1 Prevalence of nocturnal parental caregiving behaviour [RQ 1]

Synthesised data from 31 studies that were included in the systematic literature review of nocturnal caregiving in T1D found that 88% of 1,301 parents were engaging in nocturnal caregiving behaviours. There was a notable variation in nocturnal caregiving frequency that could reasonably be trifurcated into 'high frequency' (5-7 nights per week, often multiple times per night), 'moderate frequency' (2-3 times per week) and 'low frequency' (rarely or never). This finding was echoed by findings from study 4 (large-scale cross-sectional survey) and study 5, the follow up qualitative analysis. In study 4, 85% of the participants endorsed delivering nocturnal care for their child with 76% reporting experiencing sleep disruption as a result, and almost half of the sample (43%) engaging

with this practice 3-7 nights per week. In study 5, all 21 participants reported delivering nocturnal care that resulted in caregiver sleep disruption. This was interesting because study 4 and part of study 5 were hosted by a paediatric diabetes clinic in a large Irish hospital that supported high levels of technology use, which other research has linked to reduced nocturnal burden of care (Janez et al., 2021). Nonetheless, high prevalence of nocturnal caregiving practice is clearly evidenced across the studies and high levels appear to be maintained, even where children have access to diabetes assistive technology.

11.3.2 Factors driving nocturnal caregiving behaviour [RQ 2.1]

In study 1, the two most prominent drivers of nocturnal care were anxiety and hypoglycaemia mitigation. Here, for the most part, anxiety was related to hypoglycaemia threat. This finding was replicated in study 3, where concern over nocturnal hypoglycaemia was shown to be an almost universal feature of caregiving in T1D, and caregiver accounts of managing the threat of nocturnal hypoglycaemia described it as ‘terrifying’, ‘beyond stressful’ and ‘overwhelming’. Again, in study 5, hypoglycaemia anxiety emerged as a prominent theme. This aligns with recent findings from studies looking at FoH and its impact on caregiver sleep (Abitol & Palmert, 2021; Feeley et al., 2018; Macaulay et al., 2020; Schierloh et al., 2024), with authors highlighting the need to acknowledge this burden and consider the psychosocial impacts of T1D on caregivers.

Studies 1 and 4 set out to determine if any significant associations could be identified between illness related factors and engagement with nocturnal caregiving. In study 1, findings were conflicted on diagnosis duration, with one study reporting a relationship and the other finding none (Macaulay et al., 2020; Feeley et al., 2019), while the age of the child was not found to have any directional relationship (Feeley et al., 2021). Building on these findings, in study 4, both child and caregiver factors were examined for their ability to predict nocturnal care. Here, only ‘difficulty making ends meet’ and ‘insulin

pump with sensor treatment regimen' significantly predicted nocturnal care. The 'pump/sensor regimen' factor tallies with the qualitative evidence from studies 4 and 5. Regarding the predictive value of ability to make ends meet, as noted in chapter 7, questions about the direction of the finding are pertinent as 30% of this sample (n=235) reported reducing work commitments in response to the burden of care, which would of course impact negatively on household finances. Caregiver accounts of their nocturnal care burden in study 5 emphasised the person- and context-specific nature of their nocturnal caregiving practice, with widely varying accounts of personal drivers (e.g., expectations for blood glucose control; level of collaboration with their child; day-to-day factors such as activity levels), which aligns with previous evidence (Macaulay et al., 2020; Feeley et al., 2019; Jaser et al., 2017). The lack of clearly predictive or driving factors is meaningful as it implies that there is no way of reliably identifying vulnerable parent/child dyads, which supports the overarching conclusion of this dissertation that nocturnal care needs be addressed at the individual level in routine clinic appointments, as discussed below.

11.3.3 Impacts on T1D illness outcomes from receiving nocturnal care [RQ 2.2]

Findings from study 1 (SLR) suggested that the delivery of nocturnal care does not improve health outcomes for children (utilising HbA1c as a proxy for blood glucose control) (Monaghan et al., 2012; De Beaufort et al., 2021; Monaghan et al., 2009). This finding was replicated in study 4. This counterintuitive result is surprising, particularly given that higher levels of nocturnal care were associated with higher FoH in study 1 and that higher Fear of Hypoglycaemia was positively associated with better illness management in study 3. This illustrates the value of linked follow-up studies and draws attention to a conflict in the findings that suggests a more nuanced relationship between these variables, which therefore warrants further investigation. In the interim, study 4 offered a plausible explanation for the finding, suggesting that nocturnal care, as captured

by these studies, may be primarily reactive rather than proactive. As noted, the topic merits further investigation because the potential behavioural impacts from such information could yield significant benefits for children's health outcomes.

11.3.4 Impacts for caregivers from delivering nocturnal care [RQ 2.3]

Study 1 (SLR) found that 51.3% of 600 caregivers were not achieving the recommended sleep duration of 7-9 hrs. For comparison, a control group of parents in one of the included studies (n=49), found that just 27% slept < 7 hours (Bahadur et al., 2022). The SLR also reported aggregated data showing that 54% of 663 caregivers scored for clinically significant levels of poor sleep quality on the Pittsburgh Sleep Quality Index (Buysse et al., 1989). These findings were replicated in study 4, where 76% of 210 caregivers reported experiencing sleep disruption due to nocturnal caregiving and 63% reported reduced sleep quality. Participants in this study lost 7.04 hours of sleep in an average week.

Across all studies, the strongest impact experienced from nocturnal caregiving was fatigue and exhaustion, with one participant noting for example that “*some nights the exhaustion holds me like a straitjacket*” (study 1). In study 4, 53% of caregivers scored for exhaustion and fatigue on the Iowa Fatigue Scale (IFS), compared to 20.7% in a general, global population (Yoon et al., 2023). In study 1, qualitative data detailed the considerable impacts from debilitating fatigue, including cognitive, emotional and social impacts, as well as consequences for mental health including anxiety and depression. In study 4, nocturnal care-related stress or anxiety were endorsed by 44% and 36% of participants respectively, with other impacts such as reduced family wellbeing also reported (31%). In addition, 41% experienced associated sleep problems and 38% felt that sleep disruption had negatively affected their health. Study 5 reported similar findings, with one participant noting for example that “*I never switch off, never, I can't*” (Study 5). In this regard, it is

important to highlight that poor caregiver wellbeing may have adverse effects on children's physical and mental health outcomes (Pierce et al., 2017; Pena-Shaff et al., 2023).

Gender care gaps were a significant feature of all the studies, with a majority of participants in each study being female (S1/89%; S3/97%; S4/71%; S5/91%). As an example, in study 4, mothers reported personally contributing 83% of nocturnal care on average and fathers reported contributing 56%. The associated burdens were unevenly distributed also, with mothers experiencing more sleep interference, reduced sleep quality and related sleep problems. This tallies with findings from a previous review showing that women were the primary nocturnal caregivers in T1D (Azimi, 2024) and much of the body of caregiver research, which indicates that women are typically the primary caregivers for children with chronic health conditions (Toledano-Toledano & Luna, 2020).

11.3.5 The role of technology in moderating nocturnal care burden [RQ 3]

Study 1 suggested clear benefits for sleep from technology but for many caregivers, these technologies prompted an increased burden of nocturnal care, through alarms, a constant flow of data, and technology management requirements. These findings were consistent with qualitative findings from study 4, which supported the position that for some caregivers, technology provides a significant moderating effect on nocturnal burden, while for other caregivers, technology use was associated with increased the nocturnal care behaviours.

Meanwhile, in quantitative data from study 4, the highest levels of sleep disruption were found among participants using non-looping pumps and sensors (90.9%). This aligned with findings reported in study 1, which indicated that non-looping pump technology did not show the expected benefits for sleep (Biseo, 2022; Cobry, 2022; Hitt et al., 2023). In fact, Landau (2014), who used actigraphy to capture objective sleep data, found that nocturnal wakings increased with non-looping technology. However, other

research found conflicting evidence, Biseo et al. (2021) used a repeat-measures experimental design (pump condition/hybrid closed loop (HCL) condition) and found that HCL reduced the number of nocturnal awakenings. Similarly, Cobry et al. (2020) found small but non-significant benefits for sleep with HCL. These findings differ from those reported in a recent study by Schierloh et al. (2024), which showed that the benefits for sleep from non-looping technologies *and* HCL are negligible. Relatedly, in study 4, quantitative data showed no significant differences between non-looping or HCL regimens on the fatigue scale or the 'other impacts' scale. Taken together, these findings suggest that the issues at play may be significantly more nuanced or complex than appreciated in much of the research to date and are likely to be subject to unidentified individual factors in patient/caregiver dyads, which quantitative methods struggle to capture.

In contrast, qualitative data from study 5 indicated that although all 21 participants reported nocturnal caregiving behaviour, the findings clearly demonstrated that parents who use HCL technology experienced a greatly reduced burden of nocturnal care, notably, many of these participants had experience of both conditions (with and without HCL), with many deliberately emphasising the difference. This was supported by the quantitative data from study 5 showing that HCL participants were waking 2-3 per month on average, while in the non-looping group, 73% were waking 5-7 nights per week.

Although the evidence is mixed, on balance, HCL systems appear to provide some benefits for nocturnal care although, as discussed in studies 1 and 4, they are not without drawbacks. Finally, and in this regard, it should be noted that some HCL using caregivers from study 5 expressed surprise and dismay that HCL technology was not available to all, inadvertently acknowledging the significance of the digital divide (Gajewska et al., 2021).

11.3.6 Recommendations for strategies to support caregivers in nocturnal caregiving

[RQ 4]

Interestingly, the various strands of research across this group of linked studies demonstrated a high degree of coherence among the findings that spoke to the issue of ‘addressing the unmet need for support with nocturnal caregiving burden’. There were three consistent themes: (1) Access to technological supports, (2) addressing nocturnal care in routine clinic appointments and (3) 24-hour phone support from a diabetes nurse specialist.

(1) *Access to technological supports*. Unsurprisingly, this was the most representative theme for the topic of unmet need for support across the research. Among qualitative findings from study 1 (SLR), 100% of the relevant studies reported benefits for sleep from technology, though a significant minority reported that technology presented a barrier to sleep (alarms, flow of data, technology issues etc.), (Cobry et al., 2020; Burckhardt et al., 2018; Herbert et al., 2015), as discussed above. In addition, qualitative data from studies 4 and 5 showed perceived benefits from technology for caregiver confidence and anxiety. In study 5, as noted above, caregivers expressed dismay that HCL systems were not ‘standard care’ but notably, those who were in the ‘sensor only’ group appeared to have only a vague idea that the HCL would offer better illness management and a reduced burden of care, accepting that it was not available or very difficult to access.

(2) *Addressing nocturnal care in clinic*. This second theme was prominent in study 1 (SLR), firstly from the perspective of the caregiver (Sullivan-Bolyai et al., 2003; Oser et al., 2017) and secondly, from the perspective of researchers and authors (Morrow et al., 2022; Sullivan-Bolyai et al., 2003; Bahadur et al., 2022). Findings indicated that overall, nocturnal care is rarely addressed in clinic. An analysis of the authors’ conclusions and recommendations for the included studies found that researchers overwhelmingly stated (83%) that clinicians should routinely address nocturnal care in clinic with suggestions

such as; providing sleep education or behavioural support interventions. Of these, 70% suggested simply that clinicians should just “Ask about it”. These findings were replicated in study 4 and examined more closely, with this study finding that 92% of caregivers had rarely or never discussed the burden they personally experienced from providing nocturnal care in their clinic. When asked what their diabetes team could do to support them with nocturnal care, 48% didn’t know or felt that there was nothing that could help, however 27% felt that they had an unmet need for support from their team around nocturnal care delivery. For some, the desired support intervention was emotional, while for others it was instrumental or educational. In study 5, findings indicated that 91% of caregivers (n=19/21) had never been asked about nocturnal care or had unsatisfactory exchanges with clinicians when they attempted to address the topic, while 73% felt that this was a topic that should be addressed routinely in clinic. The majority want to start this conversation with the diabetes nurse specialist, they don’t want to speak about it with their child present if possible, and they would like the conversation to directly and explicitly address nocturnal caring (study 5). Across studies 3, 4 and 5, findings show how overwhelmingly caregivers are uncomfortable bringing attention to themselves, they are living with significant impacts, but many just accept this. Others recognise the value of having their difficulties acknowledged by clinicians, as they live with a huge degree of misunderstanding among their extended families, friends and the world at large about the difficulties involved in providing care support for a child with T1D. “*Nobody without a T1 kid really gets it*” (Study 5).

(3) *24-hr phone line*. This third theme represents findings from study 4 and 5, where participants envisaged accessing support at night through a 24-hr diabetes nurse specialist phone service. Participants spoke of the benefits a service such as this “*the nighttime thing when it goes wrong is quite scary*” (study 5) and some discussed using the 24-hr technology support phone service maintained by a medical technology company as a

proxy. The Health Service Executive (HSE) in Ireland, in their key recommendation from the ‘Paediatric Diabetes: Model of Care for all Children and Young People with Type 1 Diabetes’ document states that 24-hour telephone support should be made available (HSE.ie, 2015). Even though this recommendation was made 10 years ago, it has still not been implemented though it could, potentially, be a relatively affordable intervention, particularly if organised at the national level replicating the med-tech service mentioned above.

11.3.7 Overarching contribution from the collective research

This dissertation makes a substantive and original contribution to understanding the largely invisible yet highly consequential practice of parental nocturnal caregiving for juveniles with Type 1 Diabetes by integrating evidence built across six interrelated studies that were carried out within a participatory, mixed-methods framework. Collectively, the thesis advances knowledge by establishing the prevalence and detailed characteristics of nocturnal caregiving, investigating relevant constructs such as fear of hypoglycaemia, and introducing and validating novel tools to better capture caregiver challenges, engagement and knowledge-seeking behaviours. It further provides nuanced insight into the lived experience and burden of disrupted sleep, while critically examining the role of diabetes technologies in shaping caregiving practices. A unifying thread across all studies is the centrality of the caregiver voice, achieved through sustained PPI involvement, which not only shaped the research design but also ensured that findings were grounded in lived reality and responsive to unmet needs. By combining empirical rigour with participatory and innovative dissemination approaches, this thesis bridges gaps between clinical understanding, caregiver experience, and practical support needs, ultimately offering a coherent, evidence-based foundation for future research, policy change, and intervention development aimed at supporting this cohort.

11.4 Impact, benefits and learnings from utilising a participatory approach

Participatory methods were incorporated through every stage of the research process, with each study reporting its specific benefits and outcomes in the relevant chapters. From an overarching perspective, considerable insights were drawn from these collaborative processes. This first part of this section explores methods of operationalising some of these insights and discusses the benefits of deploying these methods in T1D research. The second part of this section considers the researcher's positionality and identifies aspects of the implementation of the participatory engagement processes that have been informative. In the third section, the Assessing Community Engagement Conceptual Model is examined to explore whether this research use of participatory methods mapped successfully onto this framework. Finally, the seven benefits of utilising participatory practices, as identified by Jagosh et al. (2012), are explored in the context of this research project.

11.4.1 Operationalising insights derived from consultations with experts by lived experience

As detailed in previous chapters, this project was anchored in the lived experience of the primary researcher, but it developed in response to collaborative engagement with a participatory panel of experts by lived experience. As the research agenda evolved, insights gained through feedback from these experts surfaced issues that were helpful for informing the research design at each stage of the research journey. These insights form an important element of the research output as they give voice to a perspective that is close to the topic but free of the constraints of the academic process and also highly motivated to direct change that will impact positively on the real-world experience of caring for children with T1D, which was a key objective of this project. Below, these insights are summarised with

a focus on how they could be taken into consideration when future studies are conceptualised and designed.

(1) *Research design*: In the PPI consultation on the SLR findings, the panel emphasised the point that some illness-related variables could be very impactful on research outcomes in T1D, potentially acting as confounding factors, but that this did not appear to be accounted for by the research findings in study 1. Spotlighting aspects of the experience that are obvious issues to the patients but may not necessarily be evident to the researchers could be helpful in the design of future research in T1D. For example, it was felt that inclusion criteria such as ‘time since diagnosis’ should in all cases take the well-known ‘honeymoon period’ phenomenon into account, or that standardised alarm settings or reported setting variations should be standard practice in research into diabetes assistive technologies, which was not generally the case.

(2) *Tools*. A PPI panel review of potential tools to capture aspects of illness management practice in T1D (study 2) revealed a dearth of suitable or acceptable psychometric instruments or standardised scales that were a good fit for the lived experience. This finding has implications for future research in T1D, suggesting that piloting tools and eliciting PPI feedback on their suitability for the population and phenomenon of interest should be a de facto step in all T1D research. It is plausible that this is particularly pertinent for T1D research as T1D and T2D are sometimes conflated in diabetes research and the tools may reflect this, while the lived experience of both conditions differ considerably.

(3) *Constructs*. Study 3 addressed the considerable impacts caregivers experience from managing the threat of hypoglycaemia and the associated anxiety. Almost 70% of the sample felt that FoH would apply to them and 66% felt FoH normal, an informed response to a ‘legitimate’ concern, given the level of threat. Many caregiver participants felt that there were items that fairly represented their daily concerns but questioned the use of the

resulting metric to qualify or characterise their caregiving behaviours. Some participants identified questions that caused significant concern, touching on matters that many considered irrelevant, sometimes in a tone that was alienating (e.g., “*do you worry about your child appearing stupid or clumsy?*”). Furthermore, participants felt that the construct and tool appeared to make no concession to the fact that all of the topics addressed by the items would, in the real world, be extremely context specific, prompting panel members to question whether the construct is fit for purpose, or potentially oversimplifying a complex behaviour. Future research designed to investigate FoH must take this perspective into consideration.

(4) Involving patients and their caregivers in the development of research agendas in T1D.

In each study, PPI collaborators indicated that they would value the opportunity to influence future research agendas in T1D. Recent publications in the area indicate that there has been a growing trend toward initiatives that support this approach. For example, Newman et al. (2024) published a study identifying the top 10 research priorities for adults living with T1D in Ireland using a James Lind Alliance Priority Setting Partnership. This methodology positions patients and other stakeholders at the centre of decision-making processes to ensure that health research funding is directed toward issues that are of high relevance to the individuals who are directly affected. Furthermore, the D1 Now project is national project in Ireland that is exploring ways to improve engagement between young adults with T1D and their health providers, at the centre of their project is a ‘young adult panel’ (YAP) of PPI collaborators who are “involved in all aspects of the study design and direction” (d1now.ie). These are certainly welcome developments, further research initiatives using similarly inclusive and robust methods would be welcome.

11.4.2 Reflexivity and positionality

Reflexivity is a critical component of participatory research, acknowledging that the researcher's position, experiences, and assumptions inevitably shape all stages of the research process. In the present study, reflexivity served as both a methodological and ethical practice, contributing to the credibility, authenticity, and integrity of the research. By maintaining an ongoing awareness of my own influence on the research process, I aimed to ensure that participants' voices remained central while also recognizing the co-constructed nature of meaning within this project. Completing the PPI Digital Badge (online, University College Cork (UCC) early in the research process was helpful for refining my understanding of my position within the project, first in terms of understanding my project as 'patient' led and recognising the value of that, and secondly, for deepening my understanding the value of PPI contributions, which I was now able to envision as a method for ensuring rigor in the research process; "it's been very important to recognise that at every step I have to reference the community to validate my decisions" (reflexivity journal). The section below briefly reflects on how power dynamics, expectations, and shared decision-making were navigated throughout the study. In doing so, it aims to make transparent the interpretive lens through which the findings were produced and thereby enhance the evidential credibility.

11.4.2.1 Reflexive observations and learnings

- Given my personal proximity to the topic and the phenomenon of interest, it quickly became clear that the research objectives I wished to pursue could not be carried out ethically without fostering a close collaboration with a panel of experts by lived experience. This became evident when I was grappling with formulating the initial research questions, I recognised my high level of personal investment as a potential pitfall; 'I'm going to need help stepping back' (reflexivity journal).

- It was challenging to recruit members for the panel. The nature of the panel meant that it attracted individuals who were comfortable engaging with critical and analytic discussion, and it was also the case that individuals with some previous experience of research had more willingness to engage. As a result, extra efforts were required to recruit the most demographically heterogeneous panel possible, i.e., ‘snowball’ recruitment.
- Empowering the panel was key, this was achieved by creating an environment where all contributions and insights were acknowledged and equally valued, particularly where participants may have felt a perceived power differential with academic knowledge. For example, when carrying out the collaborative PPI review of SLR findings; for some individuals there was an assumption that knowledge contained in academic publications was beyond critique.
- Furthermore, making it explicit to the panel that their expert opinion was guiding the research process (i.e., visibly reflected in research materials that had been co-designed) was helpful for bolstering the panel’s sense of empowerment and agency in the project.
- Managing opinion leaders was key for drawing the maximal value from panel discussions. This was more difficult when their views aligned with those of the researcher. This required vigilant self-reflection on the researcher’s part.
- Maintaining a research diary was helpful as small position shifts on topics of interest occur almost imperceptibly, particularly in response to discussions with the expert panel. A baseline reference text was useful for maintaining clarity.
- As a lived experience researcher, it was challenging to position myself with regard to the participants while carrying out data collection interviews and focus groups. During the initial interviews my inclination was to put participants at ease by sharing some of my own experience. I discovered that participants enjoyed sharing their stories with somebody who understood their experience but many preferred to hold the space for

their own story, which was completely understandable. This insight was helpful for supporting positive data collection engagements, evidenced by the majority of participants stating that they would like to engage further with the research if an opportunity arose.

- Nonetheless, developing rapport with participants was significantly easier when I signalled my insider status, particularly in the diabetes clinic waiting room. In that situation there were many distractions, I think it benefitted engagement with the online survey.
- Two of the studies (4 & 5) had the benefit of a research assistant and a co-researcher. Their input was particularly helpful for deciding on qualitative data to include in the reports. I believe that I found this slightly more difficult than an academic researcher might, as again, my proximity to the experience made it challenging to be impartial.

11.4.3 Mapping this project onto the ‘Assessing Community Engagement Conceptual Model’ Framework

Having completed this series of studies utilising embedded participatory methods, the current sub-section explores the effectiveness of the participatory approaches deployed by mapping the project onto the framework of the ‘assessing community engagement conceptual model’ (Aguilar-Gaxiola et al., 2022), which was outlined in Chapter 2 (section 2.5). This was deemed useful as it highlights areas for which the outcomes were particularly successful and also those where outcomes fell short of the desired objectives, which is informative.

(1) *Strengthened partnerships and alliances*. Due to the limited scope of this project, the partnership was limited to one between researcher and experts by lived experience. In an ideal scenario, this alliance would have included clinicians (diabetes specialist nurses and endocrinologists). For a variety of reasons such as limited access, this was not possible.

However, the partnership that did emerge was highly effective at many levels; it was inclusive, a heterogeneous panel was purposively recruited; it was structurally flat, perceived power differentials were well-managed; it offered experts by lived experience the opportunity to have agency by providing input into scenarios that impact on their own health and wellbeing, all being caregivers in T1D or T1D patients or both; it also recognised and acknowledged their expertise. The engagement effectively operationalised the values of trust, mutual value and shared power and with good results, this was evidenced by the sustained engagement of panel members over three years, through the different stages of the project, to the extent that they were able.

(2) *Expanded knowledge.* This is probably the domain where the project has had the most significant success. The level of participatory involvement was extensive. These involvements resulted in three studies that spotlighted issues of significant interest to the lived experience but that would not necessarily have drawn the attention of academic researchers. For instance, with the PPI consultation on the SLR findings, the expert panel generated a comprehensive list of issues based on a close examination of the studies included in the systematic review. This list of concerns provided guidance for the PhD research agenda/ research design and will also provide a valuable resource to inform future research in this area (as outlined above). In addition, study 3 focused on a theme that emerged from the PPI analysis that was carried out. The panel ascertained that ‘fear of hypoglycaemia’ as a construct was not fit for purpose. This was such a powerful theme that a stand-alone study was designed in collaboration with the panel, to investigate its validity.

(3) *Improved health, healthcare programs and policies.* This research has utilised community consultation effectively for prioritising issues that are of central concern to the patients and caregivers. This is evidenced by the summary of studies’ findings above, where the scale of the overarching issue, ‘nocturnal caregiving burden in T1D’, is clear, the impacts are meaningful and community-driven proposals for solutions are detailed and

actionable. Again, the scope of this project is limited by the lack of cross-discipline engagement with policy or clinical expertise, this suggests that its contribution to the T1D knowledge landscape will depend on its ability to cross disciplines and gain the attention of individuals who do have influence to affect change. This aspect of the project is a work in progress but will include the targeting of clinical diabetes journals for future publications.

(4) *Thriving communities*. This assessment criterion is deeply concerned with a wholistic approach to managing health, both at the individual level and the patient-carer dyad level, to support improved life-quality and wellbeing. This research is strongly aligned with those criteria. It emphasises the importance of the psycho-social aspects of delivering effective illness-management care to juveniles as well as highlighting the issue of nocturnal caregiver burden which receives scant attention in the T1D literature. Acknowledging and addressing these issues will promote community resilience by empowering these individuals to recognise their burden as significant and advocate for support, while empowering the healthcare system in diabetes to recognise that small, focused, individual level interventions can be integrated into routine care encounters, providing disproportionately positive benefits for many T1D families.

11.4.4 Identifying benefits of participatory research for this project

In their paper, Jagosh et al. (2012) identified seven distinct benefits of utilising participatory methods that align with the principles of the ‘assessing community engagement conceptual model’ (discussed in chapter 2, section 2.5). Here, these benefits are explored in the context of this project.

(1) *Culturally and logistically sound research*. Participatory methods ensured that this study utilised culturally appropriate terminology, for example through co-production of research materials. The logistics of carrying out the research were also informed by expert experience, understanding the needs of this high-burden population indicated that

adaptability and flexibility needed to be central concerns in designing the research procedures.

(2) *Enhanced recruitment capacity.* Participatory involvement had a considerable effect on recruitment, for example, by assisting in identifying and accessing suitable platforms to place recruitment invitations. In addition, an understanding of clinic procedures was helpful for designing data collection activities that would maximise participation. Lastly, it is probable that presenting to the participants as a lived experience researcher increased trust and resulted in more candid responding to questions.

(3) *Improved stakeholder capacity and competence.* This is more difficult to track but it appeared that through the 3-year process, the expert panel's capacity to engage in the participatory collaborations, with appropriate capability or skill level expanded noticeably through the process. For example, the time taken to 'set up' the engagements was reduced at each successive meeting as a result of increasing competence.

(4) *Generated stakeholder disagreements and negotiations that had positive and negative outcomes.* In some instances, for example in negotiating the priority list of items to be included in the novel tools to measure knowledge and engagement in T1D, open negotiation among the diverse stakeholders led to small disagreements. However, negotiated and inclusive decision-making practices resulted in research outcomes that better reflected community needs. In this regard, it was very beneficial that the researcher had personal lived experience and was not regarded only as an academic because it reduced the power distance, which supported inclusive practices.

(5) *Increased quality of outputs.* It is certain that participatory involvement led to better quality outputs due to the level of collaboration and its impact on the research agenda. Community involvement has highlighted a need to create outputs that speak beyond the academic environment; educational and public engagement activities have resulted.

(6) *Increased sustainability of project goals.* Funding to acknowledge the contribution of the experts had been attained but this was not commensurate with the level of engagement offered by the panel members. Their commitment to the project was such that they sustained their involvement as volunteers. Two contributors asked that their compensation be re-directed to other relevant research goals.

(7) *System change as well as new unanticipated projects and activities.* Some system change is anticipated as a result of this project, for example, the spoken word piece ‘unheard’ has spread the core message of this project, which is, ‘NOTICE’ the nocturnal T1 caregiving experience, through various avenues of the HSE and into some medical training environments. Moreover, two out of six of the studies presented in this dissertation are a direct result of participatory feedback. These findings will enter the body of literature and may contribute in part to system change or with time, direct further research.

11.5 Limitations of this research

The limitations of each individual study are discussed within the relevant chapters. However, from an overarching perspective, there are a number of limitations to consider when interpreting the findings. Arguably, the most significant limitation across the research is the lack of clinician engagement, detailed above. Study 5 in particular would have benefitted from the involvement of clinicians, both diabetes specialist nurses and endocrinologists. It is difficult to speculate on what their position might be regarding the issue of nocturnal care burden, as there is, to this researcher’s knowledge, no literature that specifically addresses this concern among that population. Secondly, the samples in all of the studies were skewed toward higher levels of education than would be representative of a normative population. In addition, due to the nature of the research, caregivers without strong English may have been disinclined to participate, this may have excluded new arrivals to Ireland. It is possible that these factors have impacted on the findings and could

limit generalizability. Another notable limitation relates to the recruitment process for studies 2, 3 & 5, which utilised an online support group to advertise for participants. It is likely that caregivers who engage with this support group will share certain characteristics, such as being more digitally engaged and more active in the T1D community. In addition, this recruitment procedure may have resulted in a sample with shared experiences or perspectives, all factors that could potentially constrain the study's applicability to wider populations. Lastly, HbA1c was used throughout the series of studies as a proxy for level of blood glucose control achieved and success with illness management. This measure is commonly used in research for this purpose, however it is recognised that it has limitations and that there are other measures, such as 'time-in-range', that are helpful when used in combination with HbA1c values to capture a more nuanced interpretation of a patient's T1D health outcomes (Battelino et al, 2019). This was not deemed feasible for this research as it required all patients to be using the relevant technologies, which did not fit with the recruitment criteria for this research.

11.6 Future Research

There is wide scope for future research to build on the findings from this research by exploring nocturnal caregiving in T1D in greater depth and across a wider range of contexts, such as other geographical regions with different health systems, to enhance understanding. Findings suggest that further exploration of the characteristics of nocturnal care practice and the role of *hyperglycaemia* mitigation in nocturnal caregiving would address significant gaps in the literature. In addition, use of actigraphy technology to capture objective data on sleep disruption would be useful for supplementing the current findings (Ancoli-Israel et al., 2003). Other gaps identified include the impacts on caregivers' physical health from sleep disruption due to nocturnal caregiving practice and the relationship between nocturnal caregiving practice, FoH and health outcomes in

children with T1D. Further studies investigating topics suggested by the expert PPI panel could also be pursued, such as the impact from nocturnal care on T1D outcomes and accepted beliefs around nocturnal blood glucose stability. A longitudinal comparative study tracking the experience of nocturnal care delivery from diagnosis through the various technological support options would be highly informative for the discussion on the moderating effects of assistive technologies, while an audit of national diabetes services would be helpful for spotlighting access issues and calling attention to the associated ‘digital divide’. In addition, studies are required that capture the clinician perspective on acknowledging caregiver burden from nocturnal care delivery (diabetes nurse specialists and endocrinologists). Understanding how clinicians feel they could feasibly address the topic during routine clinical contacts would be beneficial. Furthermore, research investigating clinicians’ perspectives on potential approaches for providing support within the clinic setting, establishing what interventions would be deemed feasible and acceptable by the clinician stakeholders who would be required to implement them, would again, be a significant step toward positive change. Finally, research that focuses on the implementation of a service offering 24-hour phone access to a diabetes nurse specialist is required to establish what facilitators and barriers exist. This initiative was proposed by the HSE, but none of the participants had encountered this service and study 5 identified it as an unmet need. Taking a broader perspective, research is required that builds the evidence base for the value of ‘feeling heard’ in clinical settings. The recent development of a ‘Feeling Heard Scale’ (Roos et al., 2023) could facilitate this. Research to standardise and validate the scale for clinical populations and caregivers (such as in T1D) would support this objective. Future research such as that outlined above, would offer novel perspectives and additional insights that would deliver a more comprehensive and nuanced understanding of nocturnal caregiving in T1D and support the continued advancement of knowledge in this field and the development of more effective and acceptable

interventions. Critically, future research should strive to embed meaningful PPI methodologies at all stages of the research process to guarantee the delivery of relevant and pertinent insights.

11.7 Conclusion

This research makes a meaningful contribution by placing the caregiver/patient dyad at the centre of the research process to capture the subtle and nuanced aspects of their lived experience and focus the research on issues that are related to real-life challenges in areas that have been underserved by previous research and clinical guidance policy. Insights have been generated that address these challenges in an actionable way and will be of direct benefit to the population of interest.

The evidence presented in this dissertation suggests that caregiver burden from nocturnal caregiving in T1D is substantial. This burden presents with real-life impacts for caregivers that are considerable and may endure for years. Responding to this caregiver need for acknowledgement and support will have significant value for supporting individuals to manage what are often extremely challenging circumstances, reducing the probability of resultant secondary harms for caregivers, both psychological and physical as well as recognising their contribution to society. The findings from this series of studies will also contribute toward two of the ten ‘priorities for research in T1D’ published recently in the aforementioned study by Newman et al. (2024): number 4 identifying interventions to reduce T1D stress and burnout and number 7, identifying ways that clinicians can take into account the psychological and social aspects of T1D. Interventions to address this need will also provide indirect support for children and adolescents with T1D as research informs us that better health outcomes for children result from supported and empowered caregiver parents.

References

- Aalders, J., Hartman, E., Pouwer, F., Winterdijk, P., van Mil, E., Roeleveld-Versteegh, A., ... & Nefs, G. (2021). The division and transfer of care responsibilities in paediatric type 1 diabetes: A qualitative study on parental perspectives. *Journal of advanced nursing*, 77(4), 1968-1979. <https://doi.org/10.1111/jan.14781>
- Aalders, J., Pouwer, F., Hartman, E., & Nefs, G. (2025). A conceptual model for understanding the division and transfer of diabetes care responsibilities between parents and children with type 1 diabetes. *Healthcare*, 13(10), 11431143. <https://doi.org/10.3390/healthcare13101143>
- Abitbol, L., & Palmert MR. (2021). When Low Blood Sugars Cause High Anxiety: Fear of Hypoglycemia Among Parents of Youth With Type 1 Diabetes Mellitus. *Canadian Journal of Diabetes* 45(5):403-403. <https://doi.org/10.1016/j.jcjd.2020.08.098>
- Abraham, M. B., Jones, T. W., Naranjo, D., Karges, B., Oduwole, A., Tauschmann, M., & Maahs, D. M. (2018). Chapter 12: Assessment and management of hypoglycemia in children and adolescents with diabetes. In: *ISPAD Clinical Practice Consensus Guidelines 2018: Compendium of Guidelines*. *Pediatric Diabetes*, 19(Suppl. 27), 178–192. <https://doi.org/10.1111/pedi.12737>
- Addala, A., Auzanneau, M., Miller, K., Maier, W., Foster, N., Kapellen, T., ... & Holl, R. W. (2021). A decade of disparities in diabetes technology use and HbA1c in pediatric type 1 diabetes: a transatlantic comparison. *Diabetes Care*, 44(1), 133-140. <https://doi.org/10.2337/dc20-0257>
- Addala, A., Amedari, M. I., Figg, L. E., & Ebekozién, O. (2025). Disparities in access to and use of diabetes technologies and therapeutics: a narrative review. *Diabetologia*, 68(11), 2430-2448. <https://doi.org/10.1007/s00125-025-06494-4>
- Aguilar-Gaxiola, S., Ahmed, S. M., Anise, A., Azzahir, A., Baker, K. E., Cupito, A., Eder, M., Everette, T. D., Erwin, K., Felzien, M., Freeman, E., Gibbs, D., Greene-Moton, E., Hernández-Cancio, S., Hwang, A., Jones, F., Jones, G., Jones, M., Khodyakov, D., Michener, J. L., Milstein, B., Oto-Kent, D. S., Orban, M., Pusch, B., Shah, M., Shaw, M., Tarrant, J., Wallerstein, N., Westfall, J. M., Williams, A., & Zaldivar, R. (2022). Assessing meaningful community engagement: A conceptual model to advance health equity through transformed systems for health. *NAM Perspectives*, 22(2). <https://doi.org/10.31478/202202c>
- Akram, U., Irvine, K., Allen, S. F., Stevenson, J. C., Ellis, J. G., & Drabble, J. (2021). Internet memes related to the COVID-19 pandemic as a potential coping mechanism for anxiety. *Scientific Reports*, 11, 22305. <https://doi.org/10.1038/s41598-021-00857-8>
- Akre, C., & Suris, J.-C. (2014). From controlling to letting go: What are the psychosocial needs of parents of adolescents with a chronic illness? *Health Education Research*, 29(5), 764–772. <https://doi.org/10.1093/her/cyu040>
- Alase, A. (2017). The interpretative phenomenological analysis (IPA): A guide to a good qualitative research approach. *International journal of education and literacy studies*, 5(2), 9-19. <https://doi.org/eric.ed.gov/?id=EJ1149107>

- Allemang, B., Sitter, K., & Dimitropoulos, G. (2022). Pragmatism as a paradigm for patient-oriented research. *Health Expectations*, 25(1), 38-47. <https://doi.org/10.1111/hex.13384>.
- Amburgey, D., O'Donnell, H., Gomer, T., Reznick-Lipina, T., Majidi, S., Driscoll, K. (2020). Assessment of Fear of Hypoglycemia in a large, clinical sample of fathers of children with Type 1 Diabetes. *Diabetes*, 69 (Suppl. 1): 2251. <https://doi.org/10.2337/db20-2251-PUB>
- American Diabetes Association. (2014). Diagnosis and classification of diabetes mellitus. *Diabetes Care*, 37 Suppl 1, S81-90. <https://doi.org/10.2337/dc14-S081>
- American Diabetes Association. (2018). Children and adolescents: standards of medical care in diabetes – 2018. *Diabetes Care* 41:S126-S136. <https://doi.org/10.2337/dc18-S012>
- American Diabetes Association Professional Practice Committee. (2025). Diagnosis and classification of diabetes. In *Standards of Care in Diabetes—2025* (2025;48 Suppl. 1, S27–S49). *Diabetes Care*. <https://doi.org/10.2337/dc25-S002>
- Amiel, S. A. (2021). The consequences of hypoglycaemia. *Diabetologia*, 64(5), 963-970. <https://doi.org/10.1007/s00125-020-05366-3>
- Amiri, F., Vafa, M., Gonder-Frederick, L., Vajda, K., Khamseh, M., Abadi, A., & Salehpour, A. (2018). Evaluating fear of hypoglycemia, pediatric parenting stress, and self-efficacy among parents of children with type 1 diabetes and their correlation with glycemic control. *Medical journal of the Islamic Republic of Iran*, 32, 119. <https://doi.org/10.14196/mjiri.32.119>
- Ancoli-Israel, S., Cole, R., Alessi, C., Chambers, M., Moorcroft, W., & Pollak, C. P. (2003). The role of actigraphy in the study of sleep and circadian rhythms. *Sleep*, 26(3), 342–392. <https://doi.org/10.1093/sleep/26.3.342>
- Andersson, N. (2018). Participatory research—A modernizing science for primary health care. *Journal of general and family medicine*, 19(5), 154-159. <https://doi.org/10.1002/jgf2.187>
- Andreopoulou, O., Kostopoulou, E., Kotanidou, E., Daskalaki, S., Vakka, A., Galli-Tsinopoulou, A., & Spiliotis, B. E. (2024). Evaluation of the possible impact of the fear of hypoglycemia on diabetes management in children and adolescents with type 1 diabetes mellitus and their parents: A cross-sectional study. *Hormones*, 23(3), 419–428. <https://doi.org/10.1007/s42000-024-00560-z>
- Andress, L., Hall, T., Davis, S., Levine, J., Cripps, K., & Guinn, D. (2020). Addressing power dynamics in community-engaged research partnerships. *Journal of Patient-Reported Outcomes*, 4(1), 24. <https://doi.org/10.1186/s41687-020-00191-z>
- Aouchiche, K., Bernoux, D., Sadoul, E. B., Haine, E., Joubert, F., Epstein, S., ... & Reynaud, R. (2024). Impact of continuous glucose monitoring on everyday life of young children with type 1 diabetes and their parents: An evaluation of 114 families. *Primary Care Diabetes*, 18(1), 91-96. <https://doi.org/10.1016/j.pcd.2023.11.002>
- Arnstein, L., Wadsworth, A. C., Yamamoto, B. A., Boswell, S., & Cross, W. (2020). Patient involvement in preparing health research peer-reviewed publications or results summaries:

A systematic review and evidence-based recommendations. *Research Involvement and Engagement*, 6, 34. <https://doi.org/10.1186/s40900-020-00190-w>

- Arumugam, A., Phillips, L. R., Moore, A., Kumaran, S. D., Sampath, K. K., Migliorini, F., Maffulli, N., Ranganadhababu, B. N., Hegazy, F., Botto-van Bemden, A. (2023). Patient and public involvement in research: a review of practical resources for young investigators. *BMC Rheumatol* 9;7(1):2. <https://doi.org/10.1186/s41927-023-00327-w>.
- Assarroudi, A., Heshmati Nabavi, F., Armat, M. R., Ebadi, A., & Vaismoradi, M. (2018). Directed qualitative content analysis: the description and elaboration of its underpinning methods and data analysis process. *Journal of research in nursing*, 23(1), 42-55. <https://doi.org/10.1177/1744987117741667>
- Azimi, T., Johnson, J., Campbell, S. M., & Montesanti, S. (2024). Caregiver burden among parents of children with type 1 diabetes: A qualitative scoping review. *Heliyon*, 10(6). <https://doi.org/10.1016/j.heliyon.2024.e27539>
- Bahadur, E. I., Özalkak, Ş., Özdemir, A. A., Çetinkaya, S., & Özmert, E. N. (2022). Sleep disorder and behavior problems in children with type 1 diabetes mellitus. *Journal of Pediatric Endocrinology and Metabolism*, 35(1):29-38. <https://doi.org/10.1515/jpem-2021-0523>
- Barnard, K., James, J., Kerr, D., Adolfsson, P., Runion, A., & Serbedzija, G. (2016). Impact of chronic sleep disturbance for people living with T1 diabetes. *Journal of diabetes science and technology*, 10(3), 762-767. <https://doi.org/10.1177/1932296815619181>
- Barnard, K., Thomas, S., Royle, P., Noyes, K., & Waugh, N. (2010). Fear of hypoglycaemia in parents of young children with type 1 diabetes: a systematic review. *BMC pediatrics*, 10, 1-8. <https://doi.org/10.1186/1471-2431-10-50>
- Bassi, G., Mancinelli, E., Di Riso, D., & Salcuni, S. (2021). Parental stress, anxiety and depression symptoms associated with self-efficacy in paediatric type 1 diabetes: a literature review. *International journal of environmental research and public health*, 18(1), 152. <https://doi.org/10.3390/ijerph18010152>
- Battelino, T., Danne, T., Bergenstal, R. M., Amiel, S. A., Beck, R., Biester, T., ... Phillip, M. (2019). Clinical targets for continuous glucose monitoring data interpretation: Recommendations from the International Consensus on Time in Range. *Diabetes Care*, 42(8), 1593–1603. <https://doi.org/10.2337/dci19-0028>
- Bauman, A. E., Sallis, J. F., Dzewaltowski, D. A., & Owen, N. (2002). Toward a better understanding of the influences on physical activity: the role of determinants, correlates, causal variables, mediators, moderators, and confounders. *American journal of preventive medicine*, 23(2), 5-14. [https://doi.org/10.1016/S0749-3797\(02\)00469-5](https://doi.org/10.1016/S0749-3797(02)00469-5)
- Baysal, Ş. G., & Çorabay, S. (2024). Caregiver burden and depression in parents of children with chronic diseases. *Turkish Archives of Pediatrics*, 59(1), 70. <https://doi.org/10.5152/TurkArchPediatri.2024.23126>
- Bebu, I., Braffett, B. H., Schade, D., Sivitz, W., Malone, J. I., Pop-Busui, R., ... & Lachin, J. M. (2020). An observational study of the equivalence of age and duration of diabetes to glycemic control relative to the risk of complications in the combined cohorts of the DCCT/EDIC study. *Diabetes care*, 43(10), 2478-2484. <https://doi.org/10.2337/dc20-0226>

- Becqué, Y. N., Rietjens, J. A., van der Heide, A., & Witkamp, E. (2021). How nurses support family caregivers in the complex context of end-of-life home care: a qualitative study. *BMC palliative care*, 20(1), 162. <https://doi.org/10.1186/s12904-021-00854-8>
- Bekele, B. T., Demie, T. G., & Worku, F. (2022). Health-related quality-of-Life and associated factors among children and adolescents with type 1 diabetes mellitus: A cross-sectional study. *Pediatric health, medicine and therapeutics*, 243-256. <https://doi.org/10.2147/PHMT.S364454>
- Benson, A., Rawdon, C., Tuohy, E., Murphy, N., McDonnell, C., Swallow, V., ... & Lambert, V. (2024). Relationship between parent–adolescent communication and parent involvement in adolescent Type 1 diabetes management, parent/family wellbeing and glycaemic control. *Chronic illness*, 20(4), 669-683. <https://doi.org/10.1177/17423953231184423>
- Berger, A. M. (2007). Sleep/wake disturbances in people with cancer and their caregivers: State of the science. *Number 6/2005*, 32(6). <https://doi.org/10.1188/05.ONF.E98-E126>
- Bergner, E.M., Williams, R., Hamburger, E.R., Lyttle, M., Davis, A. C., Malow, B., Simmons, J. H., Lybarger, C., Capin, R., & Jaser, S. S. (2018). Sleep in teens with type 1 diabetes: perspectives from adolescents and their caregivers. *The Diabetes Educator*, 44(6):541-548. <https://doi.org/10.1177/0145721718799086>
- Biggane, A. M., Olsen, M., & Williamson, P. R. (2019). PPI in research: a reflection from early stage researchers. *Research Involvement and Engagement*, 5(1), 35. <https://doi.org/10.1186/s40900-019-0170-2>
- Biggerstaff, D., & Thompson, A. R. (2008). Interpretative phenomenological analysis (IPA): A qualitative methodology of choice in healthcare research. *Qualitative research in psychology*, 5(3), 214-224. <https://doi.org/10.1080/14780880802314304>
- Bilgehan, T., & Uludaşdemir, D. (2024). Insomnia severity among caregivers of children with type 1 diabetes: A mixed method study. *Journal of Pediatric Nursing*, 77, e375-e384. <https://doi.org/10.1016/j.pedn.2024.04.054>
- Bird, J. (2022). Arts-Based Research as a Radical Methodology Within Healthcare. In K. Hinsliff-Smith, J. McGarry & P. Ali (Eds.), *Arts Based Health Care Research: A Multidisciplinary Perspective* (pp. 1–14). Springer. https://doi.org/10.1007/978-3-030-94423-0_1
- Bisio, A., Brown, S. A., McFadden, R., Pajewski, M., Yu P. L., DeBoer, M., Schoelwer, M. J., Bonner, H. G., Wakeman, C. A., Cherňavsky, D. R., & Gonder-Frederick, L. (2021). Sleep and diabetes-specific psycho-behavioral outcomes of a new automated insulin delivery system in young children with type 1 diabetes and their parents. *Pediatric Diabetes*, 22(3):495-502. <https://doi.org/10.1111/pedi.13164>
- Bisio, A., Gonder-Frederick, L., McFadden, R., Cherňavsky, D., Voelmle, M., Pajewski, M., ... & Brown, S. A. (2022). The impact of a recently approved automated insulin delivery system on glycemic, sleep, and psychosocial outcomes in older adults with type 1 diabetes: a pilot study. *Journal of diabetes science and technology*, 16(3), 663-669. <https://doi.org/10.1002/1d0o.1017g/71/01.19137272/1996382290698260897869879>

- Bispham, J. A., Hughes, A. S., Fan, L., Perez-Nieves, M., & McAuliffe-Fogarty, A. H. (2021). 'I've Had an Alarm Set for 3:00 a.m. for Decades': The Impact of Type 1 Diabetes on Sleep. *Clinical Diabetes*, 39(2):153-159. <https://doi.org/10.2337/cd20-0026>
- Bivins, R., Tierney, S., & Seers, K. (2017). Compassionate care: not easy, not free, not only nurses. *BMJ Qual Saf*: 1023-1026. <https://doi.org/10.1136/bmjqs-2017-007005>
- Black, J. E., Morrison, K., Urquhart, J., Potter, C., Courtney, P., & Goodenough, A. (2023). Bringing the arts into socio-ecological research: An analysis of the barriers and opportunities to collaboration across the divide. *People and Nature*, 5(4), 1135-1146. <https://doi.org/10.1002/pan3.10489>
- Blackburn, S., McLachlan, S., Jowett, S., Kinghorn, P., Gill, P., Higginbottom, A., ... & Jinks, C. (2018). The extent, quality and impact of patient and public involvement in primary care research: a mixed methods study. *Research involvement and engagement*, 4(1), 16. <https://doi.org/10.1186/s40900-018-0100-8>.
- Bochner, A. P., & Ellis, C. (2016). *Evocative Autoethnography: Writing Lives and Telling Stories* (1st ed.). Routledge. <https://doi.org/10.4324/9781315545417>
- Bombaci, B., Torre, A., Longo, A., Pecoraro, M., Papa, M., Sorrenti, L., ... & Salzano, G. (2024). Psychological and clinical challenges in the management of type 1 diabetes during adolescence: a narrative review. *Children*, 11(9), 1085. <https://doi.org/10.3390/children11091085>
- Bourke, L. (2009). Reflections on doing participatory research in health: Participation, method and power. *International Journal of Social Research Methodology*, 12(5), 457-474. <https://doi.org/10.1080/13645570802373676>
- Bowen, A. E., Holtman, S., Reich, J., & Simon, S. L. (2024). Supporting healthy sleep: A qualitative assessment of adolescents with type 1 diabetes and their parents. *Journal of Pediatric Psychology*, 49(11), 781–788. <https://doi.org/10.1093/jpepsy/jsae055>
- Boydell, K., Gladstone, B. M., Volpe, T., Allemang, B., & Stasiulis, E. (2012, January). The production and dissemination of knowledge: A scoping review of arts-based health research. In *Forum qualitative: Qualitative social research*, 13(1) 32. [http://nbnresolving.de/urn:nbn:de:0114-fqs1201327\(1\)](http://nbnresolving.de/urn:nbn:de:0114-fqs1201327(1))
- Bradshaw, J., Siddiqui, N., Greenfield, D., & Sharma, A. (2022). Kindness, listening, and connection: patient and clinician key requirements for emotional support in chronic and complex care. *Journal of Patient Experience*, 9, 23743735221092627. <https://doi.org/10.1177/23743735221092627>.
- Braun, V., & Clarke, V. (2006). Using thematic analysis in psychology. *Qualitative research in psychology*, 3(2), 77-101. <https://doi.org/10.1191/1478088706qp063oa>
- Braun, V., Clarke, V., Hayfield, N., Davey, L., & Jenkinson, E. (2023). Doing reflexive thematic analysis. In *Supporting research in counselling and psychotherapy: Qualitative, quantitative, and mixed methods research* (pp. 19-38). Cham: Springer International Publishing.

- Brett, J., Staniszevska, S., Mockford, C., Herron-Marx, S., Hughes, J., Tysall, C., & Suleman, R. (2014). Mapping the impact of patient and public involvement on health and social care research: A systematic review. *Health Expectations*, 17(5), 637–650. <https://doi.org/10.1111/j.1369-7625.2012.00795.x>
- Brierley, J. A. (2017). The role of a pragmatist paradigm when adopting mixed methods in behavioural accounting research. *International Journal of Behavioural Accounting and Finance*, 6(2), 140-154. <https://doi.org/10.1504/IJBAF.2017.10007499>
- Brinkmann, S., Jacobsen, M. H., & Kristiansen, S. (2014). Historical overview of qualitative research in the social sciences. *The Oxford handbook of qualitative research*, 17-42. <https://doi.org/10.1093/oxfordhb/9780199811755.013.017>
- Brown, A. (2022). *42 Factors that affect blood glucose, a surprising update!* Diatribe.org. <https://diatribe.org/diabetes-management/42-factors-affect-blood-glucose-surprising-update>
- Buchberger, B., Huppertz, H., Krabbe, L., Lux, B., Mattivi, J. T., Siafarikas, A. (2016). Symptoms of depression and anxiety in youth with type 1 diabetes: a systematic review and meta-analysis. *Psychoneuroendocrinology* 70, 8. <https://doi.org/10.1016/j.psyneuen.2016.04.019>
- Burckhardt, M. A., Abraham, M. B., Mountain, J., Coenen, D., Paniora, J., Clapin, H., Jones, T. W., & Davis, E.A. (2019). Improvement in psychosocial outcomes in children with type 1 diabetes and their parents following subsidy for continuous glucose monitoring. *Diabetes Technology and Therapeutics*, 21(10):538-545. <https://doi.org/10.1089/dia.2019.0149>
- Burckhardt, M. A., Roberts, A., Smith, G. J., Abraham, M. B., Davis, E. A., & Jones, T. W. (2018). The use of continuous glucose monitoring with remote monitoring improves psychosocial measures in parents of children with type 1 diabetes: A randomized crossover trial. *Diabetes Care*, 41(12):2641-2643. <https://doi.org/10.2337/dc18-0938>
- Burns, M., Bally, J., Burles, M., Holtslander, L., & Peacock, S. (2022). Constructivist Grounded Theory or Interpretive Phenomenology? Methodological Choices Within Specific Study Contexts. *International Journal of Qualitative Methods*, 21. <https://doi.org/10.1177/16094069221077758>
- Butalia, S., McGuire, K. A., Dyjur, D., Mercer, J., & Pacaud, D. (2020). Youth with diabetes and their parents' perspectives on transition care from pediatric to adult diabetes care services: A qualitative study. *Health science reports*, 3(3), e181. <https://doi.org/10.1002/hsr2.181>
- Buysse, D. J., Reynolds III, C. F., Monk, T. H., Berman, S. R., & Kupfer, D. J. (1989). The Pittsburgh Sleep Quality Index: a new instrument for psychiatric practice and research. *Psychiatry research*, 28(2):193-213. [https://doi.org/10.1016/0165-1781\(89\)90047-4](https://doi.org/10.1016/0165-1781(89)90047-4)
- Byrne, D. (2022). A worked example of Braun and Clarke's approach to reflexive thematic analysis. *Quality & quantity*, 56(3), 1391-1412. <https://doi.org/10.1007/s11135-021-01182-y>
- Bytheway, B. (2011). Researching age. In *Unmasking age* (pp. 23-50). Policy Press.

- Carcone, A. I., Ellis, D. A., Naar-King, S. (2012). Linking caregiver strain to diabetes illness management and health outcomes in a sample of adolescents in chronically poor metabolic control. *J Dev Behav Pediatrics*, 33(4):343-51. <https://doi.org/10.1097/DBP.0b013e31824eaac8>
- Cargo, M., & Mercer, S. L. (2008). The value and challenges of participatory research: strengthening its practice. *Annu. Rev. Public Health*, 29(1), 325-350. <https://doi.org/10.1146/annurev.publhealth.29.091307.083824>
- Carreon, S. A., Cao, V. T., Anderson, B. J., Thompson, D. I., Marrero, D. G., & Hilliard, M. E. (2021). 'I don't sleep through the night': Qualitative study of sleep in type 1 diabetes. *Diabetic medicine: a journal of the British Diabetic Association*, e14763. <https://doi.org/10.1111/dme.14763>
- Charleer, S., Mathieu, C., Nobels, F., De Block, C., Radermecker, R. P., Hermans, M. P., ... RESCUE Trial Investigators. (2018). Effect of continuous glucose monitoring on glycemic control, acute admissions, and quality of life: A real-world study. *The Journal of Clinical Endocrinology & Metabolism*, 103(3), 1224–1232. <https://doi.org/10.1210/jc.2017-02498>
- Chehregosha, H., Khamseh, M. E., Malek, M., Hosseinpanah, F., & Ismail-Beigi, F. (2019). A view beyond HbA1c: role of continuous glucose monitoring. *Diabetes Therapy*, 10(3), 853-863. <https://doi.org/10.1007/s13300-019-0619-1>
- Cherubini, V., Rabbone, I., Lombardo, F., Mossetto, G., Orsini Federici, M., & Nicolucci, A. (2019). Incidence of severe hypoglycemia and possible associated factors in pediatric patients with type 1 diabetes in the real-life, post-Diabetes Control and Complications Trial setting: A systematic review. *Pediatric Diabetes*, 20(6), 678-692. <https://doi.org/10.1111/pedi.12876>
- Chetty, T., Shetty, V., Fournier, P. A., Adolfsson, P., Jones, T. W., & Davis, E. A. (2019). Exercise management for young people with type 1 diabetes: a structured approach to the exercise consultation. *Frontiers in endocrinology*, 10, 326. <https://doi.org/10.3389/fendo.2019.00326>
- Children's health Ireland. (2019). <https://media.childrenshealthireland.ie/documents/Diabetes-HbA1c.pdf>
- Chivers, S. (2005). Julia Johnson (ed.), Writing Old Age, Centre for Policy on Ageing, *Ageing & Society*, 25(1), 138-140. <https://doi.org/10.1017/S0144686X04212909>
- Choudhary, P., & Amiel, S. A. (2018). Hypoglycaemia in type 1 diabetes: technological treatments, their limitations and the place of psychology. *Diabetologia*, 61(4), 761-769. <https://doi.org/10.1007/s00125-018-4566-6>
- Chowdhury, S. (2015). Puberty and type 1 diabetes. *Indian journal of endocrinology and metabolism*, 19(Suppl 1), S51-S54. <https://doi.org/10.4103/2230-8210.155402>
- Clarke, W. L., Gonder-Frederick, L. A., Snyder, A. L., & Cox, D. J. (1998). Maternal fear of hypoglycemia in their children with insulin dependent diabetes mellitus. *Journal of Pediatric Endocrinology & Metabolism*, 11. <https://doi.org/10.1515/JPEM.1998.11.S1.189>

- Cobry, E. C., Bisio, A., Wadwa, R. P., & Breton, M. D. (2022). Improvements in parental sleep, fear of hypoglycemia, and diabetes distress with use of an advanced hybrid closed-loop system. *Diabetes care*, 45(5), 1292-1295. <https://doi.org/10.2337/dc21-1778>
- Cobry, E. C., Hamburger, E., Jaser, S. S. (2020). Impact of the Hybrid Closed-Loop System on Sleep and Quality of Life in Youth with Type 1 Diabetes and Their Parents. *Diabetes Technology & Therapeutics*, 22(11):794-800. <https://doi.org/10.1089/dia.2020.0057>
- Cobry, E. C., Kanapka, L. G., Cengiz, E., Carria, L., Ekhlaspour, L., Buckingham, B. A., Hood, K. K., Hsu, L. J., Messer, L. H., Schoelwer, M. J., & Emory, E. (2021). Health-Related Quality of Life and Treatment Satisfaction in Parents and Children with Type 1 Diabetes Using Closed-Loop Control. *Diabetes Technology & Therapeutics*, 23(6):401-409. <https://doi.org/10.1089/dia.2020.0532>
- Cobry, E. C., Karami, A. J., & Meltzer, L. J. (2022). Friend or Foe: A Narrative Review of the Impact of Diabetes Technology on Sleep. *Current Diabetes Reports*, 1-8. <https://doi.org/10.1007/s11892-022-01468-x>
- Cole, A. L., & Knowles, J. G. (Eds.). (2008). *Handbook of the arts in qualitative research: Perspectives, methodologies, examples, and issues*. Sage Publications. <https://doi.org/10.4135/9781452226545>
- Commissariat, P. V., Harrington, K. R., Whitehouse, A. L., Miller, K. M., Hilliard, M. E., Van Name, M., ... & Laffel, L. M. (2020). "I'm essentially his pancreas": Parent perceptions of diabetes burden and opportunities to reduce burden in the care of children < 8 years old with type 1 diabetes. *Pediatric diabetes*, 21(2), 377-383. <https://doi.org/10.1111/pedi.12956>, 31808586.
- Cooke, A., Smith, D., & Booth, A. (2012). Beyond PICO: the SPIDER tool for qualitative evidence synthesis. *Qualitative health research*, 22(10):1435-1443. <https://doi.org/10.1177/1049732312452938>
- Cornish, F., & Gillespie, A. (2009). A pragmatist approach to the problem of knowledge in health psychology. *Journal of health psychology*, 14(6), 800-809. <https://doi.org/10.1177/1359105309338974>
- Cornwall, A., & Jewkes, R. (1995). What is participatory research? *Social Science & Medicine*, 41(12), 1667–1676. [https://doi.org/10.1016/0277-9536\(95\)00127-S](https://doi.org/10.1016/0277-9536(95)00127-S)
- Cox, D. J., Irvine A, Gonder-Frederick, L., Nowacek, G., Butterfield, J. (1987). Fear of hypoglycemia: Quantification, validation, and utilization. *Diabetes Care*, 10, 617–621. <https://doi.org/10.2337/diacare.10.5.617>
- Cox, L., & Hunt, J. (2015). Factors that affect adolescents' adherence to diabetes treatment. *Nurs Child Young People*, 27(1), 16-21. <https://doi.org/10.7748/ncyp.27.1.16.e565>
- CSO.ie. (2023a). *Census 2022 – profile 8: The Irish language and education*. <https://www.cso.ie/en/releasesandpublications/ep/p-cpp8/census2022profile8-theirishlanguageandeducation/levelofeducation/>
- CSO.ie. (2023b). *Census of population 2022, summary results: Health, disability, caring and volunteering*. <https://www.cso.ie/en/releasesandpublications/ep/p->

cpsr/censusofpopulation2022summaryresults/healthdisabilitycaringandvolunteering/#:~:tex
t=The%20percentage%20of%20people%20reporting,good%20to%20less%20good%20hea
lth.

CSO.ie. (2024). *Census of Population 2022 - Summary Results. Education and Irish Language*.
[https://www.cso.ie/en/releasesandpublications/ep/p-cpsr/censusofpopulation2022-
summaryresults/educationandirishlanguage/](https://www.cso.ie/en/releasesandpublications/ep/p-cpsr/censusofpopulation2022-summaryresults/educationandirishlanguage/)

Culhane, F., Cheung, V., & Austen, M. (2024). Enabling interdisciplinary research capacity for
sustainable development: self-evaluation of the Blue Communities project in the UK and
Southeast Asia. *UCL Open Environment*, 6, e1970.
<https://doi.org/10.14324/111.444/ucloe.1970>.

D1now.ie. (2025). *D1 Now young adult panel*. <https://d1now.ie/pages/young-adult-panel>

Danne, T., Bangstad, H. J., Deeb, L., Jarosz-Chobot, P., Mungaie, L., Saboo, B., . . . Hanas, R.
(2014). ISPAD Clinical Practice Consensus Guidelines 2014. Insulin treatment in children
and adolescents with diabetes. *Pediatr Diabetes*, 15 Suppl 20, 115-134.
<https://doi.org/10.1111/pedi.12184>

Dean, L., & McEntyre, J. (2004). Introduction to diabetes. In *The Genetic Landscape of Diabetes
[Internet]*. National Center for Biotechnology Information (US).
https://www.ncbi.nlm.nih.gov/books/NBK1671/?utm_source=chatgpt.com

De Beaufort, C., Pit-ten C. I. M., Schierloh, U., Cohen, N., Boughton, C. K., Tauschmann, M.,
Allen, J. M., Nagl, K., Fritsch, M., Yong, J., & Metcalfe, E., (2021). Psychological well-
being of parents of very young children with type 1 diabetes - baseline assessment.
Frontiers in Endocrinology, 12:721028. <https://doi.org/10.3389/fendo.2021.721028>

De Costa, P., Grabowski, D., & Skinner, T. C. (2020). The psychosocial experience and needs of
children newly diagnosed with type 1 diabetes from their own perspective: a systematic
and narrative review. *Diabetic Medicine*, 37(10), 1640-1652.
<https://doi.org/10.1111/dme.14354>

Denzin, N. K., & Lincoln, Y. S. (Eds.). (2011). The elephant in the living room: or extending the
conversation about the politics of evidence. *Qualitative research*, 9(2), 139-160.
<https://doi.org/10.1177/1468794108098034>

Department of Health (Ireland) & Ipsos MRBI. (2021). Healthy Ireland Survey 2021 Summary
Report. Retrieved from <https://hdl.handle.net/10147/630778>

De Wit, M., Gajewska, K. A., Goethals, E. R., McDarby, V., Zhao, X., Hapunda, G., ... &
DiMeglio, L. A. (2022). ISPAD clinical practice consensus guidelines 2022: psychological
care of children, adolescents and young adults with diabetes. *Pediatric diabetes*, 23(8),
1373. <https://doi.org/10.1111/pedi.13428>

Dhatariya, K., Mustafa, O., & Stathi, D. (2025). Hyperglycemic crises. In K. R. Feingold, S. F.
Ahmed, B. Anawalt, et al. (Eds.), *Endotext*. MDText.com, Inc.
https://www.ncbi.nlm.nih.gov/books/NBK279052/?utm_source=chatgpt.com

Diabetes Control and Complications Trial Research Group. (1993). The effect of intensive
treatment of diabetes on the development and progression of long-term complications in

- insulin-dependent diabetes mellitus. *The New England Journal of Medicine*, 329(14):977-986. <https://www.nejm.org/doi/full/10.1056/NEJM19930930303291401>
- Diabetes.ie. (2023). *Living with diabetes in Ireland: Findings from a survey on experiencing, accessing and using diabetic services by people with diabetes*. <https://www.diabetes.ie/wp-content/uploads/2023/09/Diabetes-Ireland-Survey-on-Access-and-Uptake-of-Diabetes-Services-2023-FINAL-1.pdf>
- Diabetes.ie. (2024, November 26). *Diabetes Ireland: HbA1c Targets for Children are Changing*. <https://www.diabetes.ie/hba1c-targets-children-changing/>
- Diabetes.org.uk. (2024, November 26). *Chapter 4 – Fear of Hypoglycaemia [and other Diabetes specific fears]*. <https://www.diabetes.org.uk/professionals/resources/shared-practice/psychological-care/emotional-health-professionals-guide/chapter-4-fear-hypos>
- Dicembrini, I., Cosentino, C., Monami, M., Mannucci, E., & Pala, L. (2021). Effects of real-time continuous glucose monitoring in type 1 diabetes: a meta-analysis of randomized controlled trials. *Acta diabetologica*, 58(4), 401-410. <https://doi.org/10.1007/s00592-020-01589-3>
- Dockery, L. A., McCaffrey, A., Connolly, M., Neylon, O. M., & O'Gorman, C. (2023). Adolescents with type 1 diabetes and the paediatrics diabetes clinic. <https://creativecommons.org/licenses/by-nc-sa/4.0/>
- Driscoll, K. A., Raymond, J., Naranjo, D., Patton, S. R. (2016). Fear of Hypoglycemia in Children and Adolescents and Their Parents with Type 1 Diabetes. *Curr Diab Rep*, 16(8), 77. <https://doi.org/10.1007/s11892-016-0762-2>.
- Dudovskiy, J. (2016). The ultimate guide to writing a dissertation in business studies: A step-by-step assistance. *eBook Journal of Mixed Methods Research* 4(1), 6–16. <https://static1.squarespace.com/static/5530dddf4b0679504639dc1/t/65f9bbd052269a478741e89c/1710865372066/The+Ultimate+Guide+to+Writing+a+Dissertation.pdf>.PDF
- Elbalshy, M., Boucher, S., Crocket, H., Galland, B., MacKenzie, C., De Bock, M. I., Jefferies, C., Wiltshire, E. & Wheeler, B. J. (2020). Exploring Parental Experiences of Using a Do-It-Yourself Solution for Continuous Glucose Monitoring Among Children and Adolescents with Type 1 Diabetes: A Qualitative Study. *Journal of Diabetes Science and Technology*, 14(5):844-853. <https://doi.org/10.1177/1932296819895290>
- Elliott, R., & Timulak, L. (2005). Descriptive and interpretive approaches to qualitative research. *A handbook of research methods for clinical and health psychology*, 1(7), 147-159. <https://d1wqtxts1xzle7.cloudfront.net/42208125/interpretive-libre.pdf>
- Erlingsson, C., & Brysiewicz, P. (2017). A hands-on guide to doing content analysis. *African journal of emergency medicine*, 7(3), 93-99. <https://doi.org/10.1016/j.afjem.2017.08.001>
- Faul, F., Erdfelder, E., Lang, A., & Buchner, A. (2007). G*Power 3: A flexible statistical power analysis program for the social, behavioral, and biomedical sciences. *Behavior Research Methods*, 39(2), 175–191. <https://doi.org/10.3758/BF03193146>

- Faul, F., Erdfelder, E., Buchner, A., & Lang, A.-G. (2009). Statistical power analyses using GPower 3.1: Tests for correlation and regression analyses. *Behavior Research Methods*, 41(4), 1149–1160. <https://doi.org/10.3758/BRM.41.4.1149>
- Feeley, C. A., Clougherty, M., Siminerio, L., Charron-Prochownik, D., Allende, A. L., & Chasens, E. R. (2019). Sleep in Caregivers of Children With Type 1 Diabetes. *Diabetes Educator*, 45(1):80-86. <https://doi.org/10.1177/0145721718812484>
- Feeley, C. A., Sereika, S. M., Chasens, E. R., Siminerio, L., Charron-Prochownik, D., Muzumdar, R. H., & Viswanathan, P. (2021). Sleep in Parental Caregivers and Children With Type 1 Diabetes. *Journal of School Nursing*, 37(4):259-269. <https://doi.org/10.1177/1059840519865942>
- Feilzer, Y., (2010). Doing Mixed Methods Research Pragmatically: Implications for the Rediscovery of Pragmatism as a Research Paradigm. *Journal of Mixed Methods Research*, vol. 4(1), 6-16. <https://doi.org/10.1177/1558689809349691>
- Fernando, A., & Patel, V. (2021). Fear of hypoglycaemia in paediatric diabetes: a literature review. *British Journal of Diabetes*, 21(1), 36-42. <https://doi.org/10.15277/bjd.2021.286>
- Fiest, K. M., McIntosh, C. J., Demianschuk, D., Leigh, J. P., & Stelfox, H. T. (2018). Translating evidence to patient care through caregivers: a systematic review of caregiver-mediated interventions. *BMC medicine*, 16(1), 105. <https://doi.org/10.1186/s12916-018-1097-4>
- Finlay, L. (2002) ‘Negotiating the swamp: the opportunity and challenge of reflexivity in research practice’. *Qualitative Research*, 2 (2), 209–230.
- Fisher, E., Lazar, L., Shalitin, S., Yackobovitch-Gavan, M., de Vries, L., Oron, T., ... & Lebenthal, Y. (2018). Association between glycemic control and clinic attendance in emerging adults with type 1 diabetes: a tertiary center experience. *Journal of Diabetes Research*, 2018(1), 9572817. <https://onlinelibrary.wiley.com/doi/pdf/10.1155/2018/9572817>
- Flynn, G. (2023, September 6). Blood sugar trampoline. *Insulin pump use in Ireland*. <https://bloodsugartrampoline.com/blog/2023/8/16/insulin-pump-use-in-ireland>
- Flynn, G. (2024). *Uptake of insulin pumps in the Type 1 Diabetes population in Ireland: An analysis from 2019 to 2023*. Thriveabetes.com. Retrieved from <https://nipc.ie/wp-content/uploads/2024/10/3.-uptake-of-insulin-pumps-in-the-type-1-diabetes-population-in-ireland-an-analysis-from-2019-to-2023.pdf>
- Forman, J., & Damschroder, L. (2007). Qualitative content analysis. In *Empirical methods for bioethics: A primer* (pp. 39-62). Emerald Group Publishing Limited.
- Fornasini, S., Miele, F., & Piras, E. M. (2020). The consequences of type 1 diabetes onset on family life. An integrative review. *Journal of Child and Family Studies*, 29(5), 1467-1483. https://arts.units.it/bitstream/11368/3040520/4/s10826-019-01544-z-Post_print.pdf
- Fortier, J. P., & Coulter, A. (2021). Creative cross-sectoral collaboration: a conceptual framework of factors influencing partnerships for arts, health and wellbeing. *Public health*, 196, 146-149. <https://doi.org/10.1016/j.puhe.2021.05.017>

- Foster, N. C., Beck, R. W., Miller, K. M., Clements, M. A., Rickels, M. R., DiMeglio, L. A., ... & T1D Exchange Clinic Network. (2019). State of type 1 diabetes management and outcomes from the T1D exchange in 2016–2018. *Diabetes technology & therapeutics*, 21(2), 66-72. <https://doi.org/10.1089/dia.2018.0384.correx>.
- Frank, A. W. (2005). What is dialogical research, and why should we do it? *Qualitative Health Research*, 15(7), 964–974. <https://doi.org/10.1177/1049732305279078>
- Frankish, C. J., R. Gold, L. W., Green, M. W., Kreuter, M. W., Kreuter, S., Mercer, D., Morisky, S., Nair, J., Ottoson, B., Poland, & I. Rootman. (1995). *Guidelines and Categories for Classifying Participatory Research Projects in Health*. <http://www.lgreen.net/guidelines.html> (accessed September 1, 2020).2
- Fraser, K.D., & al Sayah, F. (2011). Arts-based methods in health research: a systematic review of the literature. *Arts Health*, 3, 110145. <https://doi.org/10.1080/17533015.2011.561357>
- Fricker, M. (2007). *Epistemic injustice: Power and the ethics of knowing*. Oxford university press. <https://doi.org/10.1093/acprof:oso/9780198237907.001.0001>,
- Frier, B. M. (2008). How hypoglycaemia can affect the life of a person with diabetes. *Diabetes/metabolism research and reviews*, 24(2), 87-92. <https://doi.org/10.1002/dmrr.796>. PMID: 18088077.
- Fullerton, B., Jeitler, K., Seitz, M., Horvath, K., Berghold, A., & Siebenhofer, A. (2014). Intensive glucose control versus conventional glucose control for type 1 diabetes mellitus. *Cochrane Database of Systematic Reviews*, (2):CD009122. <https://doi.org/10.1002/14651858.CD009122.pub2>
- Gadallah, M. A., Ismail, T. A., & Aty, N. S. A. (2017). Health related quality of life among children with Type I diabetes, Assiut city, Egypt. *J Nurs Educ Pract*, 7(10), 73-82. <https://doi.org/10.5430/jnep.v7n10p73>
- Gagnum, V., Stene, L. C., Jenssen, T. G., Berteussen, L. M., Sandvik, L., Joner, G., ... & Skriverhaug, T. (2017). Causes of death in childhood-onset Type 1 diabetes: long-term follow-up. *Diabetic medicine*, 34(1), 56-63. <https://doi.org/10.1111/dme.13114>
- Gajewska, K. (2022, July 4). *Accessing Diabetes technology in Ireland*. Hospital Professional News Ireland. <https://hospitalprofessionalnews.ie/2022/07/04/accessing-diabetes-technology-in-ireland>
- Gajewska, K. A., Biesma, R., Bennett, K., & Sreenan, S. (2020). Availability of and access to continuous subcutaneous insulin infusion therapy for adults with type 1 diabetes in Ireland. *Acta diabetologica*, 57(7), 875-882. <https://doi.org/10.1007/s00592-020-01497-6>
- Gajewska, K. A., Biesma, R., Sreenan, S., & Bennett, K. (2020a). Prevalence and incidence of type 1 diabetes in Ireland: a retrospective cross-sectional study using a national pharmacy claims data from 2016. *BMJ open*, 10(4), e032916. <http://dx.doi.org/10.1136/bmjopen-2019-032916>.
- Gajewska, K.A., Bennett, K., Biesma, R., and Sreenan, S. (2020b) ‘Low uptake of continuous subcutaneous insulin infusion therapy in people with type 1 diabetes in Ireland: a

- retrospective cross-sectional study', *BMC endocrine disorders*, 20(1), 92–92.
<https://doi.org/10.1186/s12902-020-00573-w>.
- Gajewska, K. A., Biesma, R., Bennett, K., & Sreenan, S. (2021). Barriers and facilitators to accessing insulin pump therapy by adults with type 1 diabetes mellitus: a qualitative study. *Acta diabetologica*, 58(1), 93-105. <https://doi.org/10.1007/s00592-020-01595-5>
- Galicia-Garcia, U., Benito-Vicente, A., Jebari, S., Larrea-Sebal, A., Siddiqi, H., Uribe, K. B., ... & Martín, C. (2020). Pathophysiology of type 2 diabetes mellitus. *International journal of molecular sciences*, 21(17), 6275. <https://doi.org/10.3390/ijms21176275>
- Gardner, D., Tan, H. C., Lim, G. H., Zin Oo, M., Xin, X., Kingsworth, A., ... & Rama Chandran, S. (2025). Association of smartphone-based activity tracking and nocturnal hypoglycemia in people with type 1 diabetes. *Journal of Diabetes Science and Technology*, 19(2), 377-384. <https://doi.org/10.1177/19322968231186401>
- Geller, A. I., Shehab, N., Lovegrove, M. C., Kegler, S. R., Weidenbach, K. N., Ryan, G. J., & Budnitz, D. S. (2014). National estimates of insulin-related hypoglycemia and errors leading to emergency department visits and hospitalizations. *JAMA internal medicine*, 174(5), 678-686. <https://doi.org/10.1186/s12888-020-02571-7>
- Gjerløw, E. , Bjørgaas, M. R. , Nielsen, E. W. , Olsen, S. E. , & Asvold, B. O. (2014). Fear of hypoglycemia in women and men with type 1 diabetes. *Nursing Research*, 63(2), 143–149. <https://doi.org/10.1097/NNR.0000000000000020>
- Goldberg, A. E., & Allen, K. R. (2015). Communicating qualitative research: Some practical guideposts for scholars. *Journal of Marriage and Family*, 77(1), 3-22. <https://doi.org/10.1111/jomf.12153>
- Gomez-Lopera, N., Pineda-Trujillo, N., & Diaz-Valencia, P. A. (2019). Correlating the global increase in type 1 diabetes incidence across age groups with national economic prosperity: A systematic review. *World Journal of Diabetes*, 10(12), 560. <https://doi.org/10.4239/wjd.v10.i12.560>
- Gonder-Frederick, L., Nyer, M., Shepard, J. A., Vajda, K., Clarke, W. (2011). Assessing fear of hypoglycemia in children with type 1 diabetes and their parents. *Diabetes Management*, 1:627–639. <https://doi.org/10.2217/DMT.11.60>
- González-Vidal, T., Rivas-Otero, D., Agüeria-Cabal, P., Ramos-Ruiz, G., Lambert, C., Ares-Blanco, J., ... & Delgado, E. (2025). Post-hypoglycemic nocturnal hyperglycemia in type 1 diabetes: the Somogyi hypothesis revisited. *Hormones*, 1-11 <https://doi.org/10.1007/s42000-025-00680-0>
- Grace, S., O'Neill, M., Walker, T., King, H., & Baldwin, L. (Eds.). (2022). *Criminal women: Gender matters*. Bristol University Press. <https://doi.org/10.46692/9781529208443>
- Gray, R., Sinding, C., Ivonoffski, V., Fitch, M., Hampson, A., & Greenberg, M. (2000). The use of research-based theatre in a project related to metastatic breast cancer. *Health Expectations*, 3(2), 137–144. <https://doi.org/10.1046/j.1369-6513.2000.00071.x>
- Guettier, J. M., & Gorden, P. (2006). Hypoglycemia. *Endocrinology and Metabolism Clinics*, 35(4), 753-766. [https://www.endo.theclinics.com/article/S0889-8529\(06\)00068-5](https://www.endo.theclinics.com/article/S0889-8529(06)00068-5)

- Guo, J., Whittemore, R., & He, G. P. (2011). The relationship between diabetes self-management and metabolic control in youth with type 1 diabetes: an integrative review. *Journal of advanced nursing*, 67(11), 2294-2310. <https://doi.org/10.1111/j.1365-2648.2011.05697.x>
- Gupta, V., Eames, C., Golding, L., Greenhill, B., Qi, R., Allan, S., ... & Fisher, P. (2023). Understanding the identity of lived experience researchers and providers: a conceptual framework and systematic narrative review. *Research Involvement and Engagement*, 9(1), 26. <https://doi.org/10.1186/s40900-023-00439-0>
- Haller, M. J., Stalvey, M. S., & Silverstein, J. H. (2004). Predictors of control of diabetes: monitoring may be the key. *J Pediatr*, 144(5), 660-661. <https://doi.org/10.1016/j.jpeds.2003.12.042>
- Hanna, K. M., Weaver, M. T., Stump, T. E., Fortenberry, J. D., & DiMeglio, L. A. (2014). The relationship of worry about hypoglycemia with diabetes- specific and typical youth behavior among emerging adults with type 1 diabetes. *The Diabetes Educator*, 40(4), 533–542. <https://doi.org/10.1177/0145721714528997>
- Hannes, K. (2023). Tactics in support of the strategy to include artistic research as evidence in systematic reviews. *International Journal of Qualitative Methods*, 22. <https://doi.org/10.1177/16094069231176391>
- Hansen, N. H., Bjerrekær, L., Pallesen, K. J., Juul, L., & Fjorback, L. O. (2022). The effect of mental health interventions on psychological distress for informal caregivers of people with mental illness: A systematic review and meta-analysis. *Frontiers in psychiatry*, 13, 949066. <https://doi.org/10.3389/fpsy.2022.949066>
- Harrington, K. R., Boyle, C. T., Miller, K. M., Hilliard, M. E., Anderson, B. J., Van Name, M., DiMeglio, L. A., & Laffel, L. M. (2017). Management and family burdens endorsed by parents of youth <7 years old with type 1 diabetes. *Journal of Diabetes Science and Technology*, 11(5):980-987. <https://doi.org/10.1177/1932296817721938>
- Harrison, R., Jones, B., Gardner, P., & Lawton, R. (2021). Quality assessment with diverse studies (QuADS): an appraisal tool for methodological and reporting quality in systematic reviews of mixed-or multi-method studies. *BMC health services research*, 21(1):1-20. <https://doi.org/10.1186/s12913-021-06122-y>
- Hartz, A., Bentler, S., & Watson, D. (2003). Measuring fatigue severity in primary care patients. *Journal of psychosomatic research*, 54(6), 515-521. [https://doi.org/10.1016/S0022-3999\(02\)00600-1](https://doi.org/10.1016/S0022-3999(02)00600-1)
- Haugstvedt, A., Wentzel-Larsen, T., Rokne, B., & Graue, M. (2011). Perceived family burden and emotional distress: similarities and differences between mothers and fathers of children with type 1 diabetes in a population-based study. *Pediatric Diabetes*, 12(2):107-114. <https://doi.org/10.1111/j.1399-5448.2010.00661.x>
- Hawkes, C. P., & Murphy, N. P. (2014). Paediatric type 1 diabetes in Ireland results of the first national audit. <https://hdl.handle.net/10147/316148>
- Heinemann, L., Freckmann, G., Ehrmann, D., Faber-Heinemann, G., Guerra, S., Waldenmaier, D., & Hermanns, N. (2018). Real-time continuous glucose monitoring in adults with type 1

- diabetes and impaired hypoglycaemia awareness or severe hypoglycaemia treated with multiple daily insulin injections (HypoDE): a multicentre, randomised controlled trial. *The Lancet*, 391(10128), 1367-1377. [https://doi.org/10.1016/S0140-6736\(18\)30297-6](https://doi.org/10.1016/S0140-6736(18)30297-6)
- Herbert, L. J., Monaghan, M., Cogen, F., & Streisand, R. (2015). The impact of parents' sleep quality and hypoglycemia worry on diabetes self-efficacy. *Behav sleep medicine*, 13(4):308-323. <https://doi.org/10.1080/15402002.2014.898303>
- Herbert, L. J., Wall, K., Monaghan, M., & Streisand, R. (2017). Parent employment and school/daycare decisions among parents of young children with type 1 diabetes. *Children's Health Care*, 46(2), 170-180. <https://doi.org/10.1080/02739615.2015.1124776>
- Hirshkowitz, M., Whiton, K., Albert, S. M., Alessi, C., Bruni, O., DonCarlos, L., Hazen, N., Herman, J., Adams Hillard, P. J., Katz, E. S., Kheirandish-Gozal, L., Neubauer, D. N., O'Donnell, A. E., Ohayon, M., Peever, J., Rawding, R., Sachdeva, R. C., Setters, B., Vitiello, M. V., & Ware, J. C. (2015). National Sleep Foundation's updated sleep duration recommendations: final report. *Sleep health*, 1(4), 233–243. <https://doi.org/10.1016/j.sleh.2015.10.004>
- Hitt, T. A., Hershey, J. A., Olivos-Stewart, D., Forth, E., Stuart, F., Garren, P., ... Gettings, J. M. (2023). The impact of fear of hypoglycaemia on sleep in adolescents with type 1 diabetes. *Diabetic Medicine*, 40(5), e15066. <https://doi.org/10.1111/dme.15066>
- Holliman, R. (2017). Supporting excellence in engaged research. *Journal of Science Communication*, 16(5), 1-10. <https://oro.open.ac.uk/52439/1/52439.pdf>
- Holman, N., Woch, E., Dayan, C., Warner, J., Robinson, H., Young, B., & Elliott, J. (2023). National trends in hyperglycemia and diabetic ketoacidosis in children, adolescents, and young adults with type 1 diabetes: A challenge due to age or stage of development, or is new thinking about service provision needed? *Diabetes Care*, 46(7), 1404-1408. <https://doi.org/10.2337/dc23-0180>
- Holmes C.S., Chen R., Streisand R., Marschall D.E., Souter S., Swift E.E. & Peterson C.C. (2006). Predictors of youth diabetes care behaviors and metabolic control: a structural equation modeling approach. *Journal of Pediatric Psychology* 31(8), 770–784. <https://doi.org/10.1093/jpepsy/jsj083>
- Holt, R. I., DeVries, J. H., Hess-Fischl, A., Hirsch, I. B., Kirkman, M. S., Klupa, T., ... & Peters, A. L. (2021). The management of type 1 diabetes in adults. A consensus report by the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD). *Diabetes care*, 44(11), 2589-2625. <https://doi.org/10.2337/dci21-0043>
- Hormazábal-Aguayo, I., Ezzatvar, Y., Huerta-Uribe, N., Ramírez-Vélez, R., Izquierdo, M., & García-Hermoso, A. (2024). Incidence of type 1 diabetes mellitus in children and adolescents under 20 years of age across 55 countries from 2000 to 2022: A systematic review with meta-analysis. *Diabetes/Metabolism Research and Reviews*, 40(3), e3749. <https://doi.org/10.1002/dmrr.3749>
- Hou, G., Fang, Z., Cao, W., Shi, Y., Xu, X., Han, M., & Dong, J. (2021). Development and validation of a diabetes mellitus treatment adherence scale. *Diabetes Research and Clinical Practice*, 172, 108629. <https://doi.org/10.1016/j.diabres.2020.108629>

- Howard, J. A. (2000). Social psychology of identities. *Annual review of sociology*, 26(1), 367-393. Retrieved from: <https://www.jstor.org/stable/223449>
- Howard, V., & Adan, A. (2022). "The end justifies the memes": A feminist relational discourse analysis of the role of macro memes in facilitating supportive discussions for victim-survivors of narcissistic abuse. *Cyberpsychology: Journal of Psychosocial Research on Cyberspace*, 16(4). <https://doi.org/10.5817/CP2022-4-10>
- Howard, V., Corrigan, S., & Maguire, R. (2022). Nocturnal caregiving practice among parent caregivers for juveniles with Type 1 Diabetes: A systematic review protocol. PROSPERO 2022CRD42022298562.
- Howard, V., Maguire, R., De Bruin, E., Deane-King, J., Duda, N., & Corrigan, S. (2025). Around-the-clock: Caregiving at night for juveniles living with type 1 diabetes—a systematic review. *Psychology, Health & Medicine*, 1-22. <https://doi.org/10.1080/13548506.2025.2468529>
- HSE.ie (2015). *Model of Care for All Children and Young People with Type 1 Diabetes*. HSE. <https://www.hse.ie/eng/services/publications/clinical-strategy-and-programmes/moc-young-people-with-type-1-diabetes.pdf>
- HSE.ie. (2020). *National Framework for the Integrated Prevention and Management of Chronic Disease in Ireland 2020-2025*. Dublin: Health Service Executive. <https://www.hse.ie/eng/about/who/cspd/icp/chronic-disease/documents/national-framework-integrated-care.pdf>
- HSE.ie. (2023). *Counting Carbohydrates*. <https://www2.hse.ie/conditions/type-1-diabetes/counting-carbohydrates/>
- HSE.ie. (2024). *Type 1 Diabetes: HSE paediatric diabetes resource pack*. <https://www.hse.ie/eng/about/who/cspd/ncps/paediatrics-neonatology/resources/paediatric-type-1-diabetes-resource-pack.pdf>
- HSE.ie. (2024a). *National clinical guideline: Management of paediatric Type 1 Diabetes patient with a HbA1c greater than 75mmol per mol* <https://www2.healthservice.hse.ie/files/493/>
- HSE.ie. (2024b). *National clinical guideline: Annual review and co-morbidity screening in paediatric Type 1 Diabetes*. <https://www2.healthservice.hse.ie/files/216/>
- HSE.ie. (2024c). *Health Regions Programme Team Proposal on Patient and Service User Partnership in Health Regions Design*. https://assets.hse.ie/media/documents/Patient_and_service_user_partnership_proposal_for_the_design_of_health_regions.pdf
- HSE.ie. (2025). *Paediatric Diabetes: Model of Care for all Children and Young People with Type 1 Diabetes*. <https://www.hse.ie/eng/services/publications/clinical-strategy-and-programmes/moc-young-people-with-type-1-diabetes.pdf>
- HSE.ie. (April, 2025a). *National clinical guidelines for the care of the child newly diagnosed with Type 1 Diabetes without DKA*. <https://www2.healthservice.hse.ie/files/494/>

- HSE.ie. (June, 2025b). *National clinical guidelines: Management of paediatric diabetic ketoacidosis*. <https://www2.healthservice.hse.ie/files/459/>
- Hsieh, H. F., & Shannon, S. E. (2005). Three approaches to qualitative content analysis. *Qualitative health research*, 15(9), 1277-1288. <https://doi.org/10.1177/1049732305276687>
- Hurley, L., O'Donnell, M., O'Hara, M. C., Carey, M. E., Willaing, I., Daly, H., & Dinneen, S. F. (2017). Is diabetes self-management education still the Cinderella of diabetes care? *Patient Education and Counseling*, 100(10), 1957-1960. <https://doi.org/10.1016/j.pec.2017.05.026>
- International Diabetes Federation. *Diabetes Atlas*. (2021). Int. Diabetes Fed. 10th ed.; 2021:5. <https://www.ncbi.nlm.nih.gov/books/NBK581933/>
- International Diabetes Federation. (2025). *IDF Diabetes Atlas* (11th ed.). International Diabetes Federation. https://diabetesatlas.org/media/uploads/sites/3/2025/04/IDF_Atlas_11th_Edition_2025.pdf
- IPPOSI.ie. (2021). *Strategic plan 2021-2014*. <https://ipposi.ie/wp-content/uploads/2023/05/IPPOSI-Strategic-Plan-2021-2024-2nd-Draft-8.pdf>
- Irish Universities Association. (2022). *Engaged research principles and good practices*. https://www.iua.ie/wp-content/uploads/2023/12/Guide-IUA-Engaged-Research-Principles-Good-Practices-2022-Update_V5-471-3.pdf
- ISPAD.org. (2018). *ISPAD clinical practice consensus guidelines 2018*. <https://www.ispad.org/page/ISPADGuidelines2018>
- ISPAD.org. (2024). *Clinical practice guidelines consensus guidelines 2024*. <https://www.ispad.org/resources/ispad-clinical-practice-consensus-guidelines/2024-cpcg.html>
- Israel, B. A., Schulz, A. J., Parker, E. A., & Becker, A. B. (1998). Review of community-based research: assessing partnership approaches to improve public health. *Annual review of public health*, 19(1), 173-202.
- Iversen, A. S., Graue, M., Haugstvedt, A., & Råheim, M. (2018). Being mothers and fathers of a child with type 1 diabetes aged 1 to 7 years: a phenomenological study of parents' experiences. *International journal of qualitative studies on health and well-being*, 13(1), 1487758. <https://doi.org/10.1080/17482631.2018.1487758>
- Jackson, T., Pinnock, H., Liew, S. M., Horne, E., Ehrlich, E., Fulton, O., ... & De Simoni, A. (2020). Patient and public involvement in research: from tokenistic box ticking to valued team members. *BMC medicine*, 18(1), 79. <https://doi.org/10.1186/s12916-020-01544-7>
- Jagosh, J., Macaulay, A. C., Pluye, P., Salsberg, J. O. N., Bush, P. L., Henderson, J. I. M., ... & Greenhalgh, T. (2012). Uncovering the benefits of participatory research: implications of a realist review for health research and practice. *The Milbank Quarterly*, 90(2), 311-346. <https://doi.org/10.1111/j.1468-0009.2012.00665.x>
- Jamieson, M. K., Govaart, G. H., & Pownall, M. (2023). Reflexivity in quantitative research: A rationale and beginner's guide. *Social and Personality Psychology Compass*, 17(4), e12735.

- Janez, A., Battelino, T., Klupa, T., Kocsis, G., Kuricová, M., Lalić, N., ... Zelinska, N. (2021). Hybrid closed-loop systems for the treatment of type 1 diabetes: A collaborative, expert group position statement for clinical use in Central and Eastern Europe. *Diabetes Therapy*, 12(12), 3107–3135. <https://doi.org/10.1007/s13300-021-01160-5>
- Jaser, S. S., Foster, N. C., Nelson, B. A., Kittelsrud, J. M., DiMeglio, L. A., Quinn, M., Willi, S. M., Simmons, J. H. & T1D Exchange Clinic Network. (2017). Sleep in children with type 1 diabetes and their parents in the T1D Exchange. *Sleep Medicine*, 39:108-115. <https://doi.org/10.1016/j.sleep.2017.07.005>
- Jaser, S. S., Lord, J.H., Simmons, J. H., & Malow, B. A. (2016). Brief report: Sleep disturbances in young children with type 1 diabetes. *Diabetes Research & Clinical Practice*, 120:232-234. <https://doi.org/10.1016/j.diabres.2016.08.012>
- Jaser, S. S., Whittemore, R., Ambrosino, J.M., Lindemann, E., & Grey, M. (2009). Coping and psychosocial adjustment in mothers of young children with type 1 diabetes. *Children's Health Care*, 38(2):91-106. <https://doi.org/10.1080/02739610902813229>
- Ji, X., Wang, Y., & Saylor, J. (2021). Sleep and Type 1 Diabetes Mellitus Management Among Children, Adolescents, and Emerging Young Adults: A Systematic Review. *Journal of Pediatric Nursing*, 61:245-253. <https://doi.org/10.1016/j.pedn.2021.06.010>
- Jones, K. (2006). A biographic researcher in pursuit of an aesthetic: The use of arts-based (re)presentations in "performative" dissemination of life stories. *Qualitative Sociology Review*, 2(1), 66-85. https://eprints.bournemouth.ac.uk/1178/1/Jones_Output_1.pdf
- Jovanović, G. (2011). Toward a social history of qualitative research. *History of the Human Sciences*, 24(2), 1–27. <https://doi.org/10.1177/0952695111399334>
- Kahanovitz, L., Sluss, P.M., & Russell, S.J. (2017). Type 1 diabetes—a clinical perspective. *Point of care*, 16(1):37-40. <https://doi.org/10.1097/POC.0000000000000125>
- Kamps, J. L., Roberts, M. C., Varela, R. E. (2005). Development of a new Fear of Hypoglycemia scale: preliminary results. *Journal of Pediatric Psychology*, 30(3), 287-291. <https://doi.org/10.1093/jpepsy/jsi038>
- Karpatschhof, B. (2010). The qualitative research-form. In S. Brinkmann, M. H. Jacobsen & S. G. Kristiansen (Eds.), *Historical overview of qualitative research in the social sciences* (pp. 22–58). In P. Leavy (Ed.), *The Oxford Handbook of Qualitative Research*. Oxford University Press.
- Kaur, J., & Seaquist, E. R. (2023). Hypoglycaemia in type 1 diabetes mellitus: risks and practical prevention strategies. *Nature Reviews Endocrinology*, 19(3), 177-186. <https://doi.org/10.1038/s41574-022-00762-8>
- Kerner, J., Rimer, B., & Emmons, K. (2005). Introduction to the special section on dissemination: dissemination research and research dissemination: how can we close the gap? *Health Psychology*, 24(5), 443. <https://doi.org/10.1037/0278-6133.24.5.443>
- Khunti, K. , Alsifri, S. , Aronson, R. , Cigrovski Berković, M. , Enters-Weijnen, C. , Forsén, T. , Galstyan, G. , Geelhoed-Duijvestijn, P. , Goldfracht, M. , Gydesen, H. , Kapur, R. , Lalic,

- N. , Ludvik, B. , Moberg, E. , Pedersen-Bjergaard, U. , & Ramachandran, A. (2016). Rates and predictors of hypoglycaemia in 27 585 people from 24 countries with insulin-treated type 1 and type 2 diabetes: the global HAT study. *Diabetes, Obesity & Metabolism*, 18(9), 907–915. <https://doi.org/10.1111/dom.12689>
- Kimbell, B., Lawton, J., Boughton, C., Hovorka, R., & Rankin, D. (2021). Parents’ experiences of caring for a young child with type 1 diabetes: a systematic review and synthesis of qualitative evidence. *BMC pediatrics*, 21, 1-13. <https://doi.org/10.1186/s12887-021-02569-4>
- Kobos, E., & Imiela, J. (2015). Factors affecting the level of burden of caregivers of children with type 1 diabetes. *Applied Nursing Research*, 28(2), 142-149. <https://doi.org/10.1016/j.apnr.2014.09.008>
- Koch, T., Mann, S., Kralik, D., & van Loon, A. M. (2005). Reflection: Look, think and act cycles in participatory action research. *Journal of Research in Nursing*, 10(3), 261-278. <https://journals.sagepub.com/doi/pdf/10.1177/174498710501000304?>
- Kovács, G. Spens, K.M., 2005. Abductive reasoning in logistics research. *International Journal of Physical Distribution & Logistics Management*, 35 (2), 132 -144. <http://dx.doi.org/10.1108/09600030510590318>
- Kuluski, K., Peckham, A., Gill, A., Arneja, J., Morton-Chang, F., Parsons, J., ... Sheridan, N. (2018). “You’ve got to look after yourself, to be able to look after them”: A qualitative study of the unmet needs of caregivers of community-based primary health care patients. *BMC Geriatrics*, 18(1), 275. <https://doi.org/10.1186/s12877-018-0962-5>
- Kwame, A., & Petrucka, P. M. (2021). A literature-based study of patient-centered care and communication in nurse-patient interactions: barriers, facilitators, and the way forward. *BMC nursing*, 20(1), 158. <https://doi.org/10.1186/s12912-021-00684-2>.
- Lambert, S. D., & Loiselle, C. G. (2008). Combining individual interviews and focus groups to enhance data richness. *Journal of advanced nursing*, 62(2), 228-237. <https://doi.org/10.1111/j.1365-2648.2007.04559.x>
- Landau, Z., Rachmiel, M., Pinhas-Hamiel, O., Boaz, M., Bar-Dayana, Y., Wainstein, J., & Tauman, R. (2014). Parental sleep quality and continuous glucose monitoring system use in children with type 1 diabetes. *Acta Diabetologica*, 51(3):499-503. <https://doi.org/10.1007/s00592-013-0545-z>
- Lang, I., King, A., Jenkins, G., Boddy, K., Khan, Z., & Liabo, K. (2022). How common is patient and public involvement (PPI)? Cross-sectional analysis of frequency of PPI reporting in health research papers and associations with methods, funding sources and other factors. *BMJ open*, 12(5), e063356. <https://doi.org/10.1136/bmjopen-2022-063356>
- Langberg, E. M., Dyhr, L., & Davidsen, A. S. (2019). Development of the concept of patient-centredness—A systematic review. *Patient education and counselling*, 102(7), 1228-1236. <https://doi.org/10.1016/j.pec.2019.02.023>
- Larkin, M., Flowers, P., & Smith, J. A. (2021). *Interpretative phenomenological analysis: Theory, method and research*. SAGE Publications Ltd.

- La Verde, M., Torella, M., Riemma, G., Narciso, G., Iavarone, I., Gliubizzi, L., ... & De Franciscis, P. (2022). Incidence of gestational diabetes mellitus before and after the Covid-19 lockdown: A retrospective cohort study. *Journal of Obstetrics and Gynaecology Research*, 48(5), 1126-1131. <https://doi.org/10.1111/jog.15205>
- Lawrence, M. G., Williams, S., Nanz, P., & Renn, O. (2022). Characteristics, potentials, and challenges of transdisciplinary research. *One Earth*, 5(1), 44-61. <https://doi.org/10.1016/j.oneear.2021.12.010>
- Lawton, J., Blackburn, M., Allen, J., Campbell, F., Elleri, D., Leelarathna, L., ... & Hovorka, R. (2018). Patients' and caregivers' experiences of using continuous glucose monitoring to support diabetes self-management: qualitative study. *BMC endocrine disorders*, 18(1), 12. <https://doi.org/10.1186/s12902-018-0239-1>
- Lazard, L., & McAvoy, J. (2020). Doing reflexivity in psychological research: What's the point? What's the practice? *Qualitative research in psychology*, 17(2), 159-177. <https://doi.org/10.1080/14780887.2017.1400144>
- Leavy, P. (2015). *Method meets art: Arts-based research practice* (2nd ed.). Guilford Press.
- Lewin, A. B., LaGreca, A. M., Geffken, G. R., Williams, L. B., Duke, D. C., Storch, E. A., & Zamanzadeh, J. H. (2009). Validity and reliability of an adolescent and parent rating scale of type 1 diabetes adherence behaviors: The Self-Care Inventory (SCI). *Journal of pediatric psychology*, 34(9), 999-1007. <https://doi.org/10.1093/jpepsy/jsp032>
- Li, L., Andrews, E. B., Li, X., Doder, Z., Zalmover, E., Sharma, K., ... & Wu, C. (2021). Incidence of diabetic ketoacidosis and its trends in patients with type 1 diabetes mellitus identified using a US claims database, 2007–2019. *Journal of Diabetes and its Complications*, 35(7), 107932. <https://doi.org/10.1016/j.jdiacomp.2021.107932>
- Li, J., & Yu, Q. (2024). Scientists' disciplinary characteristics and collaboration behaviour under the convergence paradigm: A multilevel network perspective. *Journal of Informetrics*, 18(1), 101491. <https://doi.org/10.1016/j.joi.2024.101491>
- Lindström, C., Åman, J., & Norberg, A. L. (2011). Parental burnout in relation to sociodemographic, psychosocial and personality factors as well as disease duration and glycaemic control in children with Type 1 diabetes mellitus. *Acta Paediatrica*, 100(7):1011-1017. <https://doi.org/10.1111/j.1651-2227.2011.02198.x>
- Lindström, C., Åman, J., Norberg, A. L., Forssberg, M., & Anderzén-Carlsson, A. (2017). "Mission impossible"; the mothering of a child with type 1 diabetes—from the perspective of mothers experiencing burnout. *Journal of Pediatric Nursing*, 36, 149-156. <https://doi.org/10.1016/j.pedn.2017.06.002>
- Lopez-Hartmann, M., Wens, J., Verhoeven, V., & Remmen, R. (2012). The effect of caregiver support interventions for informal caregivers of community-dwelling frail elderly: a systematic review. *International journal of integrated care*, 12, e133. <https://doi.org/10.5334/ijic.845>
- Luger, T. M., Hamilton, A. B., & True, G. (2020). Measuring community-engaged research contexts, processes, and outcomes: a mapping review. *The Milbank Quarterly*, 98(2), 493-553. <https://doi.org/10.1111/1468-0009.12458>

- Lune, H., & Berg, B. L. (2017). *Qualitative research methods for the social sciences*. Pearson.
- Macaulay, A. C. (2017). Participatory research: What is the history? Has the purpose changed? *Family practice*, 34(3), 256-258.
<https://doi-org.elib.tcd.ie/10.1093/fampra/cmw117>
- Macaulay, G. C., Boucher, S. E., Yogarajah, A., Galland, B. C., & Wheeler, B. J. (2020). Sleep and night-time caregiving in parents of children and adolescents with type 1 diabetes mellitus - A qualitative study. *Behavioral sleep medicine*, 18(5):622-636.
<https://doi.org/10.1080/15402002.2019.1647207>
- MacLure, M. (2013). The wonder of data. *Cultural Studies - Critical Methodologies*, 13(4), 228–232. <https://doi.org/10.1177/1532708613487863>
- Magliano, D. J., Boyko, E. J., & Atlas, I. D. (2021). COVID-19 and diabetes. In *IDF DIABETES ATLAS [Internet]. 10th edition*. International Diabetes Federation.
<https://www.ncbi.nlm.nih.gov/books/NBK581938/>
- Malik, A., & Zahra, T. (2022). Pragmatic analysis of internet memes on distant learning. *Pakistan Journal of Society, Education and Language*, 8(2), 303-317.
https://www.researchgate.net/profile/Tehseen-Zahra/publication/361788057_links/62c52f68aa8bfe1f73c119d7/
- Marks, V. & Richmond, C. (2007). *Insulin Murders – true life cases*. Royal Society of Medicine Press. London, UK.
- Márkus, B., Hargittay, C., Iller, B., Rinfel, J., Bencsik, P., Oláh, I., ... & Vörös, K. (2022). Validation of the revised Diabetes Self-Management Questionnaire (DSMQ-R) in the primary care setting. *BMC Primary Care*, 23(1), 2. <https://doi.org/10.1186/s12875-021-01615-5>
- Martínez, A., Frías, O. M., & Romero-Moreno, R. (2022). Prevalence and associated factors with poor sleep quality in non-professional caregivers. *International Journal of Environmental Research and Public Health*, 19(4), 2143. <https://doi.org/10.3390/ijerph19042143>
- Mayoclinic.org. (2024). *Blood sugar testing: Why, when and how*.
<https://www.mayoclinic.org/diseases-conditions/diabetes/in-depth/blood-sugar/art-20046628#:~:text=Your%20healthcare%20professional%20may%20suggest,after%20and%20sometimes%20during%20exercise>
- McIntyre, M., & Cole, A. (2008). Love stories about caregiving and Alzheimer's disease: A performative methodology. *Journal of Health Psychology*, 13(2): 213–225.
<https://doi.org/10.1177/1359105307086701>
- Medic, G., Wille, M., & Hemels, M. E. (2017). Short-and long-term health consequences of sleep disruption. *Nature and science of sleep*, 151-161. <https://doi.org/10.2147/NSS.S134864>
- Meltzer, L. J., Moore, M. (2008). Sleep Disruptions in Parents of Children and Adolescents with Chronic Illnesses: Prevalence, Causes, and Consequences, *Journal of Pediatric Psychology*, 33(3):279–291. <https://doi.org/10.1093/jpepsy/jsm118>

- Mercer, S. L., Green, L. W., Cargo, M., Potter, M. A., Daniel, M., Olds, S., & Reed-Gross, E. (2008). Appendix C: Reliability-tested guidelines for assessing participatory research projects. In M. Minkler & N. Wallerstein (Eds.), *Community-based participatory research for health: From process to outcomes* (2nd ed., pp. 407–418). Jossey-Bass.
- Midland103.com. (2024, April 12). Midland news: Minister commits to keeping midlands paediatric diabetes service open. <https://www.midlands103.com/news/midlands-news/health-minister-commits-to-keeping-rhm-paediatric-diabetes-services-open/?utm>
- Minogue, V. (2021). Health service executive: research and development. *Knowledge translation, dissemination and impact: A practical guide for researchers. Guide no 8: Patient and public involvement in HSE research*. <https://hseresearch.ie/wp-content/uploads/2021/12/Guide-no-8-Patient-and-Public-Involvement-in-HSE-Research.pdf>
- Minogue, V., Morrissey, M., & Terres, A. (2022). Supporting researchers in knowledge translation and dissemination of their research to increase usability and impact. *Quality of Life Research*, 31(10), 2959-2968. <https://doi.org/10.1007/s11136-022-03122-1>
- Missambou Mandilou, S. V., Atipo-Ibara Ollandzobo, L. C., Kitemo Mpolo, F. L. G., Ngoulou, B. P. S., Elenga Bongo, C. L., Bouénizabila, E., & Mabiala Babela, J. R. (2021). Psychosocial functioning and health related quality of life in children, adolescents and young adults with type 1 diabetes mellitus in Congo. *Pediatric Diabetes*, 22(4), 675-682. <https://doi.org/10.1111/pedi.13187>
- Mitchell, G. J., Jonas-Simpson, C., & Ivonoffski, V. (2006). *Research-Based Theatre: The Making of I'm Still Here!* *Nursing Science Quarterly*, 19(3), 198–206. <https://doi.org/10.1177/0894318406289878>
- Mobasser, M., Shirmohammadi, M., Amiri, T., Vahed, N., Fard, H. H., & Ghojaziadeh, M. (2020). Prevalence and incidence of type 1 diabetes in the world: a systematic review and meta-analysis. *Health promotion perspectives*, 10(2):98. <https://doi.org/10.34172/hpp.2020.18>
- Moghadam, Y. H., Zeinaly, Z., & Alhani, F. (2022). How mothers of a child with type 1 diabetes cope with the burden of care: a qualitative study. *BMC endocrine disorders*, 22(1), 129. <https://doi.org/10.1186/s12902-022-01045-z>
- Monaghan, M., Herbert, L. J., Cogen, F. R., & Streisand, R. (2012). Sleep Behaviors and Parent Functioning in Young Children with Type 1 Diabetes. *Children's Health Care*, 41(3):246-259. <https://doi.org/10.1080/02739615.2012.685385>
- Monaghan, M. C., Hilliard, M. E., Cogen, F. R., & Streisand R. (2009). Nighttime caregiving behaviors among parents of young children with Type 1 diabetes: associations with illness characteristics and parent functioning. *Families, Systems & Health: The Journal of Collaborative Family HealthCare*, 27(1):28-38. <https://doi.org/10.1037/a0014770>
- Morgan, D. L. (2014). Pragmatism as a paradigm for social research. *Qualitative inquiry*, 20(8), 1045-1053. <https://doi.org/10.1177/1077800413513733>
- Morrow, T., Bhatia, S. H., Parmar, A. M., Baker, L., Abadula, F., Williamson, D., Choudhary, A., & Jaser, S. S. (2022). Sleep Habits of Early School-Aged Children with Type 1 Diabetes

- and Their Parents: Family Characteristics and Diabetes Management. *Behavioral sleep medicine*, 20(5), 649-658. <https://doi.org/10.1080/15402002.2021.1977305>
- Naranjo, D., Tanenbaum, M. L., Iturralde, E., & Hood, K. K., (2016). Diabetes technology: uptake, outcomes, barriers, and the intersection with distress. *Journal of diabetes science and technology*, 10(4):852-858. <https://doi.org/10.1177/1932296816650900>
- Nelson, R. (2013). *Practice as research in the arts: Principles, protocols, pedagogies, resistances*. Springer.
- Newman, C., Kinsella, S., Rooney, P., Bromley, J., Connor, R., Gajewska, K., ... & Dunne, F. P. (2024). The top 10 priorities in adults living with type 1 diabetes in Ireland and the United Kingdom—A James Lind Alliance priority setting partnership. *Diabetic Medicine*, 41(12), e15429. <https://doi.org/10.1111/dme.15429>
- Ng, S. M., Evans, M. L., Oliver, N., Rankin, D., Dlugatch, R., Tonga, E., ... & Lawton, J. (2024). Bridging the digital divide: the UNBIASED national study to unravel the impact of ethnicity and deprivation on diabetes technology disparities in the United Kingdom. *Diabet Med*, 41(7), e15346. <https://doi.org/10.1111/dme.15346>
- NHS.uk. (2024). *Treatment for Type 1 Diabetes*. <https://www.nhs.uk/conditions/type-1-diabetes/treatment/>
- Nishihama, K., Eguchi, K., Maki, K., Okano, Y., Tanaka, S., Inoue, C., Uchida, A., Uemura, M., Suzuki, T., Yasuma, T., D'Alessandro-Gabazza, C. N., Gabazza, E. C., & Yano, Y. (2021). Sudden Death Associated with Severe Hypoglycemia in a Diabetic Patient During Sensor-Augmented Pump Therapy with the Predictive Low Glucose Management System. *The American journal of case reports*, 22, e928090. <https://doi.org/10.12659/AJCR.928090>
- Noca.ie. (may, 2022). National paediatric diabetes audit feasibility study report. National office of clinical audit. <https://s3-eu-west-1.amazonaws.com/noca-uploads/general/National%5FPaediatric%5FDiabetes%5FAudit%5FFeasibility%5FStudy%5FReport%5FFINAL.pdf>
- Nyström, M. E., Karlton, J., Keller, C., & Andersson Gäre, B. (2018). Collaborative and partnership research for improvement of health and social services: researcher's experiences from 20 projects. *Health research policy and systems*, 16(1), 46. <https://doi.org/10.1186/s12961-018-0322-0>
- O'Brien, B. C., Harris, I. B., Beckman, T. J., Reed, D. A., & Cook, D. A. (2014). Standards for reporting qualitative research: a synthesis of recommendations. *Academic medicine*, 89(9), 1245-1251. <https://doi.org/10.1097/ACM.0000000000000388>
- Ogden, J., Lo, J. (2012). How meaningful are data from Likert scales? An evaluation of how ratings are made and the role of the response shift in the socially disadvantaged. *Journal of Health Psychology*, 17(3):350-361. <https://doi.org/10.1177/1359105311417192>
- Ogle, G. D., Wang, F., Haynes, A., Gregory, G. A., King, T. W., Deng, K., ... & Maniam, J. (2025). Global type 1 diabetes prevalence, incidence, and mortality estimates 2025: Results from the International diabetes Federation Atlas, and the T1D Index Version 3.0. *Diabetes Research and Clinical Practice*, 112277. <https://doi.org/10.1016/j.diabres.2025.112277>

- O'Hara, M. C., Hynes, L., O'Donnell, M., Nery, N., Byrne, M., Heller, S.R., Dineen, S. F., & Irish Type 1 Diabetes Young Adult Study Group. (2016). A systematic review of interventions to improve outcomes for young adults with Type 1 diabetes. *Diabetic Medicine*, 34(6):753-769. <https://doi.org/10.1111/dme.13276>
- O'Neill, M. (2022). *Gender Matters: Women's lives and experiences in the criminal justice system* [CPD module description]. Institute for Social Science in the 21st Century, University College Cork.
- Oser, T. K., Oser, S. M., McGinley, E. L., & Stuckey, H. L. (2017). A novel approach to identifying barriers and facilitators in raising a child with type 1 diabetes: qualitative analysis of caregiver blogs. *JMIR diabetes*, 2(2):e8966. <https://doi.org/10.2196/diabetes.8966>
- Owusu, B., Ofori-Boateng, P., Forbes, A., Doku, D. T. (2023). Knowledge of young people living with type 1 diabetes and their caregivers about its management. *Nurs Open.*, 10(4):2426-2438. <https://doi.org/10.1002/nop2.1498>.
- Page, M. J., McKenzie, J. E., Bossuyt, P. M., Boutron, I., Hoffmann, T. C., Mulrow, C. D., ... & Moher, D. (2021). The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. *Bmj*, 372. <http://dx.doi.org/10.1136/bmj.n71>
- Pallant, J. (2013). SPSS survival manual. *Checking the reliability of a scale*. (5th Ed.). Routledge. <https://www.taylorfrancis.com/chapters/mono/10.4324/9781003117445-12/checking-reliability-scale-julie-pallant>
- Patience, M., Janssen, X., Kirk, A., McCrory, S., Russell, E., Hodgson, W., & Crawford, M. (2023). 24-Hour movement behaviours (physical activity, sedentary behaviour and sleep) association with glycaemic control and psychosocial outcomes in adolescents with type 1 diabetes: a systematic review of quantitative and qualitative studies. *International Journal of Environmental Research and Public Health*, 20(5), 4363. <https://doi.org/10.3390/ijerph20054363>
- Patterson, C. C., Harjutsalo, V., Rosenbauer, J., Neu, A., Cinek, O., Skrivarhaug, T., ... & Green, A. (2019a). Trends and cyclical variation in the incidence of childhood type 1 diabetes in 26 European centres in the 25 year period 1989–2013: a multicentre prospective registration study. *Diabetologia*, 62(3), 408-417. <https://doi.org/10.1007/s00125-018-4763-3>
- Patterson, C.C., Karuranga, S., Salpea, P., Saeedi, P., Dahlquist, G., Soltesz, G., & Ogle, G. D. (2019b). Worldwide estimates of incidence, prevalence and mortality of type 1 diabetes in children and adolescents: Results from the International Diabetes Federation Diabetes Atlas. *Diabetes research and clinical practice*, 157:107842. <https://doi.org/10.1016/j.diabres.2019.107842>
- Patton, S. R., Noser, A. E., Clements, M. A., Dolan, L. M., & Powers, S. W. (2017). Re-examining the Hypoglycemia Fear Survey for Parents of Young Children in a Sample of Children Using Insulin Pumps. *Diabetes technology & therapeutics*, 19(2), 103–108. <https://doi.org/10.1089/dia.2016.0389>
- Parsons, J. A., & Boydell, K. M. (2012). Arts-based research and knowledge translation: Some key concerns for health-care professionals. *Journal of interprofessional care*, 26(3), 170-172. <https://doi.org/10.3109/13561820.2011.647128>

- Pavarini, G., Smith, L. M., Shaughnessy, N., Mankee-Williams, A., Thirumalai, J. K., Russell, N., & Bhui, K. (2021). Ethical issues in participatory arts methods for young people with adverse childhood experiences. *Health Expectations*, 24(5), 1557-1569. <https://doi.org/10.1111/hex.13314>.
- Peck, B., & Mummery, J. (2018). Hermeneutic constructivism: An ontology for qualitative research. *Qualitative health research*, 28(3), 389-407. <https://doi.org/10.1177/1049732317706931>
- Pena-Shaff, J., Heckart, A., Mannion, C., & Barry, K. (2023). Caregivers' anxiety and perception of their children's wellbeing: a year into the COVID-19 pandemic. *Frontiers in Psychology*, 14, 1115322. <https://doi.org/10.3389/fpsyg.2023.1115322>
- Peng, H., Wu, Y., Xie, F., Li, J., & Chen, Y. (2020). Sleep disturbance, mental health symptoms, and quality of life: A structural equation model assessing aspects of caregiver burden. *BMC Geriatrics*, 20, 312. <https://doi.org/10.1186/s12877-020-01737-1>
- Perestelo-Pérez, L. (2013). Standards on how to develop and report systematic reviews in Psychology and Health. *International journal of clinical and health psychology*, 13(1), 49-57. [https://doi.org/10.1016/S1697-2600\(13\)70007-3](https://doi.org/10.1016/S1697-2600(13)70007-3)
- Perez, K. M., Hamburger, E. R., Lyttle, M., Williams, R., Bergner, E., Kahanda, S., Cobry, E., & Jaser, S. S. (2018). Sleep in type 1 diabetes: implications for glycemic control and diabetes management. *Current diabetes reports*, 18:1-8. <https://doi.org/10.1007/s11892-018-0974-8>
- Perlmutter, L. C., Flanagan, B. P., Parinda H. Shah, P. H., Singh, S. P. (2008). Glycaemic Control and Hypoglycaemia: Is the loser the winner? *Diabetes Care*, 31(10), 2072–2076. <https://doi.org/10.2337/dc08-1441>
- Pickup, J. C. (2019). Is insulin pump therapy effective in Type 1 diabetes? *Diabetic Medicine*, 36(3), 269-278. <https://onlinelibrary.wiley.com/doi/pdf/10.1111/dme.13793>
- Pierce, J., S., Aroian, K., Caldwell, C., Ross, J., L., Lee, J., M., Schifano, E., Novotny, R., Tamayo, A. & Wysocki, T. (2017). The Ups and Downs of Parenting Young Children With Type 1 Diabetes: A Crowdsourcing Study. *Journal of Pediatric Psychology*, 42(8): 846–860. <https://doi.org/10.1093/jpepsy/jsx056>
- Pietkiewicz, I., & Smith, J. A. (2014). A practical guide to using interpretative phenomenological analysis in qualitative research psychology. *Psychological journal*, 20(1), 7-14. <https://doi.org/10.14691/CPPJ.20.1.7>
- Popay, J., Roberts, H., Sowden, A., Petticrew, M., Arai, L., Rodgers, M., ... & Duffy, S. (2006). Guidance on the conduct of narrative synthesis in systematic reviews. *A product from the ESRC methods programme Version, 1*(1), b92. <https://citeseerx.ist.psu.edu/document?repid=rep1&type=pdf&doi=ed8b23836338f6fdea0cc55e161b0fc5805f9e27>
- Powers, M., Bardsley, J., Cypress, M., Funnell, M., Harms, D., Hess-Fischl, A., ... & Uelman, S. (2020). Diabetes self-management education and support in adults with type 2 diabetes: a consensus report of the American Diabetes Association, the Association of Diabetes Care & Education Specialists, the Academy of Nutrition and Dietetics, the American Academy

- of Family Physicians, the American Academy of PAs, the American Association of Nurse Practitioners, and the American Pharmacists Association. *Journal of the American Pharmacists Association*, 60(6), e1-e18.
<https://journals.sagepub.com/doi/pdf/10.1177/0145721720930959>
- Prahalad, P., Tanenbaum, M., Hood, K., & Maahs, D. M. (2018). Diabetes technology: improving care, improving patient-reported outcomes and preventing complications in young people with Type 1 diabetes. *Diabetic Medicine*, 35(4), 419-429.
<https://doi.org/10.1111/dme.13588>
- Purtle, J., Marzalik, J. S., Halfond, R. W., Bufka, L. F., Teachman, B. A., & Aarons, G. A. (2020). Toward the data-driven dissemination of findings from psychological science. *American Psychologist*, 75(8), 1052. <https://dx.doi.org/10.1037/amp0000721>
- Przezak, A., Bielka, W., & Mołęda, P. (2022). Fear of hypoglycemia-An underestimated problem. *Brain and behavior*, 12(7), e2633. <https://doi.org/10.1002/brb3.2633>
- Rankin, D., Harden, J., Waugh, N., Noyes, K., Barnard, K. D., & Lawton, J. (2016). Parents' information and support needs when their child is diagnosed with type 1 diabetes: a qualitative study. *Health Expectations*, 19(3), 580-591. <https://doi.org/10.1111/hex.12244>
- Rankin, D., Harden, J., Barnard, K., Bath, L., Noyes, K., Stephen, J., & Lawton, J. (2018). Barriers and facilitators to taking on diabetes self-management tasks in pre-adolescent children with type 1 diabetes: a qualitative study. *BMC endocrine disorders*, 18(1), 71. <https://doi.org/10.1186/s12902-018-0302>
- Rawdon, C., Kilcullen, S. M., Murphy, N., Swallow, V., Gallagher, P., & Lambert, V. (2024). Parents' perspectives of factors affecting parent-adolescent communication about type 1 diabetes and negotiation of self-management responsibilities. *Journal of Child Health Care*, 28(3), 514-535. <https://doi.org/10.1177/13674935221146009>
- Rechenberg, K., Grey, M., & Sadler, L. (2017). Stress and post traumatic stress in mothers of children with type 1 diabetes. *Journal of family nursing*, 23(2), 201-225.
<https://doi.org/10.1177/1074840716687543>
- Reed-Knight, B., Blount, R. L., & Gilleland, J. (2014). The transition of health care responsibility from parents to youth diagnosed with chronic illness: A developmental systems perspective. *Families, Systems, & Health*, 32(2), 219-234. <https://doi.org/10.1037/fsh000039>
- Reid, A., & Gough, S. (2000). Guidelines for reporting and evaluating qualitative research: what are the alternatives? *Environmental Education Research*, 6(1), 59-91.
<https://doi.org/10.1080/135046200110494>
- Research Ireland. (2017, Jan 16). *Engaged research: Society & higher education — working together to address grand societal challenges*. Research Ireland.
<https://research.ie/assets/uploads/2017/04/Engaged-Research.pdf>
- Reynolds, Robin. (June 24, 2024). *Spoken word: Everything to know about the art of oral poetry*. <https://www.backstage.com/magazine/article/spoken-word-poetry-definition-examples-77413/>

- Riessman, C. K. (2008). *Narrative methods for the human sciences*. Sage.
- Rifshana, F., Breheny, M., Taylor, J. E., & Ross, K. (2017). The parental experience of caring for a child with type 1 diabetes. *Journal of Child and Family Studies*, 26(11), 3226-3236. <https://doi.org/10.1007/s10826-017-0806-1>
- Roche, E. F., McKenna, A. M., O'Regan, M., Ryder, K. J., Fitzgerald, H. M., & Hoey, H. M. (2023). The incidence of type 1 diabetes in children under 15 years of age is rising again—a nationwide study. *European journal of pediatrics*, 182(10), 4615-4623. <https://doi.org/10.1007/s00431-023-05125-7>
- Roos, C. A., Postmes, T., & Koudenburg, N. (2023). Feeling heard: Operationalizing a key concept for social relations. *Plos one*, 18(11), e0292865. <https://doi.org/10.1371/journal.pone.0292865>
- Roos, T., Hermanns, N., Groß, C., Kulzer, B., Haak, T., & Ehrmann, D. (2024). Effect of automated insulin delivery systems on person-reported outcomes in people with diabetes: A systematic review and meta-analysis. *EClinicalMedicine*, 76, 102852. <https://doi.org/10.1016/j.eclim.2024.102852>
- Rose, S. (2023). The role and impact of glucose monitoring technology on glucose testing and sleep patterns in adolescents and young adults with type 1 diabetes (Doctoral dissertation, University of Otago). <https://hdl.handle.net/10523/36224>
- Rossiter, K., Kontos, P., Colantonio, A., Gilbert, J., Gray, J., & Keightley, M. (2008). *Staging data: Theatre as a tool for analysis and knowledge transfer in health research*. *Social Science & Medicine*, 66(1), 130–146. <https://doi.org/10.1016/j.socscimed.2007.07.021>
- Rustad, J. K., Musselman, D. L., Skyler, J. S., Matheson, D., Delamater, A., Kenyon, N. S., ... & Nemeroff, C. B. (2013). Decision-making in diabetes mellitus type 1. *The Journal of neuropsychiatry and clinical neurosciences*, 25(1), 40-50. <https://doi.org/10.1176/appi.neuropsych.12010016>
- Rzepczyk, S., Dolińska-Kaczmarek, K., Uruska, A., & Żaba, C. (2022). The other face of insulin—overdose and its effects. *Toxics*, 10(3), 123. <https://doi.org/10.3390/toxics10030123>
- Saßmann, H., Kim-Dorner, S. J., Berndt, V., Biester, T., Dehn-Hindenberg, A., Heidtmann, B., ... & Lange, K. (2022). Understanding daily, emotional, and physical burdens and needs of parents caring for children with type 1 diabetes. *Journal of diabetes research*, 2022(1), 9604115. <https://doi.org/10.1155/2022/9604115>
- Saini, P., Hassan, S. M., Morasae, E. K., Goodall, M., Giebel, C., Ahmed, S., ... & Gabbay, M. (2021). The value of involving patients and public in health services research and evaluation: a qualitative study. *Research involvement and engagement*, 7(1), 49. <https://doi.org/10.1186/s40900-021-00289-8>
- Sandelowski, M. (1998). Writing a good qualitative research report. *Research in Nursing & Health*, 21(3), 375–382. [https://doi.org/10.1002/\(SICI\)1098-240X\(199806\)21:3<375](https://doi.org/10.1002/(SICI)1098-240X(199806)21:3<375)

- Satterfield, B. C., & Killgore, W. D. S. (2019). Sleep loss, executive function, and decision-making. In M. A. Grandner (Ed.), *Sleep and Health* (pp. 339–358). Elsevier. <https://doi.org/10.1016/B978-0-12-815373-4.00026-5>
- Saunders, B., Sim, J., Kingstone, T., Baker, S., Waterfield, J., Bartlam, B., ... & Jinks, C. (2018). Saturation in qualitative research: exploring its conceptualization and operationalization. *Quality & quantity*, 52(4), 1893-1907. <https://doi.org/10.1007/s11135-017-0574-8>
- Schierloh, U., Aguayo, G. A., Fichelle, M., De Melo Dias, C., Schritz, A., Vaillant, M., ... de Beaufort, C. (2024). Fear of hypoglycemia and sleep in children with type 1 diabetes and their parents. *Frontiers in Endocrinology*, 15, 1419502. <https://doi.org/10.3389/fendo.2024.1419502>
- Schunk, M., Stark, R., Reitmeir, P., Meisinger, C., & Holle, R. (2015). Towards patient-oriented diabetes care: results from two KORA surveys in southern Germany. *Journal of diabetes research*, 368570. <https://doi.org/10.1155/2015/368570>
- Schmitt, A., Kulzer, B., Ehrmann, D., Haak, T., Hermanns, N. (2022). A self-report measure of diabetes self-management for type 1 and type 2 diabetes: The diabetes self-management questionnaire-revised (DSMQ-R) - Clinimetric evidence from five studies. *Front Clin Diabetes Healthc*, 13;2:823046. <https://doi.org/10.3389/fcdhc.2021.823046>
- Schunk, M., Stark, R., Reitmeir, P., Meisinger, C., & Holle, R. (2015). Towards patient-oriented diabetes care: results from two KORA surveys in southern Germany. *Journal of diabetes research*, 368570. <https://doi.org/10.1155/2015/368570>
- Shaw, R. (2010). Embedding reflexivity within experiential qualitative psychology, *Qualitative Research in Psychology*, 7(3), 233-243. <https://doi.org/10.1080/14780880802699092>
- Shepard, J.A., Vajda, K., Nyer, M., Clarke, W., Gonder-Frederick, L. (2014). Understanding the construct of fear of hypoglycemia in pediatric type 1 diabetes. *J Pediatr Psychol.*, 39(10):1115-25. <https://doi.org/10.1093/jpepsy/jsu068>. Epub 2014 Sep 11.
- Shifman, L. (2013). Memes in a digital world: Reconciling with a conceptual troublemaker. *Journal of Computer-Mediated Communication*, 18(3), 362–377. <https://doi.org/10.1111/jcc4.12013>
- Silverstein, J., Klingensmith, G., Copeland, K., Plotnick, L., Kaufman, F., Laffel, L., Deeb, L., Grey, M., Anderson, B., Holzmeister, L. A., & Clark, N. (2005). Care of children and adolescents with type 1 diabetes: a statement of the American Diabetes Association. *Diabetes care*, 28(1):186-212. <https://doi.org/10.2337/diacare.28.1.186>
- Silverthorne, C., Daniels, J., Thompson, M., Robson, J. C., Ndosi, M., Swales, C., ... & Dures, E. (2023). Health professionals' perspectives on psychological distress and meeting patients' support needs in rheumatology care settings: A qualitative study. *Musculoskeletal Care*, 21(2), 537-544. <https://doi.org/10.1002/msc.1730>
- Sinisterra, M., Hamburger, S., Tully, C., Hamburger, E., Jaser, S., & Streisand, R. (2020). Young Children with Type 1 Diabetes: Sleep, Health-Related Quality of Life, and Continuous Glucose Monitor Use. *Diabetes Technology & Therapeutics*, 22(8):639-642. <https://doi.org/10.1089/dia.2019.0437>

- Skrivarhaug, T., Bangstad, H. J., Stene, L. C., Sandvik, L., Hanssen, K. F., & Joner, G. (2006). Long-term mortality in a nationwide cohort of childhood-onset type 1 diabetic patients in Norway. *Diabetologia*, 49(2), 298-305. <https://doi.org/10.1007/s00125-005-0082-6>
- Smith, J. A. (2011). Evaluating the contribution of interpretative phenomenological analysis. *Health psychology review*, 5(1), 9-27. <https://doi.org/10.1080/17437199.2010.510659>
- Smith, J. A., & Hodgkinson, P. (2009). Relativism, criteria, and politics. *Journal of Philosophy of Education*, 43(4), 611–622. <https://doi.org/10.1111/j.1467-9752.2009.00704.x>
- Song, H., Li, J., Yang, H., Kong, B., Xu, Y., Li, X., & Li, H. (2025). Enhancement of functional insulin-producing cell differentiation from embryonic stem cells through MST1-silencing. *Diabetology & Metabolic Syndrome*, 17(1), 93. <https://link.springer.com/content/pdf/10.1186/s13098-025-01666-z.pdf>
- Sousa, F. A., Andrade, M. L., & Oliveira, C. M. (2023). Transition from parents to caregivers of a child with type 1 Diabetes Mellitus: a scoping review. *Revista brasileira de enfermagem*, 76(1), e20220201. <https://doi.org/10.1590/0034-7167-2022-0201>
- Speight, J., Holmes-Truscott, E., Browne, J., Hendrieckx, C., Halliday, J., & Schabert, J. (2011). *Diabetes MILES-Australia 2011 survey report*. https://dro.deakin.edu.au/articles/book/Diabetes_MILES_Australia_2011_Survey_Report/20598519
- Stallwood, L. (2006). Relationship between caregiver knowledge and socioeconomic factors on glycemic outcomes of young children with diabetes. *Journal for Specialists in Pediatric Nursing*, 11(3), 158-165. <https://doi.org/10.1111/j.1744-6155.2006.00062.x>
- Steiner, C. J. (2002). The technicity paradigm and scientism in qualitative research. *The Qualitative Report*, 7(2), 1–28. <https://doi.org/10.46743/2160-3715/2002.1981>
- Street Jr, R. L., Makoul, G., Arora, N. K., & Epstein, R. M. (2009). How does communication heal? Pathways linking clinician–patient communication to health outcomes. *Patient education and counselling*, 74(3), 295-301. <https://doi.org/10.1016/j.pec.2008.11.015>
- Streisand, R., & Monaghan, M. (2014). Young children with type 1 diabetes: challenges, research, and future directions. *Current diabetes reports*, 14(9):1-9. <https://doi.org/10.1007/s11892-014-0520-2>
- Sullivan-Bolyai, S., Deatrick, J., Gruppuso, P., Tamborlane, W., & Grey, M. (2003). Constant vigilance: mothers' work parenting young children with type 1 diabetes. *Journal of Pediatric Nursing*, 18(1):21-29. <https://www.embase.com/search/results?subaction=viewrecord&id=L36495975&from=export>
- Sweeting, A., Hannah, W., Backman, H., Catalano, P., Feghali, M., Herman, W. H., ... & Benhalima, K. (2024). Epidemiology and management of gestational diabetes. *The Lancet*, 404(10448), 175-192. [https://doi.org/10.1016/S0140-6736\(24\)00825-0](https://doi.org/10.1016/S0140-6736(24)00825-0)
- Symons, J., Crawford, R., Isaac, D., & Thompson, S. (2015). "The whole day revolves around it": Families' experiences of living with a child with Type 1 diabetes-a descriptive study.

- Neonatal, Paediatric & Child Health Nursing*, 18(1), 7-11.
<https://doi.org/10.3316/ielapa.343409790704357>
- Tanenbaum, M., L., Commissariat, P., V. (2023). Experience with burdens of diabetes device use that affect uptake and optimal use in people with type 1 diabetes. *Endocr Connect*, 12(10):e230193. <https://ec.bioscientifica.com/view/journals/ec/12/10/EC-23-0193.xml>
- The Diabetes Control and Complications Trial Research Group. (1993). The Effect of Intensive Treatment of Diabetes on the Development and Progression of Long-Term Complications in Insulin-Dependent Diabetes Mellitus. *New England Journal of Medicine*, 329(14), 977-986. <https://doi.org/10.1056/NEJM199309303291401>
- Thomas, S., Ryan, N. P., Byrne, L. K., Hendrieckx, C., & White, V. (2024). Psychological distress among parents of children with chronic health conditions and its association with unmet supportive care needs and children's quality of life. *Journal of Pediatric Psychology*, 49(1), 45-55. <https://doi.org/10.1093/jpepsy/jsad074>.
- Thriveabetes.ie. (2025). *Insulin pumps and sensors; information and support*.
<https://thriveabetes.ie>
- Toledano-Toledano, F., & Luna, D. (2020). The psychosocial profile of family caregivers of children with chronic diseases: A cross-sectional study. *BioPsychoSocial Medicine*, 14(29). <https://link.springer.com/article/10.1186/s13030-020-00201-y>
- Tong, A., Sainsbury, P., & Craig, J. (2007). Consolidated criteria for reporting qualitative research (COREQ): A 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care*, 19(6), 349–357. <https://doi.org/10.1093/intqhc/mzm042>
- Tong, F., Wu, R., Huang, W., Yang, Y., Zhang, L., Zhang, B., ... & Zhou, Y. (2017). Forensic aspects of homicides by insulin overdose. *Forensic science international*, 278, 9-15. <https://doi.org/10.1016/j.forsciint.2017.06.015>
- Tong, H. J., Qiu, F., & Fan, L. (2021). Effect of hospital discharge plan for children with type 1 diabetes on discharge readiness, discharge education quality, and blood glucose control. *World Journal of Clinical Cases*, 9(4), 774. <https://doi.org/10.12998/wjcc.v9.i4.774>
- Toobert, D. J., Hampson, S. E., & Glasgow, R. E. (2000). The summary of diabetes self-care activities measure: results from 7 studies and a revised scale. *Diabetes care*, 23(7), 943-950. <https://doi.org/10.1111/j.1464-5491.2009.02697.x>
- Toschi, N., Passamonti, L., & Bellesi, M. (2021). Sleep quality relates to emotional reactivity via intracortical myelination. *Sleep*, 44(1), 146. <https://doi.org/10.1093/sleep/zsaa146>
- Tracy, S. J. (2010). Qualitative quality: Eight “Big-Tent” criteria for excellent qualitative research. *Qualitative Inquiry*, 16(10), 837–851. <https://doi.org/10.1177/1077800410383121>
- Triki, N., Yekutieli, N., Levi, L., & Azuri, J. (2021). The effects of continuous glucose monitoring system on patient outcomes and associated costs in a real-world setting. *Diabetic Medicine*, 38(5), e14518. <https://doi.org/10.1111/dme.14518>

- Trott, C. D., Even, T. L., & Frame, S. M. (2020). Merging the arts and sciences for collaborative sustainability action: A methodological framework. *Sustainability Science*, 15(4), 1067-1085. <https://doi.org/10.1007/s11625-020-00798-7>
- Usher-Smith, J. A., Thompson, M., Ercole, A., & Walter, F. M. (2012). Variation between countries in the frequency of diabetic ketoacidosis at first presentation of type 1 diabetes in children: a systematic review. *Diabetologia*, 55(11), 2878-2894. <https://doi.org/10.1007/s00125-012-2690-2>.
- Van Duinkerken, E., Snoek, F. J., & De Wit, M. (2020). The cognitive and psychological effects of living with type 1 diabetes: a narrative review. *Diabetic Medicine*, 37(4), 555-563. <https://doi.org/10.1111/dme.14216>
- Van Name, M. A., Hilliard, M. E., Boyle, C. T., Miller, K. M., DeSalvo, D.J., Anderson, B. J., Laffel, L. M., Woerner, S. E., DiMeglio, L. A., & Tamborlane, W.V. (2018). Nighttime is the worst time: Parental fear of hypoglycemia in young children with type 1 diabetes. *Pediatric Diabetes*, 19(1):114-120. <https://doi.org/10.1111/pedi.12525>
- Van Rijnsoever, F. J., & Hessels, L. K. (2011). Factors associated with disciplinary and interdisciplinary research collaboration. *Research policy*, 40(3), 463-472. <https://doi.org/10.1016/j.respol.2010.11.001>
- Vidich, A. J., & Lyman, S. M. (1994). Qualitative methods: Their history in sociology and anthropology. *Handbook of qualitative research*, 2, 23-59.
- Vignesh, J. P., & Mohan, V. (2004). Hypoglycaemia unawareness. *Journal of the Association of Physicians of India*, 52, 727-732. http://mdrfeprints.in/124/1/Hypoglycaemia_Unawareness.pdf
- Von Elm, E., Altman, D. G., Egger, M., Pocock, S. J., Gøtzsche, P. C., & Vandenbroucke, J. P. (2007). The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement: guidelines for reporting observational studies. *The lancet*, 370(9596), 1453-1457. <https://doi.org/10.1371/journal.pmed.0040296>.
- Walker, A., Schatz, D., Johnson, C., Silverstein, J., Lyles, S., & Rohrs, H. (2016). Type 1 diabetes through two lenses: Comparing adolescent and parental perspectives with photovoice. *International Journal of Pediatric Endocrinology*, 1-10. <https://doi.org/10.1186/s13633-016-0020-z>
- Whitesell, N. R., Sarche, M., Keane, E., Mousseau, A. C., & Kaufman, C. E. (2018). Advancing scientific methods in community and cultural context to promote health equity: Lessons from intervention outcomes research with American Indian and Alaska Native communities. *American Journal of Evaluation*, 39(1), 42-57. <https://doi.org/10.1177/1098214017726872>
- Wigham, S., Bourne, J., McKenzie, K., Rowlands, G., Petersen, K., & Hackett, S. (2022). Improving access to primary care and annual health checks for people who have a learning disability: a multistakeholder qualitative study. *BMJ open*, 12(12), e065945. <https://doi.org/10.1136/bmjopen-2022-065945>
- Wild, D., von Maltzahn, R., Brohan, E., Christensen, T., Clauson, P., & Gonder-Frederick, L. (2007). A critical review of the literature on fear of hypoglycemia in diabetes: implications

- for diabetes management and patient education. *Patient education and counseling*, 68(1), 10-15. <https://doi.org/10.1016/j.pec.2007.05.003>
- Wilkinson, S. (1988). The role of reflexivity in feminist psychology. *Women's Studies International Forum*, 11(5), 493–502. [https://doi.org/10.1016/0277-5395\(88\)90024-6](https://doi.org/10.1016/0277-5395(88)90024-6)
- Willemen, A. M., Kuzminskaite, E., Maurice-Stam, H., Grootenhuis, M. A., Last, B. F., Schuengel, C., & Scholten, L. (2022). The working mechanisms of parental involvement in interventions for children with chronic illness. *Journal of Child and Family Studies*, 31(11), 3037-3046. <https://doi.org/10.1007/s10826-022-02329-7>
- Williamson, K., Given, L. M., & Scifleet, P. (2018). Qualitative data analysis. *Research Methods: Information, Systems, and Contexts*, 2(2), 453-476. <https://doi.org/10.1016/B978-0-08-102220-7.00019-4>
- Wilson, D. M., Xing, D., Beck, R. W., Block, J., & others for the JDRF CGM Study Group. (2011). Hemoglobin A_{1c} and mean glucose in patients with type 1 diabetes: analysis of data from the Juvenile Diabetes Research Foundation continuous glucose-monitoring randomized trial. *Diabetes Care*, 34(3), 540–544. <https://doi.org/10.2337/dc10-1054> pubmed.ncbi.nlm.nih.gov/2diabetesjournals.org/2
- Wolpert, H., Polonsky, W. H., & Rodbard, D. (2021). Insulin metrics: need for development of consensus standards for reporting of insulin dosing data. *Diabetes Technology & Therapeutics*, 23(7), 522-526. <https://doi.org/10.1089/dia.2020.0631>
- Wood, S. (2020). Beyond Messiaen's birds: the post-verbal world of dementia. *Medical Humanities*, 46(1), 73-83. <https://doi.org/10.1136/medhum-2018-011616>
- Woolgar, S. (1988). *Knowledge and reflexivity*. Sage.
- World Health Organisation. (1978). *Declaration of Alma Ata: report of the International Conference on primary health care*. World Health Organisation.
- Wysocki, T., Buckloh, L. M., Antal, H., Lochrie, A., & Taylor, A. (2012). Validation of a self-report version of the diabetes self-management profile. *Pediatric diabetes*, 13(5), 438-443. <https://doi.org/10.1111/j.1399-5448.2011.00823.x>
- Wysocki, T., & Greco, P. (2006). *Social support and diabetes management in childhood and adolescence: Influence of parents and friends*. *Current Diabetes Reports*, 6(2), 117–122. <https://doi.org/10.1007/s11892-006-0022-y> [Nemours+1](#)
- Yale, J. F., Paty, B., Senior, P. A., & Diabetes Canada Clinical Practice Guidelines Expert Committee. (2018). Hypoglycemia. *Canadian journal of diabetes*, 42, S104-S108. <https://doi.org/10.1016/j.jcjd.2017.10.010>
- Yardley, L. (2000). Dilemmas in qualitative health research. *Psychology and health*, 15(2), 215-228. <https://doi.org/10.1080/08870440008400302>
- Yassi, A., Spiegel, J. B., Lockhart, K., Fels, L., Boydell, K., & Marcuse, J. (2016). Ethics in community-university-artist partnered research: Tensions, contradictions and gaps identified in an 'arts for social change' project. *Journal of Academic Ethics*, 14(3), 199-220. <https://doi.org/10.1007/s10805-016-9257-7>

- Yoon, J. H., Park, N. H., Kang, Y. E., Ahn, Y. C., Lee, E. J., & Son, C. G. (2023). The demographic features of fatigue in the general population worldwide: a systematic review and meta-analysis. *Frontiers in public health*, *11*, 1192121. <https://doi.org/10.3389/fpubh.2023.1192121>.
- Young, M. T., Lord, J. H., Patel, N. J., Gruhn, M. A., & Jaser, S. S. (2014). Good cop, bad cop: quality of parental involvement in type 1 diabetes management in youth. *Curr Diab Rep*, *14*(11), 546. <https://doi.org/10.1007/s11892-014-0546-5>
- Young-Hyman, D., de Groot, M., Hill-Briggs, F., Gonzalez, J. S., Hood, K., & Peyrot, M. (2017). Erratum. Psychosocial care for people with Diabetes: A position statement of the American Diabetes Association. *Diabetes Care*, *40*(2), 287. <https://doi.org/10.2337/dc16-2053>
- Yuen, L., & Wong, V. W. (2015). Gestational diabetes mellitus: challenges for different ethnic groups. *World journal of diabetes*, *6*(8), 1024-32. <https://doi.org/10.4239/wjd.v6.i8.1024>

Appendices

Appendix 1. Ethics approval letters

Trinity College Dublin.



Coláiste na Tríonóide, Baile Átha Cliath
Trinity College Dublin
Ollscoil Átha Cliath | The University of Dublin

F.A.O. Vivienne Howard

Approval ID: SPREC0272023-02

School of Psychology Research Ethics Committee
13th September 2023

Dear Vivienne,

The School of Psychology Research Ethics Committee has reviewed your application entitled “Nocturnal caregiving for juveniles with Type 1 Diabetes”, and I am pleased to inform you that it was approved.

Please note that you will be required to submit a completed **Project Annual Report Form** on each anniversary of this approval, until such time as the research is complete and the thesis is submitted. The form is available for download from the Ethics section of the School website.

Adverse events associated with the conduct of this research must be reported immediately to the Chair of the Ethics Committee.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'Richard Carson'.

Richard Carson
Chair,
School of Psychology Research Ethics Committee

Scoil na Siceolaíochta
Dámh na nEolaíochtaí Sóisialta agus Daonna,
Áras an Phiarsaigh,
Coláiste na Tríonóide,
Baile Átha Cliath,
Ollscoil Átha Cliath,
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CHI Research Ethics Office

Email: ethics.committee2@childrenshealthireland.ie
Tel: 01-409 6307 / 6243

Vivienne Howard
School of Psychology
Trinity College Dublin
Dublin 2

2nd November 2023

REC REF: **REC-344-23**

Nocturnal Caregiving for Juveniles with Type 1 Diabetes

Principal Investigator: Dr Siobhán Corrigan

Co-investigators: Prof Declan Cody, Dr Vincent McDarby, Vivienne Howard, Dr Rebecca Maguire

Dear Vivienne,

Further to your email correspondence dated 25th October 2023, I can confirm that the submitted updated application form and associated documents have successfully addressed all of the minor issues raised by the CHI Research Ethics Committee.

This project is **APPROVED** with the expectation that it is conducted as stated in the reviewed application. An annual report for this project should be submitted to the CHI Research Ethics Office on or before the anniversary of this approval.

I wish you every success with this study and should you require any assistance in the future please do not hesitate to contact me.

Yours sincerely,

Dr Eugene Dempsey
CHI Research Ethics Officer

Cc: Dr Siobhán Corrigan, Assistant Professor, Trinity College Dublin, Dublin 2
Prof Declan Cody, Consultant Paediatric Endocrinologist, CHI at Crumlin

Appendix 2.1. Completed Guidelines and Categories for Classifying Participatory Research Projects in Health (Frankish et al., 1995)

CONCEPTUAL MODEL DOMAIN(S) AND INDICATOR(S)	ASSESSMENT INSTRUMENT QUESTIONS	RESPONSES:
STRENGTHENED PARTNERSHIPS + ALLIANCES; Diversity + inclusivity	1a) Is the community of interest clearly described or defined?	YES (5/5)
	1b) Do members of the defined community participating in the research have concern or experience with the issue?	NO (5/5)
	1d) Is attention given to barriers to participation, with consideration of those who have been under-represented in the past?	YES (4/5)
	3d) Does the scope of the research encompass some combination of political, social and economic determinants of health?	YES (4/5)
	5b) Is the potential of the defined community for action reflected by the research process?*	YES (5/5)
STRENGTHENED PARTNERSHIPS + ALLIANCES; Partnerships + opportunities	4b) For community participants, does the process allow for learning about research methods?	YES (5/5)
	5a) Is the potential of the defined community for individual and collective learning reflected by the research process?	YES (3/5)
STRENGTHENED PARTNERSHIPS + ALLIANCES; Acknowledgment, visibility, recognition	5b) Is the potential of the defined community for action reflected by the research process?*	YES (4/5)
STRENGTHENED PARTNERSHIPS + ALLIANCES; Mutual value	5c) Does the process reflect a commitment by researchers and community participants to social, individual or cultural actions consequent to the learning acquired through research?	YES (5/5)
	6a) Do community participants benefit from the research outcomes?	YES (4/5)
STRENGTHENED PARTNERSHIPS + ALLIANCES; Trust	1e) Has attention been given to establishing within the community an understanding of the researchers' commitment to the issue?	YES (5/5)
	1c) Are interested members of the defined community provided opportunities to participate in the research process?	YES (5/5)

STRENGTHENED PARTNERSHIPS + ALLIANCES; Shared power	1f) Are community participants enabled to contribute their physical and/or intellectual resources to the research process?	YES (5/5)
	2a) Did the impetus for the research come from the defined community?	YES (5/5)
	2b) Is an effort to research the issue supported by members of the defined community?	YES (5/5)
	4a) Does the research process apply the knowledge of community participants in the phases of planning, implementation and evaluation?	YES (5/5)
	4f) Are community participants involved in analytic issues: interpretation, synthesis and the verification of conclusions?	YES (5/5)
	Is there attention to or an explicit agreement 6b) for acknowledging and resolving in a fair and open way any differences between researchers and community participants in the interpretation of the results?* 6c) between researchers and community participants with respect to ownership of the research data?*	YES (5/5) YES (5/5)
	6d) between researchers and community participants with respect to the dissemination of the research results?*	YES (5/5)
STRENGTHENED PARTNERSHIPS + ALLIANCES; Structural supports for community engagement	4d) Does the process allow for flexibility or change in research methods and focus, as necessary?	YES (5/5)
	4e) Are procedures in place for appraising experiences during implementation of the research?	NO (1/5)
	Is there attention to or an explicit agreement 6b) for acknowledging and resolving in a fair and open way any differences between researchers and community participants in the interpretation of the results?* 6c) between researchers and community participants with respect to ownership of the research data?*	YES (5/5) YES (5/5)
	6d) between researchers and community participants with respect to the dissemination of the research results?*	YES (5/5)
EXPANDED KNOWLEDGE; Bi-directional learning	3a) Can the research facilitate learning among community participants about individual and collective resources for self-determination?	YES (4/5)

	4c) For researchers, does the process allow for learning about the community health issue?	YES (4/5)
THRIVING COMMUNITIES; Community capacity and connectivity	3b) Can the research facilitate collaboration between community participants and resources external to the community?	NO (1/5)
THRIVING COMMUNITIES; Community power	3c) Is the purpose of the research to empower the community to address determinants of health?	YES (5/5)

*Note that these questions are duplicated to reflect their alignment with multiple domains and/or indicators in the Conceptual Model.

Reference: Frankish, C. J., R. Gold, L. W. Green, M. W. Kreuter, M. W. Kreuter, S. Mercer, D. Morisky, S. Nair, J. Ottoson, B. Poland, and Rootman. 1995. Guidelines and Categories for Classifying Participatory Research Projects in Health. Available at: <http://www.lgreen.net/guidelines.html> (accessed September 1, 2020).²

Appendix 2.2. Completed Guidelines for Assessing Participatory Research Projects (Mercer et al., 2008)

Guidelines

1. Participants and the Nature of Their Involvement

1a. Are the intended users (may include users, beneficiaries, and/or stakeholders)¹ of the research described adequately enough to assess their representation in the project?

- No description or description provides minimal help in assessing representation [or there are no plans to include intended users in the research process].
- Description provides partial but not adequate help in assessing representation.
- **Description is adequate for assessing representation.**

1b. Is the mix of participants included in the research process sufficient to consider the needs of the project's intended users?

- The mix suggests that the research will not consider or will minimally consider the needs of the intended users [or there are no plans to include intended users in the research process].
- The mix suggests that the research will partially but not sufficiently consider the needs of the intended users.
- **The mix suggests that the research will sufficiently consider the needs of the intended users.**

1c. Is effort made to address barriers to participation in the research

¹ Please refer to the *Key Terms* for an explanation of how *intended users* is defined and used in this and all subsequent guidelines.

process by intended users who might otherwise tend to be underrepresented?

- No or minimal effort to address barriers that might limit their participation [or there are no plans to include intended users in the research process].
- Partial but not substantial effort to address barriers that might limit their participation.
- **Substantial effort to address barriers that might limit their participation.**

1d. Has provision been made to build trust between researchers and intended users participating in the research process?

- No or minimal provision has been made [or there are no plans to include intended users in the research process].
- Moderate provision has been made.
- **Substantial provision has been made.**

1e. Do the researchers and intended users participating in the research process have a formal or informal agreement (verbal or written) regarding management of the project?

- There is no mention of a formal or informal agreement or of plans to develop a formal or informal agreement [or there are no plans to include intended users in the research process].
- There are plans to develop a formal or informal agreement.
- **A formal or informal agreement has been developed.**

Formal agreement is construed here as the participants being fully informed about the management of the project and providing consent.

2. Shaping the Purpose and Scope of the Research

2a. Was (were) the research question(s) developed (or refined) through a collaborative process between researchers and intended users?

- Research question(s) was (were) developed (or refined) mostly or entirely by the researchers with no or minimal contributions from the intended users [or development of the research question(s) is not discussed].
- Research question(s) was (were) developed (or refined) mostly or entirely by the intended users with no or minimal contributions from the researchers.
- **Both intended users and researchers made relatively substantial contributions to development (or refinement) of the research questions.**

2b. Has the proposed research project applied the knowledge and experience of intended users in conceptualizing and/or designing the research?

- Knowledge and experience of intended users has not been applied or has been minimally applied.

- Knowledge and experience of intended users has been partially but not sufficiently applied.
 - Knowledge and experience of intended users has been sufficiently applied.
- 2c. Does the proposed research project provide for mutual learning among intended users and researchers?
- No or minimal provision for mutual learning.
 - Moderate provision for mutual learning.
 - Substantial provision for mutual learning.
- 2d. Does the proposed research project consider multiple levels of determinants of health (for example, individual, familial, organizational, political, social, and/or economic)?
- Consideration of determinants at only one level.
 - Consideration of determinants at two levels.
 - Consideration of determinants at three or more levels.
- 2e. Does the proposed research project plan to build the capacity of intended users to address individual or broader determinants of health?
- No or minimal plans to build capacity.
 - Moderate plans to build capacity.
 - Substantial plans to build capacity.
- 3. Research Implementation and Context**
- 3a. Does the proposed research project apply the knowledge and experience of intended users in the implementation of the research?
- No or minimal application of knowledge and experience of intended users.
 - Moderate application of knowledge and experience of intended users.
 - Substantial application of knowledge and experience of intended users.
- 3b. Does the proposed research project provide intended users participating in the research process with *opportunity* to learn about research (whether or not the intended users choose to take that opportunity)?
- No or minimal opportunity to learn about research methods [or there are no plans to include intended users in the research process].
 - Moderate opportunity to learn about research methods.
 - Substantial opportunity to learn about research methods.
- 3c. Does the proposed research project provide researchers with *opportunity* to learn about user perspectives on the issue(s) being studied?

- No or minimal opportunity to learn about user perspectives.
 - Moderate opportunity to learn about user perspectives.
 - **Substantial opportunity to learn about user perspectives.**
- 3d. Do the researchers and intended users participating in the research process have a formal or informal agreement (verbal or written) regarding mutual decision making about potential changes in research methods or focus?
- There is no mention of a formal or informal agreement or of plans to develop a formal or informal agreement [or there are no plans to include intended users in the research process].
 - There are plans to develop a formal or informal agreement.
 - **A formal or informal agreement has been developed.**
- 3e. Does the proposed research project provide intended users with *opportunity* to participate in planning and executing the data collection (whether or not the intended users choose to take that opportunity)?
- No or minimal opportunity to participate.
 - **Moderate opportunity to participate.**
 - Substantial opportunity to participate.
- 3f. Does the proposed research project provide intended users with *opportunity* to participate in planning and/or executing the analysis (whether or not the intended users choose to take that opportunity)?
- No or minimal opportunity to participate.
 - Moderate opportunity to participate.
 - **Substantial opportunity to participate.**
- 3g. Are plans to involve intended users in interpreting the research findings sufficient to reflect knowledge of the particular context and circumstances in the interpretation?
- Plans to involve intended users suggest that knowledge of the particular culture and circumstances will not be reflected or will be minimally reflected in the interpretation [or there are no plans to involve intended users in interpretation of the research findings].
 - Plans to involve intended users suggest that knowledge of the particular culture and circumstances will be partially but not sufficiently reflected in the interpretation.
 - **Plans to involve intended users suggest that knowledge of the particular culture and circumstances will be sufficiently reflected in the interpretation.**

4. Nature of the Research Outcomes

- 4a. Does the proposed research project reflect sufficient commitment by researchers and intended users participating in the research process to action (for example, social, individual, and/or cultural) following the (learning acquired through) research?

- Proposed project reflects no or minimal commitment to action by both researchers and intended users, or partial commitment by one and no or minimal commitment by the other [or there are no plans to include intended users in the research process].
 - Proposed project reflects partial but not sufficient commitment to action by both researchers and intended users, or sufficient commitment to action by one and partial, minimal, or no commitment by the other.
 - **Proposed project reflects sufficient commitment to action by both researchers and intended users.**
- 4b. Do the researchers and intended users engaged in the research process have a formal or informal agreement (verbal or written) for acknowledging and resolving in a fair and open way any differences in the interpretation of research results?
- There is no mention of a formal or informal agreement or of plans to develop a formal or informal agreement [or there are no plans to include intended users in the research process].
 - There are plans to develop a formal or informal agreement.
 - **A formal or informal agreement has been developed.**
- 4c. Do the researchers and intended users engaged in the research process have a formal or informal agreement (verbal or written) regarding ownership and sharing of the research data?
- There is no mention of a formal or informal agreement or of plans to develop a formal or informal agreement [or there are no plans to include intended users in the research process].
 - There are plans to develop a formal or informal agreement.
 - **A formal or informal agreement has been developed.**
- 4d. Do the researchers and intended users engaged in the research process have a formal or informal agreement (verbal or written) regarding feedback of research results to intended users?
- There is no mention of a formal or informal agreement or of plans to develop a formal or informal agreement [or there are no plans to include intended users in the research process].
 - There are plans to develop a formal or informal agreement.
 - **A formal or informal agreement has been developed.**
- 4e. Do the researchers and intended users engaged in the research process have a formal or informal agreement (verbal or written) regarding the dissemination (and/or translation or transfer) of research findings?
- There is no mention of a formal or informal agreement or of plans to develop a formal or informal agreement [or there are no plans to include intended users in the research process].
 - There are plans to develop a formal or informal agreement.
 - **A formal or informal agreement has been developed.**

- 4f. Does the proposed research project provide intended users with *opportunity* to participate in dissemination of project findings to other intended users and researchers (whether or not the intended users choose to take that opportunity)?
- No or minimal opportunity to participate in dissemination to other intended users and researchers, or moderate opportunity to participate in dissemination to either intended users or researchers and no or minimal opportunity to participate in dissemination to the other.
 - Moderate opportunity to participate in dissemination to other intended users and researchers, or substantial opportunity to participate in dissemination to either intended users or researchers and moderate, minimal, or no opportunity to participate in dissemination to the other.
 - Substantial opportunity to participate in dissemination to other intended users and researchers.
- 4g. Is there sufficient provision for assistance to intended users to indicate a high probability of research results being applied?
- No or minimal provision for assistance has been made. Not considered relevant.
 - Partial but not sufficient provision for assistance has been made.
 - Sufficient provision for assistance has been made.
- 4h. Does the proposed research project plan for sustainability in relation to the purpose of the research (for example, by fostering collaboration between intended users and resource providers, funding sources, policymakers, holders of community assets, and the like)?
- No or minimal plans for sustainability.
 - Moderate plans for sustainability.
 - Substantial plans for sustainability.

Reference: Mercer, S. L., Green, L. W., Cargo, M., Potter, M. A., Daniel, M., Olds, S. R., & Reed-Gross, E. (2008). Reliability-tested guidelines for assessing participatory research projects. Community-based participatory research for health: from process to outcomes. Edited by: Minkler M, Wallerstein N. 2nd ed. San Francisco: Jossey-Bass

Appendix 3.1. Completed PRISMA checklist for study 1 (SLR)

Section and Topic	Item #	Checklist item	Location where item is reported
TITLE			
Title	1	Identify the report as a systematic review.	Yes p.1
ABSTRACT			
Abstract	2	See the PRISMA 2020 for Abstracts checklist.	See below for completed abstract checklist
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of existing knowledge.	p.4
Objectives	4	Provide an explicit statement of the objective(s) or question(s) the review addresses.	p.5
METHODS			
Eligibility criteria	5	Specify the inclusion and exclusion criteria for the review and how studies were grouped for the syntheses.	Eligibility criteria p.6 ¶1 Synthesis methods p.8; 9
Information sources	6	Specify all databases, registers, websites, organisations, reference lists and other sources searched or consulted to identify studies. Specify the date when each source was last searched or consulted.	Information sources p.6 ¶2
Search strategy	7	Present the full search strategies for all databases, registers and websites, including any filters and limits used.	Summary of search strategy p.6 ¶2 Sample search strategy is included in 'supplementary materials' (Table S3)
Selection process	8	Specify the methods used to decide whether a study met the inclusion criteria of the review, including how many reviewers screened each record and each report retrieved, whether they worked independently, and if applicable, details of automation tools used in the process.	Selection process p.7 ¶1
Data collection process	9	Specify the methods used to collect data from reports, including how many reviewers collected data from each report, whether they worked independently, any processes for obtaining or confirming data from study investigators, and if applicable, details of automation tools used in the process.	Data collection process p.7 ¶2
Data items	10a	List and define all outcomes for which data were sought. Specify whether all results that were compatible with each outcome domain in each study were sought (e.g. for all measures, time points, analyses), and if not, the methods used to decide which results to collect.	p.7 ¶2
	10b	List and define all other variables for which data were sought (e.g. participant and intervention characteristics, funding sources). Describe any assumptions made about any missing or unclear information.	p.7 ¶2
Study risk of bias assessment	11	Specify the methods used to assess risk of bias in the included studies, including details of the tool(s) used, how many reviewers assessed each study and whether they worked independently, and if applicable, details of automation tools used in the process.	p.7 ¶3
Effect measures	12	Specify for each outcome the effect measure(s) (e.g. risk ratio, mean difference) used in the synthesis or presentation of results.	N/A
Synthesis methods	13a	Describe the processes used to decide which studies were eligible for each synthesis (e.g. tabulating the study intervention characteristics and comparing against the planned groups for each synthesis (item #5)).	p.8; 9
	13b	Describe any methods required to prepare the data for presentation or synthesis, such as handling of missing summary	p.9

Section and Topic	Item #	Checklist item	Location where item is reported
		statistics, or data conversions.	
	13c	Describe any methods used to tabulate or visually display results of individual studies and syntheses.	p.8
	13d	Describe any methods used to synthesize results and provide a rationale for the choice(s). If meta-analysis was performed, describe the model(s), method(s) to identify the presence and extent of statistical heterogeneity, and software package(s) used.	p.8
	13e	Describe any methods used to explore possible causes of heterogeneity among study results (e.g. subgroup analysis, meta-regression).	p.19 ¶2 - 21
	13f	Describe any sensitivity analyses conducted to assess robustness of the synthesized results.	N/A
Reporting bias assessment	14	Describe any methods used to assess risk of bias due to missing results in a synthesis (arising from reporting biases).	N/A
Certainty assessment	15	Describe any methods used to assess certainty (or confidence) in the body of evidence for an outcome.	N/A
RESULTS			
Study selection	16a	Describe the results of the search and selection process, from the number of records identified in the search to the number of studies included in the review, ideally using a flow diagram.	p.10
	16b	Cite studies that might appear to meet the inclusion criteria, but which were excluded, and explain why they were excluded.	N/A
Study characteristics	17	Cite each included study and present its characteristics.	Supplementary materials Table S4
Risk of bias in studies	18	Present assessments of risk of bias for each included study.	Supplementary materials Table S5
Results of individual studies	19	For all outcomes, present, for each study: (a) summary statistics for each group (where appropriate) and (b) an effect estimate and its precision (e.g. confidence/credible interval), ideally using structured tables or plots.	N/A Main findings for each study are presented in supplementary materials Table S4
Results of syntheses	20a	For each synthesis, briefly summarise the characteristics and risk of bias among contributing studies.	p.11 ¶2; p.12 ¶2; p.16 ¶2; p.19 ¶2; p.23 ¶2
	20b	Present results of all statistical syntheses conducted. If meta-analysis was done, present for each the summary estimate and its precision (e.g. confidence/credible interval) and measures of statistical heterogeneity. If comparing groups, describe the direction of the effect.	N/A
	20c	Present results of all investigations of possible causes of heterogeneity among study results.	p.19 ¶2 - 21
	20d	Present results of all sensitivity analyses conducted to assess the robustness of the synthesized results.	N/A
Reporting biases	21	Present assessments of risk of bias due to missing results (arising from reporting biases) for each synthesis assessed.	N/A
Certainty of evidence	22	Present assessments of certainty (or confidence) in the body of evidence for each outcome assessed.	N/A
DISCUSSION			
Discussion	23a	Provide a general interpretation of the results in the context of other evidence.	p.25; 26; 27; 28
	23b	Discuss any limitations of the evidence included in the review.	p.28 ¶2; p.29 ¶1
	23c	Discuss any limitations of the review processes used.	p.28 ¶2
	23d	Discuss implications of the results for practice, policy, and future research.	p.29 ¶2

Section and Topic	Item #	Checklist item	Location where item is reported
OTHER INFORMATION			
Registration and protocol	24a	Provide registration information for the review, including register name and registration number, or state that the review was not registered.	p.5 ¶3
	24b	Indicate where the review protocol can be accessed, or state that a protocol was not prepared.	Included in References
	24c	Describe and explain any amendments to information provided at registration or in the protocol.	N/A
Support	25	Describe sources of financial or non-financial support for the review, and the role of the funders or sponsors in the review.	p.29 ¶3
Competing interests	26	Declare any competing interests of review authors.	N/A
Availability of data, code and other materials	27	Report which of the following are publicly available and where they can be found: template data collection forms; data extracted from included studies; data used for all analyses; analytic code; any other materials used in the review.	Where information is not available in the supplementary materials, the author will be happy to make all listed information available when requested.

From: Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. *BMJ* 2021;372:n71. doi: [10.1136/bmj.n71](https://doi.org/10.1136/bmj.n71)

Appendix 3.2 Sample search strategy for SLR

“type 1 diabet*” OR “type 1 diabetes mellitus” OR “diabetes mellitus type 1” OR T1DM OR “insulin dependent diabetes mellitus” OR “insulin dependent diabet*” AND child OR children* OR childhood OR youth* OR adolescen* OR pediatric* OR paediatric* OR juvenile* OR minor* OR baby OR babies OR infant* AND carer* OR “care giv*” OR caregiv* OR family OR families OR parent* OR guardian* OR mother* OR father* AND night OR nights OR sleep* OR nocturnal OR “sleep disruption” OR “disturbed sleep”

Appendix 3.3 Summary of study characteristics for included articles in SLR

Author/Year	Title	Aim	Design	Sample Size	Sample Characteristics	Main Findings
Abitol, 2020 Canada	When low blood sugars cause high anxiety: Fear of Hypoglycaemia among parents of youth with type 1 diabetes	To determine extent of fear of hypo among parents of children with T1D and to identify factors	QUANT Paper Survey	264	Carer 80% Patient: Age 2-18 (mean 12) A1c 8.0% Dx 6+mo (mean 5.9yr)	Most frequent worry: hypo while asleep or away from home Higher FoH associated with frequent and severe

		associated with greater FoH			Pump 45% Cgm 18%	hypoglycaemic events (HE); higher anxiety; CGM use; more bg checks; worse parental sleep quality; less engagement with treatment plan.
Bahadur, 2022 Turkey	Sleep Disorder and Behaviour Problems in Children with Type 1 Diabetes	To examine sleep and behaviour problems in children with T1D compared to controls and evaluate interaction of sleep on behaviour problems, maternal sleep and maternal depressive symptom.	QUANT Questionnaire	75 children 49 healthy controls	Patient: Age 4-12yrs (median 8.8) A1c 7.3% Dx 1.6-4.4yrs (mean 3) Pump Cgm	Children with T1D slept less than controls. No association with treatment modality or A1c. Children with T1D should be evaluated for sleep problems.
Barnard, 2016 USA	Impact of Chronic Sleep Disturbance for People Living with T1 Diabetes	Quantify extent of sleep disruption and explore personal experiences and determine impact of impaired sleep on wellbeing and diabetes related activities in cohort	MIXED-METHODS Online Survey	258 parents	Carer 86%f Pump 65%	Parents: Chronic sleep interruption was associated with detrimental impact on mood, work, family relationships, ability to exercise regularly or eat healthily, and happiness
Bergner, 2018 USA	Sleep in Teens with Type 1 Diabetes Perspectives from Adolescents and Their Caregivers	To identify barriers, facilitators, and consequences of obtaining sufficient sleep in adolescents with T1D	QUAL Interviews	25 adolescents/ parent dyads	Carer 88%f Patient: Age 13-17 (mean 15.6) A1c 8.9% Dx 1yr+ (mean 6.2) Pump 56% Cgm 20%	Barriers for adolescent sleep: electronics and diabetes management. Caregiver strategies: enforcing bedtimes, limit distractions. Many adolescents couldn't identify sleep facilitators
Bisio, 2020 USA	Sleep and diabetes-specific psycho-behavioural outcomes of a new automated insulin delivery system in young children with T1D and their parents (Loop)	Assesses sleep, psycho-behavioural and glycaemic outcomes of loop compared to sensor/pump in young children and their parents	QUANT Two consecutive 4-week phases A. Cgm/pump B. Loop Actigraph	13 children and 13 primary caregivers (one per child)	Carer 92%f Patient: Age 9.1 (7-10yrs) A1c 7.6% Dx >= 1yr (mean 5.6yr) Pump use mean 3.8 yrs Cgm 12/13 mean 3.5yrs	Actigraphy; no sig diff in sleep btw CGM and Loop Loop reduced number of nocturnal awakenings and sig improvements in sleep quality, hypoglycaemia fear, diabetes-related distress and depression Loop also improved 'Time in Range'
Bispham, 2021 USA	"I've had an alarm set for 3.00am for decades": The impact of Type 1 Diabetes on sleep	Understand impact of T1D on sleep and daily life in patients and caregivers	QUAL Focus groups	14 caregivers	Carer 93%f Patient: Age <18yrs (mean 11.36) A1c 7.2% Dx 1+yr (mean 5.57) Pump 93% Cgm 64%	Several hours sleep lost per week Reasons: hypo/hyper/anxiety More research needed on factors that cause sleep disruption Need diabetes-specific measure to capture these factors Many waken in response to cgm alerts

						Should be considered by diabetes care teams
Burckhardt, 2018	The use of CGM with Remote monitoring	To explore the effect of CGM plus remote on psychosocial outcomes in parents of T1D	QUANT	49 children and their parents	Patient: Age 2-12 yrs (mean 9.5) Dx 1+ yrs (mean 3.9yrs) A1c 7.7% Pump 64% Sensor 98%	Fear of hypoglycaemia reduced with use of CGM with remote monitoring Also, quality of life, family functioning, stress, anxiety and sleep improved significantly
Australia	Improves psychosocial measures in parents of children with T1D: a randomized crossover trial					
Burckhardt, 2019	Improvement in psychosocial outcomes in children with T1D and their parents following subsidy for CGM	Government program; free CGMs in Australia in 2017 (not flash) to <21yrs Opportunity to study effectiveness of CGM on psychosocial outcomes	QUANT	65 Parents 46 children	Age 0-18 yrs (13.3 mean) A1c 8.4% Dx mean 5 yrs	Fear of hypoglycaemia reduced (decrease in worry subscale) Parent sleep quality improved and nocturnal blood tests decreased A1c decreased
Australia						
Carreon, 2021	'I don't sleep through the night': Qualitative study of sleep in Type 1 Diabetes	Explore and characterise the perspectives of parents, partners and individuals with diabetes about T1D-related sleep issues.	QUAL (Secondary analysis of data from other project)	24 parents	Carer 96% Dx >1yr Child 1-25 yrs	Two Key themes identified: Emotional Distress and Sleep Disruption. Themes linked via shared sub-theme: Worry impacting sleep.
USA						
Cobry, 2020	Impact of the hybrid closed loop system on sleep and quality of life in youth with Type 1 Diabetes and their parents	determine the impact of real-world use of loop on sleep quality and duration in adolescents with T1D and their parents. Evaluation of FoH, diabetes-related distress and glucose monitoring satisfaction in both adolescents T1D and their parents. We hypothesized that system would improve sleep quality and duration and psychosocial measures.	QUANT	31 parent/child dyads	Age 10-17yrs (mean 13.9) A1c 8.3% Dx 1+yr (mean 6.5) Pump 78% Cgm 62% No DKA or SH in last 3 mo	Actigraphy: Neither parent or adolescent sleep characteristics changed Parent total sleep time reduced from 6h47min to 6h38min Moderate improvement in sleep quality for parents
USA						
Cobry, 2021	Health related QoL and treatment satisfaction in parents and children with T1D using closed-loop control	Describe the experience of children with T1 (6-13yrs) and parents on loop, device expectations, ease of use, impact on sleep and FoH and QoL	QUANT	101 dyads	Age 6-13 yrs (mean 11.2) A1c 7.7% Dx 1+ yrs (mean 5.2) 10+ u per day Normal weight Pump 80% Cgm 92%	Sleep scores for parent improved from 'poor quality' to 'adequate quality' with move from CGM to Loop but not statistically significant No statistical benefits seen for parent quality of life or treatment satisfaction
USA						
De Beaufort, 2021	Psychological well-being of	Pilot phase of larger study	QUANT Questionnaire	23 completed	Patient:	FoH: higher scores for hypo fear

Luxembourg	Parents of very young children with type 1 Diabetes – Baseline assessment	evaluating a hybrid closed-loop. Establish baseline in parents of association between FoH, well-being and child behaviour			Age 1-7 (median 5) A1c 7.4% Dx 6+m (mean 3yrs) Pump 100% Cgm 87.5%	behaviour than hypo worry. Daytime sleepiness scores high in 22% parents (5/23) Parental wellbeing negatively associated with FoH and positively associated with age and duration. Wellbeing, HFS nor sleepiness are associated with A1c
Elbalshy, 2020 New Zealand	Exploring parental experiences of using a do-it-yourself solution for CGM among children and adolescents with T1D: A Qualitative study	To explore the experience of families using mm-cgm, challenges faced and advice to others	QUAL	12	Age <=16 yrs A1c 7.2% Dx 3+mo (mean 2 yrs) Pump 75% Recent use of Maio Maio	Use of CGM led to perceived decrease in frequency of hypoglycaemia. Reported that easy access to bg readings, trends and alarms decreased their disease burden and improved their sleep quality. Difficulties; tech challenges and lack of support from clinical teams
Feeley, 2019 USA	Sleep in Caregivers of Children with Type 1 Diabetes	To explore caregivers' descriptions of their experience of night-time sleep	MIXED-METHODS	22 caregivers	86% mothers (+2 grandmas) Patient: Age 10-18 (mean 12.2) Dx 2-16 (mean 5.4) Pump 81% Cgm 0%	Caregivers reported short sleep duration. Over half need more than 7 hrs to feel best, 64% trouble sleeping at night, 86% caregiving interferes with sleep, 54% sleep very important. Themes: Anxiety about blood glucose and Night-time disruption.
Feeley, 2021 USA	Sleep in Parental Caregivers and Children with Type 1 Diabetes	To explore associations between parent and child sleep in school-age children (6-12). Also, to examine relationship between sleep, stress and depression in parents and anxiety, fatigue and A1c in children.	QUANT	18 dyads	Carer 83.3% Patient: Age 6-12 yrs (mean 9.6) A1c 7.53% Dx 2-6 (mean 3) Pump 22%	Mean sleep duration 7.6 hrs parents/ 8.8 hrs child. Strong correlations between actigraphy (sleep quantity) and other measures ie depressive symptoms and sleep quality, short parent sleep and higher A1c
Harrington, 2017 USA	Management and Family Burdens Endorsed by Parents of Youth <7 Years Old with Type 1 Diabetes	To understand present-day burdens experienced by parents caring for their young child with T1D. Also, to understand the impacts at different development stages (<4yrs, 4-6, 6-7)	QUANT	597 children	Patient: Age <7yrs (mean 5.2) A1c 8.2% Dx >1yr (mean 2.4) Pump 58% Cgm 31%	Most frequently endorsed burden: Worry low blood sugar (74%) Future complications (70%) Management 'off track' (61%) Sleep, diminished quality and quantity (59%) Work responsibility and care (55%)
Haugstvedt, 2011 Norway	Perceived Family Burden and Emotional distress: Similarities and	To analyse a.) perceived burden and emotional	QUANT	115 children 200 parents: 103 mothers 97 fathers	Patient: Age 0-15 yrs (mean 10.6) A1c 8.1%	Greatest burden; long term health concern for mothers and fathers

	Differences between mothers and fathers of children with type 1 diabetes in a population-based study	distress in mothers and fathers of children with T1D and b.) associations between parental burden and distress and factors related to the child		85 both parents 18 mother only 12 father only	Dx 0.3-14.2yr (mean 3.9yrs) Pump 43%	Mother's carried sig greater burden related to medical management and greater emotional distress than fathers NBGM sig association with perceived parental burden Nocturnal hypo. sig. assoc. with parental emotional distress
Herbert, 2015 USA	The Impact of Parent's Sleep Quality and Hypoglycaemia Worry on Diabetes Self-Efficacy	Part of a baseline assessment for a RCT. Aim 1. Describe sleep characteristics among parents of juveniles T1D Aim 2. Investigate the relationship among hypo worry, parent's sleep and Diabetes self-efficacy Aim 3. Determine if parents' sleep quality mediates the Relationship btw hypo. worry and D. self-efficacy.	QUANT	134 parents	Carer 90% Patient: Age 1-6yrs (mean 5.33yrs) A1c 8.13% Dx >6mo (mean 2yrs)	Parents report sleeping less than guidelines Endorsed greater global sleep problems than standardized norms for healthy populations 33.3% reported overall sleep quality as fairly or very bad Hypoglycaemia worry and parent's sleep quality sig related to diabetes self-efficacy Many parents experienced disrupted sleep that impacts their perceived ability to perform T1D management
Jaser, 2016 USA	Brief Report: Sleep Disturbances in Young Children with Type 1 Diabetes	To conduct a pilot study to collect multi-method data on sleep in young children with T1D. We hypothesise that young children and their parents would exhibit significant sleep disturbances	QUANT	10 parents & 10 children	Patient: Age 2-5yrs (mean 4.1) A1c 8.4% Dx >6mo Pump 50% Cgm 10%	Insufficient sleep duration in patients and their parents Parent's self report 6.2hrs 80% endorsed not reaching 7-9hrs recommended 100% carry out NCP Downloads of glucometer readings showed mean 1.7 NCP per night
Jaser, 2017 USA	Sleep in Children with Type 1 Diabetes and Their Parents in the T1D Exchange	Sought to characterise sleep in children with T1 and their parents and to examine the associations between child sleep, glycemic control and adherence, parent sleep and wellbeing, parental FoH and nocturnal caregiving behaviour And diabetes outcomes (a1c, HE and DKA) as well as pump and cgm.	QUANT	515 parents	Patient: Age 2-12 yrs (2-4; 5-12) (mean 9yrs) A1c 7.8% (8.4 clinic) Dx >1yr (mean 4) Pump 80% Cgm 39%	67% children met criteria for poor sleep quality Trend higher A1c where poorer sleep quality Poorer child sleep quality associated with poorer parent sleep quality and parental wellbeing and fear of hypoglycaemia

Landau, 2014 Israel	Parental sleep quality and continuous glucose monitoring system in children with T1D	Hypothesised that use of cgm may reduce parental anxiety and improve the quality of sleep. Purpose to compare objective and subjective sleep quality and sleep patterns of parents and children before and during cgm use.	QUANT	13 parents	Carers 77% Patient: Age <17 yrs (mean 9.3yrs) A1c 7.5% Dx 3.4yrs Pump 100%	PSQI total score demonstrated similar quality of sleep with and without use of the CGM. Six of thirteen parents reported severe sleep problems, with and without CGM. More awakenings with CGM although self-perception of sleep quality remained unchanged
Lindstrom, 2011 Sweden	Parental burnout in relation to sociodemographic, psychosocial and personality factors as well as disease duration and glycaemic control in children with T1D	To examine associations btw burnout in fathers and mothers of T1D and a number of factors known to be associated with burnout in other contexts; SES, Psychosocial, Personality, Medical	QUANT	148 children 142 mothers 109 fathers	Dx (mean 5.4yrs)	Psychosocial background factors associated with burnout but no associations btw burnout and sociodemographic or medical factors. Low support; lack of leisure time; financial concerns; perception that illness affects everyday life. Low self-esteem and high need for control were risk factors for maternal burnout
Mccauley, 2020 New Zealand	Sleep and Night-time Caregiving in Parents of Children and Adolescents with T1D – A Qualitative Study	Explore and describe: the rang and interplay of diabetes specific factors affecting parental sleep' the nature of such sleep disturbance; the respective experience mother/father; impact daytime; proposed solutions Actigraph used to authenticate findings.	MIXED-METHODS	10 mothers 10 fathers 4 sets from same household Actigraphy 16 parents/14 child	Patient: Age 1-17 yrs (mean 8.7) Pump 57% Cgm 61%	Poor quality sleep in 13/20 parents; awakenings and perception of sleeping lightly Drivers: glucose monitoring and fear of hypoglycaemia Greater sleep disturbance in period following diagnosis and when transitioning to new technology Mothers greater nocturnal care burden Technology advocated to improve nocturnal burden but also perceived to contribute to sleep disturbance
Monaghan, 2009 USA	Night-time caregiving behaviours among parents of young children with T1D: Associations with illness characteristics and parent functioning	Designed to examine parent nighttime management behaviour, specifically nocturnal blood glucose monitoring, in a sample of young children with T1, and to explore the relationships among NCP, child illness characteristics;	QUANT Secondary analysis of data from larger study	71 families	Carer 97% Patient: Age 0-6 yrs (mean 4.45) A1c 7.49% Dx >6mo (mean 1.43yrs) Pump 4%	33.3% of parents regularly monitor nocturnal bg levels Positive association with basal/bolus regimen; longer duration of illness; increased parent reported anxiety; parenting stress

		health outcomes; parent emotional factors.				
Monaghan, 2012 USA	Sleep behaviours and parent functioning in young children with T1D	To descriptively assess child sleep habits and evaluate associations with parent sleep characteristics, emotional functioning, and diabetes care. Predict sig sleep problems with stress, anxiety and depression.	QUANT Phone interviews	24 parents	Carer 88%f Patient: Age 2-5yrs (mean 4.1) A1c 7.87% Dx >6mo (mean 2.1yr) MDI 54% Conventional 46%	Child sleep characteristics were within normal limits. Increased bedtime resistance and behavioural insomnia were related to greater parent stress, anxiety and depression. Also, with intensive insulin regimen. T1D illness management may impact child and parent sleep and parent emotional functioning.
Morrow, 2021 USA	Sleep habits of early school-aged children with T1D and their parents: Family characteristics and Diabetes management	Sought to describe sleep habits in children and their caregivers and examine associations between sleep characteristics and demographic and clinical factors. Also explored associations between child and parent sleep with family functioning, parental 'fear of hypo', diabetes distress, and family chaos	QUANT	40 parent-child dyads	Carer 92.5%f Patient: Age 5-9yrs (mean 8.1) A1c 8.5% Dx 12mo+ (mean 3.5yrs) Pump 62.5% Cgm 62.5%	Most children and parents obtained insufficient sleep. Actigraph: child 7.9hr and parent 6.7hrs Parents sleep duration and efficiency were related to child's A1c. Parental fear of hypoglycaemia was associated with poorer sleep quality in parents and parental diabetes distress
Oser, 2017 USA	A novel approach to identifying barriers and facilitators in raising a child with T1D: Qualitative analysis of caregiver blogs	To better understand the issues faced by caregivers to children with T1D via qualitative analysis of blog content	QUAL	140 blog posts and 663 associated comments Authors 2 mother/1 father of children aged 4-16	n/a	5 major themes: - Impact of child's diagnosis - Burden of intense self-management for caregivers - Technology impacts on fear of hypoglycaemia and caregiver burden - Caregiver issues with delayed diagnoses - Caregiver resilience Misinformation rare and benign
Sinisterra, 2020 USA	Young children with T1D: sleep, health-related qol, and CGM use	Describes sleep characteristics of young children with T1D and explores how child sleep and BBGM disturbances relate to paediatric and	QUANT Secondary analysis of data from a larger behaviour intervention	46	Carer 89%f Patient: Age 2-5 yrs (mean 4.7) A1c 8.3% Dx >1yr (mean 2.0) Pump 26% Cgm 63%	Child sleep disturbance was negatively associated with parental life satisfaction. Use of CGM reduced child sleep disturbance but increased parent sleep disturbance

		parental HRqol, while considering the relationship with CGM				and NCP. Parental QOL relationship to sleep disturbance mediated by NCP.
Sullivan-Bolyai, 2003 USA	Constant Vigilance: Mothers' work parenting young children with T1D	To provide a detailed description of day-to-day management experiences of mothers raising young children	QUAL	28 mothers	Carer 100% Patient: Age <4 yrs (mean 2.9) A1c Dx 3m+ (mean 1.25yr)	Mothers manage patient illness with "constant vigilance" Concerns; hypoglycaemia and providing competent care Learning in action and adjusting to hypoglycaemic events and developmental milestones Resulting in maternal physical and emotional problems
Van Name, 2018 USA	Night-time is the worst time: parental fear of Hypoglycaemia in young children with T1D	Undertaken to characterize the extent of parental fear of hypo in parents of young children under 7 and to identify enquire into associations with demographic and clinical characteristics, A1c and technology Hypothesis: greater FoH = younger, high A1c, recent SH and use pump and cgm	QUANT	549	Patient: Age 0-7yrs (mean 5.2) A1c 8.2% Dx>1yr (mean 2.4) Pump 58% Cgm 32%	Mean parental fear of hypoglycaemia score 36.1 Most frequent worries: Nocturnal hypoglycaemia and not recognising Mean score not associated with age, A1c or recent severe Hypo event Nocturnal worries significantly higher in pump and cgm users
Walker, 2016 USA	T1D through two lenses: comparing adolescent and parental perspectives with photovoice	To better understand the ways adolescents living with T1D and their caregivers perceive and experience this disease.	QUAL 'Photovoice'	40 youths 33 parent caregivers	Carer 79% (24mothers/ 2granny) Patient: Age 12-19yrs (mean 15) A1c Dx 2+ yrs (mean 6)	4 Key themes - diabetes supplies - food - coping and resilience - disease encroachment Adolescents took pictures of their bodies to depict how T1 trespasses on their lives while parents took pictures of clocks to denote sleep disruption or exhaustion from constant care demands

Appendix 3.4 Quality Analysis Utilising the Quality Assessment with Diverse Studies (QuADS) Tool for study 1 (SLR) (Harrison et al., 2021)

Criteria #	Description
1.	Theoretical or conceptual underpinning to the research
2.	Statement of research aim/s
3.	Clear description of research setting and target population
4.	The study design is appropriate to address the stated research aim/s
5.	Appropriate sampling to address the research aim/s
6.	Rationale for choice of data collection tool/s
7.	The format and content of data collection tool is appropriate to address the stated research aim/s
8.	Description of data collection procedure
9.	Recruitment data provided
10.	Justification for analytic method selected
11.	The method of analysis was appropriate to answer the research aim/s
12.	Evidence that the research stakeholders have been considered in research design or conduct
13.	Strengths and limitations critically discussed

QuADS Criteria	Abitol	Bahadur	Barnard	Bergner	Bisio	Bispham	Burckhardt 2018
1.	3	2	3	2	2	2	1
2.	3	3	3	2	2	3	2
3.	3	3	2	3	2	2	2
4.	3	3	3	3	3	3	3
5.	2	2	1	2	3	2	2
6.	2	3	2	2	2	2	2
7.	2	3	2	3	3	3	3
8.	3	2	2	3	2	2	3
9.	3	1	1	1	1	2	1
10.	2	1	2	3	2	1	2
11.	3	3	2	3	3	2	3
12.	1	1	1	1	1	1	1
13.	3	3	2	1	3	3	1
Totals	33	30	26	29	29	28	26

QuADS Criteria	Burckhardt 2019	Carreon	Cobry 2020	Cobry 2021	De Beaufort	Elbalshy	Feeley 2019
1.	2	3	3	3	2	3	3
2.	2	3	3	3	1	3	3
3.	3	3	3	2	1	2	3
4.	3	3	3	3	3	3	3
5.	2	3	3	2	2	2	2
6.	3	3	3	3	1	3	3
7.	3	3	3	2	3	3	3
8.	3	3	3	2	2	3	3
9.	1	3	3	1	1	2	1
10.	2	3	3	3	3	3	2
11.	3	2	3	3	2	3	3
12.	1	1	1	1	1	1	2
13.	3	3	3	3	2	1	3
Totals	31	36	37	31	24	32	34

QuADS Criteria	Feeley 2021	Harrington	Haugstvedt	Herbert	Jaser 2016	Jaser 2017	Landau
1.	3	3	3	3	2	2	3
2.	2	3	3	3	2	1	3
3.	3	2	2	2	2	2	2
4.	3	2	3	3	3	2	3
5.	2	3	2	2	3	2	1
6.	3	2	2	2	2	2	2
7.	3	2	3	3	3	3	3
8.	3	2	3	3	1	2	2
9.	1	1	2	3	1	1	1
10.	3	2	2	3	1	3	2
11.	3	3	3	3	3	3	3
12.	1	1	1	1	1	1	1
13.	3	3	3	3	1	3	1
Totals	33	29	32	34	25	27	27

QuADS Criteria	Lindstrom	Macaulay	Monaghan 2009	Monaghan 2012	Morrow	Oser	Sinisterra
1.	3	3	3	3	3	2	2
2.	3	3	3	3	3	3	3
3.	2	3	3	3	3	2	2
4.	3	3	3	3	3	3	3
5.	2	3	2	2	2	2	2
6.	2	2	3	3	3	1	2
7.	3	3	3	3	3	2	3
8.	1	3	2	1	2	3	2
9.	3	1	3	3	3	1	2
10.	2	3	3	3	3	1	1
11.	3	3	3	3	3	3	3
12.	1	2	1	1	1	2	1
13.	3	3	3	3	2	3	2
Totals	31	35	35	34	34	28	28

QuADS Criteria	Sullivan- Bolyai	Van Name	Walker
1.	3	3	2
2.	3	3	2
3.	2	2	2
4.	3	3	3
5.	2	3	2
6.	3	2	3
7.	3	3	3
8.	3	2	3
9.	2	1	1
10.	3	3	2
11.	3	3	3
12.	1	1	1
13.	1	3	2
Totals	32	32	29

Appendix 6.1 Study 3 (Fear of Hypoglycaemia) online questionnaire

SECTION 1. Demographics Questionnaire

To begin, we would like to ask you some standard demographic questions.

Firstly, about you, the **parent caregiver**:

Questions
What is your gender? 1. Male 2. Female 3. Gender non-binary 4. Prefer not to say
What is the highest level of education you hold? 1. No Formal Education / Training 2. Primary School Level 3. Secondary School Level 4. Apprenticeship / Diploma 5. University Graduate 6. Post-Graduate
Please indicate your age group? 18-24 25-34 35-44 45-54 55-64 65+
What is your current employment status? 1. Employed full time 2. Employed part time 3. Looking after family / home 4. Not working due to my own illness or disability 5. Other Did your employment status change as a result of your child's diagnosis?
A household may have different sources of income and more than one household member may contribute to it. Thinking of your household's total monthly income: is your household able to make ends meet....?

1. Very easily
2. Easily
3. Fairly easily
4. With some difficulty
5. With difficulty
6. With great difficulty

SECTION 2

Now, about your child with Type 1 Diabetes (T1D).

If you have more than one child with T1 please **choose one** to keep in mind when you answer the questions below and respond to the survey.

Questions
What age is your child with Type 1 Diabetes?
What age was your child when they were diagnosed?
Which of the following do you use on a daily basis? (Select all that apply) 1. Insulin injection (pens or syringe) 2. Insulin pump 3. Blood testing meter 4. Flash Glucose Monitoring (Libra) 5. Continuous glucose monitoring without closed loop (Dexcom or Medtronic) 6. Continuous glucose monitoring with closed loop (CGM linked to pump) 7. Other (please specify)
What was your child's most recent HbA1c result that you can remember (approx.)?
Has your child experienced a severe hypoglycaemic event (low blood glucose) requiring medical assistance? 1. Y / 2. N If yes, how many times?
Has your child had an episode of diabetic ketoacidosis (DKA) that required medical assistance? 1. Y / 2. N If yes, how many times?

SECTION 3 KNOWLEDGE AND ENGAGEMENT

In this section we want to explore how comfortable parent caregivers are with the large amount of information needed for managing their child's condition.

Below are some statements about the information required to manage your child's T1D. Please indicate on the scale how much you disagree or agree with each statement:

	1. Strongly Disagree 2. Disagree 3. Neutral 4. Agree. 5. Strongly Agree
1	I feel comfortable with all the information needed for managing my child's type 1 diabetes
2	My level of T1D knowledge is very good?
3	I always try to learn more about Diabetes management
4	Sometimes I find that all the information for managing my child's diabetes is overwhelming
5	I contact the Diabetes team to ask questions between appointments
6	I follow diabetes discussion groups, blogs and advocacy groups to get more information
7	I try to find reliable online sources of information on managing T1 Diabetes
8	I don't like to think about T1D between clinic appointments
9	I like to talk to and learn from other people living with T1D (family, friends, wider T1D community)

SECTION 4. Managing your child's type 1 Diabetes

In this section we're looking at the behaviours and decisions involved in managing your child's condition

For this section, in the questions below, "I" means yourself as caregiver or both you and your child together or your child alone.

Please read the statements below and indicate on the scale the degree to which you feel that the statement applies to you:

	1.Does not apply to me 2. Slightly applies to me 3. Applies to me. 4. Strongly applies to me 5. Very strongly applies to me
1	I check my child's glucose levels before each meal.
2	I adjust my child's insulin doses to the carbohydrate content of their meals.
3	I always make sure my child boluses before they eat

4	I try to time insulin boluses according to whether my child is eating fast or slow acting carbohydrates
5	I adjust my child's insulin doses according to their current glucose levels and any planned physical activities
6	I try my best to correct for my child's high glucose levels whenever necessary
7	I carry fast acting carbohydrates to enable quick treatment of low blood glucose
8	When my child has low blood glucose, I try to calculate the amounts of carbohydrates needed that will avoid causing rebound high blood glucose
9	I always change my child's blood glucose sensor on schedule
10	I vary my injection or pump canula insertion site consistently
11	I use records, food diaries and sensor or pump reports to help with diabetes management planning
12	I usually know what my child's insulin sensitivity factor is
13	I regularly check if my child's insulin sensitivity/correction factor needs to be changed
14	I regularly check that my child's insulin ratios are correct (basal, bolus)

SECTION 5
Hypoglycaemia Fear Survey – parent version (HFS-P)

This section of the survey contains a questionnaire about the behaviour and worries of parent caregiver for juveniles with T1D. After the survey there will be some questions asking your opinion of the questionnaire.

I. Behaviour: Below is a list of things people with diabetes sometimes do in order to avoid low blood sugar. Read each item carefully. Click on one of the numbers that best describes your activity (ACTIONS)
1 = never 2 = rarely 3 = sometimes 4 = often 5 = very often

HFSB1	Have your child eat large snacks at bedtime	1	2	3	4	5
HFSB2	Avoid having your child being alone when their sugar is likely to be low (hypo)	1	2	3	4	5
HFSB3	Allow blood sugar to be a little high to be on the safe side	1	2	3	4	5
HFSB4	Keep child's sugar higher when they will be alone for a while	1	2	3	4	5
HFSB5	Have child eat something as soon as they feel the first sign of low blood sugar (hypo)	1	2	3	4	5
HFSB6	Reduce my child's insulin when I think their blood sugar is too low	1	2	3	4	5
HFSB7	Keep my child's blood sugar higher when they plan to be away from me for a while	1	2	3	4	5
HFSB8	Have your child carry fast-acting sugar	1	2	3	4	5
HFSB9	Have your child avoid a lot of exercise when you think their blood sugar is low	1	2	3	4	5
HFSB10	Check my child's sugar often when they plan to go on an outing	1	2	3	4	5

What do you think about the questions asked in the 'Behaviour' part of the questionnaire?

II. Worry: Below is a list of concerns parents of children with diabetes sometimes have. Please read each item carefully. Click on one of the numbers that best describes How often you WORRY about each item 1 = never 2 = rarely 3 = sometimes 4 = often 5 = very often						
HFSW1	Child not recognising or realising they are having a low blood sugar (hypo)	1	2	3	4	5
HFSW2	Child not having carbohydrate with them	1	2	3	4	5
HFSW 3	Child feeling dizzy or passing out in public	1	2	3	4	5
HFSW4	Child having a low blood sugar (hypo) while asleep	1	2	3	4	5
HFSW5	Child embarrassing self or friends/family in a social situation	1	2	3	4	5
HFSW6	Child having a low blood sugar (hypo) when alone	1	2	3	4	5
HFSW7	Child appearing stupid or clumsy	1	2	3	4	5
HFSW8	Child losing control	1	2	3	4	5
HFSW9	No one being around to help child during a low blood sugar (hypo)	1	2	3	4	5
HFSW10	Child making a mistake or having an accident at school	1	2	3	4	5
HFSW11	Child getting a bad evaluation at school because of something that happens when their blood sugar is low (hypo)	1	2	3	4	5
HFSW12	Child having seizures or convulsions	1	2	3	4	5
HFSW13	Child developing long term complications from frequent low blood sugar (hypo)	1	2	3	4	5
HFSW14	Child feeling light-headed or faint	1	2	3	4	5
HFSW15	Child having a low blood sugar (hypo) in response to insulin	1	2	3	4	5

What do you think of the questions asked in the 'Worry' part of the questionnaire?

The HFS-P questionnaire you just completed measures ‘Fear of Hypoglycaemia’ in parent caregivers.

What do you think about the concept ‘Fear of Hypoglycaemia’?

Do you think it applies to you?

1. yes
2. No
3. Not sure

Can you describe how this does or doesn’t apply to you?

What do you think a higher score on the questionnaire (mostly often/very often) would represent?

What do you think a lower score on the questionnaire (mostly rarely/never) would represent?

What other thoughts about the questionnaire did you have?

THANK YOU very much for taking part in this survey, we really appreciate you sharing your experience with us.

If you are interested in participating further in this research project, by taking part in an online interview or an online focus group, please use the email below (screenshot page) to contact the researcher and express your interest.

Please press the DONE button to complete.

Appendix 6.2 The STROBE cross-sectional study checklist for study 3 (Fear of Hypoglycaemia)

	Item No	Recommendation	Check box	Location
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	X	p.1 line 16
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	X	p.2 line 23
Introduction				
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	X	p.3 line 62
Objectives	3	State specific objectives, including any prespecified hypotheses	X	p.6/line 134 p.7/line 168 p.10/line 243
Methods				
Study design	4	Present key elements of study design early in the paper	X	p.6 line 141

Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	X	Phase 1: p.8/line 171 Phase 2: p.10/line 248
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants	X	Phase 1: p.8/line 171 Phase 2: p.10/line 248
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	X	p.8 line 190
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	X	p.8 line 190
Bias	9	Describe any efforts to address potential sources of bias	X	p.7/line 156 p.10/line 258
Study size	10	Explain how the study size was arrived at	X	p.8 line 183
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	X	p.9 line 219
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	X	Quant. p.9/line 219 Qual. p.9/line 227 & p.11/line 270-
		(b) Describe any methods used to examine subgroups and interactions	X	p.9/line 224
		(c) Explain how missing data were addressed	X	p.9/line 226
		(d) If applicable, describe analytical methods taking account of sampling strategy	N/A	
		(e) Describe any sensitivity analyses	N/A	
Results				
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	X	Phase 1: p.12/line 291 Phase 2: p.15/para.3
		(b) Give reasons for non-participation at each stage	N/A	
		(c) Consider use of a flow diagram	N/A	
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	X	Phase 1: p.12/line 291- Phase 2: p.16/line 403-

		(b) Indicate number of participants with missing data for each variable of interest	X	P.12/line 291-, 303
Outcome data	15*	Report numbers of outcome events or summary measures	X	P.8/line 190-
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	N/A	
		(b) Report category boundaries when continuous variables were categorized	X	p.12/line 309, 314, 319
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	N/A	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	X	Phase 1: p.13/line 330- Phase 2: p.17-
Discussion				
Key results	18	Summarise key results with reference to study objectives	X	p.24/line 535-
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	X	p.27/line 609
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	X	p.24-26
Generalisability	21	Discuss the generalisability (external validity) of the study results	X	p.24/line 533
Other information				
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	X	p.28/line 635

Appendix 6.3 Completed SRQR qualitative study checklist for study 3 (Fear of Hypoglycaemia)

		Reporting Item	Page/Line Number
Title	1	Concise description of the nature and topic of the study identifying the study as qualitative or indicating the approach (e.g. ethnography, grounded theory) or data collection methods (e.g. interview, focus group) is recommended	2/16
Abstract	2	Summary of the key elements of the study using the abstract format of the intended publication; typically includes background, purpose, methods, results and conclusions	2/23-
Problem formulation	3	Description and significance of the problem / phenomenon studied: review of relevant theory and empirical work; problem statement	3/62-
Purpose or research question	4	Purpose of the study and specific objectives or questions	Phase 1: 7/174 Phase 2: 10/243
Qualitative approach and research paradigm	5	Qualitative approach and guiding theory if appropriate; identifying the research paradigm is also recommended; rationale. The rationale should briefly discuss the justification for choosing that theory, approach, method or technique rather than other options available; the assumptions and limitations implicit in those choices and how those choices influence study conclusions and transferability. As appropriate the rationale for several items might be discussed together.	Phase 1: 8/227 Phase 2: 11/270
Researcher characteristics and reflexivity	6	Researchers' characteristics that may influence the research, including personal attributes, qualifications / experience, relationship with participants, assumptions and / or presuppositions; potential or actual interaction between researchers' characteristics and the research questions, approach, methods, results and / or transferability	7/157

Context	7	Setting / site and salient contextual factors; rationale	Phase 1: 8/179 Phase 2: 10/248
Sampling strategy	8	How and why research participants, documents, or events were selected; criteria for deciding when no further sampling was necessary (e.g. sampling saturation); rationale	Phase 1: 8/179 Phase 2: 10/249, 266
Ethical issues pertaining to human subjects	9	Documentation of approval by an appropriate ethics review board and participant consent, or explanation for lack thereof; other confidentiality and data security issues	8/186
Data collection methods	10	Types of data collected; details of data collection procedures including (as appropriate) start and stop dates of data collection and analysis, iterative process, triangulation of sources / methods, and modification of procedures in response to evolving study findings; rationale	Phase 1: 9/215 Phase 2: 10/259
Data collection instruments and technologies	11	Description of instruments (e.g. interview guides, questionnaires) and devices (e.g. audio recorders) used for data collection; if / how the instruments(s) changed over the course of the study	Phase 1: 9/215 Phase 2: 10/256-
Units of study	12	Number and relevant characteristics of participants, documents, or events included in the study; level of participation (could be reported in results)	Phase 1: 12/291 Phase 2: 16/403
Data processing	13	Methods for processing data prior to and during analysis, including transcription, data entry, data management and security, verification of data integrity, data coding, and anonymisation / deidentification of excerpts	Phase 1: 9/227 Phase 2: 11/265
Data analysis	14	Process by which inferences, themes, etc. were identified and developed, including the researchers involved in data analysis; usually references a specific paradigm or approach; rationale	Phase 1: 9/227 Phase 2: 11/275

Techniques to enhance trustworthiness	15	Techniques to enhance trustworthiness and credibility of data analysis (e.g. member checking, audit trail, triangulation); rationale	7/157 11/281
Syntheses and interpretation	16	Main findings (e.g. interpretations, inferences, and themes); might include development of a theory or model, or integration with prior research or theory	Phase 1: 13/326- Phase 2: 17-24
Links to empirical data	17	Evidence (e.g. quotes, field notes, text excerpts, photographs) to substantiate analytic findings	Phase 1: 13/330- Phase 2:17-19
Integration with prior work, implications, transferability and contribution(s) to the field	18	Short summary of main findings; explanation of how findings and conclusions connect to, support, elaborate on, or challenge conclusions of earlier scholarship; discussion of scope of application / generalizability; identification of unique contributions(s) to scholarship in a discipline or field	24/535-
Limitations	19	Trustworthiness and limitations of findings	27/610
Conflicts of interest	20	Potential sources of influence of perceived influence on study conduct and conclusions; how these were managed	28/633
Funding	21	Sources of funding and other support; role of funders in data collection, interpretation and reporting – no funding	28/635

Appendix 7.1 Full online survey as deployed for study 4, in the hospital diabetes clinic

Nocturnal Caregiving for Juveniles with Type 1 Diabetes (T1D)

STUDY INFORMATION SHEET

THE STUDY

The aim of this project is to understand more about the night-time experience of parents caring for children living with Type 1 Diabetes (T1D). Before you decide whether or not you wish to take part, please read this information sheet carefully.

WHY HAVE I BEEN INVITED TO TAKE PART?

We have asked you to take part in the study because you are a caregiver for a child with T1D, it is your experience that we are interested in.

DO I HAVE TO TAKE PART?

Participation is completely anonymous and voluntary, if you decide not to take part, it won't affect your child's current or future medical care in any way.

CAN I CHANGE MY MIND?

You can change your mind about taking part in the study and opt out at any time by logging off. This won't affect you in any way and you don't have to give any reason. As the data is collected anonymously, it will not be possible to withdraw after you have pressed the submit button.

WHAT WILL HAPPEN DURING THE RESEARCH?

You will be invited to fill out a survey taking approximately 10-15 minutes. There will be demographic and illness-related questions, some questions about your night-time caregiving practices and some open questions about your personal experiences and opinions on night-time caregiving.

ARE THERE ANY BENEFITS FROM YOUR PARTICIPATION?

Taking part in this study will not directly benefit you. However, research work done with your responses will help us to understand more about caregiving at night for children with T1D, which will contribute to the development of supports and interventions that may help relieve the burden for those who experience it.

ARE THERE ANY RISKS FROM YOUR PARTICIPATION?

There will not be any material risks from your participation, it is possible that answering questions about the burdens of caregiving for your child will cause you some distress. If this is the case, you may choose to stop taking the survey or to take a break and resume when you feel comfortable doing so.

DATA PROTECTION

WHAT INFORMATION ABOUT ME WILL BE COLLECTED AND HOW WILL IT BE KEPT?

- The survey will be completed anonymously and will be hosted on a secure digital platform, which does not extract any data other than that explicitly referenced by the survey questions.
- Demographic and health-related data that will be collected anonymously will include; gender, parent education level achieved, age of child, length of time since diagnosis, HbA1c, insulin delivery regimen (injections/pump), use of other technology (CGM; closed loop).
- Data collected from the survey will be downloaded and stored digitally on a double password protected external hard drive that will be kept in a locked drawer at the researcher's home. All data will be kept for a maximum of 4 years and will then be destroyed.

Your privacy is important to us. A full data risk assessment has been completed and measures have been put in place to ensure that your confidentiality will be secure and that all your rights (GDPR) have been protected.

FUNDING AND ETHICS APPROVALS

HAS THIS STUDY BEEN APPROVED BY AN ETHICS COMMITTEE?

Yes, this study has been approved by Trinity College Dublin, School of Psychology ethics committee, approval date; Oct, 2023.

WHO IS FUNDING THIS RESEARCH?

This research is being conducted with the financial support of Science Foundation Ireland under Grant number 18/CRT/6222

4. FURTHER INFORMATION

If you have any concerns or any questions, please feel free to contact us:

<i>Researcher</i> Vivienne Howard howardv@tcd.ie	<i>Research Supervisors</i> Dr Siobhan Corrigan scorrig@tcd.ie Dr Rebecca Maguire Rebecca.maguire@mu.ie	<i>Data Protection Officer</i> Secretary's Office Trinity College Dublin Dublin 2 dataprotection@tcd.ie

SURVEY CONSENT FORM

Each of the following sections has a statement and asks you to indicate that you agree with the statement by ticking the box.

GENERAL	Tick Box
I confirm that I have read and understood the Information leaflet for this study. I am comfortable that I am fully informed about the risks and benefits of participating.	
I understand that this study is entirely voluntary, and if I decide that I do not want to take part, I can stop taking part in this study at any time without giving a reason. I understand that deciding not to take part will not affect my future medical care.	
I understand that questions on demographic information and information relating to my child's medical condition (e.g., age at diagnosis, HbA1c) will be asked.	
I understand that I will not be paid for taking part in this study.	
I know how to contact the research team if I need to.	
I understand that there are no direct benefits to me from participating in this study. I understand that results from analysis of my personal information will not be given to me.	
I understand that my data will be stored for a maximum of four years.	

DATA PROCESSING	Tick Box
I agree to allow personal anonymised information about me to be shared with third parties including; national and international hospitals, and academic research institutions for the purpose of research, as described in the information leaflet.	
I understand that anonymised personal information about me, including the transfer of this personal information about me outside of the EU, will be protected in accordance with the General Data Protection Regulation (GDPR).	

Please click NEXT if you are happy to proceed with the survey.
Thank you for participating, it is much appreciated.

ONLINE SURVEY

SECTION 1.
Demographics Questionnaire

To begin, we would like to ask you some standard demographic questions.

Firstly, about you, the parent caregiver:

Question	Response
1. What is your gender? Male Female Gender non-binary Prefer not to say	
2. What is the highest level of education you hold? No Formal Education / Training Primary School Level Secondary School Level Apprenticeship / Diploma University Graduate Post-Graduate	
3. Please indicate your age group? 18-24 25-34 35-44 45-54 55-64 65+	
4. What is your occupational status? Employed full time Employed part time Looking after family / home Not working due to my own illness / disability Other	
5. A household may have different sources of income and more than one household member may contribute to it. Thinking of your household's total monthly income: is your household able to make ends meet....? 1. Very easily 2. Easily 3. Fairly easily 4. With some difficulty 5. With difficulty	

6. With great difficulty	
6. What percentage of the caregiving for your child with T1 do you feel that you personally do (approx.)? 25% 50% 75% 100% Other %	
7. What percentage of the night-time caregiving for your child with T1 do you feel that you personally do (approx.)? 25% 50% 75% 100% Other %	
8. Do you attend at a hospital with a pump clinic? Y / N / Not sure	

Secondly, about your child with Type 1 Diabetes (T1D), if you have more than one child with T1 please choose one to keep in mind when you answer the questions:

Question	Response
9. What age is your child?	
10. What is your child's gender? Female Male Gender non-binary Prefer not to say	
11. What age was your child when they were diagnosed with Type 1 Diabetes?	
12. Is there a family history of type 1 diabetes? If yes, what is the relationship to your child (example: father, grandmother)?	
13. What was your child's most recent HbA1c result that you can remember (approx.)?	
14. What tools do you use to manage your child's diabetes on a daily basis? (Select all that apply) Insulin injection (pens or syringe)	

Insulin pump Blood testing meter Flash Glucose Monitoring (Libra) Continuous glucose monitoring (CGM) (i.e., Dexcom or Medtronic) Closed loop (pump linked to CGM) Other	
15. Has your child experienced a severe hypoglycaemic event (low blood glucose) requiring medical assistance? If yes, how many times?	
16. Has your child had an episode of diabetic ketoacidosis (DKA) that required medical assistance? If yes, how many times?	
17. On a scale of 1-5 (with 1 being very uncomfortable and 5 being very comfortable), how comfortable do you generally feel with all the information needed for managing your child's type 1 diabetes?	

SECTION 2. Night-Time Caregiving Practice

We'd like to get a detailed picture of what night-time caregiving practice looks like:

Question	Response
18. How often do you wake up at night to take care of your child's diabetes? Never [if this is selected the participant will be directed straight to section 3, then sections 4 & 7] Every night Most nights A few times a week About once a week 2-3 times a month About once a month Less than once a month Varies Would you like to explain further?	
19. If you're taking care of your child with T1D at night we know that every night can be different, we'd like to get a more detailed picture of your own night-time caregiving activities over a month (approx. 30 nights):	

Approximately how many nights in an average month do you wake once to take care of your child with T1D? Approximately how many nights in an average month do you wake twice to take care of your child with T1D? Approximately how many nights in an average month do you wake 3–4 times to take care of your child with T1D? Approximately how many nights in an average month do you wake more than 4 times to take care of your child with T1D? Could you estimate how many nights in an average month you do not need to wake up to take care of your child with T1D?	
20. Is there anything that you would like to add about your night-time caregiving wakings?	
21. Do you set alarms on your phone or clock to wake you so that you can monitor your child's glucose levels during the night? Y/N	
22. Does your child with T1 sleep in your bed with you (to make caregiving easier)? Never Sometimes Often Always	
23. What do you do when you wake to take care of your child's diabetes during the night? (Please select all that apply) • Test blood glucose with a finger prick • Bolus insulin to correct high • Feed child carbohydrates in response to low • Set pump to suspend • Set a temporary basal • Check blood glucose and wait up to recheck • Wake in response to an alarm • Check glucose readings using a flash monitoring (libra) • Check glucose readings from a CGM • Check glucose trend data on own phone (i.e., follow app) • Check glucose trend data on child's phone • Replace sensor • Refill insulin cartridge on pump • Check for compression lows • Charge pump or CGM receiver	
24. Is there anything else, not listed above, that you do to take care of your child's T1D at night?	

25. Approximately what percentage of your night-time caregiving activities cause you to get out of your bed?	

SECTION 3.

Engagement with Health Care Team on Night-Time Caregiving

We'd like to know about the support that you need or are getting, around night-time caregiving, from your child's diabetes team.

Question	Response
26. Do you discuss night-time caregiving with your diabetes nurses? Yes – regularly Yes – occasionally Yes – rarely No -- never If you don't, why not?	
27. Do you discuss night-time caregiving with the doctors? Yes – regularly Yes – occasionally Yes – rarely No -- never If you don't, why not?	
28. If relevant, have you discussed the effects of night-time caregiving on yourself - the parent, with any of your clinical team (doctors, nurses, others)? Yes – regularly Yes – occasionally Yes – rarely No – never If yes, who did you have that conversation with? If you answered No, why not?	
29. Have you had any conversations with your clinic team that have helped with the burden of night-time care for your child with T1D? Y/N/Unsure/Not applicable If yes, could you please tell us a bit more about the discussion?	

SECTION 4
Sleep

Question	Response
30. Approximately how many hours sleep do you get per night?	
31. How many hours of sleep do you need per night to feel at your best?	
32. Does taking care of your child's diabetes interfere with you getting enough sleep? Y/N/Unsure/Not applicable If you answered yes, approximately how many hours of sleep do you lose per week because of your night-time caregiving activities?	
33. Do you think that the quality of your sleep has been affected by night-time caregiving? (For example, do you find that you sleep lightly) Y/N/Unsure/Not applicable If yes, could you briefly explain?	
34. Have you experienced any sleep problems that you think might have developed as a result of taking care of your child at night? Y/N/Unsure/Not applicable If yes, could you describe them?	

SECTION 5
Impacts on Caregiver

We are trying to understand any impacts that night-time caregiving might sometimes have on your life. First, we are looking at Fatigue:

Please tick the number that best indicates how you have felt in the past Month:

Iowa Fatigue Scale (IFS)		Not at all	A little	Moderately	Quite a bit	Extremely
1	I feel worn out	1	2	3	4	5
2	I feel energetic	1	2	3	4	5
3	I feel slowed down in my thinking	1	2	3	4	5
4	I do quite a lot within a day	1	2	3	4	5

5	I have trouble concentrating	1	2	3	4	5
6	I feel drowsy	1	2	3	4	5
7	Physically I feel in good shape	1	2	3	4	5
8	I have low output	1	2	3	4	5
9	I have trouble with my memory	1	2	3	4	5
10	I feel rested	1	2	3	4	5
11	I can concentrate well	1	2	3	4	5

We'd like to know if there are **any other impacts** that you have experience from night-time caregiving

Question	Response
35. Could you rate on a scale of 1-5 (with 1 indicating no impact and 5 indicating significant impact) to what extent night-time caregiving practice has impacted on the issues below: • Increased feelings of stress • Impacts on family wellbeing • Impacts on relationships • Feeling anxious • Low mood • Difficulty with motivation • Less clear thinking • Difficulty making complex treatment decisions (i.e., calculating a bolus) • Decisions regarding employment	
36. Could you describe any other impacts that you have experienced, which aren't listed above?	
37. How would you rate your health, generally? (excellent, very good, good, fair, poor).	
38. Do you have any long-standing health issues or any chronic illnesses? Y/N/Unsure If yes, could you briefly describe them?	

Now, looking at possible solutions...

Question	Response
39. Do you think that diabetes technology (pump, cgm, loop) could help you to manage the night-time burden? Y/N/Unsure If yes, could you explain how?	
40. Is there anything else, apart from technology, that would be helpful to you around night-time caregiving?	
41. How could your clinic team (doctors, nurses, others) support you with the burden of night-time caregiving?	
42. Is there anything that makes night-time caregiving <i>more difficult</i> for you?	
43. Could you indicate on a scale of 0-7, how much the people in your life understand your night-time caregiving responsibilities (0 being not understanding at all and 7 being understanding completely) Would you like to add a comment on this subject?	

SECTION 7

Hypoglycaemia Fear Survey – parent version (HFS-P)

Lastly, 'Fear of Hypoglycaemia' is a term and concept that researchers use to talk about issues related to hypoglycaemia ('hypos' or low blood glucose). This is the tool often used to measure it among parents of children with T1D. Please fill it in and we'll ask you about it briefly afterwards.

I. Behaviour: Below is a list of things people with diabetes sometimes do in order to avoid low blood sugar. Read each item carefully. Click on one of the numbers that best describes your activity (ACTIONS)						
1 = never 2 = rarely 3 = sometimes 4 = often 5 = very often						
1	Have your child eat large snacks at bedtime	1	2	3	4	5
2	Avoid having your child being alone when his/her sugar is likely to be low	1	2	3	4	5
3	Allow blood sugar to be a little high to be on the safe side	1	2	3	4	5
4	Keep child's sugar higher when he/she will be alone for a while	1	2	3	4	5
5	Have child eat something as soon as he/she feels the first sign of low blood sugar	1	2	3	4	5
6	Reduce my child's insulin when I think his/her sugar is too low	1	2	3	4	5

7	Keep my child's blood sugar higher when he/she plans to be away from me for a while	1	2	3	4	5
8	Have your child carry fast-acting sugar	1	2	3	4	5
9	Have your child avoid a lot of exercise when you think his/her sugar is low	1	2	3	4	5
10	Check my child's sugar often when he/she plans to go on an outing	1	2	3	4	5

II. Worry: Below is a list of concerns parents of children with diabetes sometimes have. Please read each item carefully. Click on one of the numbers that best describes How often you WORRY about each item 1 = never 2 = rarely 3 = sometimes 4 = often 5 = very often						
11	Child not recognising or realising she/she is having a low blood sugar	1	2	3	4	5
12	Child not having carbohydrate with him/her	1	2	3	4	5
13	Child feeling dizzy or passing out in public	1	2	3	4	5
14	Child having a low blood sugar while asleep	1	2	3	4	5
15	Child embarrassing self or friends/family in a social situation	1	2	3	4	5
16	Child having a low blood sugar when alone	1	2	3	4	5
17	Child appearing stupid or clumsy	1	2	3	4	5
18	Child losing control	1	2	3	4	5
19	No one being around to help child during a low blood sugar	1	2	3	4	5
20	Child making a mistake or having an accident at school	1	2	3	4	5
21	Child getting a bad evaluation at school because of something that happens when his/her blood sugar is low	1	2	3	4	5
22	Child having seizures or convulsions	1	2	3	4	5
23	Child developing long term complications from frequent low blood sugar	1	2	3	4	5
24	Child feeling light-headed or faint	1	2	3	4	5
25	Child having an low blood sugar	1	2	3	4	5

We would like to explore this concept and the tool further, to see how well it reflects the real-life experience. To do this we'd like to get your opinion on the 'hypoglycaemia fear survey' (HFS-P; behaviour and worry) that you've just completed:

Question	Response
44. What do you, personally, think about the HFS-P survey, which you just completed?	
45. Do you think it reflects your experience?	
46. How do you feel about the concept 'Fear of Hypoglycaemia'?	
47. Is there anything in particular that you like or do not like about this questionnaire?	

THANK YOU very much for taking part in this survey, we really appreciate you sharing your experience with us.

Please press the submit button to complete.

If you are willing to being included in further research on this study, such as taking part in an individual interview or a focus group, could you follow this link to provide your email address. Your email address will not in any way be linked to the survey you just completed.

Your survey has been submitted. Thank you again.

Appendix 8.1 Completed Standards for Reporting Qualitative Research (SRQR) checklist for study 5

		Reporting Item	Page
Title	1	Concise description of the nature and topic of the study identifying the study as qualitative or indicating the approach (e.g. ethnography, grounded theory) or data collection methods (e.g. interview, focus group) is recommended	171
Abstract	2	Summary of the key elements of the study using the abstract format of the intended publication; typically includes background, purpose, methods, results and conclusions	171
Problem formulation	3	Description and significance of the problem / phenomenon studied: review of relevant theory and empirical work; problem statement	172
Purpose or research question	4	Purpose of the study and specific objectives or questions	172
Qualitative approach and research paradigm	5	Qualitative approach and guiding theory if appropriate; identifying the research paradigm is also recommended; rationale. The rationale should briefly discuss the justification for choosing that theory, approach, method or technique rather than other options available; the assumptions and	175

limitations implicit in those choices and how those choices influence study conclusions and transferability. As appropriate the rationale for several items might be discussed together.

Researcher characteristics and reflexivity	6	Researchers' characteristics that may influence the research, including personal attributes, qualifications / experience, relationship with participants, assumptions and / or presuppositions; potential or actual interaction between researchers' characteristics and the research questions, approach, methods, results and / or transferability	175
Context	7	Setting / site and salient contextual factors; rationale	176
Sampling strategy	8	How and why research participants, documents, or events were selected; criteria for deciding when no further sampling was necessary (e.g. sampling saturation); rationale	177
Ethical issues pertaining to human subjects	9	Documentation of approval by an appropriate ethics review board and participant consent, or explanation for lack thereof; other confidentiality and data security issues	174
Data collection methods	10	Types of data collected; details of data collection procedures including (as appropriate) start and stop dates of data collection and analysis, iterative process, triangulation of sources / methods, and modification of procedures in response to evolving study findings; rationale	178
Data collection instruments and technologies	11	Description of instruments (e.g. interview guides, questionnaires) and devices (e.g. audio recorders) used for data collection; if / how the instruments(s) changed over the course of the study	177
Units of study	12	Number and relevant characteristics of participants, documents, or events included	181

in the study; level of participation (could be reported in results)

Data processing	13	Methods for processing data prior to and during analysis, including transcription, data entry, data management and security, verification of data integrity, data coding, and anonymisation / deidentification of excerpts	179
Data analysis	14	Process by which inferences, themes, etc. were identified and developed, including the researchers involved in data analysis; usually references a specific paradigm or approach; rationale	179
Techniques to enhance trustworthiness	15	Techniques to enhance trustworthiness and credibility of data analysis (e.g. member checking, audit trail, triangulation); rationale	180
Syntheses and interpretation	16	Main findings (e.g. interpretations, inferences, and themes); might include development of a theory or model, or integration with prior research or theory	182
Links to empirical data	17	Evidence (e.g. quotes, field notes, text excerpts, photographs) to substantiate analytic findings	190
Integration with prior work, implications, transferability and contribution(s) to the field	18	Short summary of main findings; explanation of how findings and conclusions connect to, support, elaborate on, or challenge conclusions of earlier scholarship; discussion of scope of application / generalizability; identification of unique contributions(s) to scholarship in a discipline or field	196
Limitations	19	Trustworthiness and limitations of findings	199
Conflicts of interest	20	Potential sources of influence of perceived influence on study conduct and conclusions; how these were managed	175 199
Funding	21	Sources of funding and other support; role of funders in data collection, interpretation and reporting – no funding	N/A

Appendix 8.2 Participant information sheet, consent and Full questionnaire for study 5 (FGs, interviews and open response questionnaire).

PARTICIPANT INFORMATION SHEET

Research Site	Online – Focus Group, Interviews, Online Questionnaire	
Researcher	Vivienne Howard Email: howardv@tcd.ie	
Research Supervisors/Sponsor	Prof Declan Cody Dr Vincen McDarby Dr Siobhan Corrigan TCD (principal investigator) Dr Rebecca Maguire MU	
Data Controllers	Trinity College Dublin	CHI Crumlin
Data Protection Officer	Data Protection Officer Secretary's Office Trinity College Dublin Dublin 2 Email: dataprotection@tcd.ie	Data Protection Officer Data Protection Office CHI at Crumlin D12 N512 Email: dpo@childrenshealthireland.ie

1. THIS PROJECT

THE STUDY

The aim of this project is to understand more about the night-time experience of parents caring for children living with Type 1 Diabetes (T1D), it is particularly interested in what kind of interventions or supports that you might find helpful with the burden you experience from nocturnal care, if indeed you do experience this burden. It is being carried out by Vivienne Howard as part of her PhD project. Before you decide whether or not you wish to take part, please read this information sheet carefully.

WHY HAVE I BEEN INVITED TO TAKE PART?

We have asked you to take part in the study because you are a caregiver for a child with T1D, it is your experience that we are interested in. Your contribution will be completely anonymised.

DO I HAVE TO TAKE PART?

Participation is totally voluntary.

ARE THERE ANY BENEFITS FROM YOUR PARTICIPATION?

Taking part in this study will not directly benefit you. However, research work done with your responses will help us to understand more about caregiving at night for children with T1D, which will contribute to the development of supports and interventions that may help relieve the burden for those who experience it.

2. DATA PROTECTION

WHAT INFORMATION ABOUT ME WILL BE COLLECTED AND HOW WILL IT BE KEPT?

- All data that will be collected will be anonymised.

Your privacy is important to us. A full data risk assessment has been completed, and measures have been put in place to ensure that your confidentiality will be secure and that all your rights (GDPR) have been protected.

WHO SHOULD I CONTACT FOR FURTHER INFORMATION OR TO MAKE A COMPLAINT?

If you have any questions or concerns, you can contact:

- *Principal Investigator: Dr Siobhán Corrigan, scorrig@tcd.ie*
- *Data protection officer, Trinity College Dublin, dataprotection@tcd.ie*

3. FUNDING AND ETHICS APPROVALS

HAS THIS STUDY BEEN APPROVED BY AN ETHICS COMMITTEE?

Yes, this study has been approved by two research ethics committees, Trinity College Dublin, School of Psychology ethics committee and CHI Crumlin ethics committee.

WHO IS FUNDING THIS RESEARCH?

This research is being conducted with the financial support of Research Ireland under Grant number 18/CRT/6222

4. FURTHER INFORMATION

If you have any concerns or any questions, please feel free to contact us:

<i>Researcher</i> Vivienne Howard howardv@tcd.ie	<i>Research Supervisors</i> Dr Siobhan Corrigan scorrig@tcd.ie Dr Rebecca Maguire Rebecca.maguire@mu.ie	<i>Data Protection Officer</i> Trinity College Dublin Dublin 2 dataprotection@tcd.ie DPO CHI at Crumlin dpo@childrenshealthireland.ie

SURVEY CONSENT FORM

Each of the following sections has a statement and asks you to indicate that you agree with the statement by ticking the box.

GENERAL	Tick Box
I confirm that I have read and understood the Information leaflet for this study. I am comfortable that I am fully informed about the risks and benefits of participating.	
I consent to taking part in this study.	
I understand that this study is entirely voluntary, and if I decide that I do not want to take part, I can stop taking part in this study at any time without giving a reason. I understand that deciding not to take part will not affect my future medical care.	
I understand that questions on demographic information and information relating to my child's medical condition (e.g., age at diagnosis, HbA1c) will be asked.	
I understand that I will not be paid for taking part in this study.	
I know how to contact the research team if I need to.	
I understand that there are no direct benefits to me from participating in this study. I understand that results from analysis of my personal information will not be given to me.	
I understand that my data will be stored for a maximum of four years.	
DATA PROCESSING	Tick Box

I agree to allow personal anonymised information about me to be shared with third parties including national and international hospitals, and academic research institutions for the purpose of research, as described in the information leaflet.	
I understand that anonymised personal information about me, including the transfer of this personal information about me outside of the EU, will be protected in accordance with the General Data Protection Regulation (GDPR).	

Questionnaire: Individual Interviews, FGs, open response questionnaires.

Introduction:

Please indicate that you have received information about the study and are happy to consent to proceed: Yes / No

The following questions are asking you about your experience of caring for your child or your teen's T1D at night, we hope to learn about your thoughts on nighttime care and what the Diabetes Clinic can do to help you manage that burden.

Background information:

- What is your child's age:
- What age they were diagnosed:
- What if any diabetes technology they use:
- How long have they had that technology:

Opening Questions:

- Do you take care of your child's diabetes in the night-time, does anybody share the responsibility?
- Does caregiving at night interfere with your sleep?
- How often would this happen, just roughly, per week?

Intermediate Questions:

- Do you have any impacts from this caregiving activity in your life?
- What could others do for you to make it easier for you?
- Have you tried to discuss any issue around night-time care with anybody in the clinic?
- If so, what happened?
- Would you like to be asked about night-time care in clinic?
- Have you any suggestions for how they might bring this topic up with you?
- How might they word it?
- Who in the clinic would you feel most comfortable discussing this topic with?
- What could they say to you that would be helpful?

Concluding Questions:

- Is there anything else your medical team could do to help with night-time care?
- If you were talking to another T1D parent about night-time care, what advice would you give them?

Final Question:

- Is there anything else you think is important or that you'd like to add....

Thank you for your time. Your input is extremely helpful. Please contact me if you have any questions or would like any further information.

Appendix 8.3 Coding framework for study 5

	Question topics	Sub-categories	Main Categories
1.	Age	Demographics	Demographics
2.	Age Dx		
3.	Diabetes Technology	Technology	
4.	Technology Time		
5.	Do you NCP	NCP characteristics	NCP Current burden
6.	Share responsibility		
7.	Sleep interference		
8.	How often/weekly		
9.	Impacts	Impacts	
10.	How could others help	Help	
11.	Discuss in clinic	Discuss previously	Discuss in clinic; previous experience and desired
12.	What happened		
13.	Would you like to be asked	Conversation?	
14.	How might they bring it up		
15.	How word it		
16.	Who would be comfortable	Who/What	
17.	What could they say to be helpful		
18.	Anything else your team could do	Anything else	Other supports, thoughts
19.	Advice for new T1D parent	Advice	
20.	Anything to add	To add...	