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The Difference in A1C of Children and Adolescents with Type 1 Diabetes Mellitus using Carbohydrate Counting compared to those using a Structured Meal Plan

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Abstract and Keywords

Carbohydrate (CHO) counting is a nutrition education tool used by patients with type 1 diabetes mellitus (T1DM). The primary objective was to assess glycated hemoglobin (A1C) in participants with T1DM using CHO counting vs. those using a structured meal plan (SMP). The secondary objectives were to determine if BMI-for-age, parental income, parental involvement, and mothers' educational level were associated with their children's glycemic control. A cross sectional study was conducted, where participants aged 4-18 years, or their parents completed a survey. Total sample size was 88 participants (77 in the CHO counting group and 11 in the SMP group). There were no differences in demographic variables or A1C between the two groups. Unexpectedly, there was a very high proportion of participants in the CHO counting group; so there were few statistical differences between the groups. The qualitative data emphasized CHO counting as a challenge patients faced, especially when eating out.

Keywords: type 1 diabetes, children, glycemic control, A1C, carbohydrate counting, structured meal plan, and nutrition education

Summary for Lay Audience

When people have type 1 diabetes, Registered Dietitians (RD) may encourage them to count the amount of CHO in the grains, rice, pasta, starchy vegetables, and bread they eat; this is called CHO counting. Another approach is when the RD gives patients a SMP to follow with a specific amount of grains, rice, pasta, and starchy vegetables that they can have at each meal and snack. The purpose of this study was to determine if there was a difference in A1C levels of children with T1DM on the CHO counting approach vs. those on the SMP approach. A1C is a measure of the amount of sugar that sticks to hemoglobin in the red blood cells.

This study was done at Windsor Regional Hospital with patients, ages 4-18 years, who have T1DM. Parents or adolescents filled out a survey that asked questions about the patients' health conditions, insulin schedule, meal plan, family income, and mother's education level. Height, weight, and A1C levels were collected from the clinic charts. The researchers analyzed the data to look at A1C levels between patients using the two different meal plans and if there were any familial factors that influenced the A1C.

There was a total of 88 people in this study, 77 in the CHO counting group and 11 in the SMP group. There were no differences in the characteristics of the participants including A1C levels between the two groups. There was a meaningful relationship between physical activity and BMI-for-age. One of the important themes that came out of the survey was that participants found it hard to count CHOs, especially when eating out. Therefore, it is important to provide sufficient knowledge to help patients count CHOs, especially when eating away from home and at restaurants.

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List of Abbreviations

Abbreviation	Meaning
ABC	automated bolus calculator
A1C	glycated hemoglobin
BMI	body mass index
CHO	carbohydrate
CPG	Clinical Practice Guidelines
DCE	diabetes care and education
DKA	diabetic ketoacidosis
DCCT	diabetes control and complications trial
DM	diabetes mellitus
GD	gestational diabetes
IP	insulin pump
MDI	multiple daily injections
Registered Dietitian	RD
SMBG	self-monitoring of blood glucose
SMP	structured meal plan
SD	standard deviation
T1DM	type 1 diabetes mellitus
T2DM	type 2 diabetes mellitus
WRH	Windsor Regional Hospital

Chapter 1
Introduction and Literature Review

Diabetes mellitus (DM) is a chronic disease characterized by the lack of insulin and/or impaired insulin action, which causes hyperglycemia (Understanding Your Diabetes and Living a Healthly Life, 2009). The prevalence of diabetes continues to rise globally (World Health Organization, 2019). It was estimated that the prevalence of diabetes in 2016 was 3.5 million or 9.2% of the population and the projections for 2026 are up to 4.9 million or 11.6% of the population (Diabetes Charter for Canada, 2019). This is an estimated increase of 41% from 2016 to 2026 (Diabetes Charter for Canada, 2019). In the 21st century, this chronic disease is considered to be a global emergency (International Diabetes Federation, 2019).

DM can be classified into prediabetes, type 2 DM (T2DM), gestational diabetes (GD), or type 1 DM (T1DM) (CPG, 2018, Modern Nutrition in Health and Disease, 2006). Prediabetes is categorized by blood glucose levels that are higher than normal but not in the diabetes diagnosis range (CPG, 2018). Risk factors for developing DM include prediabetes, obesity, physical inactivity, and age (Modern Nutrition in Health and Disease, 2006). GD occurs when there is glucose intolerance during pregnancy especially between the 24th and 28th week; as this is the time when the need for insulin increases (CPG, 2018). GD can resolve after partuition. For people with DM, 90% have T2DM, which occurs when there is insulin resistance in addition to impaired beta cell function (Modern Nutrition in Health and Disease, 2006). The remaining 5-10% have T1DM (Public Health Agency of Canada, 2009). This type usually develops in children or adolescents but can develop in adults as well (CPG, 2018). In children 14 years or younger, Canada has the sixth highest incidence of T1DM (International Diabetes Federation, 2019). The remainder of this thesis, will focus on T1DM.

Pathogenesis of T1DM

T1DM occurs when the pancreatic beta cells that produce insulin are destroyed by the immune system of the body (Daneman, 2006). The autoimmune destruction is hypothesized to occur due to genetic predisposition and environmental influences, such as exposure to a virus (Gregory et al., 2013). Beta cell destruction results in insulin deficiency, which causes hyperglycemia. This condition happens because carbohydrates (CHO) are broken down into glucose molecules in the bloodstream. This is managed by subcutaneous injections of exogenous insulin by multiple daily injections (MDI) or an insulin pump (IP) (CPG, 2018). The exogenous insulin helps facilitate metabolism and storage of the consumed CHOs to achieve normoglycemia (CPG, 2018). Normoglycemia is the optimal goal of diabetes management to prevent microvascular and macrovascular complications.

T1DM is diagnosed with the presence of anti-glutamic acid decarboxylase or anti-islet cell autoantibodies and low C peptide levels (CPG, 2018). People with T1DM present clinically with classic symptoms such as polyuria (excessive urination), polydipsia (excessive thirst), polyphagia (excessive appetite), weight loss, diabetic ketoacidosis (DKA), or as an incidental finding (Modern Nutrition in Health and Disease, 2006, Gregory et al., 2013). Insulin deficiency can lead to worsening hyperglycemia, DKA, starvation, and ultimately death (Gregory et al., 2013). To compensate for this the body goes through different mechanisms including glucosuria (glucose excreted in the urine), which causes increased urination and then this leads to increased thirst (The Essentials, 2013). The consequence of insulin deficiency leads to hyperglycemia, which forces the body to use fat for energy resulting in an accumulation of ketone bodies in the blood leading to DKA (Silverstein et al., 2005). DKA presents as hyperglycemia and ketonemia, nausea, confusion, vomiting, abdominal pain, and if left untreated it can ultimately lead to a coma or death (Modern Nutrition in Health and Disease, 2006, CPG, 2018). It is important that patients with T1DM receive an adequate amount of insulin to resolve hyperglycemia to avoid symptoms such as blurred vision, thirst, genital organ and bladder infections, delayed wound healing, fatigue, drowsiness, and irritability (Understanding Your Diabetes and Living a Healthly Life, 2009). Long term hyperglycemia can lead to further complications such as blindness, end stage renal disease, neuropathy, heart and blood vessel damage, and amputations (Understanding Your Diabetes and Living a Healthly Life, 2009, CPG, 2018). It is crucial to provide patients with interventions to achieve glycemic control to reduce all microvascular and macrovasucular complications of this chronic disease (Nathan et al., 2014). T1DM is a complex disease with many components that need to be managed well by visiting a pediatric focused multidisplinary health care team.

Diabetes Management Components

Diabetes management includes many components including pharmacological therapies, nutrition management, activity and exercise, self-monitoring of blood glucose (SMBG) levels, insulin pump management, A1C monitoring, and mental health management (The Essentials, 2013). Nutrition education and meal planning are important components in the management of diabetes (CPG, 2018). Best practice is for the child with diabetes and their parent(s) to be scheduled quarterly for appointments to see Certified Diabetes Educators including Registered

Dietitians (RDs) and Registered Nurses. Patients receive nutrition education by attending individual counselling sessions at Diabetes Education Centres or with Chronic Care or Diabetes Teams. Diabetes education is focused on self-management to empower the patients to manage their eating behaviors, insulin regimen, physical activity, SMBG levels, and sick days (The Essentials, 2013, CPG, 2018). As young children are dependent on their parents, most of the education for these patients is tailored to the parents initially; however, both the parent and child need to participate in the learning process (Modern Nutrition in Health and Disease, 2006).

Healthcare professionals facilitate a gradual shift from educating the parents to educating the children as they are growing and maturing to encourage self-management of the child with T1DM (Gregory et al., 2013). Additionally, education and support, through counselling sessions and/or phone visits, need to be ongoing, considering age, fears of the child, the developmental stage, and the level of understanding of the child (Silverstein et al., 2005, Modern Nutrition in Health and Disease, 2006). The ultimate goal of diabetes management is to empower patients to self-manage their diabetes, reduce likelihood of acute and chronic complications, and achieve optimal glycemic control to improve their quality of life and autonomy (Modern Nutrition in Health and Disease, 2006, Gregory et al., 2013, Tascini et al., 2018, CPG, 2018).

The gold standard for glycemic control is the A1C test, which measures the amount of glycated hemoglobin in the bloodstream (The Essentials, 2013). It reflects the average pre-prandial and post-prandial blood glucose levels over the last 2-3 months, which is the normal lifespan of the red blood cell (The Essentials, 2013). A1C is used as a diagnostic criteria and/or treatment target for diabetes and needs to be measured using a validated assay (CPG, 2018).

Current Diabetes Canada Clinical Practice Guidelines (CPG) recommend the following glycemic targets for children <18 years of age with T1DM **(Table 1)**. Glycemic targets are individualized and may be set higher if patients experience hypoglycemia or nocturnal hypoglycemia (CPG, 2018). To assess if these targets are being met, clinicians teach patients how to self-monitor their blood glucose levels.

Table 1: Glycemic Targets

Indicator	**Glycemic Target**
A1C	<7.5%
Fasting/pre-prandial plasma glucose:	4.0-8.0 mmol/L
2-hour postprandial plasma glucose:	5.0-10.0 mmol/L
Adapted from Table 1, Chapter 42, Type 1 Diabetes in Children and Adolescents, Clinical Practice Guidelines (CPG, 2018)	

Self-Monitoring of Blood Glucose

SMBG is crucial as it allows patients to assess the effect of nutrition, physical activity, stress, and insulin on their blood glucose levels; identify episodes of hypoglycemia/ hyperglycemia; and adjust their insulin doses accordingly. Ultimately it aids in enhancing confidence, safety and autonomy in diabetes management, and improving glycemic control (Understanding Your Diabetes and Living a Healthly Life, 2009). Karter et al. found that increased frequency of SMBG (greater or equal to three times daily for T1DM and at least daily for T2DM) was statistically associated with 1% and 0.6% lower A1C levels for patients with T1DM and T2DM on medications, respectively ($p<0.0001$) (Karter et al., 2001). In another study, the use of continuous glucose monitoring, which is a more rigorous form of SMBG, was found to improve the glycemic control of children, adolescents, and young adults with poorly controlled T1DM by a reduction of 1.46% in A1C (p=0.001) (Lewis et al., 2017). The authors stated this was clinically relevant, although this level of change may not be considered clinically relevant by all authorities. These findings support the SMBG recommendations outlined by Diabetes Canada for patients with T1DM using insulin more than once a day, which recommend testing blood glucose levels at least three times per day and to include before and after meal tests (CPG, 2018).

Most patients with T1DM are educated to check their blood glucose levels at least three times a day: before each meal, during the day before taking insulin, two hours after eating, and especially before bedtime to prevent nocturnal hypoglycemia (CPG, 2018). Patients may be specifically advised to check their blood glucose two hours after eating to assess the load of the consumed CHO on their blood glucose levels. It is recommended that patients are taught and encouraged to check their blood glucose levels frequently to minimize excursions, achieve their target blood glucose level, and to prevent complications. The Diabetes Control and Complications Trial (DCCT) with T1DM patients showed that maintaining glycemic control as close to target as possible reduces the development of microvascular complications by as much as 76% for diabetic retinopathy, 60% for neuropathy, and 50% for nephropathy (Diabetes Control and Complications Trial Research Group, 1993). Overall, SMBG is an elemental component of T1DM management and increased frequency has been shown to have better clinical outcomes (CPG, 2018).

Hypoglycemia

One of the major challenges for children with T1DM is hypoglycemia. A study conducted in the United Kingdom found that hypoglycemia was more frequent in patients with T1DM than those with T2DM, with a mean rate of 36 episodes per subject per year in T1DM patients compared to four episodes per subject per year in T2DM patients($p<0.001$) (Heller et al., 2007). Therefore, one major component of testing frequently is also identifying any hypoglycemic events (CPG, 2018). Hypoglycemia is crucial to avoid as it may impair cognitive function in children as there is a failure of cerebral glucose supply and it may impair neuropsychological skills (Heller et al., 2007, CPG, 2018). Hypoglycemia can be very dangerous, especially in children as it can lead to unconsciousness, confusion, and comas (Heller et al., 2007). Amin et al. studied the prevalence of hypoglycemia in 28 children < 12 years old (Amin et al., 2003). These authors found that 43% of the children had hypoglycemia on at least two out of three nights and that hypoglycemia was more prevalent at night (Amin et al., 2003). The symptoms of hypoglycemia include confusion, headaches, lack of coordination, altered brain function, shakiness, anger, sweating, irritability, coma, death, extreme hunger, and blurred vision (Modern Nutrition in Health and Disease, 2006). Children who experience nocturnal hypoglycemia may also have episodes of crying, nightmares, or night sweats (Kids Health, 1995). The goal is to achieve the targets mentioned above but clinical judgement for higher targets may be required if children are experiencing hypoglycemia and especially nocturnal hypoglycemia (CPG, 2018).

Insulin Management

Insulin therapy is required for the treatment of T1DM. Insulin doses are developed based on the weight and age of the patient, and range from 0.2 units/kg/day to 0.8 units/kg/day (Lemieux et al., 2010). There are different types of insulin that can be used including basal (long or intermediate acting), bolus (rapid or short acting), and premixed analogues or regular. The dosage is prescribed based on the child's body weight, age, and pubertal status (Silverstein et al., 2005). Insulin can be administered through an IP or by MDI, which are injections that are given three or more times per day. Over the past two decades, the use of IPs has increased more than using MDI (Gregory et al., 2013, Olsen et al., 2015). The IP delivers insulin continuously, causes less hyperglycemia and hypoglycemia, more accurately delivers the amount of insulin required, and allows for a more flexible lifestyle (Joslin Diabetes Center, 2019). Blackman et al. found that the use of IPs compared to MDI, in children with T1DM, showed a significant improvement in glycemic control i.e., A1C levels decreased by an average of 0.2% (Blackman et al., 2014). The DCCT followed 1,441 subjects with T1DM and compared intensive therapy with the use of MDI three or more times per day or via an IP to the conventional therapy group (CON) who received one or two daily insulin injections (Nathan et al., 2014). This study found that subjects on the intensive therapy showed a 35-76% reduction in microvascular disease compared to the CON group after 6.5 years of follow-up (Nathan et al., 2014). Additionally, those on intensive therapy had a median A1C of 7% compared to 9% for those on CON (Nathan et al., 2014). The intensive therapy group also had less fatal and nonfatal myocardial infarctions and strokes, with 58% less cardiovascular events overall, after a mean follow-up of 18 years (Nathan et al., 2014). Therefore, intensive therapy is more effective to achieve glycemic control, and reduces microvascular complications of diabetes and cardiovascular events (Nathan et al., 2014).

The IP attempts to mimic the action of the pancreatic beta cell as it delivers insulin combining both basal and bolus components (Gregory et al., 2013). IPs have a bolus calculator where the total CHOs consumed are entered and the pump calculates the dose to be delivered to the patient, based on the prescribed insulin to CHO ratio (Butler et al., 2011). Younger children using IPs require more family support than preadolescents and adolescents (Silverstein et al., 2005). Therefore, parents are encouraged to attend all diabetes appointments with their children.

One disadvantage of the IP and its necessary supplies is the cost. However, in Ontario, children under the age of 24 years with an Ontario health card number qualify for OHIP plus. This covers various insulins, oral agents, and diabetes test strips (Ministry of Long-Term Care, 2019). Additionally, children are eligible for the Assistive Devices Program, which covers insulin pumps and insulin pump supplies (Government of Canada, 2019).

Alternatively, insulin given in MDI may be used as a combination of the following: rapid, short, intermediate, or long acting insulin (Silverstein et al., 2005). Typically, patients take a rapid insulin at meal times and a long acting basal insulin in the morning and/or at bedtime. If patients have a large snack between their meals, they may take a rapid acting insulin at that time as well. The amount of insulin needed at a meal or snack is calculated by dividing the total grams of CHOs ingested by the grams of CHO covered by a unit of insulin (Butler et al., 2011). This is called the insulin to CHO ratio, which is the amount of CHOs that are covered by one unit of insulin (Butler et al., 2011). For example, if a child consumes 72 grams of CHOs and their insulin to CHO ratio is 1:12, you would divide 72 by 12, which equals six units of insulin needed for that meal or snack. MDI help patients match insulin to their CHO intake at each meal and snack to help them achieve glycemic control.

Nutrition Counselling

Nutrition counselling is a critical aspect of diabetes management to help patients achieve optimal glycemic control. Regular visits with a RD with experience in pediatric nutrition and diabetes management is important and recommended to patients. It has been shown that nutrition therapy can reduce A1C levels by 1% to 2%, and when combined with other diabetes care it can enhance metabolic and clinical outcomes (CPG, 2018). The goal of nutrition counselling is to help patients achieve glycemic control and to prevent or slow the rate of complications that can occur (The Essentials, 2013). The recommendations given should be individualized to meet the child's nutrition needs, food preferences, culture, lifestyle, family eating habits, ability, interest, and physical activity (Silverstein et al., 2005, CPG, 2018). Achieving glycemic control through a balanced diet and adequate insulin is crucial to promote healthy growth and development in terms of height, weight, and pubertal growth (Silverstein et al., 2005).

During the nutrition counselling sessions, RDs teach children and their families about the foods that affect their blood glucose levels and sources of dietary CHOs; as they are the main nutrient that raise blood glucose levels (Butler et al., 2011). These foods include grains (e.g., breads, pastas, cereals, rice, etc.), some vegetables (e.g., potatoes, corn, sweet potatoes, peas) and fruits, milk, and alternatives (e.g., milk and yogurt but not cheese), meat alternatives (e.g., pulses such as beans and lentils), and sweet foods (e.g., sugar-sweetened beverages, desserts, etc.) (Understanding Your Diabetes and Living a Healthly Life, 2009, The Essentials, 2013). RDs provide nutrition education to help patients match the amount of CHOs consumed to the prandial insulin that they inject to achieve glycemic control. RDs ask patients to fill out three-day food records and use these to provide nutrition recommendations. In addition, RDs provide nutrition counselling regarding CHO consistency, high fibre CHO sources, healthy fat sources, and encourage the consumption of protein at every meal (The Essentials, 2013). Overall, exogenous insulin must be matched to the food intake and any planned exercise (Butler et at., 2011).

Recommendations from Diabetes Canada's CPGs are flexible and recommend that children follow a healthy diet according to Eating Well with Canada's Food Guide (CPG, 2018). Generally, it is recommended that patients with T1DM either CHO count or follow a structured meal plan (SMP); as there is no evidence that either type of nutrition counselling is preferential in achieving glycemic control (CPG, 2018). Similarly, Diabetes Care and Education (DCE) developed by the Academy of Nutrition and Dietetics recommends either: following a consistent meal plan with consistent CHO intake and insulin dosage; or flexible CHO intake together with CHO counting and insulin adjustments (American Dietetic Association- Diabetes Care and Education, 2010). A consistent meal plan may be easier for some families, especially when their child is newly diagnosed with diabetes (American Dietetic Association-Diabetes Care and Education, 2010). Thus, two types of nutrition care plans can be recommended: CHO counting or a SMP. In the 1980s, SMPs with controlled CHO portions were recommended most often (Tascini et al., 2018). In the 1990s, however, the DCCT found that CHO counting provided flexibility and helped patients achieve glycemic control (Nathan et al., 2014), and as such it has been increasingly introduced into nutrition care plans (Tascini et al., 2018). The two-main types of meal plan approaches will be explained below.

CHO Counting

CHO counting is a technique whereby patients are taught to estimate the amount of CHOs ingested at a meal or snack (Butler et al., 2011). This is a flexible method to plan meals; whereby, the CHOs in all CHO-containing foods are counted. This is done by reading the nutrition facts table, looking at the serving size, and identifying the amount of CHO (not just the sugar) that will be consumed. The total CHOs are broken down into fibre and sugars (Butler et al., 2011). To determine the total available amount of CHOs, the amount of fibre is subtracted from the amount of CHOs (Network of Ontario Pediatric Diabetes Program, 2007). It is important to subtract the amount of fibre; as fibre does not raise blood glucose levels appreciably (Butler et al., 2011). Once the total available amount of CHO per meal is quantified, the amount of rapid acting insulin to inject is determined by the recommended insulin to CHO ratio (Butler et al., 2011). The accuracy of counting CHO will lead to the correct calculation of insulin injected, which will then help control postprandial blood glucose levels. In practice, the insulin to CHO ratio is individualized for each patient, and generally ranges from one unit of rapid acting insulin to every 7-15 grams of CHO (American Dietetic Association-Diabetes Care and Education, 2010). For example, two slices of toast may have 34 grams of CHOs with four grams of fibre; so, the total amount of CHOs would be 30 grams. If the insulin to CHO ratio of 1:10 is recommended, the patient would take three units of rapid acting insulin to match the CHO ingested. The priority remains to eat balanced meals as this is crucial for the optimal well-being and growth of children. While this method allows for flexibility, overeating is discouraged as it may lead to weight gain and an increased incidence of obesity (Understanding Your Diabetes and Living a Healthly Life, 2009).

In practice, CHO counting is often the ultimate goal for nutrition therapy; however, results of studies are inconclusive. Marigliano et al. conducted a study, where 25 children ages 7-14 years were provided with CHO counting education and they found that participants' mean A1Cs were significantly and clinically different (Marigliano et al., 2013). The A1C levels decreased from 8.50±0.8% to 7.92±0.7% ($p < 0.001$) after 18 months of follow up (Marigliano et al., 2013).

Conversely, one randomized controlled trial conducted in Turkey showed that there was no difference in A1C between the CHO counting group and the control group at the end of the first year; however, at the end of the second year, A1C was significantly lower in the CHO counting group (7.87±1.4%) compared to the control group (8.76±1.8%) (p=0.01) (Goksen et al., 2014). The authors of this study suggested that it takes time for CHO counting to show an effect on A1C but there was no conclusive proof provided.

Structured Meal Plan

An alternative approach to counsel patients with T1DM is to provide a SMP with consistent predetermined grams of CHO and consistent insulin dosages at meals and snacks (Network of Ontario Pediatric Diabetes Program, 2007). This approach; however, limits flexibility in intake because CHO intake cannot be altered or it may cause fluctuations in blood glucose levels. For consistent meal plans, the DCE recommendations are provided in **Table 2.**

Table 2: DCE Meal and Snack Recommendations (American Dietetic Association-Diabetes Care and Education, 2010)

Age (years)	**CHO (g) recommended for each meal**	**CHO (g) recommended for each snack**
<5	30-45	15-30
5-12	45-60	15-30
Teens		
Female	45-75	15-30
Male	60-75+	15-30

A consistent meal plan may be easier for some families, especially when their child is newly diagnosed, as CHO counting and insulin adjustments can be quite complex. Another rationale for using SMPs is that patients who CHO count may focus too much on the quantity of CHOs and not the quality of CHO or appropriate macronutrient distribution (i.e., CHO, fat, protein, and caloric intake overall, as would be considered in a SMP) (Marigliano et al., 2013). This can contribute to weight gain, increase in fat intake and fat mass, uncontrolled blood glucose levels, and increased blood lipids (Marigliano et al., 2013). These outcomes can lead to vascular problems, and ultimately increase the risk of cardiovascular disease and obesity (Marigliano et al., 2013).

Nutrition recommendations given to patients need to be realistic and flexible. Rabonne et al. conducted an observational study in Italy by evaluating 85 children with T1DM between the ages of 9-16 years (Rabbone et al., 2014). They divided the children into four different groups: 23 in the control group, 19 in the experienced CHO counting group, 18 in the experienced CHO group with an automated bolus calculator (ABC), and 25 in the non-experienced CHO counting with an ABC. The ABC provides insulin bolus advice based on the patient's current blood glucose levels and insulin to CHO ratio (Rabbone et al., 2014). During this study, A1C, insulin use, and glycemic variability were assessed at baseline, after 6 months, and then after 18 months. The authors noted that the A1C improved from 10.6±4.4% to 8.7±3.2% ($p<0.001$) in the non-experienced CHO counting participants using an ABC who received CHO counting education over the 6-month period. The A1C of the experienced CHO counting group using an ABC actually worsened from 8.3±2.9% to 9.1±4.6% ($p<0.001$) as did the control from 9.3±5.9% to 11.4±5.4 % ($p<0.001$) (Rabbone et al., 2014). The authors stated this may have been due to compliance issues within the control group (Rabbone et al., 2014).

Despite the worsening of A1C in the experienced CHO counters, it was concluded that CHO counting is recommended as it provides a more flexible approach for patients and allows them to have more variability in their food choices (Rabbone et al., 2014).

A meta-analysis and systematic review assessed seven studies, including 703 participants with T1DM (599 adults and 104 children) (Bell et al., 2014). Five studies favored CHO counting and two favored general nutrition education and usual care (Bell et al., 2014). Of the five favoring CHO counting, the A1C values at the end of the intervention were reduced by 0.64% ($p<0.0001$) (Bell et al., 2014). The authors noted that while there is limited available evidence to favor CHO counting, international recommendations often suggest CHO counting based on narrative review or consensus (Bell et al., 2014). Several limitations were also reported in the studies they reviewed, including unreported compliance/adherence and lack of assessment of parental ability to estimate CHO quantity (Bell et al., 2014). Goksen et al. noted this to be one of their limitations as well, as they did not include a measure of CHO counting knowledge or accuracy (Goksen et al., 2014).

Accurate CHO counting is an important factor to consider as the accuracy of CHO counting ultimately affects overall glycemic control. Bishop et al. found that only 23% of adolescents estimated the amount of CHOs within 10 grams of the actual amount in a group of meals that were commonly eaten by this age group (Bishop et al., 2009). As parents often assist their children and adolescents with T1DM in meal planning and CHO counting, a study looking a CHO counting accuracy in adults was also reviewed. This study conducted by Meade et al. showed that 82% of the adults overestimated the CHO amount by an average of 40% (Meade et al., 2016). Furthermore, a study conducted by Mehta et al. assessed the precision of CHO counting by 67 parents of 4-12 year olds and they found that greater precision of CHO counting and more frequent blood glucose monitoring was associated with a 0.8% lower A1C (Mehta et al., 2009). Another study done by Smart et al. found that 73% of all estimates were within 10-15 grams of actual CHO content and there was no relationship between the percent error and type of CHO counting, or A1C ($p > 0.05$) (Smart et al., 2010). Interestingly, they also found that the longer children had been CHO counting, the greater the percent error ($r = 0.173$, $p = 0.014$); however, the r-value indicates little to no association, and significance may be driven by sample size (Smart et al., 2010). Nevertheless, ongoing diabetes education sessions with RDs is important to review and reeducate patients and their families on the CHO content of foods. Sometimes hidden CHOs like those from condiments (i.e., ketchup, barbeque sauce, pasta sauce) or from flavored milk are missed (Butler et al., 2011). Overall, studies suggest that the accuracy of CHO counting should be accounted for as well.

In practice presently, RDs either recommend CHO counting or a SMP as “there is no strong evidence that one form of nutrition therapy is superior to another in attaining age appropriate glycemic targets” (CPG, 2018).

Socioeconomic Factors affecting A1C

Socioeconomic factors including parental education and involvement have been shown to have an effect on A1C levels (Gesuita et al., 2016). Gesuita et al. found that children and adolescents who reached the target A1C more often had high levels of family socioeconomic status ($p=0.03$) and high levels of maternal education ($p=0.03$) (Gesuita et al., 2016). Mothers who understand T1DM and specific management strategies are able to help their children with insulin titration, hypoglycemia, glycemic variations, physical activity, and CHO counting (Gesuita et al., 2016). Furthermore, those patients who reached the target A1C were more frequently at a normal weight, used continuous subcutaneous insulin infusions, and CHO counting (Gesuita et al., 2016). Other factors that significantly affect A1C levels include the length of years the patient has had diabetes, BMI, and physical activity levels (Nadella et al., 2017). Therefore, these confounding factors need to be considered when assessing diabetes management in patients.

Previous research studies have been done on glycemic control and meal plans but only one of them assessed socioeconomic factors (Gesuita et al., 2016). Therefore, the present study will assess if children who CHO count have different A1C levels than those using a SMP and explore familial and socioeconomic factors that may affect glycemic control. The rationale for conducting this study began as a practice-based research question by an RD at WRH who was questioning which nutrition approach was better for the glycemic control for her patients.

Research Objectives

The primary objective of the proposed observational cross-sectional study was to determine if in a practice-based setting there is a difference in A1C levels of children with T1DM using CHO counting compared to those on the SMP. The secondary objectives were to determine if potential confounding factors (i.e., BMI-for-age, CHO intake and adherence, parental income, parental involvement, mothers' educational attainment, etc.) were associated with glycemic control. In addition, the accuracy of participants' CHO counting was proposed to compare CHO intake to their estimation of CHO counts. Similarly, for the SMP group CHO intake was proposed for comparison to the meal plan.

This study aims to compare glycemic control in children following the CHO counting approach or SMP approach and may provide a greater understanding of the familial factors (i.e. family income and mothers' education level) that influence glycemic control in the dietary treatment of children and adolescents with T1DM. Ultimately, this may help RDs in their everyday practice as RDs play an important role as part of the diabetes team and nutrition education continues to be a major cornerstone in the diabetes management of patients.

Chapter 2
Methodology

Study Design

Using an observational study design children/adolescents aged 4-18 years with T1DM were recruited from Windsor Regional Hospital (WRH) Pediatric Diabetes Centre. The patients were categorized into one of two groups (CHO counting or SMP) based on their nutrition care plan as provided by the WRH RD. These patients are assessed by the diabetes team quarterly, and it was estimated that 60% of them CHO count while the other 40% follow a SMP (personal communications with Michelle Knezic, RD, CDE). The recruitment process occurred at WRH during the T1DM patient's quarterly diabetes clinic visits between September 2018 and January 2019. Recruitment occurred primarily over a three-month period; however, to ensure we were able to invite all eligible participants, we maintained recruitment for an additional month to invite participants who missed their previous appointment. The consent and assent letters were approved by the Research Ethics Boards at the University of Western Ontario and WRH.

Inclusion/Exclusion Criteria

To be included patients must have had T1DM for longer than one year and the parents and/or child/adolescent had to be able to read and write English (unless an interpreter was available to assist with the survey completion). Children/adolescents were excluded if they had T1DM for less than 1 year, celiac disease, on medication for attention deficit hyperactivity disorder, or medications (other than insulin) that affected their blood glucose levels (e.g., steroids).

Data Collection

During diabetes clinic visits, the research study was introduced by the RD or registered nurse and explained to the families. Participants who were interested, reviewed the letters of information and completed the consent letters (Appendix A or B) and/or assent letter (Appendix C). To ensure participants met the inclusion criteria, the research team used a screening tool (Appendix D).

The participants completed an online survey on the clinic computer and data was extracted from the participants' chart by the RD. The participants were given instructions to complete the online survey with their patient ID (Appendix E). Two versions of the survey, one for parents (Appendix F) and one for adolescents 16 years or older (Appendix G) were developed and inputted into an online software called Qualtrics (Qualtrics Customer Survey Software, 2019). The 30-item surveys included quantitative and qualitative questions. Respondents were able to skip questions if desired. Patient ID (as provided and linked to a master code), birth date (to calculate BMI-for-age), and dietary treatment were considered necessary; therefore; those questions were mandatory.

The online survey was developed based on practice-based considerations of diabetes, a review of the most recent literature, and research expertise. The questions in the survey included demographic characteristics and focused on diabetes management, including the involvement of the parent and child, and open-ended questions that provided insight and a reflection of the childrens' and parents' experience living with T1DM.

The online survey collected data such as child's age, sex, age at diagnosis, insulin regimen, parental involvement in meal planning and glycemic management, physical activity levels, screen time, family income, and educational attainment of the mother to capture familial factors, which could affect blood glucose control. The first 14 questions of the survey were asked to all participants. The 15th question asked participants what meal plan approach they followed and based on their response they were then directed to the questions that related to their specific meal plan approach. Several questions in the survey included an 11-point scale from 0 to 100, mimicking a percentage, which ranged from never (0-20%), sometimes (>20-40%), about half the time (>40-60%), most of the time (>60-80%), and always (>80-100%) (Courneya et al., 2001). This scale provided the participants an opportunity to indicate what % they felt involved in their diabetes management and meal planning, flexibility with food intake, confidence in following the meal plan, how often they counted CHOs, how often they followed the meal plan, and how often they found it difficult to follow the meal plan. Some qualitative questions about their experience with CHO counting or following a SMP were also included to acquire more depth and understanding about the advantages and disadvantages they experienced with their dietary treatment protocol. Additionally, open-ended questions were asked such as what made each meal plan easy or difficult to follow to gain an understanding of the participants' experience and feelings.

It is noteworthy that the RD at WRH used patient information sheets produced by the Network of Ontario Pediatric Diabetes Programs (Network of Ontario Pediatric Diabetes Program, 2007). These documents refer to CHO counting as a 'Variable Carbohydrate' method, and to the SMP as 'Carbohydrate Counting to Target'. Thus, to avoid confusion among parent/child/adolescent participants, the same language was offered on the survey.

A clinic data collection form (Appendix H) was used to capture each participant's dietary treatment protocol (CHO counting vs. SMP), weight, height, last two A1C values, and details of the SMP (i.e., CHO (g) recommendations per meal/snack). At each visit, the RD measured the patients' weight and height, and included it in the clinic data collection form. Body mass indexes (BMI)-for-age were calculated from weights and heights, and World Health Organization growth charts were used to calculate gender-specific BMI-for-age z scores and percentiles (World Health Organization, 2019).

Three-day food intake records (Appendix I) were intended to be collected; however, only a few participants brought completed food intake records with them to their next appointment. Therefore, the ability to quantify CHO intake and assess CHO counting accuracy or adherence was not possible.

Based on the RD account of the patient roster at WRH Diabetes Education Centre it was estimated that there were 300 patients with T1DM (personal communications with Michelle Knezic, RD, CDE). Of these 300, it was estimated that 60% were following the CHO counting approach while 40% were following the SMP approach (personal communications with Michelle Knezic, RD, CDE). The calculated sample size (Appendix J) was 233 patients, which was feasible based on the communicated estimates of patients at the WRH.

For this study, the independent variable was diet type (CHO counting vs. SMP) and the primary dependent variable was A1C. Additional factors such as BMI, BMI-for-age, BMI-z-scores, weight, height, age, age at diagnosis, insulin regimen, as well as survey parameters such as the mothers' education level, and total family income were assessed to determine differences between the two groups.

Statistical Analysis

Statistical analysis was done using SPSS Version 25 and included descriptive and inferential statistics (IBM Corp, Version 25.0, 2017). Continuous variables were described by means and standard deviations. All continuous variables were compared using an independent samples t-test to determine differences between the two groups (CHO counting vs. SMP), with the level of significance defined as $p<0.05$. Categorical variables were summarized as proportions and compared by chi-squared analyses. If both variables were continuous a correlation was computed.

Qualitative Analysis

The qualitative survey responses were analyzed verbatim to provide more depth and breadth to survey responses. Two researchers coded the qualitative data independently to identify recurrent themes that emerged. Each quote from the participants was inputted into an excel worksheet, and themes were identified and coded. Some quotes were long and contained multiple themes. Once themes were identified, the researchers came together for discussion. Some themes were grouped together into broader categories, and sub-themes that pertained to these broader themes were identified. Each individual theme and sub-theme was given a distinct code for quantification purposes. The number of responses per theme and subtheme were calculated and percentages were determined.

Ethics Approval

This study was approved by the Western University Health Sciences Research Ethics Board (Appendix K) and WRH Research Ethics Board (Appendix L). All participants provided written informed consent.

Chapter 3
Results

Quantitative Results

Despite clinic estimates of 300 potential participants, there were only 120 patients during the 3 months of data collection who were available to be approached to participate in this study; of these, 21 were ineligible and 11 did not consent, for a total of 88 participants. More patients than expected were ineligible to participate as they had T1DM for less than one year or had celiac disease or took medications (other than insulin) that affected their blood glucose levels. Additionally, in spite of estimates of 60% in the CHO counting group and 40% in the SMP group, there were 77 (88%) in the CHO counting group and only 11 (12%) in the SMP group.

Total Sample Data

The participant demographic, anthropometric, and biochemical data is presented in **Table 3.** The mean age for the total sample was 13.7±3.0 years, with 47% female and 53% male. The mean age at diagnosis was 6.3±3.6 years and the mean A1C was 8.53±1.05%. Thirty-two parents filled out the parent survey and 56 adolescents filled out the adolescent survey. The mean weight and height were 59.4±19.5 kg and 160.4±16.4 cm, respectively, and the mean BMI was 22.4±5.0 kg/m^2. Out of the total participants, 3% were in the underweight category for BMI-for age, 52% were in the normal/healthy range, while 17% were in the overweight category, and 27% in the obese category. Additionally, 24% of the mothers had a high school degree or less and 76% had a college or university degree. The following were reported by the participants for their total family household income: 6% reported less than \$25,000, 11% reported \$25,000-\$49,999, 18% reported \$50,000-\$74,999, 18% reported \$75,000-\$99,999, 36% reported greater than \$75,000, and 11% did not report their total family household income. Overall, 59% of the participants were on IPs and 41% on MDI. Seventy-six percent reported that the child/adolescent checks their own blood glucose, 10% reported the parent checks their child's blood glucose, 13% reported that both the child and parent check the blood glucose levels, and 1% did not respond to this question. Finally, 51% were physically active for 30-59 minutes per day, 48% were active for 60 minutes per day or more, 26% spent two hours or less on screen time, and 74% spent two or more hours on screen time.

Comparisons between the CHO Counting and SMP Group

Table 3 also compares the characteristics between the two groups. While the CHO counting group and the SMP group had quite different sample sizes, comparisons were still conducted as per the primary objective of the study. There were no differences in demographic variables (i.e. gender, age, and height) between the groups. Similarly, variables related to lifestyle and diabetes, such as A1C level, age at diagnosis, diabetes camp attendance, mothers' education levels, family income, and screen time were not significantly different.

The mean weight for the CHO counting group was 59.4±20.3 kg and 53.3±12.4 kg for SMP group (p=0.33). BMI between the CHO counting group and SMP (22.7±5.3 kg/m^2 vs. 20.4±2.3 kg/m^2, respectively) was significantly different (p=0.02). For children, BMI is not as relevant as BMI-for-age, so BMI-for-age was also studied. BMI-for-age was significantly different between the CHO counting group and SMP group (p=0.01).

Table 3 Participant demographic, anthropometric, and biochemical data.

Characteristics	Total participants	CHO Counting	SMP	p value
Number of participants, n	88	77	11	
Sex, n (%)				
Female	41 (47)	35 (45)	6 (55)	0.57
Male	47 (53)	42 (55)	5 (45)	
Age, years (mean±SD)	13.7±3.0	13.6±3.0	14.4±2.3	0.60
Age at diagnosis, years (mean±SD)	6.3±3.6	6.1±3.6	7.3±3.2	0.33
BMI (kg/m^2) (mean±SD)	22.4±5.0	22.7±5.3	20.4±2.3	**0.02**
BMI-for-age, n (%)				**0.01**
Underweight	3 (3)	3 (4)	0 (0)	
Normal/healthy	46 (52)	36 (47)	10 (91)	
Overweight	15 (17)	14 (18)	1 (9)	
Obese	24 (27)	24 (31)	0 (0)	
BMI z-score (mean±SD)	0.8±1.2	0.9±1.2	0.2±0.9	0.07
Weight (kg) (mean±SD)	58.7±19.5	59.4±20.3	53.3±12.4	0.33
Height (cm) (mean±SD)	159.6±16.4	159.5±16.9	160.4±13.3	0.86
Mean A1C (%) (mean±SD)	8.53±1.05	8.57±1.06	8.30±0.96	0.44
Mothers'education, n(%)				0.78
< High school	4 (5)	3 (4)	1 (9)	
High school	17 (19)	15 (20)	2 (18)	
College	31 (35)	29 (38)	2 (18)	
University	36 (41)	30 (39)	6 (55)	
Family Income, CAN$, n (%)				0.54
< 25,000	5 (6)	5 (6)	0 (0)	
25,000-49,999	10 (11)	10 (13)	0 (0)	
50,000-74,999	16 (18)	14 (18)	2 (18)	
75,000-99,999	16 (18)	15 (20)	1 (9)	
>$100,000	32 (36)	27 (35)	5 (46)	
Declined to answer	10 (11)	6 (8)	3(27)	

SD=standard deviation, CHO=carbohydrate, SMP=structured meal plan, CAN$=Canadian $

Specifically, in the normal/healthy category, there were 47% and 91% in the CHO counting and SMP groups, respectively. In the overweight category, there were 18% in the CHO counting group and 9% in the SMP group. Additionally, there were 31% in the obese category in the CHO counting group vs. 0% in the SMP group.

Furthermore, insulin regimen was significantly different between the CHO counting group and SMP (p=0.02) as shown in **Table 4**. In the CHO counting group there were 64% on IPs and 36% on MDI, while the SMP group had 55% on IPs and 46% on MDI.

Additionally, there was no statistically significant difference between the person who checks blood glucose levels (p=0.62). The mean age of the children/adolescents was significantly higher in the group that indicated blood glucose levels were checked by the child/adolescent, vs. when it was checked by parents or both (i.e., 14.7±2.1 years vs, 10.0±2.9 and 10.7±3.4 years, respectively; p=0.00). Furthermore, there was no statistically significant difference (p=0.92) between the two groups for diabetes camp attendance. The majority of the participants spent two or more hours on screen time per day: 73% in the CHO counting group and 82% in the SMP group, and this was not significantly different between the two groups (p=0.52).

Comparisons between MDI and IP

There was no significant difference (p=0.36) in the mean A1C of participants on MDI vs. IPs (8.66±1.21% vs. 8.45±0.92%, respectively). There were no statistically significant associations between insulin regimen (i.e., MDI vs. IP) and age of diagnosis, weight, age, diabetes camp, screen time, physical activity, mothers' education, or yearly income.

Additionally, gender and diabetes camp attendance was not significantly associated with any of the other variables.

Table 4 Diabetes Self-Management Characteristics.

Characteristics	Total Participants	CHO Counting	SMP	p value
Sample size, n	88	77	11	
Insulin Regimen (n, %)				**0.02**
MDI	36 (41)	36 (36)	5 (46)	
IP	52 (59)	49 (64)	6 (55)	
Person who checks blood sugars (n, %)				0.62
Child	67 (76)	59 (76)	8 (73)	
Parent	9 (10)	6 (7)	3 (27)	
Both	11 (13)	12 (16)	0 (0)	
Unreported	1 (1)	0 (0)	0 (0)	
Diabetes Camp Attendance (n, %)				0.92
Yes	15 (17)	13 (17)	2 (18)	
No	74 (83)	64 (83)	9 (82)	
Physical Activity (minutes/day) (n, %)				0.43
30-59	45 (51)	41 (53)	4 (36)	
60 or more	42 (48)	36 (47)	6 (55)	
Screen Time (hours/day) (n, %)				0.52
< 2	23 (26)	21 (27)	2 (18)	
> 2	65 (74)	56 (73)	9 (82)	

CHO=carbohydrate, SMP=structured meal plan, MDI=multiple daily injections, IP=insulin pump

Physical Activity

As expected, there was a statistically significant association between the level of physical activity and BMI-for-age (p=0.03, r=-0.24), with 66% of the participants in the normal/healthy BMI category who did greater than 60 minutes of physical activity per day. The remaining 33% were in the overweight category and they reported being physically active for less than 60 minutes per day. Physical activity has many benefits and one of them is weight maintenance.

Participant Involvement in Diabetes Management

Participants were asked about their % involvement in diabetes management. One of the questions in the survey asked how often the parents or children were involved in planning the meals and is referred to as the % involvement in planning meals. The mean % involvement in planning meals for the parent respondents (88.2± 19.3%) was significantly higher (p=0.00) than for the adolescent respondents (57.7±24.6%). There was a negative correlation between age and % involvement in planning meals (r=-0.42, n=84, p=0.00). However, the mean % involvement in managing diabetes (85.2± 16.4% vs. 88.1±20.6%, p=0.48) and being flexible (67.4± 24.6% vs. 70.5±27.3%, p=0.58) with food intake was not significantly different between the adolescent and parent respondents, respectively.

Finally, there was a significant association between mean A1C and BMI (r=0.22, p=0.04), but that did not hold when assessing the association between A1C and BMI-for-age (r=0.14, p=0.19). There were also no statistically significant associations between BMI-for-age and insulin regimen, total family income, mothers' education, screen time, and involvement in planning meals.

Qualitative Results

Responses from participants on CHO counting approach

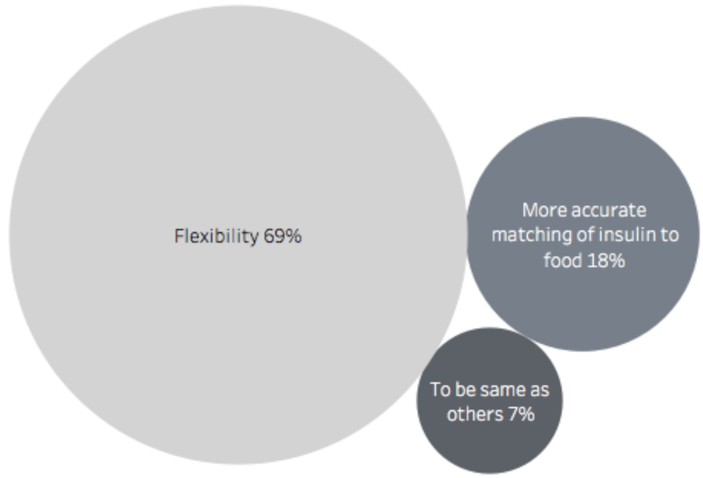
From the participants following the CHO counting approach, 87% (67/77) responded when asked about the advantages of following the CHO counting approach. Three major themes were identified by the responses: flexibility of the meal plan was identified by 69%; more accurate matching of insulin to food intake by 18%; and easier to be the same as other children/adolescents by 7% of these respondents (**Table 5).** Flexibility was the most often identified theme, with subthemes including meal planning (49%), tailored to child preferences (24%), tailored to appetite (9%), and time (9%). Overall, as shown by the quotes in **Table 5**, respondents identified the advantages of following the CHO counting approach as flexibility in meal planning, and being able to accommodate preferences and appetite.

The themes identified for the disadvantages of following the CHO counting approach included: hard to count CHOs, as identified by 54% of these respondents; and nothing/none by 15% **(Table 6)**. The subthemes identified under hard to count CHOs included: nothing/none (15%); less accurate matching of insulin to food intake (14%); effort required (11%); hyperglycemia (9%); restaurant/eating out (8%); and hypoglycemia (6%). The quotes in **Table 6** provide context about the impact of these themes and what the children, adolescents, and parents experienced.

The major themes identified for why is it easy to follow the CHO counting approach included **(Table 7):** use of IP by 25% of these respondents; food label availability by 21%; experience/understanding CHO counting by 16%; and flexibility of meal planning by 16%.

Table 5 Advantages of following the CHO counting approach (n=67/77*)

Themes Identified	**Major Themes**

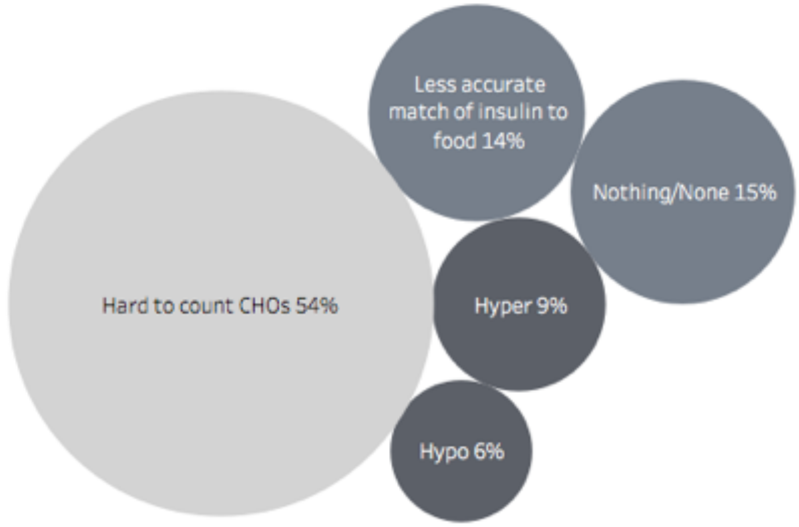


	Responses %	**Quotes from parent or child**
Flexible	69	"I can eat what I want" **A, M, 15y**
Subthemes		
Meal Planning	49	"Not as restricted with food, can eat more freely with types of food intake and time allocations" **P of M, 13y**
Time	9	"I can eat whenever I want" **A, M, 15y**
Tailored to preferences	24	"You can eat the things you want" **A, F, 13y**
Tailored to appetite	9	"It gives you freedom of what you want to eat. You are not stuck with the same amount of carbs everyday" **A, M, 15y**
More accurate matching of insulin to food intake	18	"It's easier to match your insulin count to the correct carbs" **A, M, 17y** "You don't have to worry about not having enough food with the amount of insulin given" **A, F, 17y**
To be the same as other children/adolescents	7	"She can eat like everyone else" **P of F, 12y** "Able to be spontaneous with travel and extra - curricular activities, freedom to feel normal for an adolescent child" **P of M, 11y**

A=adolescent respondent, C=child respondent, P=parent respondent, M=male, F=female, y=years old, CHO=carbohydrate, *67 of 77 participants in the CHO counting group responded to this question.

Table 6 Disadvantages of following the CHO counting approach (n=65/77*)

Themes Identified	Major Themes

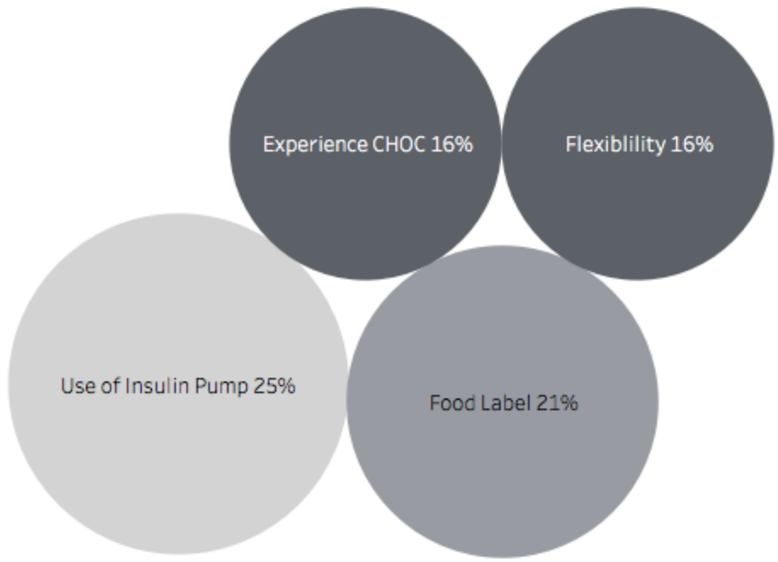


	Responses%	Quotes from parent or child
Hard to count CHOs	54	"You are always counting carbs" **P of F, 17y** "It's not always right" **C, F, 13y**
Subthemes		
Effort required	11	"It takes too much time and effort and is kind of a pain to do so" **A, M, 17y**
Restaurant/Eating out	8	"Don't know what the exact carb is for eating out and food without labels" **A, M, 15y** "Difficult when you're eating at a restaurant" **A, F, 16y**
Less accurate matching of insulin to food intake	14	"If you give too much insulin for an unfamiliar meal" **A, F, 17y**
Nothing/None	15	"We find this approach much better & really have no problems with following it" **P, M, 8y**
Hyperglycemia	9	"High/low b[lood] s[ugar] when counts are off"**P, M, 5y**
Hypoglycemia	6	"If carb count is not available you must give a best guess based on previous experience and decide if carb on higher or lower end which can cause hyper/hypo events, always have water and fast acting sugar to offset variables/inaccuracy in carb count" **P, M, 11y**

A=adolescent respondent, C=child respondent, P=parent respondent, M=male, F=female, y=years old, CHO=carbohydrate, *65 of 77 participants in the CHO counting group responded to this question.

Table 7 Responses (n=67/77*) to why is it easy to follow the CHO counting approach.

Themes Identified	**Major Themes**



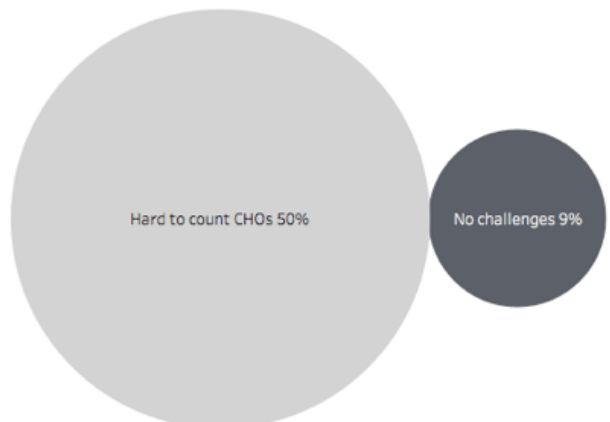
	Responses%	**Quotes from parent or child**
Use of insulin pump	25	"The pump does it for me" **A, M, 15 y** "The carb calculator on my pump" **A, F, 14y** "We love being on a pump, it makes carb counting very easy" **P of M, 11y**
Food label availability	21	"Counting carbs from food labels, allows it to be easier to count and add values to the insulin pump for doses" **P of M, 5y**
Experience/understanding CHO counting	16	"Once the learning curve has been overcome, knowing the amount of carbohydrates in most foods allows easier insulin delivery. There is no worry to make up for any differences in carbohydrates" **P of M, 7y**
Flexible meal planning	16	"The flexibility makes it easy. Also, I can eat what I want when I want". **C, M, 12y** "It's easier to plan his meals, he can have more variety as we can carb [count] in whatever he eats". **P of M, 8y**

A=adolescent respondent, C=child respondent, P=parent respondent, M=male, F=female, y=years old, CHO=carbohydrate, *67 of 77 participants in the CHO counting group responded to this question.

The major theme identified for why it is difficult to follow the CHO counting approach was hard to count CHOs, which was identified by 50% of these respondents **(Table 8).** Out of the 50%, 11% identified that it was hard to count CHOs when eating out or at a restaurant. In contrast, 9% of the respondents identified no challenges.

Table 8 Responses (n=66/77*) to why is it difficult to follow the CHO counting approach.

Themes Identified	**Major Themes**



	Responses%	**Quotes from parent or child**
Hard to count CHOS	50	"I'd say if you aren't the greatest at math it'd be hard." **A, M, 17y** "Can be very annoying to do when I just want to eat". **A, F, 17y**
Subtheme		
Eating out/ restaurant food	11	"When I don't know exactly how many carbs are in my meal (i.e. eating out)" **A, F, 16y** "Carb counting can be difficult when you are at restaurant or someone else's house because you may not know how many carbs are in what you eat, or the way it was prepared". **A, F, 14y**
No challenges	9	"I don't find anything difficult with following this approach". **C, M, 13y**

A=adolescent respondent, C=child respondent, P=parent respondent, M=male, F=female, y=years old, CHO=carbohydrate, *66 of 77 participants in the CHO counting group responded to this question.

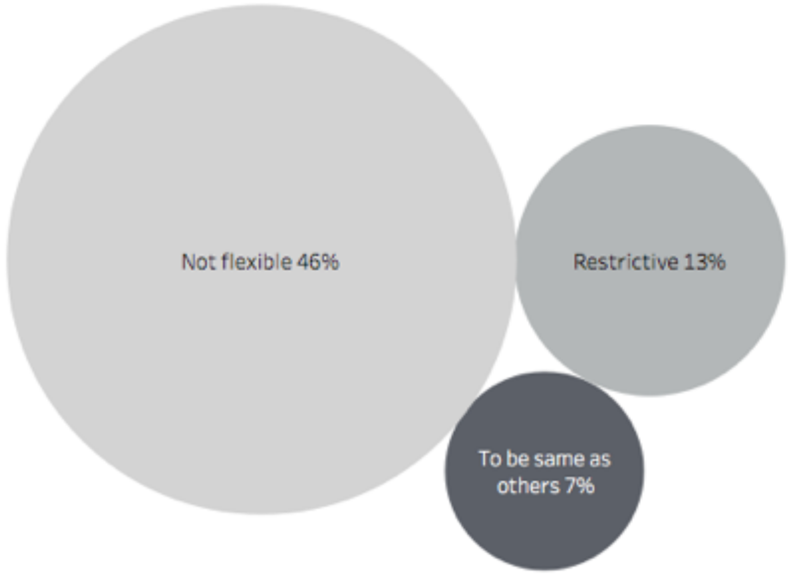
When the CHO counting participants were asked why they did not follow the SMP approach, three major themes were identified: not flexible by 46% of these respondents; restrictive by 13%; and harder to be the same as other children/adolescents by 7% **(Table 9).** Within the theme of not flexible, subthemes were identified which included: not a flexible meal plan (25%), not tailored to appetite (16%), and not tailored to child preferences (5%).

Responses from participants on SMP approach:

From the participants following the SMP approach, 82% (9/11) responded when asked about the advantages of following this approach. For this question, a major theme emerged and was identified by 56% of respondents: more effective diabetes management. A subtheme of better glycemic control was identified by 44% of the respondents **(Table 10).** The two other major themes included insulin consistency and regular meal plans, which were identified by 33% and 22% of the respondents, respectively.

The themes identified for why it was easy to follow the SMP approach were: regular meal plans and insulin consistency indicated by 57% and 14% of the respondents, respectively **(Table 11).** The major themes identified for the disadvantages of following the SMP approach included: not tailored to appetite and not flexible, which were each identified by 37% of the respondents. A subtheme emerged which was eating out, which was identified by 25% of the respondents **(Table 12).**

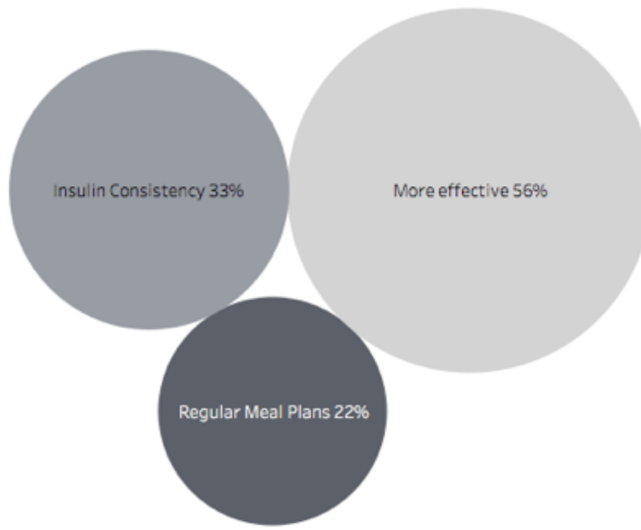
Table 9 Responses (n=61/77*) to why the participants did not follow the SMP.

Themes Identified	Major Themes	
		
	Responses%	**Quotes from parent or child**
Not Flexible	46	"So that I have the freedom to eat what I want, when I want" **A, F, 17y** "I don't use the meal plan approach because I enjoy the freedom of setting how much insulin I want to give for the amount of food I want to eat. **A, M, 16y** "Little flexibility. Also, impractical for a growing teenager" **P of M, 12y**
Subthemes		
Meal plan	25	"My son is 4! He likes the flexibility of different foods and NOT a set menu. As an adult that would be easier to commit to". **P of M, 4y**
Not tailored to appetite	16	"Because I like to eat different amounts depending on how hungry I am" **A, F, 16y**
Not tailored to child preferences	5	"Because I want my son to be able to eat what he wants when he wants. That does not mean unhealthy food choices, just more flexible food options". **P of M, 10y**

Restrictive	13	"VERY hungry between meals" **A, F, 12y** "Too regimented for kids" **P of M, 14y**
To be the same as other children/ adolescents	7	"I'm not using this approach because I want to live a normal as possible life, and eat what all my family and friends can eat". **A, F, 14y**

A=adolescent respondent, C=child respondent, P=parent respondent, M=male, F=female, y=years old, CHO=carbohydrate, *61 of 77 participants in the SMP group responded to this question.

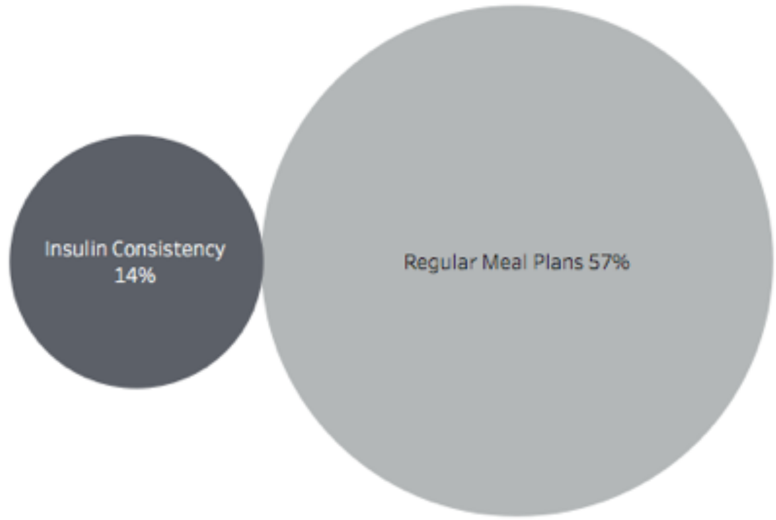
Table 10 Advantages of following the SMP approach. (n=9/11*)

Themes Identified	**Major Themes**	
		
	Responses%	**Quotes from parent or child**
More effective	56	"Tighter numbers" **A, F, 13y**
Subtheme		
Better glycemic control	44	"More predictable post-meal blood sugars" **A, F, 17y**
Insulin Consistency	33	"You always know how many units of insulin your child needs" **P of M, 9y**
Regular Meal Plans	22	"Regular meal plans" **A, F, 15y** "Helps with set limit" **P of F, 14y**

A=adolescent respondent, C=child respondent, P=parent respondent, M=male, F=female, y=years old, CHO=carbohydrate, *9 of 11 participants in the SMP group responded to this question.

Table 11 Responses (n=7/11*) to why is it easy to follow the SMP approach.

Themes Identified	**Major Themes**	

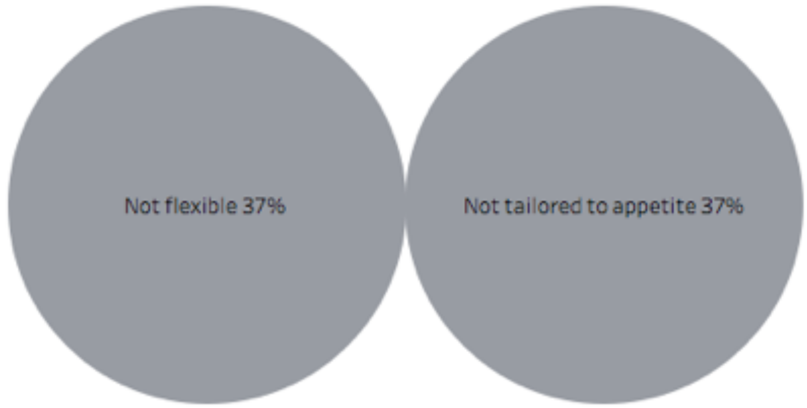


	Responses%	**Quotes from parent or child**
Regular meal plans	57	"I know how many carbs are in each food that I eat so making a meal with a set number of carbs is not difficult" **A, F, 17y**
Insulin Consistency	14	"Knowing what to eat and what insulin to do". **P of M, 17y**

A=adolescent respondent, C=child respondent, P=parent respondent, M=male, F=female, y=years old, CHO=carbohydrate, *7 of 11 participants in the SMP group responded to this question.

Table 12 Disadvantages of following the SMP approach. (n=8/11*)

Themes Identified **Major Themes**



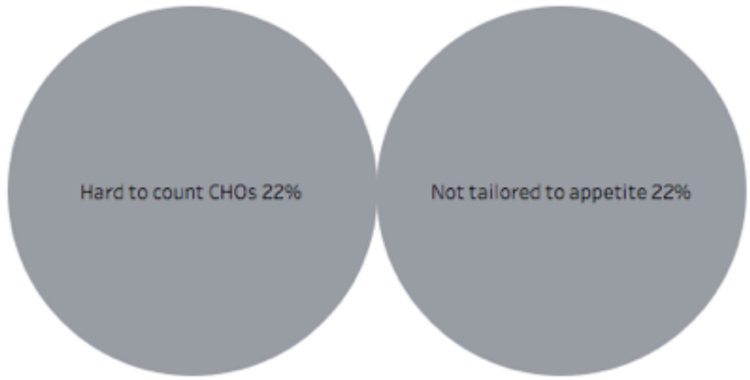
	Responses%	Quotes from parent or child
Not tailored to appetite	37	"You can't eat all the food that you want and you can't eat if you are hungry" **P of M, 9y**
Not flexible	37	"It is not flexible when you and your child are not home" **P of M, 12y**
Subtheme		
Eating out	25	"Activity levels and not eating at home". **A, F, 15y**

A=adolescent respondent, C=child respondent, P=parent respondent, M=male, F=female, y=years old, CHO=carbohydrate, *8 of 11 participants in the SMP group responded to this question.

For the question asking why it is difficult to follow this approach, two major themes were identified: not tailored to appetite and hard to count CHOs, which were each identified by 22% of the respondents. Additionally, a subtheme of eating out was identified by 11% of the respondents **(Table 13).**

Table 13 Responses (n=9/11*) to why is it difficult to follow the SMP approach.

Themes Identified	**Major Themes**	



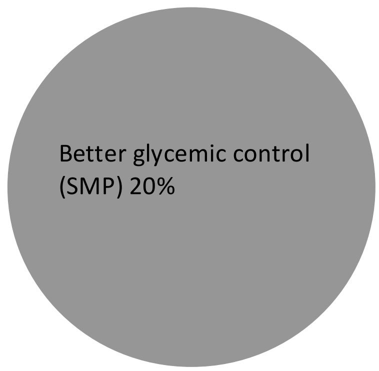
	Responses%	**Quotes from parent or child**
Not tailored to appetite	22	"To stop eating when you are still hungry". **P of M, 12y**
Hard to count CHOs	22	"Sometimes I eat and don't know how much carbs are there" **A, F, 17y**
Subtheme		
Eating out	11	"When eating out, I am not always aware of exactly how many carbohydrates are present in certain foods". **A, F, 17y**

A=adolescent respondent, C=child respondent, P=parent respondent, M=male, F=female, y=years old, CHO=carbohydrate, *9 of 11 participants in the SMP group responded to this question.

When the participants were asked why they did not follow the CHO counting approach, one major theme was identified by 20% of these respondents, which was better glycemic control following the SMP **(Table 14).**

Table 14 Responses (n=5/11*) to why the participants did not follow the CHO counting approach.

Themes Identified	Major Themes



	Responses%	Quotes from parent or child
Better glycemic control (following SMP)	20	"I found that when eating variable amounts of carbs. I had bigger fluctuations in blood sugars. This way I have tighter control". **A, F, 17y**

A=adolescent respondent, C=child respondent, P=parent respondent, M=male, F=female, y=years old, CHO=carbohydrate, *5 of 11 participants in the SMP group responded to this question.

Chapter 4
Discussion

The primary objective of this study was to assess A1C in participants with T1DM following the CHO counting approach or SMP approach. Originally, the number of participants at the WRH pediatric diabetes clinic was estimated to be 300 with 60% following the CHO counting approach and 40% following the SMP approach. However, during recruitment there were fewer participants in the SMP group, making the analyses comparing the two groups quite unbalanced.

The mean age of our total sample was 13.7±3.0 years, which is in the higher range of our inclusion criteria and is similar to other studies conducted by Goksen et al. (mean age for the CHO counting group was 16.4±4.5 years and 17.0±5.0 years for the control group) and Rabbone et al. reported the mean age to be 12.5±2.5 years (Goksen et al., 2014, Rabbone et al., 2014). This may be due to the inclusion criteria of each study indicating a specific age range or that older patients were more likely to participate in the study.

In our study, there were no differences in gender, age, weight, height, BMI-z-scores, age at diagnosis, and screen time between the CHO counting group and SMP group. Additionally, the mean A1C was not statistically different between the two groups; however, this may be due to the disproportionate number between the two groups. Goksen et al. conducted a randomized control study and found no difference in A1C between the CHO counting group and the control group at the end of the first year (Goksen et al., 2014). Conversely, A1C was significantly lower in the CHO counting group (7.87±1.38%) compared to the control group (8.76±1.77%) (p=0.01) at the end of the second year (Goksen et al., 2014). The participants in our study had diabetes for more than one year, so we were anticipating that there would be differences in the A1C between the two groups after a period of time like the participants from the study mentioned above.

Marigliano et al. found that participants' who received CHO counting education had significantly reduced A1C values from 8.50± 0.77% to 7.92 ± 0.74% (p< 0.001) after 18 months of follow up (Marigliano et al., 2013). Additionally, Rabonne et al. conducted a study in Italy with 85 children and their A1C improved from 10.6±4.4% to 8.7±3.2% (p<0.001) for those who received CHO counting education over the 6-month period (Rabbone et al., 2014). Moreover, a meta-analysis and systematic review found five studies to favor CHO counting and improve A1C by 0.64%, which is clinically relevant (Bell et al., 2014). Overall, the majority of the studies favored CHO counting as it had a positive effect on glycemic control.

The mothers' education level and total family household income were not associated with mean A1C. This is not consistent with the findings by Gesuita et al. as they found the participants who met the A1C target to have a high level of mothers' education and a high level of socioeconomic status (Gesuita et al., 2016).

Our analyses indicated a positive correlation between the mean A1C and BMI for the total sample. Similarly, Gesuita et al. found a strong association between achieving A1C target and being in the normal BMI category (Gesuita et al., 2016). Our analyses of anthropometric data indicated that the BMI in the CHO group was statistically higher than in the SMP group. There was also a higher percentage of participants in the overweight and obese category in the CHO counting group compared to the SMP. The authors in the study conducted by Marigliano et al. discuss that CHO counting allows more flexibility in meal planning and choices of food (Marigliano et al., 2013), and that this may result in patients having inappropriate macronutrient distributions (Marigliano et al., 2013). Specifically, patients may focus too much on the quantity of CHOs and not the quality. Furthermore, CHO counting may allow patients so much flexibility, which could lead to overeating (Gillespie et al., 1998, Kawamura et al., 2007), weight gain, and uncontrolled blood glucose levels (Marigliano et al., 2013). This may be problematic as children and adolescents may gain weight and increase their fat mass, which would ultimately affect their glycemic control, lipid profile, and cardiovascular disease risk. These factors may help to explain our findings of higher BMI in the CHO counting group compared to the SMP group; however, we cannot rule out that the small sample in the SMP group may not be representative of this population.

The importance of healthy eating behaviors is also confirmed by a previous study conducted on diet quality and T1DM patients, which showed that overall diet quality with greater fruit and whole grain consumption is associated with lower BMI percentiles (Nansel et al., 2012). Specifically, Nansel et al. found that daily energy intake of almost half of the participants came from processed grain products, chips, dessert, and high sugar beverages, with excess intake of saturated fat by almost twice the recommended amount, and fruit, vegetable, and whole grain intake less than half of the recommended amount (Nansel et al., 2012). Therefore, healthcare professionals are encouraged to emphasize to their patients the importance of consuming balanced meals with appropriate macronutrient distributions to help them with weight maintenance, glycemic control, and to reduce the risk of cardiovascular disease when teaching CHO counting.

The number of participants who filled out the adolescent survey was higher than those who filled out the parent survey, which may suggest a higher level of involvement of adolescents in their diabetes care compared to the younger participants in the study. When looking at who was responsible for checking blood glucose levels, the mean age was higher for the participants who selected the child/adolescent was responsible vs. the mean age of those who selected the parents or both the child and parents. This also shows the involvement of the adolescents in their self-care. This is supported by findings from a qualitative study where two of the themes that emerged from interviews were that children ages 9-12 years wanted to become more autonomous (to reduce demands on their parents), and be more involved in managing their diabetes (so they could spend more time with their friends) (Rankin et al., 2018). This is managed in practice-settings by ensuring that education is geared to both the parents and children/adolescents during counselling sessions.

In our study, as one might expect, there was a significant association between meal plan type and insulin regimen (IP vs. MDI), whereby the CHO counting group was more likely to use an IP compared to the SMP. However, perhaps of more relevance is that there were more participants on IPs vs. MDI in both groups. We observed no significant difference between mean A1C in participants on these different insulin regimens. This is not consistent with other studies in the literature, as IPs have been shown to improve A1C levels, lower glycemic variability, and result in fewer complications (Johnson et al., 2013, Elbarbary et al., 2013, Overgaard et al., 2015, Colino et al., 2016, Zabeen et al., 2016). A prospective observational study conducted by Deeb et al. found that patients who switched from MDI to IPs, had their mean A1C reduced by 1.09% ($p < 0.000$) for adolescents and young adults, who operated their own IPs, and 0.79% ($p= 0.09$) for school aged children, who depended on parents/guardians to operate the IPs (Deeb et al., 2019). Using IPs also decreased insulin doses by 6% ($p=0.03$) (Deeb et al., 2019). Patient's favored IPs over MDI as indicated by increased reported satisfaction with IPs (Deeb et al., 2019). In addition, other studies have shown that IPs increased patient and parent satisfaction, and caused overall improvement in quality of life (Rendell et al., 2013, Bayrakdar et al., 2014, Birkebaek et al., 2014). Future studies are required to assess the patient's experience with CHO counting and IPs.

The guidelines set by the Canadian Society for Exercise Physiology recommend a maximum of two hours daily of recreational screen time for children ages five years and above (Canadian Society for Exercise Physiology, 2011). In our study, the majority of the participants spent two or more hours on screen time. A systematic review and meta-analysis looking at screen time and overweight/obesity showed that children who spent two or more hours of screen time per day had an increased risk of being overweight/obese compared to those who spent less than two hours of screen time per day ($p<0.0001$) (Fang et al., 2019). While there was no significant association in our study between screen time and BMI-for-age, patients should be asked about screen time during clinic visits. This would give healthcare professionals the opportunity to discuss strategies to reduce screen time, with the patient and their families, as this may help improve glycemic control and prevent childhood obesity (Fang et al., 2019).

For children ages 5-11 years and youth ages 12-17 years, the Canadian Physical Activity Guidelines recommend at least 60 minutes of moderate to vigorous intensity physical activity daily (Canadian Physical Activity Guidelines, 2019). One of the findings of our study was a negative association between BMI-for-age and physical activity, meaning the participants who met the recommendation of at least 60 minutes of physical activity per day were more likely to have a normal/healthy BMI. This is very important as weight gain can occur with intensive insulin therapy. In particular, one review study found that the number of individuals with T1DM who were overweight and obese was higher than the general population and the prevalence of overweight and obesity is continuing to rise in this population (Driscoll et al., 2017). RDs and registered nurses can empower their patients to achieve the physical activity recommendations on a daily basis to help them obtain a normal/healthy BMI and ultimately help them optimize their glycemic control.

Only 17% of the total sample reported attending diabetes camp. Diabetes Canada plans two diabetes camps: Camp Huronda, which is located in the Muskoka Area and Camp Discovery, which is located in London, Ontario (Diabetes Canada, 2019). The cost is $1,100 for 6 days. The low attendance may be attributed to only having two camps in the summer in Ontario, the traveling distance from Windsor, transportation cost, or the cost of the camp. This is unfortunate because it has been shown that parents, teenagers, and children reported significant improvements in the campers' self-care skills after attending diabetes camp (Weissberg-Benchell et al., 2017). Additionally, campers from this study reported learning more information about diabetes, checking their blood glucose levels more often, counting CHOs accurately, sharing experiences with others who had diabetes, making new friends, and enjoying the camp

(Weissberg-Benchell et al., 2017). Therefore, diabetes camp provides campers with a safe environment to learn more about T1DM self-management and improve their self-care skills.

Overall, the facilitators identified for following the CHO counting approach included: flexibility of meal planning, with subthemes including time, tailored to preferences, and appetite. Another theme identified by the participants was the ability to match insulin to food intake more accurately. These are advantages with the CHO counting approach because patients can eat to appetite and then match their insulin based on their food intake.

In contrast, the major theme that made CHO counting difficult to follow was that it was hard to count CHOs. Specifically, 50% identified hard to count CHOs as a reason why it was difficult to follow the CHO counting approach. Similarly, 22% in the SMP approach identified this theme as a reason why they didn't use the CHO counting approach. This theme is similar to themes found by Rankin et al. which was participants required "strategies to minimize needing to perform complex math to count CHOs" and "lack of mathematical skills to count CHOs" (Rankin et al., 2018). A subtheme of why it was hard to count CHOs was eating out for both groups. For the CHO counting group additional subthemes for why it was difficult, were identified which included: effort required, less accurate matching of insulin to food intake if it is an unfamiliar meal, hyperglycemia, and hypoglycemia. This emphasizes the importance of teaching patients how to count CHOs in practice and to ensure they can do it in challenging situations. It would be beneficial if RDs continue to review CHO counting with their patients on a regular basis to assess difficulties and challenges. In practice currently, RDs educate patients using Your Game Plan handouts and Beyond the Basics Poster (Network of Ontario Pediatric

Diabetes Programs, 2007, Diabetes Canada, 2005). RDs can also provide patients with resources to help them count CHOs when they are eating out e.g., calorie counter books, such as the New Carb & Calorie Counter and Your Pocket Guide to Dining Out, which include the amount of CHOs in restaurant foods; applications like eatracker or myfitness pal; and they can also encourage and teach patients to look up menu options on restaurant websites before going out to eat (Carpender D, 2009, Poirier I and Cote G, 2003, Dietitians of Canada, 2019, Under Armour Inc, 2019).

Reasons for why it was easy to follow the CHO counting approach included the availability of the food label, experience/understanding CHO counting, flexible meal planning, and the use of IPs. The availability of the food label was identified as a major theme by the participants, likely because the food label provides the amount of CHOs and fibre for the families to be able to estimate the total available amount of CHOs per meal. The total available amount of CHOs is then inputted into the IP, so the correct amount of insulin is given to help achieve glycemic control. The use of IPs was favored by patients and increased their satisfaction in other studies as well (Rendell et al., 2013, Bayrakdar et al., 2014, Birkebaek et al., 2014, Deeb et al., 2019). Healthcare professionals can help patients following this approach start on IPs, educate them on food label reading, and ensure patients understand CHO counting thoroughly. RDs can have patients do a return demonstration during clinic visits or plan CHO counting group education sessions to help patients understand CHO counting further.

An example of a beneficial group session is called Kids in Control of Food (KICk-Off) (Price et al., 2016). This is a five-day group education course that provides interactive learning focused on CHO counting and insulin titration to meet the learning needs of adolescents with T1DM (Price et al., 2016). The educational structure with the topics to cover is also available, therefore, RDs can use this structure to run this program for their patients (Price et al., 2016). Price et al. found that the participants in the KICk-off program had an increase in their quality of life factors including physical and psychosocial domains, and a decrease in diabetes symptoms (Price et al., 2016). Taha et al. conducted a study to assess the effect of a culturally adapted KICk-Off course in Kuwait for youth ages 11-16 years with T1DM (Taha et al., 2014). They found this program to: increase the self-confidence of the youth in managing their diabetes, increase the mothers' confidence in allowing their adolescent to lead their own diabetes management, increase the knowledge about glucose metabolism, increase the feeling of autonomy, enhance coping skills with T1DM, allow an increase in social freedom, and decrease family stress related to T1DM (Taha et al., 2014).

hAnother study on an educational program was conducted in the Netherlands with 25 patients who had poorly controlled T1DM (Verbeek et al., 2011). This educational program focused on psychosocial factors, included three sessions for the patients and one session for the parents, and significantly (p=0.08) improved the A1C levels by 0.65% after 9 months of follow up (Verbeek et al., 2011). Additionally, St Joseph's hospital in London, Ontario has advanced CHO counting classes to assist patients in accurately counting CHOs, matching CHOs to insulin, and using insulin pumps (St. Joseph's Health Care London, 2019). Educational sessions can help patients with T1DM manage their diabetes more effectively and allow them to connect with other children/adolescents with T1DM as well.

Another theme, which was identified by a smaller number of participants, was the desire to be the same as other children/adolescents. This was identified by 7% of the participants in the CHO counting group and 7% in the SMP group. The ability to feel normal, and participate in eating and activities was important to the parents as identified by quotes from the survey. This is a small percent of the sample but may denote an important finding as this theme is similar to results found by Freeborn et al. who studied the challenges of living with T1DM from child and youth perspectives (Freeborn et al., 2013). After analyzing transcripts from the focus group, one of the themes that emerged was feeling different and/or alone (Freeborn et al., 2013). The authors discuss that feeling different or wanting to feel the same as their peers may hinder the patients from doing daily diabetes self-care activities such as checking blood glucose levels, taking insulin with meals, and/or treating a low blood glucose level, which would ultimately affect glycemic control and the child's overall well-being (Freeborn et al., 2013).

In the school setting, Peters et al. found that teachers and peers singled out children with T1DM when they checked their blood glucose levels and injected their insulin as they appeared to be different from their classmates (Peters at al., 2008). Diabetes Canada has school guidelines to help principals, parents, and students manage diabetes in the school setting (Diabetes Canada, 2014) These guidelines provide goals, information on managing hypoglycemia and hyperglycemia, roles and responsibilities of the parents, student, school personnel, and healthcare providers (Diabetes Canada, 2014). However, there was no specific guidelines for teachers. The theme of wanting to be the same as other children/adolescents and not feeling different is an important finding, which will be helpful if added to these guidelines to help teachers, principals, and school personnel avoid bias and ensure that children/adolescents with

T1DM feel more supported.

These findings are relevant to practice as healthcare professionals dealing with patients with T1DM should be trained to discuss these challenges and ensure patients do not feel different than their peers and alone. One studied conducted by Wagner et al. found that if youth were given the flexibility to decide where to perform self-care diabetes activities, they had significantly better glycemic control than those who had less flexibility (Wagner et al., 2006). The children who reported leaving the classroom for diabetes care activities had higher A1Cs than those who performed the activity in the class or were not restricted (Wagner et al., 2006). Therefore, RDs and registered nurses working with children/adolescents with T1DM should be encouraged to communicate with patients regarding these challenges, discuss the importance of checking blood glucose levels, if flexibility in self-care activities is an option, to ensure that patients feel supported and included with their peers.

Many of the themes related to the SMP approach were overlapping as well. This is illustrated as the same themes “not flexible” and “eating out”, which emerged from two different questions in regard to following the SMP. Participants identified these themes “not flexible” and “eating out” as a disadvantage and also why those on the CHO counting approach chose not to follow the SMP. The overlapping of the themes, may suggest saturation was achieved as the same theme kept emerging. Additionally, the overlapping of the themes from different participants and different questions shows the importance of these themes. Furthermore, participants in both groups identified hard to count CHOs when eating out as a challenge. This shows the importance of ensuring patients are routinely asked about their ability and experience in counting CHO during counseling sessions and that RDs continue to provide patients with additional education and CHO counting resources to help them overcome this challenge. The resources can be similar to ones used in other studies. One study done by Rhyner et al. found that using a mobile phone app called GoCARB helped participants count carbohydrates more accurately (Rhyner et al., 2016). A cross sectional study was conducted on 50 adults with T1DM, where participants were asked to fill out food diaries and to estimate the amount of CHOs per meal (Brazeau et al., 2013). Then, the RD inputted the food intake into the Food Processor SQL (ESHA) to compare the estimates (Brazeau et al., 2013). The results of this study showed that 63% of the 448 meals were underestimated by the participants, and lower accuracy of CHO counting was an indicator of longer duration of hyperglycemia (blood glucose value >10 mmol/L) and less time between 4-10 mmol/L (Brazeau et al., 2013).

Some of the participants following the SMP identified this approach to be more effective in terms of controlling their blood glucose levels and stated this was the reason why they chose the SMP over the CHO counting approach. Furthermore, some patients identified regular meal plans and insulin consistency as factors that made the SMP easy to follow. Following the SMP approach with a specific amount of CHOs at each meal period without eating to appetite like the CHO counting approach may be a rationale to help control blood glucose levels and weight. Contrary to these themes, some participants felt like the SMP was not flexible, restrictive, and not tailored to their appetite and preferences. This is another reason the SMP is difficult to follow as children/adolescents are growing and they are hungry between meals. The SMP has advantages and disadvantages, which need to be discussed with healthcare professionals, patients, and their family members to determine is this is the best option for the patient.

The strengths of this study included: 1.) the use of open-ended questions in the survey, which provided an insight on the perspective of parents and children on each meal plan approach; 2.) the potential use of these results in practice to help RDs understand the challenges with T1DM to help the patients optimize their metabolic control and improve their diabetes management; 3.) an observational study provides a reflection of the patient's experience from the clinic setting.

We acknowledge that the present study had some limitations, which included the low number of participants recruited and the unbalanced number between the groups. Therefore, the majority of analysis between the two groups was not feasible. Additionally, the majority of participants did not bring in their three-day food records to clinic visits, so we were unable to assess the accuracy of CHO counting. Proxy error may have occurred as some of the parents answered the survey on behalf of their children. Conducting a randomized control trial to assess the difference in A1C between the two groups would be a stronger study; however, this may not be feasible as there is a reduction in patients following the SMP as evidenced by our study.

Chapter 5
Conclusion

T1DM is a chronic, lifelong condition that requires ongoing diabetes education and interventions by an interprofessional healthcare team including RDs, registered nurses, social workers, and pediatric endocrinologists. Nutrition education is an integral component of diabetes management, which is effective in improving glycemic control by 1-2% (CPG, 2018).

During counseling sessions, nutrition education needs to address healthy eating, balanced meals between all of the food groups, limiting intake of fat and processed foods, CHO counting and consistency, physical activity, and SMBG levels. Clinicians should continue to monitor weight and ensure patients are within a healthy weight range for their age and gender. RDs conduct a 24-hour diet recall to assess CHO intake. If the CHO intake is high and glycemic targets are not met RDs provide further dietary counselling to their patients. RDs use CHO counting resources such as Beyond the Basics Poster, Your Game Plan-Dietary Principles, Your Pocket Guide to Dining Out, label reading, and CHO counting mobile applications to educate the patients (Diabetes Canada, 2005, Network of Ontario Pediatric Diabetes Programs, 2007, Poirier I and Cote G, 2003).

Overall, there was a very high proportion of participants in the CHO counting group compared to the SMP in this present study. There was no difference in mean A1C between the two groups. However, this may be due to the limitation of having unbalanced groups. BMI-for-age was higher in the CHO counting group compared to the SMP group. It is possible that using a CHO counting approach may negatively affect weight and BMI as patients can eat to appetite and more frequently. This approach may encourage overeating, unbalanced meals, and an increased consumption of processed foods. Additional factors that affect BMI include physical activity and screen time. Therefore, clinicians need to continue to counsel patients to consume balanced meals, engage in regular physical activity, and limit screen time to help promote glycemic control and weight maintenance.

The participants favored the CHO counting approach due to its flexibility in meal planning and being able to tailor it to their preferences and appetite. One of the major themes that emerged from the survey as a disadvantage of following both meal plan approaches was hard to count CHOs, especially when eating out and at restaurants. The use of IPs and food label availability can help patients and their families CHO count to optimize their glycemic control.

The present study explored familial factors that affect diabetes care in patients with T1DM. The qualitative results from this study provided a greater understanding of familial factors that influence glycemic control and patient perspectives regarding each meal plan approach. These factors can help healthcare professionals understand the challenges patients' face with each meal plan approach and their diabetes management. Healthcare professionals can then tailor the education and counselling sessions to assist patients to overcome these challenges.

To address the various challenges identified, patients need ongoing education and support with their nutrition care plans and frequent follow ups with their healthcare providers. Clinicians need to continue to identify the challenges that their patients face and provide interventions to allow their patients to effectively manage their diabetes to improve their blood glucose control, prevent microvascular and macrovascular complications, and ultimately reduce the daily burden of living with T1DM.

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Appendix A: Parent and Child 13 years+ Letter of Information and Consent Form

Project Title: Glycosylated hemoglobin (A1C) in children and adolescents with Type 1 Diabetes Mellitus using carbohydrate counting versus a structured meal plan.

Document Title: Letter of Information and Consent-Child 13 years or older or Parent / Legal Guardian / Substitute Decision Maker:

Principal Investigator:

Dr. Paula Dworatzek, Chair and Associate Professor, School of Food and Nutritional Sciences, Brescia University College at the University of Western Ontario.

Graduate Student: Alia El Kubbe, MScFN(c), RD School of Food and Nutritional Sciences, Brescia University College at the University of Western Ontario.

1. **Invitation to Participate**
   The pronouns 'you' and 'your' refer to the child with Type 1 Diabetes. You are being invited to participate in this research study that will see if A1c is different between the carbohydrate counting and structured meal plan groups.

2. **Purpose of this Study**
   The purpose of this study is to assess differences in A1c in children using carbohydrate counting vs. those using a structured meal plan.

3. **Length of the Study**
   It is expected that you will be in this study for 1 day.

4. **Study Procedures**
   If you agree to participate in this study, a chart review will be done to obtain your A1c blood values, height, weight and 3-day food record. Your BMI-for-age will be calculated by the research team. If you are 16 years or older (or your parent if you are under 16), you will complete an online survey, to assess your (or your parents' perspective) on the type of meal plan you follow and their involvement in your diabetes care. Only the research team involved in this study will have access to this information. We are aiming to recruit 180 participants.

5. **Possible Risks and Harms**
   There are no known or anticipated risks or discomforts associated with participation in this study. There will be no additional blood samples required to participate in this study. There is always a risk of privacy breach.

6. **Possible Benefits**
   This study may provide the Registered Dietitian the opportunity to provide the best possible meal planning advice to children with Type 1 Diabetes. This may also help you and your

family make a decision on which treatment is better to follow to help you achieve better glucose control.

7. **Participants can choose to leave the study**
   If you decide to withdraw from the study, you have the right to request withdrawal of information collected about you. If you wish to have your information removed please let the researcher know.

8. **Confidentiality**
   Representatives of The University of Western Ontario Health Sciences Research Ethics Board may contact you or require access to your study-related records to monitor the conduct of the research. All data collected will remain confidential and accessible only to the investigators of this study. If you choose to withdraw from this study, your data will be removed and destroyed. While we will do our best to protect your information there is no guarantee that we will be able to do so. The inclusion of your name and your date of birth may allow someone to link the data and identify you. If data is collected during the project, which may be required to report by law, we have a duty to report. The researcher will keep any personal information about you in a secure and confidential location for a minimum of 5 years. A list linking your study number with your name will be kept by the researcher in a secure place, separate from your study file. If the results of the study are published, your name will not be used.

9. **Compensation**
   You will not be compensated for your participation in this research.

10. **Voluntary Participation**
    Your participation in this study is voluntary. You may decide not to be in this study. Even if you consent to participate you have the right to not answer individual questions or to withdraw from the study at any time. If you choose not to participate or to leave the study at any time it will have no effect on your future diabetes care.

11. **Contacts for Further Information**
    If you require any further information regarding this research project or your participation or the results of this study you may contact Dr. Paula Dworatzek. If you have any questions about your rights as a research participant or the conduct of this study, you may contact The Office of Human Research Ethics.

This letter is yours to keep for future reference. Thank you.

12. Written Consent
Project Title:
Glycosylated hemoglobin (A1C) in children and adolescents with Type 1 Diabetes Mellitus using carbohydrate counting versus a structured meal plan.

Document Title: Letter of Information and Consent

Principal Investigator:
Dr. Paula Dworatzek, Chair and Associate Professor, School of Food and Nutritional Sciences, Brescia University College at the University of Western Ontario.
Co-investigator: Alia El Kubbe, MScFN(c), RD School of Food and Nutritional Sciences, Brescia University College at the University of Western Ontario.

I have read the Letter of Information, have had the nature of the study explained to me, and I agree to participate. All questions have been answered to my satisfaction.

By completing the attached consent form, you are consenting for your participation in this study and allow the study team members to review your clinic flow sheet to obtain your height, weight, 3-day food record, and A1c blood values.

Do you consent to the use of unidentified quotes obtained from the survey in the dissemination of this research?
☐ **YES** ☐ **NO**

Print Name of Child ________________________**Age** ______________

Parent / Legal Guardian / Substitute Decision Maker (Print): ________________________

Child 13 years old or above or Parent / Legal Guardian / Substitute Decision Maker

Sign: ___________________________________

Date: ___________________________________

My signature means that I have explained the study to the participant named above. I have answered all their questions.

Print name of Person Obtaining Consent________________________________
Signature of Person Obtaining Consent____________________________________
Date_______________________________

Appendix B: Parent Letter of Information and Consent Form

Project Title: Glycosylated hemoglobin (A1C) in children and adolescents with Type 1 Diabetes Mellitus using carbohydrate counting versus a structured meal plan.

Document Title: Letter of Information and Consent-Parent

Principal Investigator:

Dr. Paula Dworatzek, Chair and Associate Professor, School of Food and Nutritional Sciences, Brescia University College at the University of Western Ontario.
Graduate Student: Alia El Kubbe, MScFN(c), RD School of Food and Nutritional Sciences, Brescia University College at the University of Western Ontario.

1. **Invitation to Participate**
   The pronouns 'you' and 'your' refer to the parent of the child with Type 1 Diabetes. You are being invited to participate in this research study that will see if A1c is different between the carbohydrate counting and structured meal plan groups.

2. **Purpose of this Study**
   The purpose of this study is to assess differences in A1c in children using carbohydrate counting vs. those using a structured meal plan. By completing an online survey, your perspective will be assessed on the type of meal plan your child follows and your involvement in your child's diabetes care. You may complete the survey today.

3. **Length of the Study**
   It is expected that you will be in this study for 1 day and once you have completed the online survey you will be finished with the study.

4. **Study Procedures**
   If you agree to participate in this study, you are invited to complete the online survey during your clinic visit. It will take you about 7-10 minutes to complete. The 3-day food diary you fill out for your child for their clinic visit will also be used by the research team. Only the research team involved in this study will have access to this information. We are aiming to recruit 180 participants.
5. **Possible Risks and Harms**
   There are no known or anticipated risks or discomforts associated with participation in this study. There will be no additional blood samples required to participate in this study. There is always a risk of privacy breach.
6. **Possible Benefits**
   This study may provide the Registered Dietitian the opportunity to provide the best possible meal planning advice to children with Type 1 Diabetes. This may also help you and your family make a decision on which treatment is better to follow to help your child achieve better glucose control.

7. **Participants can choose to leave the study**
   If you decide to withdraw from the study, you have the right to request withdrawal of information collected about you. If you wish to have your information removed please let the researcher know.

8. **Confidentiality**
   Representatives of The University of Western Ontario Health Sciences Research Ethics Board may contact you or require access to your study-related records to monitor the conduct of the research. All data collected will remain confidential and accessible only to the investigators of this study. If you choose to withdraw from this study, your data will be removed and destroyed. While we will do our best to protect your information there is no guarantee that we will be able to do so. The inclusion of your child's name and date of birth may allow someone to link the data and identify them. If data is collected during the project, which may be required to report by law, we have a duty to report. The researcher will keep any personal information about your child in a secure and confidential location for a minimum of 5 years. A list linking your child's study number with their name will be kept by the researchers in a secure place, separate from their study file. If the results of the study are published, your name will not be used.

9. **Compensation**
   You will not be compensated for your participation in this research.

10. **Voluntary Participation**
    Your participation in this study is voluntary. You may decide not to be in this study. Even if you consent to participate you have the right to not answer individual questions or to withdraw from the study at any time. If you choose not to participate or to leave the study at any time it will have no effect on your child's future diabetes care.

11. **Contacts for Further Information**
    If you require any further information regarding this research project or your participation or the results of this study you may contact Dr. Paula Dworatzek. If you have any questions about your rights as a research participant or the conduct of this study, you may contact The Office of Human Research Ethics.

This letter is yours to keep for future reference. Thank you.

12. Written Consent

Project Title:
Glycosylated hemoglobin (A1c) in children and adolescents with Type 1 Diabetes Mellitus using carbohydrate counting versus a structured meal plan.

Document Title: Letter of Information and Consent-Parent

Principal Investigator:
Dr. Paula Dworatzek, Chair and Associate Professor, School of Food and Nutritional Sciences, Brescia University College at the University of Western Ontario.

Co-investigator: Alia El Kubbe, MScFN(c), RD School of Food and Nutritional Sciences, Brescia University College at the University of Western Ontario.

I have read the Letter of Information, have had the nature of the study explained to me, and I agree to participate. All questions have been answered to my satisfaction.

By completing the attached consent form, you are consenting for your participation in this study and allow the study team members to review the online survey.

Do you consent to the use of unidentified quotes obtained from the survey in the dissemination of this research?
☐ **YES** ☐ **NO**

Print Name of Child _________________________Age _______________
Parent Participant (Print): _____________________________________
Parent Participant (Sign): _____________________________________
Parent Participant (Date): _____________________________________

My signature means that I have explained the study to the participant named above. I have answered all their questions.
Print name of Person Obtaining Consent__________________________________
Signature of Person Obtaining Consent______________________________________
Date_________________________________

Appendix C: Assent Letter

Project Title: Glycosylated hemoglobin (A1C) in children and adolescents with Type 1 Diabetes Mellitus using carbohydrate counting versus a structured meal plan.

Document Title: Assent Letter

Principal Investigator: Dr. Paula Dworatzek, Associate Professor, School of Food and Nutritional Sciences, Brescia University College at the University of Western Ontario.
Co-investigator: Alia El Kubbe, MScFN(c), RD School of Food and Nutritional Sciences, Brescia University College at the University of Western Ontario.

12. **Why are you here?** You are being invited to take part in a study that looks at your food intake, hemoglobin A1c, weight, height, and your diabetes.
13. **Why are they doing this study?** The researchers in this study would like to see if blood sugar levels and diabetes control is different with carbohydrate counting compared to a structured meal plan.

14. **What will happen to you?**
    If you want to be in the study, two things will happen:
    1. The researchers will collect information about you, such as your hemoglobin A1c, meal plan, food records, weight, and height from your clinic visits.
    2. Your parent(s) will be asked to fill out a survey that asks questions about your health, food intake, and blood sugar levels.

15. **Will there be any tests?** Nothing in addition to your regular clinic visit.

16. **Will the study help you?** This study may help you and other children with diabetes, by looking at the best way to plan your meals.

17. **Do you have to be in the study?** You do not have to be in the study. No one will be upset at you if you do not want to be in this study. If you do not want to be in the study, tell the researchers or your parents. Even if you say yes, you can change your mind later. It is up to you.
18. **What if you have any questions?** You can ask questions at any time, now or later. You can talk to the research team, your family, and/or the Diabetes Team.

This letter is yours to keep for future reference. Thank you

8. Assent
I want to participate in this study.
Print Name of Child ______________________
Date________________________________

Age __________________________________
Name of Person Obtaining Assent____________________________________
Signature of Person Obtaining Assent____________________________________

Appendix D: Screening Tool

Questions:	Yes	No
Is the child less than 4 years or older than 18 years of age?		
Has the child had diabetes for less than 1 year?		
Does the child have celiac disease?		
Does the child take medications for attention deficit hyperactivity disorder (ADHD) or any other medications, other than insulin, that affect their blood glucose levels (e.g. steroids)?		

If any of the above are "yes", the participant is not eligible to participate in the study.

Appendix E: Instructions to complete the online survey

1.) Enter the following code: ____________________________

2.) Parents of children ages 4-15 please fill out the **parent survey.**

3.) Adolescents ages 16-18 please fill out the **adolescent survey.**

4.) You can also download the QR code app and scan the following QR code.

Appendix F: Parent Survey

Block 1

.
Project Title: Glycosylated haemoglobin (A1c) in children and adolescents with Type 1 Diabetes Mellitus using carbohydrate counting versus a structured meal plan.
Investigators: Dr. Paula Dworatzek, RD, Associate Professor and Alia El Kubbe MScFN (c), RD, School of Food and Nutritional Sciences, Brescia University College at the University of Western Ontario; and Michelle Knezic, RD, Windsor Regional Hospital.

Parent Version

Q1. **What is your child's ID number?**

Q2.
What is your child's birth date?

Month

Day

Year

Q3. **What grade is your child in?**

Q4. **What is your child's sex?**

Male ○ Female ○ Other ○

Q5. **At what age was your child diagnosed with diabetes?**

Q6.

What medications is your child currently taking, other than insulin?

Q7. **Does your child have any of the following health conditions?**

○ Celiac Disease

○ Attention Deficit Hyperactivity Disorder (ADHD)

○ Other

Q8. **What type of insulin regimen is your child on?**

○ Multiple Daily Injections

○ Insulin Pump

Q9.

What is your child's current insulin schedule?

○ 3 times/day (Breakfast, Lunch, Dinner)

○ 4 times/day (Breakfast, Lunch, Dinner, Bedtime)

○ Insulin Pump

○ Other, please specify:

_Q10._
When does your child typically check his/her blood sugar levels?
Please respond to each below.

Breakfast

Snack

Lunch

Snack

Dinner

Bedtime

_Q11._ Who checks your child's blood sugar levels?

○ My child checks them

○ Parent/Caregiver checks them

○ Other, please specify:

_Q12._

How often are you involved in planning your child's meal plans?

Never	Sometimes	About half the time	Most of the time	Always

Q13.
How often are you involved in the management of your child's diabetes?

	Never	Sometimes	About half the time	Most of the time	Always

0 10 20 30 40 50 60 70 80 90 100

Q14.
How often are you flexible with your child's food intake?

	Never	Sometimes	About half the time	Most of the time	Always

0 10 20 30 40 50 60 70 80 90 100

Q15. **What meal plan approach do you follow for your child?**

Set carbohydrate with a meal plan: is a well-balanced meal plan that specifies a set amount of carbohydrates at each meal.

Variable carbohydrate counting with matching insulin ratio: is a flexible dietary approach, where carbohydrate grams are counted at meals and then insulin is matched.

◯ Set carbohydrate with a meal plan

◯

Variable carbohydrate counting with matching insulin ratio

Block 2 Set CHO with meal plan

Q16. **How many years has your child been following the set carbohydrate with a meal plan approach?**

Q17. **How confident are you in following the set carbohydrate with a meal plan approach?**

Not at all Confident	Somewhat Confident	Moderately Confident	Very Confident	Extremely Confident

0 10 20 30 40 50 60 70 80 90 100

Q18. **How often do you count carbohydrates to follow the meal plan?**

Never	Sometimes	About half the time	Most of the time	Always

0 10 20 30 40 50 60 70 80 90 100

Q19. **How often do you find it difficult to follow the set carbohydrate with a meal plan approach?**

Never	Sometimes	About half the time	Most of the time	Always

Q20. **Does your child know how to count carbohydrates to follow the meal plan?**

○ Yes

○ No

Q21. **Please describe the advantages of following the set carbohydrate with a meal plan approach.**

Q22. **Please describe the disadvantages of following the set carbohydrate with a meal plan approach.**

Q23. **What makes it easy to follow this meal plan?**

Q24. **What makes it difficult to follow this meal plan?**

Q25. **An alternative approach to following the set carbohydrate with a meal plan approach is following the variable carbohydrate counting with insulin ratio approach, please tell us why you are not using this approach.**

Block 4

***Q26.* What is your child's current level of physical activity during a typical day?**

- <30 minutes/day
- 30-59 minutes/day
- 60-90 minutes/day
- More than 90 minutes/day

***Q27.* How many hours of the day does your child spend in front of a screen (including TV, computer, tablet or smartphone)?**

- <2 hours/day
- 2-4 hours/day
- >4 hours/day

***Q28.* Has your child attended a diabetes camp before?**

- Yes
- No

***Q29.* What is the highest level of education that the mother (or primary caregiver) of the child has completed?**

- Less than high school
- High school
- College
- University

Q30. **What is your yearly total household income?**

- Less than $25,000
- $25,000 - $49,999
- $50,000 - $74,999
- $75,000 - $99,999
- More than $100,000

Block 3 Variable CHO Counting with insulin ratio

Q31. **How many years has your child been following the variable carbohydrate counting with insulin ratio approach?**

Q32. **How confident are you in following the variable carbohydrate counting with insulin ratio approach?**

Not at all Confident	Somewhat Confident	Moderately Confident	Very Confident	Extremely Confident

0 10 20 30 40 50 60 70 80 90 100

Q33. **How often do you follow the variable carbohydrate counting with insulin ratio approach?**

Never	Sometimes	About half the time	Most of the time	Always

0 10 20 30 40 50 60 70 80 90 100

Q34. **How often do you find it difficult to follow the variable carbohydrate counting with insulin ratio approach?**

	Never	Sometimes	About half the time	Most of the time	Always

0 10 20 30 40 50 60 70 80 90 100

Q35. **Does your child know how to follow the variable carbohydrate counting with insulin ratio approach?**

○ Yes

○ No

Q36. **Please describe the advantages of following the variable carbohydrate counting with insulin ratio approach.**

Q37. **Please describe the disadvantages of following the variable carbohydrate counting with insulin ratio approach.**

Q38. **What makes it easy to follow the variable carbohydrate counting with insulin ratio approach?**

Q39. **What makes it difficult to follow the variable carbohydrate counting with insulin ratio approach?**

Q40. **An alternative approach to following the variable carbohydrate counting with insulin ratio approach is the set carbohydrate with a meal plan approach, please tell us why you are not using this approach.**

Appendix G: Adolescent Survey

Block 1

Project Title: Glycosylated haemoglobin (A1c) in children and adolescents with Type 1 Diabetes Mellitus using carbohydrate counting versus a structured meal plan.
Investigators: Dr. Paula Dworatzek, RD, Associate Professor and Alia El Kubbe MScFN (c), RD, School of Food and Nutritional Sciences, Brescia University College at the University of Western Ontario; and Michelle Knezic, RD, Windsor Regional Hospital.

16 years and older Version

Q1. **What is your ID number?**

Q2.
What is your birth date?

Month

Day

Year

Q3. **What grade are you in?**

Q4. **What is your sex?**

Male	Female	Other
○	○	○

Q5. At what age were you diagnosed with diabetes?

Q6.
What medications are you currently taking, other than insulin?

Q7. Do you have any of the following health conditions?

- Celiac Disease
- Attention Deficit Hyperactivity Disorder (ADHD)
- Other

Q8. What type of insulin regimen are you on?

- Multiple Daily Injections
- Insulin Pump

Q9.
What is your current insulin schedule?

- 3 times/day (Breakfast, Dinner, Bedtime)
- 3 times/day (Breakfast, Lunch, Dinner)

- 4 times/day (Breakfast, Lunch, Dinner, Bedtime)
- Insulin Pump
- Other, please specify:

Q10.
When do you typically check your blood sugar levels?
Please respond to each below.

Breakfast

Snack

Lunch

Snack

Dinner

Bedtime

Q11. **Who checks your blood sugar levels?**

- I check them
- Parent/Caregiver checks them
- Other, please specify:

Q12.
How often are you involved in planning your meal plans?

Never	Sometimes	About half the time	Most of the time	Always

0 10 20 30 40 50 60 70 80 90 100

Q13.
How often are you involved in the management of your diabetes?

Never	Sometimes	About half the time	Most of the time	Always

0 10 20 30 40 50 60 70 80 90 100

Q14.
How often are you flexible with your food intake?

Never	Sometimes	About half the time	Most of the time	Always

0 10 20 30 40 50 60 70 80 90 100

Q15. **What meal plan approach do you follow?**

Set carbohydrate with a meal plan: is a well-balanced meal plan that specifies a set amount of carbohydrates at each meal.

Variable carbohydrate counting with matching insulin ratio: is a flexible dietary approach, where carbohydrate grams are counted at meals and then insulin is matched.

- ○ Set carbohydrate with a meal plan
- ○ Variable carbohydrate counting with matching insulin ratio

Q16. **How many years have you been following the set carbohydrate with a meal plan approach?**

Q17. **How confident are you in following the set carbohydrate with a meal plan approach?**

Not at all Confident	Somewhat Confident	Moderately Confident	Very Confident	Extremely Confident

0 10 20 30 40 50 60 70 80 90 100

Q18. **How often do you count carbohydrates to follow the meal plan?**

Never	Sometimes	About half the time	Most of the time	Always

0 10 20 30 40 50 60 70 80 90 100

Q19. **How often do you find it difficult to follow the set carbohydrate with a meal plan approach?**

Never	Sometimes	About half the time	Most of the time	Always

0 10 20 30 40 50 60 70 80 90 100

Q20. **Do you know how to count carbohydrates to follow the meal plan?**

- ○ Yes
- ○ No

Q21. **Please describe the advantages of following the set carbohydrate with a meal plan approach.**

Q22. **Please describe the disadvantages of following the set carbohydrate with a meal plan approach.**

Q23. **What makes it easy to follow this meal plan?**

Q24. **What makes it difficult to follow this meal plan?**

Q25. **An alternative approach to following the set carbohydrate with a meal plan approach is following the variable carbohydrate counting with insulin ratio approach, please tell us why you are not using this approach.**

***Q26*. What is your current level of physical activity during a typical day?**

- ○ <30 minutes/day
- ○ 30-59 minutes/day
- ○ 60-90 minutes/day
- ○ More than 90 minutes/day

***Q27*. How many hours of the day do you spend in front of a screen (including TV, computer, tablet or smartphone)?**

- ○ <2 hours/day
- ○ 2-4 hours/day
- ○ >4 hours/day

***Q28*. Have you attended a diabetes camp before?**

- ○ Yes
- ○ No

***Q29*. What is the highest level of education that your mother (or primary caregiver) has completed?**

- ○ Less than high school
- ○ High school
- ○ College
- ○ University

***Q30.* What is your families yearly total household income?**

- ○ Less than $25,000
- ○ $25,000 - $49,999
- ○ $50,000 - $74,999
- ○ $75,000 - $99,999
- ○ More than $100,000

Block 3 Variable CHO Counting with insulin ratio

***Q31.* How many years have you been following the variable carbohydrate counting with insulin ratio approach?**

***Q32.* How confident are you in following the variable carbohydrate counting with insulin rati approach?**

Not at all Confident | Somewhat Confident | Moderately Confident | Very Confident | Extremely Confident

0 10 20 30 40 50 60 70 80 90 100

***Q33.* How often do you follow the variable carbohydrate counting with insulin ratio approach?**

Never | Sometimes | About half the time | Most of the time | Always

0 10 20 30 40 50 60 70 80 90 100

***Q34.* How often do you find it difficult to follow the variable carbohydrate counting with insulin ratio approach?**

	Never	Sometimes	About half the time	Most of the time	Always

0 10 20 30 40 50 60 70 80 90 100

***Q35.* Do you know how to follow the variable carbohydrate counting with insulin ratio approach?**

○ Yes

○ No

***Q36.* Please describe the advantages of following the variable carbohydrate counting with insulin ratio approach.**

***Q37.* Please describe the disadvantages of following the variable carbohydrate counting with insulin ratio approach.**

***Q38.* What makes it easy to follow the variable carbohydrate counting with insulin ratio approach?**

Q39. **What makes it difficult to follow the variable carbohydrate counting with insulin**

ratio approach?

Q40. **An alternative approach to following the variable carbohydrate counting with insulin ratio approach is the set carbohydrate with a meal plan approach, please tell us why you are not using this approach.**

Appendix H: Clinic Data Collection Form

Chart Data Collection Form-OFFICE USE ONLY

	Value	**Date**
Height (cm)		
Weight (kg)		
A1c (%) Value #1		
A1c (%) Value #2		

Treatment Plan

What treatment plan does the child follow? Please check only one.

☐ Carbohydrate Counting ☐ Structured Meal Plan

If using structured meal plan specify CHO amount (g) per meal:

Breakfast	
AM snack	
Lunch	
PM snack	
Dinner	
Evening snack	

Appendix I: 3 Day Food Record Example: List Food (Include food, amount, brand names, & carb value)

My blood glucose correction is: 1 unit drops blood glucose ______mmol/L.

Breakfast	Am Snack	Lunch	Pm Snack	Supper	Evening Snack
Time: 7:15 **Blood Sugar:** 8.4 **Meal Bolus:** 2.5 u NR **Correction:** **Total Bolus:** _2.5 u NR_ **Activity:**	**Time:** 10:00 **Blood Sugar:** **Meal Bolus:** **Correction:** **Total Bolus:** ________ **Activity:** Recess	**Time:** 11:30 **Blood Sugar:** 11.8 **Meal Bolus:** 3 u NR **Correction:** 1 u NR **Total Bolus:** 4 u NR **Activity:** Active Play	**Time:** 2:15 **Blood Sugar:** 15.4 **Meal Bolus:** **Correction:** **Total Bolus:** ______ **Activity:** Recess & walked home	**Time:** 5:00 **Blood Sugar:** 9.3 **Meal Bolus:** 4 u NR **Correction:** 1 u NR **Total Bolus:** _5 u NR **Activity:** Homework	**Time:** 8:00 **Blood Sugar:** 22.7 **Meal Bolus:** 1.5 u NR **Correction:** 2 u NR **Total Bolus:** _1.5 u NR_ **Activity:** Rollerblading 1 hour
½ cup cherrios 11 grams	1 yogurt (Yoplait) 19 grams	3 celery sticks 0 grams	1 chocolate pudding (Jello) 33 grams	1 cup penne pasta 30 grams	5 cups (Orville Smart Pop) popcorn 22.5 grams
½ milk (2%) 7.5 grams	1 chocolate chip cookie (Chips Ahoy) 10 grams	1 turkey sandwich on whole wheat with mustard 30 grams		½ meat sauce 11 grams	1 diet pop 0 grams
1 slice whole wheat toast with peanut butter 15 grams		1 medium pear 15 grams	After School Snack at 3 pm 2 cheese strings 5 ritz crackers 10 grams	1 cup salad with vegetables and ranch dressing 2 grams	
½ cup apple juice 15 grams		Sugar free Kool-aid 0 grams		1 cup milk 15 grams	
½ cup milk (2%) 7.5grams				¾ cup strawberries Cool Whip 7 grams	
Total Carb: 56g	**Total Carb:** 29 g	**Total Carb:** 45 g	**Total Carb:** 33 & 10g	**Total Carb:** 65 g	**Total Carb:** 22.5 g

My insulin:carb ratio is: __1_____unit for __20____grams of carb (breakfast).
My insulin:carb ratio is: _______unit for _______grams of carb (breakfast).
My insulin:carb ratio is:__1_____unit for __15____grams of carb (lunch).
My insulin:carb ratio is: ___1____unit for ___15___grams of carb (supper).
My insulin:carb ratio is: __1_____unit for __15____grams of carb (bedtime snack).

My blood glucose correction is: 1 unit drops blood glucose ______ mmol/L.

Breakfast **Time:** **Blood Sugar:** **Meal Bolus:** **Correction:** **Total Bolus:** _ _ **Activity:**	Am Snack **Time:** **Blood Sugar:** **Meal Bolus:** **Correction:** **Total Bolus:** ________ **Activity:**	Lunch **Time:** **Blood Sugar:** **Meal Bolus:** **Correction:** **Total Bolus:** **Activity:**	Pm Snack **Time:** **Blood Sugar:** **Meal Bolus:** **Correction:** **Total Bolus:** ______ **Activity:**	Supper **Time:** **Blood Sugar:** **Meal Bolus:** **Correction:** **Total Bolus:** **Activity:**	Evening Snack **Time:** **Blood Sugar:** **Meal Bolus:** **Correction:** **Total Bolus:** **Activity:**
Total Carb:	**Total Carb:**	**Total Carb:**	**Total Carb:**	**Total Carb:**	**Total Carb:**

My insulin:carb ratio is: _______unit for _______grams of carb (breakfast).
My insulin:carb ratio is: ________unit for _______grams of carb (lunch).
My insulin:carb ratio is: ________unit for _______grams of carb (supper).
My insulin:carb ratio is: ________unit for _______grams of carb (bedtime snack).

Appendix J: Sample Size Calculation

Based on the RD account of the patient roster at WRH Diabetes Education Centre it was estimated that there were 300 patients with T1DM (personal communications with Michelle Knezic, RD, CDE). Of these 300, it was estimated that 60% were using CHO counting while 40 % were following a SMP (personal communications with Michelle Knezic, RD, CDE).

Based on a study by Stein et al., where they were successful in recruiting 91% of potential participants, and had complete data on 82% of these participants; we assumed 90% recruitment with 85% providing complete data (Stein et al., 2016).

The following sample size equation for comparing two means was used, with an adjustment for unequal groups (as described below): $n = 2 (Z_{1-\alpha/2} + Z_{1-\beta})^2 \times \sigma^2 / \Delta^2$

where $Z_{1-\alpha/2}$=1.96 and $Z_{1-\beta}$ =0.84, assuming $p \leq 0.05$ and a power of 80%

Estimates based on Stein et al. (Stein et al., 2016) assumed $\sigma = 0.8$ and the Δ for A1C that is considered clinically relevant = 0.3 (CPG, 2018).

$n = 2 (Z_{1-\alpha/2} + Z_{1-\beta})^2 \times \sigma^2 / \Delta^2$ $n = 2 (1.96 + 0.84)^2 \times 0.8^2 / 0.3^2$

n = (15.68) x 0.64/0.09 n = 15.68 x 7.11 n = 112 participants per group

We estimated unequal groups so we required an adjustment to n, based on the following formula (Kirkwood, 2003). The adjustment factor is f, where f = (c + 1) / 2c, where c = ratio of the larger group to the smaller group. In our case c = 60/40 = 1.5, therefore f = (1.5 + 1) / 2(1.5) = 0.833. The final sample size estimates were: fn = n x f = 112 x 0.833 = 93 for the SMP group, and cfn = c x fn = 1.5 x 93 = 140 for the CHO counting group. Therefore, 93 individuals were needed in the SMP group and 140 in the CHO counting group (total = 233) to have an 80% chance of detecting a clinically meaningful difference between the 2 groups, assuming an α of 5% and SD of 0.8.

Appendix K: Ethics Approval Forms from Western University Ethics Board

Western Research

Research Ethics

Western University Health Science Research Ethics Board
HSREB Delegated Initial Approval Notice

Principal Investigator: Dr. Paula Dworatzek
Department & Institution: Brescia\Nutrition and Food Sciences, Brescia University College

Review Type: Delegated
HSREB File Number: 109558
Study Title: Glycosylated haemoglobin (A1c) in children and adolescents with Type 1 Diabetes Mellitus using carbohydrate counting versus a structured meal plan.

HSREB Initial Approval Date: February 02, 2018
HSREB Expiry Date: February 02, 2019

Documents Approved and/or Received for Information:

Document Name	Comments	Version Date
Western University Protocol		2018/01/11
Instruments	3 Day Food Record	2017/07/07
Data Collection Form/Case Report Form		2017/07/06
Instruments	Parental Online Survey - Received July 13, 2017	
Letter of Information & Consent	Child	2018/01/11
Caregiver Letter of Information & Consent	Parent	2018/01/11
Assent		2018/01/11

The Western University Health Science Research Ethics Board (HSREB) has reviewed and approved the above named study, as of the HSREB Initial Approval Date noted above.

HSREB approval for this study remains valid until the HSREB Expiry Date noted above, conditional to timely submission and acceptance of HSREB Continuing Ethics Review.

The Western University HSREB operates in compliance with the Tri-Council Policy Statement Ethical Conduct for Research Involving Humans (TCPS2), the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use Guideline for Good Clinical Practice Practices (ICH E6 R1), the Ontario Personal Health Information Protection Act (PHIPA, 2004), Part 4 of the Natural Health Product Regulations, Health Canada Medical Device Regulations and Part C, Division 5, of the Food and Drug Regulations of Health Canada.

Members of the HSREB who are named as Investigators in research studies do not participate in discussions related to, nor vote on such studies when they are presented to the REB.

The HSREB is registered with the U.S. Department of Health & Human Services under the IRB registration number IRB 00Q00940.

Date: 22 August 2018

To: Paula Dworatzek

Project ID: 109558

Study Title: Glycosylated haemoglobin (A1c) in children and adolescents with Type 1 Diabetes Mellitus using carbohydrate counting versus a structured meal plan.

Application Type: HSREB Amendment Form

Review Type: Delegated

Full Board Reporting Date: 04/Sep/2018

Date Approval Issued: 22/Aug/2018 14:25

REB Approval Expiry Date: 02/Feb/2019

Dear Paula Dworatzek ,

The Western University Health Sciences Research Ethics Board (HSREB) has reviewed and approved the WREM application form for the amendment, as of the date noted above.

Documents Approved:

Document Name	Document Type	Document Date	Document Version
LetterofinformationandConsentform13+orParent	Consent Form	22/Jun/2018	2
Qualtrics Survey-16yearsandolderversion	Online Survey	22/Jun/2018	1
RevisedWesternProtocol (Aug 12)	Protocol	12/Aug/2018	1

Documents Acknowledged:

Document Name	Document Type	Document Date	Document Version
WRH Ethics Approval - 18-338 Cat A 20180530	Sponsor Correspondence	10/Jun/2018	1

REB members involved in the research project do not participate in the review, discussion or decision.

The Western University HSREB operates in compliance with, and is constituted in accordance with, the requirements of the TriCouncil Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2); the International Conference on Harmonisation Good Clinical Practice Consolidated Guideline (ICH GCP); Part C, Division 5 of the Food and Drug Regulations; Part 4 of the Natural Health Products Regulations; Part 3 of the Medical Devices Regulations and the provisions of the Ontario Personal Health Information Protection Act (PHIPA 2004) and its applicable regulations. The HSREB is registered with the U.S. Department of Health & Human Services under the IRB registration number IRB 00000940.

Please do not hesitate to contact us if you have any questions.

Sincerely,

Katelyn Harris, Ethics Officer on behalf of Dr. Joseph Gilbert, HSREB Chair

Note: This correspondence includes an electronic signature (validation and approval via an online system that is compliant with all regulations).

Appendix L: Ethics Approval from WRH Ethics Board

WINDSOR REGIONAL HOSPITAL
OUTSTANDING CARE – NO EXCEPTIONS!

Research Ethics Board
Windsor Regional Hospital
1995 Lens Avenue
Windsor, Ontario
N8W 1L9

Meeting Review Date:	May 30, 2018
Project Title:	The Difference in A 1 c of Children and adolescents with Type 1 Diabetes Mellitus Using Carbohydrate Counting Compared to Those Using a Structured Meal Plan
Principal Investigator:	Dr. Paula Dworatzek Alia El Kubbe
Site PI:	Michelle Knezic
REB File Reference:	18-338

SUBMISSIONS REVIEWED:

- Revised Informed Consent documents for parent/caregivers and consent documents for youth 16 or older
- Revised Surveys for parent/caregivers and surveys for youth 16 or older

TYPE OF APPROVAL:

[X] Category A: **Approved**
[ ] Category B: **Approval – with some concerns addressed – Board Comments attached**
[ ] Category C: **Decision Deferred. More information / revisions required - Comments attached**
[ ] Category D: **Not Approved**

Thank you for providing the additional information requested by the WRH Research Ethics Board for consideration. A quorum was present and only Research Ethics Board members who are independent of the investigator(s) conducting the study participated in decisions relating to this research.

This Research Ethics Board is constituted and operated in accordance with the Tri-Council Policy Statement for Ethical Conduct of Research Involving Humans (TCPS), Canadian Food & Drug Regulations, Division 5 (Clinical Trials), ICH Good Clinical Practice Guidelines E6, U.S. Code of Federal Regulations Title 21 & 45.

Any amendments to protocol must be submitted for REB approval. Please use above REB reference number on all correspondence. This approval is for one year and expires on May 29, 2019. Should you wish to continue the research beyond this, application for renewal must be submitted. Applicable forms are available by email from erin.link@wrh.on.ca.

Curriculum Vitae

Name:	Alia El Kubbe
Post-secondary Education and Degrees:	University of Western Ontario Honors Specilization in Nutriton and Dietetics 2009-2013 BSc.
	University of Western Ontario Masters of Science in Foods and Nutrition Candidate 2016-2019 MScFN(c)
	Dietetic Practicum London, Ontario 2014-2015 RD
Awards:	Dr. Patricia M. Giovannetti Graduate Studies Award 2016
Related Work Experience:	Registered Dietitian Diabetes Education Program Grand Bend Area Community Health Centre 2018-Present
	Registered Dietitian Diabetes Education Program West Elgin Community Health Centre 2017-2018
	Teaching Assistant Food Science Course and Lab 2016-2017
Publications:	Ahmadi, L, El Kubbe, A, Roney S. Potential Cardio-Protective Effects of Green Grape Juice: A Review. Cur Nutr & Food Sc. 2019;15 (3): 202-7.