Project summary

Type 1 diabetes (T1D) is a chronic disease which requires daily calculations of food intake and insulin dose adjustment to achieve good glycaemic control and minimise the risk of developing diabetic complications. However, even when glycaemic control appears to be good, as demonstrated by average glycated haemoglobin (HbA1c), children and young people with T1D frequently experience glucose variability, with levels above and below the target range. The main cause of diurnal glucose variability is food intake, which can cause postprandial hyperglycaemia. Postprandial hyperglycemia can occur after any meal, although there is some evidence that it may be worse after breakfast. There is limited data on the occurrence and cause of this and its association with different variables, including food composition and the glycaemic load of a meal.

Methods:

This project will be a quantitative study. The study proposes to recruit 90 children and young people who have T1D and who regularly use Dexcom continuous glucose monitoring (CGM). Recruitment will be via their managing dietitian. The dietitian will be asked to provide baseline information about the participants which will include demographic data and information on clinical data, treatment and anthropometrics. Participants will be asked to provide access to Dexcom CGM data throughout the period of recording. Participants will be asked to test three breakfast meals (high glycaemic load, high glycaemic with 10g added protein and medium glycaemic load) plus a control meal (usual breakfast), repeating each meal twice in a randomized order using a Latin square randomisation. The dietitian will be asked to optimise the participants insulin doses prior to commencing test meals. Participants will be asked to complete a questionnaire for each of the postprandial test and control meal periods. This will include questions about their diabetes management, food and fluid intake in addition to questions on activities all of which took place during the three-hour postprandial period. The glycaemic response to the test and control meals will be analysed using the CGM data and the results statistically described using univariate, bivariate and multivariate analysis.

Study protocol

Full Study Title:

The Breakfast Rise, Education and Knowledge Study in Children and Young People who have Type 1 Diabetes (T1D): The BREAK study.

Short title

The BREAK study.

Summary Protocol, date: 08/10/2022, version number 2 IRAS ID:316676. NICR reference (8017) REC reference: 22/NS/0123

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Ethics approval:	This study has been reviewed and provided a favorable opinion by the NHS, Invasive or Clinical Research (NICR) Panel, University of Stirling and the North of Scotland (1) Research Ethics Committee has reviewed the study (REC Reference 22/NS/0123).

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Rationale

Introduction

Type 1 diabetes (T1D) is caused by autoimmune destruction of the beta-cells that secrete insulin (Eisenbarth, 1986; Bluestone *et al.* 2010). It requires life-long treatment of insulin therapy, with the aim to achieve near-normoglycaemia, gauged by the amount of glycated haemoglobin, or HbA1c concentration, there is in the erythrocytes (Bunn *et al.* 1978). This measurement of HbA1c, against a clinically 'desired' target (DiMeglio *et al.* 2018), is a gold standard element of diabetes management (DCCT, 1993) but as a mean measurement, it does not reflect the full pattern of glycaemia (Derr & Garrett, 2003) and cannot be used to foresee glucose variability (Boland *et al.* 2001). Even when HbA1c is in target, nocturnal and diurnal glucose variability, involving both hypo- and hyperglycaemia can be a daily occurrence for children and young people with T1D (Boland *et al.* 2001; Tansey *et al.* 2016). Data from continuous glucose monitoring (CGM) has shown that children experience nocturnal hypoglycaemia and diurnal hyperglycaemia, particularly postprandial hyperglycaemia (Boland *et al.* 2001; Tansey *et al.* 2016) and there is some evidence that this is worse after breakfast (Boland *et al.* 2001; Heptulla *et al.* 2004; Gandrud *et al.* 2007).

Complications

One of the reasons glucose variability and postprandial hyperglycaemia are a concern is that they both contribute to overall diabetes control (Standl *et al.* 2011). Poor glycaemic control causes cumulative and deleterious effects on both the cardiovascular (Koivisto *et al.* 1996) and microvascular systems (Kaiser *et al.* 1993). A further concern for children and young people, living with diabetes, is that they are vulnerable to alterations in glucose concentrations in the central nervous system owing to their high requirement for glucose for brain growth and development (Chugani *et al.* 1987). Several studies have observed alterations to both white and grey matter in children and adults with T1D (Perantie *et al.* 2007; Perantie *et al.* 2011; Marzelli *et al.* 2014; Mauras *et al.* 2015; Marziaka *et al.* 2016) and studies using CGM have observed an association with this and both glucose variability and hyperglycaemia (Marzelli *et al.* 2014; Barnea-Goraly *et al.* 2014; Mauras *et al.* 2015; Marziaka *et al.* 2016). Children with T1D often perform worse on cognition tests than those without the disease and decreases in IQ have been noted during periods of hyperglycaemia (Gonder-Frederick *et al.* (2009). T1D also appears to increase the risk of mental health difficulties (Butwicka *et al.* 2015) and this has been associated with hyperglycaemia (McDonnell *et al.* 2007).

Glycaemic index and glycaemic load

Postprandial hyperglycaemia following the breakfast meal has been shown to be associated with the glycaemic index of the meal consumed (Birnbacher *et al.* 1995). The glycaemic index

(GI), introduced by Jenkins *et al*. (1981), is based on the two-hour postprandial glucose response to a test carbohydrate food. A Cochrane review of the GI in diabetes populations (Thomas & Elliott, 2009) and a meta-analysis of glycaemic response to the GI of breakfast meals in healthy adults, (Toh *et al.* 2019) have demonstrated the lower glycaemic response after low GI meals. However, the evidence in paediatric diabetes is limited. A further limitation is that the GI fails to take account of the effect, on glycaemia, of other foods within a meal. A more accurate way to measure glycaemic response is to calculate the glycaemic load of a meal. This is calculated by multiplying the GI of each carbohydrate in a meal by the grams of available carbohydrate (Salmeron *et al.* 1997) within the meal. There appears to be a paucity of evidence for the impact of the glycaemic load of breakfast meals on postprandial glycaemia in children and young people who have T1D.

Possible solutions to postprandial hyperglycaemia

One method to establish the impact of glycaemic load on glycaemia is to utilise CGM data. CGM is able to identify postprandial hyperglycaemia because of the density of data it affords (Tansey *et al.* 2016; Mangrola *et al.* 2017). CGM will likely help identify diverse responses to the myriad of dietary components (Bell *et al.* 2015) and thus CGM will likely allow for better prandial decision-making. As well as considering glycaemic load, another aspect of better prandial decision making may be found in dietary manipulation with protein. In those without diabetes, dietary protein intake is known to stimulate insulin production (van Loon *et al.* 2000). In children and young adults with T1D, 75g of protein consumed in isolation has a similar impact on blood glucose levels as 20g of glucose taken without insulin (Paterson *et al.* 2014). The glucose response to this amount of protein is however dissimilar to glucose as the rise in blood glucose is much slower with a later peak in glucose levels (Paterson *et al.* 2014). This suggests the addition of protein to a carbohydrate containing meal may help reduce postprandial hyperglycaemia by slowing the glycaemic response. 25g of protein has been shown to reduce postprandial glucose levels in the evening (Paterson *et al.* 2017).

Although the additional of a moderate amount of protein to a carbohydrate containing meal is recommended in international guidelines (Smart *et al.* 2018) there appears to be no evidence for this as a prevention of postprandial hyperglycaemia at breakfast. It is agreed that further research into the dietetic management of T1D is required (Smart *et al.* 2018). There is also a dearth of evidence on prevalence and management of postprandial hyperglycaemia after breakfast. Seven studies tested meals at breakfast time (Ryan *et al.* 2008; Smart *et al.* 2012; Smart *et al.* 2013; Piechowiak *et al.* 2017; Faber *et al.* 2017; Lopez *et al.* 2018) however none of the aims of these studies were to establish prevalence nor resolution of postprandial hyperglycaemia at breakfast. Only two considered diet quality at breakfast (Ryan *et al.* 2008;

Groele *et al.* 2014) and neither of these provided any evidence of how to manage postprandial hyperglycaemia after breakfast.

Conclusion

It is known that chronic hyperglycaemia causes increased risk of diabetic complications. It is possible that both glucose variability and postprandial hyperglycaemia are independent risk factors for this as well. There is some evidence that glucose variability and postprandial hyperglycaemic are common occurrence for children who have T1D. However, there is a paucity of published data on the prevalence of postprandial hyperglycaemia after breakfast in children and young people with T1D and limited evidence for the impact of glycaemic load and manipulation with protein. The need for closer examination of postprandial glucose variability to elucidate methods to reduce this, has been highlighted (Tansey *et al.* 2016). Although this applies to all meals, focusing on minimising postprandial hyperglycaemia after breakfast is paramount. This can help ensure good control through the morning and rest of the day when children are at school and actively learning (Tansey *et al.* 2016).

Aim:

To describe the distribution and dispersion of glucose variability and postprandial hyperglycaemia following test and control meals at breakfast, in children and young people with T1D, using measurements from Dexcom CGM.

Objectives:

- To determine the glucose variability diurnally, nocturnally and in the three-hour postprandial breakfast test meal period using measurement of ‘time in range’, ‘time above range’ and ‘time below range’.
- To determine the variability of glucose excursion, level and peak and the recovery time in the three-hour postprandial period.
- To describe comparisons between all the above measurements and the variables of sex, age, disease duration, BMI, HbA1c, insulin dose/sensitivity and insulin regimen.
- To describe comparisons between all the above measurements and the glycaemic load and composition of the test and control meals.

Study design

This is a quantitative study. Dexcom CGM data will be collected for the period of recording. Participants will be asked to test three breakfast meals on two occasions and submit a postprandial questionnaire after each test meal to confirm it has been tested. The postprandial period will be three hours following the end of the breakfast test meal. The test meal recipes

will be provided by the chief investigator. The dietary composition of the meals has been analysed using the Nutritics dietary analysis programme (Nutritics, 2022). The glycaemic index and load of the meals is estimated from the Nutritics programme which uses available date from the international tables of glycaemic index and glycaemic loads (Atkinson *et al.* 2008; 2021). Most foods were based on average composition across different brands. For the added fibre bread used in test meal 3, an average of three known brands was used calculated by the chief investigator. The meals will be taken in the home environment with the food provided by the families. The participants will be asked to take the test meal on a day when their CGM reading is between 4-10mmol/l and when there has been no nocturnal hypoglycaemia on the night before the planned test. The participants will act as their own control. They will be asked to complete a postprandial questionnaire for control meals as well. The control meals will be there usual breakfast of choice. The study duration, commencing with the recruitment of the first participant and ending when data has been fully described, is anticipated to be two years.

Participants

Eligibility criteria

- Children and young people aged between 5-17 years
- Diagnosis of type 1 diabetes for a minimum of one year
- On multiple daily injections (MDI) together with carbohydrate counting or Continuous Subcutaneous Insulin Infusion (CSII) using either open or closed loop systems.
- Use Dexcom continuous glucose monitoring (CGM) on a regular basis
- Have a Dexcom Clarity account and use the Clarity App
- Regularly eats a breakfast meal before midday
- Access to internet and email

Exclusion criteria

- Prescribed anti-hyperglycaemia agents *i.e.* Glucophage (Metformin) and or antidepressants.
- Any other medical conditions that may impact on the digestion and or absorption of nutrients, including coeliac disease and gastroparesis.
- Vegans
- Allergic or intolerant to the test meals
- Experiencing difficulties with food including diagnosed eating disorders
- Currently actively taking part in another research study

Recruitment

Paediatric diabetes dietitians, working across the UK, will be enrolled to help recruit participants and become principal investigators (PI) for their site. On enrolment, the chief investigator will provide the dietitians with all the relevant participant information sheets and consent forms as well as an Excel spreadsheet for entering the baseline information. The study documentation is presented in Appendices 1-9.

Sample size

The sample size power calculation is 64. This is based on using ANOVA repeated measures, within factors with four groups and measurements (3 test meals and control) with small effect size (0.15), P value 0.05 and power 0.80 and correlation among repeated measure of 0.5. The drop rate of clinical trials is often over 40%. Therefore, the aim is to recruit 90 participants to allow for this dropout rate and meet the sample size of 64. It may be possible to recruit this number of participants. There are approximately 29,000 children and young people living in the UK with T1D (Juvenile Diabetes Research Federation (JDRF), 2018). In the first phase of this study, 12 NHS sites were enrolled, and 96 children and young people were recruited to the study.

Methodology

Baseline data

In order to make comparisons between relevant variables and glucose levels, the following baseline data will be collected from the dietitians and sent to the chief investigator, along with the artificial identifier on the Excel spreadsheet as discussed earlier at the stage of recruitment of participants:

- Parent's email address
- Sex, date of birth and recent weight and height (for calculation of BMI and BMI centile) and date of when this was taken
- Date of diagnosis of T1D
- Last four HbA1c
- Total daily insulin dose (TDD)
- Insulin: carbohydrate ratios (ICR) and Insulin Sensitivity Factor (ISF)
- Current insulin regimen - including the type of insulin prescribed and if applicable type of insulin pump i.e. open or closed loop system.

Run-in period

At recruitment the dietitians will be asked to arrange a review of the participants insulin regimen including the insulin to carbohydrate ratio's (ICR), insulin sensitivity factor (ISF) and basal background insulin doses/rates. The dietitian will be asked to inform the chief investigator when this has taken place. Participants will be asked to commence the test meals following this.

Glucose measurement

Data on interstitial glucose will be collected via Dexcom CGM. The Dexcom CGM data will be accessed by an NHS Highland research 'Clarity Clinic' with Dexcom CLARITY® Clinic Portal (Dexcom In, San Diego, CA, USA). The chief investigator is administrator of this clinic. Once the managing dietitian has obtained each participant's consent, the participant's parent's email address will be sent to the chief investigator along with the baseline information/data as described above. The chief investigator, as administrator of the Clarity Clinic account, will then invite the participant, via email, to be added to the clinic. Once the invite has been accepted, it will stand for the period of the recording i.e. until all the test meals and questionnaires have been completed. Once the participant has submitted their last questionnaire, they will be removed from the Dexcom CLARITY® Clinic Portal. They will be removed from the clinic portal if they withdraw from the study.

Test and control meals

Following the provision of CGM data and review of the insulin regimen by the diabetes team, participants will be randomised to test each of the three test meals on two separate occasions with a control meal (usual breakfast meal) for each test meal. Randomisation will be achieved using a Latin square randomisation. The tool used for this will be http://www.jerrydallal.com/random/randomize.htm. Randomisation will be done in a block of four.

The test meals are based on foods children and young people enjoy eating. There are three meals. Test meal one includes a high glycaemic index cereal meal with milk and has a high glycaemic load (> 20), test meal two is the same cereal meal with a high glycaemic load (>20) with addition of 10g protein and test meal three has a medium glycaemic load (10-20). For test meals one and two there are three portion size options to meet age appropriate requirements and appetites. The participants will be able to choose from two different cereals for test meal 1 and a choice of protein sources for test meal 2. They will be asked to keep to the same choice of cereal and protein source for the repeat meal. They will be asked to consume at least 75% of the meal to ensure the threshold of the glycaemic load is met. The

instructions and details of the test meals are presented in Appendix 11. The control meals will be the participant's usual breakfast of choice.

Participants will be asked to follow their usual insulin regimen as advised by their diabetes team i.e. their usual insulin dose and dose timing. For both test and control meals participants will be asked to avoid any further food intake during three-hour postprandial period other than carbohydrate adjustments required to treat any hypoglycaemia. Participants will also be asked to avoid drinks except water or carbohydrate free juices. They will also be asked to avoid physical activity of more than 30 minutes in duration. To minimise disruption to their normal daily activities, they will be advised to test the meal on a day when there is no planned physical activity i.e. a school day with no morning physical education. The CGM data will be collected throughout this time as discussed above.

Postprandial Questionnaire

The participants will be asked to complete a postprandial questionnaire using 'online survey'. This includes questions about the meal and the three-hour postprandial period. The questionnaire is presented in Appendix 10. They will be asked to wait a minimum of three hours before answering and submitting the questionnaire. They will be encouraged to complete it on the same day as the test or control meal.

Outcome measures

Primary and secondary outcome measures will be based on international guidelines and consensus DiMegloi *et al.* 2018; Battelino *et al.* 2019) of the metrics and target glucose levels to be used in CGM analysis in clinical practice. These are agreed to be:

Metrics:

- Mean glucose
- Glucose variability (GV) % coefficient of variation (COV) target ≤36%
- Time in range (TIR) % and time spent between 3.9-10mmol/l
- Time above target (TAR) % and time spent >10.1-<13.9mmol/l) and >13.9mmol/l
- Time below range (TBR) % and time spent 3.0-3.8mmol/l and <3mmol/l

Target glucose levels:

- TIR - % of readings >70% or 16hr 48min
- TAR - % of readings <25% or <6hr high and <5% 1hr 12min very high
- TBR- % of readings <4% or <1hr low and <1% or <15min very low

Primary outcome measure:

- Mean glucose (mmol/l) in the three-hour postprandial breakfast period calculated from the CGM measurements at 5 minutes intervals.

Secondary outcome measures – post prandial period:

- Number and percentage who had pre-prandial glucose in target, mean peak glucose level (mmol/l), mean time to peak (mins), mean time to recover (to pre-prandial levels) (mins) in the three-hour postprandial breakfast period
- TIR, TBR and TAR (% and time) in the three-hour postprandial breakfast period
- Comparisons of the above measurements between cohorts and breakfast test meal compositions.

Data analysis

This will be a mix of univariate, bivariate and multivariate analysis as this is best suited to describing, summarising and visualising these data. Outputs will include the distribution of glucose levels post-breakfast to determine the spread and dispersion of the data.

Safety considerations

Recruitment/consent

Assent and parental consent will be obtained for the participants who are aged under 16 years. Where possible consent should be taken face to face. However, consent can be taken electronically. This will involve the dietitians meeting with the families either virtually or via telephone to go through the study and read through the consent form. As per the HRA/MRC Consent and Participant Information guidance, 'electronic methods for documenting consent can be considered to be in writing'. The dietitian should provide a copy of the signed consent form to the participant and this can be sent electronically. Electronic signature can be a simple electronic signature which can be a typed name (http://www.hra-decisiontools.org.uk/consent/glossary). Consideration will be given to those potential participants/families who are experiencing difficulties managing their condition, for example 'diabetes burnout'; poor glycaemic control or other stressors, for example, family difficulties, stress at school, for example, dealing with bullying or exam pressures. This will be minimised by recruiting via the managing dietitian who will have significant knowledge of the potential participant and who will be expected to discourage recruitment, if it is felt the family have enough to cope with. Those who are newly diagnosed will not meet the eligibility criteria as it is felt this would be unethical given the pressure they will be experiencing dealing with a new diagnosis of a chronic disease. Participants will not be asked to change their usual diabetes management. Participants will not be expected to eat the breakfast meal if it is something they do not like. Rather than adjusting their postprandial activities, participants will be asked to test the meals on days when they have less than 30minutes of exercise planned. The postprandial

period is three hours in order that most participants will be able to partake in their usual mid-morning snack as it is anticipated this will be more than three hours after the end of breakfast.

Personal data collection

Personal data as described above will be collected and will be securely managed. How this will be managed is described in the 'Data Management' section.

Burden on dietitians

The dietitians will need to be allowed additional time to recruit participants. Dietitians will be asked to discuss this with their line managers and gain their approval for this and with their diabetes teams. Although the dietitians will be asked to optimise the participants insulin management prior to them commencing the test meals this is part of their usual diabetes management and could be undertaken by another member of the diabetes team at a routine appointment.

Burden on families

The meals are based on foods that are commonly eaten by children and young people and that is easily accessible and affordable and, in some cases, may already be available in the household without additional cost implications. The time required to read the instructions is minimised by using flowcharts. Additionally, the time required to complete the questionnaires is minimised by utilisation of digital technology to ensure that completion of questionnaire surveys is not too time consuming.

Data management

Assessment of existing data

There appears to be a dearth of available data on the distribution and dispersal of glucose levels in children and young people who have T1D. Nor does there appear to be any published data comparing glucose measurements from Dexcom CGM with different breakfast compositions in children and young people with T1D. The project is therefore not creating new data when existing data could be re-used.

Creation of new data

This will include the following:

- Dexcom CGM measurements of interstitial glucose when testing meals at breakfast time.
- Information on activities and adjustments in the three-hour postprandial period as discussed earlier.

Methods of anonymisation, pseudonymisation and encryption

None of participants names and addresses will be collected. Surnames are likely to be known, owing to the need to obtain email address for the CGM data collection. The participants date of birth is required for the Dexcom Clarity clinic. Password for the Pseudonymisation will take place as recommended by GDPR regulation (General Data Protection Regulation (GDPR) 2018). Artificial identifiers, to be used for all communication and data storage, will be provided for each participant at the stage of recruitment. All data, including parent's email addresses, will be stored on an NHS Highland secure remote server which is password protected with files encrypted. Breeches of data will be reported through both the Data Management Committee (see below) and the NHS Highland incident reporting system (DATIX).

Collection, storage and transfer of data - baseline information

Baseline information will be collected by the participant's managing dietitians, taken from diabetes clinical records. These data will be pseudonymised with the artificial identifier and entered on an Excel spreadsheet, by the enrolled dietitian and communicated via 'NHS mail' (see Appendix 1) to the Chief Investigator. Only the Chief Investigator will have access to this information. This information includes the participants date of birth. 'NHS mail' is accredited to government official status for sharing patient identifiable and sensitive information and meets the secure email standard (DCB1596). All data, including the participants date of birth, will be stored on the NHS Highland server.

Collection, storage and transfer of data - Dexcom CGM data

The chief investigator in administrator of the NHS Highland research clinic on Dexcom CGM Clarity which is accessed via the internet and is password and username protected. The chief investigator will then invite the participants, via their parent's email address, to join the clinic. This a standard way of accessing Dexcom CGM data. The invite will include the artificial identifier, and this is the identifier that will be visible when the data is accessed and not the name of the participant. For the invite to work it must include the participant's date of birth for verification purposes. Email addresses and date of birth will be recorded in the baseline information spreadsheet and this will be stored on the NHS Highland laptop. Dexcom have their own security management and personal information is transmitted in encrypted form. CGM data will transferred to a CSV file, saved as an Excel file and stored on an NHS Highland laptop. An example of this in presented in Appendix 12. As consumers of Dexcom CGM the participants will have access to the Dexcom, Inc Privacy Policy which complies with the GDPR) 2016.
(https://www.dexcom.com/en-GB/linked/documentservice/PrivacyPolicy).

Collection, storage and transfer of data - survey questionnaires

The researcher plans to use Jisc 'Online Surveys' (formerly BOS). The University of Stirling subscribes to this service and the researcher has a unique username and password for accessing this, known only to the researcher. Jisc is registered with the Information Commissioners Office (ICO) (registration number Z9546606) and meets the requirements of GDPR (https://www.onlinesurveys.ac.uk/gdpr-and-online-surveys/) and is certified to ISO 27001 (https://www.jisc.ac.uk/about/certification). All survey responses are collected over encrypted SSL (TLS) connections. The university GDPR statement is added to all the survey questionnaires. Responses to the survey will be transferred to a CSV file then saved as an Excel file on the NHS Highland laptop.

Collection, storage and transfer of data - Nutritional analysis

The control breakfast meals will be analysed using Nutritics or similar diet analysis programme which will be accessed via an NHS Highland desktop. Only details of the food will be entered into the programme. The analysis will be transferred to a CSV file, saved as an Excel file and emailed via NHS mail to be saved on the NHS Highland laptop.

Data ownership

It is anticipated that new data, arising from the study, and the associated intellectual property will be owned jointly by the University of Stirling and NHS Highland with a sharing agreement.

Destruction of data

The Dexcom Clarity clinic only stores CGM data for three months. Once these data have been collected for the period of the study, the Dexcom research clinic will be closed. Any transferred data will be stored on the NHS Highland secure remote server for 10 years before being deleted. Personal data (emails addresses, artificial identifiers, dates of birth will be deleted 6-12 months after the study ends).

Definition of end of study

The study will end when all the participants have completed the test and control meals and submitted their questionnaire responses and their CGM data for the period of the meals has been exported and they have been removed from the Clarity clinic.

Expected outcomes

The aim of this study is to describe the distribution and dispersion of glucose variability and postprandial hyperglycaemia after test meals at breakfast and establish comparisons of these between variables obtained from baseline information and nutrient analysis. It is hoped this

will provide evidence of the impact of high and medium glycaemic load breakfast meals have on glycaemic response in children and young people who have T1D. It is also hoped the study will provide evidence of the impact additional protein has on glycaemic response when taken as part of a mixed high glycaemic load meal.

This will increase the knowledge of diabetes educators, patients and families and ensure diabetes education includes evidence-based information on how to minimise postprandial hyperglycaemia at breakfast time.

Dissemination of results

It is anticipated that one paper will be submitted for publication. The proposed journals for publication include:

- *Pediatric Diabetes*
- *Diabetic Medicine*
- *Diabetologia*
- *Diabetes Technology & Therapeutics*
- *Acta Diabetologica*.

Ethical considerations

This study has been reviewed and provided a favorable opinion by… *to be added when obtained*

Consent will be obtained from parents and/or carers and, where appropriate, the children and young people themselves. As Principal Investigators, the recruiting dietitians will be asked to encourage, where possible, the children and young people to be involved in the decision to participant in the study. The dietitians will therefore be asked to ensure conversations regarding the study be discussed when the child/young person is present. It should be noted that in Scotland, children over the age of 12 years old are usually considered to be mature enough to give a view about taking part in research even if they are not fully able to give consent. The recruiting dietitians will be asked to discourage parents from consenting to participate if their child expresses either verbally or non-verbally that they do not wish to participate.

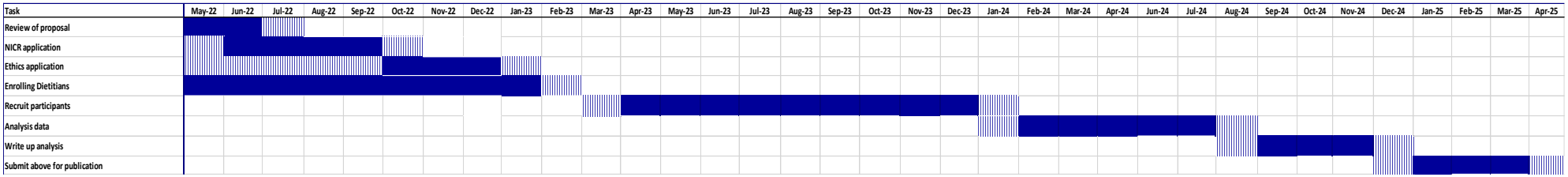
Budget

Only participants already self-funding or receiving NHS funding for Dexcom CGM will be recruited therefore there will no cost for using Dexcom CGM. The University of Stirling already subscribe to www.onlinesurveys.ac.uk. The NHS Highland laptop is already available to the researcher. Funding will be applied for with the aim to provide some backfill for the researcher to undergo some of the research during work time.

Insurance

The University of Stirling provide indemnity insurance although the risk of adverse events is low given that participants will be asked to follow their usual diabetes management as advised by their diabetes team.

Proposed timetable



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