1 Project Details			
Protocol/Research Project Title:	An innovative care model using continuous glucose monitoring metric data to provide real-time personalised care for children with diabetes		
Protocol Number (Version and Date):	4.0 19.07.2024		
Project Start Date:	02/01/2023	**Project Finish Date:**	02/02/2025
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1.1 Project Summary

Models of diabetes care have not changed a lot in decades despite significant advances in therapies and technology. In Australia, the majority of young people with diabetes do not meet internationally agreed blood glucose targets. Continuous glucose monitoring (CGM) allows insights into glucose trends in real time and has been widely utilised in children with Type 1 Diabetes in Western Australia.

This study will test a new model of care to ask the question whether using CGM data outside of routine clinic appointments to provide personalised intervention can improve blood glucose outcomes, individual reported outcomes, quality of life and economic efficiency.

This single centre, parallel group study involves children with T1D aged 5-14 years attending comparable clinics at Perth Children's Hospital. Children recruited from one clinic will be allocated to intervention and children recruited from an age matched clinic will act as control. Participants in the intervention arm will have their CGM upload reviewed every fortnight and those meeting pre-defined glycaemic parameters will be contacted for targeted feedback and intervention.

Glycaemic outcomes of Time in range, hypoglycaemia and HbA1c will be measured at baseline, 3 months and 6 months. Given this is a non-randomised study difference-in-difference analysis will be used to minimise bias, comparing change over time in each group. Treatment satisfaction and quality of life questionnaires will be completed at baseline and 6 months. Clinician time and occasions of service will be collected for economic analysis.

2 Rationale / Background

Type 1 diabetes is a chronic condition in children that places significant demand on young people and their families and results in significant morbidity and reduced life expectancy. A key goal of diabetes management is to prevent acute and chronic complications by maintaining blood glucose levels as close to normal as possible. Haemoglobin A1c (HbA1c) can provide an estimation of the exposure of blood to elevated glucose levels. Internationally, the target of HbA1c <7.0% is recommended to minimise long term complications of diabetes (1). However, population based registries have shown that most young people with type 1 diabetes do not achieve this recommended target for HbA1c and optimal glucose control (2, 3). Adolescents living with diabetes have double the rate of mental health illness compared with their healthy peers and poor mental health correlates closely with poor glycaemic control, with evidence suggesting improvement in glycaemic control can reduce rates of mental health illness (4).

Despite major improvements in technologies and treatments the model of medical care provided to people living with diabetes has changed little over the last 4 decades. A routine face to face clinic visit with the diabetes team four times a year remains standard care (5). For a disease that affects a child 24 hours a day, a maximum of 4 hours with the treating team may not provide sufficient support to result in optimal outcomes. The recent introduction of continuous glucose monitoring (CGM) offers a potential to radically alter how care is provided to families living with type 1 diabetes.

Continuous glucose monitoring systems are devices that people living with diabetes wear that provides real-time estimations of blood glucose levels via a sub-cutaneous sensor without requiring multiple daily finger-prick blood tests. The glucose levels generated by CGM are transmitted to the "cloud" and with consent from the person with diabetes can be accessed in real time by clinicians, to guide diabetes management. Population based studies have shown that uptake of CGM has increased over the past decade (2, 6). In Australia the government has fully subsidised CGM for young people <21 years of age in 2017. This has resulted in a significant uptake in CGM utilisation with 79% of young people with diabetes registering for CGM through the National Diabetes Subsidy Scheme (NDSS) with ongoing use of CGM >75% of the time in 55% of young people with diabetes (7). In Western Australia, the Perth Children's Hospital (PCH) data indicates that CGM is used in over 90% of young people with Type 1 Diabetes... The wide uptake of CGM in Australia has provided dramatically increased data that can be accessed continuously and that can be utilised to improve models of care and outcomes. While CGM use has been shown to improve outcomes (8, 9), the full potential of the technology remains to be harnessed

Because we are not meeting glycaemic targets using current recommended care models, it is important to continue to review care delivery and consider opportunities to improve models of care. It should also be noted that Type 1 diabetes is increasing in incidence and innovations to models of care that improve outcomes without increased resources are required. During the covid-19 pandemic, care has been adapted to provide telehealth reviews using CGM data to assess control and guide management. The use of CGM data to detect changes in glycaemic control provides an opportunity to adapt our model of care to deliver more personalised and targeted care for young people with diabetes. Early consultation with diabetes focus groups and healthcare professionals in the PCH diabetes department has shown enthusiasm for this concept.

This study will be formative research to test a new model of care, aiming to use CGM data to detect early adverse changes in glycaemic control and provide targeted and tailored intervention to those individuals needing more intensive support. The first iteration of this new approach as proposed is anticipated to be somewhat resource intense, requiring staff to manually review CGM data to prioritise patients for contact. However, if the model is acceptable to families and staff, and has positive outcome, the next phase will be to automate CGM prioritisation, by development of a digital dashboard, which is expected to save considerable staff time.

3 Project Aims / Objectives / Hypotheses

Aim:

This study aims to investigate if using fortnightly review CGM for early identification of adverse markers in glycaemic control, with implementation of targeted intervention improves glycaemic outcomes and patient reported outcomes in children living with diabetes compared to those receiving care using the current standard model of care.

Objectives:

1) To investigate if targeted intervention based on adverse glycaemic control on CGM metrics improves glycaemic control compared to standard models of care

2) To investigate if patient and family reported satisfaction and outcomes are improved with targeted intervention based on CGM metrics

3) To conduct cost-benefit analysis of targeted intervention compared to standard models of care

4) To conduct post study consultation with consumers and health care professionals for feedback on the study and relevant comments on next stages of digital dashboard development

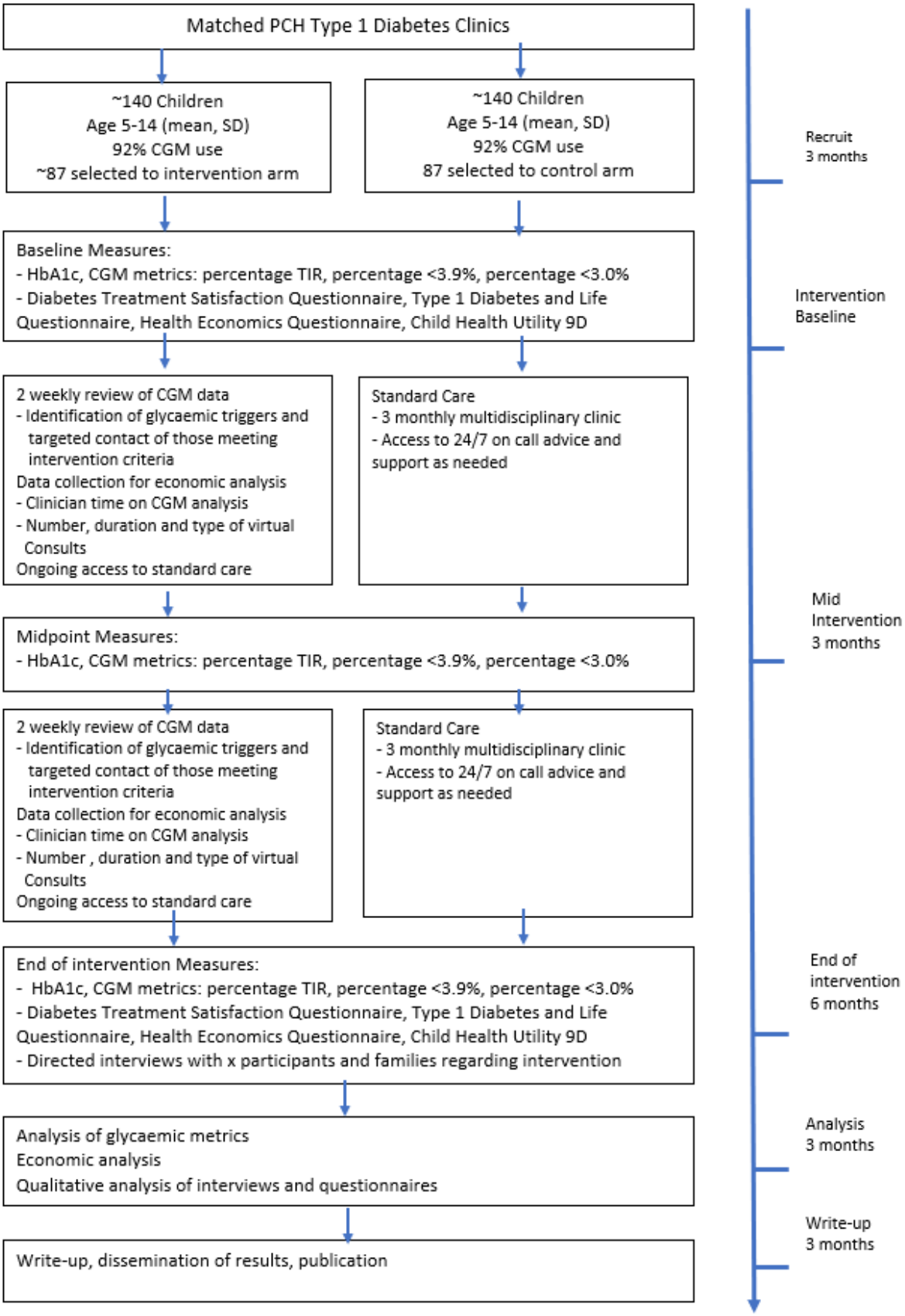
Hypotheses:

1. Using fortnightly review of digital CGM upload for early identification of adverse changes in glycaemic control with targeted personalised clinical intervention can improve overall glycaemic control and patient and family satisfaction compared to 3-monthly review at multidisciplinary appointments.

4 Project Design

4.1 Project Design

This is a single-centre observational, parallel-groups study in children aged 5-14 years with T1D using CGM. Intervention and age-matched control participants will be recruited from existing PCH diabetes clinics. Figure 1: Flow chart of proposed study design and timeline.



4.2 Bias

Given this is a non-randomised, non-equivalent parallel groups design, difference in difference analysis will be used to minimise bias. This means outcomes will be analysed in terms of change from baseline rather than direct comparison in outcomes between control and intervention groups to limit bias where there are imbalances at baseline in non-randomised allocation of participants.

4.3 Blinding and Randomisation

This is a non-randomised, non-blinded study. Because this study is testing a model of care, it will be carried out over an entire clinic cohort to best replicate care delivery.

4.4 Method

Participants will be recruited from two existing clinics which are comparable in size, age and HbA1c. The clinics will be randomly allocated to a control and intervention clinic. All families with a child living with diabetes, and attending these clinics, will be invited to be participate in the study. All participants will receive usual standard outpatient T1D care including 3-monthly attendance at a multidisciplinary outpatient clinic and 24 hour-a-day access to T1D telephone support as needed. Participants recruited to the intervention arm will also have the glycaemic metrics of their CGM upload reviewed on a fortnightly basis, 75% sensor use will be required for analysis of data each fortnight. Participants who have pre-defined adverse change in their glycaemic control will be flagged each fortnight for clinician review of their CGM upload and virtual consult with the child and family via contact method nominated by the family (SMS, phone-call, email or telehealth). Participants who have pre-defined positive changes in their CGM upload will receive positive feedback via SMS. Participants will continue their usual CGM device and insulin delivery regimen as decided in conjunction with their treating clinicians.

Pre-defined flags of adverse CGM metrics will include:

Major flags:

- >10% reduction in time-in-range (TIR) (3.9-10mmol/L)
- TIR <50%
- Incidence of hypoglycaemia (SGL <3.9mmol/L) >4% of the time
- CGM use <75%

Minor flag:

- TIR <70%

All participants with adverse flags will then be ranked by number of flags and ascending time in range. Major flags will be prioritised above minor flags for contact. Participants will be contacted for intervention in order of ranking. Participants will receive an SMS message to notify them that they have flagged for clinical review each fortnight period with an opportunity to reply with preferred method of contact (phone, telehealth, email). Intervention will include discussion of factors impacting glycaemic control and suggestions regarding insulin dosing, meals and exercise. Links to educational modules related to the participants specific needs will be emailed to the participant and family if requested.

Participants with positive flags will receive an automated SMS with positive feedback regarding their CGM upload.

Pre-defined flags of positive CGM metrics will include

- Time-in-range ≥70%
- Participant's glycaemic metrics demonstrate that they have met a goal from the previous fortnight's contact (improvement in TIR, hypoglycaemia or CGM use)

Throughout the study, percentage of CGM use per fortnight for intervention participants will be recorded. Control group participants will have CGM metrics recorded fortnightly with key timepoints of baseline, 3 months and completion of study used for primary and secondary outcomes.

Outcome measures

1. Glycaemic outcomes will be recorded in all participants at baseline, 3 months and completion of the intervention period. They include:
    - Time In Range (Sensor glucose readings between 3.9-10mmol/L),
    - Time in hypoglycaemia (Sensor glucose readings <3.9 mmol/L)
    - Time in significant hypoglycaemia (Sensor glucose readings <3.0mmol/L) ,and
    - HbA1c

2. Psychosocial Outcomes:
    - All participants will complete Diabetes Treatment Satisfaction Questionnaires and Type 1 Diabetes and Life Questionnaire at baseline and at the end of the 6 month study period.
    - Participants in the intervention group and their families will be approached for directed interviews regarding the intervention experience (optional).
    - A subgroup of staff from the clinics involved will also be invited to complete a semi-structured interview to explore effects of the intervention on routine clinic experience and workflow.

3. Cost benefit analysis - Data will be collected for economic analysis including clinician time spent on CGM review, number of participant contacts, time spent on participant contacts and type of participant contact. Number of contacts per participant will be recorded. Time spent in routine clinic visits and number of emergency calls to the 24/7 diabetes support number will also be measured for intervention and control participants. Days absent from school or work and access to heath facilities will be recorded using a questionnaire. The Child Health Utility 9D will be used at baseline and end of the six-month study period. Economic cost-benefit analysis of the intervention will be performed at the completion of the intervention period.

	Run-in	Baseline	3 months, mid-intervention	6 months, end of intervention
Informed consent	x			
Demographics	x			
Usual clinic appointments	x	x	x	x
Type 1 Diabetes and Life Questionnaire		x		x
Treatment Satisfaction Questionnaire		x		x
Health Economics Questionnaire		x		x
Child Health Utility (D		x		x
HbA1c		x	x	x
CGM metrics TIR %Hypoglycaemia		x	x	x
Semi-structured interview				x

Figure 2: Study schedule

4.5 Project Duration/Schedule

It is anticipated that it will take 2 months for HREC and Governance approval. recruitment and data collection will take 9 months to complete. A further 3 months has been allocated to data analysis, economic analysis and manuscript preparation for a total period of 12 months. Participants will be in the study for 6 months.

4.6 Project Termination

Study participation is voluntary, and participants may withdraw at any time.

5 Treatment of Participants

5.1 Source and Selection of Participants

All children and their families who attend two diabetes clinics at Perth Children's Hospital will be invited to participate. Children involved in the intervention and control arms of the study will be recruited from two diabetes clinics at PCH which run on different days but are comparable in patient age, numbers, duration of diabetes, CGM usage and outcomes and are run by comparable multidisciplinary teams. There are between 130-160 children in each clinic with 90-92% CGM usage. All families with children who meet the inclusion criteria will be invited to participate in the study. Families and children will receive information about the study via email and will be approached by a member of the research team when they are attending their routine clinic appointment. All families within the clinic would be anticipated to attend and be approached over a three month period.

5.2 Participant inclusion criteria.

- Children aged 5-14 years attending PCH diabetes clinics
- CGM use ≥75% of the time in the 2-week period leading up to study start
- Insulin administration via multiple daily injections (MDI) or continuous subcutaneous insulin infusion (CSII)

5.3 Participant exclusion criteria.

- Families who have not consented to research participation
- Children not using CGM

5.4 Participant withdrawal criteria

Participants can withdraw from the project if:

a) The family no longer wants regular contact and intervention from the investigating team

Participants who withdraw from the project will continue to have routine standard care including HbA1c and analysis of CGM data every three months. HbA1c and CGM data will be collected at these routine three-monthly time points for withdrawn patients.

5.5 Description and justification for treatments, interventions or methods to be utilised

The intervention of this study is low risk and involves participants being contacted at most on a fortnightly basis for support in diabetes management if CGM reports identified triggers for contact. Participants in intervention and control groups will complete questionnaires as previously identified at the beginning and end of the intervention period. All participants will continue to attend their usual

outpatient multidisciplinary appointments and will have HbA1c measured 3-monthly as part of current standard care.

5.6 Permitted medications/treatments

There are no restrictions to medications or treatments during the project. Participants allocated to the intervention arm will receive usual clinical diabetes care in addition to the intervention. Usual treating teams can adjust diabetes management as indicated throughout the study period.

5.7 Monitoring of participant compliance

Percentage of CGM use by intervention participants will be recorded on a fortnightly basis. Participants who are using CGM <75% of the time on a particular fortnight will be contacted to support CGM use. Control participants will have percentage of CGM use reviewed at baseline, 3 months and 6 months.

6 Assessment of Efficacy

6.1 Outcomes

Primary outcome

The primary outcome is the percentage of time spent in target glucose range (3.9-10mmol/L) measured at 5-minutely intervals by CGM over a two week period. This will be measured at baseline, 3 months and 6 months (end of study)

Secondary Outcomes

Glycaemic Outcomes

Measured at baseline, 3 months and 6 months (end of study). As recorded on CGM upload in the 2 weeks prior to time of assessment.

- Percentage of time spent hypoglycaemic with sensor glucose <3.9mmol/L
- Percentage of time spent with sensor glucose <3.0mmol/L. As recorded on CGM upload in the 2 weeks prior to time of assessment.
- Time above range with sensor glucose >10.0mmol/L
- Hba1c

Consumer Satisfaction Outcomes

Measured at baseline and end of study by participants and caregivers.

- The Diabetes Treatment Satisfaction Questionnaire (DTSQ)
- The Diabetes Treatment Satisfaction Questionnaire change (DTSQc)
- Type 1 Diabetes and Life Questionnaire (T1DAL)
  - Ages 8-11 and 12-17
  - Parents of children under 8, 8-11, 12-17

Patient and family experiences and reported satisfaction from interviews with a subgroup of families who participated in the study.

Effects of the intervention on routine clinic experience and workflow as perceived by clinic staff from interviews with a subgroup of clinical staff who participated in the study.

Economic Outcomes

Data will be collected on

Clinician time:

- Spent on CGM analysis
- Spent on participant contact and intervention

Number of:

- Participants flagging for intervention each fortnight
- Episodes of intervention per fortnight
- Participants receiving intervention
- Episodes of intervention per participant

Routine Care:

- Number of calls to 24/7 T1D support phoneline

School/Work Attendance and Access to Health Services:

- Health Economics Health Questionnaire at baseline and end of intervention

Quality-adjusted life years (QALY)

- Child Health Utility 9D Questionnaire (CHU9D) at baseline and end of intervention

Assessment of population generalisability

To assess generalisability of the outcomes, characteristics of the recruited study participants (both control and intervention) will be compared with the clinical cohort who are eligible but not participating. The characteristics analysed will include demographic characteristics (age, sex, diabetes duration, BMI, ethnicity), management characteristics (insulin delivery regimen, clinic attendance) and baseline glycaemic outcomes (HbA1c and CGM metrics). This data will be de-identified and extracted from the Western Australian Children's Diabetes Database (WACDD – HREC Ref 2013051EP) for the eligible clinic cohort.

6.2 Efficacy assessment

As described in statistics section

7 Assessment of Safety

7.1 Risks and Benefits

It is not anticipated that the protocol for this study will increase the risks for participants beyond those associated with usual management of T1D.

Hypoglycaemia may occur during the study period, however, this is a regular occurrence in the routine management of T1D. Participants will all be wearing Continuous Glucose Sensors during the study with alerts set for low levels as part of their routine care. The participants will be advised to follow their routine clinical advice in relation to treating hypoglycaemia.

Participants in the intervention aim may benefit from increased team contact and intervention at times of need with improvement in blood glucose levels and diabetes management.

7.2 Safety

There are no anticipated participant safety risks for this negligible risk study.

7.3 Data and Safety Monitoring Board

To safeguard the interests of the study participants, monitor the main safety outcome measures, and monitor the overall conduct of the study, DSMB will be established. The board will receive and review information on the progress and accruing data and provide advice on the conduct of the study to the Investigators.

7.4 Adverse events reporting

This is a negligible risk study with participants assuming their normal activities. Participants will be able to contact the research team by telephone during the study if they have any concerns and a member of the research team will contact the participant or their carer during the study period to enquire about the incidence of adverse events.

7.5 Follow-up of Adverse Events

Participant will be followed-up according to their routine clinical follow-up visits.

8 Data Management, Statistical Analysis and Record Keeping

8.1 Statistics and Interim Analysis

A difference-in-difference analysis will be conducted using a mixed model framework to analyse the primary outcome. The model will include main effects for time (baseline, end of study), group (intervention, control) and an interaction term for time x group, and a random intercept for individual. The treatment effect will be estimated based on the interaction term. The difference-in-difference approach is preferred over ANCOVA in non-equivalent group designs as it is less prone to bias where there are imbalances at baseline due to the non-random allocation of participants. Tests will be two-sided and a p value < 0.05 will be considered statistically significant. Secondary outcomes will be analysed using a similar approach outlined above, or non-parametric comparisons of change scores where assumptions for parametric modelling are not met.

For the assessment of population generalisability statistical analysis will be conducted using an unpaired t-test to compare means of numerical data and a chi-squared test for the categorical data. When assumptions do not hold for a t-test, non-parametric tests will be used. As multiple outcomes will be analysed, a False Discovery Rate (FDR) will be used to control for type 1 errors. Any missing data will be corrected for using the Last Observation Carried Forward (LOCF) imputation.

Semi-structured interviews will be transcribed and imported into qualitative data management software NVivo (QRS International Pty Ltd, 2014) for management, retrieval, and interrogation. Qualitative data collected during this study will be analysed using Reflexive Thematic Analysis (10). All qualitative data will be analysed inductively to develop themes and the processes will be audited. Analysis will be conducted according to Braun and Clarke's six phases of reflexive thematic analyses: Familiarisation with the data; Coding; Generating initial themes; Reviewing themes; Defining and naming themes; and writing up.

8.2 Sample Size, Study Power and Significance

All patients in the two clinics will be invited to participate in the study. We anticipate that approximately 70% of the 126 participants in each of the two clinics will partake (n = 87 in each group). With alpha set at 0.05, a sample size of 87 in each arm will provide 80% power to detect a difference-in-difference between groups of 4.27 percentage points in %TIR (estimating a SD of the change in each group of 10.0, based on longitudinal research previously conducted by the Children's Diabetes Centre). A change in %TIR of ≥4.27 more percentage points in the intervention group compared to the change in the control group (from baseline to the end of the six-month period) would be detectable. Direct estimates of the variability of the difference (or change from baseline) were used in the power calculation. No within person correlation was used. The detectable effect size, based on detecting the difference between two independent means, was estimated using GPower.

8.3 Statistical plan deviations

Any deviation to the statistical plan will be declared in the final report arising from this study.

8.4 Selection of participants for analyses

All eligible participants recruited will be analysed in their allocated group of intervention or control.

8.5 Data Management

Any information collected in connection with this project will remain confidential. Demographic, CGM and intervention data will be collated in password protected spreadsheets and stored on password protected computers accessible only by the diabetes research team. This electronic data will be then stored on a password protected CAHS REDCap database. All data collection (including questionnaires and CGM), reports, and administrative forms will be identified with a unique identifier to

maintain participant confidentiality. Questionnaires will be collected online within CAHS REDCap. To prevent errors in recall, and reduce the burden on participants, demographic and clinical regimen data collected in the WACDD will be de-identified and extracted from the secure Department of Health server at PCH accessible only by authorised users. Paper copies of semi-structured interviews and questionnaires will be stored in a locked cabinet in a restricted access area within the Perth Children's Hospital. At the completion of the study, de-identified files will be archived and retained for twenty-five years.

CGM data will be accessed by study team members through existing DexCom, Medtronic or FreeStyle Libre portals with clinic accounts that participants will have already established as part of standard diabetes care. This data will be accessed by staff using personal passwords provided by the CGM portals.

De-identified data will be shared with the study statistician through the Telethon Kids Institute to assist with analysis.

Where data collected by the research team is also collected by the clinical team, data will be transferred to the clinical database (WACDD) if the parent /caregivers would like (see Parent Consent Form).

8.6 Procedure for accounting for missing, unused, and spurious (*false*) data.

No imputation will be made on missing, unused, and spurious data i.e. all data will be used as collected.

9 Monitoring / Audit

9.1 Monitoring, Audit and Regulatory Inspections Statement

The investigators will make available all data to the relevant bodies for monitoring, audits and regulatory inspections.

9.2 Procedures for Monitoring and auditing

The study is internally monitored by a project manager and the coordinating principal investigator monthly and a DSMB will be established.

10 Quality Control And Quality Assurance

10.1 Compliance statement

Statement that the project will be conducted in compliance with the protocol, Good Clinical Practice and the application regulatory requirements.

The trial will be conducted in compliance with the protocol, Good Clinical Practice and the application regulatory requirements. All staff involved in this study will have GCP certification and will be well-versed in the study protocol including the consent process, adverse event management, and data collection.

10.2 Quality control

All staff will be trained to ensure appropriate data collection in accordance with ICH-GCP guidelines.

11 Ethics

This study will commence once approval is obtained from the Perth Children's Hospital Human Research Ethics Committee.

All eligible participants will be provided with an information sheet and an opportunity to ask questions to a member of the study team, before signing a consent form indicating their willingness to participate. Online e-consent forms (generated and stored within CAHS REDCap) will be completed via an online link and access code which is unique to each participant. Participants will be advised that

they may withdraw from the study at any time, by informing any study staff member that they wish to do so.

The WACDD is primarily a clinical database which contains medical history and demographic, clinical and glycaemic data of the patients attending the diabetes clinics at PCH. Parents of PCH patients and PCH patients over 16 years of age are provided with an information sheet and consented to have their health information recorded in the PCH component of the shared database (WACDD), HREC Ref 2013051EP, for clinical, audit and research purposes.

12 Budget, Financing, Indemnity And Insurance

This study is funded from a WA government Research Excellence Award (REA) awarded to Professor Elizabeth Davis for this particular project.

13 Publication

The outcomes of this research will be submitted for publication in peer reviewed journals and for presentation at scientific meetings. The results will be disseminated to patients and families through the Rio Tinto Children's Diabetes Centre Newsletter and website and to diabetes clinicians through professional development events.

14 References

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