Fear of hypoglycaemia in paediatric diabetes: a literature review

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Abstract

Background: **Type 1 diabetes mellitus is one of the most common chronic childhood illnesses and, despite ongoing technological advances, hypoglycaemia remains an inevitable therapeutic risk. Hypoglycaemia results in unpleasant physiological outcomes, social embarrassment and – in extremis – life-threatening consequences. Overlying this inescapable clinical risk is a fear of this risk, ranging from fleeting to overwhelming, and substantially impacting the trajectory of diabetes.**

Aim: **The aim of this literature review is to identify, summarise and critically appraise works pertaining to the development, impact and management of paediatric fear of hypoglycaemia (FoH).**

Methods: **A search was conducted on Embase, MEDLINE and PsycINFO for studies published between 2000 and 2020, with cross-referencing searches for articles not detected in the original keyword search. Study quality was assessed using recognised tools, and relevant data were extracted systematically.**

Results: **Forty-three studies met the inclusion criteria. FoH was a moderate problem throughout the studies, increased by a history of hypoglycaemia and predisposition to psychological stress. There was conflicting evidence on the influence of age, diabetes duration, technology and parental demographics. Some studies showed a significant impact on glycaemic control and quality of life (QoL), more consistently for the latter. Only 13 intervention trials were included, showing mixed success with cutting-edge technology, and decent gains with psychological interventions.**

Conclusions: **FoH is clearly a ubiquitous issue among some families with type 1 diabetes. Prospective longitudinal studies are required to assess potential risk factors at diagnosis, monitor for the development of FoH at regular intervals, and enable a more comprehensive assessment of the long-term impact on glycaemic control and QoL. Further randomised controlled trials must demonstrate the value of technological and psychological therapies in order to make such interventions commonplace offerings for families suffering from intractable fear.**

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Key words: diabetes, hypoglycaemia, fear, HbA_{1c}, quality of life

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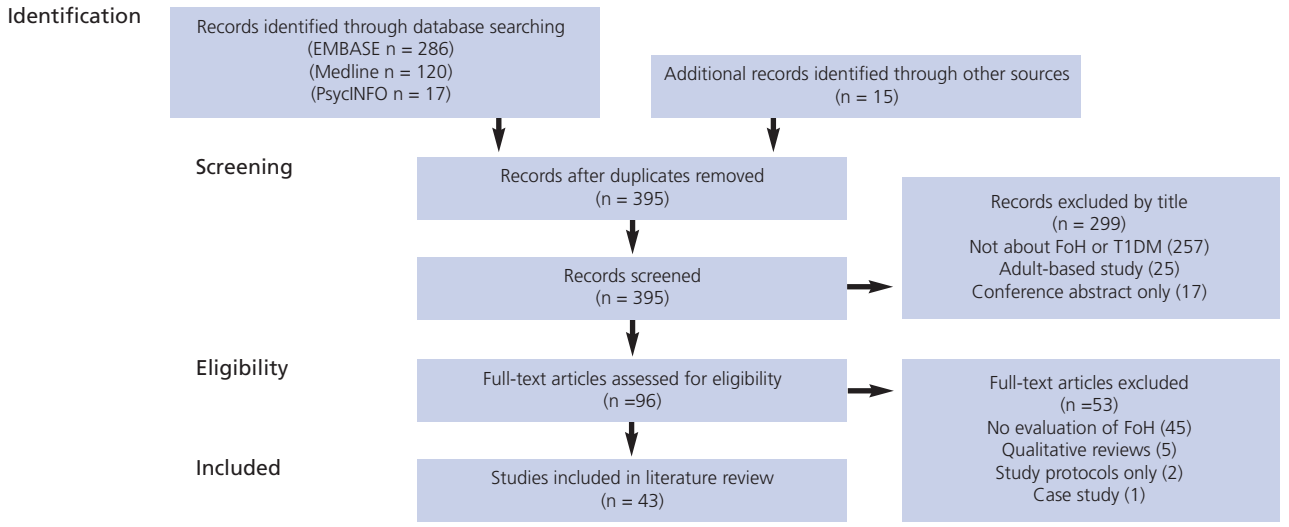
Introduction

Type 1 diabetes mellitus (T1DM) is one of the most common chronic childhood illnesses, affecting 196 per 100,000 children aged 0–15 years in England and Wales.[1] Despite rapid technological advances in diabetes therapy,[2] hypoglycaemia remains the commonest acute complication of diabetes care.[3] Intensive insulin therapy can increase hypoglycaemic frequency three-fold,[4] and individuals with a <5-year T1DM duration experience on average 1.1 severe hypoglycaemic episodes per patient per year.[5] Hypoglycaemia can result in unpleasant physiological symptoms, social embarrassment and – in extremis – life-threatening consequences. Overlying this inescapable clinical risk is a fear of this risk. This construct has been labelled a fear of hypoglycaemia (FoH) and can substantially impact the trajectory of diabetes. Individuals with strong FoH indulge in compensatory mechanisms to avoid hypoglycaemia, maintaining a 'safe' hyperglycaemia while carrying increased diabetes distress (DD) and poorer quality of life (QoL).

The aim of this literature review is to identify, summarise and critically appraise works pertaining to the development, impact and management of paediatric FoH. This will encompass examining FoH measurement tools, identifying predictive factors, exploring its impact and evaluating minimisation strategies. Prior works include a systematic review in parents of young children (PYC) containing six eligible studies[6] and a broader review of children, adolescents and parents, comprising 16 studies.[7] Although both highlighted the significance of FoH, its consequences were not fully explored, technology was less abundant, and paediatric behavioural trials non-existent. The current review aims to clearly delineate the impact of FoH on glycated haemoglobin (HbA_{1c}) and QoL, underscoring the need for resource allocation. Moreover, diabetes care has been transformed by a decade of technological innovation, from

Figure 1. PRISMA flow diagram of study selection process.[16]



continuous subcutaneous insulin infusions (CSII) and continuous glucose monitors (CGM) to sensor-augmented pump therapy (SAPT) and closed-loop systems, and the debate deserves reinvigorating.[8-10]

Methods

The research question was generated using the Population, Intervention, Comparator and Outcome (PICO) approach.[11] The population comprised children and young people (CYP) aged 0–18 years with T1DM or their parents, and whether FoH influenced glycaemic control and QoL. A literature search was conducted on Embase, MEDLINE and PsycINFO. The bibliographies of retrieved papers were also reviewed. Letters to the editor, abstracts and scientific meeting proceedings were excluded. The search was restricted to English language publications from 2000 to 2020, to capture recent changes in technology (see Appendix 1, available online www.bjd-abcd.com, for full search strategy).

Titles and abstracts were examined for inclusion. All study designs meeting PICO parameters were eligible. Exclusion criteria included primarily adult-based studies, a failure to quantitatively assess FoH or either primary outcome. Included studies were critically appraised using recognised tools: the Centre for Evidence Based Medicine criteria for cross-sectional studies,[12] the National Heart, Lung, Blood Institute checklist for pre-post prospective studies,[13] and the Critical Appraisal Skills Programme checklist for randomised controlled trials (RCTs)[14] and systematic reviews[15] (Appendix 2 available online www.bjd-abcd.com).

Data extracted included study design, demographics, diabetes duration, insulin mode, HbA_{1c}, FoH and QoL assessments, hypoglycaemia prevalence, pertinent results, strengths and limitations (Appendix 3 available online www.bjd-abcd.com). Due to differences in populations, treatment regimens and outcome measures, a meta-analysis was not conducted. Instead, a narrative synthesis is presented.

Results

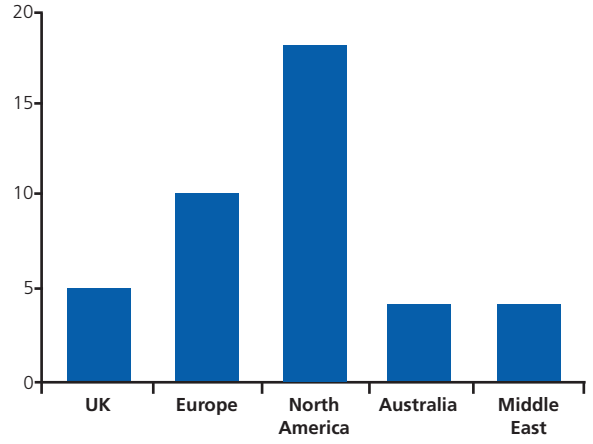
Search results

Of the 395 abstracts screened, 43 papers were included in the final analysis (see Figure 1).

The majority were cross-sectional studies (n=28), of which two datasets were used twice[17-20] and three papers aggregated several studies.[21-23] There were two literature reviews,[6,7] five pre-post prospective studies and eight RCTs. Sample size ranged from 16 to 549 (mean 142) and 90% were of Western origin (Figure 2).

Eleven studies investigated parent-child dyads. Nineteen explored parental FoH, with 11 focusing on PYC, facing specific challenges of irregular eating and activities, difficulty matching insulin, greater aberrant glycaemia and subtleties in detection. Seven of 11 studies examining children's FoH explored adolescents, confronting the complexities of puberty, subversion and peer influences.

Figure 2. Geographical distribution of selected studies



Measurement of fear of hypoglycaemia

The Hypoglycaemia Fear Survey (HFS) is the most well-established measure assessing FoH, using a worry (HFS-W) and behaviour (HFS-B) subscale with 33 items graded from never to always on a Likert scale.[24] The tool was modified to 25 items for parents (HFS-P)[25] and revised for PYC (HFS-PYC).[26] An adaptation for 6–18-year-olds also exists (HFS-C).[27]

The HFS-P demonstrates acceptable reliability with an internal consistency range of 0.88–0.91 for the HFS-W and 0.72–0.76 for the HFS-B.[21] The HFS-B often displays slightly reduced internal consistency, registering appropriate hypoglycaemia avoidance strategies alongside inappropriate FoH-driven actions.[7] Modified versions also show sufficient test-retest reliability.[21] Although less used, the HFS-C has similarly been shown to have an internal consistency of 0.86 and good convergent validity.[28] A key limitation of all HFS versions is the absence of established clinical cut-offs, making clinical interpretability challenging.[7]

The Children's Hypoglycaemic Index (CHI) is a contemporary alternative, encompassing a fear, situation and behaviour subscale, demonstrating a good internal consistency of 0.89, decent test-retest reliability with a Pearson's correlation coefficient of 0.76 and strong convergent validity among its various subscales. It was purposefully developed for children, explores more areas and comprises FoH-specific behaviours.[29] However, it is less popular and requires further validation in practice.

Predictors of fear of hypoglycaemia

Hypoglycaemic frequency and severity is a key factor in FoH development.[26,28] In a large Australian study of 325 parents of 8–18-year-olds, severe hypoglycaemia (SH) conveyed a 6.3 higher HFS-P score (p=0.004),[30] while a Slovenian work linked SH with maternal hypoglycaemia preventative behaviours (r=0.25; p=0.03).[31] SH also positively correlated with HFS-C helplessness scores (r=0.19; p=0.01) in an aggregated US study of 259 6–18-year-olds.[22] SH clearly has a major role in the construct of FoH, although it can of course flourish irrespective of hypoglycaemic experience: in a large US study of PYC, recent SH was wholly unrelated to 549 HFS-P worry scores.[32] Other studies show adolescent emergency glucose carriage (F=6.36; p<0.05)[28] or diabetes management confidence (r=0.3; p<0.01) to be more predictive,[33] highlighting the ability to deal with SH to be at least as important as experience of SH in the development of FoH.

A second hypothesis is that predisposition to stress, anxiety and depression contributes to FoH.[34] Less mindful parenting was associated with higher HFS-P scores (p=0.006) for 421 Dutch parents,[35] and a Norwegian study correlated the Hopkins Symptom Checklist-25 (HSCL-25) for depression and anxiety with HFS-P worry scales among 200 mothers (r=0.04; p<0.001) and fathers (r=0.28; p=0.006).[19] Among CYP social anxiety and HFS-C scores positively correlated for North American boys (r=0.45; p<0.01) and girls (r=0.30; p<0.005),[36] as did emotional disorders and HFS-B scores among Saudi adolescents.[37] Of course, such psychological co-morbidities are also associated with certain sociodemographic factors, compounding vulnerability to FoH. For instance, parenting stress has been linked to having younger children, lower socioeconomic status and a non-Caucasian background, factors all also independently associated with FoH.[38]

The most noteworthy demographic variable was gender. Several international studies demonstrated significantly higher maternal HFS scores.[18,19,26,31] Girls had higher HFS-C helplessness scores (F=4.33; p=0.039) than boys,[22] and twice as high FoH scores (p<0.0001) in a 453-strong adolescent Swedish study.[39] Few studies depicted no gender disparity.[40] Age was also influential: parents of 6–11-year-olds had higher HFS-P scores than parents of children aged 0–5 years (p=0.003) or >12 years (p=0.003), perhaps reflecting care transition from parent to school,[40] and adolescent age correlated with higher HFS-C social consequence scores.[22] However, associations between age and FoH were inconsistent.[32,41] The impact of technology was also indeterminate, ranging from higher HFS-P behaviour scores with multiple daily injections,[19] and lower HFS-C worry scores with CSII (p<0.05),[37] to no impact[28,42] or moderate FoH encouraging CSII use.[43]

Impact of fear of hypoglycaemia

FoH is postulated to cause hypoglycaemia-avoidant behaviour, prolonged hyperglycaemia, poor glycaemic control and increased HbA_{1c} levels. Hyper-vigilant parents admit to accepting higher target ranges where such vigilance is implausible,[44] as do adolescents seeking to avoid humiliating public hypoglycaemia. Several studies confirmed significant associations between FoH scores and HbA_{1c}.[19,30,31,43] Others demonstrated no correlations between HFS-P,[18,26,32] HFS-C[17,37] and HbA_{1c}. In some cases, despite high maternal HFS-B,[45] or HFS-C maintain high blood glucose factor scales[22] correlating with hyperglycaemia, there was no corresponding rise in HbA_{1c}. It is clear that HbA_{1c} is a multi-factorial derivation, often poorly reflective of everyday blood glucose excursions. More detailed glycaemic data are required to truly capture the impact of FoH on glycaemic control. Contrary to the initial hypothesis, FoH can also intensify diabetes control, negating any negative impact on HbA_{1c} or even improving glycaemic control,[21,23] although this was a far less common pattern.

The second key FoH impact is upon QoL, although few studies cite QoL as a primary outcome. It is challenging to deduce whether predisposition to stress, anxiety and depression increases FoH, or if FoH intensifies pre-existing psychological burden. In reality, this relationship is bi-directional and there is likely to be an element of reverse causality.[34] Parents and children in the highest fear quartile have been shown to have lower scores on the Paediatric Quality of Life Inventory (PedsQL) by 20–22%,[30] and significant associations have been demonstrated between FoH and DD in adolescent girls (p=0.044) and boys (p=0.026).[39]

Minimisation of fear of hypoglycaemia

The 13 paediatric intervention trials identified highlight the ambiguity of using technology to reduce hypoglycaemia risk and fear. The Juvenile Diabetes Research Foundation CGM RCT failed to exhibit appreciable reductions in HFS-P and HFS-C scores across 10 UK sites,[46] while a smaller UK study of 16 adolescents did show HFS-P (98.69 vs 66.69; p<0.0021) and HFS-C (97.38 vs 59.75; p=0.003) reductions with 12 months' CGM,[47] as did an Australian

crossover RCT evaluating remote monitoring mobile CGM.[48] In a multicentre German observational study, CSII use for 6 months conferred significant reductions in HFS-P worry scores (d=0.4-0.6; p<0.01),[49] with replicable results a decade later,[50] and in Saudi Arabia, flash glucose monitoring improved adolescent HFS-C scores (p=0.0001).[51] A multicentre crossover RCT involving Israel, Slovenia and Germany comparing an artificial pancreas system with SAPT for 4 nights demonstrated significant HFS-C worry reductions (1.04 vs 0.90; p=0.017),[52] whereas a UK crossover RCT comparing closed loop systems with SAPT did not,[53] nor did a multicentre Australian RCT comparing predictive low glucose management versus SAPT.[54]

A comprehensive adult literature review showcased blood glucose awareness training and cognitive behavioural therapy (CBT) as effective interventions.[55] A US multisite RCT involving 258 adolescents evaluated the Flexible Lifestyles Empowering Change (FLEX) programme of motivational interviewing and problem-solving skills. Significant improvements were found in adolescent worry/helplessness criteria (–0.16; p=0.04), adolescent health-related QoL (3.18; p=0.009) and parents' behaviours to maintain high blood glucose (–0.21; p=0.005).[56] Another American intervention using video-based telehealth (REDCHiP) involved 36 parents of 2–6-year-olds. REDCHiP comprised a 10-week programme applying CBT principles to recognise FoH-related thoughts and behaviours, refining coping strategies and practising exposures to challenges. At 3 months there were significant reductions in HFS-PYC and DD scores.[57]

Discussion

Main findings

FoH is a pervasive problem, dependent on a range of factors. Negative hypoglycaemic experience is clearly key, with psychological comorbidity serving as both a predictive and confounding factor. Greater female FoH prevalence undoubtedly reflects a higher female psychological burden with double the DD[39] and greater anxiety levels,[36,37] although paternal FoH is poorly represented with the only dedicated study displaying low FoH and state anxiety.[58] FoH often results in deteriorating glycaemic control, which is sometimes reflected in increased HbA_{1c} levels. The impact of FoH on QoL is also more nuanced, as innumerable variables contribute to QoL, not least of which is chronic illness itself.[59]

Technology has a definitive role in minimising FoH, which is most beneficial in conjunction with psychological gains. Successful intervention studies reveal significant reductions in PedsQL,[49] parental health-related QoL, stress and anxiety, alongside FoH reductions.[48] Psychological intervention is clearly vital, but requires significant buy-in. A UK pilot of problem-solving workshops highlighted significant recruitment issues: although over 90% of the 89 families approached had high HFS-P scores, only 25% participated, citing reluctance to miss school, lack of time, interest or travel difficulties.[60] Lessons must be learnt for future directives and further statistically powered RCTs are needed to confirm the validity of this approach.

Strengths and limitations

The majority of papers were cross-sectional studies, relatively quick, low-cost undertakings, useful in displaying prevalence, associations and new hypotheses, but unable to establish causality or temporality. Only seven studies performed power calculations to justify sample size; others were likely woefully underpowered. Inter-study variability also rendered some comparisons or aggregations redundant. For instance, a third of studies lacked a definition for SH, definitions varied widely, and most SH was self-reported. Only four intervention trials listed FoH as a primary outcome, nevertheless 92% provided significant p values with precise confidence intervals. Sadly, all lacked a cost-benefit analysis (Appendix 2).

Although FoH measurement was largely comparable and robust, with 93% of studies using the psychometrically strong HFS, this questionnaire is subject to recall bias, requires literacy, self-assessment and abstract reasoning. Age-specific considerations include the ability of younger children to hypothecate, adolescents to be candid and parental engagement in diabetes care. The impact of FoH was chiefly assessed upon HbA_{1c} and QoL. The validity of the former was marred by historic clinic records, different laboratories, self-report[35] and missing data.[45] It is also likely that time spent in range is a more useful marker than HbA_{1c}. QoL was assessed using an array of established tools, limiting comparability, and was coloured with recall bias.

Selection bias was a fundamental limitation: most recruited opportunistically from diabetes clinics or camps, 22 were restricted to single centres and only a handful accessed national registries.[32,35,39] Participants were self-selected by virtue of attending clinic, answering calls or adverts, reflecting a motivated cohort. Further commitment involved questionnaire completion, regular self-monitoring of blood glucose or embracing technology. Response rates across 27 studies ranged from 21% to 96% (mean 61%). Engaged respondents generally revealed better glycaemic control than non-respondents,[30,31,39,57] with a mean study participant HbA_{1c} of 66.6 mmol/mol and CSII use of 5–86%, often deviating markedly from UK rates of 36.7%.[1] Studying populations with better glycaemic control potentially skews the FoH burden and its confounders.

Reviewing only English language publications delivered populations fairly reflective of the UK. Middle Eastern studies relied on questionnaire translation and back-translation,[17,18,37,51] as did many European studies.[19,20,31,49,50] This may have introduced inaccuracies and cultural inconsistencies. Study cohorts reflected narrow socioeconomic groups: 20 of 23 studies describing ethnicity were 71–97% Caucasian, 15 had a 69–98% married population and 22 demonstrated higher parental education, employment or income (Appendix 3). This diminishes the wider applicability of the results while highlighting the time, interest and literacy often decisive in study participation. Future studies need selection processes which overcome these biases. Mothers represented 52–98% of parent participants (mean 80%) across 20 studies, excluding exclusively maternal or paternal studies.[45,58,59] Achieving gender parity is challenging, as mothers are usually the primary caregivers whereas fathers undertake <20% of diabetes-related tasks.[58] It is nevertheless important that future studies are more representative.

Implications for future research and practice

There has been a substantial body of work evaluating the scope of

Key messages

- Fear of hypoglycaemia can be a significant issue among children and young people with type 1 diabetes and their parents
- Hypoglycaemic experience and psychological vulnerability are core features in the construct
- The impact on glycaemic control and quality of life is potentially considerable for children and their families
- Prospective longitudinal studies are needed to accurately assess the true causality and implications of fear of hypoglycaemia
- Both technological and psychological therapies can be beneficial in its management; however, there is an urgent need for more robust paediatric intervention trials to validate these therapies

paediatric FoH, but to truly capture the natural history of an often transient phenomenon, large-scale prospective longitudinal studies are required. An assessment of FoH should include the validated HFS and an objective psychological evaluation. The outcome of glycaemic control should be broadened to include CGM data, acute and secondary complications. QoL should be assessed by both subjective questionnaires and objective psychological appraisal. To limit selection bias, studies must aim to include both parents of all patients within a named diabetes centre, with efforts to minimise language and travel barriers. Further statistically powered RCTs must confirm the validity and applicability of interventions. Awareness of FoH should be raised among local paediatric diabetes multidisciplinary teams, CYP and their parents, with a view to including HFS-P, HFS-PYC and HFS-C surveys within the annual diabetes review so at-risk families can be offered appropriate interventions.

Conclusions

This review indicates that FoH is an important issue among CYP with T1DM and their parents. There are several factors involved in the development of FoH. Personal experience of hypoglycaemia and psychological vulnerability are core features in the construct, but the weight of these factors depends on a host of other sociodemographic variables. The true causality and burden of FoH can be better established in prospective longitudinal studies, assessing these potential risk factors at diagnosis and monitoring for the development of FoH at regular intervals. Significant FoH can invariably impact diabetes management and glycaemic control; longitudinal results with CGM data will enable a subtler evaluation of this relationship. Study spans over decades can also assess the psychological burden of FoH more comprehensively than snapshot cross-sectional data. Although such studies are costly and susceptible to high drop-out rates, they are necessary to accurately define the long-term impact of FoH. This enables at-risk individuals to be identified more readily, and intervention measures to be better tailored. Despite a recent expansion in paediatric FoH intervention trials, numbers are still small. A greater volume of such trials, with larger study numbers, are desperately needed to demonstrate the value of technological and psychological therapies in order to make such interventions commonplace offerings for families suffering from intractable fear.

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Author contributions AF conducted the literature review and wrote the first draft. VP reviewed the content and suggested amendments which AF incorporated.
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Appendix 1. Search Strategies

A. Embase

1 type 1 diabetes mellitus.mp. or insulin dependent diabetes mellitus/ (117090)
2 (T1DM or T1D or IDDM).mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word, candidate term word] (30663)
3 1 or 2 (122864)
4 hypoglycemia/ or fear of hypoglycaemia.mp. or fear/ (150043)
5 hypoglycemia/ or FoH.mp. or fear/ (150230)
6 4 or 5 (150251)
7 HbA1c.mp. or hemoglobin A1c/ (113493)
8 glycosylated hemoglobin/ or glycemic control.mp. or glycemic control/ or glucose blood level/ (323176)
9 7 or 8 (376656)
10 quality of life.mp. or "quality of life"/ (566645)
11 (depression or anxiety).mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word, candidate term word] (879500)
12 10 or 11 (1366021)
13 3 and 6 and 9 and 12 (1501)
14 limit 13 to (english language and yr="2000 - 2020" and child <unspecified age>) (286)

B. Medline

1 type 1 diabetes mellitus.mp or Diabetes Mellitus, Type 1/ (77260)
2 (T1DM or T1D or IDDM).mp (16468).
3 1 or 2 (80748)
4 Hypoglycaemia/ or fear of hypoglycaemia.mp (27064)
5 Fear/ or FoH.mp. or Hypoglycemia/ (57847)
6 4 or 5 (57902)
7 HbA1c.mp. or Glycated Hemoglobin A/ (51919)
8 Glycated Hemoglobin A/ or Blood Glucose/ or glycemic control.mp. (190137)
9 7 or 8 (202638)
10 "quality of life.mp. or "Quality of Life"/ (317349)
11 Depression/ or Anxiety/ (525114)
12 10 or 11 (803362)
13 3 and 6 and 9 and 12 (303)
14 Limit 13 to (English language and yr="2000-2020" and "all child (0 to 18 years)" and last 20 years) (120)

C. PsycINFO

1 (type 1 diabetes mellitus or diabetes mellitus).mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures, mesh] (11675)
2 (T1DM or T1D or IDDM).mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures, mesh] (785)
3 1 or 2 (11928)
4 exp Hypoglycemia/ or exp Fear/ or hypoglycaemia.mp. (21131)
5 exp Fear/ or exp Hypoglycemia/ or FoH.mp. (20993)
6 4 or 5 (21147)
7 HbA1c.mp. (1750)
8 exp Glucose/ or exp Blood Sugar/ or glycemic control.mp. (5846)
9 7 or 8 (7008)
10 quality of life.mp. or exp "Quality of Life"/ (86860)
11 exp "Quality of Life"/ or QoL.mp. (44348)
12 (depression or anxiety).mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures, mesh] (456241)
13 10 or 11 or 12 (519192)
14 9 or 13 (524970)
15 3 and 6 and 14 (89)
16 limit 15 to (english language and (childhood <birth to 12 years> or adolescence <13 to 17 years>) and last 20 years) (17)

Appendix 2. Quality Assessment Tables

A. Cross-Sectional Studies (n = 28)
CEBM Critical Appraisal of a Cross-Sectional Study (CEBM, 2014)

1. Did the study address a clearly focused question/ issue?
2. Is the research method (study design) appropriate for answering the research question? 3. Is the method of selection of the subjects (employees, teams, divisions, organizations) clearly described?
4. Could the way the sample was obtained introduce (selection) bias?
5. Was the sample of subjects representative with regard to the population to which the findings will be referred?
6. Was the sample size based on pre-study considerations of statistical power? 7. Was a satisfactory response rate achieved? 8. Are the measurements (questionnaires) likely to be valid and reliable?
9. Was the statistical significance assessed?
10. Are confidence intervals given for the main results?
11. Could there be confounding factors that haven't been accounted for?
12. Can the results be applied to your organization?

Appendix 2. Quality Assessment Tables (continued)

Study	1	2	3	4	5	6
First Author Publication Year	Clearly focused question	Appropriate research method	Clear study design	Selection bias	Representative sample	Power calculation
1. Aalders (2018)	Yes Mindfulness and parental FoH	Yes	Yes	Perhaps Time commitment No data on non-participants	Partially of local population 3% non-Dutch; 89% married 83% paid job	No
2. Al Hayek (2015)	Yes FoH and anxiety	Yes	Yes	Yes Selected from military medical centre	Reflective of local population 100% Arabic	No
3. Amiri (2014)	Yes FoH, self-efficacy and HbA1c	Yes	Yes	Yes Selected from a limited database	Reflective of local population 100% Iranian	No
4. Amiri (2018)	Yes FoH, self-efficacy and parenting stress	Yes	Yes	Yes Selected from a limited database	Reflective of local population 100% Iranian	No
5. Di Battista (2009)	Yes Effect of FoH on social anxiety, adherence and QoL	Yes	Yes	Perhaps Time commitment $10 incentive	Representative of clinic population 82% white; 12% African-American but higher SES	No
6. Forsander (2016)	Yes Gender and DD, including FoH	Yes	Yes	Perhaps Time commitment	Partially- national database 69% married; 90% economic status above average, more girls	No
7. Freckleton (2014)	Yes Maternal FoH and adherence	Yes	Yes	Yes Time commitment Opportunistic from camp/ advert	Yes, most likely 83% Australian-born Little other demographic data	No
8. Frederick (2011)	Yes FoH and diabetes self-management	Yes	Yes	Yes Time commitment Opportunistic from clinic/ camp	Yes- diverse sample 66% white, 32% black, 2% Hispanic; no SES data	No
9. Gonder-Frederick (2006)	Yes Influence of trait anxiety and hypoglycaemic history on FoH	Yes	Yes	Perhaps Time commitment with no compensation	Representative of clinic population 87% Caucasian; 13% African-Am 70% married; 75% >high school	No
10.Gonder-Frederick (2011)	Yes FoH and diabetes control	Yes	Yes	Unclear	88% Caucasian	No
11.Grey (2009)	Yes Anxiety & depression in mothers related to FoH, coping and metabolic control	Yes	Yes	Yes Baseline data from an RCT on coping skills training	Representative of clinic population 85% white; 14% Black 55% income >$80,000	No
12.Haugstvedt (2010)	Yes FoH, hypoglycaemia and parental emotional distress	Yes	Yes	Perhaps Time commitment	Representative of clinic population 97% Norwegian	No
13.Haugstvedt (2015)	Yes Examine psychometric properties of HFS-P	Yes	Yes	Perhaps Time commitment	Representative of clinic population 87% married; 92% men employed full-time	No
14.Hawkes (2014)	Yes Parental FoH and glycaemic control	Yes	Yes	Perhaps Time commitment	Unclear Demographics not recorded	No
15.Herbert (2014)	Yes Relationship of sleep, FoH and diabetes self-efficacy	Yes	Yes	Yes Baseline data from an RCT on behavioural intervention	Comparable to US diabetes population- 78% Caucasian; 84% married, 76% income >$50,000	No
16.Johnson (2013)	Yes Evaluate FOH, hypoglycaemia and quality of life	Yes	Yes	Yes Time commitment Non-responders were younger and had shorter DM duration	Representative of clinic population but few parental demographics provided	No
17.Kamps (2005)	Yes Provision of preliminary psychometric data on CHI	Yes	Yes	Yes Recruitment from within a summer camp	Less so- 87% Caucasian, summer camp attendees, limited other information	No
18.Markowitz (2012)	Yes Comparison of psychological characteristics CGM v. SMBG	Yes	Yes	Yes One site data from those already recruited to larger JDRF-CGM trial	Unclear Limited demographics included	No
19.Mitchell (2009)	Yes Correlates of fathers parenting stress including FoH	Yes	Yes	Perhaps Questionnaires time commitment $10 gift card incentive Participants from larger study	Reflective of Atlanta population Only fathers explored, 96% married, 78% income >$75,000	No
20.Pate (2019)	Yes Parental FoH, anxiety and well-being	Yes	Yes	Perhaps Questionnaires time commitment	Partially Majority married & employed Sample HbA1c significantly lower	No
21.Patton (2007)	Yes Parental FoH & BG levels	Yes	Yes	Perhaps 2 weeks of SMBG 4 times/day $20 gift card incentive	Representative of clinic population 96% white; 92% married 96% >SES class III	No
22.Patton (2008)	Yes Development of HFS-PYC	Yes	Yes	Perhaps 2 weeks SMBG 4 times/day $20 gift card incentive	Representative of clinic population 72% white; 74% married 85% >SES class III	No
23.Patton (2011)	Yes Parenting stress & FoH/ depression	Yes	Yes	Perhaps $50 reimbursement English must be spoken at home	Representative of clinic population 82% white; 74% married 54% income >$50,000	No
24.Patton (2017)	Yes Update psychometric properties of HFS-PYC	Yes	Yes	NA	Representative of clinic population 91% white	No
25.Shepard (2014)	Yes Exploring constructs of HFS-P and HFS-C	Yes	Yes	Perhaps 4 weeks SMBG 4 times/day	Representative of clinic population 93% Caucasian, 4% African 87% married Better glycaemic control	No
26.Streisand (2005)	Yes Parenting stress and its correlates (including FoH)	Yes	Yes	Yes - participants consented to longitudinal study $25 reimbursement	Yes 79% Caucasian; 84% married 46% SES class III	No
27.Van Name (2017)	Yes FoH in parents of young children	Yes	Yes	Perhaps Questionnaire time commitment	Yes 77% white 10% Hispanic 6% black But 52% income >$75,000	No
28.Viaene (2017)	Yes Parenting stress, FoH and metabolic control	Yes	Yes	Perhaps Opportunistic recruitment from clinic attendance; Dutch-speaking	Perhaps 76% married; limited other demographic information available	No

Appendix 2. Quality Assessment Tables (continued)

Study	7	8	9	10	11	12
Authors Year	**Satisfactory response rate**	**Valid & reliable measures (Cronbach's alpha= a)**	**Statistical significance assessed**	**Confidence intervals given**	**Confounders accounted for**	**Results applicable locally**
1. Aalders (2018)	Yes- 79%	Yes- HFS-P worry scale (a= 0.88) Freiburg Mindfulness Inventory (a= 0.83) Interpersonal Mindfulness in Parenting Scale (a=0.85)	Yes	No	Yes	Partially Similar demographics but higher SES and married state; higher CSII
2. Al Hayek (2015)	Unknown	Yes- HFS-C (a= 0.86) Arabic translated Screen for Child Anxiety-Related Disorders (a=0.91) Socio-demographic/ clinical questionnaire	Yes	Yes	Yes	Less so- Saudi Arabia based
3. Amiri (2014)	Yes- 81%	Yes- HFS-C (a= 0.89) Persian translated Self-Efficacy for Diabetes Scale- Child Version (SED-C) Diabetes History Questionnaire	Yes	Yes	Yes	Less so – Iran based Different cultural environment- only 25% mothers employed; all MDI
4. Amiri (2018)	Yes- 81% Same data 2014	Yes- HFS-P (a= 0.94) Persian translated SED-P (a= 0.84) Paediatric Inventory for Parents (PIP) (a= 0.95-6)	Yes	No	Yes	Less so – Iran based Different cultural environment- only 25% mothers employed; all MDI
5. Di Battista (2009)	No- 23% US; 45% Canada	Yes- HFS-P (a= 0.87) Self-report demographics/HbA1c; Diabetes QoL Measure Social Anxiety Scale for Adolescents Summary of Diabetes Self-Care Regimen	Yes	No	Yes	Partially Small North American sample with poor response rate
6. Forsander (2016)	No- 21% But large sample	No- scale of 1 to 10 to assess FoH Diabetes Distress Scale	Yes	Yes	Yes	Partially Large European sample Poor response rate; high SES
7. Freckleton (2014)	Yes- 62%	Yes- HFS (a= 0.86) Illness Perception Questionnaire 7-day diabetes diary management	Yes	No	Yes	Partially All mothers and all children MDI users
8. Frederick (2011)	Unknown	Yes- CHI (a= 0.89) Diabetes Behaviour Rating Scale (DRBS)	Yes	Yes	Yes	Partially Diverse sample, decent size No SES data
9. Gonder-Frederick (2006)	Yes- 63%	Yes- HFS-P (a= 0.89) & HFS-C (a=0.86) State Trait Personality Inventory (STPI) State Trait Anxiety Inventory for Children (STAIC) Diabetes specific questionnaire	Yes	No	Yes	Partially Only one father included Limited SES diversity
10.Gonder-Frederick (2011)	NA Aggregated data	Yes- HFS-P (a= 0.86) & HFS-C (a=0.85) STPI STAIC	Yes	No	Yes	Yes Good sample size and variance But aggregated data over a decade
11.Grey (2009)	No- 40%	Yes- HFS, STAI a= 0.93 Center for Epidemiological Studies Depression Scale Issues in Coping with IDDM-Parent scale (a= 0.87-88)	Yes	No	Yes	Partially Only mothers included
12.Haugstvedt (2010)	Yes- 71%	Yes- HFS-P (a= 0.87- 0.94) Demographic questionnaire Hopkins Symptom Checklist-25 (HSCL-25) (a= 0.87-92)	Yes	Yes	Yes	Partially Decent sample size and comparable with UK
13.Haugstvedt (2015)	Yes- 71% Same data 2010	Yes- HFS-P HSCL-25	Yes	No	Yes	Partially Decent sample size and comparable with UK
14.Hawkes (2014)	Unknown	HFS-PYC Demographic questionnaire & self-report hypoglycaemia	Yes	No	Unclear	Perhaps Limited parental demographics Irish population similar to UK
15.Herbert (2014)	No- 47%	Yes- HFS-PYC (a=0.92) Pittsburgh Sleep Quality Index (PSQI); SED-P (a= 0.78) Demographic & medical questionnaires 24h recall interview of diabetes tasks + glucometer data	Yes	No	Yes	Yes Relatively diverse US population
16.Johnson (2013)	No- 49% But large sample	Yes- HFS PedsQL Diabetes Module Clarke's hypoglycaemia awareness questionnaire Clinical data from W Australia Childhood Diabetes Database	Yes	No	No	Yes Large sample; similar CSII use But no parental demographics
17.Kamps (2005)	Yes- 65%	Yes- HFS-C and CHI RCMAS Hypoglycaemia History Form	Yes	No	Unclear	Partially High SES in sample Summer camp attendants
18.Markowitz (2012)	Yes- 96% Of participants already recruited to JDRF-CGM trial	Yes- HFS Pediatric QOL Inventory; Short Form Health Survey Center for Epidemiologic Studies Depression scale (CES-D) BGM Communication Questionnaire Diabetes Family Conflict Scale (DFCS); STAI & PAID; Children's Depression Inventory	Yes	No	Yes	Partially Very small study but UK based Limited demographics included Included adult participants but result separated by age group
19.Mitchell (2009)	Yes- 86%	Yes- HFS-P (a= 0.92), PIP (a = 0.95); recall interview Eyberg Child Behaviour Inventory Self-Efficacy for Diabetes Scale (SED) STAI (a=0.93); Hope Scale (a=0.79)	Yes	No	Yes	Partially Only fathers; high income/ married Not generalisable to single fathers
20.Pate (2019)	Yes- 62%	Yes- HFS-P (a = 0.89), STAI (a = 0.90) Positive and Negative Affect Schedule (PANAS) Satisfaction with Life Scale (SWLS) (a= 0.87)	Yes	No	Yes	Partially Reliance on translated HFS Sample HbA1c significantly lower
21.Patton (2007)	Yes- 86%	Yes - HFS-PYC (a = 0.86) SMBG + HbA1c Self-report demographic & hypoglycaemia history	Yes	No	No	Partially Small sample & limited diversity Single clinic Cincinnati 100% CSII users
22.Patton (2008)	Yes- 73%	Yes - HFS-PYC (a= 0.91) SMBG + HbA1c Self-report demographic & hypoglycaemia history	Yes	No	No	Partially Limited diversity Single clinic Cincinnati Majority had HbA1c 7.5-8.5%
23.Patton (2011)	Just- 51%	Yes- HFS-PYC Behavioural Pediatric Feeding Assessment Scale Pediatric Inventory for Parents (PIP) Beck Depression Inventory-Second Edition (BDI-II)	Yes	No	Yes	Partially Small homogenous sample 2 clinics in the Midwest High CSII use; majority mothers
24.Patton (2017)	NA 3 datasets	Yes- HFS-PYC	Yes	No	Unclear	Partially 3 datasets over 5 years Homogenous sample 100% CSII users
25.Shepard (2014)	NA 5 studies	Yes- HFS-C and HFS-P STPI (a = 0.8-87), STAIC Self-report demographics & hypoglycaemic history	Yes	No	Yes	Partially 5 studies data over 10 years All from same Virginia lab Narrow demographics
26.Streisand (2005)	Yes -80%	Yes- HFS-P (a = 0.90) Diabetes Family Responsibility Questionnaire (DFRQ) PIP (a= 0.94); SED (a = 0.87) Demographic and Medical History Questionnaire	Yes	No	Yes	Yes But note wide child age range Majority mothers
27.Van Name (2017)	Yes- 71% at site level Unclear at individual level	Yes- HFS-P Worry scale Self-report demographics, DKA & SH	Yes	No	Yes	Yes Large registry T1DM exchange Diverse sample but high SES High CGM use (32%) No parent gender identification
28.Viaene (2017)	Yes- 74%	Yes- HFS-P (a = 0.86); HFS-C (a = 0.68) Nijmegen Parenting Stress Index- Short form (NPSI-S)	Yes	Yes	Yes	Yes But small dataset a Limited demographics available

Appendix 2. Quality Assessment Tables (continued)

B. Randomised Controlled Trials (n = 8)
CASP Randomised Control Trial Checklist (CASP, 2018)

1. Did the trial address a clearly focused issue?
2. Was the assignment of patients to treatments randomised?
3. Were all of the patients who entered the trial properly accounted for at its conclusion?
4. Were patients, health workers and study personnel 'blind' to treatment'?
5. Were the groups similar at the start of the trial?
6. Aside from the experimental intervention, were the groups treated equally?
7. How large was the treatment effect?
8. How precise was the estimate of the treatment effect?
9. Can the results be applied to the local population, or in your context?
10. Were all clinically important outcomes considered?
11. Are the benefits worth the harms and costs?

Appendix 2. Quality Assessment Tables (continued)

	1	2	3	4	5	6
First Author Publication Year	**Clearly focused issue**	**Assignment randomised**	**Patient accountability**	**Blinded intervention**	**Similar baseline characteristics**	**Equal treatment of two groups**
1. Abraham (2018)	Yes PLGM v. SAPT	Yes Minimisation at randomisation	Yes- consort diagram 19% loss (withdrawal/ deviation)	No	Yes	Yes
2. Barnard (2014)	Yes CLS v. SAPT	Yes Permuted block-four approach	Yes 52% recruitment; 1 withdrawal	Not to patient Allocation concealed to staff	Unclear	Almost CLS- extra supervision
3. Burkhardt (2018)	Yes CGM v. SMBG	Yes Computer generated	No	No	Unclear	Yes
4. JDRF CGM (2010)	Yes CGM v. SMBG	Yes Permuted block design Stratified- centre, age,HbA1c	Yes 95-100% completion rate	No	Yes	Almost CGM- additional direction
5. Mayer-Davis (2018)	Yes FLEX v. control	Yes Automated block method Stratified by site & HbA1c	Yes- consort diagram 16.5% ineligible; 51% refused Final sample- 93% retention rate	Not to patient Allocation concealed to staff	Yes	Yes
6.Mueller-Godeffroy (2018)	Yes CSII v. MDI	Yes Software; stratified by centre	Yes- consort diagram 57% recruitment 15% loss to follow up	Not to patient Allocation concealed to staff	Yes	Yes
7. Patton (2019)	Yes RECHiP v. control	Yes Block assignment by child sex	Yes- consort diagram 32% recruitment 16% excluded final analysis	No	Unclear	Yes
8. Ziegler (2015)	Yes AP v. SAPT	Yes Computer software blocked randomisation	No	No	Unclear	Unclear

Study	**7**	**8**	**9**	**10**	**11**
First Author Publication Year	**Treatment Effect**	**Precision Estimate**	**Applicable Results**	**Significant outcomes explored**	**Benefits outweigh harms/ costs**
1. Abraham (2018)	Primary outcome: time spent in hypoglycaemia PGLM hypo reduction from 2.8% to 1.4% No differences for HbA1c, HFS and Peds QL scores	Reduction more with PGLM v. SAPT (p<0.0001) (mean difference -0.95% [95% CI -1.30 to −0.61)	Somewhat 5 Australian centres Limited demographics	Yes	No adverse events Cost not explored
2. Barnard (2014)	Primary outcome: time spent in target BG range Nocturnal hypo less in CLS than CGM 10 v. 17% Mixed results for HFS scores	Time spent in target increased from 47% to 64% with CLS (p<0.001) HFS changes were not statistically significant	Yes- UK based trial 2 units; home trial But very small sample	Yes	No adverse events Cost not explored
3. Burkhardt (2018)	Primary outcome: parental FoH on HFS HFS-P lower after intervention: 54.9 v. 44.7	Least square mean difference control v CGM: -8.5 (95% CI -12.7 to −4.4; p<0.001)	Somewhat Australian study- small Limited demographics	Yes	No adverse events Cost not explored
4. JDRF CGM Study Group (2010)	Primary outcome: HbA1c – no significant difference for CYP; for HFS scores slight improvement in CGM group >18y (<0.05)	No significant HFS changes in youth or parents	Yes- 10 UK centres Included adults Limited diversity	Yes	5-10% at least one SH No difference in groups Appears cost-effective
5. Mayer-Davis (2018)	Primary outcome: HbA1c; no effect All domains of HFS decreased with intervention	Only significant HFS reductions in behaviour to maintain high BG in parents (p=0.005) and worry/ helplessness in adolescents (p=0.04)	Somewhat Diverse US sample	Yes	34 adverse events None study related Cost not explored
6.Mueller-Godeffroy (2018)	Significant improvement in parental HFS	Primary outcome DHRQOL significantly better for CSII (MD 5.95, 1.19-01.71 p=0.016)	Yes Multiple centres Germany	Yes	No adverse events Cost not explored
7. Patton (2019)	Primary outcome: HFS + PIP score Significant reduction in HFS (p=0.04) and in parenting stress frequency p=0.092)	Parental HFS-PYC total score 71.5 to 59.9 (6.53-16.61; p<0.001)	A little Small US sample Homogenous	Yes	59.5% hypo 1-2/ week Maintenance only at 3m Cost not explored
8. Ziegler (2015)	After 4 nights on the AP system HFS worry decreased significantly (p=0.017)	Significant change only in HFS-W not HFS-B Too short a duration of intervention	Multinational Limited demographics 19 adults included	Yes	Cost not explored

Appendix 2. Quality Assessment Tables (continued)

C. Pre-Post Prospective Studies (n = 5)
NIH Quality Assessment Tool for Before-After (Pre-Post) Studies (NIH, 2018)

1. Was the study question or objective clearly stated?
2. Were eligibility/ selection criteria for the study population prespecified and clearly described?
3. Were the participants in the study representative of those who would be eligible for the intervention in the general/clinical population of interest?
4. Were all eligible participants that met the prespecified entry criteria enrolled?
5. Was the sample size sufficiently large to provide confidence in the findings?
6. Was the test/ service/ intervention clearly described and delivered consistently across the study population?
7. Were the outcome measures prespecified, clearly defined, valid, reliable, and assessed consistently across all study participants
8. Were the people assessing the outcomes blinded to the participants' exposures/ interventions?
9. Was the loss to follow-up after baseline 20% or less? Were those lost to follow-up accounted for in the analysis?
10. Did the statistical methods examine changes in outcome measures from before to after the intervention and provide p values?
11. Were outcome measures of interest taken multiple times before the intervention and multiple times after the intervention (i.e., did they use an interrupted time-series design?
12. If the intervention was conducted at a group level (e.g., a whole hospital, a community, etc) did the statistical analysis take into account the use of individual-level data to determine effects at the group level?

Study	**1**	**2**	**3**	**4**	**5**	**6**
First Author Publication Year	**Clearly stated objective**	**Clearly described eligibility criteria**	**Study participants representative**	**All eligible participants enrolled**	**Sample size sufficient**	**Intervention clear and consistent**
1.Al Hayek (2017)	Yes (3m) FGM- FoH/ QoL HbA1c	Yes: 13-19 years Minimum 6m T1DM No recent SH/ DKA	Yes- of Saudi Arabia Limited demographics	Unclear	No (n= 47) No power calculation	Yes
2. Cai (2017)	Yes (3m) Workshop- FoH/QoL HbA1c	Yes: 8-16 years Minimum 6m T1DM No co-morbidity	Yes- of UK clinic population Ethnically diverse	No- pilot study Only 89 of 300- 33% recruitment	Almost (n= 22) Aimed 32 for pilot	Yes
3.Ng (2019)	Yes (12m) CGM- FoH/ HbA1c	Yes: <18 years Minimum 12m CGM English speaking	Yes- of UK clinic population Limited demographics	Unclear	No (n= 16) No power calculation	Clear intervention 58% uncompliant
4.Kamps (2010)	Yes Trauma- FoH/Anxiety HbA1c	Yes: 8-16 years Minimum 6m T1DM No chronic illness	Yes- of US clinic population Higher income, education, duration in x2 completers	Most 89% recruitment	Moderate (n= 158) No power calculation	No No measure of exposure/ stress
5.Muller-Godeffroy (2009)	Yes (6m) CSII-Psychosocial	Yes: 4-16 years Minimum 6m T1DM Sufficient literacy	Yes-18 centres in Germany Limited demographics	Unclear	Almost (n= 117) 80% power = 120	Yes

Study	**7**	**8**	**9**	**10**	**11**	**12**
First Author Publication Year	**Outcomes defined, valid, reliable & consistent**	**Assessors blinded**	**Loss to follow up <20% and accounted for**	**P values provided for pre- to post- changes**	**Outcomes measured multiple times**	**Group-level intervention v. individual data**
1.Al Hayek (2017)	Yes HFS-C, Peds QL	No	Yes No loss to follow up cited	Yes	No	NA
2.Cai (2017)	Yes HFS, Peds QL	No	Accounted for but high: 34% loss to follow up	No Pilot intervention	Yes- outcomes at 1 and 3m	NA
3. Ng (2019)	Yes HFS/ HbA1c	No	Yes Only 8% loss to follow up	Yes	Yes- HbA1c at 3,6,9,12m	NA
4.Kamps (2010)	Yes CHI, RCMAS/ HbA1c	No	Accounted for but high: 25% loss to follow up	Yes	No	NA
5.Muller-Godeffroy (2009)	Yes HRQOL, PIP, HFS HbA1c	No	Accounted for but high: 23% in CYP 18% in parents	Yes	No	NA

Appendix 2. Quality Assessment Tables (continued)

D. Literature Reviews/Systematic Reviews (n = 2)
CASP Systematic Review Checklist (CASP, 2018)

1. Did the review address a clearly focused question?
2. Did the authors look for the right type of papers? 3. Do you think all the important, relevant studies were included?
4. Did the review's authors do enough to assess quality of the included studies? 5. If the results of the review have been combined, was it reasonable to do so?
6. What are the overall results of the review?
7. How precise are the results?
8. Can the results be applied to the local population?
9. Were all important outcomes considered?
10. Are the benefits worth the harms and costs?

Study	**1**	**2**	**3**	**4**	**5**
First Author Publication Year	**Focused question**	**Appropriate papers**	**Important relevant studies included**	**Quality assessment**	**Results combination**
1.Barnard (2010)	Yes FoH in parents of young children	Yes Cross-sectional	Mostly: CRD principles; 2 reviewers Multiple databases, meeting abstracts, bibliographies, experts, But only 6 studies; nil interventional	Yes: Crombie criteria 2 reviewers X1 7/7 quality indicators x3 3 met 6/7; x2 met 4/7	No Dissimilar cohorts/ outcomes Lack of data Narrative synthesis
2.Driscoll (2016)	Yes FoH in CYP and parents Literature review	Yes Cross-sectional	Greater breadth- 16 studies	Unclear	No Narrative analysis

Study	**6**	**7**	**8**	**9**	**10**
First Author Publication Year	**Overall results**	**Result precision**	**Locally applicable**	**All-important outcomes considered**	**Benefits worth harms and costs**
1.Barnard (2010)	Parental FoH/ anxiety/ depression are common Hypoglycaemia severity predicts FoH > frequency	Some results precise p values given	Somewhat 4 studies representative Mostly US studies; similar to UK	Yes Except intervention/ education	NA
2.Driscoll (2016)	Parent report of SH was the most common predictor o Most studies failed to find an association with HbA1c	Unclear	Somewhat 16 studies- mainly US/ European	Yes Associated factors, behavioural interventions, technology	NA

Appendix 3. Data Extraction Tables

Paper First author Year	Study Design Target population	Country Recruitment site	Response rate	Number of participants Female (F): Male (M) Mean age y=years (age range) Parents	 CYP (Children & Young People)	Exclusion criteria m=months	Mean diabetes duration (range)	Insulin regime	Mean HbA1c (range)	Ethnicity	Married/ Partner	SES
1. Aalders (2018)	Cross-sectional Parents	Netherlands MILES Youth data	421 of 533 79%	421 F 359 (85%) M 62 (15%) 43.1y (29-66)	421 F 194 (46%) M 227 (54%) 11.3y (4-18)	NR	4.6y (0-16)	MDI 114 (27%) CSII 307 (73%)	7.8% -parent report 355	Non-Dutch 3%	89%	High education 38% Paid job 83%
2. Al Hayek (2015)	Cross-sectional Adolescents	Saudi Arabia Diabetes Centre Jun 13-Feb 14	NR	NA	187 F 95 (51%) M 92 (49%) 15.3y (13-18)	<1y T1DM Chronic illness Cognitive impairment	7.1y	MDI 151 (81%) CSII 36 (19%)	NR	Arabic 100%	NR	NR
3. Amiri (2014)	Cross-sectional Young children	Iran Gabric Diabetes Education Assoc 2005-12	61 of 75 81%	105 F 60 (57%) 36.2y (25-49) 45 M (43%) 42y (30-58)	61 F 26 (43%) M 35 (57%) 9.2y (6-12.7)	<6m T1DM Autoimmune condition Growth disorder	5.1y (0.5-10.5)	MDI 61 (100%) CSII 0	9.4% -initiation (6.1-13.7)	Iranian 100%	NR	High School 66% Employed 25% F 95% M
4. Amiri (2018)	Cross-sectional Same data 2014 Parents	Iran Gabric Diabetes Education Assoc	61 of 75 81%	105 F 60 (57%) 36.2y (25-49) 45 M (43%) 42y (30-58)	61 F 26 (43%) M 35 (57%) 9.2y (6-12.7)	<6m T1DM Autoimmune condition Growth disorder	5.1y (0.5-10.5)	MDI 61 (100%) CSII 0	9.4% -initiation (6.1-13.7)	Iranian 100%	NR	High School 66% F 64% M Employed 25% F 95% M
5. Di Battista (2009)	Cross-sectional Adolescents	North America Nashville/Toronto May 04-Apr 07	72 of 307 23% US 10 of 22 45%Canada	NA	76 F 43 (57%) M 33 (43%) 15.9y (13-18)	<6m T1DM Poor English	6.42y	NR	8.9% -initiation	White 82% African 12% Other 4%	NR	Average income $40,000-$59,999
6. Forsander (2016)	Cross-sectional Adolescents	Sweden DIABKIDS database	453 of 2112 21%	NA	453 F 299 (66%) 154 M (34%) 17y (15-18)	NR	6.6y	MDI 237 (53%) CSII 216 (47%)	7.7% -recent	NR	69%	Economic status above average 90%
7. Freckleton (2014)	Cross-sectional Parents	Australia Diabetes camp JDFA advert	71 of 115 62%	71 F 71 (100%) M 0	71 F 38 (53%) M 33 (47%) 8y (2-12)	NR	3.1y (1-22)	MDI 71 (100%) CSII 0	8.1% -initiation (5.6-12.9)	Australian born 83%	NR	NR
8. Frederick (2011)	Cross-sectional Children	US Diabetes camp Clinic Atlanta	NR	NR	127 F 75 (59%) M 52 (41%) 11.8y (8-15)	<9m T1DM Lack of fluency in English	4.5y (1-13)	MDI 60 (47%) CSII 67 (53%)	8.0% -recent	White 66% Black 32% Hispanic 2%	NR	NR
9. Gonder-Frederick (2006)	Cross-sectional Parents Adolescents	US Clinic Virginia	78 of 124 63%	39 F 38 (97%) 1 M (3%)	39 F 17 (44%) M 22 (56%) 15.36y (12-17)	<1y T1DM Co-morbidity Learning disability (LD)	7.03y	MDI 25 (64%) CSII 14 (36%)	7.85% -6-8wks	Caucasian 87% African 13%	70%	Beyond high school 75%
10.Gonder-Frederick (2011)	Literature review Aggregated data Parents & CYP	24 articles US lab Several datasets over 10y	NR	250 F 203 (81%) M 47 (19%)	259 F 118 (46%) M 141 (54%) 10.56y (6-18y)	<1y T1DM	5.24y	MDI 161 (62%) CSII 98 (38%)	8.01%	Caucasian 88%	NR	Mean education 15.5y

NA (not applicable), NR (not recorded)

Appendix 3. Data Extraction Tables (continued)

11.Grey (2009)	Cross-sectional RCT data Parents of young children	US Clinic Connecticut	70 of 177 40%	67 F 67 (100%) M 0 37.2y (26-51)	67 F 35 (52%) M 32 (48%) 4.8y (1-8y)	<6m T1DM Chronic illness Mental illness	1.4y	MDI 21 (32%) CSII 46 (68%)	6.86% -last 3m	White 85% Black 14%	NR	Income >$80,000 55%
12.Haugstvedt (2010)	Cross-sectional Parents	Norway University Hospital Dec 2006	115 of 161 71%	200 F 103 (52%) 39.6y (21-52) M 97 (48%) 42.6y (32-58)	115 F 58 (50%) M 57 (50%) 10.6y (<16)	NR	3.9y (0.3-14.2)	MDI 65 (57%) CSII 50 (43%)	8.1% -last 3m -2m after (5.3-11.7)	Norwegian 97%	NR	NR
13.Haugstvedt (2015)	Cross-sectional Factor analysis Same data 2010 Parents 6-16y	Norway University Hospital Dec 2006	115 of 161 71%	176 F 91 (52%) 40.2y M 85 (48%) 43.4y	102 F 50 (49%) M 52 (51%) 11.4 (6.1-15.9)	NR	3.9y (0.3-14.2)	MDI 57 (56%) CSII 45 (44%)	8.2% 6.1-11.7	NR	87%	College 36% Employed full-time 37% F 92% M
14.Hawkes (2014)	Cross-sectional Parents	Ireland Clinic Dublin Jan 13-Apr 13	NR	106 F 73 (69%) M 33 (31%)	106 F 51 (48%) M 55 (52%) 11.1y (<18)	<3m T1DM	4.8y	MDI 55 (52%) CSII 51 (48%)	7.9% -recent	NR	NR	NR
15.Herbert (2014)	Cross-sectional RCT Baseline Parents	US 3 clinics	134 of 285 47%	134 F 120 (90%) M 14 (10%) 36.8y	134 F 66 (49%) M 68 (51%) 5.3y (1-6)	<6m T1DM Chronic illness Development disorder	2y (0.54-5.95)	Intensive regime 72%	8.13% -last 1m	Caucasian 78%	84%	Employed 71% Income >$50,000 76%
16.Johnson (2013)	Cross-sectional Parents Children 8-18	Western Australia Clinic Aug 09-Aug 10	325 of 539 49%	325 NR	325-196 8-18y F 154 (47%) M 171 (53%) 11.8y (2-18)	<6m T1DM Co-morbidity LD	4.8y	MDI 212 (65%) CSII 113 (35%)	8.0% -last clinic	NR	NR	NR
17.Kamps (2005)	Cross-sectional Children	US ADA Summer Camp Mid-West	109 of 168 65%	NA	109 F 67 (61%) M 41 (39%) 11.9y (8-16)	NR	NR	NR	NR	Caucasian 87%	NR	Most parents college education
18.Markowitz (2012)	Cross-sectional Parents Children	UK Single-site of JDRF CGM trial	49 of 51 96%	28 F 20 (71%) M 8 (29%)	28 F 17 (61%) M 11 (39%) 13.4y (8-18)	NR	7.2y	MDI 4 (14%) CSII 24 (86%)	7.6%	NR	NR	NR
19.Mitchell (2009)	Cross-sectional Fathers young children	US Clinic Mid-Atlanta	100 of 114 88% 76 complete	43 F 0 M 43 (100%) 38.3y (29-56)	43 F 25 (58%) M 18 (42%) 4.5y (2-6)	<6m T1DM Chronic illness Develop delay No English	1.3y	MDI 41 (95%) CSII 2 (5%)	7.5% -recent	Caucasian 77%	98%	High School 84% Employed 98% Income >$75,000 78%
20.Pate (2019)	Cross-sectional Parents	Slovenia Clinic Ljubljana Jun-Sep 14	125 of 201 62%	199 F 120 (60%) 41.7y (31-58) M 79 (40%) 44.9y (33-65)	125 F 59 (47%) M 66 (53%) 12.4y (7-17)	<1y T1DM	4.9y (1-14)	MDI 25 (20%) CSII 100 (80%) CGM 18 (9%)	7.6% -initiation 5.5-9.4)	NR	Majority married	Majority employed
21.Patton (2007)	Cross-sectional Parents of young children	US Clinic Cincinnati	24 of 28 86%	24 F 20 (83%) M 4 (17%)	24 F 12 (50%) M 12 (50%) 5.7y (2-8)	<6m T1DM <3m CSII use	3.1y	MDI 0 CSII 24 (100%)	8.3%- 0m 7.8%- 3m	White 96%	92%	>Class III 96%
22.Patton (2008)	Cross-sectional Parents of young children	US Clinic Cincinnati	81 of 109 families 73%	145 F 81 (56%) M 64 (44%)	81 F 49 (60%) M 32 (40%) 5.6y (2-8)	<6m T1DM	3.4y	MDI 101 (70%) CSII 44 (30%)	8.1% (5.4-10.4)	White 72%	79%	>Class III 85%
23.Patton (2011)	Cross-sectional Parents of young children	US 2 clinics in the Midwest	39 of 77 51%	39 F 32 F (82%) M 7 (18%) 35y	39 F 19 (49%) M 20 (51%) 5.1y (2-7)	<1y T1DM English not spoken at home	NR	MDI 15 (38%) CSII 24 (62%)	8.6% -last 3m	White 82%	74%	>$50,000 54%

NA (not applicable), NR (not recorded)

Appendix 3. Data Extraction Tables (continued)

24.Patton (2017)	Cross-sectional Data analysis Parents	US 3 datasets over 5y	NA	116 F 108 (93%) M 8 (7%)	116 F 58 (50%) M 58 (50%) 5.2y (2-7.9)	<6m T1DM No English Chronic illness	NR	MDI 0 CSII 116 (100%)	8.2% -last 3m (5-12.7)	White 91%	NR	NR
25.Shepard (2014)	Cross-sectional Factor analysis Parents + CYP	US Virginia lab 5 studies 2002-10	NA	250 F 220 (88%) M 30 (12%)	259 F 124 (48%) M 135 (52%) 10.56y (6-18)	<1y T1DM Co-morbidity LD	5.24 y	MDI 155 (60%) CSII 104 (40%)	8.01%	Caucasian 93% African 4%	87%	Mean education 15y
26.Streisand (2005)	Cross-sectional Parents	US 2 city clinics	80%	134 F 115 (86%) M 19 (14%) 42.3y	134 F 64 (48%) M 70 (52%) 12.9y (9-17)	<6m T1DM	4.9y (6-14)	MDI 107 (80%) CSII 27 (20%)	8.5% (5.8-14) -last 6m	Caucasian 79%	84%	Hollingshead Class III 46%
27.Van Name (2017)	Cross-sectional Parents of young children	US T1DM Exchange 58 centres Feb 15-May 16	41 of 58 centres 71%	549	549 (41 sites) F 254 (46%) M 295 (54%) 5.2y (<7y)	<1y T1DM	2.4y (1-6)	MDI 231 (42%) CSII 318 (58%) CGM 176 32%	8.2% -last 6m	White 77% Hispanic 10% Black 6%	NR	Income >$75,000 52%
28.Viaene (2017)	Cross-sectional Parents Children >8y	Belgium Single clinic centre	63 of 85 74%	63 F 53 (84%) M 10 (16%)	63 F 28 (44%) M 35 (56%) 12.36y (2-18)	<6m T1DM Non-Dutch speaking	4.07y	NR	8.28% -last clinic	NR	76%	NR
29.Abraham (2018)	RCT PLGM v. SAPT CYP	Australia 5 tertiary centres	NR	NA	154 F 73 (47%) M 81 (53%) 13.2y (8-20)	<1y T1DM <6m CSII use >10% HbA1c Pregnancy	7.1y	MDI 0 CSI 154 (100%)	7.5% (<10%) -initiation -6m	NR	NR	NR
30.Barnard et al (2014)	Open label Crossover RCT CLS v. SAPT Adolescents	England Clinic UCLH & Cambridge Jul 12-Mar 13	17 of 33 52% 1 withdrew	13 F 12 (92%) M 1 (8%)	16-80% power F 6 (38%) 10 M (62%) 15.6y (12-18)	Complications TDD >2U/kg/d CGM last 1m Pregnancy/ BF	7.2y	MDI 0 CSII 16 (100%) Min 3m CSII	8.2% <10% >4 BG/d	NR	NR	NR
31.Burckhardt (2019)	Open label Crossover RCT CGM v. SMBG Parents	Australia	NR	49	49 F 31 (63%) M 18 (37%) 9.5y (2-12)	<1y T1DM CGM last 6m	3.9y	MDI 20 (36%) CSII 29 (64%)	7.7% -initiation -3m	NR	NR	NR
32.JDRF CGM Study Group (2010)	RCT CGM v. control Parents + CYP	UK 10 centres	451 adults + CYP	223 NR	223 110 CGM 113 Control 8-18y	<1y T1DM HbA1c >10% Pregnancy Sensor naive		Unable to stratify out for <18y	7.4% -initiation -13wk -26wk	NR	NR	NR
33.Mayer-Davis (2018)	RCT FLEX v. conventional Adolescents	US Clinic Colorado & Ohio Jan 14-Apr 16	258 of 8714 36% 141ineligible	258 F 217 (84%) M 41 (16%)	258 F 128 (50%) M 130 (50%) 14.9y (13-16)	<1y T1DM Other serious medical illness Pregnancy	6.4y	MDI 75 (29%) CSII 183 (71%)	9.6% (8-13)	White 78% Hispanic 13% Black 4%	87%	Public health insurance 18%
34.Mueller-Godeffroy (2018)	RCT Open-label Parents	Germany 18 centres Feb 11-Oct 14	211 of 367 randomised 179 analysed	NR	179 F 77 (43%) M 102 (57%) 11.6y (6-16)	<0.5U/kg/d insulin Insufficient literacy	3.5y Min 6m	MDI 89 (49%) CSII 90 (51%)	7.5%	NR	NR	69% medium-high SES
35.Patton (2019)	RCT REDCHiP v. conventional Parents	US Clinic Midwest	36 of 132 27%	36 F 34 (98%) M 2 (2%) 35.2y	36 F 15 (41%) M 21 (59%) 4.4y (1-6)	<6m T1DM	NR	MDI 8 (22%) CSII 28 (78%) CGM 15 (41%)	8.01% -initiation	Caucasian 95% Hispanic 5%	81%	Hollingshead index SES >4 78%
36.Ziegler (2015)	Crossover RCT AP v. SAPT Children	International Clinic Germany, Israel, Slovenia Nov 12-Jan 14	59 of 75 79% 10-65y	NA	40 F 18 (45%) M 22 (55%) 13.95y (10-18)	DKA/ SH -1m Co-morbidity Pregnancy Other Study	8.0y	MDI 0 CSII 40 (100%) Min 3m	8.12% (7-10)	NR	NR	NR
37.Al Hayek (2017)	Prospective Pre-/post FGM Adolescents	Saudi Arabia Diabetes Centre Jan-May 17	NR	NA	47 F 27 (57%) M 20 (43%)	<6m T1DM Skin issue SH/ DKA	NR	MDI 29 (62%) CSII 18 (38%)	8.5%	NR	NR	NR

NA (not applicable), NR (not recorded)

Appendix 3. Data Extraction Tables (continued)

					(13-19y)	Co-morbidity						
38.Cai (2017)	Prospective Pre-Post workshop	UK OP UCLH Jul-Dec 14	22 of 89 25%	22	22 F 8 (36%) M 14 (64%) 11.2y (8-16)	Co-morbidity <1y T1DM	6.2y	NR	8.2% -initiation -2-6m	White 77% Asian 14% Black 5%	NR	NR
39.Ng (2019)	Prospective Pre-/post CGM Parents Children >12y	UL NW England Single centre	NR	16	16 F 8 (50%) M 8 (50%) 13.5y (2-17)	<12m	7.6y Min 12m CGM (3-12.4y)	MDI 0 CSII 16 (100%)	14.6% -3,6,12m	NR	NR	NR
40.Kamps (2010)	Longitudinal Pre-/post trauma Parents Children	US OP New Orleans 1.Mar 05-Aug 05 2.Mar 05-May 06	221 of 248 89% 8 excluded 55 loss FU	158 NR	158 F 85 (54%) M 73 (46%) 12.7-13 (8-16)	<6m T1DM Chronic illness, T2DM LD	5y	NR	8.35% D0	Caucasian 71% African 23% Hispanic 4%	NR	Income >$60,000 36%
41.Muller-Godeffroy (2009)	Prospective Pre-/post CSII Parents Children >7y	Germany 18 centres Dec 05-Aug 06	117 of 143 completed 82%	114 F 96 (84%) M 18 (16%)	117 F 53 (45%) 64 M (55%) 10.5y (4-16)	LD Insufficient literacy <6m T1DM	3.8y	MDI 117 → CSII for 6m	7.7% -recent	NR	NR	NR
42. Barnard (2010)	Systematic review Parents of young children	6 studies	NA	79 (24-114) F 60-100%	24-81 4.45y (2-11)	NA	<3.5y 1m-5y	MDI + CSII	8.19% 6-11 5 studies	NR	NR	NR
43. Driscoll (2016)	Literature review	16 studies	NA	NR	NR	NA	NR	NR	NR	NR	NR	NR

NA (not applicable), NR (not recorded)

Appendix 3. Data Extraction Tables (continued)

Paper First Author Year	FoH Tool	Other assessment tools	Hypoglycaemia (Hypo) Definition Hypo Frequency	Results	Strengths & Limitations
1. Aalders (2018)	HFS-P Worry scale a= 0.88	Parent-reported questionnaire Freiburg Mindfulness Inventory Interpersonal Mindfulness in Parenting Scale (IM-P) a= 0.85	SH: requiring glucagon, hospital admission or an emergency call >1 SH in last 12m: 7%	Demographics, mindfulness, clinical characteristics accounted for 19% FoH variance; younger parental age (p=0.006), low parental educational level (p=0.018), non-Dutch nationality (p=0.003), higher number BG readings/ day (p<0.001) and less mindful parenting (p=0.006) were related to higher parental FoH; SH was not related	Only 355 parent-reported HbA1c levels No data available on non-responders Sample had higher employment, higher CSII use and lower HbA1c levels
2. Al Hayek (2015)	HFS-C a= 0.86	Socio-demographic/ clinical questions Screen for Child Anxiety-Related Disorders (SACRED) a= 0.91	American Diabetes Association Hypo definition: <3.9mmol/L Hypo>12/12m: 41.8% Hypo at school: 80.7% 'Low BG big problem': 63.1%	Females had higher scores on HFS & SACRED (p<0.05) 16-18y had higher HFS & SACRED SAD scale scores (p<0.05) CSII users had lower levels of worry, panic, SAD (p<0.05) DM duration >7 years correlated with greater FOH & SACRED scores Higher hypo frequency had higher HFS scores (p<0.05) HFS scores correlated with SACRED scores; no effect HbA1c Risk factors for FoH = age, MDI, longer DM duration, higher SH	Single centre study Limited socio-demographic factors No control group Arabic translation of questionnaires
3. Amiri (2014)	HFS-C a= 0.89	Diabetes History Questionnaire Self-Efficacy for Diabetes Scale-Child version (SED-C) a= 0.86	SH: requiring assistance Hypo in the last 3m: 97% Hypo at school: 72%	CYP <9y had higher HFS score than those >10y (p<0.0001) CYP <9y also had lower mean SED scores (p<0.0005) CYP with significant FoH concerns had higher HFS scores (p<0.004) No significant association with HbA1c, demographics or SH	Selection of children from a database SED-C not designed for 6-8y- adapted Questions read aloud- verbal answers Persian translation of questionnaires
4. Amiri (2018)	HFS-P a= 0.94	Diabetes History Questionnaire Paediatric Inventory for Parents (PIP) a=0.96F a=0.95M SED-P a= 0.74	SH: requiring assistance Hypo in the last 3m: 97% Hypo at school: 72%	HFS-P scores were higher for mothers than fathers (p=0.022) HFS-P scores correlated positively with several PIP scores HFS scores did not correlate with number of hypo episodes Mothers with child DM duration <2 years had lower HFS-B (p=0.008) No significant association between HbA1c and HFS, PIP or SED	Persian translation of questionnaires Lack of cultural adaptation of questions Reduced completion rate among fathers
5. Di Battista (2009)	HFS a= 0.87	Self-report demographics/HbA1c Social Anxiety Scale for Adolescents Diabetes QoL Measure (DQoL) Summary of Diabetes Self-Care	NR	Social anxiety was positively correlated with HFS for boys (p<0.01) and girls (p<0.05) FoH = independent correlate of lower adherence (p=0.046)	Significant missing data for 6 CYP $10 incentive to participants Self-report measures Majority Caucasian US sample
6. Forsander (2016)	FoH scale 1 to 10	Selected items from Diabetes Distress Scale	NR	Females scored twice as high on FoH scale (p<0.0001) Twice the proportion of females had moderate-severe DD FoH was associated with DD (p=0.044 F; 0.026 M)	No validity to FoH scale; 21% uptake Participants had low HbA1c and tended to be female (p<0.0001)
7. Freckleton (2014)	HFS a= 0.86	Illness Perception Questionnaire 7 day diabetes diary management	Hypo: <5mmol/L if <6 y <4mmol/L if 6-12y	HFS behaviour associated with high BG but not with hypo Model not significant in predicting HbA1c	Poor HbA1c record + different centres Participants volunteers; only mothers
8. Frederick (2011)	CHI	Diabetes Behaviour Rating Scale	NR	CHI was reduced by 7.4% for repeat campers (>2 years) than those who had attended <2 years Total CHI reduced by 6.6% for every 1 year over 12 years age Lower self-management correlated with higher HbA1c	Convenience sample from camp/ clinic Socioeconomic data not collected
9. Gonder-Frederick (2006)	HFS-P a= 0.89 HFS-C a= 0.86	Diabetes specific questionnaire State Trait Personality Inventory (STPI) State Trait Anxiety Inventory for Children (STAIC)	MH: affecting functioning SH: requires assistance MH 6.74/ year SH 0.46/ year	HFS-worry score higher for girls than boys (p= 0.02) Adolescent trait anxiety and SH frequency (p<0.01) account for 45% variance in HFS score; nil predicted HFS-B HFS-P influenced by provision of emergency glucose (p<0.05) History of unconsciousness→ higher HFS-C (p= 0.011) Hypo at school → higher HFS-P (64.6 v. 43.8; p= 0.007) Parental & adolescent anxiety scores correlated (p<0.001) No difference with CSII or MDI use; no correlation with HbA1c	22 families failed to return questions No demographic data on non-participating families Only one father included
10. Gonder-Frederick (2011)	HFS-P a= 0.86 HFS-C a= 0.85	STPI STAIC	NR	Good correlation between STPI/ STAIC and HFS scores Higher HFS-W scores in 9-11y than 6-8y (p=0.04) Parent HFS-B scores higher for 6-11y than 12-18y (p<0.01) CYP in highest HFS quartile had more BG readings >300mg/dl than lowest quartile (4.7% vs. 3%; p=0.02) Higher HFS-P scores = lower HbA1c (7.7% vs.8.2% p= 0.01)	Cross-sectional design Narrow sample sizes No clear outcome measures

NA (not applicable), NR (not recorded)

Appendix 3. Data Extraction Tables (continued)

11.Grey (2009)	HFS	Center for Epidemiological Studies Depression Scale (CES-D) a= 0.88 STAI a= 0.93) Issues in Coping with IDDM-P	NR	Variance in maternal depression: 27% demographics, 7% FoH Variance in maternal anxiety: 18% demographics, 6% FoH Prevalence of depression- 24.2%, anxiety: 20.9%	Parents required to commit to 6-weeks RCT Only 2 fathers, so excluded in analysis
12.Haugstvedt (2010)	HFS-P a=0.87 F a=0.94 M	Demographic questionnaire Hopkins Symptom Checklist-25 (HSCL-25) a=0.92 F a= 0.87 M	Problematic hypo: as perceived by parent >7 problematic/12m: 23% Unconsciousness: 21%	Higher HFS-P worry score associated with higher HbA1c and more problematic hypos, but not with hypo severity HFS-B score higher in MDI use; HSCL-25 correlated with maternal (p<0.001) & paternal (p=0.006) HFS-W; mothers HFS scores > fathers	Non respondents: 1.7 years older (p=0.04) & 1.3 years longer diabetes duration (p=0.016); although similar HbA1c Norwegian translation of questionnaires
13.Haugstvedt (2015)	HFS-P	HSCL-25	>7 problematic episodes/12m: 22% Unconsciousness: 24%	Worry subscale is a valid instrument to measure anxiety-provoking aspects of hypoglycaemia; validity of behaviour scale is more questionable; weak correlations between the 2 HFS-B reflects both inappropriate behaviours related to fear and appropriate behaviour to avoid hypoglycaemia	Limited sample size 50-70% parents reported shared responsibility for diabetes care so differences between mother and fathers can be taken to be legitimate
14.Hawkes (2014)	HFS-PYC	Demographic questionnaire	Hypo-seizure 19.8% Hypo-disorientation 51.9%	Mean scores for parents of children 6-11y were higher at 70.7 versus 67.6 in 0-5y (p=0.025) and 61.6 >12y (p=-0.003) HbA1c <7.5% associated with lower total scores (p=0.025) No difference mothers versus fathers or CSII versus MDI	Assumed that parent in outpatients was the primary diabetes carer Limited parental demographic information
15.Herbert (2014)	HFS-PYC a= 0.92	Demographic/ medical questionnaire 24h recall interview of DM tasks Pittsburgh Sleep Quality Index(PSQI) SED-P (a= 0.78)	NR	36% parents indicated overall sleep quality was fairly bad or very bad 34% performed daily night-time BG checks FoH worry was negatively correlated with parents confidence in managing diabetes (p<0.01) and higher scores = greater PSQI scores	Gift card for baseline questionnaires Retrospective and subjective data No differences between non-participants
16.Johnson (2013)	HFS	PedsQL Diabetes Module Clarke's questionnaire Clinical data from W Australia Childhood Diabetes Database	MH: requiring assistance SH: seizure/ coma SH: 19%	Primary outcome: PedsQL score; primary variable: HFS Parents & children with highest FoH had 20% & 22% lower QoL, compared to those in lowest fear quartile; not associated with SH/MH Children with highest FoH had 0.6% higher HbA1c (> in 13-18y) Parents with SH children had 6.3 point higher FoH (p-0.004)	Non-responders were 1.4 years younger (p<0.001) with shorter diabetes duration by 0.8 years (p= 0.003) No difference in SH rates Limited parental demographics
17.Kamps (2005)	HFS-C CHI	RCMAS Hypoglycaemia History Form	NR	CHI positively correlated with HFS-C and RCMAS Demonstrated good convergent validity and internal consistency Good test-retest reliability SH consistent predictor of situation and general fear scale of CHI	Wide age range with high SES Behaviour scale modified to reflect behaviours motivated by FoH
18.Markowitz (2012)	HFS	Pediatric QOL Inventory STAI, PAID, CDI, CES-D, DFCS BGM Communication Questionnaire	NR	No differences in reported FoH between CGM and BGM Parents reported more FoH than youth (p=0.01)	Not powered to find significant results Questions not completed at baseline Compensation for ancillary study Small study; limited demographic information
19.Mitchell (2009)	HFS a=0.92	PIP (a = 0.95) STAI, SED, Hope Scale Recall interview Eyberg Child Behaviour Inventory	NR	Low levels of FoH 16.7 (0-44) and low state anxiety compared to mothers in other studies. However, fathers completed <20% of diabetes related tasks	Only study exploring fathers' attitudes Small sample, limited diversity, although is reflective of ethnic diversity in Atlanta $10 gift card incentive
20.Pate (2019)	HFS-P 0.89	STAI a=0.90 Positive and Negative Affect Schedule (PANAS) Satisfaction with Life Scale (SWLS)	SH: 8.5% parents	Higher parental FoH associated with higher HbA1c Higher FoH= more frequent monitoring at night (p=0.01) At least one SH→ more preventative behaviours p=0.03 Mothers > FoH than fathers and more engaged in daily tasks	Non-responders had higher HbA1c (8.3% v. 7.6%) Parental relationship not discussed Slovenian translated questionnaires
21.Patton (2007)	HFS-PYC a= 0.86	Self-report demographics Self-report hypoglycaemia history SMBG for 2 weeks using study meter HbA1c at enrolment + 3 months later	Hypo: BG <60mg/dL 3-5 hypos/week: 50% Hypo seizure in 6m: 25%	Mean total HFS-PYC score 81 (26-130)- moderate FoH FoH correlated positively with mean daily BG level (p=0.05) Parents with hypo seizures worried more (50.7 v. 41.7) HFS-B score correlated with HbA1c at 3m (p=0.04) Higher socioeconomic status protected from FoH	Small sample with limited diversity Commitment to 2 weeks SMBG 4 times/day Reimbursement $20 gift card
22.Patton (2008)	HFS-PYC a=0.91	Self-report demographics Self-report hypoglycaemia history SMBG for 2 weeks using study meter	Hypo: <60mg/dL/ Rx 3-5 hypos/ week: 38% Hypo seizure: 32% Average 4.1 hypo/ 2 weeks	Mothers' HFS-PYC score > fathers (75 v. 66.5; p=0.006) Positive correlation between mothers' HFS-W and frequency of hypoglycaemic events (p<0.05); higher scores with seizure No correlation with HbA1c/ average BG readings Good internal consistency & test-retest reliability for HFS-PYC	Small sample with limited diversity Commitment to 2 weeks SMBG 4 times/day Reimbursement $20 gift card Majority had target HbA1c 7.5-8.5%
23.Patton (2011)	HFS-PYC	Behavioural Pediatric Feeding Scale Pediatric Inventory for Parents (PIP) Beck Depression Inventory (BDI)	NR	PIP associated with greater HFS scores and higher BDI Parents' depressive symptoms and FoH accounted for 68% of the variance in parents' stress difficulty	Small homogenous sample Relatively high CSII use Majority mothers

NA (not applicable), NR (not recorded)

Appendix 3. Data Extraction Tables (continued)

24.Patton (2017)	HFS-PYC	Self-report demographics SMBG for 2 weeks using glucometer	NR	Recommends a modified version of the HFS-PYC to 22 items HFS-W negatively correlated with BG and % of very high BG Greater FoH with better glycaemic control	Homogenous sample; no temporality Reimbursement $25-50 14 days BG data for only 91 children
25.Shepard (2014)	HFS-C HFS-P	Self-report demographics Self-report hypoglycaemic history STPI a= 0.8-0.87 STAIC	Hypo: BG< 70mg/dL Mean number of hypos: 8.53%	Highest tertile of HFS-C maintain high BG factor associated with higher mean BG readings, but not HbA1c, and not HFS-P Girls scored higher than boys on HFS-C helplessness (p=0.039 Adolescents scored higher HFS-C on social consequences (p=0.026) HFS-B lower for adolescents on maintain high BG (p<0.0005) SH episodes correlated with HFC-C helplessness (p=0.01)	Aggregated data collected over 10 years Engaged cohort willing to perform BG check minimum 4 times/day
26.Streisand (2005)	HFS-P a=0.90	Demographic and Medical History Diabetes Family Responsibility Questionnaire (DFRQ) a=0.82 PIP a=0.94-5 SED a=0.87	NR	Variance PIP-F (32%) and PIP-D (19%) associated with lower self-efficacy, greater FoH and greater responsibility for diabetes More PIP: younger child, non-Caucasian, lower SES, MDI	Self-report from mainly mothers Reimbursement $25 Part of an ongoing longitudinal study
27.Van Name (2017)	HFS-P Worry scale	Self-report demographics Self-report DKA & SH history	SH: seizure/ loss of consciousness >1 SH in 3m: 7%	Mean HFS-W was 36.1 (0-100); no link with age, SH, HbA1c Most frequent worries: low while asleep/ child not recognising low HFS-W more for parents checking BG >6/d (p=0.004) Nocturnal hypo worry > with CSII (61% v. 45% p<0.001) & CGM (62% v 51%; p=0.02)	Large registry- valid + generalizable results 2-3-fold higher CGM use than population Lack of gender identification of parents
28.Viaene (2017)	HFS-P a=0.86 HFS-C a=0.68	Nijmegen Parenting Stress Index-Short form (NPSI-S) a=0.96		Greater FoH associated with greater parenting stress Greater stress associated with increased HbA1c Parental FoH not directly related to metabolic control Age, gender, diabetes duration not linked to FoH	Non-participants had higher age (p=0.04) and shorter diabetes duration (p=0.017) Limited other demographics available HbA1c lacks sensitivity
29.Abraham (2018)	HFS	PedsQL Clarke's hypoglycaemia awareness Pump satisfaction questionnaire	Hypo: <3.5mmol/L Mean % time hypo: 2.5%	Primary outcome: time spent hypo (powered 80%) Reduction in time spent in hypoglycaemia more with PLGM than SAPT, reduction from 2.8% to 1.4% (p<0.0001) No difference in HbA1c levels, HFS and PedsQL scores	Small sample; missing demographics 19% withdrawal/ exclusion rate PLGM does not abolish hypoglycaemia
30.Barnard et al (2014)	HFS	Semi-structured interviews Diabetes Technology Questionnaire	Hypo: <70mg/dl Time spent hypo: very low	Primary outcome: glucose in target range 11pm-7am (power 80%) HFS scores decreased for CYP but increased in parents Night BG <63mg/dL less in closed loop (10% v. 17%; p= 0.01) DTQ 66.7% reported 'much/little better' worries regarding sleep hypo	Small sample selected by availability Telephone interviews
31.Burckhardt (2019)	HFS-P	PedsQL, STAI, PSQI Depression Anxiety Stress Scale CGM Satisfaction Survey	NR	Primary outcome: FoH as measured by HFS-P (powered) HFS-P lower after intervention (54.9 v. 44.7; p<0.001) Parental stress, state and trait anxiety lower; HbA1c same	Only parental outcomes studied Parental demographic data not available
32.JDRF CGM Study Group (2010)	HFS-W	PedsQL Problem Areas in Diabetes (PAID-P) CGM Satisfaction Questionnaire	SH: requires assistance	Primary outcome: HbA1c; planned to have a power of 90% At 26 weeks there was a slight improvement in CGM group >18y (<0.05) for HFS but not in youth or parents; high baseline QOL scores	Commit to sensor 6/7 days during run-in High survey completion 93-97% Lack of full parent demographics
33.Mayer-Davis (2018)	HFS	Motivation and Intention Questions Social Problem-Solving Inventory Diabetes Self-Management Profile CES-D, PedsQL, DFCS	Hypo: <3.9mmol/L Hypo experienced: 37-48% Median time spent hypo/24h: 17-30 minutes	Primary outcome: HbA1c; 80% power; no effect on HbA1c All 3 domains of FoH decreased with intervention; only significant in behaviour to maintain high BG in parents (p=0.005) and worry/ helplessness by adolescents (p=0.04)	Retention 93.4%; fidelity 4.6/5 Participants more likely to be Caucasian (p=0.02) & privately insured (p=0.001) No difference in HbA1c, sex, DM duration Incentives up to $845 for completion
34.Mueller-Godeffroy (2018)	HFS-P	Diabetes-specific module of KINDL-R HRQOL questionnaire DFCS, DTSQs PIP WHO-Five Well-Being Index	NR	Primary outcome: HRQOL/ diabetes burden (80% powered) 8-11y CSII group significantly better DHRQOL compared to MDI group No difference in adolescents; main caregivers reported significantly reduced PIP, HFS and DTSQ. No changes in HbA1c/ SH.	Patients needed to be willing to wait for CSII-missed the cohort ideal for CSII Patients <8y too small cohort Baseline CSII group had 0.5% better HbA1c
35.Patton et al (2019)	HFS-PYC	PIP PAID-PR	1-2 hypos/ week: 60%	Primary outcome: parental FoH? powered- limited Parents randomized to REDCHiP saw significant reduction in HFS (71.5 v. 59.9 p<0.001) and PIP-F; HbA1c reduction in children who entered trial with HbA1c level above 7.5% (8.62% to 8.39% p<0.05)	Randomised; use of single lab Participants had younger diagnosis age (p=0.002) and lower HbA1c (p<0.001) Only 3m FU to assess maintenance
36.Ziegler et al (2015)	HFS-P a=0.9 HFS-C a=0.86	Technology Acceptance Model Questionnaire (TAM) a= 0.91 Satisfaction with use of an AP	NR	Primary outcome: nocturnal hypoglycaemia After 4 nights on the AP system HFS worry decreased significantly (p=0.017); overall satisfaction score was high; FoH at study entry low	Short duration of study- only 4 nights Patients with SH history not included Inadequately powered

NA (not applicable), NR (not recorded)

Appendix 3. Data Extraction Tables (continued)

37.Al Hayek (2017)	HFS-C a= 0.86	PedQL Diabetes Module	SH: BG <70mg/dL 1-2 / month low BG is a big problem: 53%	Use of flash glucose monitor resulted in significant reduction in HFS (p=0.0001), HbA1c (p=0.008), QoL (p=0.002) and hypoglycaemia (p=0.023)- reduced to 0.37 per month; monitoring 0.84/d to 6.76/d	Small sample; single centre Arabic translation 3m use of sensor
38.Cai (2017)	HFS	Acceptability rating 1 to 10 Follow up questionnaires / feedback	Hypo last 1m: 9	Primary outcomes: acceptability and feasibility of intervention HFS scores reduced in adolescents post sessions High FoH: 68% CYP and 91% parents	11 failed to complete follow up Not powered to detect pre-/post-test differences
39.Ng (2019)	HFS HFS-P	NA	SH: 3rd party assistance/ hospitalization	Primary outcomes: HFS/ HbA1c (no power calculation) Significant improvements in parental (p<0.001) and patient (p=0.003) FoH scores. No change in HbA1c	Small sample size Poor compliance in 58%
40.Kamps (2010)	CHI a= 0.89	Revised Children's Manifest Anxiety Scale (RCMAS) a= 0.87	%time BG<70mg/dL: 11.6%	Hurricane-Interrupted group higher % of BG readings >300mg/dL (p<0.05) and higher RCMAS scores (p<0.05) High FoH in specific situations at time 1 associated with higher HbA1c at time 2 if hurricane-interrupted	Participants: higher income (p<0.01), paternal education (p<0.05), duration diabetes (p<0.05); no difference age/ HbA1c; hurricane exposure unmeasured
41.Muller-Godeffroy (2009)	HFS-P	KIDSCREEN10-Index (HRQOL) PIP, DFCS a= >0.7 in all scales translated except KINDL0DM (a=0.59) and MC frequency subscale of PIP (a=0.44)	Hypo: ISPAD definitions Hypo in last 6m: ISPDA II: 3 ISPAD III: 1	Sample of 100 for 80% power on 0.05 probability level DRQOL improved in all age groups (p<0.001) Reduced frequency/difficulty of parenting stress & HFS-W(p<0.001) No significant decrease in SH frequency; HbA1c reduction only teens	Required 6m commitment to CSII No demographics on 8 non-responders German translation questionnaires Loss to follow up 23% CYP/18% parents No difference between groups; no control
42.Barnard (2010)	HFS-P	Multiple	Multiple	Severity more important than frequency in predicting FoH Maternal depression & anxiety associated with greater FoH Fear of nocturnal hypoglycaemia independent of hypo risk	Only 6 studies; no interventions Lack of power calculation Poor response rates
43.Driscoll (2016)	HFS CHI	Multiple	Multiple	Most common predictor of FoH was parent report of their children experiencing SH episodes (not verified on downloads) Majority of studies failed to find a relationship with HbA1c Interventions focused on CBT/ BG awareness training/ technology	Cross-sectional studies No behavioural intervention studies in CYP

NA (not applicable), NR (not recorded)