Flash glucose monitoring in children with Type 1 diabetes to improve diabetes control: The FLASH-1 Study

Study Investigators

Principal Investigator:	A/Prof (Hon) Craig Jefferies[1,2] Ph. 021 957 877 Email: craigj@adhb.govt.nz
Principal Investigator:	A/Prof Ben Wheeler[3,4] Ph: 027 4701980 Email: ben.wheeler@otago.ac.nz
Co-Investigator (A):	Dr Vicki Cunningham[5] Email: vicki.Cunningham@northlanddhb.org.nz Ph: (09) 430 4101
Co-Investigator (B):	Professor Wayne Cutfield[1,2] Email: w.cutfield@auckland.ac.nz Ph: 021 734 441
Co-Investigator (C):	Dr Anita Lala[6] Email: anita.lala@bopdhb.govt.nz Ph: 027 381 9329
Co-Investigator (D):	Dr Martin de Bock[7, 8] Email: martin.debock@otago.ac.nz Ph: 021 1956579
Co-Investigator (E):	Dr Sara Boucher[3] Email: sara.boucher@otago.ac.nz Ph: 022 1909532
Co-Investigator (F):	Dr Anna Serlachius[9] Ph: 64 9 923 3073 Email: a.serlachius@auckland.ac.nz
Co-Investigator (G):	Dr Michel de Lange[10] Email: michel.delange@otago.ac.nz Ph: 028 4155096
Co-Investigator (H):	Dr Hamish Crocket[11] Email: hamish.crocket@waikato.ac.nz Ph: 07 838 4466 ext 6529
Co-Investigator (I):	Dr Dana Signal[1,2] Email: danez_01@hotmail.com Ph: 021 1571628
Co-Investigator (J):	Dr Alisa Boucsein[3] Email: a.boucsein@otago.ac.nz

1. Paediatric Diabetes and Endocrinology, Starship Children's Health, Grafton, Auckland 1050
2. Liggins Institute, The University of Auckland, 2-6 Park Avenue, Grafton, Auckland 1023
3. Department of Women's and Children's Health, University of Otago, PO Box 56, Dunedin 9054

4. Paediatrics, Southern District Health Board, Dunedin, 9054
5. Paediatrics, Northland District Health Board, Whangarei, 0148
6. Paediatrics, Bay of Plenty District Health Board, Tauranga 3112
7. Department of Paediatrics, University of Otago, Christchurch 8140
8. Paediatrics, Canterbury District Health Board, Christchurch 8011
9. Psychological Medicine, The University of Auckland, 2-6 Park Avenue, Grafton, Auckland 1023
10. Centre for Biostatistics, Te Pokapū Tatauranga Koiora, Division of Health Sciences, PO Box 56, Dunedin 9054 New Zealand
11. Health, Sport and Human Performance, School of Health, University of Waikato, Hillcrest Rd, Hillcrest, Hamilton 3240

Universal Trial Number (UTN): U1111-1237-0090

ANZCTR registration number: ACTRN12620000190909

1. Introduction

There are approximately 2,500 NZ children and youth living with T1D [1-3]. T1D cannot be cured; therefore children must intensely manage blood glucose (BG) levels and inject insulin accurately for the rest of their lives to maintain good glycaemic control, and in turn reduce acute and chronic diabetes-related complications [4, 5]. Despite current BG testing guidelines and increasing use of multiple injections or insulin pumps, less than one in four children achieve standards of glycaemic control[6] as recommended by the International Society for Pediatric and Adolescent Diabetes (HbA1c <58 mmol/mol (<7.5%)[4].

Conventional self-monitoring blood glucose (SMBG) involves intermittent finger stick BG tests that show the glucose value at the time of the test only. However, to enable good glycaemic control this has to be repeated multiple times each day. The new technology of flash glucose monitoring (FGM) has the potential to increase glucose monitoring, and in turn diabetes control, among children with T1D. Users of FGM attach a small sensor to their arm to monitor interstitial glucose levels. They scan the sensor with a reader which immediately displays on its screen 1) their current interstitial glucose level, 2) a graph of retrospective glucose data for the previous 8 hours and 3) a glucose trend prediction arrow. Each sensor lasts up to 2 weeks before needing to be replaced while the reader can be used ongoing. Neither retrospective nor predicted glucose trends are available with SMBG technology which makes FGM an appealing alternative. FGM can provide accurate, rapid, up-to-date glucose information in a discrete, user friendly way (simple to scan the sensor, no limit to scanning frequency, can scan through clothing); all allowing for marked increased in frequency of testing.

The proposed research would identify if FGM is an appropriate and safe glucose monitoring tool for our target population of children not achieving diabetes control. FGM is not funded by PHARMAC in NZ and therefore not available for most of our children, nor are such devices covered by private health insurance. Rigorous evidence demonstrating a benefit will be crucial in informing such funding bodies of the benefit these devices may result in when used appropriately. We will conduct a randomised controlled trial to determine whether FGM can improve diabetes control in children with T1D aged 4-13, inclusive, who are not currently achieving adequate diabetes control.

2. Background

In New Zealand, there are an estimated 2,500 youth aged 0-18 years living with type 1 diabetes (T1D)[1-3]. New Zealand has one of the highest rates of paediatric diabetes in the world, with the incidence growing annually[7]. Only one in four children with diabetes achieve international standards of glycaemic control HbA1c (<58 mmol/mol (<7.5%)[6]. This increases their risk for short and long term diabetes complications as shown by the Diabetes Care and Control Trial (DCCT)[8-10].

Frequent and timely SMBG is essential for keeping glucose levels in a safe range. Conventional SMBG involves finger-stick blood tests six or more times each day[11]. Children infrequently SMBG because of social pressure to not be seen as ‘different’,

physical discomfort from pricking their fingers, and the technology is not user friendly (requires multiple steps to obtain a reading).

Improvements in diabetes technology and non-SMBG approaches to glucose monitoring are available. Continuous glucose monitoring (CGM) systems use subcutaneous glucose sensors that transmit interstitial glucose data to a pump/reader with a 5-15 min lag compared to blood glucose readings, require calibration with finger stick and need replacing weekly. Despite CGM systems being available they are costly and uptake is low with the current generation of devices. Small studies show that when CGM is used for the majority of the time (6-7 days/week) in highly motivated families with already good diabetes control there is an associated improvement in HbA1c (marker of glycaemic control over the previous 3 month)[12]. Such studies of the current CGM-systems are not generalizable to the vast majority of children in clinic not achieving glycaemic control: they require a degree of motivation and oversight that is not generalizable, are high cost, have low user-friendliness, involve SMBG calibrations and there are no PHARMAC funded or private rebates for CGM.

A slightly different technology, Flash glucose monitoring (FGM) (FreeSyle Libre™), could be an acceptable alternative to improve glucose monitoring and glycaemic control as it provides accurate and up-to-date glucose information[13]. FGM involves applying a small sensor to the back of the arm to monitor interstitial glucose levels for up to 2 weeks (see Figure 1). No finger sticks are required to calibrate the system. FGM users then scan the sensor with a reader, as often as they like, which immediately displays their glucose level. Given children's propensity for new technology, the ease of being able to scan (even through clothing) and the reduction in SMBG testing, such an intervention may provide an important opportunity to engage them in their diabetes care and help them and their families improve self-management behaviours[14].

Figure 1: Apply sensor to arm, scan sensor with reader, reader displays current glucose level, glucose trend arrow and previous 8 hours of data.

Children with T1D could potentially benefit from FGM in many ways. The availability of glucose level trends, which fluctuate daily in response to a number of factors including diet, exercise, illness, stress, and medication, allow for better informed decision making around insulin dosing and food intake. Frequent glucose monitoring can detect diabetes-related acute complications such as hypoglycaemia (low blood glucose levels), as well as contribute to preventing long-term nerve, eye and kidney damage. FGM displays current glucose data, a predictive glucose trend arrow, as well as 8-hours of retrospective glucose levels; all of these parameters facilitate user engagement and enable achievement of safe glucose levels[15].

FGM is highly acceptable to children and young people with diabetes[16] and their caregivers[17], while in comparison only one-third of CGM users continue CGM technology at 6 months [18, 19]. The advantages of FGM include its use of a factory calibrated sensor, longer sensor sessions and lower ongoing costs compared to some CGM systems, and the option of no alarms for out-of-target glucose levels which can create "alarm fatigue". There are very few studies of FGM in children or adolescents and no RCTs of FGM in paediatric patient populations, although one RCT among New Zealand adolescents with T1D and high-risk glycaemic control is underway [14]. Despite limited evidence of its usefulness, approximately 10% of NZ paediatric patients in our clinics (mostly those already experiencing good glycaemic control) are self-funding FGM. Such observational studies in clinics of those who purchased the device out-of-pocket show that in a self-select group of young T1D patients there does appear to be a significant and sustained reduction in HbA1c, but not in the overall group[20]. Research is needed on the effectiveness and sustained use of FGM for monitoring and managing glucose levels among young people with poor glycaemic control. There is also a need to improve the education and user engagement to counter the increased stress that such information could cause family[4].

3. Aim(s) of Study

This study aims to investigate the effectiveness of FGM in a real-world setting in children with type 1 diabetes most at risk for acute and chronic diabetes complications, those not achieving international targets for glycaemic control (International Society of Paediatric and Adolescent Diabetes target has recently been lowered to an HbA1c <53 mmol/mol (7.0%), previously HbA1c < 58 mmol/mol [<7.5%])[4, 21]. This research will also provide much needed evidence of its benefit for national funding bodies.

4. Objectives

4a. Primary Objective

To determine the impact of FGM on glycaemic control as measured by glycated haemoglobin (HbA1c) in children aged 4-13 years, inclusive, with T1D and a current HbA1c between 58 – 110 mmol/mol (7.5 – 12.2%), inclusive.

4b. Secondary Objectives

To investigate the impact of FGM on:

- short-term glycaemic control (as measured by time in range: 3.9-10.0 mmol/L (70-180 mg/dl))
- self-monitoring (as measured by FGM sensor scanning frequency)
- quality of life
- safety (i.e., diabetic ketoacidosis, severe hypoglycaemia)
- time in range overnight
- frequency of insulin injections
- appropriate treatment of hypoglycaemia

5. Hypothesis

5a. Primary Hypothesis

At 12 weeks (i.e. end of week 14 of study), there will be a 7 mmol/mol greater improvement (reduction) in glycaemic control (HbA1c) in the intervention group compared to the change in glycaemic control in the control group.

6. Study Design

This is a multi-site randomized controlled trial. As shown in Figure 2, children with T1D will be randomized into one of two groups (FGM intervention group or control group). Both groups will then be offered to participate in a further 12-week extension period (i.e.: all participants on FGM) (see Figure 2).

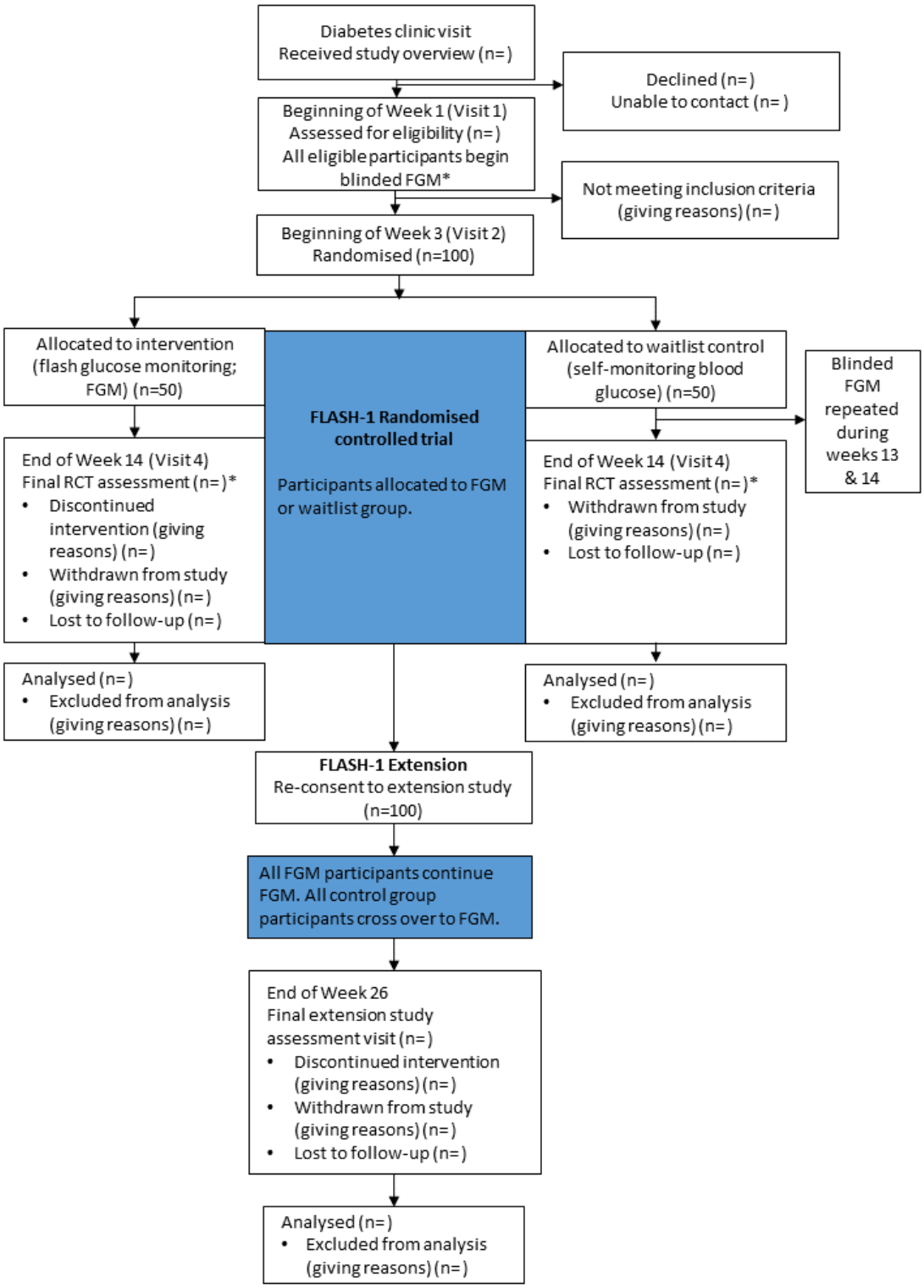

Figure 2. Study flow diagram

7. Study Setting/ Location

The study will be conducted in Auckland, Dunedin, Tauranga, and Whangarei.

8. Study Population

Participants will be paediatric patients receiving standard diabetes care through district health board (DHB) diabetes services. Auckland DHB, Southern DHB, Bay of Plenty DHB, and Northland DHB diabetes services provide care for approximately 450 children in the study age range.

9. Eligibility Criteria

9a. Inclusion criteria

1. Children aged 4 to 13 years, inclusive, on day of consent;
2. A diagnosis of T1D ≥ 6 months;
3. Current HbA1c ≥ 58 mmol/mol and ≤ 110 mmol/mol, on day of consent;
4. On an insulin dose per day > 0.05 units of insulin/kg/day;
5. No regular use of FGM or CGM in the previous 3 months.

9b. Exclusion criteria

There will be no restriction on insulin regimen.

1. Any severe chronic diabetes related complications;
2. Severe medical or psychiatric co-morbidity/severe mental illness;
3. Participation in another study that could affect glucose measurements;
4. Plans to leave study site regions prior to study completion;
5. Regular continuous use of FGM or CGM;
6. HbA1c <58 mmol/mol or >110mmol/mol.

10. Study Outcomes

10a. Primary Outcome

The primary outcome is the difference in change in HbA1c between groups at the end of the RCT .

10b. Secondary Outcome(s)

1. RCT – between groups analysis at the end of RCT
    a. Clinical
        i. Time in target (time spent in target range 3.9 – 10 mmol/L)
        ii. Time in hypoglycaemia (glucose <3.9 mmol/L)
        iii. Time in hyperglycaemia (glucose >10 mmol/L)
    b. Glucose monitoring
        i. SMBG/FGM scanning frequency

c. Psychological
    i. Quality of Life
    ii. Diabetes treatment satisfaction
    iii. Fear of hypoglycaemia
d. Safety outcomes
    i. Episodes of diabetic ketoacidosis (DKA)
    ii. Episodes of severe hypoglycemia (defined as blood glucose value ≤ 3.9 mmol/L and resulting in loss of consciousness, a call for an ambulance and/or admission to hospital, or use of glucagon)
    iii. Cutaneous adverse events (eg, infection, itching, pain, redness, subcutaneous haemorrhage)
e. FGM acceptability

2. Extension – within group analysis at the end of the 12 week extension
    a. Clinical
        i. HbA1c
        ii. Time in target (time spent in target range 3.9 – 10 mmol/L)
        iii. Time spent in hypoglycaemia (glucose <4 mmol/L)
        iv. Time in hyperglycaemia (glucose >10 mmol/L)
    b. ** Use of trend arrows (assessment to be determined)
    c. ** Appropriate treatment of hypos (assessment to be determined)
    d. ** FGM scanning frequency
    e. All other RCT outcomes (i.e., glucose monitoring, psychological, and safety outcomes, FGM acceptability)

11. Study Procedures

11a. Recruitment of participants

Children with a history of suboptimal glycaemic control (mean HbA1c ≥ 58 mmol/mol (7.5%) in the past 6 months), will be identified by their usual paediatric endocrinologist/diabetologist/paediatrician during routine clinical visits and invited to participate. Recruitment will begin approximately in July/August 2020, pending HDEC approval and locality approvals, and will continue until the target sample size is reached. Participants will be re-consented at Week 14 for the extension study.

11b. Randomisation

Patients who give consent for participation and fulfil the eligibility criteria will be enrolled in the study and randomly allocated by an offsite biostatistician in batches using a 1:1 ratio to either the control (SMBG) group or the intervention (FGM) group. The statistician will be blinded to allocation arm and will use non-informative group codes until all planned analyses are completed. As insulin regimen, gender and pre-study HbA1c may significantly affect the primary outcomes, minimisation will be used (based on insulin regimen [insulin pump, insulin injections]; gender [male, female]; HbA1c [58 to 74 mmol/mol, ≥ 75 mmol/mol; 7.5 to 8.9%, ≥ 9.0%]) and with a small random component (20%) along with randomly ordering the participants in each batch

used to preserve allocation concealment. The study group will be revealed to the participant at the randomization/group allocation visit.

11c. Study procedures

Study timeline: RCT (initial study) + Extension study

2020 – delayed due to COVID

Recruitment	July to Sept
Enrolment, screening & blinded FGM (all), and baseline visits (randomisation to groups)	Aug to Oct
Blinded FGM (control group only)	Sept to Dec
End of week 14 follow-up visits and end of primary outcome	Oct to Dec
Re-consent for extension study at end of RCT	Nov to Dec
Completion of extension phase	Jan to Mar
Write up, completion of study and submission for publication	June 2021

Flash-1 RCT study visits

Visit 1 - Screening/enrollment/start blinded FGM (beginning of week 1)
Visit 2 - Randomization/group allocation (beginning of week 3)
Visit 3 (intervention group) - follow-up (beginning of week 3)
Visit 3 (control group) - restart blinded FGM (for weeks 13 and 14)
Visit 4 – end of RCT follow-up (end of week 14) and consent for extension study

FLASH-1 extension study visits

Visit 5 for those who were in previous control group - follow-up *(14 days from start of FGM)*
Ongoing online and open access support/resources available to all subjects.
Visit 6 - end of extension follow-up for everyone (end of week 26)

Visit 1 – Screening and enrolment (beginning of Week 1)

Potential participants will be provided with an overview of the study, information sheet, and their questions will be answered. After being given an opportunity to review the participant information sheet and consider whether they want to be involved in the study, for those who are interested in taking part in the study, a point of care (POC; DCA Vantage Analyzer, Siemens Healthcare Diagnostics, Ireland) HbA1c will be measured to confirm their eligibility. Written consent and/or assent will then be obtained, as appropriate. Written informed consent will be obtained from parents and written informed assent will be obtained from participants aged 7 to 13 years (inclusive). Verbal assent will be obtained from participants aged 4 to 6 years.

Date of diabetes diagnosis for subsequent calculation of duration of diabetes (month and year will be recorded when the exact date is unknown), current insulin regimen, insulin dosing, HbA1c measurements in previous 6 months, and co-morbidities will be recorded from electronic medical records. Diabetic ketoacidosis in the past 6 months, and severe hypoglycaemia events (defined as a blood glucose value ≤ 3.9 mmol/L and

resulting in loss of consciousness, a call for an ambulance and/or admission to hospital, or use of glucagon) in the past 6 months will also be recorded from electronic medical records to provide baseline estimates of frequency for these events.

All participants will start blinded FGM (FreeStyle Libre Pro (Abbott)) to continually measure and store glucose level data for up to 14 days[22]. This glucose monitoring system uses the same sensor technology as the FreeStyle Libre system in the intervention; however, the Pro system masks all glucose data until it is downloaded at Visit 2.

Any patient can withdraw (or be withdrawn by their parent or guardian) from the study at any point and return to their usual medical care. All participants will receive standard diabetes care from their usual paediatric diabetes care provider. Routine diabetes clinics are attended regularly (every 3 months) to provide diabetes care by a multi-disciplinary team (paediatric endocrinologist/diabetologist/paediatrician, diabetes nurse specialist, dietitian, psychologist). Between scheduled study visits, participants will have the usual ability to contact the clinical team as is routine for all patients.

Visit 2 – Randomization/group allocation (beginning of Week 3)

Control group

Participants randomized to the control group will receive standard diabetes care (as described above) from their usual provider. Participants in this group will continue SMBG using conventional finger stick BG testing with a glucometer for weeks 3 to 14 of the study. They will wear another blinded FGM for weeks 13 and 14 of the study with no additional intervention provided during the primary study period. To maximize study recruitment all subjects will be invited to continue in an open and supported 12 week extension phase where they will receive a FGM system.

Intervention group

Participants randomized to the intervention group will continue routine care (as described above) and receive a FGM system, which includes a reader, USB cable, power adapter, user's manual, and quick start guide. Participants will have the Abbott Freestyle Libre fitted by trained research staff, and will be provided with full system education including sensor insertion, interpreting the readings, and optimization of insulin dosages, if appropriate, in addition to being supplied a reader and sensors to continue FGM use for 12 weeks. Participants will be instructed to scan a minimum of 6-10 times each day with no longer than 8 hours between two scans. Additional FGM supplies will be provided at the follow-up visits. All diabetes care will be as per standard clinic care, with qualified research staff providing medical recommendations as needed.

The FreeStyle Libre FGM system (Figure 1) consists of an easy to apply, wear and use interstitial glucose sensor and glucose reader or personal smartphone with the LibreLink app installed. The sensor is worn in the upper arm for up to 14 days and requires no blood tests for calibration. The reader or smartphone with near-field communication is held over the sensor to obtain a reliable and accurate glucose reading on demand. The reader/app settings will be adjusted so that alerts will indicate when

participants' glucose levels are out of range (3.9-10.0 mmol/L). A research nurse will access glucose data online through LibreView, a secure, cloud-based system for creating reports, to generate a report of a participant's average interstitial glucose level, time above/in/below range, and scans per day. The LibreView Privacy Notice is available in Appendix 2. If the report shows time spent 'low' is >4% or time spent 'very low' is >1% then the report is forwarded to the participant's clinical team for follow-up.

As a safety precaution, participants will be instructed to perform SMBG to confirm their glucose level before therapeutic interventions or corrective action are taken if hypo- or hyperglycaemic levels or symptoms occur.

To prevent sensor loss prior to the end of the 14-day sensor session, participants will be provided with either Rockadex (pre-cut sports tape), Hypafix® (BSN medical GmbH, Hamburg, Germany) or cohesive tape to be used to attach the sensor securely if the adhesive becomes loose.

Visit 3 – beginning of Week 5 (FGM group only)

14 days from the start of FGM participants will insert their own FGM sensor under supervision and for the remainder of the study.

Visit 3 – beginning of Week 13 (control group only)

Control group participants will be fitted with another blinded FGM, which they will wear for weeks 13 and 14 of the RCT.

Visit 4 – end of RCT follow-up (end of Week 14)

Participants will complete end of RCT assessments.

12 Week Extension Phase of Study (post-RCT outlined above)

All participants will be invited to participate in the 12 week extension phase of this study, and re-consented for this should they choose to take part.

During this 12 week extension study all participants will be able to use FGM. Those who were in the control group during the initial study will follow the *Visit* format of the FGM group in the initial study.

If at the end of the RCT the control participant does not wish to enter the extension study, they will receive the equivalent number of FGM sensors but no additional study support.

Aspects of the extension phase will include the following and will be an amendment to this study once finalized.

- The extensive phase will include a qualitative component and include criteria for getting extra assistance (HbA1c changes or not, Flash scanning times/day)

- Reframing FreeStyle Libre information as data to inform management decisions (rather than as good/bad/a sign of failure).

- Getting resources available online to support development of users decision-making, including how to use trend arrows, treat lows, what actions to take in different situations.

- Educational videos, then also some online quizzes using Kahoot or a similar platform so participants can practice their decision-making.

- Gamification of FreeStyle Libre use may encourage the children (and some parents) to participate in this.

- Helping with some behavioural cues, such as setting alarms to remind participants to test. Possibly worth thinking about routines here as well.

- Open access to upload interpretation by study nurse

Visit 5 – beginning of Week 17 (ex-control group only, after crossing over into FGM; same as beginning of Week 5 Visit)

The visit will follow the Visit 3 protocol.

Visit 6 - end of extension follow up (end of Week 26)

Participants will complete 26-week assessments.

Key point: end of study

11d. Measurement tools used

The timing of all assessments is presented in Table 1. Trained research staff will be responsible for completing assessments.

Table 1. Study assessments

Assessment	Beginning of Week 1	Weeks 5, 7 & 11	End of RCT	End of extension study	Ongoing
Demographics	*X*				
Anthropometry	*X*				
HbA1c	*X*		*X*	*X*	
Libre glucose metrics		*X*	*X*	*X*	
Glucose monitoring behaviour	*X*		*X*	*X*	
Glucose monitoring device performance			*X*	*X*	
Psychosocial assessments*	*X*		*X*	*X*	
Sensor failure (FGM only)			*X*	*X*	*X*
Acute DM complications**			*X*	*X*	*X*

* Pediatric Quality of Life Inventory (PedsQL) 3.2 Diabetes Module, Hypoglycaemia Fear Survey (HFS), Self-Efficacy for Diabetes Self-Management (SEDM)-** Diabetic ketoacidosis, moderate and severe hypoglycaemia, issues related to glucose monitoring device use

Demographics

A self-administered questionnaire will collect demographic information including age, gender, ethnicity, address, and education level. Participants may choose to select more than one ethnicity; however, each person will be allocated to a single ethnic group for the purposes of statistical analyses that will be prioritised in the order of Māori, Pacific, Asian and European/Other[23]. The address where the participant lives more than 50% of the time will be used to assess their NZDep2013 deprivation score, which is a validated index of the relative socioeconomic deprivation of the area in which an individual lives[24].

Clinical outcomes

Anthropometry

Weight and height will be measured using standard procedures and calibrated instruments. Weight will be measured with a fixed scale (DigiTol, Toledo, Switzerland or similar) or portable scale (Tanita Corporation, Japan or similar) to the nearest 0.1 kg, with shoes and heavy clothing removed. Height will be measured 3 times to the nearest

0.1 cm, and the average used, by wall-fixed stadiometer (Harpenden stadiometer, Holtain Limited, Pembs, UK or similar) or a portable stadiometer (Leicester Height Measure, Invicta Plastics Ltd., Oadby, England). Height and weight will be used to calculate body mass index (BMI)-z-scores using Centers for Disease Control and Prevention growth standards[25].

Diabetes-specific outcomes

HbA1c

Glycated haemoglobin (HbA1c) will be measured by traditionally calibrated point-of-care instruments (DCA Vantage Analyzer, Siemens Healthcare Diagnostics, Ireland), which meets acceptance criteria for HbA1c[26]. Measurements >130mmol/mol (maximum reading possible) will be recorded as 130.

Hypoglycaemia, time in range, hyperglycaemia (FGM group only)

During all follow-up visits, all retrospective glucose readings from the previous 2 weeks will be downloaded from the FGM reader or LibreView (the secure, cloud-based diabetes management system that will receive glucose data from all synced phones).

Hypoglycaemia (time below target) will be recorded as percentage of time below target (<3.9 mmol/L).

Time in range will be recorded as the percentage of time in the range (3.9-10.0 mmol/L)[27, 28]

Hyperglycaemia (time above target) will be recorded as percentage of time above target (>10 mmol/L).

Glucose levels <3.9 mmol/L between 10pm and 7am (nocturnal hypoglycaemia) will be reported to the appropriate diabetes care provider for follow-up.

Glucose monitoring

Glucose monitoring adherence will be defined as scanning (intervention group) or SMBG (control group) four or more times per day, which is to be determined by device downloads of retrospective self-monitoring data.

Glucose monitoring device performance

FGM performance (i.e. sensor problems, reader problems), FGM adherence (i.e., duration of time each sensor is worn) and blood glucose meter performance
(i.e. device malfunctions) will be self-reported at follow-up visits. Flash glucose monitoring acceptability will be evaluated using a non-validated instrument adapted from previous similar research [18]. On an ordinal scale from 0 (strongly disagree) to 5 (strongly agree), participants will rate their opinion in regards to the following areas: acceptability of sensor application, wear/use of the device and comparison to SMBG.

Psychosocial assessments

Psychosocial data and overall diabetes treatment acceptance will be collected through validated self-report questionnaires completed online using (REDCap Research Electronic Data Capture) software self-administered questionnaires or paper questionnaires prior to clinical assessments and the order of administration will be standardized to increase reliability. REDCap is a secure, web-based application designed to support data capture for research studies[29]. Together the questionnaires will take between 30 and 45 min to complete. All questionnaires are administered in English. Participant reported outcomes including health-related diabetes-specific quality of life, fear of hypoglycaemia, self-efficacy for diabetes management, , and diabetes treatment satisfaction will be monitored during the study and clinical care teams will be notified if participants report physical or mental problems necessitating follow-up.

Quality of life

1. Diabetes-specific quality of life

The 33-item Pediatric Quality of Life Inventory (PedsQL) 3.2 Diabetes Module is a measure of diabetes-specific health-related quality of life that assesses participant's and parent's/caregiver's perceptions of the participant's diabetes-specific symptoms and management problems [30]. The PedsQL 3.2 Diabetes Module measures five domains: Diabetes Symptoms, Treatment Barriers, Treatment Adherence, Worry and Communication. Participant self-report forms are specific for ages 5-7, (young child), 8-12 (child), and 13-14 (adolescent). The parent proxy form is specific to ages 2-4 (toddler), 5-7 (young child), 8-12 (child), 13-14 (adolescent). The PedsQL 3.2 Diabetes Module Diabetes Symptoms and Diabetes Management Summary scores have demonstrated excellent measurement properties and are recommended as useful standardized patient-reported outcomes of diabetes symptoms and diabetes management in clinical research in children and adolescents with type 1 diabetes.

2. Fear of hypoglycaemia

The Hypoglycaemia Fear Survey for Children (HFSC) is a 25-item instrument adapted from the adult HFS[31]. The HFSC will be completed by children and adolescents in the study aged 6 years and older. Overall, higher scores reflect greater fear of hypoglycaemia, a higher score on the Behaviour Subscale reflects a greater tendency to avoid hypoglycaemia and/or its negative consequences, and a higher score on the Worry Subscale indicates more worry concerning episodes of hypoglycaemia and its consequences. The CHFS has shown adequate internal consistency (HFSC behaviour subscale alpha = 0.70; CHFS worry subscale alpha = 0.89; and CHFS-Total alpha = 0.85)[31]. HFSC worry subscale and total scores have been shown to correlate significantly with other measures of anxiety[31]. Total scores and subscale scores will be calculated as z-scores standardised to the instrument-specific and baseline means and standard deviations.

3. Self-efficacy for diabetes management

The Self-Efficacy for Diabetes Self-Management (SEDM) is a 10-item self-report questionnaire for youth aged 10-16 years that examines confidence to carry out self-care behaviours and covers all the key areas of diabetes self-management[32]. The SEDM will be completed by participants who are 10 years and older. Participants are asked "How sure are you that you can do each of the following, almost all the time" and items are rated from 1 (not at all sure) to 10 (completely sure) and averaged. Higher scores indicate higher self-efficacy. The SEDM has demonstrated good validity and reliability (Cronbach's alpha 0.9)[32].

Parent/caregiver reported outcomes

At the first visit (beginning of week 1), parents of enrolled participants who provide written consent for their own participation in the study will complete a short questionnaire collecting demographic characteristics (e.g. age, gender, education level, and ethnicity). At the week 1, week 14 and week 26 visits, parents' will complete questionnaires to assess their perceptions of their own fear of their child experiencing hypoglycaemia[31].

11e. Safety considerations/Patient safety

For safety monitoring purposes, participants will be asked to report any episodes of moderate (blood glucose values ≤ 3.9 mmol/L) and severe (child is having altered mental status and unable to assist in their care, or is semiconscious or unconscious) hypoglycaemia and/or diabetic ketoacidosis (DKA), sensor failure rates, and cutaneous adverse events (e.g., pain, itching, redness, subcutaneous haemorrhage, infection) to research staff at each visit or by phone call every four weeks throughout the study. All adverse events will be recorded in an Adverse Event form.

In the event of cutaneous adverse events - Participants will contact research staff immediately (by sending a photo of their affected skin site, if possible) if they notice a cutaneous issue associated with wearing the sensor. Clinical research staff will then advise if medical treatment is necessary. Participants will be referred to their general practitioner or emergency department, as appropriate, for management of medical events.

For more significant or persistent adverse events involving skin a barrier product will be offered (eg, Cavilon spray, SkinTac™) or drug therapy (eg, zinc ointment, Fenistil gel, or hydrocortisone cream) prescribed, and the participant's caregiver will be instructed to relocate the sensor to another area of the skin such that the effects are maintained at a tolerable level. Ultimately, the decision to continue or discontinue the use of the FreeStyle Libre when localized skin symptoms occur will be made in consultation with the participant.

The severity of the adverse event will be recorded based on the following definitions:

Mild adverse event: within normal limits, intervention not indicated

Moderate adverse event: minimal or non-invasive interventions indicated

Severe adverse event: life-threatening, disabling, or related to death

An internal Safety Monitoring Committee will be notified of severe adverse events immediately after being reported to research staff. The Committee will then discuss any necessary action. Non-urgent events (moderate events) will be reported to the lead investigator after being reported to research staff. The internal Safety Monitoring Committee will be comprised of clinical investigators (CJ, BW).

The following Adverse Events should be reported to the Safety Monitoring Committee:

Medical

Severe hypoglycaemia (blood glucose value ≤ 3.9 mmol/L and resulting in loss of consciousness, a call for an ambulance and/or admission to hospital, or use of glucagon); Diabetic ketoacidosis (DKA; being unwell due to hyperglycaemia and high ketones, and requiring a visit to the doctor, emergency room, or admission to hospital).

Subcutaneous problems

Skin irritation or reaction related to FGM sensor insertion/wear or SMBG (e.g., infection, redness, itching, rash, pain, bleeding, bruising, swelling, hardening, lumps under the skin, a dent that doesn't go away, scarring).

11f. Data management

All study participants will be assigned a non-informative study identification number. Only research staff and investigators will have access to the electronic study records for the purposes of recording data and checking completeness of data. Data will be recorded and stored electronically in REDCap, which is securely hosted at the University of Otago. REDCap prevents unauthorized access to data by:

- Requiring all new REDCap users to obtain permission from the University of Otago to use REDCap
- All users must enter their username and password to access study data
- Access to identifiable data is determined by 'user rights' so that only appropriate research staff access identifiable data (e.g., a biostatistician would not be able to access identifiable data)
- Research staff at regional sites will be assigned to a Data Access Group so that staff only see data for participants within their study region
- REDCap automatically logs all activity and creates an audit trail

Identifiable information (e.g., date of diagnosis, address, date of birth) will not be stored in REDCap. Instead, age in whole numbers and length of diabetes in whole numbers will be recorded in REDCap. Local sites will, however, hold in locked Excel sheets their own participants with address and contact details (phone number and emails), so that if the local sites need to make contact (for replacement Libre devices etc.) they can do so.

REDCap features (e.g. calendar and colour-coding forms to indicate complete or missing data) will help ensure adherence to time-frames, compliance to measurement procedures, and completeness of data. Data will be routinely checked for missing and/or erroneous values by the study coordinator. At the end of the study, original data collection sheets and written informed consent will be stored securely at the lead site along with copies of all data collected electronically. At the end of the study, the lead investigator will retain an anonymised electronic copy of the cleaned data set, with all identifying information removed. The data set may be shared as part of the scientific peer-review process or shared to conduct a meta-analysis (e.g. impacts of flash glucose monitoring on glycaemic control). The electronic dataset will be destroyed 10 years from the end of the study.

12. Statistical Considerations and Data Analysis

12a. Sample size and statistical power

A sample size of 88 (44 participants in each group) would provide 80% power to detect a difference in changes in HbA1c of 7 mmol/mol (0.75%) between the intervention and control group using standard deviation of 15 and correlation of 0.7 between repeated observations on the same person and a two-sided test at the 0.05 level. This is a clinically important difference and similar to other proven technologies such as insulin pumps or CGMS. To account for a small amount of missing data and loss to follow-up, we will recruit a sample size of 100 (50 participants per group) at baseline.

12b. Statistical methods

Descriptive statistics will be calculated for all variables. The primary outcome is the between group change in HbA1c at 12-weeks (i.e. end of week 14 of study). The primary analysis will follow the intention-to-treat principle with all participants analyzed in the group to which they were randomized, regardless of actual sensor wear. Additional analyses include: HbA1c, glucose monitoring frequency and adherence, episodes of moderate and severe hypoglycaemia, episodes of DKA, and psychosocial variables using Poisson and linear mixed models as appropriate. Statistical analysis will be performed using Stata software with two-sided $p < 0.05$ considered significant.

13. Ethical Considerations

The study will be conducted in full conformance with principles of the "Declaration of Helsinki" and Good Clinical Practice (GCP).

14. Outcomes and Significance

FGM technology has the potential to significantly improve diabetes control in children. Increasing time in range, reducing HbA1c and improving quality of life for children with this lifelong chronic disease is important and improving glycaemic control reduces the risk of diabetes acute and chronic complications. If FGM is effective in an RCT, it will then increase our ability to have this device funded for children with diabetes in NZ.

15. Research with Māori

15a. Interest to Māori

Approximately 10% of children with T1D are Māori. We anticipate that in this group of children not achieving optimal control (from our diabetes database-Starbase) that there will be higher percentage who are Māori. Māori children with T1D may well benefit from improved diabetes control, in which case increased national funding for FGM will be warranted to prevent acute and chronic diabetes complications. Diabetes nurses in each DHB will ensure that Māori children with T1D are actively encouraged to enrol in this study. We will collect self-reported ethnicity using the latest census question on ethnicity. There are no anticipated cultural issues for Māori: all children who have T1D will have access to the multi-disciplinary teams in the different DHBs. We will be disseminating our findings to appropriate Māori health providers.

16. Abbreviations

BG	Blood glucose
BMI	Body mass index
CGM	Continuous glucose monitoring
DHB	District health board
DKA	Diabetic ketoacidosis
FGM	Flash glucose monitoring
HbA1c	Glycated haemoglobin
RCT	Randomized controlled trial
SMBG	Self-monitoring blood glucose
T1D	Type 1 diabetes

17. References

1. Karvonen, M., Viik-Kajander, M., Moltchanova, E., Libman, I., LaPorte, R., Tuomilehto, J. Incidence of childhood type 1 diabetes worldwide. Diabetes Mondiale (DiaMond) Project Group. Diabetes Care 2000, 23(10), 1516-1526.
2. Campbell-Stokes, P.L., Taylor, B.J., New Zealand Children's Diabetes Working, G. Prospective incidence study of diabetes mellitus in New Zealand children aged 0 to 14 years. Diabetologia 2005, 48(4), 643-8.
3. You, W.P., Henneberg, M. Type 1 diabetes prevalence increasing globally and regionally: the role of natural selection and life expectancy at birth. BMJ Open Diabetes Res Care 2016, 4(1), e000161.
4. DiMeglio, L.A., Acerini, C.L., Codner, E., Craig, M.E., Hofer, S.E., Pillay, K., Maahs, D.M. ISPAD Clinical Practice Consensus Guidelines 2018: Glycemic control targets and glucose monitoring for children, adolescents, and young adults with diabetes. Pediatr Diabetes 2018, 19(S27), 105-114.
5. McKnight, J., Wild, S., Lamb, M., Cooper, M., Jones, T., Davis, E., Hofer, S., Fritsch, M., Schober, E., Svensson, J. Glycaemic control of Type 1 diabetes in clinical practice early in the 21st century: an international comparison. Diabet Med 2015, 32(8), 1036-1050.
6. de Bock, M., Jones, T.W., Fairchild, J., Mouat, F., Jefferies, C. Children and adolescents with type 1 diabetes in Australasia: An online survey of model of care, workforce and outcomes. J Paediatr Child Health 2019, 55(1), 82-86.
7. Derraik, J.G., Reed, P.W., Jefferies, C., Cutfield, S.W., Hofman, P.L., Cutfield, W.S. Increasing incidence and age at diagnosis among children with type 1 diabetes mellitus over a 20-year period in Auckland (New Zealand). PLoS One 2012, 7(2), e32640.
8. Gubitosi-Klug, R.A., Braffett, B.H., White, N.H., Sherwin, R.S., Service, F.J., Lachin, J.M., Tamborlane, W.V., Diabetes, C., Complications Trial /Epidemiology of Diabetes, I., Complications Research, G. Risk of Severe Hypoglycemia in Type 1 Diabetes Over 30 Years of Follow-up in the DCCT/EDIC Study. Diabetes Care 2017, 40(8), 1010-1016.
9. The Diabetes, C.C.T.E.o.D., Interventions Complications Research, Group,. Effect of Intensive Diabetes Therapy on the Progression of Diabetic Retinopathy in Patients with Type 1 Diabetes: 18 Years of Follow-up in the DCCT/EDIC. Diabetes 2014.
10. Tamborlane, W.V., Attia, N., Saif, R., Sakati, N., Al Ashwal, A. Impact of the diabetes control and complications trial (DCCT) on management of insulin-dependent diabetes mellitus: A pediatric perspective. Ann Saudi Med 1996, 16(1), 64-8.
11. Miller, K.M., Beck, R.W., Bergenstal, R.M., Goland, R.S., Haller, M.J., McGill, J.B., Rodriguez, H., Simmons, J.H., Hirsch, I.B., Network, T.D.E.C. Evidence of a strong association between frequency of self-monitoring of blood glucose and hemoglobin A1c levels in T1D exchange clinic registry participants. Diabetes Care 2013, 36(7), 2009-14.
12. Giani, E., Snelgrove, R., Volkening, L.K., Laffel, L.M. Continuous glucose monitoring (CGM) adherence in youth with type 1 diabetes: associations

with biomedical and psychosocial variables. J Diabetes Sci Technol 2017, 11(3), 476-483.
13. Ajjan, R.A., Cummings, M.H., Jennings, P., Leelarathna, L., Rayman, G., Wilmot, E.G. Accuracy of flash glucose monitoring and continuous glucose monitoring technologies: Implications for clinical practice. Diab Vasc Dis Res 2018, 1479164118756240.
14. Boucher, S.E., Gray, A.R., de Bock, M., Wiltshire, E.J., Galland, B.C., Tomlinson, P.A., Rayns, J., MacKenzie, K.E., Wheeler, B.J. Effect of 6 months' flash glucose monitoring in adolescents and young adults with type 1 diabetes and suboptimal glycaemic control: managing diabetes in a 'flash' randomised controlled trial protocol. BMC Endocr Disord 2019, 19(1), 50.
15. Lang., Jangam, S., Dunn, T., Hayter, G. Expanded Real-world use confirms strong association between frequency of flash glucose monitoring and glucose conrol. Daibetes Technology and Therapeutics 2019, 21(S1).
16. Boucher, S., Blackwell, M., Galland, B., de Bock, M., Crocket, H., Wiltshire, E., Tomlinson, P., Rayns, J., Wheeler, B. Initial experiences of adolescents and young adults with type 1 diabetes and high-risk glycemic control after starting flash glucose monitoring-a qualitative study. Journal of Diabetes & Metabolic Disorders 2019, 1-10.
17. Boucher, S., Aum, S.H., Crocket, H., Wiltshire, E., Tomlinson, P., de Bock, M., Wheeler, B. Exploring parental perspectives after commencement of flash glucose monitoring for type 1 diabetes in adolescents and young adults not meeting glycaemic targets: a qualitative study. Diabet Med 2019, 1-8.
18. Edge, J., Acerini, C., Campbell, F., Hamilton-Shield, J., Moudiotis, C., Rahman, S., Randell, T., Smith, A., Trevelyan, N. An alternative sensor-based method for glucose monitoring in children and young people with diabetes. Arch Dis Child 2017, 102(6), 543-549.
19. Giani, E., Snelgrove, R., Volkening, L.K., Laffel, L.M. Continuous Glucose Monitoring (CGM) Adherence in Youth With Type 1 Diabetes: Associations With Biomedical and Psychosocial Variables. J Diabetes Sci Technol 2017, 11(3), 476-483.
20. Landau, Z., Abiri, S., Gruber, N., Levy-Shraga, Y., Brener, A., Lebenthal, Y., Barash, G., Pinhas-Hamiel, O., Rachmiel, M. Use of flash glucose-sensing technology (FreeStyle Libre) in youth with type 1 diabetes: AWeSoMe study group real-life observational experience. Acta Diabetol 2018, 1-8.
21. Battelino, T., Danne, T., Bergenstal, R.M., Amiel, S.A., Beck, R., Biester, T., Bosi, E., Buckingham, B.A., Cefalu, W.T., Close, K.L. Clinical targets for continuous glucose monitoring data interpretation: recommendations from the international consensus on time in range. Diabetes Care 2019, 42(8), 1593-1603.
22. Distiller, L.A., Cranston, I., Mazze, R. First clinical experience with retrospective flash glucose monitoring (FGM) analysis in South Africa: characterizing glycemic control with ambulatory glucose profile. J Diabetes Sci Technol 2016, 10(6), 1294-1302.
23. Carter, P.J., Cutfield, W.S., Hofman, P.L., Gunn, A.J., Wilson, D.A., Reed, P.W., Jefferies, C. Ethnicity and social deprivation independently influence metabolic control in children with type 1 diabetes. Diabetologia 2008, 51(10), 1835-42.

24. Atkinson, J., Salmond, C., Crampton, P. NZDep2013 index of deprivation. New Zealand, Ministry of Health 2014.
25. Ogden, C.L., Kuczmarski, R.J., Flegal, K.M., Mei, Z., Guo, S., Wei, R., Grummer-Strawn, L.M., Curtin, L.R., Roche, A.F., Johnson, C.L. Centers for Disease Control and Prevention 2000 growth charts for the United States: improvements to the 1977 National Center for Health Statistics version. Pediatrics 2002, 109(1), 45-60.
26. Lenters-Westra, E., Slingerland, R.J. Six of eight hemoglobin A1c point-of-care instruments do not meet the general accepted analytical performance criteria. Clin Chem 2010, 56(1), 44-52.
27. Beck, R.W., Bergenstal, R.M., Riddlesworth, T.D., Kollman, C., Li, Z., Brown, A.S., Close, K.L. Validation of Time in Range as an Outcome Measure for Diabetes Clinical Trials. Diabetes Care 2019, 42(3), 400-405.
28. Beck, R.W., Bergenstal, R.M., Cheng, P., Kollman, C., Carlson, A.L., Johnson, M.L., Rodbard, D. The Relationships Between Time in Range, Hyperglycemia Metrics, and HbA1c. J Diabetes Sci Technol 2019, 13(4), 614-626.
29. Harris, P.A., Taylor, R., Thielke, R., Payne, J., Gonzalez, N., Conde, J.G. Research electronic data capture (REDCap)—a metadata-driven methodology and workflow process for providing translational research informatics support. J Biomed Inform 2009, 42(2), 377-381.
30. Varni, J.W., Delamater, A.M., Hood, K.K., Raymond, J.K., Chang, N.T., Driscoll, K.A., Wong, J.C., Joyce, P., Grishman, E.K., Faith, M.A. PedsQL 3.2 diabetes module for children, adolescents, and young adults: reliability and validity in type 1 diabetes. Diabetes Care 2018, 41(10), 2064-2071.
31. Gonder-Frederick, L., Nyer, M., Shepard, J.A., Vajda, K., Clarke, W. Assessing fear of hypoglycemia in children with type 1 diabetes and their parents. Diabetes Manag (Lond) 2011, 1(6), 627.
32. Iannotti, R.J., Schneider, S., Nansel, T.R., Haynie, D.L., Plotnick, L.P., Clark, L.M., Sobel, D.O., Simons-Morton, B. Self-efficacy, outcome expectations, and diabetes self-management in adolescents with type 1 diabetes. J Dev Behav Pediatr 2006, 27(2), 98-105.

Appendix 1 (Enclosed separately)

Participant information sheets:

- Pictorial information sheet for 4 – 7 year olds
- Information sheet with assent form for 8 – 11 year olds
- Information sheet with assent form for 12 – 13 year olds
- Information sheet with consent forms for parents/caregivers

Appendix 2

The LibreView Privacy Notice can be found at https://www.aus.abbott/privacy-policy.html and can be read as new patient accounts are created (https://www1.libreview.com/auth/register/createNewPatient).

What health information will be collected?

Abbott will process data from sensors and readers, such as how often participants scan or use their sensors or readers, glucose values and glucose level targets.

What identifiable information will be collected?

Name and date of birth

The study ID will be used in place of First Name. The study name will be used in place of Last Name.

All participants' date of birth will be entered as January 01 1900.

Email addresses

A parent's email address will be used to create a patient account that receives all glucose data from the device that collects and displays glucose sensor data (i.e., FreeStyle handheld reader or personal smart phone).

If de-identified information is collected, how is the information de-identified and who de-identifies it?

Glucose data will be identified by the participant's study ID. Research staff will ensure the participant's study ID is used.

What measures will be taken to protect participants' privacy?

Abbott has clear privacy guidelines on how data is shared, stored and used. See https://www.aus.abbott/privacy-policy.html.

FreeStyle sensors transmit personal glucose information to FreeStyle mobile apps and readers using NFC (Near Field Communication) and Bluetooth technologies. NFC and Bluetooth are both secure means of transferring information between devices. NFC has the added level of protection by requiring very close physical proximity. Bluetooth connections for FreeStyle sensors are established during an encrypted NFC communication between a FreeStyle sensor and a FreeStyle mobile app or reader.

Abbott will not sell or license personal information to third parties except in connection with the sale or transfer of a product line or division, or in connection with a joint marketing program. Abbott shares personal information with health care practitioners (as part of treatment) and authorised research staff through LibreView.

Abbott has the following recommendations to protect patient accounts against unauthorised access:

- Choose a robust password (8 to 36 characters, at least 1 number, at least 1 special character)
- Implement security settings on mobile devices or computers such as a password to access it and keep devices locked when not in use.

Abbott asks for permission to send emails providing information about Abbott Diabetes Care and other Abbott products and services. If a parent consents to these emails they can unsubscribe at any time.

Abbott stores data on secured servers in several countries around the world (Australia, New Zealand, the United States, Malaysia, Singapore, Germany, Japan, and India). Abbott takes reasonable steps to protect personal information from misuse, interference, loss, unauthorized access, modification or disclosure. It is Abbott's practice to secure each Abbott Web Site that collects personal information; however, when information is collected online the confidentiality of personal information transmitted over the Internet cannot be guaranteed.

Appendix 3 – FreeStyle Libre 2 Education

Flash 1 Study: Education Programme Checklist	
Date of Education: ___/___/___ Educator: _____ Parent/Caregiver In Education: _____	
CHECKLIST	**DATE/COMMENT**
❑ What is a Freestyle Libre / FGM	
❑ Difference between SMBG and FGM - SMBG vs FGM - Why they don't always match - Reason for 5 – 10 minute delay	
❑ Freestyle Libre Sensor Overview - Size of sensor - demo - Frequency of site change – 14 days - Preserving the sensor (care with swimming, exercise, and play). - How to remove a sensor	
❑ Freestyle Libre Sensor Application - How to apply sensor - Securing the sensor/compatible dressings - Start-up reader by scanning	
❑ Freestyle Libre Reader - Set up target range (3.9 – 10 mmol/L) - Set up alarm settings - Current glucose reading - Trend arrow - 8 hour history - Charging the Reader	
❑ How to get a reading/test - How to scan sensor with reader - Frequency of scanning with reader - Accuracy when levels are out of range	
❑ When to do finger prick checks	
❑ What to do if Libre reads a low BGL (Hypo) - Always confirm with finger prick	
❑ What to do if reader reads a high BGL (Hyperglycaemia) - Always confirm with finger prick	
❑ How to do an upload - Steps to uploading via reader	
❑ Interpreting arrow trends	
❑ Who to contact if sensor/reader stop working	

FREESTYLE LIBRE FLASH GLUCOSE MONITORING (FGM) SYSTEM

Sensor

- Measures glucose levels in the tissues under your skin
- Worn on upper outer arm
- Each sensor lasts up to 14 days
- Insert each new sensor in a different position to the last. Alternate arms to prevent skin problems. Make sure skin is clean and dry prior to insertion.
- It takes 1 hour for the sensor to warm up after insertion. If you need to know what your glucose level is during this time you will need to do a finger prick glucose.
- Can be worn when showering or swimming
    - Is water-resistant in up to 1 metre of water
    - Don't immerse in water for longer than 30 minutes
- Don't wear sensor during an x-ray, CT or MRI scan.
- Sweat during intense exercise may cause the sensor to loosen and need to be replaced
- Use Tegaderm, Tubigrip or K tape to protect your sensor. Cut a hole in the tape overlying the sensor vent. The vent allows moisture to escape and shouldn't be covered
- Some people experience skin reactions to the sensor or its adhesive. If this happens take a photo of the skin reaction and send it to the research team.

Reader

- The reader is a hand-held touch screen device
- Glucose levels are not constantly shown on the reader. You need to scan the reader over the sensor to transmit data from the sensor to the reader
- The reader has to be within 4cm of the sensor when scanning
- You can scan through clothing with thickness up to 4mm
- After scanning over the sensor the screen on the reader will show
    - Current glucose level
    - A trend arrow
    - Graph of glucose level trends over previous 8 hours

- The reader can store up to 90 days of glucose data

TARGET GLUCOSE RANGE

- 3.9 – 10 mmol/L (this range can be set on your Libre reader)

ALARMS

- This device has an in-built alarm that will alarm if your glucose level is low or high
- It won't however automatically tell you what the glucose level is when it alarms, you need to scan the sensor to see what the glucose level is. You may then need to follow this up with a finger prick glucose check (see below)

FREQUENCY OF SCANNING

- As a minimum you should scan the sensor to check your glucose levels
    - Before meals
    - Before bed
    - Before and after exercise

- You can scan the sensor as often as you like but you must scan at least **6 - 10 times every day**. There should be no longer than 8 hours between two scans including the last scan at night and first scan the following morning

WHEN TO DO FINGER PRICK GLUCOSE CHECKS

- If glucose level on Libre reader is ≤ 4 mmol/L or ≥ 14 mmol/L. This is to confirm what your blood glucose level is and if action is required e.g. hypo treatment or extra-insulin

- If glucose level on Libre reader is rising or falling quickly i.e. trend arrow is going straight up or straight down
- Before giving any therapy e.g. hypo treatment or extra-insulin
    - e.g. when glucose level < 4 mmol/L on Libre reader OR having symptoms of a hypo check finger prick blood glucose level. If finger prick blood glucose level < 4 mmol/L then give hypo treatment.
- If you have symptoms that may be due to low or high blood glucose
- If you have symptoms that don't match the glucose level on the Libre reader
- If you suspect the glucose level on the reader may be inaccurate for any reason
- If your finger prick glucose is ≥ 15 mmol/L or you feel unwell check ketones
- Compression of sensor e.g. lying on the arm your sensor is in when you are asleep can cause the Libre system to give falsely low glucose levels. If in doubt, check a finger prick glucose to confirm your blood glucose level and whether hypo treatment is needed
- Keep yourself hydrated. Dehydration can cause the Libre system to give inaccurate glucose levels

HOW TO INTERPRET TREND ARROWS ON LIBRE READER

- Trend arrows show which way and how quickly your glucose level is changing

Arrow on Reader	Glucose Direction	Predicted Change in 10 minutes
	Glucose rising quickly	Rise by more than 1 mmol/L
	Glucose rising	Rise by 0.6 – 1 mmol/L
	Glucose steady and changing slowly	Rise/fall less than 0.6 mmol/L
	Glucose falling	Fall by 0.6 – 1 mmol/L
	Glucose falling quickly	Fall by more than 1 mmol/L

**Please contact your local diabetes team if you are unsure what to do with your insulin doses*

WHAT TO DO IF MY SENSOR OR READER STOP WORKING

- Contact the research team for advice if your reader or sensor stop working

FURTHER LIBRE INFORMATION RESOURCES AVAILABLE FROM

https://iray.campaign-view.com/ua/viewinbrowser?od=27218d28c96aa859e9afe3a6a54f72fbe1185630859ca1fd0&rd=17d82f84a6156306&sd=17d82f84a615621f&n=11699e4c0f9a4b5&mrd=17d82f84a615620d&m=1

Appendix 4 – Assessments

Pediatric Quality of Life Inventory (PedsQL) 3.2 Diabetes Module
Note: Teens Report (ages 13-18) has similar wording

ID#_____

Date:_____

PedsQL™
Diabetes Module

Version 3.2

CHILD REPORT (ages **8-12**)

Do not use without permission
Review copy

DIRECTIONS

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

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

There are no right or wrong answers.
If you do not understand a question, please ask for help.

Not to be reproduced without permission
Copyright © 1998 JW Varni, Ph.D.
All rights reserved

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

ABOUT MY DIABETES *(problems with...)*	Never	Almost Never	Some-times	Often	Almost Always
1. I feel hungry	0	1	2	3	4
2. I feel thirsty	0	1	2	3	4
3. I have to go to the bathroom too often	0	1	2	3	4
4. I have tummy aches	0	1	2	3	4
5. I have headaches	0	1	2	3	4
6. I feel like I need to throw up	0	1	2	3	4
7. I go "low"	0	1	2	3	4
8. I go "high"	0	1	2	3	4
9. I feel tired	0	1	2	3	4
10. I get shaky	0	1	2	3	4
11. I get sweaty	0	1	2	3	4
12. I feel dizzy	0	1	2	3	4
13. I feel weak	0	1	2	3	4
14. I have trouble sleeping	0	1	2	3	4
15. I get cranky or grumpy	0	1	2	3	4

Review copy
Do not use without permission

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

TREATMENT - I *(problems with...)*	Never	Almost Never	Some-times	Often	Almost Always
1. It hurts to get my finger pricked	0	1	2	3	4
2. It hurts to get insulin shots	0	1	2	3	4
3. I am embarrassed by my diabetes treatment	0	1	2	3	4
4. My parents and I argue about my diabetes care	0	1	2	3	4
5. It is hard for me to do everything I need to do to care for my diabetes	0	1	2	3	4

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

TREATMENT - II *(problems with...)*	Never	Almost Never	Some-times	Often	Almost Always
1. It is hard for me to take blood glucose tests	0	1	2	3	4
2. It is hard for me to take insulin shots	0	1	2	3	4
3. It is hard for me to play or do sports	0	1	2	3	4
4. It is hard for me to keep track of carbohydrates	0	1	2	3	4
5. It is hard for me to carry a fast-acting carbohydrate	0	1	2	3	4
6. It is hard for me to snack when I go "low"	0	1	2	3	4

PedsQL 3.2 - (8-12) Diabetes
04/09

Not to be reproduced without permission

Copyright © 1998 JW Varni, Ph.D.
All rights reserved

PedsQL 3

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

WORRY *(problems with…)*	Never	Almost Never	Some-times	Often	Almost Always
1. I worry about going "low"	0	1	2	3	4
2. I worry about going "high"	0	1	2	3	4
3. I worry about long-term complications from diabetes	0	1	2	3	4

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

COMMUNICATION *(problems with…)*	Never	Almost Never	Some-times	Often	Almost Always
1. It is hard for me to tell the doctors and nurses how I feel	0	1	2	3	4
2. It is hard for me to ask the doctors and nurses questions	0	1	2	3	4
3. It is hard for me to explain my illness to other people	0	1	2	3	4
4. I am embarrassed about having diabetes	0	1	2	3	4

Review copy
Do not use without permission

PedsQL 3.2 - (8-12) Diabetes
04/09

Not to be reproduced without permission

Copyright © 1998 JW Varni, Ph.D.
All rights reserved

Note: Parent Reports for all ages has similar wording

ID#_____

Date:_____

PedsQL™
Diabetes Module

Version 3.2

PARENT REPORT for **CHILDREN** (ages **8-12**)

Revised copy
Do not use without permission

DIRECTIONS

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

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

There are no right or wrong answers.
If you do not understand a question, please ask for help.

Not to be reproduced without permission

Copyright © 1998 JW Varni, Ph.D.
All rights reserved

PedsQL 2

*In the past **ONE month**, how much of a **problem** has your child had with …*

DIABETES *(problems with...)*	Never	Almost Never	Some-times	Often	Almost Always
1. Feeling hungry	0	1	2	3	4
2. Feeling thirsty	0	1	2	3	4
3. Having to go to the bathroom too often	0	1	2	3	4
4. Having tummy aches	0	1	2	3	4
5. Having headaches	0	1	2	3	4
6. Feeling like he/she needs to throw up	0	1	2	3	4
7. Going "low"	0	1	2	3	4
8. Going "high"	0	1	2	3	4
9. Feeling tired	0	1	2	3	4
10. Getting shaky	0	1	2	3	4
11. Getting sweaty	0	1	2	3	4
12. Feeling dizzy	0	1	2	3	4
13. Feeling weak	0	1	2	3	4
14. Having trouble sleeping	0	1	2	3	4
15. Getting cranky or grumpy	0	1	2	3	4

*In the past **ONE month**, how much of a **problem** has your child had with …*

TREATMENT - I *(problems with...)*	Never	Almost Never	Some-times	Often	Almost Always
1. Finger pricks causing him/her pain	0	1	2	3	4
2. Insulin shots causing him/her pain	0	1	2	3	4
3. Getting embarrassed about his/her diabetes treatment	0	1	2	3	4
4. Arguing with me or my spouse about diabetes care	0	1	2	3	4
5. It is hard for my child to do everything he/she needs to do to care for his/her diabetes	0	1	2	3	4

Review copy
Do not use without permission

*Whether your child does these things **independently or with your help**, please answer how difficult these things were to do in the past **ONE month.** (Note: This section is **not** asking about your child's independence in these areas, just how hard they were to do).*

TREATMENT - II *(problems with...)*	Never	Almost Never	Some-times	Often	Almost Always
1. It is hard for my child to take blood glucose tests	0	1	2	3	4
2. It is hard for my child to take insulin shots	0	1	2	3	4
3. It is hard for my child to play or do sports	0	1	2	3	4
4. It is hard for my child to track carbohydrates	0	1	2	3	4
5. It is hard for my child to carry a fast-acting carbohydrate	0	1	2	3	4
6. It is hard for my child to snack when he/she goes "low"	0	1	2	3	4

PedsQL 3.2 - Parent (8-12) Diabetes
04/09

Not to be reproduced without permission

Copyright © 1998 JW Varni, Ph.D.
All rights reserved

PedsQL 3

*In the past **ONE month**, how much of a **problem** has your child had with …*

WORRY *(problems with…)*	Never	Almost Never	Some-times	Often	Almost Always
1. Worrying about going "low"	0	1	2	3	4
2. Worrying about going "high"	0	1	2	3	4
3. Worrying about long-term complications from diabetes	0	1	2	3	4

*In the past **ONE month**, how much of a **problem** has your child had with …*

COMMUNICATION *(problems with…)*	Never	Almost Never	Some-times	Often	Almost Always
1. Telling the doctors and nurses how he/she feels	0	1	2	3	4
2. Asking the doctors or nurses questions	0	1	2	3	4
3. Explaining his/her illness to other people	0	1	2	3	4
4. Getting embarrassed about having diabetes	0	1	2	3	4

Review copy
Do not use without permission

PedsQL 3.2 - Parent (8-12) Diabetes
04/09

Not to be reproduced without permission

Copyright © 1998 JW Varni, Ph.D.
All rights reserved

ID# _____

Date:_____

PedsQL™

Diabetes Module

Version 3.2

YOUNG CHILD REPORT (ages 5-7)

Review copy
Do not use without permission

Instructions for interviewer:

I am going to ask you some questions about things that might be a problem for some children. I want to know how much of a problem any of these things might be for you.

Show the child the template and point to the responses as you read.

If it is <u>not at all</u> a problem for you, point to the smiling face

If it is <u>sometimes</u> a problem for you, point to the middle face

If it is a problem for you <u>a lot</u>, point to the frowning face

I will read each question. Point to the pictures to show me how much of a problem it is for you. Let's try a practice one first.

	Not at all	Sometimes	A lot
Is it hard for you to snap your fingers	☺	😐	☹

Ask the child to demonstrate snapping his or her fingers to determine whether or not the question was answered correctly. Repeat the question if the child demonstrates a response that is different from his or her action.

Not to be reproduced without permission

Copyright © 1998 JW Varni, Ph.D.
All rights reserved

PedsQL 2

Think about how you have been doing for the last few weeks. Please listen carefully to each sentence and tell me how much of a problem this is for you.

After reading the item, gesture to the template. If the child hesitates or does not seem to understand how to answer, read the response options while pointing at the faces.

ABOUT MY DIABETES *(problems with...)*	Not at all	Some-times	A lot
1. Do you feel hungry	0	2	4
2. Do you feel thirsty	0	2	4
3. Do you have to go to the bathroom a lot	0	2	4
4. Do you have tummy aches	0	2	4
5. Do you have headaches	0	2	4
6. Do you feel like you need to throw up	0	2	4
7. Do you go "low"	0	2	4
8. Do you go "high"	0	2	4
9. Do you feel tired	0	2	4
10. Do you get shaky	0	2	4
11. Do you get sweaty	0	2	4
12. Do you feel dizzy	0	2	4
13. Do you feel weak	0	2	4
14. Do you have trouble sleeping	0	2	4
15. Do you get cranky or grumpy	0	2	4

Remember, tell me how much of a problem this has been for you for the last few weeks.

ABOUT MY TREATMENT - I *(problems with...)*	Not at all	Some-times	A lot
1. Does it hurt to prick your finger	0	2	4
2. Does it hurt to get insulin shots	0	2	4
3. Are you embarrassed about your diabetes treatment	0	2	4
4. Do you and your parents argue about your diabetes care	0	2	4
5. Is it hard for you to do everything you need to do to care for your diabetes	0	2	4

Review copy
Do not use without permission

Whether you do these things on your own or with the help of your parents, please answer how hard these things were to do in the last few weeks.

ABOUT MY TREATMENT - II *(problems with...)*	Not at all	Some-times	A lot
1. Is it hard for you to take blood glucose tests	0	2	4
2. Is it hard for you to take insulin shots	0	2	4
3. Is it hard for you to play or do sports	0	2	4
4. Is it hard for you to keep track of carbohydrates	0	2	4
5. Is it hard for you to carry a fast-acting carbohydrate	0	2	4
6. Is it hard for you to snack when you go "low"	0	2	4

PedsQL 3.2 (5-7) Diabetes
04/09
Not to be reproduced without permission
Copyright © 1998 JW Varni, Ph.D.
All rights reserved

PedsQL 3

Think about how you have been doing for the past last few weeks. Please listen carefully to each sentence and tell me how much of a problem this is for you.

After reading the item, gesture to the template. If the child hesitates or does not seem to understand how to answer, read the response options while pointing at the faces.

WORRY *(problems with…)*	Not at all	Some-times	A lot
1. Do you worry about going "low"	0	2	4
2. Do you worry about going "high"	0	2	4

Remember, tell me how much of a problem this has been for you for the last few weeks.

COMMUNICATION *(problems with…)*	Not at all	Some-times	A lot
1. Is it hard for you to tell the doctors and nurses how you feel	0	2	4
2. Is it hard for you to ask the doctors and nurses questions	0	2	4
3. Is it hard for you to explain your illness to other people	0	2	4
4. Are you embarrassed about having diabetes	0	2	4

Review copy
Do not use without permission

PedsQL 3.2 (5-7) Diabetes
04/09

Not to be reproduced without permission

Copyright © 1998 JW Varni, Ph.D.
All rights reserved

How much of a problem is this for you?
Not at all
Sometimes
A lot
Review Copy
Do not use without permission
PedsQL 3.2 (5-7) Diabetes
04/09
Not to be reproduced without permission
Copyright © 1999 JW Varni, Ph.D. All rights reserved

Self-Efficacy for Diabetes Self-Management (SEDM; ages 10-14 years)

How sure are you that you can do each of the following almost all the time?

Please circle one response for each item below.

1. Adjust your insulin correctly when you eat more or less than usual. 1 2 3 4 5 6 7 8 9 10 Not sure at all Completely sure
2. Choose healthful foods when you go out to eat. 1 2 3 4 5 6 7 8 9 10 Not sure at all Completely sure
3. Exercise even when you don't really feel like it. 1 2 3 4 5 6 7 8 9 10 Not sure at all Completely sure
4. Adjust your insulin or food accurately based on how much exercise you get. 1 2 3 4 5 6 7 8 9 10 Not sure at all Completely sure
5. Talk to your doctor or nurse about any problems you're having with taking care of your diabetes. 1 2 3 4 5 6 7 8 9 10 Not sure at all Completely sure
6. Do your blood sugar checks even when you are really busy. 1 2 3 4 5 6 7 8 9 10 Not sure at all Completely sure
7. Manage your diabetes the way your health care team wants you to. 1 2 3 4 5 6 7 8 9 10 Not sure at all Completely sure
8. Manage your diabetes even when you feel overwhelmed. 1 2 3 4 5 6 7 8 9 10 Not sure at all Completely sure
9. Find ways to deal with feeling frustrated about your diabetes. 1 2 3 4 5 6 7 8 9 10 Not sure at all Completely sure

10. Identify things that could get in the way of managing your diabetes.

1	2	3	4	5	6	7	8	9	10
Not sure at all									Completely sure

Hypoglycaemia Fear Survey, child version (ages 6-14)

Today's Date: _____ Study ID # _____

University of Virginia

Child/Teen Low Blood Sugar Survey

We want to find out more about what low blood sugar makes young people feel and do. Please answer the questions below as honestly as you can.

I. Below is a list of things young people with diabetes sometimes DO TO KEEP FROM HAVING LOW BLOOD SUGAR. Circle the number that best describes YOU.

0=NEVER 1=RARELY 2=SOMETIMES 3=OFTEN 4=ALMOST ALWAYS

1. Eat large snacks at bedtime.	0	1	2	3	4
2. Try not to be by myself when my sugar is likely to be low.	0	1	2	3	4
3. Keep blood sugars a little high to be on the safe side.	0	1	2	3	4
4. Keep blood sugar higher when I will be alone for awhile.	0	1	2	3	4
5. Eat something as soon as I feel the first sign of low blood sugar.	0	1	2	3	4
6. Take less insulin when I think my blood sugar might get too low.	0	1	2	3	4
7. Keep my blood sugar higher when I am going to be away from home.	0	1	2	3	4
8. Carry some kind of sugar, drink, or food with me.	0	1	2	3	4
9. Try not to do a lot of exercise when I think my sugar is low.	0	1	2	3	4
10. Check my blood sugar often when I go away from home.	0	1	2	3	4

II. Below is a list of things that young people with diabetes sometimes worry about concerning low blood sugars. Circle the number that best describes YOU.

0=NEVER 1=RARELY 2=SOMETIMES 3=OFTEN 4=ALMOST ALWAYS					
11. Not recognizing that my blood sugar is low.	0	1	2	3	4
12. Not having food, fruit, or juice with me when my blood sugar gets low.	0	1	2	3	4
13. Feeling dizzy or passing out in public because of low blood sugar.	0	1	2	3	4
14. Having a low blood sugar while asleep.	0	1	2	3	4
15. Embarrassing myself because of low blood sugar.	0	1	2	3	4
16. Having low blood sugar while I am by myself.	0	1	2	3	4
17. Looking "stupid" or clumsy in front of other people.	0	1	2	3	4
18. Losing control because of low blood sugar.	0	1	2	3	4
19. No one being around to help me during a low.	0	1	2	3	4
20. Making a mistake or having an accident at school.	0	1	2	3	4
21. Getting in trouble at school because of something that happens when my sugar is low.	0	1	2	3	4
22. Having seizures.	0	1	2	3	4
23. Getting long term complications from low blood sugar.	0	1	2	3	4
24. Feeling dizzy or woozy when my blood sugar is low.	0	1	2	3	4
25. Having a low blood sugar.	0	1	2	3	4

Hypoglycaemia Fear Survey, parent version (child up to 14 years of age)

Study Visit: _____
Date: __ __ / __ __ / __ __ __ __

Participant Study ID:__ __ __ __ __ __ __ __
Initials __ __ __

University of Virginia
Low Blood Sugar Survey - Parents

This survey is intended to find out more about how low blood sugar makes people feel and behave. Please answer the following questions as frankly as possible about how you felt during the past month.

Below is a list of things **parents** of children with diabetes sometimes DO IN ORDER TO AVOID LOW BLOOD SUGAR and related problems in their children.
Read each item carefully. Circle one of the numbers that best describes **YOU** during the past month.

	0=NEVER	1=RARELY	2=SOMETIMES	3=OFTEN	4=ALMOST ALWAYS
1	Have my child eat large snacks at bedtime	0	1	2	3	4
2	Avoid having my child being alone when his/her sugar is likely to be low	0	1	2	3	4
3	Allow my child's blood sugar to be a little high to be on the safe side	0	1	2	3	4
4	Keep my child's sugar higher when he/she will be alone for awhile	0	1	2	3	4
5	Have my child eat something as soon as he/she feels the first sign of low blood sugar	0	1	2	3	4
6	Reduce my child's insulin when I think his/her sugar is too low	0	1	2	3	4
7	Keep my child's blood sugar higher when he/she plans to be away from me for awhile	0	1	2	3	4
8	Have my child carry fast-acting sugar	0	1	2	3	4
9	Have my child avoid a lot of exercise when I think his/her sugar is low	0	1	2	3	4
10	Check my child's sugar often when he/she plans to go on an outing	0	1	2	3	4

Study Visit: _____
Date: __ __ / __ __ / __ __ __ __

Participant Study ID:__ __ __ __ __ __ __ __ __
Initials __ __ __

Worry: Below is a list of **concerns** parents of children with diabetes sometimes have.
Read each item carefully.
Circle one of the numbers that best describes
HOW OFTEN YOU WORRY ABOUT EACH ITEM

0=NEVER	1=RARELY	2=SOMETIMES	3=OFTEN	4=ALMOST ALWAYS

11	Child not recognizing/realizing that he/she is having a low	0	1	2	3	4
12	Child not having food, fruit, or juice with him/her	0	1	2	3	4
13	Child feeling dizzy or passing out in public	0	1	2	3	4
14	Child having a low while asleep	0	1	2	3	4
15	Child embarrassing self or friends/family in a social situation	0	1	2	3	4
16	Child having a low while alone	0	1	2	3	4
17	Child appearing to be "stupid" or clumsy	0	1	2	3	4
18	Child losing control of behavior due to low blood sugar	0	1	2	3	4
19	No one being around to help my child during a low	0	1	2	3	4
20	Child making a mistake or having an accident at school	0	1	2	3	4
21	Child getting a bad evaluation at school because of something that happens when his/her sugar is low	0	1	2	3	4
22	Child having seizures or convulsions	0	1	2	3	4
23	Child developing long term complications from frequent low blood sugar	0	1	2	3	4
24	Child feeling light-headed or faint	0	1	2	3	4
25	Child having a low	0	1	2	3	4

Study ID: _____ Date: _____

FreeStyle Libre acceptance questionnaire *(final study visit only)*
Children may complete the questionnaire with assistance. Parents will complete a version that states 'my child' for relevant items.

This questionnaire is intended to find out more about how well you *(your child)* like*(s)* using the FreeStyle Libre.

INSTRUCTIONS: Read each item carefully. Circle the number that gives the best answer for **you *(your child)***. Please provide an answer for each question.

	Strongly disagree	Disagree	Undecided	Agree	Strongly agree
After sensor applied					
1. It does not hurt *(my child)* when the sensor is put on	0	1	2	3	4
2. It is easy to put the sensor on *(my child)*	0	1	2	3	4
After sensor worn					
3. I do *(my child does)* not mind wearing the sensor on my arm	0	1	2	3	4
4. It is comfortable *(for my child)* to wear the sensor	0	1	2	3	4
5. It is easy to scan the sensor	0	1	2	3	4
Comparison to finger prick testing					
6. It is more comfortable *(for my child)*	0	1	2	3	4
7. It is less painful *(for my child)*	0	1	2	3	4
8. It is more private *(for my child)*	0	1	2	3	4
9. It is quicker *(for me or my child)* to check my glucose level	0	1	2	3	4
10. It is easier *(for me or my child)*	0	1	2	3	4
11. It does not get in the way of my *(child's)* activities	0	1	2	3	4
12. I like how my glucose readings are shown on the screen	0	1	2	3	4
13. It gives me more information than my *(child's)* current glucose meter to take care of my *(child's)* diabetes	0	1	2	3	4

14. It helps me to understand how my *(child's)* activities change my *(child's)* glucose levels	0	1	2	3	4
15. It makes me feel more interested in taking care of my *(child's)* diabetes	0	1	2	3	4

Please answer the following questions.

1. Is the use of the FreeStyle Libre beneficial (helpful)?

   ☐ Yes ☐ No

2. If yes, please name the top 3 advantages of using the FreeStyle Libre:

   1) ……

   2) ……

   3) ……

3. If no, please name the top 3 disadvantages of using the FreeStyle Libre:

   1) ……

   2) ……

   3) ……

4. Are you willing to use the FreeStyle Libre in the future?

   ☐ Yes ☐ No

5. Would you recommend using FreeStyle Libre to other young people with type 1 diabetes?

   ☐ Yes ☐ No

   Why or why not?

   ……