EFFECT OF STRUCTURED CAREGIVER NUTRITION EDUCATION ON MANAGEMENT OF PAEDIATRIC TYPE 1 DIABETES IN UGANDA: A CLUSTER RANDOMIZED TRIAL

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DECLARATION

This thesis is my original work and has not been presented for a degree in any other University or any other award.

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This thesis is dedicated to Elizabeth, Ezekiel, Nehemiah and Natalia. Thank you for the love and unconditional support.

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TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

LIST OF ABBREVIATIONS AND ACRONYMS

AADE	American Association of Diabetes Educators
ADA	American Diabetes Association
ANCOVA	Analysis of Covariance
ANOVA	Analysis of Variance
CDiC	Changing Diabetes in Children
CHO	Carbohydrate
DAFNE	Dose Adjustment for Normal Eating
DE	Design Effect
DDQ	Dietary Diversity Questionnaire
DDS	Dietary Diversity Score
DHS	Demographic and Health Survey
DIAMOND	Diabetes Mondiale
DiD	Difference in Differences
DKA	Diabetic Ketoacidosis
F	Fisher's *F* ratio
FAO	Food and Agriculture Organization
FGD	Focus Group Discussions
GAD	Glutamic Acid Decarboxylase
H_0	Hypothesis under test
HbAlc	Glycated Haemoglobin
HDDS	Household Dietary Diversity Score
HLA	Human Leukocyte Antigen
ICC	Intra-cluster Correlation Coefficient
ICR	Insulin to Carbohydrate Ratios
IDDM	Insulin-Dependent Diabetes Mellitus
IDDS	Individual Dietary Diversity Score
IDF	International Diabetes Federation
IFG	Impaired Fasting Glycaemia
IGT	Impaired Glucose Tolerance
ISPAD	International Society for Pediatric and Adolescent Diabetes
IU	International Units
KAP	Knowledge Attitude and Practices
KES	Kenyan Shillings
KII	Key Informant Interviews
MAR	Mean Adequacy Ratio
Mdn	Median
n	Number of cases in a subsample
N	Total number of cases
η^2	Eta-squared
NAR	Nutrient Adequacy Ratio
NKS	Nutrition Knowledge Survey
OGTT	Oral Glucose Tolerance Test
r	Effect size
R^2	Measure of strength of association
rho	Estimate of Spearman's rank correlation coefficient
SMBG	Self-Monitoring of Blood Glucose
SOP	Standard Operating Procedure
St	Saint

t	Independent samples t-test
T1D	Type 1 Diabetes
T1DM	Type 1 Diabetes Mellitus
T2DM	Type 2 Diabetes Mellitus
U	The Mann-Whitney test statistic
UAE	United Arab Emirates
UDA	Uganda Diabetes Association
US	United States
USD	United States Dollar
VIF	Variance Inflation Factor
WHO	World Health Organization
$\chi 2$	Chi-Square
z	Standardised score

DEFINITION OF TERMS

Diabetic ketoacidosis: The biochemical criteria for the diagnosis of diabetic ketoacidosis (DKA) are hyperglycemia (blood glucose >11 mmol/L [≈ 200 mg/dL]), venous pH <7.3 or serum bicarbonate <15 mmol/L and ketonemia (blood ß-hydroxybutyrate ≥ 3 mmol/L) or moderate or large ketonuria (Chiang et al., 2018).

Glycated haemoglobin: HbA1c (glycated haemoglobin) provides information about average blood glucose levels over the last 2-3 months. This test measures the amount of glucose that attaches to haemoglobin (Ogle et al., 2017).

Hyperglycaemia: Impaired fasting glucose measure of 6.1 to 6.9mmol/l (110mg/dl to 125mg/dl) (Steyn et al., 2006).

Hypoglycaemia: Blood glucose measure of less than 3.9 mmol/L (70mg/dl) (Ogle et al., 2017).

OPERATIONAL DEFINITION OF TERMS

Adverse event:	An unexpected medical problem that happens during treatment with a drug or other therapy and may be caused by something other than the drug or therapy being given.
Compliance:	Degree or extent of conformity to the recommendations about day- to- day treatment by the provider with respect to the timing, dosage, and frequency.
Dietary diversity:	The number of selected food groups consumed by a household or individuals over a reference period, such as a one day (Ty & Krawinkel, 2016).
Effectiveness:	Producing a result that is wanted, having an intended effect.
Good glycaemic control:	HbA1c (glycated haemoglobin) of less than 7.5% (58 mmol/mol) (Elise et al., 2019).
Nutrient adequacy:	Nutrient adequacy is the comparison between the nutrient requirement and the intake of a certain individual or population (Castro-Quezada et al., 2014).
Socio-demographic characteristics:	Individual’s age, level of education, marital status, occupation, religion, wealth index and family size.
T1DM management practices:	Compliance with recommended dietary practices and medical advice.

ABSTRACT

Nutrition education is a vital component in the successful management of diabetes among paediatric type 1 diabetes mellitus (T1DM) patients. However, in Uganda, no published study has been done to find out if nutrition education affects the nutrition knowledge of caregivers and the glycaemic and dietary outcomes of their children.This study, therefore, evaluated the effect of the provision of a structured nutrition education course to caregivers of children and adolescents with T1DM on their level of type 1 diabetes nutrition knowledge and their children's glycaemic control, dietary intake and diversity (DDS) in Uganda. The study was a cluster-randomised controlled trial in which study participants were randomly assigned to two groups; a control group and an intervention group at a ratio of 1:1. The total sample size was 100 caregiver-child dyads. Data was collected at baseline and 3 months post-intervention. The participants in the control group continued to receive routine medical care, while those in the intervention group received routine medical care and attended a structured group nutrition education course. The intervention lasted 12 weeks, it consisted of eight face-to-face sessions lasting 45 minutes each. The primary outcome was glycated haemoglobin (HbA1c) and the secondary outcomes (caregivers' level of nutrition knowledge, children's DDS and mean adequacy ratio (MAR). Data was collected using researcher-administered questionnaires. The data was analysed using SPSSVersion 26. Descriptive statistics such as frequencies, percentages, mean, standard deviation and medianwere used to describe the demographic, socioeconomic, diabetes-related characteristics, nutrient and dietary adequacy from the 24-hour recall. Independent samples t-test, Mann–Whitney *U*-test, analysis of variance (ANOVA) and Kruskal-Wallis Htest were used to determine the differences in continuous variables between the study groups. A Chi-square test was used to test for associations among categorized variables between the study groups.Spearman's rank correlation coefficient was used to test for an association between the caregiver's T1DM nutrition knowledge and dietary intake indices. The baseline findings revealed that 87.6%of the caregivers had low T1DM nutrition knowledge and this was significantly different across the levels of education (Kruskal-Wallis Htest: p = 0.007). Most type 1 diabetic children and adolescents had a mean DDS of 5.5 with adequate carbohydrate and protein but were found to be at risk of essential fatty acid and micronutrient deficiencies. The children's mean HbA1c, DDS and MAR after the intervention were HbA1c (intervention: 10.87 versus control: 10.86; p= 0.347), (intervention: 5.93 versus control: 5.26; p=0.006) and (intervention: 0.81 versus control: 0.77; p = 0.021) respectively. The intervention group had a higher mean type 1 diabetes nutrition knowledge score (45.14%) compared to the control group (33.73%). There was no significant difference in the children's HbAlc levels following their caregiver's participation in the structurednutrition education course (Wilcoxon signed-rank test: p = 0.748). However, there was a 0.7 % decrease in the children's HbAlc levels in the intervention group 3 months after the intervention compared to a 0.1 increase in the control group. A significant positive correlation between the caregiver's nutrition knowledge scores and nutrient adequacy ratios (NARs) of vitamin B_6, biotin, folic acid, and iron were observed (Spearman's rank correlation: p< 0.05). Based on the gaps in the existing nutrition education module, a nutrition education guide for caregivers of children with T1DM in Uganda was developed and used during the intervention. This study concluded that structured nutrition education for caregivers of paediatric T1D patients can improve their nutrition knowledge and their children's overall dietary adequacy. Therefore, the study recommends the developed contextualized guide should be used to conduct nutrition education sessions with caregivers of children with T1DM.

CHAPTER ONE: INTRODUCTION

1.0 Introduction

This chapter focuses on the background to the study, problem statement, purpose of the study, objectives of the study, hypotheses of the study, significance of the study, delimitations of the study, limitations of the study, strengthens of the study, assumption of the study and the conceptual framework of the study and its theoretical rationalization.

1.1 Background to the study

Diabetes mellitusis a life long chronic metabolic condition that develops when the body fails to manufacturesufficient insulin or is unable to utilise the insulin it manufactures effectively, due to its worldwide increase and burden of co-morbidities and premature deaths diabetes mellitus is now considered a worldwide health priority (Butt et al., 2016). The main types of diabetes are type 2 diabetes mellitus (T2DM) which is associated with lifestyle factors such as sedentary behaviour and obesity, and type 1 diabetes mellitus (T1DM) which hasan autoimmune pathophysiology (Chatterjee et al., 2018).T1DM is the most commontype of diabetesamongchildren and adolescents and can present at any age(Hasan et al., 2021; International Diabetes Federation, 2019).

T1DM is an autoimmune response in which the body's immune system attacks the insulin-producing beta cells resulting in the body producing limited or no insulin. The development of T1DM has been linked to genetic susceptibility, viral infections and environmental risk factors. Individuals with T1DM require daily insulin injectionsto maintain near-normal glucose levels. In addition, they need to regularly pay attention to their blood glucose levels, insulin administration and dietary intake. Furthermore, they require education and support (American Diabetes Association, 2018; International Diabetes Federation, 2019; Troncone et al., 2020). Additionally, T1DM requires multidimensional clinical care and lifelong involvement and significantly influences the psychological, physical and emotional state in children and adolescents with T1DM and their caregivers (d'Annunzio et al., 2020).

The incidence of T1DM is increasing globally, however with substantial variations across countries and regions(International Diabetes Federation, 2019). The mechanisms underlying the variations in geographical incidence rates and increased incidence rates of T1DM are currently unknown but it is stipulated that the environment plays a role (Atkinson et al., 2014). Over 1,000,000 children and adolescents are estimated to have T1DM globally. Approximately 98,200 children under the age of 15 years are diagnosed with T1DM annually. The regions estimated to have the largest number of prevalent type 1 diabetes are Europe, North America and the Caribbean. India, Brazil and the United States of Americahave the largest number of children and adolescents with new and existing T1DM. In terms of incidence per 100,000 population per year, Finland (62.3 per 100,000) and Sweden (43.2 per 100,000) have the highest incidence rates of type 1 diabetes among children and adolescents aged 0–14 years (Carracher et al., 2018; International Diabetes Federation, 2019).

Data on the incidence of T1DM in children and adolescents in the African region especially in sub-Saharan Africa are scarce, though the burden of T1DM is increasing(Ogugua et al., 2021). It is estimated thatover 25,000 children and adolescents have T1DM in Africa, with10,300 new cases every year. However, due to the limited number of data sources, estimates for Africa should be interpreted with caution as most of the data have been extrapolated from the few studies conducted (International Diabetes Federation, 2019). A recent study in Rwanda by Marshall et al. (2015)documented the prevalence and incidence of TIDM at 4.8 per 100,000 and 1.2 per 100,000 per year for those less than 15 years respectively. Older studies conducted in the African region by Afoke et al. (1992) and (Elamin et al., 1997)documented the prevalence of T1DM as 0.33 per 1000 in Nigerian children and 0.95 per 1000 in Sudanese school children. In Sudan and Tanzania, incidence was documented at 10.1 per 100,000 per year and 1.5 per 100,000 per year respectively (Elamin et al., 1992; Swai et al., 1993).

According to Bahendeka (2017), the estimated number of children and adolescents with T1DM has been increasing in Uganda from about 150 in 2009 to almost 800 by 2014 witha very high morbidity and mortality rate. Before 2009, children and adolescents with T1DM in Uganda were often treated inthe T2DM clinics oroutpatient clinics. However, in 2009, a project was foundedto establish a harmonised system for the comprehensive management of children and adolescents with T1DM(Diabetes Care Uganda, 2017). The project helped to establish specialised paediatric T1DM clinics at 4 health facilities namely; Mulago National Referral Hospital, Arua Regional Referral Hospital, St. Francis Hospital, and Wakiso Health Centre IV. In 2010, a consortium of Changing Diabetes in Children (CDiC) for Uganda as a result of a partnership between Novo Nordisk and Roche Pharmaceuticals was formed. Under the consortium, children and adolescents with T1DM received supplies of insulin,lancing devices, glucose meter strips for self-monitoring of blood glucose (SMBG) and syringes(Bahendeka et al., 2019).

The quality of life of individuals with T1DM has greatly improved over the years due toimprovements in the management and treatment of T1DM. However, the challenges of inadequate patient education and psychosocial support still exist. These need to be addressed to improve the future care of patients with T1DM across Africa (Godman et al., 2020). Furthermore, the effect of nutrition education and caregivers' influence as aspects of diabetes care and management have not been adequately researched in sub-Saharan Africa, and yet caregiver-focused nutrition education has been shown to improve blood glucose control and help reduce the risk of developing complications(Muchiri et al., 2016; Tuomilehto, 2013).

According to Ochola and Masibo (2014) and Kyokunzire and Matovu (2018),strengthening caregiver participation in the children's diet could help improve adherence to dietary recommendations. A nutrition education intervention study by Patton et al. (2014) that focused on caregivers involvement during mealtimes also reported a reduction in the mean daily blood glucose levels among young children with T1DM. Therefore, if caregivers are empowered with sufficient and up-to-date nutrition knowledge through structured nutrition education sessions they can serve as positive change agents and therefore bring about a change in their children's feeding behaviours and disease outcomes(Sunguya et al., 2013). However, like in many other least developed countries; access to structured nutrition education sessions in Uganda is limited and is probably contributing to inadequately controlled paediatric T1DM. It is therefore important that children and adolescents diagnosed with T1DM and their caregivers be educated and trained with adequate nutritional management knowledge and skills to enable themto manage and survive the onset of T1DM safely and successfully (Lange et al., 2014; Nansel et al., 2015; Ogle et al., 2017).

1.2 Problem statement

Type 1 diabetic children regularly need the support of their caregivers to assist them to conduct their T1DM-related care tasks.Furthermore, the nutrition management of T1DM requires collaboration with the caregiver as they play a fundamental role in the dietary management of chronic disease in children (Pugh et al., 2021; Rosolowsky et al., 2018). A caregiver's nutritional management knowledge is vital in assisting children to attain and maintain good metabolic control (Ogle et al., 2017).Several studies have demonstrated the influence of caregivers' level of diabetes knowledge on T1DM care and management. Additionally, caregivers influence their children's food choices and the timing of meals (Verdonschot et al., 2021).

A study conducted among paediatric patients with T1DMdocumented a correlation between caregiver level of nutrition knowledge and better glycaemic control (Beck & Cogen, 2015).In Tanzania, a statistically significant correlation between diabetes knowledge of the caregivers and their children's glycated haemoglobinwas also reported(Noorani et al., 2016). In Kenya, a study also found a significant association between the nutrition knowledge level of caregivers and the dietary practices of their children (Chege & Kuria, 2017). A study conducted in Uganda suggested strengtheningand supporting caregiver participation in the children'sdiet could help improve compliance with dietary recommendations (Kyokunzire & Matovu, 2018; Ochola & Masibo, 2014).

When made simple to comprehend and centred on the patient and their caregiver, nutrition education improves blood glucose control and helps reduce the risk of the development of diabetes-related complications (Chiang et al., 2018; Muchiri et al., 2016). However, caregiver focused nutrition education is little explored in sub-Saharan Africa, despite being an essential component in the management of paediatric diabetes. The role modelling function of caregivers in the development of healthy eating behaviours in children is recognized in most nutrition education interventions, however, most often active involvement of the caregivers at home isnot considered (Morgan et al., 2020; Verdonschot et al., 2021).

In Uganda, no study has been conducted to establish if nutrition education of children with T1DM and their caregivers has an effect on glycaemic control, nutrition knowledge and dietary practices despite literature evidencing the crucial role of caregivers in achieving optimal T1DM outcomes. In addition, there is little evidence about the impact of parental caregiving on glycaemic control of their children. Ugandadoes not have astructured nutrition education course for type 1 diabetic patients and their caregivers. The lack of structured nutrition education courses for type 1 diabetic patients has been cited as one of the reasons contributing to the suboptimal management of type 1 diabetic patients in Africa(Mbanya et al., 2020). Furthermore,the nutrition education module in the current diabetes education curriculum is not Ugandan contextualized for the paediatric T1DM patients for example, Ugandan food sources examples are not included, secondly, topics such as the MyPlate model, glycaemic index, the importance of fresh fruits and vegetables and how to interpret food labels are lacking. In addition, there is no facilitator’s manual with specified instructional methods and teaching materials required to aid the delivery of the content during a nutrition education session. And yet structured therapeutic education is fundamental in paediatric diabetes management in order to empower their ability to successfully manage their condition. Furthermore, educational interventions have been shown to have a positive effect on blood glucose management in adolescents (Zhao et al., 2021). Additionally, it is still not clear if the involvement of caregivers in children's nutrition education interventions contributes to the effectiveness of the interventions. Therefore, there is still a gap in the evidence from studies involving individuals with T1DM with respect to the effect of nutrition education, hence having a better understanding may contribute to the development and effectiveness of future culturally appropriate nutrition education interventions (Dehayem et al., 2016; Sterner Isaksson et al., 2021).

1.3 Purpose of the study

The purpose of this study was to develop and evaluate the effect of the provision of a structured nutrition education course to caregivers of children with T1DM attending selected T1DM clinics in Uganda, on their level of type 1 diabetes nutrition knowledge and their children's glycaemic control, dietary intake and diversity.

1.4 Objectives of the study

The objectives of this study were;

1. To determine the demographic and socio-economic characteristics of caregivers of children (3-14 years) with T1DM at selected hospitals in Uganda.

2. To assess the level of T1DM nutrition knowledge among caregivers of children (3-14 years) with T1DM at selected hospitals in Uganda.

3. To analyse the dietary intake and nutrient adequacy of children (3-14 years) with T1DM at selected hospitals in Uganda.

4. To develop a structured nutrition education course for caregivers and children (3-14 years) with T1DM at selected hospitals in Uganda.

5. To determine the effect of nutrition education on the level of T1DMnutrition knowledge of caregivers of children (3-14 years) with T1DM at selected hospitals in Uganda.

6. To assess the effect of nutrition education of caregivers of children (3-14 years) with T1DM on HbAlc levels of their children at selected hospitals in Uganda.

7. To establish the relationship between caregiver's level of T1DM knowledge and HbA1c, dietary diversity, macronutrient intake, nutrient and mean adequacy ratios.

1.5 Hypotheses of the study

H_{01}. There is no statistically significant association between caregiver's level of T1DMnutrition knowledge and HbAlc levels of children (3-14 years) with T1DM.

H_{02}. There is no statistically significant association between caregiver's level of T1DM nutrition knowledge and nutrient adequacy ratios of children (3-14 years) with T1DM.

H_{03}. Nutrition education has no significant effect on caregiver's level of T1DM nutrition knowledge.

H_{04}. Nutrition education of caregivers has no significant effect on children's dietary diversity and mean adequacy ratio.

H_{05}. Nutrition education of caregivers has no significant effect on children's HbA1c levels.

1.6 Significance of the study

The study provided data on the level of knowledge about T1DM and dietary management practices of caregivers with children diagnosed with T1DM and can be used to identify other possible areas that can be improved by the Ministry of Health, the Uganda Diabetes Association (UDA) and other healthcare providers. The study led to the development and pre-testing of a nutrition education guide that addresses the identified gaps in nutrition knowledge and dietary management practices of paediatric type 1 diabetes patients in Uganda. The findings of the study have also added to the body of knowledge on T1DM.

1.7 Delimitations of the study

The study was only conducted among caregivers of and type 1 diabetic children and adolescents aged 3-14 years attending selected diabetes clinics in Uganda. Therefore, generalizations can only be made to similar populations or other areas with similar characteristics.

1.8 Limitations of the study

The use of a 24 hour-recall to assess dietary intake depended on the participant's ability to recall. This could have introduced recall bias during data collection. To overcome recall bias, quantification of food consumed was done using household measures (Bradburn et al., 1987; Hassan, 2005). The 24-hour dietary recall was also conducted on two separate days during the week on a weekday and weekend to cater for day-to-day variability in foods consumed.Another potential limitation of the study was that it only assessed nutrition knowledge and dietary intake at a point in time, a longitudinal study would have been an ideal study design to compare caregivers' nutrition knowledge and children's dietary intake over different seasons in time. In addition, the study did not track changes in insulin regimes and dosages and this could have had an effect on glycaemic control and hence affected the detection of a statistically significant reduction in HbA1c.

1.9 Strengths of the study

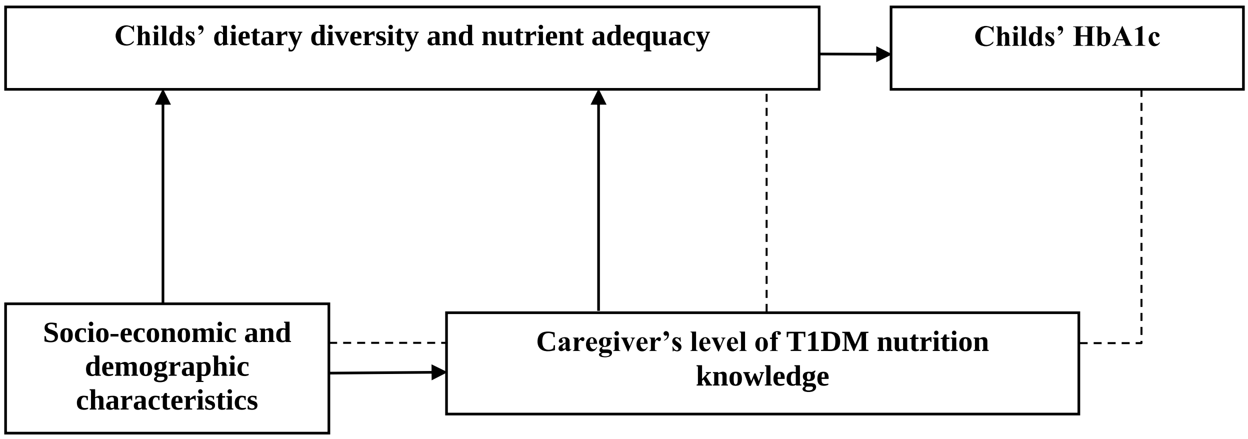
In terms of strengths, the study did identify caregiverknowledge deficits such as carbohydrate counting that need to be addressed. A pilot study was conducted before the trial, this ensured that the trial processes were tested and corrected before the actual trial. There was concealment of which study arm the participants would be allocated to during the recruiting phase of the trial. In addition, the clinics (clusters) were randomly assigned furthermore, the biostatistician was blinded to control for bias during data analysis, and the study had a low attrition rate. In addition, one of the key outputs of this study was facilitator and participant training guides for structured nutrition education of caregivers of children and adolescents with type 1 diabetes, these guides are applicable in the East African region due to the similarity in the types of food consumed. Furthermore, the findings of the studyhave built on the extant literature by providing preliminary evidence to help inform larger studies to further examine the nutrition knowledge of caregivers of children and adolescents with T1D in the sub-Saharan region.

1.10 Assumption of the study

The study assumed that there was no major change in the dietary practices of the study population during the study period.

1.11 Conceptual framework

The conceptual framework recognizes the relationship between the dependent variables (child's HbAlc level, dietary diversity, nutrient adequacy, caregiver's level of T1DM nutrition knowledge) and the independent variables (socio-economic and demographic characteristics). The relationships are illustrated in Figure 1.1.



Source: Primary author

Note. This figure illustrates the relationship between the dependent and independent variables.

Figure 1.1Conceptual framework of the study

In this study, both cross-sectional and longitudinal associations were analysed. Specifically, the cross-sectional and longitudinal associations between caregiver's level of T1DM nutrition knowledge, child's dietary diversity score, nutrient adequacy and HbA1c. In addition, the moderating roles of socioeconomic and demographic characteristics, disease duration, family history of T1DM and insulin regime were also explored.

Figure 1.1 demonstrates that socio-demographic characteristics such as socioeconomic status (SES), household size, marital status and educational attainment affect metabolic control and influence compliance with diabetes management and treatment recommendations(Abubakari et al., 2016; McBrien et al., 2016). For example; a study by Tahirovic and Toromanovic (2010) reported that low SES was significantly associated with higher levels of HbA1c. Ellis and Jayarajah (2016), reported that 17.1 % of the variance in adherence in adolescents with T1DM was due to socio-demographic factors. The Pittsburgh Epidemiology of Diabetes Complications study found that individuals with type 1 diabetes from lower SES backgrounds were more likely to poorly self-manage and experience more diabetes-related complications (Secrest et al., 2011). Therefore, understanding the socio-demographic characteristics of paediatric patients with type 1 diabetes is vital because early efforts to establish optimal glycaemic control happens within the broader social environment. In addition, caregivers of a low SES when faced with a diabetes-related problem of their child engage in few coping activities and hardly identify a primary care provider as the main point of contact (Walker et al., 2015). Consequently, socio-economic and demographic characteristics are potential effect modifiers of the association between caregiver's level of T1DM nutrition knowledge and the child's HbA1c. These characteristics may therefore play a role in differences in HbA1c levels. The potential effect modification by socio-economic and demographic characteristicshas been represented by a dotted line in the conceptual framework.

The framework also hypothesizes that a caregiver's level of T1DM nutrition knowledge has an impact on the degree of metabolic control (Stefanowicz et al., 2016). For example, a study by Fahimeh et al. (2015) reported that a higher awareness of a mother about T1DM was correlated with better glycaemic control in their children. It is, therefore, vital that individuals with diabetes mellitus and their caregivers appreciate the basics about diabetes mellitus such as the type of diabetes they were diagnosed with, signs and symptoms, treatment plan, and the importance of maintaining optimal glycaemic control (Mabaso & Oduntan, 2016). However, as earlier mentioned, research considering nutrition education as an element of T1D education is not well documented in sub-Saharan Africa, thus studies about how nutrition education affects glycaemic control are limited but a study by Wilson et al. (2003) reported that clinical nutrition education is associated with favourable trends in glycaemic control. Another study by Moskovitz et al. (2018), reported that improvednutrition knowledge amongcaregivers of children with T1DM was associated with an HbA1c of ≤ 9%. Caregivers that are well-informed about diabetes and its related complications are more likely to adhere to the recommended dietary practices and thus reduce the likelihood of the development of complications in the patients they look after (Herath et al., 2017; Saleh et al., 2012).Therefore, previous nutrition and diabetes education/training is a potential confounder of the relationship between the child's HbA1c and caregiver's level of T1DM nutrition knowledge.

1.12Theoretical rationalization ofthe conceptual framework

The concept of reciprocal determination derived from Bandura’s social learning theory is the connecting theory in the conceptual framework of the study (Bandura & McClelland, 1977). Reciprocal determination denotes that behaviours are not just the result of personal and environmental factors but rather behaviours, the environmental and personal factors constantly interact and any change to either will affect the other. For example, a caregiver may decide to include more vegetables and fruits in the family’s meal plan after attending a nutrition education session (behaviour). This behaviour may lead to an attitude change that it is possible to include more vegetables and fruits in one’s diet (personal factor). This may lead to morehealthy food options being available in the home setting for other family members such as the children to consume (environment). Additionally, caregivers tend to have significant influence over their children’s eating behaviours through modelling, which can eventually lead to children adopting positive eating behaviours(Crockett et al., 1988; Phillips & Orton, 1983). Therefore, a caregiver’s level of T1DM nutrition knowledge can influence the child’s dietary intake and nutrient adequacy as hypothesized in the conceptual framework (Figure 1.1).

CHAPTER TWO: LITERATURE REVIEW

2.0 Introduction

This chapter presents an overview of type 1 diabetes, its nutritional management and the role of nutrition education and caregivers in its management. The literature has been presented under several headings reflective of the study objectives.

2.1 Overview of diabetes mellitus

Diabetes is a group of metabolic disorders that present with hyperglycaemia due to defects in insulin secretion, insulin action, or both. Different pathogenic processes are responsible for the development of diabetes. These include autoimmune destruction of the beta-cells of the pancreas resulting inabsolute insulin deficiencyand abnormalities that result in insulin resistance and action (American Diabetes Association, 2018).

Diabetes is diagnosed as glycated haemoglobin A1c (HbA1c) ≥ 6.5% (48 mmol/mol) which is surveillance of glycaemic controlfor the last three months. The other diagnostic tests are random plasma glucose level ≥ 11.1mmol/L(200mg/dL),fasting plasma glucose level ≥ 7.0mmol/L (126mg/dL) or a plasma glucose level ≥ 11.1mmol/L (200mg/dL) 2 hours after a 75g load of glucose givenorally (the oral glucose tolerance test – OGTT) (International Diabetes Federation, 2019).

There are two main types of diabetes: type 1 which is caused byautoimmune destruction of the insulin-producing beta-cells of the pancreas and type 2 which is due to both impaired insulin secretion and resistance to its action. However, other types of diabetes do exist such as impaired glucose tolerance (IGT), impaired fasting glycaemia (IFG) and gestational diabetes mellitus (GDM). There is also monogenic diabetes which isa result of a genetic mutation. Examples of monogenic diabetes include maturity-onset diabetes of the young and neonatal diabetes mellitus. Secondary diabetes arises as a complication of other diseases, such as hormone disturbances (e.g., Cushing's disease or acromegaly) or diseases of the pancreas. Symptoms of diabetes include polyuria, polydipsia, weight loss, polyphagia, and blurred vision. In children, growth impairment and susceptibility to certain infections also occur (American Diabetes Association, 2018; Fortunato et al., 2016; International Diabetes Federation, 2019).

Ogle et al. (2017), mention that diabetes complications not only lead to severe morbidity but at times to mortality. Complications of diabetes can be classified as either macrovascular complications such as peripheral vascular disease, cardiovascular disease and cerebrovascular and or microvascular complications such as retinopathy which results in visual loss and blindness, nephropathy which can lead to hypertension and renal failure and neuropathy which can cause muscle weakness and autonomic dysfunction(Harding et al., 2019). Another significant complication in type 1 diabetics is using less insulin than prescribed which can lead to growth failure and pubertal delay in children(Ogle et al., 2017).

2.1.1 Overview of the pathophysiology of type 1 diabetes mellitus (T1DM)

Type 1 diabetes mellitus is formerly referred to as insulin-dependent diabetes or juvenile-onset diabetes(Fortunato et al., 2016). T1DM is often diagnosed in childhood and adolescence but it can present at any age, usually presenting with ketoacidosis as the first sign of the disease and usually manifests with a classic trio of symptoms namely; abnormal thirst, constant hunger and frequent urination, in addition to hyperglycaemia due to a total deficiency of insulin secretion and/or ketoacidosis in the presence of an infection or other stress (Shojaeian & Mehri-Ghahfarrokhi, 2018).

There is consensus that T1DM is an autoimmune disorder that results from an immune-mediated attack on the insulin-secreting beta-cells of the pancreas, resulting in the development of one or more autoantibodies directed against islet-specific antigens in the patients' bodies(Rich & Concannon, 2015). Although, not all T1DM patients possess this characteristic; this has led to another school of thought that has proposed a classification of type 1A or autoimmune diabetes which accounts for 85% to 90% of T1DM for patients presenting with autoimmune properties, and the rest whose specific pathogenesis is not clear to be classified as type 1B (Svärd, 2022).

2.2 Prevalence and incidence of type 1 diabetes mellitus

Globally age-standardized prevalence of diabetes in the adult population has nearly doubled since 1980 from 4.7% to 8.5%. In the past ten years, diabetes prevalence has risen faster in low and middle-income countries compared to high-income countries (WHO, 2016).

Distinguishing type 1 and type 2 diabetes requires laboratory tests for pancreas function. However, many countries do not have the necessary facilities and equipment to perform these tests, thus distinct global estimates of the prevalence of diabetes for type 1 and type 2 do not exist (WHO, 2016). The current estimated number of people with diabetes is close to 463 million; thus, the number of those with T1DM is approximately 46 million as individuals with T1DM make up approximately 10 % of all cases of diabetes. It is estimated that more than 90,000 children aged 15 years and below develop T1DM globally annually. It is further estimated that 600,900 children under 15 years of age are living with type 1 diabetes (International Diabetes Federation, 2019).

Recent data shows that the incidence of type 1 diabetes varies among countries with an increase in all parts of the world. Nordic countries have the highest incidence rates; Finland and Sweden with more than 60 per 100,000 per year and 47 per 100,000 per year respectively. Another place with a high rate is Sardinia (40 per 100,000 per year) an autonomous region of Italy in the Mediterranean Sea (Della Manna et al., 2016; Samuelsson et al., 2020).

A meta-analysis study by Mobasseri et al. (2020) documented the incidence and prevalence of type 1 diabetes in the world at 15 per 100,000 population and 9.5 per 10,000 people respectively. In the same study, the incidenceof type 1 diabetes inEurope was 15 per 100,000 populationand the prevalence was 12.2 per 10,000 people. The United States ranks second worldwide with an annual number of incident cases in the 0–14 age group at 14,700 (Patterson et al., 2019).

In Africa, very few countries have incidence and prevalence data for the 0–14 years agegroup. However, incidence among type 1 diabetic children aged 15 years and below in Eritrea has been documented at 11.5 per 100,000 individuals with the highest incidence (19per 100,000) among those aged 10 to14 years (Mebrahtu et al., 2021). In Mali, as of 2016, the incidence and prevalence rates among type 1 diabetic children aged 15 years and below were reported at 0.35 per 100,000 per year and 1.02 per 100,000(Sandy et al., 2021). In Rwanda, a study by Marshall et al. (2015)reported that the prevalence of TIDM at 4.8 per 100,000 in those aged 15 years and below.

Incidence figures were reported at 1.2 per 100,000 per year for the same age group. Despite the low incidence ratesin the African region, the estimated deaths among type 1 diabetic children are high (Patterson et al., 2019). The major challenge regarding type 1 diabetes in most countries in sub-Saharan Africa is limited documentation of the pattern of incidence and prevalence of the condition (Ganu, 2020).

In Uganda, the prevalence of type 1 diabetes has not been documented. However, the number of type 1 diabetic children has increased from approximately 178 children in 2009 to 1187 by 2018. Currently, there are over 600 children enrolled at the Nsambya CDiC programme clinics and about 70 children at the different clinics under the auspice of the Ministry of Health Uganda. Unfortunately, many of the would-be type 1 diabetic cases in Uganda are never diagnosed and those that are diagnosed often experience early onset of complications due to poor management of their condition (Bahendeka et al., 2019; Bahendeka, 2017).

2.2.1 Management of TIDM in Uganda

Children and adolescents with T1DM in Uganda were often managed in the T2DM clinics or outpatient clinics However, in 2009 a project that aimed to create a harmonised system for the comprehensive management of children and adolescents with T1DM was established (Diabetes Care Uganda, 2017). The project established clinics along the chronic care model and were integrated into the health structure of the management of other chronic diseases.

All children with diabetes below 18 years of age were encouraged to enrol on the programme by attending the nearest established T1DM clinic. At the start of the programme, only 178 type 1 diabetic patients were receiving care in various health facilities with established T1DM clinics. By 2018 the programme had a total of 32 clinics with 1187 children and adolescents. At the clinics, the children and adolescents receive supplies of insulin, lancing devices, glucose meters, testing strips and syringes. However, the established T1DM clinics still face difficulties in conducting timely diagnosis, providing adequate care and helping children and adolescents achieve pre-defined glycated haemoglobin (HbA1c) goals (Bahendeka et al., 2019).

2.3 Socio-demographic characteristics and type 1 diabetes mellitus

Abubakari et al. (2016) point out that appropriate self-management skills which include lifestyle and behavioural changes in areas such as meal and dietary planning, monitoring and interpretation of blood glucose and compliance to medication are a prerequisite to minimise the risk of developing complications associated with type 1 diabetes and ensure improved health outcomes. In addition, a patient’s level of understanding, motivation and compliance may also be unfavourably affected by their SES(Jansen et al., 2018).

Socio-demographic characteristics influencecompliance with self-management (Abubakari et al., 2016; McBrien et al., 2016). Other studies have reported that socio-demographic characteristics such as marital status, family density (size), the level of education andSESaffect metabolic control and the development of health complications(Butalia et al., 2013). A survey carried out on children and adolescents aged 5 to 18 years at the Muhimbili National Hospital clinic for diabetes in Tanzania by Noorani et al. (2016) reported lower mean HbA1c levels among children with mothers as the primary caregivers as compared to those whose caregivers were a father, a sibling or another family member.

Parents or caregivers of children with a chronic disease such as T1DM find it difficult to adapt to their child's illness and are often subject to distress. However, single parents may be more distressed as they often carry the burden alone (Mullins et al., 2011; Söderström et al., 2014). A study by Thompson et al. (2001) reported that children from two-parent households had lower HbA1c levels, improved metabolic control and higher adherence to blood glucose monitoring and meal frequency than single-parent households.According to Caccavale et al. (2015), high family density (family's total child to adult ratio) and parenting multiple children may impact a parent's ability to be involved in disease care behaviours and lessen financial resources. This can also contribute to poorer adherence, especially in lower socioeconomic groups.

Type 1 diabetes mellitus in the paediatric population has a major economic impact on patients, as patients have to take insulinreplacement therapies for the rest of their lives. In addition,patients are often hospitalized due to severe hypoglycaemic or ketoacidosis as well as other type 1 diabetes associated illnesses thus incurring health care costs. Apart from the financial costs associated with treatment, considerable time is also dedicated to childcare by the parents and or caregivers. Thus, the burden of care and the opportunity cost of time spent on informal care is also a highly relevant cost that is incurred (López-Bastida et al., 2017).

This study,therefore,established the socio-demographic characteristics of caregivers of children and adolescents with T1DM and explored the various associations with dietary diversity, nutrient adequacy and HbA1c. The findings further guided the development of an education tool tailored to the needs of type 1 diabetics and their caregivers in Uganda.

2.4 Nutrition knowledge and type 1 diabetes mellitus

The major treatment goal for type 1 diabetic children is to achieve and maintain normoglycemia and also ensure the appropriate healthy growth of the child. A caregiver's knowledge of T1DM; in particular, its nutritional management and their active involvement in their child's diabetes management are crucial tools to achieving the above-mentioned goals (Ogle et al., 2017). A study by Noorani et al. (2016) conducted in Tanzania reported a significant association between diabetes knowledge of caregivers with HbA1c levels.

A study by Chege and Kuria (2017), documented that the caregiver's nutritional knowledge level was significantly associated with dietary practices, the study, therefore, recommended that interventions that aim to educate caregivers on good nutritional and dietary practices be initiated. Another study conducted in Ghana found an effect of caregiver feeding behaviours on the child's nutritional outcomes (Nti & Lartey, 2007). However, most of the studies conducted observed the association between a caregiver's nutrition knowledge and the child's nutritional status. Studies that assess the impact of caregivers' knowledge on metabolic control of children with T1DM are lacking.

Berlin et al. (2015) also point out that management of T1DM is majorly characterized by the transference of responsibility from the health personnel to the caregivers (Al-Odayani et al., 2013; Stefanowicz et al., 2016). The day-to-day care and monitoring of children with diabetes necessitate that the caregivers know the physiopathology of diabetes and its management to ensure optimal metabolic control and thus reduce the risk of the development of macro-vascular and micro-vascular complications, as studies have proven that greater diabetes knowledge is associated with better adherence (Chiang et al., 2018; International Diabetes Federation, 2019).

Poorglycaemic and dietary outcomes among children with type 1 diabetes mellitus may happen because caregivers possibly fail to understand the provided diabetes education, asknowledge insufficiencies in both the patients and healthcare providers do exist (Fox et al., 2020). Therefore, it is fundamental to conduct knowledge assessments among individuals involved in the management of type 1 diabetes mellitus so as to be able to address the identified gaps. This study, therefore, assessed the nutrition knowledge of caregivers and identified knowledge gaps.

2.5 Dietary management of type 1 diabetes mellitus

Children with diabetes need a nutritious diet that improves glycaemic control but allows the flexibility of appropriate food choices that cater for their growth and development. The nutrient recommendations for diabetic children are based on requirements for all healthy children. However, it is vital that a diabetic child takes the right amount/dose of insulin for the right type and amount of food (Ogle et al., 2017).

Insulin doses must be matched to the carbohydrate content of the food consumed by the child as carbohydrates are the major nutrient that affectpostprandial blood glucose levels(Bayram et al., 2020; Shafaeizadeh et al., 2018). Alternatively, the carbohydrate content of food consumed can be matched to the timing and the type of insulin injections.However, excessive restriction of carbohydrate intake should be avoided as this could lead to hypoglycaemia (Ogle et al., 2017). The matching of the carbohydrate content of the food consumed, and insulin dosage can be achieved by an approach known as carbohydrate (CHO) counting. This study, therefore, sought to determine the knowledge and ability of caregivers to perform accurate carbohydrate counting.

2.5.1 Dietary diversity

Dietary diversity is a method for assessing the variety and nutrient adequacy of diets. This is done by considering the number of food groups consumed over a reference period, which can range from one to fifteen days(Sealey-Potts & Potts, 2014; Zhao et al., 2017). The food groups are selected from an array of recommended food groups, ranging from 6 to 21. Any of the food group categories can be used in dietary assessment studies on children, but the 13 food group category is slightly better(Steyn et al., 2014). The DDS is calculated from an FFQ, weighed observation of food intakes or a 24-hour dietary recall. Ingredients in mixed dishes or foods that are not mixed in any quantity are matched to a food group and given a score of one, each food group is only considered once and the total number of food groups counted to find the DDS (Caswell et al., 2018; Steyn et al., 2014).

The two main DDS types are; household dietary diversity score (HDDS) which assesses a household's access to food and individual dietary diversity score (IDDS) which assesses the nutritional quality of an individual's diet (Habte & Krawinkel, 2016). DDS has been identified as a potentially useful proxy indicator of nutrient adequacy of one's diet as several studies have indicated a positive correlation between dietary diversity and micronutrient intake. A study by Zhao et al. (2017), found that DDS was positively correlated with indicators of micronutrient adequacy and ascore of six to eight indicated the lowest risk of micronutrient inadequacy in different groups of children. Meng et al. (2018), also reported a positive correlation between dietary diversity and dietary micronutrient intake among Chinese children aged three to seventeen years.

According to Caswell et al. (2018), there is no current consensus on the best score of minimum dietary diversity score for children older than 2 years, however, a study in children 1 to 9 years old conducted in South Africa by Steyn et al. (2006), using a 9 food group indicator showed that a DDS of 4 was the best cut-off. In a review conducted by Ruel (2003), one of the studies conducted in Kenya by Onyango et al. (1998), reported that a DDS of more than 5 was associated with a greater intake of all nutrients.

2.5.2 Dietary intake among type 1 diabetic children

ISPAD and ADA recommend type 1 diabetic childrenadhere to a healthy and balanced diet (Garonzi et al., 2021). Several dietary intake studies among type 1 diabetic children have reported a high fat intake and insufficient consumption of fruits and vegetables (Deepa et al., 2014). Another study conducted among type 1 diabetic Chinese patients observed that nutritional macronutrient composition was a risk factor for the occurrence of hypoglycemia (Zhou et al., 2021).

A review of the United Kingdom national diet and nutrition survey by Guo et al. (2019) also found that higher fat and lower carbohydrate intakes were associated with higher HbA1c. A randomized controlled trial at two mid-Atlantic children's hospitals also reported a higher percentage of daily energy intake from fatsbeing associated with poorer HbA1c (Mackey et al., 2018). Unfortunately, there is a significant gap in the literature concerning dietary intake studies among type 1 diabetic children most especially in Sub-Saharan Africa.

2.6 Management practices of type 1 diabetes mellitus

The risk of vascular complications linked to irregular glucose levels can be reduced by ensuring broad diabetes management which includes but is not limited to diabetes education, monitoring of blood glucose, insulin therapy, physical activity, nutritional managementand psychosocial support (Ogle et al., 2017).

2.7 Insulin types and requirements in type 1 diabetes mellitus

Type 1 diabetes used to be a death sentence with a life expectancy estimated from between 6 to 18 months. However, with the introduction of insulin in 1923, the life expectance oftype1diabetics has greatly improved(Bhutta et al., 2021). Type 1 diabetic children require insulin for their entire lives due to the autoimmune destruction of their insulin producing beta cells,the goalof insulin replacement is to ensure blood glucose levels are within the target rangeto avoid hypoglycaemia and sustained hyperglycaemia as prolonged use of less insulin than prescribed results in chronic hyperglycaemia which increases the risk of stunted growth and diabetes complications, including diabetic ketoacidosis (Begum et al., 2020; Ogle et al., 2017).

Insulin requirements of type 1 diabetic children are subjective, but pre-pubertal children usually require 0.7-1.0 IU/kg/day, although during puberty requirements may increase to 2 IU/kg/day. It should be noted that the insulin dosage should achieve the best attainable glycaemic control without causing apparent hypoglycaemia and result in normal growth and development (Ogle et al., 2017). Commonly used insulins in Uganda are shown in Table 2.1.

Table 2.1 Commonly used insulins in Uganda

Type of insulin	Example
Short-acting (regular/soluble/neutral)	Actrapid, Humulin R, Insuman Rapid
Intermediate-acting NPH insulin	Humulin N, Biosulin L, Insulatard
Pre-mixed short-acting (regular) and intermediate-acting (NPH) insulins	Usually in the combination 30/70 or 70/30
Rapid-acting	Aspart, Glulisine, Lispro
Long-acting	Glargine, Detemir, Degludec

Abbreviations: NPH, Neutral Protamine Hagedorn.

2.8 Self-monitoring of blood glucose in type 1 diabetes mellitus

Blood glucose monitoring is an important component of the effective management of T1DM. It gives an indication of blood glucose levels over a period of 24 hours and allows patients to assess their response to treatment and evaluate whether they are achieving their set glycaemic targets and also helps prevent asymptomatic hypoglycaemia and hyperglycaemia. Patients with T1DM should measure their blood glucose levels before, after meals and snacks, at bedtime, before and after exercise (Chiang et al., 2014).

Ideally, blood glucose levels monitoring and record-keeping should be carried out 4-6 times a day, but in resource-limited settings, this may not be possible, therefore a minimum of two tests per day is recommended (Ogle et al., 2017). The American Diabetes Association (2015) recommends blood glucose ranges of 90-130 mg/dL

(5.0-7.2 mmol/L) before meals and 90-150 mg/dL (5.0-8.3 mmol/L) at bedtime/overnight.The caregivers of type 1 diabetic children need to understand and appreciate the benefits of frequent blood glucose testing.

2.9 Glycated haemoglobin (HbAlc) levels of children with type 1 diabetes mellitus

Haemoglobin A1c or HbA1c or glycosylated haemoglobin is a component of haemoglobin to which glucose is bound, therefore the more glucose found in the blood, the higher the HbA1c level.Therefore, the HbA1c test is a vital blood test as it revealstime-averaged blood glucose during the previous 2–3 months and is considered the gold standard for long-term follow-up of glycaemic control and the best marker of longer-term diabetes control. Ideally, HbA1c is measured four times per year. If resources are limited, less frequent measurements are still helpful(DiMeglio et al., 2018).

ISPADand the American Diabetes Association currently recommend an HbA1c goal of less than 7.5% across all paediatric agegroups. Previously, the recommendations were; an HbA1c goal of 8.5% for youth under the age of 6 years, 8% for those 6–12 years old, and 7.5% for those13–19 years old. However, prolonged hyperglycaemia can also lead to the early development of cardiovascular disease and kidney disease which were once believed only to occur in adults (Chiang et al., 2014).

2.10 Nutrition education of caregivers

Nutrition education has been defined as:

> Any combination of educational strategies, accompanied by environmentalsupports, designed to facilitate voluntary adoption of food

choices and other food and nutrition-related behaviours conducive to health and well-being.Nutrition education is delivered through multiple venues and involves activities at the individual, community, and policy levels(Contento, 2008, pp. 176-177).

Nutrition education can improve metabolic control among diabetics(Thuita et al., 2020). When combined with other aspects of diabetes care and treatment, nutrition education can reduce glycated haemoglobin (HbA1c) and improve clinical and metabolic outcomes(Sterner Isaksson et al., 2021).

Internationally it is recommended that when educating children and adolescents with diabetes and their families, culturally and socially applicable healthy eating habits should be recommended and emphasized (Pihoker et al., 2018). However, it is still not clear on what teaching methods and materials to use, thereforethe implementation of nutrition education programmes among children and adolescents with diabetes and their families remain inconsistent with likely areas for improvement (Battersby et al., 2017). Additionally, different type 1 diabetes educational approaches have caused regional disparities in T1DM control as well as different clinical T1DM practice routines across different healthcare settings (Xie et al., 2020). Although many nutrition education programmes for children and adolescents with diabetes use a variety of approaches informed by local context which has the potential to improve glycemic outcomes (Alonso et al., 2020).

A six-week nutrition education intervention among school-age children (aged 6–12 years) and their caregivers in Ghana reported an improvement in the nutrition knowledge of caregivers of children in the intervention group (Antwi et al., 2020). A study conducted among Dutch children to evaluate the caregiver's role in the effectiveness of two school-based nutrition education programmes for children aged 7-12 years, found that caregivers' health promotion behaviours were positively associated with children's healthy eating behaviours. The study highlighted the importance of caregivers in supporting healthy eating behaviours in children (Verdonschot et al., 2021).

In the United Kingdom, attending a 5-day structured education course for adolescents with T1DM was associated with improved total quality of life score but not glycaemic control (Price et al., 2016). Another pediatric diabetes clinic study reported an association between the high level of knowledge of caregivers and good metabolic control. Furthermore, the study also recommended more research in studies that assess the impact of caregivers' knowledge on the metabolic control of children (Martín et al., 2016).

2.10.1 Meal planning

One of the key components of nutrition education in diabetes care and management is meal planning. There is no"*diabetic diet*" but rather a normal diet is modified through proper meal planning (scheduling of foods that will be eaten in advance for the next days). Both nutrition education and meal planning have to be individualized to ensure healthful eating, glycaemic control and compliance to diet recommendations with emphasis on consistency of timing and amount of food eaten. Consistency of timing and amount of food eaten can be achieved through several approaches such asthe exchange lists for meal planning and CHO counting(Pafili & Dimosthenopoulos, 2021; Rose et al., 2021).

2.10.2 The exchange lists for meal planning

The exchange lists for meal planning were developed by the Academy of Nutrition and Dietetics and the American Diabetes Association. The exchange lists allow flexibility and consistency of appropriate food choices and comprise of 3 food groups, namely: carbohydrate group (starches, fruit, milk and vegetable), meat and meat substitutes and fat group.Exchange lists allow the individual to substitute food items of a similar nutritional profile thus avoiding monotony and keeping blood-glucose levels consistent from day to day (Lim, 2015).

2.10.3 Carbohydrate counting

CHO counting is a meal planning method that aims to improve glycaemic control of a diabetic individual by matching the carbohydrate content of the food consumed and insulin dosage (Ogle et al., 2017; Partridge et al., 2016).

Insulin doses must be matched to the carbohydrate content of the food consumed by the child as carbohydrates are the major nutrient that affectpostprandial blood glucose levels (Bayram et al., 2020; Furthner et al., 2021; Shafaeizadeh et al., 2018). Alternatively, the carbohydrate content of food consumed can be matched to the timing and the type of insulin injections. However, excessive restriction of carbohydrate intake should be avoided as this could lead to hypoglycaemia (Ogle et al., 2017).

2.11 Gaps in nutrition education of caregivers

Nutrition education in T1DM is longer just about carbohydrate counting but now also acknowledges the significant influence of whole food choices on improving glycaemic and dietary outcomes (Annan, 2017). The ADA recommends comprehensive nutrition education by an experienced registered dietitian that is individualized considering cultural needs, family habits, and food preferences(Chiang et al., 2014). Thoughthe application of western-based nutritional advice has been identified as a challenge in other regions, however adapting western nutrition education guidelines to the cultural and socioeconomic context of sub-Saharan Africa with a focus on a wider target audience may contribute to the management of T1DM (Owolabi et al., 2018; Tremblay et al., 2021). It is vital that nutrition education is tailored to patients' individual, social and cultural needs as adequate patient education can lead to improved knowledge and self-management skillswhich reduces the risk of developing complications. Knowledge gaps change and occur at different points in the course of the disease, therefore delivery of individualised nutrition education should take into account these dynamics and be regularly updated, and provided on a regular and ongoing basis(Donnelly et al., 2022).

Nutrition education is critical in the management of diabetes and empowers not only children and adolescents with type 1 diabetes mellitus but also their caregivers to successfully manage their condition. Furthermore, contextualized nutrition education materials can be used by the non-primary caregivers to help them increase their understanding of the nutritional management of T1DM and thus reduce the burden of care on the primary caregivers (Tremblay et al., 2021). Unfortunately, structured nutrition education courses for type 1 diabetic patients and their caregivers are lacking in Africa and this has been cited as one of the contributing factors tothe suboptimal management of type 1 diabetic patients in the region(Mbanya et al., 2020; Zhao et al., 2021).Therefore, it is important that culturally appropriate structured nutrition education courses informed by the local context be developed and made readily available to children and adolescents with type 1 diabetes mellitus and their caregivers as parental care positively influences glycemic and dietary outcomes of children with T1DM (Schiaffini et al., 2020).

2.12 Summary of literature review

In summary, the following gaps were identified:

1. The current diabetes education curriculum used in the nutrition education sessions at the paediatric type 1 diabetes clinics is not Ugandan contextualized.
2. Vital topics such as the MyPlate model, glycaemic index, the importance of fresh fruits and vegetables and how to interpret food labels were not included.
3. There is no facilitator's manual with specified instructional methods and teaching materials required to aid the delivery of the content during a nutrition education session.
4. No study had been conducted to establish if the involvement of caregivers in children's nutrition education interventions contributes to the effectiveness of the interventions.

Therefore, this study aimed to address the above-mentioned gaps with the hope that study findings may contribute to the development and effectiveness of future culturally appropriate nutrition education interventions to reduce glycated haemoglobin (HbA1c), improve clinical and metabolic outcomes and can have a profound effect on compliance.

CHAPTER THREE: METHODOLOGY

3.0 Introduction

This chapter presents the methodology that was used in the study and has been divided into the following sections; research design, study area, target population, sampling techniques sample size determination, research instruments, validity and reliability of study instruments, data collection and analysis techniques and ethical considerations.

3.1 Research design

The study design was a cluster randomised controlled trial. T1DM clinics (clusters) were randomly allocated to the intervention and control groups rather than individuals (Hemming et al., 2017).A cluster randomised controlled trial design was used because individual randomisation of study participants to the intervention group was not possible because of the high potential for contamination among the study participants (Dron et al., 2021). The study comprised of two stages: a baseline study and the intervention phase.

3.2 Study variables

The study variables are shown in Table 3.1.

Table 3.1 Dependent and independent study variables

Dependent variables	Independent variables
HbAlc level	Demographic characteristics (sex, age, marital status and religion)
Nutrient adequacy (NARs, MAR) Dietary diversity (DDS)	Socio-economic characteristics (level of education, occupation, household size and income)
Caregiver's level of type 1 diabetes	Duration of T1DM, insulin regimen and

nutrition knowledge (NKS)	family history of T1DM

3.2.1 Primary outcome

The primary outcome of the study was the percentage change in mean HbA1c levels of study participants. A 1.0% difference in HbA1c was deemed to be of clinical significance(Stratton et al., 2000; The Diabetes Control and Complications Trial Research Group, 1993).

3.2.2 Secondary outcomes

Secondary outcomes included; caregiver's level of type 1 diabetes nutrition knowledge,children's mean intake of macronutrients (energy, proteinand fat) dietary diversity,NAR'sand MAR.

Table 3.2 Sequence of trial measurements of primary and secondary outcomes

Timepoint	Baseline	Endline^
Primary outcome		
Children's HbAlc level	X	X
Secondary outcomes		
Caregiver's type 1 diabetes nutrition knowledge score	X	X
Children's nutrient and mean adequacy ratios	X	X
Children's dietary diversity score	X	X

Abbreviations: ^, three months after the intervention; X, data collected.

3.3 Study area

The study was conducted at 10 health facilities located in 8 different districts (Appendix O) in Uganda as indicated in Table 3.5. The mentioned health facilities were selected because they had established paediatric type 1 diabetes clinics.

Table 3.3 Selected diabetes clinics in Uganda

Number	District	T1DM clinics (clusters)
1	Kampala	Mulago hospital
2	Kampala	St Francis Nsambya hospital
3	Kampala	Lubaga hospital
4	Wakiso	Wakiso health centre IV
5	Mbale	Mbale regional referral hospital
6	Soroti	Soroti regional referral hospital
7	Mbarara	Holy innocents' children's hospital
8	Kabarole	Virika hospital
9	Kasese	Kagando hospital
10	Rukungiri	Nyakibale hospital

3.4 Target population

The target population were caregivers of/and children diagnosed with T1DM aged between three to fourteen years.

3.4.1 Inclusion criteria

Caregivers of/and children diagnosed with T1DM aged between 3-14 years. The patients should have attended the diabetic clinic for a minimum of six months. In addition, the caregivers should have consented, and the children assented to taking part in the study.

3.4.2 Exclusion criteria

Children diagnosed with and receiving treatment for acute infections such as urinary tract infections, skin infections, respiratory infections, and chronic complications such as diabetic neuropathy, nephropathy and retinopathyas illness is associated with hyperglycemia which would have impacted the primary outcome of the study (HbA1c). The presence of acute infections and chronic complications was assessed and ascertained using the patients' medical files at the health facilities. Children who attend boarding schools were also excluded as the feeding practices are predetermined by the school management and this would have introduced bias in the study.

3.5 Sampling techniques

Ten health facilities with established T1DM clinics were purposively selected because the study targeted children with type 1 diabetes, however, the number of health faculties with fully functional paediatric type 1 diabetes clinics in Uganda is limited, therefore purposive sampling was the most appropriate. Simple random sampling was used to distribute the T1DM clinics into the study groups rather than the study participants because of the high potential for contamination between the study participants(Dron et al., 2021). Consecutive sampling was used to select the study participants in each of the T1DM clinics due to the low number of participants in the 3-14 years age group, therefore all participants who met the inclusion criteria were recruited until the required sample size was obtained.

3.6 Sample size determination

To have 80% power to detect a 1.0% difference in HbA1c; the sample size (n) was calculated using the following formula cited in Florey (1993); Noordzij et al. (2010).

$$\frac{n = 2[(a+b)^2\sigma^2]}{(\mu_1 - \mu_2)^2}$$

n = the sample size in each of the groups
μ_1= population mean in intervention group (HbA1c = 9.9) (Krishnavathana et al., 2006).
μ_2 = population mean in the control group (HbA1c = 8.9)
μ_1-μ_2 = the differenceto be detected
σ^2 = standard deviation 1.6 (Krishnavathana et al., 2006).
The power of the test was set at 80% and significance at 5%.
a = 1.96 (conventional multiplier for alpha = 0.05)
b = 0.842 (conventional multiplier for power = 0.80, (beta = 0.20)

Therefore:

$$n = \frac{2[(1.96 + 0.842)^2 1.6^2]}{(9.9 - 8.9)^2}$$

$$n = 40.19$$

To adjust for the clustering effect the sample size was inflated by a design effect (DE) to get the adjusted sample size (Campbell & Walters, 2014).

$$\text{DE} = 1 + (\bar{m}\text{-}1)\rho$$

Where $\bar{m}$ is the average cluster size as the clusters vary in size and $\rho$is the intra-cluster correlation coefficient (ICC). Since there was no previous study documenting the ICC, an ICC of 0.01 was considered and the average cluster size was 12 (Appendix XV).

$$\text{DE} = 1.11$$

The calculated sample size was 40.19 * DE (1.11) = 44.61. The sample size wasincreased by 10 % to 49.07 participants per study group to cater for a non-response and loss to follow-up (Magnani, 1999). This was rounded off to 50 respondents in each study group, therefore the final sample size was 100 study participants.

3.6.1 Sample size per study site

The sample size proportional to the total number of child-caregiver pairs was calculated using the formula below:

(study site population *calculated sample size)/total study site population.

For exampleSt Francis Nsambya hospital = (31*50)/69 = 22.

The calculated sample sizes per study site are shown in Table 3.3:

Table 3.4 Sample size of child-caregiver dyads per study site

Study group	T1DM clinics (clusters)	Number of child-caregiver dyads	Sample size per study site	Collected sample
Intervention	St Francis Nsambya hospital	31	22	22
	Lubaga hospital	5	4	4
	Virika hospital	14	10	10
	Holy innocents' children's hospital	16	12	12
	Nyakibale hospital	3	2	2
Total		**69**	**50**	**50**
Control	Mulago hospital	19	19	18
	Wakiso health centre IV	3	3	3
	Mbale regional referral hospital	10	10	10
	Soroti regional referral hospital	9	9	9
	Kagando hospital	10	10	10
Total		**51**	**51**	**50**

3.7 Research instruments

The study used researcher administered structured questionnaires such as the type 1 diabetes nutrition knowledge questionnaire, the 24-hour recall and the dietary diversity questionnaire (DDQ) (Eigenmann et al., 2011; FAO, 2013; Fitzgerald et al., 2016; Fitzgerald et al., 1998; Rovner et al., 2012).

3.7.1 Caregiver questionnaire

The caregiver questionnaire was used to obtain socio-demographic information, medical history and type 1 diabetes and nutrition education training. The caregiver questionnaire also included a section that measured the caregiver's wealth index based on the validated EquityTool© that simplifies equity assessment(Chakraborty et al., 2016; Metrics for Management, 2021a)(Appendix E).

3.7.2 Type 1 diabetes nutrition knowledge survey (NKS) questionnaire

The NKS questionnaire is a validated, brief questionnaire that was used to assess the caregiver's level of specific and general diabetes nutrition knowledge based on four domains, namely carbohydrate counting, healthful eating, nutrition label reading and blood glucose response to food. The results of the NKS questionnaire were scored based on the percentage of correct answers ranging from 0% to 100% with a higher percentage indicating better nutrition knowledge (Appendix F). The scores were categorized, those that scored 50 and below were categorized as having low type 1 diabetes nutrition knowledge, 51 to 75% type 1 diabetes nutrition knowledge and ≥ 76% high type 1 diabetes nutrition knowledge.

3.7.3 The 24-hour dietary recall

Therepeated 24-hour dietary recall was used to collect quantitative information on the study participants individual diets. The study participants were asked to report all the foods and drinks they consumed in the 24 hours preceding the interview in terms of quantities of household measures. Food albums and models were used to assist the participants in correctly identifying and quantifying the foods and drinks consumed (Appendix G).

3.7.4 Dietary diversity questionnaire

The 9-food group dietary diversity questionnaire was used to collect food consumption data from the 24-hour dietary recall.The 9 food groups considered includedstarchy staples (cereals, roots, tubers), vitamin A-richvegetables and fruits, meat, poultry and fish, legumes, nuts and seeds, oils and fats, eggs, milk and milk products,other vegetables and fruits. For dishes that were mixed, the individualingredients were matched to a particular food group for a score of1, each food group was only considered once, and the totalnumber of food groups was counted to give the final dietary diversityscore. To determine the minimum DDS, a cut-off of atleast 5 out of the 9 food groups wasconsidered (Appendix H).

3.8 Piloting of the study and pretesting of research instruments

A pilot study was conducted on 10 caregiver-child dyads attending the type 1 diabetes clinic at St. Francis, Nsambya hospital, with the same characteristics as the study sample. The participants that took part in the pilot study were not included in the main study. The purpose of the pilot study was tovalidate and standardize the study instruments, proceduresand pre-test the intervention.Questions in the instruments were tested for clarity, coherence and consistency. In addition, the research assistants were able to master the flow of the procedure from recruitment to baseline datacollection, to laboratory phlebotomy, intervention, follow up and exit from the study. They also practised how to keep records of various instruments of the study.

The pilot study provided an opportunity for the entire research team toget an experience of the possible challenges that they may face during the main study and how to overcome them. The nutrition educators were also able to pre-test the various teaching methods and duration for every topicand identified emerging challenges during the nutrition education sessions.During the pilot study, various oral translations in the local languages (Luganda, Rutooro, Runyankole, Rukonzo, Lugishu and Swahili) were sought to give the exact meaning of questions in the questionnaires for accuracy. The nutrition education team realized that the 45 minutes were adequate for each lesson and not 1 hour as was proposed. Furthermore, the team realized that buying and storingfresh food items for the food demonstrations was not feasible and recommended the use of food models. The study was pilotedfrom March to April 2019 and data collected and analyzed (AppendixI).

3.9 Validity of study instruments

Face validity of the study instruments was ensured by sending the study instruments to three experts in the fields of human nutrition and child health; from the Departments of Pediatrics and Child Health, Makerere University, Uganda and Food, Nutrition and Dietetics, Kenyatta University, Kenya, who assessed the questions of the instruments for accuracy and completeness (Tabachnick & Fidell, 2007).

Content validity was ensured by conducting a literature review as per the study objectivesand the study instruments were developed in line with the same. Additionally, some of the study instruments like the 24-hour recall, dietary diversity questionnaire and NKSquestionnaire have been previously standardized and validated by individuals and internationally recognised bodies such as the Food and AgricultureOrganizationand adapted for global use;and henceenabled comparisons with other studies(FAO, 2013; Karros, 1997; Nightingale et al., 2016; Rovner et al., 2012).

3.10 Reliability of study instruments

The test-retest method was used to test the consistency of the questionnaire in producing the same results.The questionnaire was used to interview ten caregivers on two different occasions after seven days and the correlation coefficient determined. A correlation coefficient of 0.76 was established(AppendixI).Which was acceptable, as a correlation coefficient of 0.70 and above is considered adequate (Mukaka, 2012; Pallant, 2016).

3.11 Data collection techniques

The study variables, indicators and measurement tools are shown in Table 3.5

Table 3.5 Study variables, indicators and measurement tools

Study variables	Indicators	Measurement tools
Socio-economic and demographic characteristics	Sex, age, relation to the child, marital status, household size, religion, level of education, occupation, income and wealth index	Caregiver questionnaire
Children's T1DM-related characteristics	Sex, age, family history of T1DM, duration of T1DM, insulin regimen, family history of T1DM relation to child	Caregiver questionnaire
Caregivers' level of T1DM nutrition knowledge	NKS scores	NKS questionnaire
Children's dietary diversity and nutrient adequacy	NARs, MAR and DDS	Dietary diversity questionnaire, 24-hour dietary recall
HbA1c	HbA1c level	Point of care HbA1c testing device

3.11.1 Recruitment and training of research assistants

A total of six research assistants with a minimum requirement of a Bachelor of Science degree in Human Nutrition and Dietetics were recruited. The research assistants were trained for two days on interviewing and probing skills, ethical and confidentiality issues in research and were oriented on the study objectives, research instruments and study procedures.

3.11.2 Face to face interviews

Face to face interviews were conducted using the researcher administered questionnaires to solicit information from caregivers of type 1 diabetic children after informed consent and assent had been granted. The questionnaires elicited information on socio-economic and demographic characteristics, medical history of type 1 diabetic children, use of insulin, diabetes and nutrition education training and foods and drinks consumed.

3.12 Study procedure

The study procedure was as follows;

3.12.1 Randomisation and blinding

The study comprised of 2 study groups; a control group and an intervention group. 10 T1DM clinics (clusters) were randomly assigned using a formula generated in Microsoft Office Excel 2016 to either the intervention or control group in a ratio of 1:1 as indicated in Table 3.6.The biostatistician who conducted the randomization and data analysis was blinded to the nature of the intervention and hypotheses of the study, this was done to control for bias during randomisation data analysis (Probst et al., 2016). The caregiver-child pairs were allocated to the study group based on the T1DM clinic they attended and were blinded to the hypotheses of the study.

Table 3.6 Randomisation of diabetes clinics

T1DM clinics (clusters)	Study group
St Francis Nsambya hospital	Intervention
Lubaga hospital	Intervention
Virika hospital	Intervention
Holy innocents' children's hospital	Intervention
Nyakibale hospital	Intervention
Mulago National Referral hospital	Control
Wakiso health centre IV	Control
Mbale Regional Referral hospital	Control
Soroti Regional Referral hospital	Control
Kagando hospital	Control

3.12.2 Recruitment of study participants

The researcher with the help of the diabetes specialist nurse at the diabetes clinic informed the caregivers of children with T1DM about the objectives of the study and the inclusion criteria. Those child-caregiver pairs that accepted to participate in the study and met the inclusion criteria were asked to give their assent and consent respectivelysince the child-caregiver pairs were sampled using consecutive sampling; this was done until the required sample size was achieved. The baseline questionnaires were then administered, and the children's HbA1c was tested in the laboratory.

3.12.3 Data collection points

The primary and secondary outcomes were assessed at twotime points: baseline and 3 months after the intervention (3 months post-intervention).

Table 3.7 Study timelines and phases

Timeline	Study phase
March-April 2019	Piloting of the study
June to November 2020	Recruitment and baseline data collection
January to March 2021	Intervention
July toOctober 2021	Endline data collection

3.12.4 Baseline

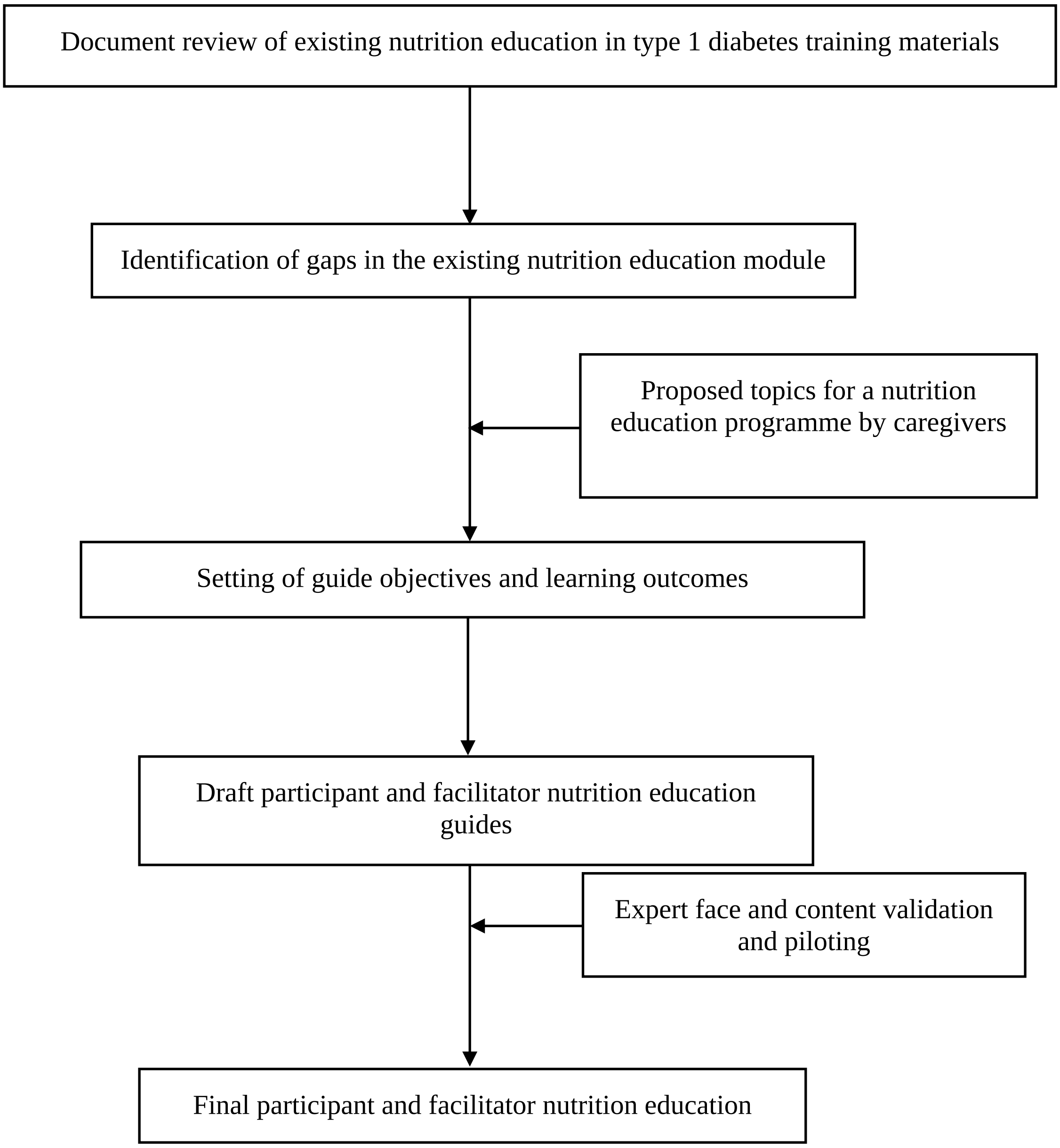
Baseline data was collected using researcher administered questionnaires. The baseline data provided an information base against which to compare the similarities between the control and intervention groups in terms of their socio-demographic characteristics, nutrition knowledge and management of type 1 diabetes and any additional gaps that existed. The information was used to compare the magnitude of change between the study groups in the parameters under study.

3.13 Description of the intervention

The participants in the control group continued to receiveroutine medical care, which comprised of insulin refills, a review of self-care plans and an assessment of weight and height. The intervention group also receivedroutine medical care; however, they also attended a structured nutrition education course. The structured nutrition education courseconsisted of a total of 8 sessions with each session lasting a total of 45 minutes. The sessions were conducted in the intervention centres at different times. Each session was conducted once a week and a question-and-answer session was held every after 2 sessions.The question-and-answer sessions provided an opportunity for the participants to reflect and consolidate their understanding.The intervention lasted a total of 12 weeks.The topics covered and brief descriptions of each of the sessions are included in Appendix J.

3.14 Development of the nutrition education participant and facilitator guides

According to Farrell-Miller and Gentry (1989), well-written education materials are a vital resource for not only the patient but also their caregivers when at home and can influence health behaviours. Furthermore, well-crafted and updated educational materials enable a trainer to easily access important information and make vibrant and well-organized presentations which make the learning process for the participants a more enjoyable experience (Stossel et al., 2012). Therefore, the development of the nutrition education guide for caregivers of children (3-14 years) with type 1 diabetes in Uganda was guided by the following steps (Figure 3.1):



Note. This figure displays the steps followed in thedevelopment of the participant and facilitator nutrition education guides.

Figure 3.1 Schematic representation of the nutrition education guide development

3.14.1 Step 1: Document review of existing nutrition education in type 1 diabetes training materials

The first vital step in developing educational materials is to perform a needs assessment. Therefore, a document review of the current available T1DM nutrition education training materials used at the study siteswas conducted to identify any gaps to be addressed and themes derived to guide the development of the structured nutrition education guide for caregivers of children and adolescents with type 1 diabetes mellitus in Uganda.

3.14.2 Step 2: Gaps in the existing nutrition education module

Gaps were identified in the nutrition education module in the current diabetes education curriculum (Appendix K). The gaps were identified by the researcher, and the nutrition educators at the study sites and these were further informed by the proposed topics for a nutrition education programme by the caregivers during the baseline data collection. In addition, topics were proposed by the caregivers. The topics were merged into a final list of 8 topics (Appendix L).

3.14.3 Step 3: Setting of nutrition education guide objectives and learning outcomes

The results from steps 1 and 2 were used to develop a matrix with competency-based objectives and learning outcomes. Relevant topics were determined based on the objectives and learning outcomes to be achieved. Resources were identified such as teaching aids, materials, and equipment for each topic. Time was also allocated for each topic that covered both theory, practical’s and learning experiences. Learner-centred instructional methods were also identified for the various topics.

3.14.4 Step 4: Development of the nutrition education guide

Based on identified topics, the content was developed, organised and put in the context of the target group. The nutrition education participant guide for caregivers of children with type 1 diabetes in Uganda© and the nutrition education facilitator guide for caregivers of children with type 1 diabetes in Uganda©were then developed.

3.14.5 Step 5: Face and content validation of the nutrition education guide

The developed participant and facilitator guides underwentface and content validation by five experts from the fields of nutrition and diabetes and the target population (Boateng et al., 2018). Face validity was conducted to evaluate the organisation, grammar and logical flow of the content in the guide. Content validity was conducted to evaluate the clinical and scientific accuracy of the content in the guide (Bannigan & Watson, 2009). The evaluations were based on four assessment domains namely; appropriate and balanced (*lessons and messages are relevant, sufficient and suitable for the target participants*), clarity (*content is easy to understand*), use of technical language and jargon (*use of technical language and jargon is minimal and appropriate*) and illustrations (*pictures used are sufficient and relate to the daily practices of the target participants*) (Appendix M). The rejection, modification or acceptance of any content was based on majority opinion, and all input was used to improve the final draft of the guide (Augustine et al., 2012). In addition, the draft messages and Information, Education and Communication (IEC) materials were pre-tested to determine the relevance, clarity of messages and general feeling about the messages during piloting. A summary of the mean score for each domain is indicated in Appendix M. In addition, qualitative feedback (comments and suggestions) was used to improve the final copy of the developed structured nutrition education guide.

3.15 Delivery of the intervention

A two-member team of experienced nutrition/health educators (a diabetes specialist nurse and a specialist diabetes dietician) were recruited to conduct the nutrition education sessions using food demonstrations and audio-visual aids at the various clinics selected for the intervention group under the supervision of the researcher. Furthermore, a printed nutrition education guide was provided to the participants. The participants were sent a reminder every week via the mobile phone of the next session and encouraged to complete all sessions. This was done to promote adherence and completion of the programme. Individual follow-up sessions were arranged for those participants that needed clarification on any component of the session. Written feedback was sought from the participants after each session and used to help improve the delivery of the sessions (Appendix N).

3.15.1 Age categorizations during healthy eating and meal panning

During the nutrition education session on healthy eating and meal panning, the feeding guidewas sub-divided into three age categories; 3 to 5 years, 6 to 12 years and 13 to 14 years this was done to ensure that the information and examples provided are age appropriate and the caregivers prepare and provide meals that meet the RDA of the children.

3.16 Prevention of adverse events during intervention

The study researcher worked with a medical doctor who is a specialist in T1DM in children and a diabetes specialist nurse whose contacts were provided to all participants, and they wereinformed to contact them in case of anadverse event. Caregivers were trained on the risks and on how to detect the early signs of hypoglycaemia and hyperglycaemia. In, addition, a diabetes emergency kit/hypo box was available at all the diabetes clinics in the intervention group. Furthermore, the intervention did not alter the participants' medication or attendance at the routine clinics in both study groups(AppendicesP).

3.17 Blood sample collection and HbA1c testing

Point-of-care HbA1c testing was conducted at thestudy sites. The Accu-Chek® Safe-T-Pro Uno single-use lancing device (Bella, Vista, Australia) was used to prick the side of the fingertip after the child washed their hands with soap and clean water. A capillary blood sample was then drawn from the side of the fingertip using the A1C EZ 2.0 Glycohemoglobin test strip (Jiangsu, China) which was then inserted into the BioHermes® A1C EZ 2.0 Glycohemoglobin Analyzer (Jiangsu, China) to analyse the HbAlc level. The Glycohemoglobin Analyzer was calibrated in accordance with manufacturer instructions. The reference levels were: good control (< 7.5%) and poor control (≥ 7.5%). The children's HbAlc levels were tested at baseline and at endline (3 months post-intervention).

3.18 Data analysis and presentation

Statistical analysis was performed using IBM Statistical Package for Social Sciences (SPSS) Statistics for Macintosh, Version 28 (IBM Corp., Armonk, N.Y., USA). The level of significance was set at a*p*-value of less than 0.05 (95% confidence level). Dietary intake data obtained from the 24-hour dietary recall was analyzed using the NutriSurvey 2007 software and the HarvestPlusfood composition table for central and eastern Uganda(Hotz et al., 2012). The NAR of a nutrient was calculated as the amount of a particular nutrient consumed divided by the recommended dietary allowance (RDA) for that particular nutrient. A NAR equal to 0 indicated a diet lackingthat particular nutrient, whereas a NAR equal to 1 or more indicated a diet that achieved or exceeded the RDA for that particular nutrient. For this study, a NAR greater than 0.7 was considered adequate; indicatingthat the individual met 70% of the RDA for that nutrient (Becquey et al., 2010; Coates et al., 2017; Marshall et al., 2001; Nithya & Bhavani, 2018; Román-Vinas et al., 2009). The MAR was calculated as a measure of overall nutrient adequacy. The MAR was calculated by summing all the NARs and dividing by the total number of nutrients assessed. A MAR of 1indicated that for all the nutrients, intake was equal or higher than recommended (Looman et al., 2019). The nutrient intake and requirements were based on ISPADand the German Societyfor Nutrition (DGE) guidelines (Smart et al., 2018).

3.19 Descriptive and inferential statistics

Descriptive summary statistics such as means, median, standard deviations, frequencies, and percentages have been presented to describe the research study population. The Kolmogorov–Smirnov statistic was used to test the variables for normality. For normally distributed continuous data, an independent sample t-test was conducted to analyse the differences between means. Analysis of variance (ANOVA) was used to analyse the differences among group means.Analysis of covariance (ANCOVA) was performed to assess the differences in the post intervention caregivers' level of T1DM nutrition knowledge. For continuous skewed data, the Mann–Whitney U-test and Kruskal-Wallis H test were used. Wilcoxon signed rank test was used to test for differences in HbA1c, DDS and MAR after the intervention.

Spearman's rank correlation coefficient was used to test for association between caregiver's T1DM nutrition knowledge scores and DDS, NARand MAR. Chi-square test was used to compare the distribution of categorical variables between groups and test if there were significant relationships between categorical variables (dietary diversity, caregivers' level of T1DM nutrition knowledge), Yates' correction for continuity was considered for the 2 by 2 categorical variable tables. However, Fisher's exact probability test was used when the lowest expected frequency in any cell was less than 5.

To determine the socio-demographic correlates of caregivers' level of type 1 diabetes nutrition knowledge and children's dietary diversity, simple linear regression analysis was conducted. This was followed by modellingvarious variables in a multiple regression model to determine which variables accounted for variance inHbA1c. Logistic regression was also conducted to identify potential predictors of HbA1c.Difference-in-differences (DiD) statistical technique was used to identify the overall changes (effect) in the primary and secondary outcomes associated with the intervention. Intention-to-treat analysis was used, this implies that all participants who were enrolled and randomly allocated to treatment were included in the statistical analysis and analysed according to the group they were originally assigned even if they withdraw, died or were lost to follow-up(Smith et al., 2021).

Table 3.8 Data analysis matrix

Objectives	Variables	Variable category	Statistical test/ analysis
Determine the demographic and socio-economic characteristics of caregivers of children (3-14 years) with T1DM at selected hospitals in Uganda.	Sex, age, relation to the child, marital status, household size, religion, level of education, occupation, income and wealth index	Categorical Continuous	Mean, standard deviation, median, frequencies and percentages, Chi-square test, Fisher's exact probability test
To assess the level of T1DM nutrition knowledge among caregivers of children (3-14 years) with T1D at selected hospitals in Uganda.	NKS score	Continuous	ANCOVA, ANOVA,Kruskal-Wallis H test Mann-Whitney U-test
To determine the dietary intake and nutrient adequacy of children (3-14 years) with T1DM at selected hospitals in Uganda.	NARs, MAR and DDS	Categorical Continuous	Mann–Whitney U-test, Chi-square test, Fisher's exact probability test
To determine the effect of nutrition education on the level of T1DM nutrition knowledge of caregivers of children (3-14 years) with T1DM at selected hospitals in Uganda.	NKS score	Continuous	DiD, Wilcoxon-signed rank test, Mann–Whitney U-test
To assess the effect of nutrition education of caregivers of children (3-14 years) with T1DM on HbAlc levels of their children at selected hospitals in Uganda.	NKS score HbAlc values	Continuous	DiD, Paired samples t-test, Mann–Whitney U-test, Wilcoxon-signed rank test
To establish the relationship between caregiver's level of T1DM nutrition knowledge and HbA1c, dietary diversity, macronutrient intake, nutrient and mean adequacy ratios.	NARs, MAR, DDS and HbA1c values	Continuous	Simple, multiple and logistic regression, Independent sample t-test, Spearman's rank correlation

3.20 Logistical and ethical considerations

Authority to conduct research wasobtained from Kenyatta university graduate school. Ethicalclearance was granted by the St. Francis Hospital Nsambya Review and Ethics Committee (reference number: SFHN/REC/83)and a research permit was obtained from the Uganda National Council of Science and Technology (reference number: HS186ES). The study was also registered with The Pan African Clinical Trials Registry (reference number: PACTR201902548129842) (Appendix Q).Study participants were informed of the objectives and purpose of the study, the principles of voluntary participation, withdrawal privilege and confidentiality (Appendix A). Signed assent and informed consentwere obtained from the children and caregivers respectively(Appendices B and C).

The study was carried out during the COVID-19 pandemic, therefore in order to prevent the study participants and facilitators from contracting COVID-19; face masks were provided to all the study participants and facilitators, furthermore, a social distance of 2 meters apart was maintained and hand sanitiser and hand washing facilities were placed at the entrance of the health facilities.

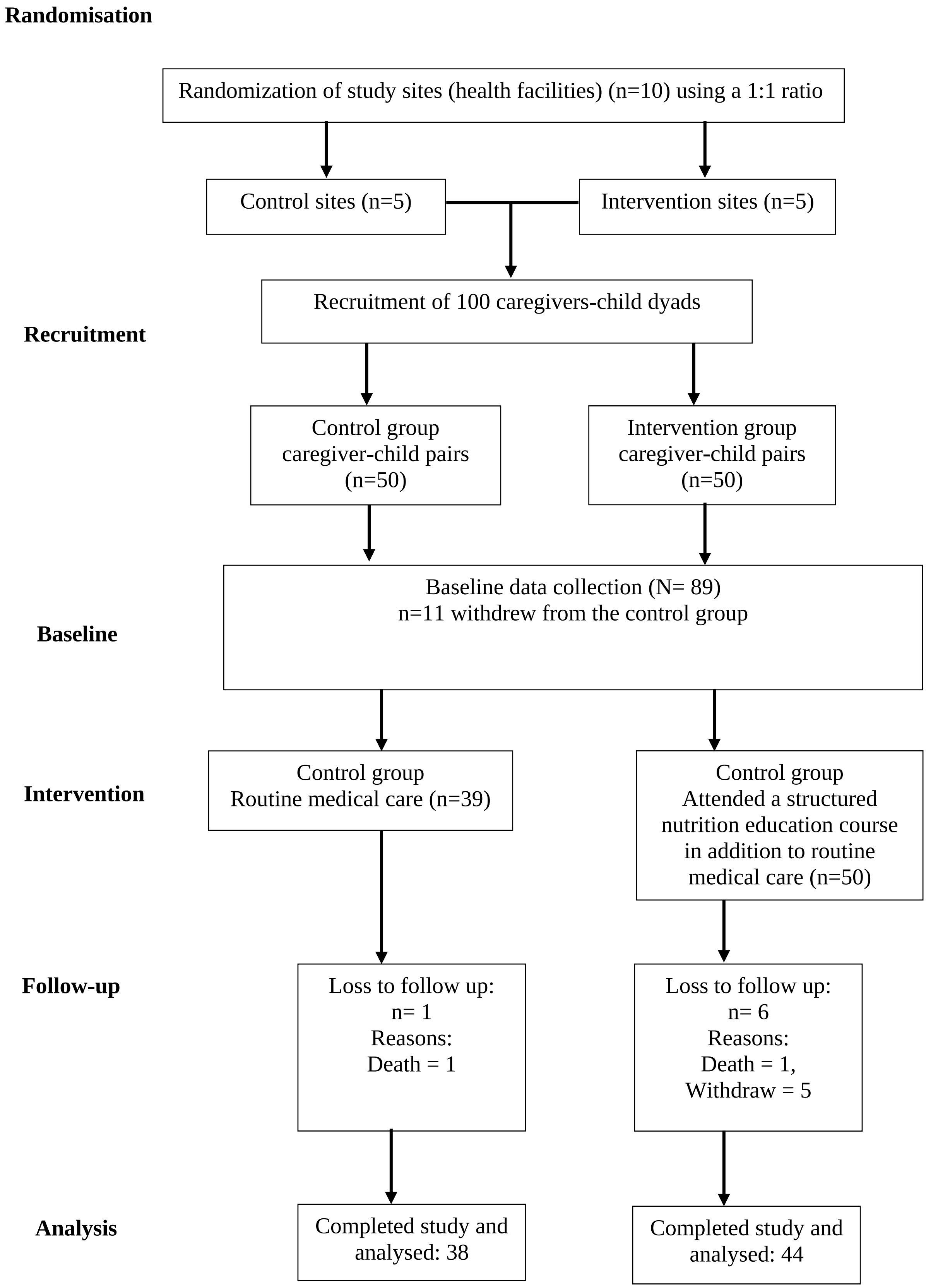
CHAPTER FOUR: RESULTS

4.1 Introduction

This chapter contains the results of the study. A baseline survey was first conducted,this was then followed by a cluster randomised controlled trial in which the caregivers in the intervention group attended a structured nutrition education course. The purpose of this study was to evaluate the effect of the provision of a structured nutrition education course to caregivers of children with T1DM attending selected T1DM clinics in Uganda, on their level of T1DM nutrition knowledge and their children's glycaemic control, dietary intake and dietary diversity.The findings of the study are presented in this chapter as per the study objectives.

4.2 Recruitment of participants and schematic presentation of the trial profile

A total number of 100 caregivers-child dyads were recruited for the study from 10 health facilities with T1DM clinics; 50 caregiver-child dyads were in the intervention group and 50 caregiver-child dyads were in the control. However, during the baseline data collection 11 caregiver-child dyads withdrew from the control group, the participants did not provide any reasons for their withdrawal. Therefore only 89 caregivers-child dyads completed the baseline study and proceeded to the intervention phase of the study. During the intervention phase of the study 6caregiver-child dyads were lost from follow up in the intervention group; 1 was due to death and 5 withdrew from the study. The participants did not provide any reasons for their withdrawal. In the control group, only 1 was lost to follow up due to death. Both deaths were attributed to hypoglycaemia.Therefore, a total of 82 caregiver-child dyads completed the study and their data was analyzed (Figure 4.1).



Note. This figure demonstrates the flow of the study through the different phases of the trial.

Figure 4.1 Schematic representation of the trial profile

FINDINGS AT BASELINE

4.3 Identified gaps in the existing nutrition education module

The following gaps were identified in the nutrition education module in the current diabetes education curriculum (Appendix K). The gaps were identified by the researcher, and the nutrition educators at the study sites and these were further informed by the proposed topics for a nutrition education programme by the caregivers during the baseline data collection.

- The content is not contextualized forUgandan paediatric type 1 diabetes mellitus patients as examples of the recommended foods lack more Ugandan food sources.
- Topics such as the MyPlate model, glycaemic index, the importance of fresh fruits and vegetables and how to interpret food labels are not included.
- A facilitator’s manual with structured time for the delivery of every topic alongside instructional methods and teaching materials was also lacking.

In addition, 14 topics were proposed by the caregivers. 11 of these were merged into a final list of 8 topics. However, 3 of the topics were not included as they were considered beyond the scope of the study (Appendix L).

4.4Baseline comparison of caregiver demographic and socio-economic characteristics by study groups

4.3.1 Caregiver demographic characteristics by study groups

The demographic characteristics of the caregivers who participated in this study are presented in Tables 4.1 and 4.2. Furthermore, the baseline findings have been reported and compared for similarities between the study groups as follows;

The highest proportion of caregivers (48.3%) were aged 40 years and above. There was no significant difference in caregiver age distributionbetween the study groups(Fisher's exact test; p=0.396). The caregivers had a mean age of 37.93 ± 10.05 years, the majority (61.8%) were female. There was no significant difference in caregiver age and sex between the study groups (Independent sample t-test; p=0.233, $\chi 2$; p=0.481) respectively.The primary caregiver was a mother (57.3%), the relation of the primary caregiver to the child was significantly different between the study groups (Fisher's exact test; p=0.012).

The average household size was 6 family members with an equal proportion (28.1%) subscribing to eitherCatholicism or Anglicanism. Both household size and religion were not significantly different between the study groups (Mann-Whitney U test; p=0.384, Fisher's exact test; p=0.371 respectively).

Most of the caregivers were married (61.8%).Marital status was not different among the participants in both intervention and control groups (Fisher's exact test; p=0.203). The majority of the caregivers and their spouses were farmers 61.8 % and 42.7% respectively. There was no statistical difference in caregiver occupation between the study groups (Fisher's exact test; $p=0.425$). However, there was a statistical difference among the occupation of their spouses (Fisher's exact test; $p=0.009$).

A total of twenty-eight caregivers (31.4%) had attained secondary education as their highest level of education. About 41.6% had primary education. Only 6.7% and 7% reported having attained a degree or diploma respectively. There was a difference in education levels between the study groups(Fisher's exact test; $p = 0.003$).Relating to average monthly income, more than half (55.1%) reported monthly earnings of 200,000 or less Ugandan shillings (Table 4.2). Monthly income was significantly different between the study groups (Fisher's exact test; $p =<0.001$).The socio-demographic characteristics of caregivers namely; relation to the child, occupation of caregiver's spouse/partner, level of education and the monthly income that were significantly different were controlled for during data analysis.

Table 4.1Socio-demographic characteristics of caregivers by study groups

Characteristics	Study groups				
	Intervention N = 50 n (%) or mean ± SD	**Control N = 39 n (%) or mean ± SD**	**Total N = 89 n (%) or mean ± SD**	**Chi-square/ Fisher's exact test value**	***p*-value**
Caregiver age distribution (years)				4.131[a]	0.396
≤ 25	4 (8)	7 (17.9)	11 (12.4)		
26-29	3 (6)	2 (5.1)	5 (5.6)		
30-35	9 (18)	8 (20.5)	17 (19.1)		
36-39	10 (20)	3 (7.7)	13 (14.6)		
≥ 40	24 (48)	19 (48.7)	43 (48.3)		
Age of caregiver (years)	39.06 ± 9.74	36.49 ± 10.37	37.93 ± 10.05		0.233[b]
Sex of caregiver				0.496[c]	0.481
Male	17 (34)	17 (43.6)	34 (38.2)		
Female	33 (66)	22 (56.4)	55 (61.8)		
Relation to the child				15.710[a]	0.012*
Father	11 (22)	10 (25.6)	21 (23.6)		
Mother	32 (64)	19 (48.7)	51 (57.3)		
Uncle	1 (2)	1 (2.6)	2 (2.2)		
Aunt	1 (2)	0 (0)	1 (1.1)		
Brother	1 (2)	2 (5.1)	3 (3.4)		
Sister	2 (4)	4 (10.3)	6 (6.7)		
Cousin	0 (0)	3 (7.7)	3 (3.4)		
Grandfather	1 (2)	0 (0)	1 (1.1)		
Grandmother	1 (2)	0 (0)	1 (1.1)		
Household size	6.12 ± 1.66	6.51 ± 2.38	6.29 ± 2.00		0.384[d]
Religion				5.417[a]	0.371
Catholic	17 (34)	8 (20.5)	25 (28.1)		
Anglican	14 (28)	11 (28.2)	25 (28.1)		
Moslem	5 (10)	6 (15.4)	11 (12.4)		
Seventh-day Adventist	2 (4)	6 (15.4)	8 (9)		
Born again Christian	10 (20)	6 (15.4)	16 (18)		
Orthodox Baptist	2 (4)	2 (5.1)	4 (4.5)		
Marital status				6.6663[a]	0.203
Single	5 (10)	6 (15.4)	11 (12.4)		
Married	35 (70)	20 (51.3)	55 (61.8)		
Co-habiting	6 (12)	5 (12.8)	11 (12.4)		
Separated	0 (0)	3 (7.7)	3 (3.4)		
Divorced	0 (0)	1 (2.6)	1 (1.1)		
Widowed	4 (8)	4 (10.3)	8 (9)		

Note. This table displays the socio-demographic characteristics of the study participants. *Abbreviations. SD, standard deviation;a, Fisher's exact probability test;b,Independentsample t-test, c, Chi-square test;d, Mann-Whitney U test, *significant at $p < 0.05$ (2-tailed).*

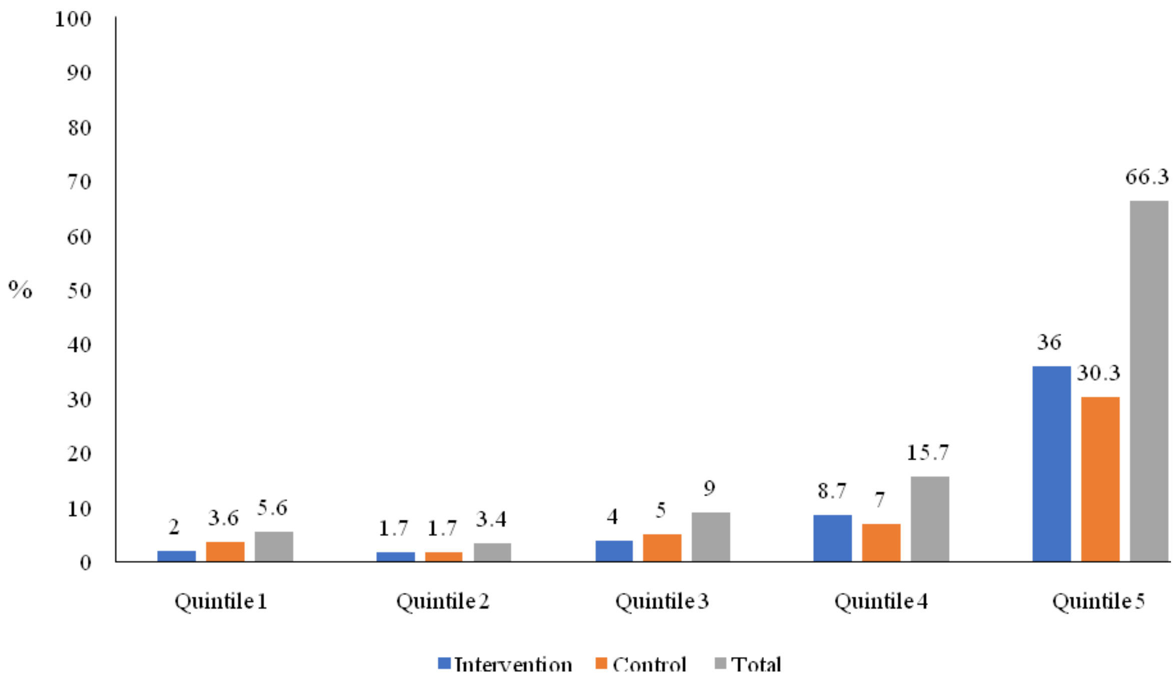
Table 4.2 Continued: Socio-demographic characteristics of caregivers by study groups

Characteristics	Study groups				
	Intervention N = 50 n (%) or mean ± SD	**Control N = 39 n (%) or mean ± SD**	**Total**	**Chi-square/ Fisher's exact test value**	***p*-value**
Occupation of caregiver				4.830[a]	0.425
Civil servant	5 (10)	3 (7.7)	8 (9)		
Private sector	6 (12)	1 (2.6)	7 (7.9)		
Business	10 (20)	6 (15.4)	16 (18)		
Education sector	1 (2)	0 (0)	1 (1.1)		
Farmer	27 (54)	28 (71.7)	55 (61.8)		
Unemployed	1 (2)	1 (2.6)	2 (2.2)		
Occupation of caregiver's spouse/partner				13.060[a]	0.009*
Civil servant	8 (16)	3 (7.7)	11 (12.4)		
Private sector	6 (12)	1 (2.6)	7 (7.9)		
Business	10 (20)	1 (2.6)	11 (12.4)		
Education sector	0 (0)	0 (0)	0 (0)		
Farmer	17 (34)	21 (53.8)	38 (42.7)		
Level of education				18.720[a]	0.003*
Primary	14 (28)	23 (59)	37 (41.6)		
Secondary (UCE)	12 (24)	10 (25.6)	22 (24.7)		
Secondary (UACE)	4 (8)	2 (5.1)	6 (6.7)		
Undergraduate					
Degree	3 (12)	0 (0)	6 (6.7)		
Diploma	3 (6)	4 (10.3)	7 (7.9)		
Postgraduate					
Master's degree	5 (10)	0 (0)	5 (5.6)		
PhD	1 (2)	0 (0)	1 (1.1)		
No formal education	5 (10)	0 (0)	5 (5.6)		
Monthly income (UGX)				21.275[a]	<0.001**
≤ 200,000	19 (38)	30 (76.9)	49 (55.1)		
201,000 - 400,000	8 (16)	4 (10.3)	12 (13.5)		
401,000 - 600,000	5 (10)	4 (10.3)	9 (10.1)		
601,000 - 800,000	1 (2)	1 (2.6)	2 (2.2)		
801,000 - 1,000,000	7 (14)	0 (0)	7 (7.9)		
≥ 1,000,000	10 (20)	0 (0)	10 (11.2)		

Note. This table displays the socio-demographic characteristics of the study participants. *Abbreviations. UCE, Uganda Certificate of Education; UACE, Uganda Advanced Certificate of Education; UGX, Ugandan Shillings; SD, standard deviation; a, Fisher's exact test;*significant at p < 0.05;(2-tailed); **significant at p < 0.001(2-tailed).*

4.3.2 Caregiver socio-economic characteristics

The socioeconomic status (SES) of the caregivers was assessed using the EquityTool©which is based on the Demographic and Health Survey (DHS) Wealth Index(Metrics for Management, 2021a). The Wealth Index segregates the population into 5equal clusters or quintiles(Chakraborty et al., 2016). Results presented in Figure 4.2 indicate how the study participants compared to the national population in terms of wealth based on the Uganda DHS of 2016. The wealth quintiles are numbered 1 (poorest 20%)to 5 (wealthiest 20%). Only 5.6% of the respondents were in the bottom quintile (quintile 1) and the majority over 60% were in the wealthiest quintile (quintile 5). The wealth index was not significantly different between the study groups ($\chi2$; p = 0.157).



Note. This figure shows the wealth quintilecategorisationof the study participants.

Figure 4.2Caregiver wealth index categorisation

4.4Comparison of T1D training, nutrition education and level of T1D nutrition knowledge among caregivers by study groups

4.4.1 T1D training among caregivers

The majority of the caregivers (79.8%) had attendedtraining on type 1 diabetes. The trainings were mostly conducted at a hospital (81.7%). 67.6% of the caregivers mentioned a nurse as the facilitator of the training. No significant differences were observed between the study groups regarding T1D training attended, venue of the training or who facilitated the training ($\chi 2$; $p > 0.05$) (Table 4.3).

Nutrition in type 1 diabetes (59.6%) was the top mentioned topic in the type 1 diabetes trainings, this was followed by hypo/hyperglycaemia management (50.6%), there was a significant difference between the study groups regarding the topic 'hypo/hyperglycaemia management', with over 60% of the caregivers in the intervention group mentioning that they attended a session where it was presented compared to 33% in the control group ($\chi 2$; $p = 0.008$). Over fifty percent (59.6%) mentioned that they mostly trusted a doctor to give them information about type 1 diabetes mellitus, this was significantly different between the study groups (Fisher's exact test; $p = 0.018$) (Table 4.3).

Having a discussion with a health facility staff was the most preferred format of getting information about type 1 diabetes mellitus and nutrition (75.3%) and group discussion was the most preferred format of learning (52.8%). However, a higher proportion of caregivers in the intervention group compared to the control preferred one on one (individual) discussions with a healthcare worker as the most preferred format of learning ($\chi 2$; $p = 0.003$) (Table 4.4).

Table 4.3 Comparison of type 1 diabetes training characteristics by study groups

Characteristics	Study group				
	Intervention N = 50 n (%) or mean ± SD	**Control N = 39 n (%) or mean ± SD**	**Total N = 89 n (%) or mean ± SD**	**Chi-square/ Fisher's exact test value**	***p*-value**
Ever been trained about type 1 diabetes				0.106[b]	0.745
Yes	41 (82)	30 (76.9)	71 (79.8)		
No	9 (18)	9 (23.1)	18 (20.2)		
Place where training was done				3.431[a]	0.213
Hospital	36 (87.8)	22 (73.3)	58 (81.7)		
Health centre	1 (2.4)	4 (13.3)	5 (7)		
Private clinic	4 (9.8)	4 (13.3)	9 (11.3)		
Who conducted the training				0.837[b]	0.360
Doctor	11 (26.8)	12 (40.0)	23 (32.4)		
Nurse	30 (73.2)	18 (60.0)	48 (67.6)		
Topics of the type 1 diabetes trainings attended					
Blood glucose monitoring	22 (44)	13 (33.3)	35 (39.3)	0.646	0.307
Hypo/hyperglycaemia management	32 (64)	13 (33.3)	45 (50.6)	7.062	0.008*
Nutrition in type 1 diabetes	32 (64)	21 (53.8)	53 (59.6)	0.564	0.453
Insulin use and dosage	15 (30)	11 (28.2)	26 (29.2)	0.000	1.000
Fruit and vegetable intake	1 (2)	2 (5.1)	3 (3.4)	0.048	0.579
Balanced diet	2 (4)	2 (5.1)	4 (4.5)	0.065	1.000
Hygiene	1 (2)	1 (2.6)	2 (2.2)	0.032	1.000
Eating in time	1 (2)	2 (5.1)	3 (3.4)	0.658	0.579
Exercise	3 (6)	3 (7.7)	6 (6.7)	0.084	1.000
Cause of diabetes and types	2 (4)	1 (2.6)	3 (3.4)	0.139	1.000
Trusted the most to give information about type 1 diabetes mellitus				6.983[a]	0.018*
Doctor	34 (68)	19 (48.7)	53 (59.6)		
Nurse	13 (26)	20 (51.3)	33 (37)		
Nutritionist	3 (6)	0 (0)	3 (3.4)		

Note. This table compares the type 1 diabetes training characteristicsof the study groups.
*Abbreviations. SD, standard deviation; a, Fisher's exact test; b, Chi-square test,*significant at p< 0.05;(2-tailed); **significant at p < 0.001(2-tailed).*

Table 4.4 Continued: Comparison of type 1 diabetes training characteristics by study groups

Characteristics	Study group				
	Intervention N = 50 n (%) or mean ± SD	**Control N = 39 n (%) or mean ± SD**	**Total N = 89 n (%) or mean ± SD**	**Chi-square/ Fisher's exact test value**	***p*-value**
The preferred format of getting information about type 1 diabetes mellitus and nutrition				3.629[a]	0.481
Brochures	9 (18)	5 (12.8)	14 (15.7)		
Posters	2 (4)	2 (5.1)	4 (4.5)		
Internet/website	1 (2)	0 (0)	1 (1.1)		
Thorough discussion with health facility staff	35 (70)	32 (82.1)	67 (75.3)		
Other (discussion with peers)	3 (6)	0 (0)	3 (3.4)		
Preferred format of learning					
Group discussion	23 (46)	24 (61.5)	47 (52.8)	1.545	0.214
Individual discussion	22 (44)	5 (12.8)	27 (30.3)	8.657	0.003*
Demonstrations	1 (2)	1 (2.6)	2 (2.2)	0.032	1.000
Note taking and reading	11 (22)	9 (23.1)	20 (22.5)	0.000	1.000

Note. This table compares the type 1 diabetes training characteristicsof the study groups. *Abbreviations. SD, standard deviation; a, Fisher's exact test; b, Chi-square test,*significant at p < 0.05;(2-tailed); **significant at p < 0.001(2-tailed).*

4.4.2Comparison of nutrition education sessionsabout T1DM attended by study groups

Caregivers were asked if they had attended any nutrition education training about type 1 diabetes, where it was conducted, who conducted the training and the topics of the training. When asked if they had attended a nutrition education session about type 1 diabetes, fifty-six (62.9%) responded that they had attended such a session.The trainings were mostly conducted at a hospital (85.7%). 64.3% of the caregivers mentioned a nurse as the facilitator of the training. Types of food to eat was the most frequent topic attended (55.1%). However, dietary diversity was the least attended topic (5.6%)(Table 4.5). No significant differences were observed between the study groups in terms of nutrition education sessions about type 1 diabetes training, venue of the training, who facilitated the training and topics presented.

Table 4.5Comparison ofnutrition education characteristics by study groups

Characteristics	Intervention N = 50 n (%) or mean ± SD	Control N = 39 n (%) or mean ± SD	Total N = 89 n (%) or mean ± SD	Chi-square/ Fisher's exact test value	*p*-value
Ever attended nutrition education sessions about type 1 diabetes				0.181[b]	0.671
Yes	30 (60)	26 (66.7)	56 (62.9)		
No	20 (40)	13 (33.3)	33 (37.1)		
Place where training was done				4.874[a]	0.084
Hospital	28 (93.3)	20 (76.9)	48 (85.7)		
Health centre	0 (0)	4 (15.4)	4 (7.1)		
Private clinic	2 (6.7)	2 (7.7)	4 (7.1)		
Who conducted the training				2.581[a]	0.314
Doctor	6 (20)	10 (38.5)	16 (28.6)		
Nurse	22 (73.3)	14 (53.8)	36 (64.3)		
Nutritionist	2 (6.7)	2 (7.7)	4 (7.1)		
Topics of the nutrition education sessions					
Types of food to eat	28 (56)	21 (53.8)	49 (55.1)	0.041[b]	0.839
Fruits and vegetables	7 (14)	7 (17.9)	14 (15.7)	0.258[b]	0.612
Food portioning	8 (16)	4 (10.3)	12 (13.5)	0.620[b]	0.431
Dietary diversity	5 (10)	0 (0)	5 (5.6)	4.132[a]	0.065

Note. This table compares the nutrition education training characteristicsof the study groups. *Abbreviations. SD, standard deviation; a, Fisher's exact test; b, Chi-square test,*significant at p < 0.05;(2-tailed); **significant at p < 0.001(2-tailed).*

4.5Developed nutrition education guide for caregivers of children with type 1 diabetes in Uganda.

The <u>nutrition education participant guide for caregivers of children with type 1 diabetes in Uganda</u>© (Ndahura, 2021b) was developed to help caregivers of children with type 1 diabetes mellitus to use foods within their reach in a way that helps their child to keep their blood sugar level closer to the target level and ensure adequate dietary intake. The guide consisted of a total of 8 sessions with each session lasting a total of 45 minutes. The topics covered and brief descriptions of each of the sessions are shown in Appendix J. Furthermore, a nutrition education facilitator guide for caregivers of children with type 1 diabetes in Uganda© (Ndahura, 2021a)was also developed to provide a roadmap to the content of each lesson in the participant guide; by highlighting the materials required and providing additional notes to help the facilitator lead the training.

4.6Comparison level of T1DM nutrition knowledge among caregivers by study groups

Most of the caregivers (87.6%) had low type 1 diabetes nutrition knowledge with the majority scoring fifty or fewer percentage points with a mean NKS score of 30.9 ± 16.4 (Table 4.6).No significant differences were observed between the study groups in terms of categorization of NKS scores. The NKS domain with the best mean percentage score of correct responses was blood glucose response to food with a score of 64.04 ± 39.15. The second-best response was on healthful eating and the third was nutrition label reading (36.52 ± 20.74 and 31.78 ± 29.43 respectively). Carbohydrate counting was the least performed domain with a mean percentage score of 7.64 ± 14.61.

A Kruskal-Wallis Htest revealed a statistically significant difference in caregivers nutrition knowledge scores across the levels of education $\chi^2(3) = 12.23$, $p = 0.007$. Caregivers who had completed university of higher had the highest mean rank of 53.61, followed by those who had completed primary education (46.68), secondary education (43.39), while those with no formal education had the least mean rank (8.90). No significant differences in NKS scores were observed based on sex of the caregiver (Mann-Whitney *U*-test; $U = 844$, $z = -0.77$, $p = 0.440$). There were no significant differences in NKS scores based on caregivers age distribution (Kruskal-Wallis Htest; $\chi^2(4) = 2.95$, $p = 0.566$).

Table 4.6Comparison of caregiver nutrition knowledge scores categories by study groups

	Intervention N = 50 n (%) or mean ± SD	Control N = 39 n (%) or mean ± SD	Total N = 89 n (%) or mean ± SD	Chi-squaretest value	*p*-value
Mean NKS score	31.5 ± 16.3	30.0 ± 16.8	30.9 ± 16.4		0.781[a]
NKS score categories				0.586	0.525[b]
Low type 1 diabetes nutrition knowledge (≤ 50%)	45 (90)	33 (84.6)	78 (87.6)		
Medium type 1 diabetes nutrition knowledge (51-75%)	5 (10)	6 (15.4)	11 (12.4)		
High type 1 diabetes nutrition knowledge (≥ 76%)	0 (0)	0 (0)	0 (0)		

Note. This table categorizes the caregiver's nutrition knowledge scores into low, medium and high of the study groups.
Abbreviations. NKS, nutrition knowledge survey; SD, standard deviation; a, Mann–Whitney U-test; b, Chi-square test; c,

4.7Comparison of children's type 1 diabetes-related characteristics by study groups

The children had a mean age of 10.40 ± 3.2 years, children in the control group were significantly older than those in the intervention group (Mann–Whitney U-test; p= 0.001). The proportion of girls was slightly more than that of boys (50.6% vs 49.4%).However, the males in the control group were significantly older than those in the intervention group (Mann–Whitney U-test; p= 0.004).

The highest proportion of children (67.4%) had T1DM for 2–5 years with an average disease duration of 4.75 ± 3.1 years. Furthermore, the majority (59.6%) reported being on a multiple daily insulin injection regimen (≥3 times a day). A significant difference was observed between the study groups in terms of the insulin regime with the majority of children in the intervention group being on three or more doses of insulin per day compared to the control group who were mostly on two or less insulin doses per day ($\chi2$;*p* = 0.001). Most of the children had no family history of T1DM (65.8%), while those who had a family history of T1DM had mainly a grandfather (21.9%) diagnosed with T1DM. A significant difference was observed between the study groups regardingfamily members with T1DM(Fisher's exact test; *p*= 0.012), the control group reported more family members with a history of T1DM. No significant differences were observed between the study groups in terms of duration of T1DM and family history of T1DM (Table 4.7).

The mean HbA1c value was 11.24 ± 2.7.No significant difference was observed between the study groups in terms of HbA1c (Mann–Whitney U-test; *p*= 0.314). An independent -samples t-test was conducted to compare the HbA1c values for males and females. There was no significant difference in HbA1c values for males (11.20 ± 2.7) and females (11.27 ± 2.6) independent sample t-test; t (87) = -0.10, p = 0.795. No significant differences in HbA1c values were observed based on the sex of the caregiver (Independent sample t-test; t (85.66) = -0.007, p = 0.995).

Table 4.7Comparison of children's T1DM related characteristics by study groups

Characteristics	Study groups				
	Intervention N = 50 n (%) or mean ± SD	**Control N = 39 n (%) or mean ± SD**	**N= 89 n (%) or mean ± SD**	**Chi-square/ Fisher's exact test value**	***p*-value**
Age of child (years)	9.58 ± 2.9	11.46 ± 3.2	10.40 ± 3.2		0.001[c]*
Age of child (male)	9.08 ± 3.4	12.00 ± 2.9	10.27 ± 3.5		0.004[c]*
Age of child (female)	10.13 ± 2.3	11.00 ± 3.4	10.53 ± 2.8		0.110[c]
Sex of child				0.111[b]	0.739
Male	26 (52)	18 (46.2)	44 (49.4)		
Female	24 (48)	21 (53.8)	45 (50.6)		
[1]**Duration of T1DM (years)**				5.027[a]	0.079
≤1	0 (0)	4 (10.3)	4 (4.5)		
2-5	35 (70)	25 (64.1)	60 (67.4)		
≥6	15 (30)	10 (25.6)	25 (28.1)		
Insulin regimen				11.306[b]	0.001*
≤ 2 times a day	12 (24)	24 (61.5)	36 (40.4)		
≥ 3 times a day	38 (76)	15 (38.5)	53 (59.6)		
[2]**Family history of T1DM**				0.000[b]	1.000
Yes	17 (34)	14 (35.9)	31 (34.8)		
No	33 (66)	25 (64.1)	58 (65.2)		
Family history of T1DM relation to child				17.710[a]	0.012*
Father	0 (0)	1 (2.6)	1 (3.1)		
Mother	0 (0)	2 (5.1)	2 (6.3)		
Uncle	0 (0)	4 (10.3)	4 (12.5)		
Aunt	0 (0)	1 (2.6)	1 (3.1)		
Brother	3 (6)	2 (5.1)	5 (15.6)		
Sister	4 (8)	1 (2.6)	5 (15.6)		
Cousin	2 (4)	0 (0)	2 (6.3)		
Grandfather	3 (6)	4 (10.3)	7 (21.9)		
Grandmother	5 (10)	0 (0)	5 (15.6)		
HbA1c (%)	11.57 ± 2.4	10.81 ± 2.9	11.24 ± 2.7		0.314[c]
Minimum HbA1c	6.1	4.7	4.7		
Maximum HbA1c	19.4	18.0	19.4		

Note. This table compares the children's T1DM related characteristics of the study groups. *Abbreviations.SD, standard deviation; a, Fisher's exact test; b, Chi-square test; c,Mann–Whitney U-test; *significant at p < 0.05;(2-tailed); **significant at p < 0.001(2-tailed); T1DM, type 1 diabetes mellitus; [1]Duration of T1DM refers to the length of time since the child was first diagnosed with T1DM; [2]Family history of T1DM means whether any other family member had been diagnosed with T1DM.*

4.8Comparison of dietary intake and nutrient adequacy of children by study groups

The children's mean DDS and calorie intake were 5.5 ± 1.4 and 1706.0 ± 628.8 kcal, respectively. A significant difference was observed between the study groups in terms of DDS with the intervention group having a higher DDS compared to the control group (Mann–Whitney *U*-test; $p = 0.003$).The majority (74.2%) had a high DDS (≥5). There was no significant difference in DDS categorization observed between the study groups(χ^2; $p = 0.056$) (Table 4.8).

The intervention group had a significantly higher fat intake compared to the control group (Mann–Whitney *U*-test; $p = 0.002$).The mean caloric energy contribution from carbohydrate and protein were both not within the recommended ranges of 45-50% and 15-20% respectively. A significant difference was observed between the study groups in terms of nutrient energy contribution from carbohydrate and fat with both being higher in the intervention group (Mann–Whitney *U*-test; $p = 0.003$) (Table 4.8).

The mean NARs of carbohydrate, protein, and fat were 1.0 ± 0.4, 0.8 ± 0.4, 0.5 ± 0.4, respectively. Inadequacies were observed with vitamins (A, B_2, B_3 B_5, B_{12}, biotin and folic acid) and minerals (calcium, iron and zinc)with all having aNAR of less than 0.7. Only vitamins B_1, B_6 had NARs of ≥0.7. The NARs of fat, vitamins B_2, B_3 B_5, B_6, B_{12}, biotin and folic acid were significantly higher in the intervention group compared to the control group. The MAR was 0.6 ± 0.3 (Table 4.8). A significant difference was observed between the study groups in terms of MAR with the intervention group having a higher MAR (Mann–Whitney *U*-test; $p = 0.025$). However, there was no significant difference in MARin terms of sex (Mann–Whitney *U*-test; $p = 0.883$).

Table 4.8Comparison of children's dietary intake characteristics by study groups

Characteristics	Study groups					
	Intervention N = 50 n (%) or mean ± SD	**Control N = 39 n (%) or mean ± SD**	**N= 89 n (%) or mean ± SD**	**Mann–Whitney U-test *p*-value**	**Independent sample t-test *p*-value**	**Chi-square *p*-value**
Mean DDS	5.96 ± 1.5	5.00 ± 1.1	5.5 ± 1.4	0.003*		
Dietary diversity score (DDS)						0.056
Low DDS (≤ 4)	9 (18)	14 (35.9)	23 (25.8)			
High DDS (≥ 5)	41 (82)	25 (64.1)	66 (74.2)			
Dietary intake						
Energy (kcal)	1723.6 ± 649.4	1683.5 ± 609.1	1706.0 ± 628.8	0.620		
Carbohydrate (g)	293.5 ± 110.9	321.1 ± 130.2	305.6 ± 119.8		0.283	
Protein (g)	55.1 ± 29.6	49.9 ± 21.4	52.9 ± 26.3	0.667		
Fat (g)	40.8 ± 35.6	27.1 ± 31.1	34.8 ± 34.2	0.015*		
Nutrient energy contribution (%)						
Carbohydrate (45 - 50)	68.2 ± 14.2	75.2 ± 13.5	71.3 ± 14.3	0.006*		
Protein (15 - 20)	12.7 ± 4.8	12.1 ± 4.7	12.4 ± 4.8	0.518		
Fat (<35)	18.9 ± 11.5	12.7 ± 11.6	16.2 ± 11.9	0.002*		
Nutrient Adequacy Ratio						
Carbohydrate	1.1 ± 0.4	1.0 ± 0.3	1.0 ± 0.4		0.283	
Protein	0.9 ± 0.4	0.8 ± 0.3	0.8 ± 0.4	0.667		
Fat	0.5 ± 0.5	0.3 ± 0.4	0.5 ± 0.4	0.015*		
Vitamin A	0.4 ± 0.6	0.6 ± 1.1	0.5 ± 0.9	0.333		
Vitamin B_1	0.7 ± 0.5	0.6 ± 0.3	0.7 ± 0.4	0.119		
Vitamin B_2	0.6 ± 0.4	0.3 ± 0.3	0.5 ± 0.4	<0.001**		
Vitamin B_3	0.4 ± 1.0	0.1 ± 0.2	0.3 ± 0.8	0.002*		
Vitamin B_5	0.5 ± 0.3	0.3 ± 0.2	0.5 ± 0.3	<0.001**		
Vitamin B_6	1.3 ± 1.0	1.0 ± 1.0	1.2 ± 1.0	0.032*		
Vitamin B_{12}	0.5 ± 0.6	0.3 ± 0.5	0.4 ± 0.6	0.020*		
Biotin	0.2 ± 0.3	0.1 ± 0.2	0.2 ± 0.3	0.004*		
Folic acid	0.6 ± 0.3	0.5 ± 0.6	0.6 ± 0.5	0.007*		
Calcium	0.3 ± 0.2	0.3 ± 0.3	0.3 ± 0.2	0.099		
Iron	1.0 ± 0.4	0.9 ± 0.4	0.9 ± 0.4	0.588		
Zinc	1.0 ± 0.6	0.8 ± 0.3	0.9 ± 0.5	0.166		
Mean Adequacy Ratio	0.7 ± 0.3	0.5 ± 0.2	0.6 ± 0.3	0.025*		

*Note. This table compares the children's dietary intake characteristics of the study groups. Abbreviations. DDS, dietary diversity score; SD, standard deviation;*significant at p < 0.05;(2-tailed); **significant at p < 0.001(2-tailed).*

4.9 Baseline predictors of elevated HbAlc

Baseline data was used to explore the predictors of elevated HbA1c (≥ 7.5%). Several variables were examined as potential predictors of elevated HbA1c (Table 4.9). A logistic regression was performed to ascertain the effects of caregiver's nutrition knowledge, training on T1DM, training on nutrition in T1DM and the child's DDS on the likelihood of the child having an elevated HbA1c. The logistic regression model was statistically significant, $\chi2(4) = 9.594$, $p = 0.048$. The model explained 22.5% (Nagelkerke R Square) of the variance in HbA1c and correctly classified 89.9.% of the cases. Increasing DDS was significantly associated with an increased likelihood of exhibiting an elevated HbA1c ($p = 0.011$).

On the contrary, the caregiver's relation to the child, age of the child, insulin regime and duration of T1DM did not predict an elevated HbA1c (logistic regression model; $\chi2\ (11) = 7.373$, p = 0.768).Similarly, sex of caregiver, sex of the child, age of the child, age of the caregiver, household size and religion did not predict an elevated HbA1c (logistic regression model; $\chi2\ (9) = 11.259$, $p = 0.258$).

Table 4.9 Baseline predictors of elevated HbAlc

		95% CI		
Variable	**Adjusted odds ratio**	**Lower**	**Upper**	**P-value**

Training on T1DM	0.913	0.047	17.839	0.952
Training on nutrition in T1DM	1.460	0.147	14.532	0.747
DDS	2.632	1.243	5.574	0.011*
Caregiver's nutrition knowledge	0.968	0.918	1.022	0.238
Caregiver's relation to the child				
Father	1			
Mother	0.300	2.841	2.841	0.294
Sister	0.196	4.248	4.248	0.299
Insulin regime				
Twice a day	1			
Three times a day	2.941	14.410	14.410	0.183
Duration of T1DM	1.013	1.276	1.276	0.911
Sexof the child				
Male	1			
Female	0.693	0.132	3.640	0.665
Sex of caregiver				
Male	1			
Female	0.220	0.022	2.253	0.202
Age of the child	0.832	1.103	1.103	0.201
Age of caregiver	0.993	0.912	1.082	0.879
Household size	0.883	0.605	1.288	0.518
Religion				
Catholic	1			
Anglican	0.909	0.112	7.352	0.929
Seventh day adventist	0.111	0.012	1.005	0.051
Born again christian	1.089	0.085	13.985	0.948

Note. This table displays the predictors of elevated HbAlc.
*Abbreviations. CI, confidence interval; *significant at p < 0.05 (2-tailed).*

FINDINGS AFTER INTERVENTION

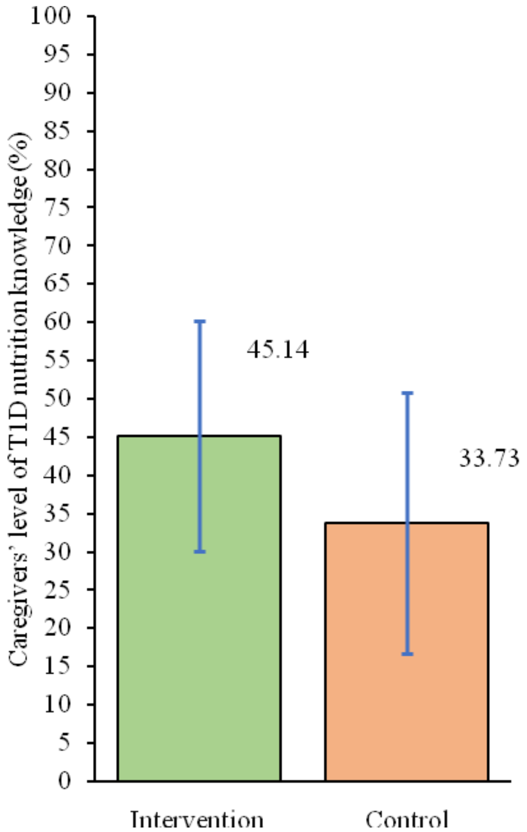
After the intervention, caregivers' level of T1D nutrition knowledge and children's HbA1c, dietary diversity score, nutrient and mean adequacy ratios were assessed3 monthspost intervention.

4.9 Comparison of caregivers' level of T1DM nutrition knowledge, children's HbA1c, dietary diversity score, nutrient and mean adequacy ratios by study groups at 3 months post intervention.

4.9.1 Effect of nutrition education on caregivers' level of T1DM nutrition knowledge at 3 months post intervention

The intervention group had a higher mean type 1 diabetes nutrition knowledge score (45.14 ± 15.04)compared to the control group (33.73 ± 17.12)(Figure 4.4). There wasa significant differencein caregivers' level of T1DMnutrition knowledge scores between the study groups3 months after the study (Mann-Whitney *U*-test; $U = 510$, $z = -3.05$, $p = 0.002$) (Table 4.10).A Wilcoxon signed-rank test revealed a statistically significant increase in caregiver's nutrition knowledge scores following their participation in the structurednutrition education training programme, $z = -4.02$, $p<0.001$, with a medium effect size (r = 0.42).

ANCOVA (Analysis of covariance) was performed to assess the differences in caregivers' level of T1DM nutrition knowledge at the end of the studyafter accounting for prior training on nutrition in T1DM. There was no statistically significant difference in the caregivers' level of T1DM nutrition knowledge between those who had attended a nutrition education session prior to the study and those that had not. ANCOVA $F(1, 79) = 0.567$, $p = 0.454$, partial $\eta^2 = 0.01$.



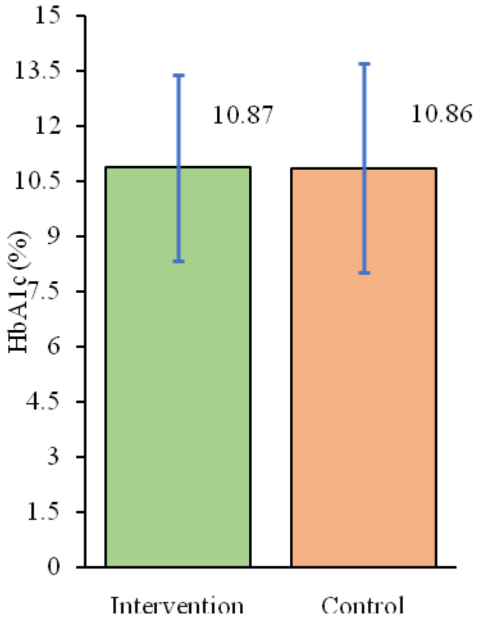
Note. This figure illustrates the change in caregivers' level of T1DM nutrition knowledge scoresafter the intervention in the two study groups.

Figure4.3 Change in caregivers' level of T1DM nutrition knowledge

4.9.2 Effect of nutrition education of caregivers onHbAlclevels of their children at 3 months post intervention

The intervention group had a higher mean HbAlc(10.87±2.54) compared to the control group (10.86 ± 2.85) (Figure 4.5). However, thedifferencein HbAlc levels of the childrenbetween the study groups at 3 months after the study was not significant(Independent sample t-test;t (80) = -0.012,p = 0.991).The hypothesis that nutrition education of caregivers has no significant effect on children's HbA1c levels was not rejected.

A Wilcoxon signed-rank test did not reveal a statistically significant difference in HbAlc levels following their caregiver's participation in the structurednutrition education training programme, $z = -0.32$, $p = 0.748$, with a small effect size ($r = 0.02$).



Note. This figure illustrates the change in HbAlc levels of the childrenatmonth 3 in the two study groups.

Figure 4.4 Change in HbAlc levels

Table 4.10 Comparison of children's dietary intake characteristics by study groups 3 months post intervention

Characteristics	Study groups					
	Intervention N = 44 n (%) or mean ± SD	**Control N = 38 n (%) or mean ± SD**	**N= 82 n (%) or mean ± SD**	**Mann–Whitney U-test *p*-value**	**Independent sample t-test *p*-value**	**Chi-square *p*-value**
Mean DDS	5.93 ± 1.03	5.26 ± 1.26	5.62 ± 1.21	0.006*		
Low DDS (≤ 4)	5 (11.4)	9 (23.7)	14 (17.1)			0.155
High DDS (≥ 5)	39 (88.6)	29 (76.3)	68 (82.9)			
MAR	0.8 ± 0.3	0.7 ± 0.8	0.7 ± 0.6	0.020*		
Dietary intake						
Energy (kcal)	1770.3 ± 580.2	1745.4 ± 531.1	1758 ± 554.7		0.841	
Carbohydrate (g)	278.5 ± 102.0	328.1 ± 128.7	301.5 ± 117.1	0.047*		
Protein (g)	62.1 ± 25.3	52.4 ± 20.8	57.6 ± 23.7		0.065	
Fat (g)	42.8 ± 38.1	28.9 ± 23.1	40.9 ± 33.8	0.004*		
Nutrient energy contribution (%)						
Carbohydrate (45 - 50)	175.1 ± 307.5	97.9 ± 148.7	141.3 ± 252.4	0.012*		
Protein (15 - 20)	15 ± 7.7	11.9 ± 4.8	13.6 ± 6.7	0.043*		
Fat (<35)	18.9 ± 11.5	12.7 ± 11.6	17.8 ± 13.0	<0.001**		
NAR						
Carbohydrate	0.9 ± 0.3	1.1 ± 0.4	1.0 ± 0.4	0.047*		
Protein	1.0 ± 0.4	0.8 ± 0.3	0.9 ± 0.3		0.065	
Fat	0.7 ± 0.5	0.4 ± 0.3	0.5 ± 0.4	0.004*		
Vitamin A	0.4 ± 0.8	0.7 ± 1.1	0.5 ± 1.0	0.218		
Vitamin B_1	0.9 ± 0.3	0.6 ± 0.3	0.8 ± 0.5	0.040*		
Vitamin B_2	0.6 ± 0.3	0.5 ± 0.3	0.6 ± 0.3	0.080		
Vitamin B_3	0.5 ± 0.9	0.2 ± 0.3	0.4 ± 0.7	0.227		
Vitamin B_5	0.5 ± 0.2	0.4 ± 0.4	0.5 ± 0.3	0.068		
Vitamin B_6	1.5 ± 0.9	1.1 ± 1.1	1.3 ± 1.0	<0.001**		
Vitamin B_{12}	0.9 ± 1.6	0.6 ± 0.7	0.8 ± 1.2	0.081		
Biotin	0.3 ± 0.5	0.1 ± 0.1	0.2 ± 0.4	0.255		
Folic acid	0.8 ± 0.3	0.5 ± 0.4	0.7 ± 0.5		0.006*	
Calcium	0.3 ± 0.2	0.3 ± 0.3	0.3 ± 0.2	0.119		
Iron	1.0 ± 0.3	2.6 ± 10.9	1.8 ± 7.4	0.020*		
Zinc	1.1 ± 0.5	0.9 ± 0.4	1.0 ± 0.5	0.094		

Note. *This table compares the children's dietary intake characteristics of the study groups.*
*Abbreviations. DDS, dietary diversity score; MAR, mean adequacy ratio; NAR, nutrient adequacy ratio; SD, standard deviation; *significant at p < 0.05;(2-tailed); **significant at p < 0.001(2-tailed).*

4.9.3Effect of nutrition education of caregivers on dietary diversity, nutrient and mean adequacy ratios of their children3 months post intervention.

The intervention group had a significantly higher mean DDS (5.93 ± 1.08) compared to the control group (5.26 ± 1.26)(Mann-Whitney *U*-test; U = 550, z = -2.74, p = 0.006).The majority (82.9%) had a high DDS (≥5). There was no significant difference in DDS categorization observed between the study groups (χ^2; p =0.155)(Table 4.10).

A Wilcoxon signed-rank test did not reveal a statistically significant difference in the DDS of the children following their caregiver's participation in the structurednutrition education training programme, z = -0.61, p = 0.536, with a small effect size (r = 0.06).

The intervention group had a significantly higher fat intake compared to the control group (Mann–Whitney *U*-test; p = 0.004)(Table 4.10). However, the control group had a significantly higher carbohydrate intake compared to the intervention group (Mann–Whitney *U*-test; p = 0.012).The mean caloric energy contribution from carbohydrate, protein and fat were all significantly higher in the intervention group (Mann–Whitney *U*-test; $p< 0.05$). In addition, the mean caloric energy contribution from carbohydrate was not within the recommended range of 45-50% in both study groups. A significant difference was observed between the study groups in terms of nutrient energy contribution from carbohydrate and fat with both being higher in the intervention group (Mann–Whitney *U*-test; $p< 0.05$)(Table 4.10).

Inadequate intakes were observed for fat, vitaminsA, B_2, B_3, B_5, biotinand calcium with all having aNAR of less than 0.7. Only vitamins B_1, B_6 had NARs of ≥ 0.7. The

NARs of fat, vitamins B_1, B_6, and folic acid were significantly higher in the intervention group compared to the control group. However, the NARs of carbohydrate and iron were significantly higher in the control group compared to the intervention group(Table 4.10).

The intervention group had a slightly higher mean MAR (0.8 ± 0.3) compared to the control group (0.7 ± 0.8)(Table 4.9). There was a significant difference in MAR of the children between the study groups with a higher median in the intervention group 3 months after the study (*Md* = 0.7) compared to the control group (*Md* = 0.5)(Mann-Whitney *U*-test; $U = 587$, $z = -2.31$, $p = 0.021$). A Wilcoxon signed-rank test did not reveal a statistically significant difference in the MAR of the children following their caregiver's participation in the structurednutrition education training programme, $z = -1.94$, $p = 0.051$, with a small effect size ($r = 0.21$). The hypothesis thatnutrition education of caregivers has no significant effect on children's dietary diversity and mean adequacy ratio was not rejected.

4.10 Effect of nutrition education on caregivers' level of T1DM nutrition knowledge, children's HbA1c, dietary diversity score and mean adequacy ratios by study groups

Findings in Table 4.11 indicate the difference in differences (DID) resultsof the baseline and endline. Caregivers T1DM nutrition knowledge scores increased significantly in the interventiongroup (t-test; $p = 0.000$). While the control group had the least change in caregivers' T1DM nutrition knowledge score (3.67). The difference in differences (DID)of the baseline and endline was 9.93 and was significant (t-test; p = 0.003). The hypothesis that nutrition education has no significant effect on caregivers' level of T1DM nutrition knowledge was rejected.

The HbA1c in the intervention group reduced (-0.70) compared to the control group which had a slight increase (0.05). No significant differencein HbA1c was observed in both study groups between baseline and end line. The DID of HbA1c was -0.75 (t-test; p = 0.155) (Table 4.11).

No significant difference in DDS was observed in both study groups, however, the intervention group had a reduction in DDS (-0.03) compared to the control group which had an increase (0.56). The DID of DDS was -0.59 (t-test; p = 0.676). The MAR increased slightly in both study groups but it was not statistically significant, the DID of MAR was -0.1 (t-test; p = 0.155) (Table 4.11).

Table 4.11 Effect of nutrition education on caregivers' level of T1DM nutrition knowledge, children's HbA1c, dietary diversity score and mean adequacy ratios by study groups

Caregivers' T1D nutrition knowledge scores				
Study group	**Baseline mean ± SD**	**Endline mean ± SD**	**Difference (SE)**	**T-test p-value**
[b]Control	30.06 ± 16.86	33.73 ± 17.12	3.67 (1.83)	0.058
[a]Intervention	31.54 ± 16.33	45.14 ± 15.04	13.60 (2.86)	<0.001**
	Baseline difference	**Endline difference**	**Difference in difference**	T-test p-value
Mean of a-b	1.48	11.41	9.93	0.003*
HbA1c				
	Baseline mean ± SD	**Endline mean ± SD**	**Difference (SE)**	**T-test p-value**
[b]Control	10.81 ± 2.90	10.86 ± 2.85	0.05 (0.29)	0.772
[a]Intervention	11.57 ± 2.42	10.87 ± 2.54	-0.70 (0.41)	0.126
	Baseline difference	**Endline difference**	**Difference in difference**	**T-test p-value**
Mean of a-b	0.76	0.01	-0.75	0.155
Dietary diversity score				
	Baseline mean ± SD	**Endline mean ± SD**	**Difference (SE)**	**T-test p-value**
[b]Control	5.00 ± 1.19	5.56 ± 1.19	0.56 (0.25)	0.254
[a]Intervention	5.96 ± 1.57	5.93 ± 1.08	-0.03 (0.26)	0.604
	Baseline difference	**Endline difference**	**Difference in difference**	**T-test p-value**
Mean of a-b	0.96	0.37	-0.59	0.676
Mean adequacy ratio				
	Baseline mean ± SD	**Endline mean ± SD**	**Difference (SE)**	**T-test p-value**
[b]Control	0.58 ± 0.27	0.77 ± 0.84	0.19 (0.12)	0.141
[a]Intervention	0.72 ± 0.32	0.81 ± 0.34	0.09 (0.55)	0.061
	Baseline difference	**Endline difference**	**Difference in difference**	**T-test p-value**
Mean of a-b	0.14	0.04	-0.10	0.554

Note. This table shows the difference in difference analysis results of the effect of nutrition education of caregivers.

*Abbreviations. HbA1c, glycated haemoglobin; SE, standard error; T1DM, type 1 diabetes mellitus; * difference in means is statistically significant at $p < 0.05$; **difference in means is statistically significant at $p < 0.001$.*

4.11 Association between socio-demographic characteristics and caregivers' level of type 1 diabetes nutrition knowledge and child's dietary diversity

Socio-demographic correlates of caregivers' level of type 1 diabetes nutrition knowledge (NKSscores) and child's dietary diversity (DDS) were examined. Results showed that a caregiver aged 25 years or younger was more likely to have a higher NKS score (p = 0.040). Also, having no formal education was significantly associated with a lower NKS score (p = 0.029) and their child having a lower DDS (p = 0.034) compared to those with primary, secondary, university or higher education.The rest of the variables were not significantly associated with either NKS scores or DDS (Tables 4.12 and 4.13).

Table 4.12 Socio-demographic correlates of caregivers' level of type 1 diabetes nutrition knowledge and child's dietary diversity

Characteristics	Correlates ofNKS scores			Correlates ofDDS		
	β	**95% CI**	***p*-value**	**β**	**95% CI**	***p*-value**
Age of caregiver (years)	-0.200	[-1.043, 0.643]	0.638	0.040	[-0.038, 0.118]	0.315
Caregiver age distribution (years)						
≤ 25	15.070	[0.675, 29.464]	0.040*	-0.200	[-1.043, 0.643]	0.638
26-29	12.269	[-3.870, 28.408]	0.134	-0.201	[-1.751, 1.350]	0.797
30-35	1.995	[-7.584, 11.574]	0.679	-0.101	[-1.021, 0.820]	0.828
36-39	-4.647	[-15.953, 6.659]	0.415	0.229	[-0.828, 1.286]	0.667
≥ 40	-0.816	[-8.752, 7.120]	0.838	0.492	[-0.250, 1.234]	0.492
Sex of caregiver						
Male	-2.711	[-10.139, 4.718]	0.469	-0.016	[-0.730, 0.698]	0.964
Female	1.996	[-5.276, 9.267]	0.586	-0.128	[-0.808, 0.552]	0.708
Household size	0.791	[-1.007, 2.588]	0.384	0.065	[-0.101, 0.231]	0.439
Marital status						
Single	-4.360	[-19.841, 11.122]	0.576	0.084	[-1.403, 1.571]	0.911
Married	4.530	[-6.362, 15.422]	0.410	0.276	[-0.770, 1.322]	0.601
Co-habiting	6.564	[-7.432, 20.561]	0.353	0.908	[-0.437, 2.252]	0.183
Separated	7.027	[-14.137, 28.190]	0.510	-0.390	[-2.368, 1.589]	0.696
Divorced	-3.519	[-36.492, 29.454]	0.832	-0.785	[-3.868, 2.297]	0.613
Widowed	-4.003	[-16.399, 8.393]	0.522	-0.656	[-1.815, 0.503]	0.263
Occupation of caregiver						
Civil servant	9.379	[-6.669, 25.426]	0.248	0.420	[-1.122, 1.961]	0.589
Private sector	11.608	[-4.386, 27.602]	0.152	0.452	[-1.084, 1.989]	0.559
Business	3.535	[-6.308, 13.377]	0.476	0.232	[-0.713, 1.178]	0.626
Education sector	-22.114	[-57.873, 13.646]	0.222	-0.526	[-3.869, 2.817]	0.755
Farmer	-4.457	[-13.639, 4.726]	0.337	-0.234	[-1.093, 0.624]	0.588
Unemployed	-8.369	[-36.205, 19.466]	0.551	1.201	[-1.401, 3.803]	0.361

Note. This table displays the socio-demographic correlates of NKS scores and DDS.
*Abbreviations. *Significant correlation at p < 0.05 (2-tailed); β, beta coefficient; CI, confidence interval; NKS scores, type 1 diabetes nutrition knowledge survey; DDS, dietary diversity score.*

Table 4.13 Continued: Socio-demographic correlates of caregivers' level of type 1 diabetes nutrition knowledge and child's dietary diversity

Characteristics	Correlates ofNKS scores			Correlates ofDDS		
	β	**95% CI**	***p*-value**	**β**	**95% CI**	***p*-value**
Primary	7.184	[-4.754, 19.121]	0.243	0.214	[-0.933, 1.361]	0.711
Secondary	3.512	[-8.319, 15.342]	0.556	0.966	[-0.170, 2.103]	0.094
University or higher	3.363	[-9.727, 16.453]	0.610	-0.403	[-1.627, 0.820]	0.513
No formal education	-18.696	[-35.378, -2.014]	0.029*	-1.687	[-3.247, -0.127]	0.034*
Monthly income (UGX)						
≤ 200,000	-8.506	[-20.941, 3.930]	0.177	-0.328	[-1.522, 0.867]	0.586
201,000 - 400,000	2.268	[-11.574, 16.109]	0.745	-0.205	[-1.534, 1.125]	0.760
401,000 - 600,000	4.129	[-11.175, 19.433]	0.592	0.104	[-1.366, 1.574]	0.888
601,000 - 800,000	-4.516	[-28.599, 19.568]	0.710	-0.133	[-2.385, 2.118]	0.906
801,000 - 1,000,000	3.680	[-11.333, 18.693]	0.627	-0.219	[-1.622, 1.185]	0.757
≥ 1,000,000	1.489	[-13.234, 16.213]	0.841	0.868	[-0.508, 2.245]	0.213

Note. This table displays the socio-demographic correlates of NKS scores and DDS.
*Abbreviations. *Significant correlation at p < 0.05 (2-tailed); β, beta coefficient; CI, confidence interval; NKS scores, type 1 diabetes nutrition knowledge survey; DDS, dietary diversity score.*

4.12Association between caregiver's nutrition knowledge scores and glycated haemoglobin, dietary diversity, macronutrient intake, nutrient and mean adequacy ratios.

Correlation coefficients (*rho*) between caregiver's nutrition knowledge scores and glycated haemoglobin, dietary diversity, macronutrient intake, nutrient and mean adequacy ratios were calculated. There was a significant positive correlation between NKS scores with NARs of vitamin B_6, biotin, folic acid, and iron (Table 4.14). The hypothesis that there is no statistically significant association between caregiver's level of T1DM nutrition knowledge and nutrient adequacy ratios of children (3-14 years) was rejected.

Correlation coefficients (*rho*) between dietary diversity, mean adequacy ratioand nutrient adequacy ratios (NARs) were calculated for the 15 nutrients by dividing the participants' actual intakes of each nutrient by the recommended daily allowance (RDA) for that nutrient. There was a significant positive correlation between DDS withNARs of fat, protein and vitamins A, B_2, B_3, B_5, B_6, B_{12}, biotin, folic acid, zinc and MAR (Table 4.14).

No significant association was observed between HbA1c level and caregivers' level of T1DM nutrition knowledge. (Spearman rank correlation; *rho* = 0.023, *p* = 0.831. The hypothesis that there is no statistically significant association between caregiver's level of T1DM nutrition knowledge and HbAlc levels of children (3-14 years) with T1DM was not rejected.

However, a positive significant association was observed between HbA1c level and DDS. Spearman rank correlation; *rho* = 0.231, *p* = 0.029.A one-way between-groups analysis of variance (ANOVA) was conducted to explore the impact of caregivers' education on the HbA1c values of the children. Caregiver's level of education was categorised into 3 groups; those that had completed primary, secondary, university or higher and those with no formal education, no significant differences were observed based on caregivers' education F (3,85) = 0.484, p = 0.695).

Table 4.14 Correlations between caregivers' level of T1DM nutrition knowledge scores and DDS, macronutrient intake, NARs, MAR and between DDS and NARs, MAR.

Characteristics	NKS scores		DDS	
	rho	***p-value (2-tailed)***	***rho***	***p-value (2-tailed)***
DDS	0.155	0.146	-	-
Energy intake	0.169	0.114	-	-
Protein intake	0.135	0.209	-	-
Fat intake	0.028	0.798	-	-
Carbohydrate NAR	0.132	0.217	0.159	0.137
Protein NAR	0.135	0.209	0.381	<0.001**
Fat NAR	0.028	0.798	0.335	0.001*
Vitamin A NAR	0.131	0.220	0.287	0.006*
Vitamin B_1 NAR	0.139	0.195	0.115	0.283
Vitamin B_2 NAR	0.137	0.200	0.439	<0.001**
Vitamin B_3 NAR	0.190	0.074	0.333	0.010*
Vitamin B_5 NAR	0.190	0.075	0.367	<0.001**
Vitamin B_6 NAR	0.235	0.028*	0.169	0.113
Vitamin B_{12} NAR	-0.031	0.774	0.451	0.000**
Biotin NAR	0.330	0.002*	0.263	0.013*
Folic acid NAR	0.232	0.029*	0.268	0.011*
Calcium NAR	0.048	0.655	0.149	0.163
Iron NAR	0.213	0.045*	0.199	0.061
Zinc NAR	0.150	0.160	0.336	0.001*
MAR	0.186	0.081	0.349	0.001*

Note. This table shows the correlation results between caregivers' level of T1DM nutrition knowledge scores, macronutrient intake, diet quality and nutrition adequacy indices.
*Abbreviations. NKS, type 1 diabetes nutrition knowledge survey; DDS, Dietary diversity score; rho, correlation coefficient; NAR, nutrient adequacy ratio; MAR, mean adequacy ratio; *significant correlation at p < 0.05); **significant correlation at p < 0.001.*

4.13Endline predictors of elevated HbAlc

Endline data was used to determine predictors for elevated HbAlc (≥7.5%). This was analyzed using linear regression. There was no significant relationship between elevated HbAlc and the variables - Caregivers' nutrition knowledge, carbohydrate intake, protein intake, fat intake, dietary diversity score and mean adequacy ratio. Linear regression model; p = 0.720)(Table 4.15).

Table 4.15 Endline predictors of elevated HbAlc

Model		Coefficients				
		Unstandardized Coefficients		**Standardized Coefficients**		
		B	**Std. Error**	**Beta**	**T**	***P*-value**
1	(Constant)	11.742	1.788		6.565	<0.001
	Caregiver nutrition knowledge	-0.007	0.019	-0.049	-0.383	0.703
	Carbohydrate intake	0.001	0.003	0.039	0.317	0.752
	Protein intake	-0.018	0.016	-0.171	-1.118	0.268
	Fat intake	0.001	0.011	0.015	0.105	0.917
	Dietary diversity score	0.140	0.258	0.068	0.542	0.589
	Mean adequacy ratio	-0.385	0.541	-0.096	-0.711	0.479

a. Dependent Variable: HbA1c ≥ 7.5%

b. Predictors: Caregivers' nutrition knowledge, carbohydrate intake, protein intake, fat intake, dietary diversity score and mean adequacy ratio.

CHAPTER FIVE: DISCUSSION

5.1 Introduction

The study was a cluster randomised controlled trial to evaluate the effect of the provision of a structured nutrition education course to caregivers of children with T1DM attending selected T1DM clinics in Uganda, on their level of T1DMnutrition knowledge and their children's glycaemic control, dietary intake and diversity. The findings of this study have been discussed based on the characteristics of the study participants in relation to the socio-economic and demographic characteristics, T1DM training and nutrition education,children's T1DM-related characteristics, children's dietary intake, nutrient adequacy and diversity, the relationship between caregiver's level of T1DMnutrition knowledge and DDS, macronutrient intake, nutrient and mean adequacy ratios. The effect of nutrition education on; caregivers' level of T1DMnutrition knowledge, children's HbA1c (glycaemic control), dietary intake, nutrient adequacy and diversity was also determined. In addition, predictors of elevated HbA1c have also been discussed.

5.2 Demographic and socio-economic characteristics of study participants-baseline findings

The caregivers in both study groups had similar characteristics in age, sex, household size, religion, marital status and occupation of caregiver. However, the two study groups were significantly different in terms of relation to the child, occupation of caregiver's spouse/partner, level of educationandmonthly income.

Several demographic and socio-economic factors influence compliance with self-management among individuals with diabetes (Abubakari et al., 2016; McBrien et al., 2016). For example, low SES and single-parent family structure have been linked to higher HbA1c levels among American children and adolescents,andlarge family size may affect a caregiver's ability toadequately participate in disease care behaviours and also reducethe financial resources available for medical care(Caccavale et al., 2015; Snyder et al., 2019). Furthermore, caregivers play a significant role in helpingchildren with T1DM implement and adhere to the recommendations in their diabetes care plan (Rosolowsky et al., 2018). The majority of the caregivers were aged forty years or more. This finding is consistent withresearch conducted by Kobos and Imiela (2015)among caregivers of polish children which reported a mean age of fathersand mothers as 43.2 ± 7.6 and 39.6 ± 6.8 years, respectively.

Parental education especially of the mother plays avital role in the achievement and maintenance of metabolic control in children with T1DM(Al-Odayani et al., 2013). In this study, mothers were the primary caregivers; this finding is similar to what was reported by a multi-centre Italian study conducted among children under 18 years and their parents by Gesuita et al. (2017). In the same study mothers' education was associated with optimal metabolic control. In another study conducted in Cameroon involving children and adolescents attending outpatient clinics, having a mother as the primary caregiver was an independent predictor of good glucose control (Niba et al., 2017). A study conducted among type 1 diabetic Tanzanian children also documentedreduced mean HbA1c levels among children whose primary caregivers were their mothers compared to those whose caregivers were another family member (Noorani et al., 2016). This probably implies that caregivers are mainly mothers and targeting them with nutrition education indicates a higher likelihood of glycaemic control in the children and adolescents.

Children from divorced or separated families tend to have poorer glycaemic control compared to those from families where the parents stay together(Snyder et al., 2019). Over half of the caregivers were married, this finding is in agreement with cross-sectional studies conducted by Rechenberg et al. (2017) and Commissariat et al. (2018) among adolescents with T1DM in the United States that reported over seventy percent of the caregivers as married. Another study conducted among newly diagnosed children with T1DM in Ethiopia also reported a similar trend (Atkilt et al., 2017).

The impact of SES on thelevelof HbA1c in children and adults has been welldemonstrated where lower SES has been associated with higher HbA1c among children(Miller et al., 2020; Zuckerman-Levin et al., 2018). In adults, low socioeconomic status is associated with higher levels of mortality and morbidity. Categorization and analysis of the Type 1 Diabetes Exchange and Diabetes Prospective Follow-up registries into lowest to highest SES by Addala et al. (2021)reported that HbA1c levels were highest in those of the lowest SES quintile. In this study, over 60% of the caregivers were in the wealthiest quintile compared to 17.6% reported to be in the wealthiest according to the 2016 national data(Metrics for Management, 2021b). A probable reason for this disparity with the national data is that most of the study sites were urban-based. Therefore, based on the trends regarding the association between SES and HbA1c, it can be predicted that most of the children had increased odds of having lower HbA1c levels.

5.3 Type 1 diabetes training among caregivers of children with T1DM-baseline findings

Diabetes education of a caregiver is related to the metabolic control of the patient and is a critical tool that helps patients achieve their treatment objectives (Martín et al., 2016). In this study,most of the caregivers confirmed that they had attendedtraining on type 1 diabetes with a nurse as the facilitator. However, all caregivers of children and adolescents with T1DM should haveaccess to and be included in the diabetes educational process. Furthermore, diabetes education should be a recurrent process conducted by a multidisciplinary team of healthcare specialists that are knowledgeable and appreciative of the ever-changing needs of children and adolescents and their caregivers over the duration of the disease (Phelan et al., 2018).

5.4 Nutrition education training among caregivers of children with T1DM-baseline findings

Properly conducted nutrition education combined with other aspects of diabetes treatment and care may contribute to an improvement in metabolic and clinical outcomes (Dłużniak-Gołaska et al., 2019). In this study,about sixty-three percent of the caregivers had attended a nutrition education session about type 1 diabetes mostly facilitated by a doctor. This is in contrast to findings from an international survey of 53 paediatric diabetes clinics where over eighty percent of participating centres reported that nutrition education was delivered by a dietitian (Alonso et al., 2020). Itis, therefore, recommended that dieticians be incorporated in the T1DM nutrition education training sessions that all children and adolescents with T1DM together with their caregivers can attend. Furthermore, the nutrition education sessions should beculture-sensitive and family-tailored.

5.5 Level of T1D nutrition knowledge among caregivers of children with T1DM-baseline findings

This study discovered that caregivers had inadequate nutrition knowledge. This finding is in contrast with the finding by Nuncio-Naud et al. (2018)who reported a high level of nutrition knowledge among the primary caregivers of children with T1DM. Another study by Pedrosa et al. (2016) also reported that the majority of caregivers of children with T1DM generally had good knowledge about the disease and its management.

Carbohydrate counting asa meal planning method allows better glycaemic control as it enablesindividual freedom in food choice(Tascini et al., 2018). Furthermore, the carbohydrate counting skills of caregivers should be evaluated and monitored as adherence to carbohydrate countingaffects metabolic control. Additionally, a parent's ability to accurately perform carbohydrate counting is positively associated with better glycaemic control in their children (Bayram et al., 2020; Hatun et al., 2016).In this study,the least performed nutrition knowledge domain was carbohydrate counting, this finding is congruent with the result of Klee (2020) whoreported that East African immigrant parents did not know the keyconcepts of carbohydrate counting. However, a differentstudyby Smart et al. (2010)documented reasonable accuracy among caregivers regarding carbohydrate counting.Therefore, these findings in this study necessitate the need for more comprehensive nutrition education programmes for parents and caregivers of children and adolescents with T1DM in Uganda. However, additional consideration and support should be given to educating caregivers on carbohydrate counting to enable them competently provide nutritional management support for their type 1 diabetic children.

5.6 Children's T1DM related characteristics-baseline findings

The proportion of girls was slightly more than that of boys, this finding concurs withafacility-based Ugandan cross-sectional study which also reported a slightly higher proportion of females (Kyokunzire & Matovu, 2018).In the present study, the average diabetes duration was about 5 years. This is similar to an average duration of five and a half years reported by Martin et al. (2017). On the contrary, a study conducted in Uganda and Kenya documented an average diabetes duration of about 7 years (McClure Yauch et al., 2020). Another Kenyan study reported a lower median duration of 3.7 years (Ngwiri et al., 2015).

The majority of the children reported that they use insulin three or more times a day, this finding concurs with the studies by Dehayem et al. (2016) and Noorani et al. (2016) who also reported most of the children were on a multiple daily insulin injection regimen. The use of multiple daily insulin injections is in agreement with the recommended gold standard of using intensive insulin regimens for all age groups in pediatric diabetology delivered by combinations of multiple daily injections(Danne et al., 2018).

At the time of diagnosis, children with T1DM often report familial type 1 diabetes (Turtinen et al., 2019). This study found that the majority of children with T1DM that participated in the study had no family history of T1DM, this is opposite to what was reported by Kyokunzire and Matovu (2018) who reported over 50% family history among their study participants. Probable explanations for this finding are that the study participants lacked the accumulative knowledge of their family disease history as reported in the study conducted amongnewly diagnosed type 1 diabetic Finnish children byParkkola et al. (2013). In addition, Olamoyegun and Ala (2019) reported that most occurrences of type 1 diabetes mellitus cases were rather sporadic rather than familial.

Analysis of glycated haemoglobin (HbA1c) indicates an individual's average blood glucose level during the preceding three months and is currently the only long-term glycaemic control measure with robust outcome data (DiMeglio et al., 2018; Sherwani et al., 2016). This study found that children had a high mean HbA1c value of 11.24 ± 2.7%, this finding is comparable to a mean HbA1c value of 11.2 ± 2.7%, which was reported by Marshall et al. (2015) among Rwandese children. A recent study by McClure Yauch et al. (2020) also reported a mean HbA1c value of 11.3 ± 2.7% among East African children and young adults with type 1 diabetes. Other studies conducted in Kenya and Tanzania among children with T1DM have also documented high mean HbA1c values of 12.1% and 11.1% respectively (Ngwiri et al., 2015; Noorani et al., 2016).

High HbA1c values (>7.5%) put children and adolescents with T1DM at a higher risk of developing microvascular complications such as retinopathy, nephropathy, and neuropathy even after a short disease duration (Najem et al., 2020). Therefore, lower HbA1c values (<7.5%) should be instituted early in the course of treatment of children and adolescents with T1DM as this will reduce the risk of developing microvascular complications later on in life (American Diabetes Association, 2020; DiMeglio et al., 2018).

HbA1c measurement is now recommended as a standard of care for testing and monitoring diabetes and is considered an important indicator of long-term glycemic control (Sherwani et al., 2016). It is therefore essential to identify possible predictors of HbAlc that would be useful in the management of blood glucose levels among type 1 diabetics. In this study, only DDS was found to be a significant predictor of elevated HbAlc, whereas children with a higher DDS were more likely to have elevated HbAlc. This finding is in agreement with Irmayanti et al. (2019) who also reported a positive association between DDS and HbA1c. However, a study by Gholizadeh et al. (2018) documented a higher DDS being associated with lower fasting blood glucose. Although studies documenting the association between DDS with HbA1c are limited.

5.7 Dietary intake and nutrient adequacy of children with T1DM-baseline findings

5.7.1 Dietary intake of children with T1DM-baseline findings

Dietary intake recommendations for children with T1DM should be based on nutrition principles suitable for healthy children. In addition, the recommendations should ensure that the nutritional requirements of children and adolescents are met and be adapted to the family traditions (Mankiewicz-Zurawska & Jarosz-Chobot, 2019; Smart et al., 2018). Carbohydrate and protein intake were adequate; however, fat intake was low. The low-fat intake putschildren and adolescents at increased risk of suffering from deficiencies of essential fatty acids.

ISPAD recommends that the dietary intake of type 1 diabetic children and adolescents should contribute approximately 15% to 20% of energy from protein, less than 35% of energy from fat and 45% to 50% of energy from carbohydrates. In this study, the approximate energy contribution from carbohydrates surpassed ISPAD's recommendation by over 20%. In this study, the energy contribution from protein was below the recommended percentage but the energy contribution from fat was within the recommended range. This finding is divergent from the findings ofSeckold et al. (2019) whodocumented macronutrient energy contributions that were within the recommended ISPAD ranges among type 1 diabetic children and adolescents of Australian descent. In addition, children and adolescents were consuming diets high in carbohydrates and hence had a higher calorie consumption from carbohydrates rather than fats which has been documented by other studies that have reported a higher calorie consumption from fats(Parthasarathy et al., 2015). In support of this finding, other studies have reported that type 1 diabetic children and adolescents often do not meet the recommended guidelines (Mayer-Davis et al., 2006; Øverby et al., 2007; Thomson et al., 2019). This, therefore, warrants the need for targeted nutritional education interventions aimed at addressinglow fat intake among children and adolescents with T1DM in Uganda.

Vitamin B_1 (thiamine), vitamin B_2(riboflavin), vitamin B_3(niacin), vitamin B_5 (pantothenic acid), vitamin B_6 (pyridoxine), vitamin B_{12} (cobalamin),folic acid and biotinare usually grouped as vitamin Bcomplex(Elbarbary et al., 2020). In this study, the children's and adolescent's dietary intake of most B-complex vitamins, vitamin A and calcium were inadequate. In agreement with the current study, several studies have documented micronutrient deficiencies among paediatric patients with T1DM. A study conducted in India documented that the intake of all micronutrients was less than the RDA among type 1 diabetic children (Parthasarathy et al., 2015). Further inadequate intakes of calcium, potassium and vitamin C were reported among young type 1 diabetic American and Canadian children(Blouin et al., 2011; Patton et al., 2007). Gilbertson et al. (2018) reported low intakes of iron, folate and calcium among Australian children with type 1 diabetes. This current finding suggests the risk of multiple micronutrient deficiencies among type 1 diabetic children and adolescents that is linked to sub-optimal physiological and neurological functioning of their bodies (Kennedy, 2016).

5.7.2 Nutrient adequacy of children with T1DM-baseline findings

A diverse diet provides essential nutrients that cannot be found in a single food and therefore a vital aspect of achieving a high-quality diet(Abris et al., 2018). The mean DDS of the current study was 5.5, this is higher than a DDS of approximately 4 reported in a study conducted among type 1 diabetic children in South Africa by Steyn et al. (2014). Despite the high mean DDS in this study, a low mean adequacy ratio was registered wherechildren met only 60% of the RDA of all nutrients combined. This signifies an overall dietary inadequacy among the type 1 diabetic children in Uganda. The mismatch between dietary diversity and the mean adequacy ratio could be due to differences in the quantities or portions of food consumed among the children.

Dietary diversity is positively associated with nutrient adequacyand can be used as a simple proxy indicator for nutrient adequacy (Ngala, 2015).There was a significant positive association between DDS withNARs of fat, protein and vitamins A, B_2, B_3, B_5, B_6, B_{12}, biotin, folic acid, zinc and MAR. Similar findings have been reported byMirmiran et al. (2004) who reported a statistically significant correlation between dietary diversity and nutrient adequacy amongadolescents in the Tehran Lipid and Glucose Study. Mekonnen et al. (2020) also documented that household dietary diversity score could be used to assess household nutrient adequacy in Ethiopia.

Hjertholm et al. (2019) also found a positive association between DDS with MAR and NARs for calcium, vitamin A, vitamin C and vitamin B_6 among pregnant women in rural Malawi. Mirmiran et al. (2004) also reported that dietary diversity was positively correlated with the mean adequacy ratio; which concurs with the findings of this study. The current study findings further concur that dietary diversity is positively correlated with indicators of micronutrient adequacy and suggests that improving dietary diversity has a positive influence on nutrient adequacy (Zhao et al., 2017).

POST-INTERVENTION

5.8 Effect of nutrition education on caregivers' level of T1D nutrition knowledge

Successful nutritional management of T1DM requires the patient andhousehold membersto have adequate skills and knowledge in several aspects of diabetes management in order to help the patient achieve near normoglycemia. Furthermore, according to Alonso et al. (2020), nutrition education for children and adolescents with T1DMis approached in diverse ways and should be informed by the local context.Additionally, adherence to recommendations and glycaemic outcomes can be improved if nutrition education is contextualised and individualised.

There is a paucity of literatureon the assessment of the effect of nutrition education on caregivers of children and adolescents with T1DMin the sub-Saharan region. This study found that caregivers that attended the structured nutrition education course had significantly higher nutrition knowledge scores than those in the control group, this finding is comparable to the finding of a nutrition education intervention study among Ghanaian children aged 6 to 12 years and their caregivers which also reported an improvement in the level of nutrition knowledge of the caregivers in the intervention group (Antwi et al., 2020). This current study finding is also in agreement with findings documented by Taha et al. (2020) who reported an increase in knowledge and self-confidence among mothers of adolescents with type 1 diabetes in Kuwait after attending a structured education programme. Similarly, another study that aimed to evaluate caregivers' role in the effectiveness of two school-based nutrition education programmes for Dutch children aged 7-12 years, reported that caregivers' health promotion behaviours were positively associated with children's healthy eating behaviours(Verdonschot et al., 2021).Martín et al. (2016), also found the level of diabetes education among Spanish caregivers of children with T1DM was high.A study by Stefanowicz et al. (2018), also reported a satisfactory level of diabetes knowledge among parents of children and adolescents in Poland.The significance of nutrition education as an intervention to improve the nutrition knowledge of caregivers cannot be overstated.Furthermore, caregivers should be encouraged to actively take part in the care and management of their children(Marinac et al., 2020).This study showed that structured nutrition education was effective in improving the knowledge ofcaregivers of type 1 diabetic children and adolescents and should be utilised in improving normoglycemia in the target groups.

5.9 Effect of nutrition education of caregivers on HbAlc levels of their children

Glycated haemoglobin (HbA1c) is animportant metric for assessing glycaemic trends in a population over time and for comparing treatment groups in trials,or glycaemic control in different populations in cross-sectional studies (Beck et al., 2017). There are contradicting findings on the effect of nutrition education on HbA1c and most of the literature on paediatric T1DM management in developing countries does not focus on parental or caregiver involvement (Friedemann-Sanchez et al., 2018). In this study, the children's HbAlc slightly attenuated 3 months after their caregiver's participated in the structured nutrition education course, however,the reduction was not significant. This finding contradicts other findings such as a five-day educational camp that educated Rwandese type 1 diabetic adolescents about diabetes knowledge and self-management skills which reported a 2.1% decrease in HbA1c levels(Kabeza et al., 2019). A pre-experimental educationalstudy conducted among Iranian type 1 diabetic adolescents aged between 10-14 years, with their caregivers,also found a significant reduction in HbA1c levels three months after the intervention(Cheraghi et al., 2015). Acaregiver-based educational intervention byPatton et al. (2014)in the United States showed an improvement in glycemic control among type 1 diabetic preschoolers.A systematic literature review by McBroom and Enriquez (2009)also indicated that family-centred interventions significantly improved HbA1c levels. A systematic review and meta-analysis of 36 prospective controlled trials involving participants of any age group also documented short-term improvements in HbA1c at 6 months after the intervention in type 1 diabetic patients who had attended type 1 diabetes self-management education sessions compared with those who received only the standard care (Pillay et al., 2015).

On the contrary, other studies are in agreement with this study's finding. Attending a five-day structured education course for adolescents with T1DM in the United Kingdom was not associated with an improvement in HbA1c(Price et al., 2016). An intervention that delivered tailored paediatric self- management resources to familiesalso found no interventional effect on HbA1c(Fiallo-Scharer et al., 2019). Another brief educational intervention among type 1 diabetics found that the intervention had no significant impact on HbA1c(George et al., 2008). A structured educational intervention in children and adolescents aged 8 to 16 years with poorly controlled type 1 diabetes also did not improve their HbA1c(Christie et al., 2016). A probable explanation for the lack of detectionof significant change in HbA1c in this study could be that the HbAlc levels are influenced by various factors outside nutrition knowledge which could be the case in this current study since nutrition knowledge among caregivers improved.

Furthermore, the stay-at-home directive (lockdown) that was enforced due to the COVID-19 pandemic could have also contributed to the observed HbA1c values in both study groups. The stay-at-home directives have been associated with an increase in HbA1c of between 0.50 to 0.83% and impaired diabetes management, for example, a recent study conducted among Ugandan T1DM patients aged between 8 to 18 years attributed the lockdown measures to a significant increase in HbA1c from 9.4% to 10.8% and from 8.3% to 9.9% in the rural and urban clinics respectively (Bahendeka et al., 2021). Similar findings have been reported in India byVerma et al. (2020). According to Lohiya et al. (2021), mothers of children with T1DM have elevated stress due todaily diabetes-related management tasks of their child’s illness. If caregivers feel distraught and stressed, they may prematurely transfer the responsibility of diabetes management to their child, leading to poor control. Caregiver/parental stress has been documented to have an effect on the child’s psychopathology and decrease adherence to recommendations and treatment, for example, a cross-sectional observational study conducted by Troncone et al. (2020) among type 1 diabetic adolescents aged 10 to 18 years found out that mothers depressive symptoms were associated with the worst metabolic control (Alaqeel et al., 2021; Costa-Cordella et al., 2020; Fragala et al., 2021).Stress resulting from the drastic societal changes and effects of COVID-19 could have also affected the children and adolescents with T1D and may have caused those with low emotional maturity to engage in various activities and behaviours such as binge eating that may have temporarily reduced their stress but negatively affected their glycaemic control (HbA1c) (Bauer et al., 2020). Another probable reason for the lack of detection of a significant reduction in HbA1c is that improvement in HbA1c at times may occur when follow-up extends beyond the immediate post-intervention period (Pillay et al., 2015). For example, a one-day intensive structured education programme conducted by Garden et al. (2021) among British adults with T1DM documented an overall mean HbA1c reduction 6 months after the intervention. A 6-month multicenter controlled clinical trial among German children with T1DM aged 1 to 16 years also reported a significant HbA1c improvement 12 months after the intervention (von Sengbusch et al., 2020). Therefore, assessment of children's HbAlc 6 to 12 months could show a significant improvement. Nutrition education remains a key pillar in the management of hyperglycaemia and a means to actualize optimal growth, development and well being in children and adolescents.

5.10 Effect of nutrition education of caregivers on dietary diversity and nutrient adequacy of their children

DDS, NAR and MARare considered apriori-defined diet quality indices(Azadbakht et al., 2015). Dietary diversity relates to the number of food groups consumed by an individual in a givenperiod (Aurino, 2017). Dietary diversity indicates a household's access to a variety of foods and can be used as a proxy for the nutrient adequacy of an individual's diet (Isabirye et al., 2020). Both study groups had DDSs of 5 and above post-intervention, this finding indicates adequate dietary diversity among the type 1 diabetic children and adolescents in Uganda as a DDS of 5 and above is associated with greater intake of all nutrients(Steyn et al., 2014; Steyn et al., 2007).

NAR and MAR compare an individual's intake of nutrients with the recommended intake. MAR is the ratio of the sum of NARs to the number of nutrients. MAR is specific to the sex and age of the individual and may therefore provide a more accurate assessment of an individual's overall diet quality. Furthermore, MAR assesses an individual's micronutrient intake and thus can be used as an indicator to identify micronutrient deficiencies as micronutrients are vital for metabolic processes in the body (Azadbakht et al., 2015). The mean nutrient adequacy ratio increased by 9% after the intervention, resulting in type 1 diabetic children and adolescents in the intervention group meeting over 80% of the RDA of all nutrients combined. This finding may imply that the provision of a structured nutrition education course to caregivers of type 1 diabetic children and adolescents may help improve the overall dietary quality and adequacy and minimize the risk of micronutrient deficiencies among their children.

Despite the positive change in the mean difference of the DDS and MAR,there were no significant differences post-intervention. This is in disagreement with a participatory community-based nutrition education study for caregivers by Kuchenbecker et al. (2017) which documented an improvement in the children's dietary diversity. Another interventional study conducted in southeast Nigeria that assessed the impact of caregivers' nutrition knowledge on preschool children's dietary diversity also found an improvement in the children's dietary diversity (Onyeneke et al., 2019).

The lack of a significant difference in dietary diversity and mean adequacy ratios of the children after their caregiver's participation in the structured nutrition education training programme could be attributed to food availability, seasonality and access to food markets among others, especially in the case of restricted movement which was enforced as aCOVID-19 containment measure at the time of the study. This is collaborated by Hirvonen et al. (2017) who reported that better nutrition knowledge led to considerable improvements in children's dietary diversity, but only in areas with relatively good market access. Mendoza et al. (2018), also documented that food insecurity was associated with high-risk glycemic control among youth with T1DM, and recommendedtargeted efforts towards the alleviation of food insecurityamong youth with type 1 diabetes. Therefore, interventions that aim to improve the nutrition knowledge of caregivers of children and adolescents who are type 1 diabetic should be enhanced with other efforts that improve household access, production and utilizationof locally available foods.

5.11 Predictors of elevated HbAlc among pediatric type 1 diabetes Children and Adolescents

In children, socioeconomic status, age, gender and family living arrangements are thought to be predictors of HbA1c. Furthermore, diabetes-related characteristics such as diet, frequency of self-monitoring of blood glucose diabetes duration, insulin regimen and family involvement in diabetes-related tasks are also associated with the level of glycaemic control. It is vital to identify the predictors of elevated HbAlc among pediatric type 1 diabetes to identify opportunities for intervention (Clements et al., 2016; Mohammad et al., 2012; Niba et al., 2017).

This study did not find any of the sociodemographic characteristics as predictors of elevated HbA1c. This finding is contrary to findings reported by other studies. A health-centre-based descriptive cross-sectional study by Taha et al. (2020) reported a significant association between the children's socioeconomic status and their glycemic control among Sudanese children aged from 1 to 18 years. A cross-sectional study conducted in Cameroon involving children and adolescents aged 0–18 years attending outpatient clinics for children living with diabetes showed that having a mother as the primary caregiver was an independent predictor of good glucose control (Niba et al., 2017). In another facility-based cross-sectional retrospective cohort study conducted among pediatric diabetes patients; the patient's age, history of treatment discontinuation and dose of treatment were the significant contributing factors to poor glycemic control (Kidie et al., 2022).

Only an increase in DDS was significantly associated with an increased likelihood of exhibiting an elevated HbA1c. This is in agreement with a study by Irmayanti et al. (2019) that found DDS was positively associated with HbA1c.

CHAPTER SIX: SUMMARY, CONCLUSION AND RECOMMENDATIONS

6.0 Introduction

The purpose of this study was to evaluate the effect of the provision of a structured nutrition education course to caregivers of children and adolescents with T1DM attending selected T1DM clinics in Uganda, on their level of T1DM nutrition knowledge and their children's glycaemic control, dietary intake and diversity. Furthermore, the study tested the relationship between caregiver's level of T1DM nutrition knowledge and DDS, macronutrient intake, NARs and MAR. This chapter gives a summary of the study findings, conclusions and recommendations for policy, practice and further research.

6.1 Summary

The majority of the caregivers were female, married and aged 40 years and above. Most of the caregivers had only attained primary education and were farmers. The average household size was 6.Relating to average monthly income, a high proportion of caregivers earned200,000 or less Ugandan shillings.

Almost eighty and sixty percent of the caregivers had attendedtraining on type 1 diabetes and nutrition education about type 1 diabetes respectively. The trainings were mostly conducted at a hospital facility with a doctor as the facilitator of the training.Caregivers had low type 1 diabetes nutrition knowledge, particularly regarding carbohydrate counting. There was a significant difference in caregivers nutrition knowledge scores across the levels of education.

A high mean HbA1c value of 11.24 ± 2.7% was found among the children and adolescents with T1DM. There was no significant difference in HbA1c values for males and females. The highest proportion of children had T1DM for 2–5 years with an average disease duration of 4.75 ± 3.1 years. Furthermore, the majority reportedthat they used insulin multiple times a day (≥3 times a day) and had no family history of T1DM.

Most of the children and adolescents had a high DDS (≥5). In addition, they were consuming diets high in carbohydrates. The mean caloric energy contribution from high carbohydrate and low protein were observed in reference to the recommended ranges of 45-50% and 15-20% respectively. Dietary intake of vitamins A, B_1, B_2, B_3 B_5, B_{12}, biotin, calcium, folic acidand fat were inadequate except for vitamin B_6. The children and adolescents only met 60% of the RDA of all nutrients combined which signified an overall dietary inadequacy among the paediatric type 1 diabetes mellitus patients in Uganda.

This study observed positive correlations between the dietary diversity score with nutrient adequacy ratios of fat, protein and vitamins A, B_2, B_3, B_5, B_6, B_{12}, folic acid, biotin, zinc and the mean adequacy ratio. The study further observed a significant positive correlation between caregivers' nutrition knowledge scores with nutrient adequacy ratios of vitamin B_6, biotin, folic acid, and iron.

No significant association was observed between HbA1c level and caregivers' level of T1DMnutrition knowledge.However, there was a0.7 % decrease in the children's HbAlc levels in the intervention group3 monthsafter the intervention compared to a

0.1 increase in the control group.Furthermore, a positive significant association was observed between HbA1c level and DDS. Caregivers' level of T1DM nutrition knowledge was not a significant predictor of either the children's dietary diversity score or HbA1c level.

6.2 Conclusions

The baseline findingsrevealed that the primary caregiver was a mother, the highest proportion of the caregivers were aged 40 years and above and were married.

The baseline findingsrevealed that the majority of type 1 diabetic children and adolescents had an averagedietary diversity score of more than 5, with adequate carbohydrate and protein intake as per the dietary intake recommendations. However, they were found to be at risk of developingmicronutrient and essential fatty acid deficiencies.

Baseline findings did not indicate any relationship between the caregiver's level of T1DMnutrition knowledge and the children's HbAlc levels. Furthermore, there was no significant difference in children's HbAlc levels despite their caregiver's participation in the structured nutrition education course.

The study demonstrated that caregiver's level of T1DM nutrition knowledge significantly andpositively correlated with the nutrient adequacy ratios of vitamin B6, biotin, folic acid, and iron.

A nutrition education participant guide for caregivers of children with type 1 diabetes in Ugandawas developed to help caregivers of children with type 1 diabetes mellitus to use foods within their reach in a way that helps their child to keep their blood sugar level closer to the target level and ensure adequate dietary intake.

A nutrition education facilitator guide for caregivers of children with type 1 diabetes in Ugandawas developed to provide a roadmap to the content of each lesson in the participant guide; by highlighting the materials required and providing additional notes to help the facilitator lead the training.

Attending the structured nutrition education training programme led tosignificantly higher nutrition knowledge scores among caregivers of type 1 diabetic children and adolescents resulting in type 1 diabetic children and adolescents in the intervention group meeting over 80% of the RDA of all nutrients combined. This finding proves that nutrition education of caregivers of type 1 diabetic children and adolescents can help improve their children’s overall dietary adequacy and help improve dietary outcomes.

There was a positive change in the mean difference of the children’s dietary diversity and mean adequacy ratio, however,the difference was not significant.

Children and adolescents in Uganda have poor glycaemic controlpredisposing them to acute and chronic complications.

6.3 Recommendations

The following recommendations were made based on the study findings;

6.3.1 Recommendations for policy

Ministry of Health

- The developed structured nutrition education course resulted in a significant increase in caregivers' nutrition knowledge, therefore, standardized contextualized and comprehensiveguidelines regarding the nutritional management of T1DM should be developed and made available for both service providers and caregivers.

6.3.2 Recommendations for practice

Paediatric diabetes clinics

- The study revealed inadequate knowledge about carbohydrate counting among the caregivers of type 1 diabetic children, therefore, paediatric diabetes clinics should routinely and objectively assess caregivers recall and mastery of nutrition education concepts as this will provide insights into the areas that need improvement.

- The study revealed inadequate micronutrient and fat intake among children and adolescents with T1DM, therefore, nutrition educators should emphasize the intake of dietary sources of micronutrients and essential fatty acids during nutrition education sessions.

6.3.3 Recommendations for further research

- A similar study with a longer intervention period and larger sample size should be conductedto determine the effect of nutrition education of caregivers of children and adolescents with T1DM on their children's HbA1c.

- Further research on new therapeutic and educational approaches on how micronutrient intake among children and adolescents with T1DM can be improved needs to be conducted.

- A similar study with a longer follow-up to cover different seasons of the year that considers both dietary practices and nutrition status should be conducted.

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APPENDICES

Appendix A: Participant information leaflet

Study title

Effect of nutrition education of caregivers of children with type 1 diabetes on glycaemic and dietary outcomes in Uganda: a cluster randomized trial.

Name of researcher and contacts

Principle investigator

Ndahura Nicholas Bari, cell-phone: +256 772 636 271, email address: barindahura@gmail.com/nbari@students.ku.ac.ke

Supervisors

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Invitation

You are being invited to take part in a research study on type 1 diabetes among children aged 3-14 years and their caregivers. The study aims to determine the effect of nutrition education on HbA1c levels of type 1 diabetic (T1D) children, knowledge and dietary management practices of their caregivers and will last 6 months.

Before you decide whether or not you wish to take part, you should read the information provided below carefully and, if you wish, discuss it with your family, friends or doctor. You should clearly understand the risks and benefits of taking part in this study so that you can make a decision that is right for you. This process is known as '**Informed Consent**'.

Why is this study being conducted?

The findings of this study will be used to improve nutrition education services provided by the Ministry of Health, diabetes clinics and also serve as basis for informed policy and diabetes management guidelines review.

Do I have to take part?

Participation in this study is on voluntary basis and a participant may discontinue participation at any point in the study. However, you are requested to explain the reason/s behind discontinuation (optional). Discontinuation will not interfere with the usual care and treatment received at the clinic.

What will I have to do?

1. Participants in this study will answer some questions which will be recorded on paper and periodically a voice recorder may be used.

2. Blood samples will be drawn from the children at the beginning of the study, at 3 months and 6 months for HbA1c testing. In the event the HbA1c is not within the recommended range, the caregiver and child will be immediately referred to the respective doctor at the diabetes clinic.

3. The selected children medical records/file will also be accessed to gather more information.

4. The participants will be expected to report to the diabetes clinics once a week and attend a nutrition education session for one hour. However, study participates will be reimbursed for their transport (a total of twenty-five thousand Uganda shillings (25,000 UGX) will be given per participant).

5. The participants will be expected to continue with their routine medication and check-ups at the diabetes clinics.

What are the possible discomforts and risks?

There are no expected risks but the researcher will work with a medical doctor who is a specialist in T1DM in children. The doctor will attend to any child that may react to a particular type of food suggested during nutrition education sessions and the food immediately discontinued. And any other signs.

Caregivers shall be trained on how to recognize the early warning signs of hypoglycaemia and hyperglycaemia. The participants will continue with the routine clinics except for the reviewed nutrition education module (intervention). The intervention will not alter their medication routine but rather will support compliance to recommendations as this will form part of the diabetes education package. Their doctor/s and nurses will still remain in charge.

What are the benefits?

Participates will be educated on dietary management practices for type 1 diabetes and taught on how to plan meals for their T1D children using locally variable foods.

What if there is a problem?

The study participant should immediately contact the principal researcher and the medical personnel at the respective diabetes clinic.

Where and when can I find the results of the study?

The baseline findings including the HbA1c results will be communicated back to participants. A copy of the final research report will be made available at the library of each participating diabetes clinic.

Will my taking part in the study be kept confidential?
All Information collected from this study will be kept confidential by the researcher and research team and used only for the purposes of the study. Identity of participants will be protected and names will be substituted by codes during analysis. Audio recording devices will be used, but the recordings will be kept securely and confidential and will only be used for purposes of this study and destroyed after completion of this study.

Who is organising and funding the research?
The researcher is a Doctor of Philosophy degree student (Ph.D.) in food, nutrition and dietetics at the department of food nutrition and dietetics of Kenyatta University. The study is funded by Kyambogo University staff development programme.

Who has approved the study?
Authority to conduct research was granted by Kenyatta university graduate school. Ethical clearance granted by the St. Francis hospital Ethical Review Board, the Uganda National Council for Science and Technology and management of the study sites.

If you would like more information about the study, please contact the principal investigator, any of the supervisors or the Chairperson, St. Francis hospital Ethical Review Board (*St. Francis Hospital-Nsambya, P.O. Box 7146, Kampala Uganda, +256414267012, nsambya@ucmb.co.ug*) for any clarification.

Thank you for taking the time to read this leaflet.

Appendix B: Assent form

Signing on this form means that you have read the participant information leaflet or have had it read to you, and that you are willing to take part in this study.
You do not have to be in this study. No one will reprimand you if you decide not to take part in this study. Even if you start, you can stop later if you want but this will not change the care that you will receive from the clinic today and in future. If you decide to be in the study all the information you provide will be kept private and securely and confidential (no one will be told what you say or do in the study). Even if your parents or doctor/s ask, they will not be told what you say or do in the study. You may ask questions about the study.
You have been given an opportunity to ask questions and the responses have been satisfactory. Your participation in this study is entirely voluntary without any duress.

Name of child………………………………………………………………

Signature ………………………………................... or thumbprint of child

Date……………………………………

Name of witness (if applicable) ………………………………………………

Signature……………………………………………………………………

Date…………………………………………………………………………

- ☐ I do not want to have this interview recorded
- ☐ I am willing to have this interview recorded
- ☐ Does not apply

Name of interviewer/person obtaining assent…………………………………

Signature ……………………………………………………………

Date ………………………………………

Name and contacts of principle investigator
Name: Ndahura Nicholas Bari
Cell-phone: +256 772 636 271/ +256 706 065 506
Email address: barindahura@gmail.com/nbari@students.ku.ac.ke

Appendix C: Informed consent form

Participant consent

The information provided in participant information leaflet regarding my participation in the study is clear to me. I have been given an opportunity to ask questions and the responses have been satisfactory. My participation in this study is entirely voluntary without any duress. I understand that all the information I provide will be kept private, securely and confidential. I also understand that I can leave the study at any time and that my decision will not change the care that I will receive from the clinic today and in future. I therefore willingly agree to participate in this study.

Name of participant ……………………………………………………………………

Signature ………………………………… or thumbprint of participant

Date.……………………………………

Name of witness (if applicable) ………………………………………

Signature…………………………………………………………………

Date……………………………………………

- ☐ I do not want to have this interview recorded
- ☐ I am willing to have this interview recorded
- ☐ Does not apply

Name of interviewer/person obtaining informed consent ……………………………

Signature ……………………………………………………………………

Date ………………………………………

Name and contacts of principle investigator
Name: Ndahura Nicholas Bari
Cell-phone: +256 772 636 271/ +256 706 065 506
Email address: barindahura@gmail.com/nbari@students.ku.ac.ke

Appendix D: Adverse event reporting form

Principal Investigator (PI):	Phone: Email:	Comments
PI Institution:		
Study title:		
Date of adverse event:		
Location of adverse event		
Brief description of adverse event		
How was the adverse event treated/handled?		
Was the adverse event reported to?	REC/IRB ☐ Yes ☐ No Date of report: STUDY SITE ADMINISTRATION ☐ Yes ☐ No Date of report:	
Severity of adverse event:	☐ Mild ☐ Moderate ☐ Severe	
Recovery of research participant:	☐ Recovered/resolved ☐ Recovering/resolving ☐ Fatal ☐ Unknown	
Was this adverse event addressed in the protocol and consent form?	☐ Yes ☐ No	
Research participant's study identification number		
Which study group was the research participant assigned to?	☐ Control ☐ Intervention	
Report prepared by:		Signature: Date:

Appendix E: Caregiver questionnaire

**A caregiver is a person (usually a relative or friend) who provides unpaid daily care by looking after the child.*
***write 999 as a response if the respondent says that he or she doesn't know or refuses to answer.*

Date of interview (dd/mm/yyyy)/__ /___/______ Respondent number______

Respondent name____________________

Respondent contact___________________ District_______________________

Town______________________________

1.0 SOCIO-DEMOGRAPHIC INFORMATION (*circle the responses appropriately*)

1.1 Sex
1. Male
2. Female

1.2 What is your date of birth?...................... Age in years…………….

1.3 How many people belong in your household***?

Serial number	Name of household member from the household head to the youngest child in order of age	Date of birth	Age in years	Age in months
1				
2				
3				
4				
5				
6				
7				

****Household is defined as a social unit having common arrangements, sharing household expenses or daily needs and in a shared common residence. A household includes either one person living alone or a group of people, not necessarily related, living at the same address with common housekeeping, i.e. sharing at least one meal per day or sharing a living or sitting room.*

1.4 What is your religion?
a. Traditionalist
b. Catholic
c. Anglican
d. Moslem
e. Other, specify __________
999= doesn't know/answer

1.5 What is your current marital status?
a. Single

b. Married
c. Co-habiting
d. Separated
e. Divorced
f. Widowed
999= doesn't know/answer

If the response to question 1.5 is (b) Married or (c) Co-habiting, answer question 1.6 If not, go to question 1.7

1.6 What is the occupation of your spouse/partner?
a. Civil servant (specify)……………………………
b. Private sector (specify)……………………………
c. Business (specify)…………………………………
d. Education sector (specify)…………………………
e. Other (specify)……………………
999= doesn't know/answer

1.7 What is your occupation?
a. Civil servant (specify)………………………………
b. Private sector (specify)……………………………
c. Business (specify)…………………………………
d. Education sector (specify)…………………………
e. Other (specify)………………………………………
999= doesn't know/answer

1.8 What is the highest level of education you have completed?
a. Primary level
b. Secondary level (UCE)
c. Secondary level (UACE)
d. Undergraduate (specify if diploma or degree) ……………………….
e. Postgraduate (specify if master's or PhD)
f. Other (specify)………………………………………
999= doesn't know/answer

1.9 What is your monthly income? (In Ugandan Shillings) …………………………
a. ≤ 200,000
b. 201,000 - 400,000
c. 401,000 - 600,000
d. 601,000 - 800,000
e. 801,000 - 1,000,000
f. ≥ 1,000,000
999= doesn't know/answer

	Question	Response *Yes=1 No=2*
1.10	Does your household have… electricity?	
1.11	a television?	
1.12	a mobile telephone?	
1.13	a clock?	
1.14	a radio?	
1.15	a table?	
1.16	a sofa set?	
1.17	a cupboard?	
1.18	Does any member of this household own a watch?	
1.19	Does any member of this household have a bank account?	
1.20	What is the main material of the floor of your house?	a = Cement b = Sand and dung c = Other (specify) ……………
1.21	What is the main material of the walls of your house?	a = Cement b = Mud and Poles c = Other (specify)……………
1.22	What type of fuel does your household mainly use for cooking?	a = Charcoal b = Wood c = Other (specify) ……………
1.23	What is the main material of the roof of your house?	a = Thatched b = Iron sheets c = Tiles b = Other (specify)……………

2.0 MEDICAL HISTORY OF TYPE 1 DIABETIC CHILD

2.1 What is your relation to the child?
a. Father
b. Mother
c. Other (specify)…………………….

2.2 How old is the child?

Birth date .... Age in years................. Age in months.................

2.3 What type of diabetes does the child you look after have?
a. Type 1 diabetes mellitus
b. Type 2 diabetes mellitus
c. Other
d. Unsure

if response is not option (a) stop data collection immediately. Data should be collected for only for children with Type 1 diabetes mellitus.

2.4 When was the child diagnosed with the above-mentioned diabetes……………….

2.5 Where was the child diagnosed? ……………………….

2.6 Does the child take any diabetes medication?
a. Yes
b. No

If the response to question 2.6 is No, go to question 2.7

2.6.1 If Yes, which one? ______________________

2.6.2 Where do you get this medication from? ……………………….

2.6.3 How and how often is the medication administered?..

2.6.7 Is the patient taking any other medication, nutrient supplements?
....

2.7 Are there any other member(s) of the nuclear or extended family suffering from Type 1 diabetes mellitus?
a. Yes
b. No

If Yes, specify the relationship to the child……………………………………

3.0 TYPE 1 DIABETES AND NUTRITION EDUCATION TRAINING
3.1 Have you ever been trained about type 1 diabetes?
a. Yes
b. No

If the response to question 3.1 is No, go to question 3.3

3.1.1 If yes, when was it done? ……………………….

3.1.2 Where was it done? ……………………….

3.1.3 Who conducted the training? ……………………….

3.1.4 Kindly list any topics of that training you remember

a. Blood glucose monitoring
b. Hypo/hyperglycaemia management
c. Nutrition in type 1 diabetes
d. ………………………….
e. ………………………….

f. ………………………….

3.2 Have you attended nutrition education session/s about type 1 diabetes?
If the response to question 3.2 is No, go to question 3.3

3.2.1 If yes, when was it done? ……………………….

3.2.2 Where was it done ……………………….

3.2.3 Who conducted the training? ……………………….

3.2.4 Kindly list any topics of that training you remember

1. ……………………….
2. ……………………….
3. ……………………….
4. ……………………….

3.3 Who do you trust the most to give you information about Type 1 diabetes mellitus?

a. Doctor
b. Nurse
c. Nutritionist/dietician
d. Other (specify)……………………….

Why………..

3.4 When you get information about Type 1 diabetes mellitus, what sort of format do you prefer that information is given to you in? How do you learn best?

a. Brochures
b. Posters
c. Internet/website
d. E-mail
e. Thorough discussion with health facility staff
e. Other (specify)……………………….

3.5 How do you learn best?

………

3.6 Imagine you are on an advisory group that can design a nutrition education programme for caregivers to children with Type 1 diabetes mellitus like you......what topics and/or activities would you include in the programme and why?

Proposed topic/activity	**Reason**

Thank you for your patience and for participating in this study

Name and signature of interviewer:

……………………………………………………………..

Appendix F: Type 1 diabetes nutrition knowledge questionnaire

The following questions are about general nutrition and nutrition related to diabetes. For each question, choose by ticking in the box of what you think is the best answer. ***Select only ONE answer for each question by ticking the answer.***

Nº	QUESTION	A	B	C	D	E
1	Which of the following are benefits of eating fruits and vegetables?	Good source of fibre	Low in fat	Good source of vitamins and minerals	All of these	Unsure
2	Which of the following foods is high in fibre?	Chapatti	Beans	Doughnuts	White bread	Unsure
3	Which of the following foods contains heart healthy fats?	Beef	Nuts	Ghee	Butter	Unsure
4	Which of the following contains more than 15 grams of carbohydrate?	1 small apple	1 medium orange	½ a small mango	1 cup (240 ml) orange juice	Unsure
5	Which of the following foods provides the most vitamins and minerals?	Irish potatoes	Fruits and vegetables	White rice	Crisps	Unsure
6	Which of the following is NOT a whole grain food?	Brown rice	White bread	Whole wheat bread	Millet	Unsure
7	Whole-grains are healthier than processed or refined grains because	They are higher in fibre	They are naturally richer in nutrients	Blood sugars rise more slowly after eating them	All of these	Unsure
8	If your child ate 15 grams carbohydrate of each of the following foods, which would cause his/her blood sugar to rise the slowest?	Millet	Doughnut	Biscuits	All the same	Unsure
9	If your child ate15 grams carbohydrate of each of the following foods, which would cause blood sugar to rise the fastest?	Apple	Apple juice	Applesauce	All the same	Unsure
10	A juice labelled "No added sugar"	Is a "free" food	Contains no sugar	Contains carbohydrate	None of these	Unsure
	Questions 11-22 are about the number of carbohydrates in different foods. For the food listed in each question, choose the ONE answer that best matches or is closest to the number of carbohydrates in that food.					
11	1 cup (240 ml) low-fat milk	6 grams	8 grams	12 grams	20 grams	Unsure
12	1 cup cooked spaghetti (white, not whole wheat)	20 grams	30 grams	45 grams	65 grams	Unsure
13	½ cup of corn/maize	Less than 5 grams	5 grams	20 grams	30 grams	Unsure
14	Salad (¾ cup) with carrots, cucumbers, tomatoes, onion (no dressing)	Less than 5 grams	10 grams	20 grams	30 grams	Unsure
15	1 cup cooked beans	Less than 5 grams	5 grams	10 grams	15 grams	Unsure

Use the nutrition label below of a can of beans to answer questions 16-19

Nutrition Facts

Serving Size 1 cup
Servings Per Container 2

Amount Per Serving	
Calories 190	Calories from Fat 50
	% Daily Value*
Total Fat 6g	**9%**
Saturated Fat 0.5g	**3%**
Trans Fat 0g	
Cholesterol 0mg	**0%**
Sodium 680mg	**28%**
Total Carbohydrate 30g	**10%**
Dietary Fiber 8g	**32%**
Sugars 6g	
Protein 13g	**26%**

*Percent Daily Values are based on a 2,000 calorie diet.

16	How many cups are in this can of beans?	½ cup	1 cup	2 cups	4 cups	Unsure
17	How many grams of fibre are in 1 cup of the beans	6 grams	8 grams	16 grams	30 grams	Unsure
18	How many total grams of carbohydrate are in 1 serving of beans?	14 grams	22 grams	30 grams	60 grams	Unsure
19	How many grams of carbohydrate would you use to calculate an insulin dose for 1 serving of beans	6 grams	14 grams	22 grams	30 grams	Unsure

Use the nutrition label below of juice to answer questions 20-22

Nutrition Facts

Serving Size (250mL)
Servings Per Container 2.5

Amount Per Serving

Calories 50

	% Daily Value*
Total Fat 0g	**0%**
Saturated Fat 0g	**0%**
Trans Fat 0g	
Cholesterol 0mg	**0%**
Sodium 110mg	**5%**
Total Carbohydrate 14g	**5%**
Dietary Fiber 0g	**0%**
Sugars 14g	
Protein 0g	**0%**

*Percent Daily Values are based on a 2,000 calorie diet.

20	How many servings are in this bottle of juice?	1 serving	2.5 serving	5 serving	8 serving	Unsure
21	How many grams of carbohydrate are in 1 serving of the juice?	14 grams	28 grams	35 grams	70 grams	Unsure
22	How many grams of carbohydrate are in this bottle of juice?	14 grams	28 grams	35 grams	70 grams	Unsure

Appendix G: 24-hour dietary recallquestionnaire

STEP 1: Please think back to when your child woke up yesterday morning to the time, he/she went to sleep in the evening. Now, please describe everything that the child ate yesterday during the day or night, whether at home or outside the home. Run through the whole day in your mind and try to remember everything that the child ate or drank. *INTERVIEWER GIVE THE RESPONDENT A LITTLE TIME TO DO THIS*.

Now, I would like you to tell me what the child ate and drank yesterday during the day or night, whether at home or outside the home from the morning after he or she got up. *AFTER THE PARTICIPANT MENTIONS AN ITEM, INTERVIEWER PROMPT (PROBE) THE RESPONDENT BY SAYING "AND THEN?" "ANYTHING ELSE?" UNTIL RESPONDENT SAYS THE CHILD WENT TO SLEEP UNTIL THE NEXT DAY. IF RESPONDENT MENTIONS MIXED DISHES LIKE A PORRIDGE, SAUCE, OR STEW, PROBE FOR WHAT INGREDIENTS WERE IN THAT MIXED DISH*

ENTER THE INFORMATION IN COLUMN 1 OF THE RECORDING SHEET (TABLE 1).

STEP 2: What the child ate/drank yesterday, was it the same as, more than or less than usual?

a. Same as usual
b. More than usual
c. Less than usual

If more or less than usual, explain why (circle appropriately)

a. Celebration
b. Religious activity
c. Little food in the household
d. Other (specify) ________________________________

STEP 3: "Now I am going to ask you more about each food or drink that your child ate/drank yesterday".

Start with the 1st item reported in column 1 of the recording sheet (Table 1).

ASK "when was the food item eaten? INDICATE WHEN AND THE TIME THE FOOD ITEM WAS EATEN AND REPORT IT IN COLUMN 2.

STEP 4 "Now I would like you to tell describe to me more about this food item…."

THIS INCLUDES A DETAILED DESCRIPTION OF THE FOOD (BRAND NAME AND THE METHOD OF PREPARATION). ENTER THIS INFORMATION IN COLUMN 3.

STEP 5: "Now I would like you to tell me how much (amount) of this food was eaten and where it was eaten?"

INTERVIEWER USE HOUSEHOLD MEASURES IN TERMS OF CUPS, SPOONS, BOWLS, GLASSES, TO DETERMINE AMOUNT, REPORT IT IN COLUMN 4 AND WHERE IT WAS EATEN IN COLUMN 5.

STEP 6: Once the respondent finishes recalling foods eaten underline the corresponding food and in the dietary diversity questionnaire (table 2), enter '1' in the column next to the food group if the food was eaten and '2'if it was not.

IF THE FOOD IS NOT LISTED IN ANY OF THE FOOD GROUPS, WRITE THE FOOD IN THE BOX LABELED 'OTHER.' IF FOODS ARE USED IN SMALL AMOUNTS FOR SEASONING OR AS A CONDIMENT, INCLUDE THEM UNDER THE CONDIMENTS FOOD GROUP.

STEP 7: Read each food group where '1' was not entered, ask the respondent if a food item from this group was consumed by the child and enter '1' if respondent says yes, '2' if no, and '9' if they don't know.

Table 1: Recording sheet for information collected in steps 1 to 5

Food item	Meal time 1=breakfast, 2=lunch, 3=dinner, 4=snack, 5=other (***also record time***)	Detailed description of the item before consumption (*ingredients, quantities and cooking methods, brand name*)	Amount of food eaten ***(use household measures and size i.e. small (S), medium (M), large (L), fingers e.g. 3 fingers of matooke, number e.g. 2 Irish potatoes)***	Where it was consumed 1= home 2=school 3=gift 4=restaurant 5=party 6=church/mosque 7=other

Appendix H: Dietary diversity questionnaire

STEP 8: When the respondent 24-hour recall is complete, fill in the food groups based on the information recorded above. For any food groups not mentioned, ask the respondent if a food item from that group was consumed by the child.

Table 2: Dietary diversity

Question number	Food group	Examples	Response Yes=1 No=2
1	Cereals	Corn/maize, rice, wheat, sorghum, millet or any other grains or foods made from these.	
2	Vitamin A rich vegetables and tubers	Pumpkin, carrots, orange/yellow/purple sweet potatoes.	
3	Roots and tubers	White potatoes, white yams, white cassava, or other foods made from roots.	
4	Dark green leafy vegetables	Dark green/leafy vegetables, including wild ones such as dodo, nakati, jobyo, cassava leaves, spinach etc.	
5	Other vegetables	Other vegetables (e.g., tomato, onion, eggplant), including wild vegetables.	
6	Vitamin A fruits	Ripe mangoes, ripe papaya, water melon, jackfruit, banana	
7	Other fruits	Other fruits, including wild fruits.	
8	Organ meats	Liver, kidney, heart or other organ meats or blood-based foods	
9	Flesh meat	Beef, pork, lamb, goat, rabbit, wild game, chicken, duck, or other birds	
10	Eggs	Chicken, duck	
11	Fish	Fresh or dried fish	
12	Legumes, nuts and seeds	Beans, peas, lentils, nuts, seeds or foods made from these	
13	Milk and milk products	Milk, cheese, yogurt or other milk products	
14	Oils and fats	Oil, fats or butter added to food or used for cooking	
15	Red palm products	Redpalm oil	
16	Sweets	Sugar, honey, sweetened soda or sugary foods such as chocolates, candies,cookies and cakes	
17	Spices, condiments, beverages	Spices (black pepper,salt), condiments (soysauce, hot sauce), coffee and tea	
18	Other	Specify:	

Thank you for your patience and for participating in this study

Appendix I: Pilot study findings and reliability of study instruments

Pilot study findings on socio-demographic characteristics of caregivers and children's type 1 diabetes related characteristics, nutrition education and type 1 diabetes training characteristics.

Socio-demographic characteristics and type 1 diabetes related characteristics

Characteristics	Intervention N = 5 n (%) or mean ± SD	Control N = 5 n (%) or mean ± SD	Total N = 10 n (%) or mean ± SD	*p*-value
Age of caregiver (years)	37 ± 16.4	37 ± 7.5	37 ± 12	1.000
Sex of caregiver				
Male	1 (20)	0 (0)	1 (10)	
Female	4 (80)	5 (100)	9 (90)	
Relation to the child				
Father	1 (20)	0 (0)	1 (10)	
Mother	3 (60)	4 (80)	7 (70)	
Brother	1 (20)	0 (0)	1 (10)	
Sister		1 (20)	1 (10)	
Household size	5.2 ± 2.2	6.4 ± 1.1	5.8 ± 1.8	0.323
Religion				
Catholic	2 (40)	1 (20)	3 (30)	
Anglican	1 (20)	1 (20)	2 (20)	
Moslem		3 (60)	3 (30)	
Seventh day Adventist	1 (20)	0 (0)	1 (10)	
Born again Christian	1 (20)	0 (0)	1 (10)	
Marital status				
Single	1 (20)	0 (0)	1 (10)	
Married	1 (20)	4 (80)	5 (50)	
Co-habiting	1 (20)	1 (20)	2 (20)	
Divorced	1 (20)	0 (0)	1 (10)	
Widowed	1 (20)	0 (0)	1 (10)	
Occupation of caregiver				
Civil servant	1 (20)		1 (10)	
Business	1 (20)	1 (20)	2 (20)	
Other	3 (60)	4 (80)	7 (70)	
Occupation of caregiver's spouse/partner				
Civil servant	0 (0)	1 (20)	1 (10)	
Other	3 (60)	4 (80)	7 (70)	
Level of education				
Primary	2 (40)	3 (60)	5 (50)	
Secondary (UCE)	0 (0)	1 (20)	1 (10)	
Secondary (UACE)	1 (20)	0 (0)	1 (10)	
Diploma		1 (20)	1 (10)	
No formal education	2 (40)		2 (20)	
Monthly income (UGX)				
≤ 200,000	5 (100)	3 (60)	8 (80)	
201,000 - 400,000		1 (20)	1 (10)	
401,000 - 600,000		1 (20)	1 (10)	
Age of child (years)	10.8 ± 4.7	12.2 ± 3.4	11.5 ± 3.9	0.608
Sex of child				
Male	4 (80)	2 (40)	6 (60)	
Female	1 (20)	3 (60)	4 (40)	
Duration of T1D (years)	3 ± 2.5	1.8 ± 1.7	2.4 ± 2.1	0.414
≤1	2 (40)	4 (80)	6 (60)	
2-5	2 (40)	1 (20)	3 (30)	
≥6	1 (20)	0 (0)	1 (10)	
Insulin regimen				
≤ 2 times a day	3 (60)	1 (20)	4 (40)	
≥ 3 times a day	2 (40)	4 (80)	6 (60)	

Continuedsocio-demographic characteristics and type 1 diabetes related characteristics

Characteristics	Intervention N = 5 n (%) or mean ± SD	Control N = 5 n (%) or mean ± SD	Total N = 10 n (%) or mean ± SD	*p*-value
Family history of T1D				
Yes	0 (0)	2 (40)	2 (20)	
No	5 (100)	3 (60)	8 (80)	
Family history of T1D relation to child				
Aunt/Uncle	0 (0)	1 (20)	1 (10)	
Grandparent	0 (0)	1 (20)	1 (10)	
HbA1c (%)	11.8 ± 2.0	10.6 ± 3.3	11.2 ± 2.6	0.512
Random blood sugar (mmol/L)	10.0 ± 11.2	12.3 ± 7.0	11.2 ± 8.9	0.704
Type 1 diabetes nutrition knowledge score	22.8 ± 15.0	29.8 ± 17.4	26.3 ± 17.4	0.557

Type 1 diabetes training characteristics

Characteristics	N= 10, n (%)
Ever been trained about type 1 diabetes	
Yes	10 (100)
No	0 (0)
Place where training was done	
Hospital	5 (50)
Health centre	3 (30)
Private clinic	1 (10)
Other	1 (10)
Who conducted the training	
Doctor	5 (50)
Nurse	4 (40)
Nutritionist/dietician	1 (10)
Topics of the nutrition education sessions	
Blood glucose monitoring	6 (60)
Hypo/hyperglycaemia management	5 (50)
Nutrition in type 1 diabetes	7 (70)
Insulin use and dosage	7 (70)
Fruit and vegetable intake	1 (10)
Balanced diet	1 (10)
Hygiene	1 (10)
Eating in time	3 (30)
Exercise	1 (10)
Cause of diabetes and types	10 (100)
Trusted the most to give information about type 1 diabetes mellitus	
Doctor	7 (70)
Nurse	2 (20)
Nutritionist/dietician	1 (10)
Why do you trust them	
They are knowledgeable	4 (40)
They are approachable	2 (20)
They have been managing the child	5 (50)
Preferred format of getting information about type 1 diabetes mellitus and nutrition	
Posters	1 (10)
Thorough discussion with health facility staff	8 (80)
Other (discussion with peers)	1 (10)
Preferred format of learning	
Group discussion	5 (50)
Individual discussion	1 (10)
Demonstrations	1 (10)
Note taking and reading	3 (30)

Nutrition education sessions about type 1 diabetes

Characteristics	N= 10, n (%)
Ever attended nutrition education sessions about type 1 diabetes	
Yes	8 (80)
No	2 (20)
Place where training was done	
Hospital	5 (50)
Health centre	3 (30)
Who conducted the training	
Doctor	5 (50)
Nurse	2 (20)
Nutritionist/dietician	1 (10)
Topics of the nutrition education sessions	
Types of food to eat	5 (50)
Fruits and vegetables	3 (30)
Food portioning	2 (20)
Dietary diversity	1 (10)

RELIABILITY

Scale: ALL VARIABLES

Case Processing Summary

		N	%
Cases	Valid	10	100.0
	Excluded[a]	0	.0
	Total	10	100.0

a. Listwise deletion based on all variables in the procedure.

Reliability Statistics

Cronbach's Alpha	Cronbach's Alpha Based on Standardized Items	N of Items
.760	.829	2

Item Statistics

	Mean	Std. Deviation	N
Type 1 diabetes nutrition knowledge score Test	9.20	1.033	10
Type 1 diabetes nutrition knowledge score Retest	10.10	1.792	10

Inter-Item Correlation Matrix

	Type 1 diabetes nutrition knowledge score Test	Type 1 diabetes nutrition knowledge score Retest
Type 1 diabetes nutrition knowledge score Test	1.000	.708
Type 1 diabetes nutrition knowledge score Retest	.708	1.000

Summary Item Statistics

	Mean	Minimum	Maximum	Range	Maximum / Minimum	Variance	N of Items
Item Means	9.650	9.200	10.100	.900	1.098	.405	2
Item Variances	2.139	1.067	3.211	2.144	3.010	2.299	2
Inter-Item Correlations	.708	.708	.708	.000	1.000	.000	2

Scale Statistics

Mean	Variance	Std. Deviation	N of Items
19.30	6.900	2.627	2

Intraclass Correlation Coefficient

		95% Confidence Interval		F Test with True Value 0			
	Intraclass Correlation[b]	Lower Bound	Upper Bound	Value	df1	df2	Sig
Single Measures	.533[a]	-.028	.854	4.168	9	9	.022
Average Measures	.695[c]	-.059	.921	4.168	9	9	.022

Two-way mixed effects model where people effects are random and measures effects are fixed.
a. The estimator is the same, whether the interaction effect is present or not.
b. Type A intraclass correlation coefficients using an absolute agreement definition.
c. This estimate is computed assuming the interaction effect is absent, because it is not estimable otherwise.

Appendix J: Structured nutrition education course content

Session	Topic	Brief description
Session 1	Overview of food and nutrients	This lesson introduced caregivers to the basics of nutrition such as the different categories of food classes, nutrients obtained from food and their food sources.
Session 2	Impact of nutrients on blood sugar	This lesson helped caregivers develop an understanding how nutrients from food affect blood sugar and help them make informed choices regarding food choices for their children.
Session 3	Blood sugar monitoring	This lesson helped caregivers appreciate the importance of self-monitoring of blood sugar as a vital aspect of the effective management of type 1 diabetes, and guide them to evaluate their child’s response to treatment and assess whether they are achieving their blood sugar targets and and also help them be able to detect of low or high blood sugar in early.
Session 4	Carbohydrate counting	This lesson introduced caregivers to carbohydrate counting as a meal planning approach that aims to help control blood sugar levels.
Session 5	Eating out and healthy snack choices	This lesson guided caregivers on how to make healthy food and snack choices when eating out in a fun and convenient way.
Session 6	Interpreting food labels	This lesson guided caregivers on how to use the nutrition information on a food label to make informed food choices for their children.
Session 7	Healthy eating and meal planning	This lesson helped caregivers learn how to develop a healthy and balanced meal planfor their children.
Session 8	Exercise	This lesson helped caregivers appreciate the importance of regular exercise or physical activity in type 1 diabetes management.

Appendix K: Diabetes education curriculum

Session 1: Overview and monitoring
a) Feelings surrounding diagnosis
b) Explanation of diabetes
c) Blood glucose and laboratory monitoring
d) Overview of how to live with diabetes
e) Self-management

Teaching objectives:
1. Participants will verbalize their feelings about the diagnosis of diabetes.

Teaching points:
Discuss feelings and recognize the impact they might have on control of diabetes.
Dispel myths that surround the reasons for contracting diabetes; i.e., the participants did something bad, or they ate too much sugar.
Ask participants what they feel is the hardest part of their diagnosis to manage and what life style changes are most difficult to incorporate into their lives.
This discussion should lead into teaching objective #2.

2. Participants will be able to define diabetes and its pathophysiology.

Teaching points for the questions, "what causes diabetes?" and "what is diabetes?"
Describe normal glucose metabolism in simple terms. Explain that most foods contain sugar (glucose) and that the body needs this sugar or glucose for energy. Explain that the brain, muscles and internal organs all use sugar (glucose) for fuel.
Emphasize that eating too much sugar did not cause participant's diabetes. Genetics, weight, family history and ethnicity all contribute to diabetes.
In diabetics, the body can't use the insulin that is produced or the pancreas doesn't produce enough insulin. Familiarize participants with the term, "insulin resistance."
Without insulin, glucose can't move from the bloodstream into body cells.
Without insulin, sugar or glucose builds up in the bloodstream.
The body can also make glucose from storage supplies in places like the liver.
Therefore, many participants with diabetes have a high glucose level in the morning even though they haven't eaten since dinner. Their bodies have been "making" sugar while they were asleep.
Because some people don't produce enough insulin and other people can't use what is produced, different people take different types of medication.

Key Teaching Point: diabetes is the inability of the body to take sugar out of the bloodstream and put it where it needs to go.

3. Participants will understand normal glucose ranges, the importance of blood glucose self-monitoring and the significance of A1c laboratory monitoring.

Teaching points:
Blood glucose levels reflect the amount of glucose in the blood at that moment.
Because most foods have sugar, blood glucose levels increase after eating.

Target blood sugar levels are 4.4 - 6.6 mmol/l 2-hrs hours after eating, a blood sugar level of 10.0 mmol/l or less is ok. i.e. an Increase of about 3.7 mmol/l
Identify test times. Stress the need to check blood sugars at different times of the day.
Stress the importance of recording the results and time of day that the reading was taken even if the meter has memory.

Describe A1C as a three-month report card that shows how much sugar has built up on the cells in a three-month period. Stress that this is the most accurate way of determining how well controlled diabetes is.
Define an A1C of below 7.0% as a goal.
Discuss complications of diabetes. Explain why a lower A1C is important.
Readings above 8.0% mean higher risk for problems.
Participants with an A1C of 7.0% or less have much less risk for heart disease, stroke, kidney disease, eye problems, foot problems and nerve damage.

Key Teaching Point: it is essential to check blood glucose levels daily and to strive for levels of 4.4 - 6.6 mmol/l (and no more than 10.0 mmol/l after eating)

4. Participants will understand that diabetes is a lifelong disease. Participants will also understand that they can self-manage their diabetes with proper nutrition, exercise and sometimes medication. This is an overview: specific points will be discussed in more detail in later sessions.

Teaching points:
1. Diet is crucial to diabetes management
2. Maintaining a healthy body weight is one of the keys to managing diabetes. Being overweight makes insulin less able to do its job (keeping glucose levels normal in the
3. blood). Losing even a small amount of weight helps lower the blood glucose levels.
4. Physical activity helps to decrease blood glucose levels and other aspects of health.
5. Stress need for MD approval before beginning any exercise regimen.
6. Discuss the role of taking medications, as prescribed.

Key Teaching Point: diabetes is a lifelong disease in which self-management is crucial

5. Hand out self-management goal sheets. Discuss the concept of self-management and have participants develop oneself management goal related to today's session. Let participants
know that these will be reviewed in future sessions. Ask participants to work on their goals in the next week and to bring the sheets back to the next session.

6. Questions and answers.

Session 2: Hypo/Hyperglycaemia and Introduction to Nutrition
a) Review of last session's information
b) Review/discussion of self-management goal set last session
c) Discussion of Hyper/hypoglycaemia

d) Introduction to Nutrition
e) Self-management goal

Teaching objectives:
1. Participants will be able to discuss the importance of SBGM (review).

Teaching Points:
Explain SBGM reflects the current amount of glucose in the blood.
Blood glucose levels depend on the type and amount of food eaten. It is normal for blood glucose to increase after eating.
Infections and stress can also increase blood glucose levels
Emphasize the importance of checking blood sugar as instructed by their provider.
Emphasize the importance of checking BS at different times of the day and why this is important.
Review target BS from session 1.
Review the difference between this reading (which is a snapshot of BS control) and A1C (which is a three-month report card).
Key Teaching Point: performing SBGM provides information to you and your provider to help manage your diabetes better. It is not a tool to say you're doing something wrong.

2. Participants will be able to distinguish between hypoglycaemia and hyperglycaemia.

Teaching Points:
Define the signs and symptoms of hypo and hyperglycaemia. Discuss the 15/15 rule.
Define the appropriate action(s) to take if experiencing hypoglycaemia.
Define appropriate action to take if experiencing hyperglycaemia.
Key teaching point: it is important to not over-treat hypoglycaemia. The participant should recognize that both situations are potentially dangerous.

What to do for low blood sugar:
The 15 / 15 rule
If you take diabetes pills that help your body make more insulin, or if you take insulin shots, you might have times when your blood sugar drops too low. This is called hypoglycaemia – or low blood sugar.

Common signs of hypoglycaemia (low blood sugar) are:
• Shaky
• Sweaty
• Tired
• Anxious, cranky, or confused
• Hungry
• Faster heartbeat
• Blurry vision or headache
• Numbness or tingling in mouth and lips
Follow the 15/15 Rule when you have signs of low blood sugar
Treat low blood sugar right away. Check your blood sugar and if it's 4.0 mmol/l or less eat or drink 15 grams of fast-acting carbohydrate.

The best choices for fast-acting carbohydrate are 4 glucose tablets or 15 grams of glucose gel. These are absorbed very quickly and are available at most drug stores and pharmacies.
Other 15-gram carbohydrate choices include:
• ½ cup (4 ounces) of fruit juice
• ½ cup (4 ounces) regular soda, such as Coke-cola, Fanta or 7-up
• 1 small box of raisins
• 1 tablespoon of sugar
• 6 or 7 small hard candies, such as Lifesavers.
Check your blood sugar again in 15 minutes – if it hasn't risen above 4.0 mmol/l, eat or drink another 15 grams of carbohydrate.
Wait another 15 minutes. Then check your blood sugar again. If your blood sugar is still 4.0 mmol/l or lower, take another 15 grams of carbohydrate
After your blood sugar returns to normal
If eating or drinking the carbohydrate brings your blood sugar back into the normal range, plan to eat your next regular meal within an hour.
If you aren't able to eat a meal within an hour, eat a snack that has both carbohydrate and protein in it.

Good snack choices include:
• 1 ounce of low-fat cheese and 4 to 5 whole grain crackers
• 1 hard-cooked egg and 1 slice whole grain bread
• 1 tablespoon of peanut butter and 3 graham crackers
• 1 ounce of nuts, such as almonds or peanuts, and 8 ounces low-fat or non-fat yogurt
• ½ cup cottage cheese and ½ small whole grain bagel
• 1 ounce of lean meat, such as turkey or chicken breast, and 1 small flour or corn tortilla

Problem solving

After you're feeling better, think back over the last 4 to 6 hours. Ask yourself these questions to find out why your blood sugar went too low:
• Did I take too much diabetes medicine?
• Did I skip a meal, or not eat enough carbohydrate?
• Did I get more exercise, or was I more active than usual?

3. Participants will be able to define the role of nutrition in the therapy of diabetes.

Teaching Points:
Good and healthy nutrition is the first step in managing your diabetes. This helps to better control blood glucose levels, decreases your risk of complications and helps us to achieve or maintain a healthy body weight.
Medication alone isn't enough to control diabetes.
Stress the positives of good nutrition and help participants realize that
favourite foods do not have to be omitted from their intake.
Help participants realize there are no good foods or bad foods; rather there are "sometimes" foods. Ask participants to share what foods they think can't be included in their diet because of diabetes. Discuss how the food may be included or try to offer a similar healthier alternative for a favourite food.

Key Teaching Point: foods are to be enjoyed and most foods can fit into a healthy diabetic menu. The key is moderation.

4. Participants will be able to define the major sources of carbohydrate, protein and fat.

Teaching Points:
Beginning with carbohydrates have participants define which foods are major contributors of each of the macronutrients, i.e. carbohydrate, protein, fat.
Stress the importance of including each of these nutrients at a meal.
Emphasize that variety is key to enjoying food, and that meals each day should include vegetables, fruits, whole grains, dairy and lean sources of protein.
Discuss portion size and emphasize that healthy blood glucose is achieved by moderate portion sizes. Use food models to help participants understand the concept portion size.

Key Teaching Point: the diabetic menu is the way everyone should eat. There is no need to prepare special foods for the person with diabetes.

5. Participants will be able to plan a basic menu which incorporates the inclusion of each of the macronutrients.

Teaching Points:
Explain the concept that woman will usually have three and men four choices of carbohydrate at a meal. Using food models, discuss that participants may choose three to four different choices of a carbohydrate at a meal, or more of just one choice. Illustrate using pasta as an example.
Explain the concept that a portion of protein must be included at lunch and supper. Generally, for woman, this may be 2-3 ounces of cooked protein and for men, 3-6 ounces of cooked protein.
Using food models have participants attempt to assemble a sample meal.

Key Teaching Point: have each participant share his/her sample meal with the class and help them to identify the source of each of the macronutrients. Use this as an opportunity to illustrate how favourite foods can be included each day.

6. Have each person develop a self-management goal related to eating. Ask that the self-management goal sheet be brought back next session.

7. Questions and answers

Session 3: Nutrition
Review self-management goals from Sessions 1 and 2
Review nutrition information from Session 2
Discuss impact of carbohydrates, protein and fat on BG
Healthy/Unhealthy fats
Critique meals
Fast Foods with a self-management goal
Make a Meal

Teaching objectives:
1. Participants will be able to discuss the impact of carbohydrate on blood glucose levels.
Teaching Points:
Review sources of carbohydrate from session 2.
Carbohydrates are necessary for important body functions. Participants don't have to avoid carbohydrates; rather they should moderate their intake.
Carbohydrate foods have the greatest effect and quickest effect on blood glucose levels.
Carbohydrate foods raise blood glucose regardless of the source. Participants need to realize that milk, fruit and bread raise blood glucose just as a cookie does.
Key Teaching Point: it is the amount of carbohydrate consumed that matters rather than the source of carbohydrate. Carbohydrate intake should be consistent from meal to meal and day to day. (Remember Quantity --- Content--- Quality)

2. Participants will be able to discuss the impact of protein on blood glucose levels and identify healthier proteins to include in their intake.

Teaching Points:
Review sources of protein from session 2.
Proteins are also necessary for important body functions. We need proteins but we don't need an excessive amount. Using food models show participants examples of 3-ounce portions of cooked protein.
Proteins affect blood glucose levels but to a much lesser extent that carbohydrates.
A source of protein should be included at each meal.
Try to choose very lean and lean protein choices if possible. Examples include: white meat chicken or turkey, fish such as cod, ngege, mputa, salmon or trout, shellfish like lobster, crabs, clams and low-fat cottage cheese.
Some red meats are also lean. These include flank steak, roasts such as a pot roast, pork tenderloin. Make sure that you trim the fat!

Key teaching point: include a protein source at each meal, especially lunch and supper. Try not to use excessive amounts of protein.

3. Participants will be able to discuss the impact of fat on blood glucose levels and identify healthier fats to include in their intake and why less healthy fats should be avoided.
Teaching Points:
Review sources of fat from session 2.
Fats have very little direct effect on blood glucose levels. Fats make us fatter!
Because excess weight makes it harder for our body to use the insulin we are making, we should avoid an excessive fat intake.
A high fat diet, especially a diet high in unhealthy fats can clog our arteries and this may lead to a heart attack or stroke.
Try to avoid fried foods or foods with extras sauces or gravies on them. When in restaurants, order gravies/sauces on the side. At fast food restaurants, order items plain, no cheese, no sauce. Lettuce, tomato and small amounts of ketchup are fine.
When using fat, choose healthy alternatives such as olive and canola oils.

Nuts in small amounts may also be included.
Use margarines that are trans-fat free. Provide examples of these margarines.
Try to use high fat foods less frequently or substitute lower fat alternatives.
Provide examples such as low-fat milk or skim milk for whole milk, reduced fat cheeses.
Key Teaching Point: fats have little direct effect on blood glucoses but fats make us fatter.
Being overweight makes it harder for our body to use insulin so indirectly fats affect diabetes.
Fats can contribute to risk of stroke and heart attack. Choose leaner alternatives and heart healthy fats.

4. Participants will understand the impact of delaying or omitting meals, and the importance of appropriate portion size will be reviewed.
Teaching Points:
Emphasize the fact that the body needs food to provide fuel for the activities we perform each day.
Food/fuel is also needed for the medicine or insulin we take each day. If we do not provide enough food, then our blood glucose levels may fall too low.
Review hypoglycaemia.
If a meal is going to be delayed for more than ½ to one hour, then a snack should be eaten at the usual mean time.
An adequate amount of food should be eaten at each meal. Food cannot be saved from one meal to the next meal. For example, if you do not eat any carbohydrate at lunch, you cannot have double your usual intake of carbohydrate at supper. Remember, balance is important!

Key Teaching Point: our body needs fuel for the activities we perform and for the medicine we take each day.

5. Participants will understand how to make healthier choices at fast food restaurants.

Teaching points:
Encourage participants to ask for foods without extra sauces and to omit cheeses.
Discourage the practice of “supersizing” selections. Illustrate the difference in calories, fats and carbohydrates between a regular portion and a “supersized” portion.
Encourage participants to choose items that are grilled, baked or roasted rather than fried.
Remind participants of the principles of good meal planning; i.e., a carbohydrate, a protein and a fat at each meal. Only a side salad or a frozen yogurt is not enough.
6. Review self-management sheets and ask participants to make a self-management goal related to visits to fast food restaurants.

7. Review basic meal planning.
Teaching focus:
As done in session 2, have participants plan sample meals using food models.

Session 4: Everyday Tips for Staying Healthy
Foot Care

Dental Care
Vitamins/Minerals
Exercise
Self-Management

Teaching objectives
1. Participants will be able to discuss foot problems caused by diabetes
Teaching Points:
Describe foot problems caused by nerve damage and poor circulation.
Tingling or burning feet
Changes in colour or temperature of feet
Blisters, sores or ulcers
Thick, yellow toenails
Fungus infections between toes
Loss of feeling

2. Participants will be able to discuss how to protect their feet
Teaching Points:
Wear shoes and socks Choose cotton or wool socks.
Trim nails carefully along the toe's natural curve
Don't cut corns and calluses. Let a podiatrist do this.
Rub lotion on tops of feet but not between toes
Check your feet every day. Look for cracks, cuts and sores. Call your doctor right away if you have a sore.
Ask your health care provider to exam your feet at least 4 times a year. Remove shoes and socks as a reminder when you go for your exam. Keep physically active. This improves circulation in the feet.
Key Teaching Point: Participants must protect their feet with shoes or slippers and report any sore to their provider.

3. Participants will understand that people with diabetes are more likely to have problems with their teeth and gums and that, like all infections, dental infections can make blood glucose go up.

4. Participants will be able to describe signs of dental disease
Teaching Points:
Sore, swollen and red gums that bleed when brushing
Gums than shrink or pull away from teeth

5. Participants will be able to describe ways to prevent dental problems
Teaching Points:
Brush teeth at least twice a day
Use a soft toothbrush and use toothpaste with fluoride
Get a new toothbrush every 3 months
Floss everyday
Visit a dentist twice a year
Key Teaching Point: Participant must brush and floss every day and visit a dentist at least
once a year.

6. Participants will be able to discuss the importance of physical activity and its impact on blood glucose levels.

Teaching points:
Never begin an exercise program without checking with your primary care provider.
Emphasize the many positive aspects of physical activity. Include:
o Lowers blood glucose levels
o Helps maintain and achieve a healthy body weight
o Helps to keep heart and lungs healthy
o May improve blood pressure

Discuss reasonable goals for beginning an exercise program. Ideally, strive for 30-45 minutes per day. May accumulate minutes of exercise; i.e., exercise 10 minutes three times per day.
Begin slowly and gradually increase activity level.
Any amount of exercise is better than none.
Always carry identification and a quick acting carbohydrate. Provide examples of quick acting carbohydrate.
Stress the importance of comfortable shoes, and visually checking the inside of the shoe before it is worn.
Discuss comfortable socks; cotton socks without seams are ideal.
Key Teaching Point: Exercise is essential to controlling diabetes.

7. Self-Management Goal: establish a self-management goal related to one of the topics of Session 5 (foot care, dental care, or exercise)

8. Questions and answers.

Appendix L: Proposed topics for a nutrition education programme by caregivers of children with type 1 diabetes mellitus

Proposed topics	Final topics
Types of food to eat Fruits and vegetables Insulin use and dosage	Overview of food and nutrients Impact of nutrients on blood sugar levels Carbohydrate counting Eating out and healthy snack choices Interpreting food labels Healthy eating and meal planning
Blood sugar monitoring Signs and symptoms of hypo/hyperglycaemia management To be able to detect hypo/hyperglycaemia episode Management of hypo/hyperglycaemia Exercise	Blood sugar monitoring (signs and symptoms of hypo/hyperglycaemia, causes and management) Exercise
Home yard gardening *Caring for children with T1D* *Income-generating activities*	*These topics were not considered as they were beyond the scope of the study*

Note. This figure highlights the topics selected for inclusion in the nutrition education guide.

Appendix M: Expert content validation

Assessment domain	**Score**			**Experts**				
	1 Not acceptable (Major modifications needed)	2 Acceptable with changes (Minor modifications needed)	3 Acceptable (No modifications needed)	Expert 1	Expert 2	Expert 3	Expert 4	Expert 5
Appropriate and balanced *The lessons and messages are relevant, sufficient and suitable for the target participants*		✓ ✓ ✓	✓ ✓	The comments and suggestions have been embedded in the document	More practical demonstrations of concepts will yield better understanding among caregivers. I feel lessons 4,6 and 7 would do better with more practical duration than indicated.	Lesson1, message1.1 the message was fine, message 1.2 the key points were very important and in message 1.4 the examples of food sources in the different food classes were used in context of the locally used food in the country. Lesson 2, message 2.1 the key point was very important cause some of the children know that carbs are the main cause of rising blood sugars, so the majority tend to eliminate them in their diet.	Acceptable, bedtime blood glucose is better 6mmol/l and bedtime snack is also important to avoid midnight hypo, lowerA1C reduces risks of developing diabetic wounds that hardly resolve, high blood glucose is also a key point to note before an exercise	
Clarity *The content is easy to understand*		✓ ✓ ✓	✓ ✓	Comments and suggestions are embedded in the source document	I feel some concepts have not been broken down very well to aid easy understanding by a lay caregiver	Lesson 3, message 3.5 in addition to what was laid in the message I would like to add that when a hypo happens the caregiver/parent should test or ask the child to	Very easy to understand though carb counting is always a challenge	Msg.2.1 6^{th} point…such food will raise blood sugar levels slowly Msg.3.6….11mmol/L(200mg/dL) and greater Title Fig.1 and Message 3.5 (placed in different positions) Msg.3.5 2^{nd} point…an example

					who understands English at a very basic level. For example, use of food grams seems difficult for me as if I need to have a scale to weigh every food item. I wish there is a way may be by use of pictures or live practical session to demonstrate those food portions indicated. The guide has used numerics with important concepts such as GI scale, food grams…...It is as though I am supposed to remember all these. Can we cut down on numeric and use some practical descriptives maybe? Shall we have a translation of this piece for at least the major dialects in Uganda?	check his or her blood sugar so that this can help you to evaluate whether your intervention has worked and also to supervise the child during hypo till recovery cause it tends to relapse i.e. don't leave the child alone. Lesson 3, message 3.8 in addition to what was laid I would like to add that whenever the child notices signs of hyperglycaemia the first thing is for them to check their blood glucose levels and keep repeating after every 2 hours and if the blood sugar levels are still high i.e. 15mmol or 270mg/dl they should consult their doctor or Nurse. Lesson 3, message 3.9 apart from having many episodes of hypo causing a low A1c, if the child was sick with severe malaria a week before the test it can also cause a low A1c cause the malaria parasites destroy the mature red blood cells that have circulated in the body for long so by the type time we do the test we find new red blood cells hence not giving us a correct figure.		of a fast-acting carbohydrate like glucose can be added Msg.8.1 3rd point…to regulate blood glucose
Use of technical	✓	✓	✓ ✓ ✓	Comments and suggestions are	Lesson 3: Hypoglycaemia	All the lessons and the messages were laid out		

language and jargon *The use of technical language and jargon is minimal and appropriate.*				embedded in the source document There is need to pitch the content to the lowest understanding of a basic English-speaking caregiver No jargon use has been identified I am not sure if there will be translations to local languages	& Hyperglycaemia – looks technical. I am not sure how many caregivers can even pronounce it. They have been the terms that have been used to explain Low blood sugar and High blood sugar. Can't we adopt 'low blood sugar vs high blood sugar? More terms include: Glycaemic control Since it is a participant guide, I reckon it is targeted for caregivers with assistance from healthcare providers Message 14: table3 – is DAIRY another food class (in addition to Go, Glow and Grow foods)?	in the language that can easily be understood by even a lay person.		
illustrations *Pictures used are sufficient and relate to the daily practices of the target*		✓ ✓ ✓	✓ ✓	Comments and suggestions are embedded in the source document I identified need to adopt pictures to our local context	Lesson 7: The plate illustration is missing typical Uganda foods. I would also suggest additional pictorial	Lesson1, message 1.3 food pictures represented the locally used food. Lesson 3, message 3.4 the heading of Figure 1: Signs of hypoglycaemia is under message 3.5 it	Need for more local foods	

participants				I also suggest or assume that there will be some extra pictorial material resource to complement the guide especially with carb portion demonstrations. ***Additional comments/suggestions:*** There is need for an agreement on the 'voice' of communication. Should the message be written in a way directed to audience for example, you need to choose healthy fats vs There is need to choose healthy fats. [In case you my point is not clear, please reach out]	materials for practical demos. I hope these will be an additional part of this training guide package	should be on top of the illustration for the signs of hypo. Lesson 7, message 7.1 the plate is fine but the illustration of the water on the side is not clear I suggest that you use a glass that can clearly show that its water. ***Additional comments/suggestions:*** I would love to appreciate you for coming up with this nutrition guide and I believe that if it's approved it will surely be of great help to our caregivers and the patients and it will also help to improve care of our patients in the country.		

Summary of assessment domains scores

Assessment domain	Ext 1	Ext 2	Ext 3	Ext 4	Ext 5	Total score	Mean score
Appropriate and balanced	2	2	3	2	3	12	2.4
Clarity	2	2	2	3	2	11	2.2
Use of technical language and jargon	2	1[a]	3	3	3	12	2.4

Illustrations	2[b]	2	2	3[c]	3	12	2.4

Note. This table displays the expert content validation scores per assessment domain.

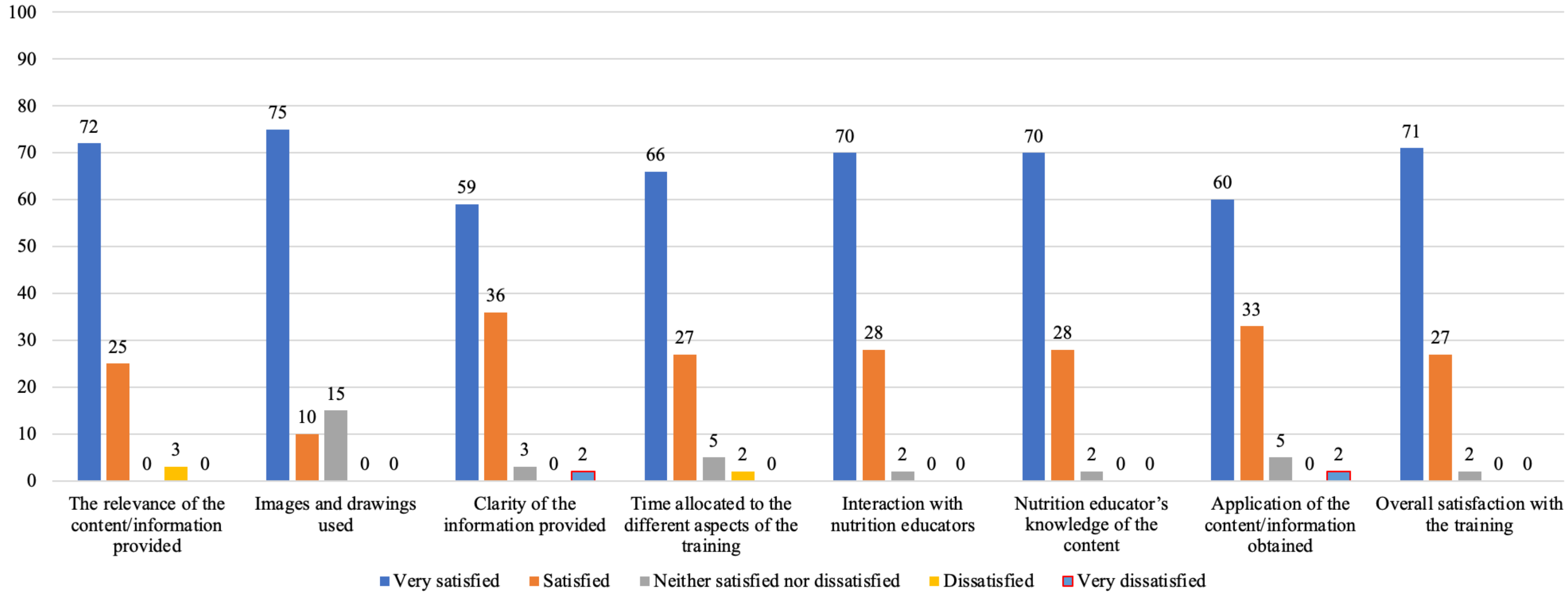
Abbreviations. Ext, Expert; 1[a], not acceptable (major modifications needed); 2[b], acceptable with changes (minor modifications needed); 3[c] acceptable (no modifications needed).

Appendix N: Evaluation and comments from the participants of the structured nutrition education sessions

The participants were given an opportunity to write or mention any additional comments regarding the structured nutrition education course, below are their comments:

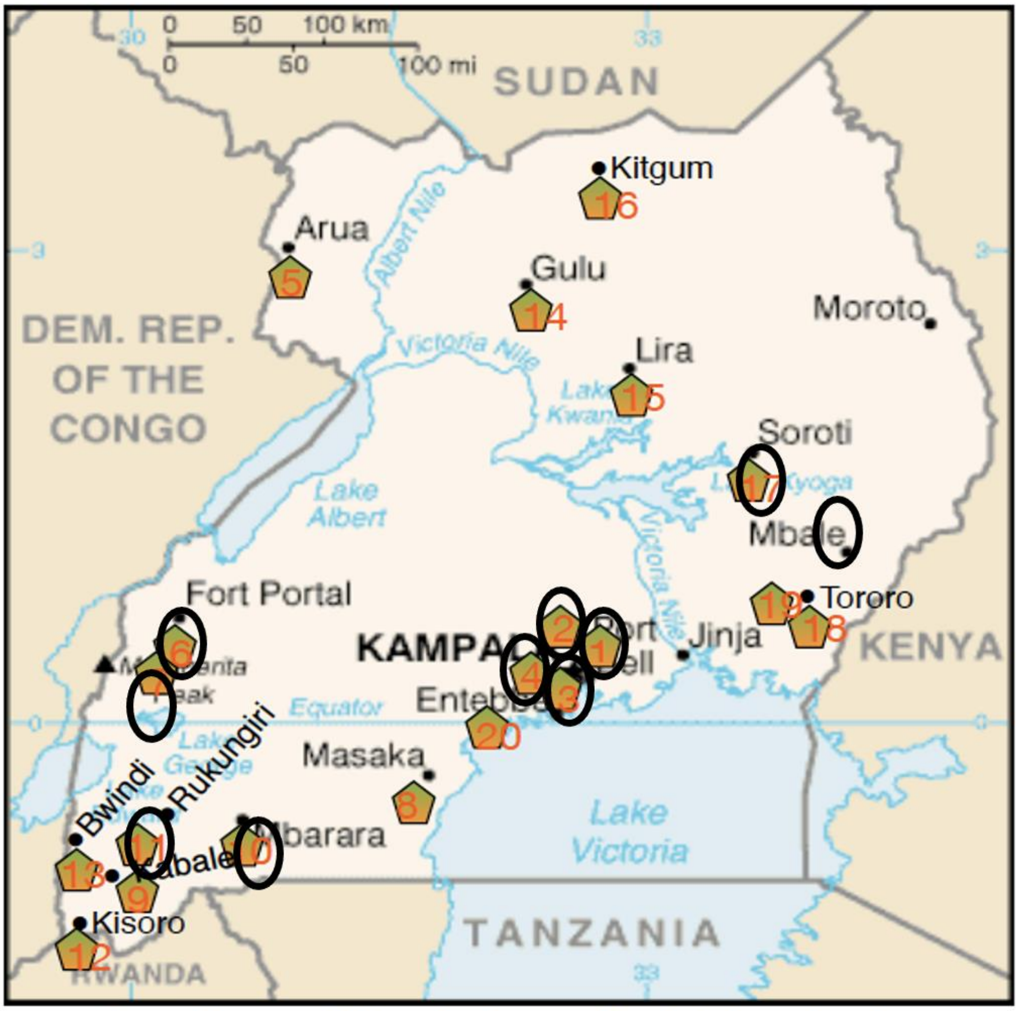
1. *The training was good. We just need more information on diabetes drugs.*
2. *The training has helped me to improve on what I know.*
3. *The training could be compressed into fewer days.*
4. *We truly appreciate how the training has helped us as a family to understand how different foods affect our son's blood sugar and therefore has equipped us better in managing his hyper's and hypo's. In the next session, we would like to understand how to combine physical exercise with different types of foods, snacks and drinks to keep his blood sugar at a range of 7- 10. Thanks a lot.*
5. *The training was very educative and we have learnt a lot and now I know how to help my child in eating habits like having a balanced diet.*
6. *I would like another opportunity for such sessions.*
7. *More time and support.*
8. *Thank you so much for teaching us. May God bless you.*
9. *Thank you for the knowledge.*
10. *First of all, thank you very much for everything and I appreciate you for the training and all the information.*
11. *Thanks for everything I am thankful for the information.*
12. *Thank you for the training.*
13. *I would love an opportunity of such education sessions in the future if it would be possible.*
14. *Personally, I am, so grateful for the training, I have learnt a lot about caregiving in our children with diabetes mellitus, may God bless you so much. My prayer is for everyone who has a child with type 1 diabetes mellitus to get a chance to attend such training. Thank you for providing us with transport. May God give you what you want. Amen.*
15. *The training was good. We just need more information on types of insulin and why some children are put on mixtard while the others use actrapid and insulatard.*
16. *I have leant a lot regarding how to properly feed my child.*
17. *I would like another opportunity for such meetings; you learn a lot and are also able to ask questions.*

The majority of the participants were either very satisfied or satisfied with the various aspects of the training as shown in Figure 4.6. Over 70% of the participants mentioned that they were very satisfied with the overall satisfaction of the training.



Percentage score of participants' experiences of the nutrition education sessions

Appendix O: Map showing T1DM clinics in Uganda and study sites



Type 1 Diabetes Clinics, St. Francis Hospital, Nsambya Arm

1. St. Francis Hospital, Nsambya,Kampala	11. Nyakibale Hospital, Rukungiri
2. Mulago Paediatric Diabetes Clinic, Kampala	12. Kisoro Hospital, Kisoro
3. Rubaga Hospital, Kampala	13. Bwindi Community Hospital, Kanungu
4. Wakiso HC IV, Wakiso	14. Lacor Hospital, Gulu
5. Arua Regional Referral Hospital, Arua	15. Lira Hospital, Lira
6. Virika Hospial, Fort-Portal	16. Kitgum Hospital, Kitgum
7. Kirembe Hospital, Kasese	17. Soroti Hospital, Soroti,
8. Kitovu, Hospital, Masaka	18. Tororo Hospital, Tororo
9. Rugarama Hospital, Kabale	19. St. Anthony Hospital, Tororo
10. Holy Innocents Hospital, Mbarara	20. Entebbe Hospial, Wakiso

Study sites

Source: Diabetes Care Uganda (2017)

Number	District	T1DM clinics (clusters)	Number of patients aged 3-14 years
1	Kampala	Mulago hospital	19
2	Kampala	St Francis Nsambya hospital	31
3	Kampala	Lubaga hospital	05
4	Wakiso	Wakiso health centre IV	03
5	Mbale	Mbale regional referral hospital	10
6	Soroti	Soroti regional referral hospital	09
7	Mbarara	Holy innocents' children's hospital	16
8	Kabarole	Virika hospital	14
9	Kasese	Kagando hospital	10
10	Rukungiri	Nyakibale hospital	03
Total			**120 (Average cluster size was 12)**

Appendix P: Management of hypoglycaemia

Background

Hypoglycaemia is a lower-than-normal level of blood glucose. It can be defined as "mild" if the episode is self-treated and "severe" if assistance by a third party is required. In a person with diabetes all documented blood glucose values below 4.0 mmol/l can be considered to represent hypoglycaemia.

Hypoglycaemia is the commonest side effect of insulin, and sulphonylureas, in the treatment of diabetes. People experiencing hypoglycaemia require quick acting carbohydrate to return their blood glucose levels to the normal range. The quick acting carbohydrate should be followed up by giving long-acting carbohydrate either as a snack or as part of a planned meal. All patients experiencing hypoglycaemia should be treated immediately. Where it is safe to do so a blood glucose measurement should be taken to confirm hypoglycaemia.

Objectives

The aim of this SOP is to describe the symptoms of hypoglycaemia and the action required to correct this condition in order to ensure the safety of patients involved in clinical research studies.

Responsibilities

It is the responsibility of the individual to ensure they are appropriately trained to care for a research patient experiencing hypoglycaemia.

Causes of Hypoglycaemia

- Delaying or skipping a meal or snack.
- Eating too little carbohydrate food at a meal.
- Participating in more exercise than usual – you can have a delayed hypo several hours after exercise.
- Taking too much diabetes medication, especially insulin or sulphonylureas.
- Drinking alcohol.
- Hot weather.
- A change in the insulin injection site e.g., from an area of lipohypertropy to normal skin.
- Stress or illness.

Patients suffering from hypoglycaemia may exhibit or present with any or all of the following symptoms:

- Sweating
- Palpitations
- Shaking
- Hunger
- Paleness
- Confusion
- Drowsiness
- Odd behaviour
- Speech Difficulty
- In coordination
- Headache
- Nausea
- Convulsions

- Coma

Procedure
Provide a Hypo box that should be kept in an easily accessible place in your clinical area and all staff must be aware of its location.
Contents for a Hypo box
- 1x 200 ml carton fruit juice or 120 ml Lucozade original 1x packet of dextrose tablets
- 1x mini pack of biscuits Bottle of Lucozade Glucogel / Hypostop Butterfly
- Cannula Dressing
- IV Glucose 20%
- Blood glucose meter and strips – meter should be calibrated and checked regularly for accuracy. Ketone meter and strips – meter should be calibrated and checked regularly for accuracy.

Hypo Box contents should be checked regularly to ensure it is complete and in date. It is the responsibility of the member of staff who uses any contents to replenish them after use.
Examples of 15-20g quick acting carbohydrates, which should be given, which will raise the blood sugar level quickly:
- 150-200ml pure fruit juice or
- 90-120ml of original Lucozade or
- 5-7 Dextrosol tablets (or 4-5 Glucotabs) or
- 150mls of ordinary coke/lemonade (half a glass)
- Examples of slow acting carbohydrate which should be given to prevent the blood sugar level falling again:
- Two digestive biscuits or
- One slice bread/toast or
- 200-300ml glass of milk or
- Normal meal if due (must contain carbohydrate)

The nurse/ delegated person or patients should not omit their insulin injection if due but a dose review may be required.
Mild hypo- the patient is able to take corrective action
1. Check the patient's blood glucose level.
2. If the blood sugar is below 4mmol/l, administer some quick acting carbohydrate followed by some slow acting carbohydrate.
3. Test the blood sugar again in 5 minutes after administrating the quick acting carbohydrate and if required take more quick acting carbohydrate again
4. The nurse/delegated person should document the event in patient notes and ensure the patient carries out regular capillary blood glucose monitoring.
5. Patients who are conscious but confused, disorientated, unable to cooperate, aggressive but are able to swallow will require assistance to treat their hypo.
6. Check the patient's blood glucose level.
7. If the blood sugar is below 4mmol/l and the patient is able to take action himself or herself provide the patient with some quick acting carbohydrate followed by some slow acting carbohydrate.

8. If the patient is unable to administer the quick acting carbohydrate themselves

but are conscious and able to swallow but or uncooperative/confused then you will need to help the patient.

9. Insert 1.5-2 tubes of GlucoGel/Dextrogel squeezed into the mouth between the teeth and gums, this should only be used on people who are conscious not unconscious.
10. Test the blood sugar again 5 minutes after administering the quick acting carbohydrate and if required take more quick acting carbohydrate again.
11. Once the patient has recovered and is able to swallow, provide them with long-acting carbohydrate.

Patients who are unconscious and /or having seizures and/ or very aggressive will always need help.

The following 3 options of treatment are appropriate

- Ask for medical help.
- Place the patient in the recovery position if appropriate.
- Check the patient's blood glucose level.
- Give GLUCAGEN™ or Glucagon l mg IM. Glucagon may take up to 15 minutes to work. Glucagon requires to be kept in the fridge.
- Glucagon may cause nausea afterwards.
- The effect of glucagon only lasts for a short time.
- Once the patient has recovered and is able to swallow, provide them with some long-acting carbohydrate.

Or

- If IV access is available, give intravenous glucose 20% preferable 75-80ml over 10-15minutes.
- Repeat capillary blood glucose measurement 10 minutes later if still less than 4.0mmol/L repeat.

Or

- If IV access available give 150-160 ml of 10 glucose over 10-15minutes.
- Repeat capillary blood glucose measurement 10 minutes later if still less than 4.0mmol/L repeat.
- Once the patient has recovered and is able to swallow, provide them with some long-acting carbohydrate.
- If the patient has been given glucagon, they will require a larger portion of long-acting carbohydrate to replenish glycogen stores (double the suggested amount above).

Appendix Q: Ethical clearance and research permit

KENYATTA UNIVERSITY
GRADUATE SCHOOL

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P.O. Box 43844, 00100
NAIROBI, KENYA
Tel. 810901 Ext. 57530

Internal Memo

FROM: Dean, Graduate School **DATE:** 6th June, 2018

TO: Mr. Nicholas B. Ndahura
C/o Department of Foods, Nutrition & Dietetics
Kenyatta University
REF: H87EA/33820/15

SUBJECT: APPROVAL OF RESEARCH PROPOSAL

We acknowledge the receipt of your revised Research Proposal entitled **"Effects of Nutrition Education on Management of Hyperglycaemia in Pediatric Type 1 Diabetics at Selected Hospitals in Uganda"** as per recommendations raised by the Graduate School Board of 11th May, 2016

You may now proceed with your Data collection, subject to clearance with the Director, Uganda National Council for Science & Technology.

As you embark on your data collection, please note that you will be required to submit to Graduate School completed supervision Tracking Forms per semester. The form has been developed to replace the progress Report Forms. The Supervision Tracking Forms are available at the University's Website under Graduate School webpage downloads.

By copy of this letter, the Registrar (Academic) is hereby requested to grant you substantive registration for your Ph.D. studies.

Thank you.

REUBEN MURIUKI
FOR: DEAN, GRADUATE SCHOOL

c.c. Registrar (Academic) Att; Mr. Likam
Chairman, Department of Foods, Nutrition & Dietetics

Supervisor

1. Prof. Judith Kimiywe
   C/o Department of Foods, Nutrition & Dietetics
   Kenyatta University

2. Dr. Judith Munga
   C/o Department of Foods, Nutrition & Dietetics
   Kenyatta University

3. Dr. Ezekiel Mupere
   Department of Pediatrics & Child Health
   C/o Department of Foods, Nutrition & Dietetics
   Kenyatta University

Committed to Creativity, Excellence & Self-Reliance

ST. FRANCIS HOSPITAL NSAMBYA
General and Maternity

LOVE AND SERVE
GO HEAL AND TEACH

APPROVAL LETTER:

ST FRANCIS HOSPITAL NSAMBYA REC No: UG-REC-020

Our Ref: SFHN/REC/83

Date: 04th February, 2019

Category of review

Mr.Nicholas Bari Ndahura
Department Of Human Nutrition
And Home Economics
Kyambogo University

[x] Initial review
[ ] Amendment
[ ] Reactivation
[ ] SAEs

Dear Mr. Nicholas

RE: EFFECTIVENESS OF NUTRITION EDUCATION ON GLYCEMIC CONTROL IN PEDIATRIC TYPE 1 DIABETES MELLITUS PATIENTS IN UGANDA

Reference is made to the above named protocol which was submitted to the St. Francis Hospital Nsambya Research and Ethics Committee for initial review and approval.

You have addressed all the issues raised earlier on by the committee and basing on the changes you made and submitted dated 1st **December 2018**

I am glad to inform you that your study has been approved for a period of 1year from **20th February 2019 to 20th February 2020** and the documents approved include the following;

Document	Language	Version	Date
Proposal	English	N/A	N/A
Data collection tools	English	N/A	N/A
Consent forms	English	N/A	N/A

Any problems of serious nature as a result of this study to the participants should be reported to the St. Francis Hospital Nsambya-REC and the Uganda National Council for Science and Technology (UNCST) immediately.

Please note that you are required to submit copies of the stamped documents to the Uganda National Council for Science and Technology (UNCST) before the study can commence. We would like to congratulate you and wish you a successful conduct of the study.

APPROVED
APPROVED DATE 20 FEB 2019
EXPIRY DATE 20 FEB 2020
ST. FRANCIS HOSPITAL NSAMBYA REC
P. O. BOX 7146, KAMPALA (U)

11/2/2019

Prof Ignatius Kakande

REC-Chairperson

Date

ST. FRANCIS HOSPITAL NSAMBYA
General and Maternity

LOVE AND SERVE
GO HEAL AND TEACH

APPROVAL LETTER:

Our Ref: SFHN/REC/83

Date: 27th October 2020

ST FRANCIS HOSPITAL NSAMBYA REC No: UG-REC-020

Category of review

[ ] Initial review
[x] continuing review

Mr.Nicholas Bari Ndahura

Department Of Human Nutrition
And Home Economics
Kyambogo University

Dear Mr. Ndahura

RE: EFFECTIVENESS OF NUTRITION EDUCATION ON GLYCEMIC CONTROL IN PEDIATRIC TYPE 1 DIABETES MELLITUS PATIENTS IN UGANDA.

Reference is made to the above named protocol which was submitted to the St. Francis Hospital Nsambya Research and Ethics Committee for continuing review.

You have addressed all the issues raised earlier on by the committee and submitted dated **19th October 2020.**

I am glad to inform you that your study has been extended for a period of 1year from **1st November 2020 to 1st November 2021.**

Any problems of serious nature as a result of this study to the participants should be reported to the St. Francis Hospital Nsambya-REC and the Uganda National Council for Science and Technology (UNCST) immediately.

Please note that you are required to submit copies of the stamped documents to the Uganda National Council for Science and Technology (UNCST) before the study can commence. We would like to congratulate you and wish you a successful conduct of the study.

Prof Ignatius Kakande

REC-Chairperson

APPROVED
EXPIRY DATE
01 NOV 2020 01 NOV 2021
ST. FRANCIS HOSPITAL NSAMBYA REC
P. O. BOX 7146, KAMPALA (U)

28|10|2020.

Date

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Uganda National Council for Science and Technology

(Established by Act of Parliament of the Republic of Uganda)

UNCST

Our Ref: HS186ES **30th April 2019**

Mr. Nicholas Bari Ndahura
Principal Investigator
Kyambogo University
Kyambogo

Dear Mr. Ndahura,

I am pleased to inform you that on **30/04/2019**, the Uganda National Council for Science and Technology (UNCST) approved your study titled, **Effectiveness of Nutrition Education on Glycaemic Control in Pediatric Type 1 Diabetes Mellitus Patients in Uganda.** The Approval is valid for the period of **30/04/2019** to **30/04/2020.**

Your study reference number is **HS186ES**. Please, cite this number in all your future correspondences with UNCST in respect of the above study.

Please, note that as Principal Investigator, you are responsible for:

1. Keeping all co-investigators informed about the status of the study.
2. Submitting any changes, amendments, and addenda to the study protocol or the consent form, where applicable, to the designated local Research Ethics Committee (REC) or Lead Agency, where applicable, for re-review and approval prior to the activation of the changes.
3. Notifying UNCST about the REC or lead agency approved changes, where applicable, within five working days.
4. For clinical trials, reporting all serious adverse events promptly to the designated local REC for review with copies to the National Drug Authority.
5. Promptly reporting any unanticipated problems involving risks to study subjects/participants to the UNCST.
6. Providing any new information which could change the risk/benefit ratio of the study to the UNCST for review.
7. Submitting annual progress reports electronically to UNCST. Failure to do so may result in termination of the research project.

Please, note that this approval includes all study related tools submitted as part of the application.

Yours sincerely,

Hellen Opolot
For: Executive Secretary
UGANDA NATIONAL COUNCIL FOR SCIENCE AND TECHNOLOGY

LOCATION/CORRESPONDENCE

Plot 6 Kimera Road, Ntinda
P. O. Box 6884
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COMMUNICATION

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THE REPUBLIC OF UGANDA

OFFICE OF THE PRESIDENT

PARLIAMENT BUILDING P.O.BOX 7168 KAMPALA, TELEPHONES: 254881/6, / 343934, 343926, 343943, 233717, 344026, 230048, FAX: 235459/256143
Email: secretary@op.og.ug, Website: www.officeofthepresident.go.ug

ADM 194/212/01

May 29, 2019

The Resident District Commissioner, Kampala District
The Resident District Commissioner, Wakiso District
The Resident District Commissioner, Arua District
The Resident District Commissioner, Mbarara District
The Resident District Commissioner, Gulu District
The Resident District Commissioner, Rukungiri District
The Resident District Commissioner, Tororo District
The Resident District Commissioner, Kabarole District
The Resident District Commissioner, Kasese District

RESEARCH CLEARANCE

This is to introduce to you **Nicholas Bari Nduhura** a Researcher who will be carrying out a research entitled "**EFFECTIVENESS OF NUTRITION EDUCATION ON GLYCAEMIC CONTROL IN PEDIATRIC TYPE 1 DIABETES MELLITUS PATIENTS IN UGANDA"** for a period of **1 year** in your district.

He has undergone the necessary clearance to carry out the said project.

Please render him necessary assistance.

By copy of this letter **Nicholas Bari Nduhura** is requested to report to the Resident District Commissioners of the above districts before proceeding with the Research.

Masagazi Deogratius
FOR: SECRETARY, OFFICE OF THE PRESIDENT

Copy: Nicholas Bari Nduhura

Telephone: General Lines: 256 – 417 – 712260
Permanent Secretary's Office: 256 – 417 – 712221
Toll Free 0800100066

E-mail: ps@health.go.ug
Website: www.health.go.ug

THE REPUBLIC OF UGANDA

Ministry of Health
P. O. Box 7272
Plot 6, Lourdel Road,
Wandegeya
KAMPALA
UGANDA

IN ANY CORRESPONDENCE ON
THIS SUBJECT PLEASE QUOTE NO. ADM. 45/526/06

13th February 2019

The Executive Secretary
Uganda National Council of Science and Technology
KAMPALA

RE: RECOMMENDATION FOR A CLUSTER RANDOMISED CONTROLLED TRIAL EXAMINING THE EFFECT OF NUTRITION EDUCATION ON GLYCAEMIC CONTROL IN PAEDIATRIC TYPE 1 DIABETES MELLITUS PATIENTS IN UGANDA

Protocol Title: Effectiveness of nutrition education on glycaemic control in paediatric type 1 diabetes mellitus patients in Uganda.
Principal Investigator: Mr. Ndahura Nicholas Bari, BSc; (Human Nutrition); Msc; (Public Health.)

Mr. Ndahura Nicholas Bari will be examining the effect of nutrition education on HbA1c levels of children with type 1 diabetes, nutrition knowledge and dietary management practices of their caregivers at the following health facilities under the St. Francis Hospital Nsambya and Ministry of health arms of the CDiC project (Mulago, Arua, Nsambya, Laco, Virika, Nyakibale, Kagando, Holly Innocents and St Anthony hospitals and Wakiso HC IV).

The study involves interviews with children with type 1 diabetes and their caregivers. The findings of this study will be used in improving nutrition education among children with type 1diabetes in Uganda.

A protocol for the study (Ref: SFHN/REC/83) has been approved by the St. Francis Hospital Nsambya Review and Ethics Committee (REC No: UG-REC-020).

The study involves minimal risk to the subjects, and will not affect the rights and welfare of the subjects. Confidentiality will be adhered to,and the study is expected to follow the ethics as outlined by the Uganda National Council of Science and Technology, and by the international community.

Ministry of Health hereby recommends this study and permits the study according to the approved protocol.

Yours sincerely,

Dr. Henry G. Mwebesa
Ag. DIRECTOR GENERAL HEALTH SERVICES

cc Permanent Secretary
cc Ag. Assistant Commissioner NCDs Prevention and Control

11 February 2019

To Whom It May Concern:

RE: EFFECTIVENESS OF NUTRITION EDUCATION ON GLYCAEMIC CONTROL IN PEDIATRIC TYPE 1 DIABETES MELLITUS PATIENTS IN UGANDA

As project manager for the Pan African Clinical Trial Registry (www.pactr.org) database, it is my pleasure to inform you that your application to our registry has been accepted. Your unique identification number for the registry is **PACTR201902548129842**.

Please be advised that you are responsible for updating your trial, or for informing us of changes to your trial.

Additionally, please provide us with copies of your ethical clearance letters as we must have these on file (via email or post or by uploading online) at your earliest convenience if you have not already done so.

Please do not hesitate to contact us at +27 21 938 0835 or email epienaar@mrc.ac.za should you have any questions.

Yours faithfully,

Elizabeth D Pienaar
www.pactr.org Project Manager
+27 021 938 0835

The South African Medical Research Council
Cochrane South Africa I PO Box 19070, Tygerberg, 7505
Tel: +27 (0)21 938 0438 I Email: cochrane@mrc.co.za I Web: www.southafrica.cochrane.org

Appendix R: Budget of the study

Activity	No. of Persons	Working Days	Quantity	Rate (UGX)	Total (UGX)
Travel	1		5	1,206,150	6,030,750
Accommodation and subsistence	1	365		49,315	18,000,000
Printing and photocopying				2,000,000	2,000,000
Pilot study and improvement of research instruments	5	4		200,000	4,000,000
Obtaining research permits				2,372,500	2,372,500
Training of research assistants	5	3		200,000	3,000,000
Venue Hire		2		1,500,000	1,500,000
Projector hire		2	1	100,000	200,000
Purchase of laptop and relevant software			1		5,000,000
Voice recorder			1	250,000	250,000
Baseline data collection	5	10		150,000	7,500,000
Participants manual development	15	4	1	450,000	27,000,000
Instructors' manual development workshop	15	4	1	450,000	27,000,000
Validation, and piloting of developed T1DM education module	15	4	1	450,000	27,000,000
Publication of nutrition management of T1DM education module materials					4,000,000
Intervention phase of the study	5	10		150,000	7,500,000
Data transcription and analysis	3	10		100,000	3,000,000
Stationary					2,000,000
Study participant refreshments and transport reimbursement			500	15,000	7,500,000
Vehicle hire		10	1	200,000	2,000,000
Internet and communication				2,000,000	2,000,000
Data analysis and end of intervention data collection	5	10		200,000	10,000,000
Journal publications			3	2,000,000	6,000,000
Draft report compilation	3	5		200,000	3,000,000
Grand Total				**14,242,965**	**177,853,250**

Appendix S: Pictures of some of the nutrition education sessions and activities