THE EVALUATION OF THREE TREATMENT STRATEGIES IN SUBJECTS WITH TYPE I DIABETES MELLITUS UNDERGOING INTENSIVE DIABETES MANAGEMENT: METABOLIC, PSYCHO-SOCIAL AND EDUCATIONAL IMPLICATIONS

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TABLE OF CONTENTS

Page

PART III. RESEARCH DESIGN

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Preface

The reader of this Masters Thesis should be aware of several aspects that are considered **original** and will be an advancement of knowledge in the area of intensive diabetes management.

The main original aspect of this thesis is the fact that this is the first time that 3 predominant approaches that are utilized in intensive management have been compared with respect to metabolic control and psycho-social adaptation, including stress and perceived complexity. The 3 approaches vary with respect to self-adjustments of insulin to food intake primarily. They have been named Protocol A (exchange system dietary strategy with no adjustments of insulin to food intake and exercise), Protocol B (exchange system dietary strategy with qualitative adjustments of insulin to food intake) and Protocol C (carbohydrate counting dietary strategy with quantitative adjustments of insulin to food intake).

Other original aspects include: the use of the Medical Outcomes Survey (MOS) and the Diabetes Quality of Life Scale (DQOL) together in the context of intensive diabetes management. The use of the Self-Efficacy scale in the context of intensive diabetes management is also original and will be an advancement of knowledge in the implementation, execution, and evaluation of treatment and educational strategies.

The assessment of *accuracy of self-monitoring of blood glucose reporting and accuracy of carbohydrate counting* in the context of intensive diabetes management will provide very useful information to centres initiating intensive diabetes management programs.

Abstract

Three approaches, differing in flexibility of self-adjustments of insulin to food intake & exercise, have been identified in intensive management of Type I diabetes mellitus. They involve the exchange system(Protocols A&B) & carbohydrate counting(Protocol C) dietary strategies. The goal of this cross-over study was to determine differences among the approaches in terms of metabolic control (primarily glycated hemoglobin-GHb) and psycho-social adaptation(quality of life (QofL), self-efficacy(SE), stress & perceived complexity) in 15 adults with insulin- dependent diabetes.

There were no significant differences in terms of metabolic control, self-efficacy and quality of life. Perceived complexity increased ($p < 0.0001$) as subjects progressed from protocols A to C (least to most flexible). However, the subjects continued with Protocol B (n=12) or Protocol C (n=3) at the end of the study. Subjects who were ***very accurate*** in their self-monitoring of blood glucose (SMBG) reporting were also ***accurate*** in counting carbohydrate($p<0.001$), more confident(SE)in their ability to adjust their insulin($p<0.05$)and more satisfied(QofL) with their diabetes($p<0.01$).

This study indicated that patients who are not ready to undertake carbohydrate counting need not be excluded from intensive management programs. Accuracy in SMBG reporting can be used to direct educational efforts.

Résumé

Trois approches variant dans leurs niveaux de flexibilité et d'auto-ajustement sont couramment utilisées dans le traitment intensif du diabète. Les deux premières (A et B) utilisent le système d'échanges pour l'apport alimentaire avec(B) ou sans(A) ajustements pour les écarts alimentaires et l'exercice. Le troisième approche(C) utilise le système de mesurer les hydrates de carbone. Le but de cette étude était de déterminer des différences les trois approches induisent dans le contrôle métabolique (principalement l'hémoglobine glycosylée) et dans les facteurs psychologiques(qualité de vie (QDV), l'auto-efficacité(AE), et la stress)chez 15 adultes atteints de diabète insulino-dependant.

Aucune différence significative n'a pu être demontrée entre les trois approches dans le contrôle métabolique. Le niveau de complexité perçu par les sujets augmenté significativement ($p<0.0001$)en passant de l'approche A à C (du moins flexible à la plus flexible). Toutefois, à la fin de l'étude, les sujets ont choisis de continuer avec l'approche B(n=12) ou C(n=3). Les sujets dont les relevés de glycémie sont ***très exacts*** sont aussi ***exacts*** dans leur calcul de glucides($p<0.001$), plus confiants (AE) dans leur capacité d'ajuster l'insuline($p<0.05$) et plus satisfaits de leur qualité de vie ($p<0.01$).

Cette étude a demontré que les patients qui ne sont pas prêts à utiliser le calcul des hydrates de carbone ne devraient pas être nécessairement écartés des programmes de thérapie intensive du diabète. L'exactitude des relevés de glycémie pourrait être utilisée pour orienter les interventions d'enseignement appliquées à la thérapie intensive du diabète.

List of Tables

List of Abbreviations

ANOVA	Analysis of Variance
ANCOVA	Analysis of Covariance
BMI	Body Mass Index
CHO	Carbohydrate
CI	Confidence Interval
DCCT	Diabetes Control and Complications Trial
DQOL	Diabetes Quality of Life
GHb	Glycated Hemoglobin
HDL	High Density Lipoprotein
HSD	Honestly Significant Difference
IDDM	Insulin-Dependent Diabetes Mellitus
IMSES	Insulin Management Self-Efficacy Scale
LDL	Low Density Lipoprotein
MDC	Metabolic Day Centre
MDI	Multiple Daily Injections of Insulin
MOS	Medical Outcomes Survey
NIDDM	Non-Insulin-Dependent Diabetes Mellitus
NNC	National Nutrition Committee
SD	Standard Deviation
SE	Standard Error
SMBG	Self-Monitoring of Blood Glucose
QofL	Quality of Life

List of Figures

PART I. INTRODUCTION

The Diabetes Control and Complications Trial(DCCT) has shown that improving glycemic control by intensive management can significantly decrease the occurrence of chronic complications(1). Various dietary strategies, including carbohydrate counting and the exchange system were used in the DCCT(2). However, a comparison was not made among the strategies. The studies that have specifically looked at different dietary strategies are few and a comparison between carbohydrate counting and the exchange system has not been made to our knowledge. Furthermore, studies report that diet remains the biggest obstacle in diabetes self-care management(3,4). The answer to this dilemma may lie in the educational process, specifically with respect to psycho-social factors that have to be considered in the implementation, execution and evaluation of educational and treatment strategies. These psycho-social variables that need to be investigated include self-efficacy and quality of life. Glasgow and Osteen(5) report that self-efficacy and quality of life are important and understudied outcome measures that should be looked at in the evaluation of diabetes education and treatment programs.

The **overall goal** of our study was to determine differences among 3 existing treatment approaches used with patients with insulin-dependent diabetes mellitus undergoing intensive insulin therapy or multiple daily injections of insulin (MDI). The 3 approaches differ in their degree of intensity and level of flexibility with respect to insulin self-adjustments: Protocol A= stable meal plan with no adjustments of insulin to food & exercise; Protocol B= qualitative insulin adjustments to food intake & exercise and Protocol C= quantitative adjustments to food intake(carbohydrate counting) and qualitative adjustments to exercise.

Our **specific objectives** were as follows:

1. To determine differences among the 3 approaches in terms of metabolic control (glycated hemoglobin, mean preprandial blood glucose, lipid profile, body weight, frequency of hypoglycemic episodes).

2. To determine differences among the 3 approaches in terms of psycho-social adaptation (self-efficacy, quality of life, stress and perceived complexity).

3. To determine the relationship between metabolic control with psycho-social factors(self-efficacy, quality of life, stress and perceived complexity) and selected demographic characteristics(e.g. duration of diabetes).

Our working **hypothesis** was as follows:

Adjusting insulin dosages according to carbohydrate counting(Protocol C) will lead to better metabolic control and improved psycho-social adaptation,including quality of life, as compared to only adjusting insulin according to blood glucose level(protocol A) or to a qualitative scale for food and exercise(protocol B).

The **implications or significance** of this study is that it will provide us with information that will help guide future care at the Royal Victoria Hospital Metabolic Day Centre (MDC) and possibly other centres world-wide that have initiated or are planning to initiate intensive diabetes management programs. As well, we believe that this study will provide answers that will have educational implications for people undergoing intensive management.

PART II. LITERATURE REVIEW (Background)

1. Insulin-Dependent Diabetes Mellitus

Diabetes mellitus is a systemic disease caused by an absolute or relative insulin deficiency resulting in derangements in carbohydrate, lipid and protein metabolism (6). Diabetes mellitus affects the health of 4% to 6% of Canadians (6). It is projected that by the year 2000, there will be over 100 Million people with diabetes mellitus world wide. There are two main types of diabetes: Insulin-dependent diabetes mellitus (IDDM) and Non-insulin-dependent diabetes mellitus (NIDDM). IDDM affects mainly children and young adults accounting for 10 to 15 % of all cases of diabetes among the white population. It appears to have an auto-immune origin (7). NIDDM accounts for 80% of cases and it usually occurs after the age of 40. It appears to have a genetic, environmental and lifestyle component. It is often associated with obesity, and weight loss can usually reduce the hyperglycemia (7).

The treatment of type I diabetes mellitus involves injections of insulin, diet, exercise, and self-monitoring of blood glucose or SMBG. Appropriate patient education is needed in order to assure successful self-care management.

There are both short-term and long-term complications that are associated with type I diabetes mellitus. The short-term complications include hypoglycemia and hyperglycemia(7). Of the two, hypoglycemia or low blood glucose levels is the most troublesome to both patients and health care providers. The long-term complications of diabetes mellitus include: retinopathy, nephropathy, neuropathy, and cardiovascular disease (7). The principal aim of diabetes management is, therefore, to reduce long-term complications without increasing

short-term complications, specifically hypoglycemia. Several studies (1,8) have shown that long-term complications can be reduced by improved metabolic control. Unfortunately, tighter blood glucose control is associated with a higher incidence of severe hypoglycemia(1).

2. Intensive Diabetes Management

2.1 The Diabetes Control and Complications Trial

The Diabetes Control and Complications Trial or DCCT(1) was a 10 year randomized, controlled trial which began in 1983 for persons with insulin-dependent diabetes mellitus. The goal of this landmark study was to determine the relationship between glycemic control and early vascular complications of diabetes.

The DCCT addressed the following issues: 1) whether an "intensive" insulin treatment program with a goal of achieving normal blood glucose levels would prevent or delay the development of early vascular complications, particularly retinopathy, when compared to conventional therapy. 2) whether such an intervention would prevent the progression of early vascular complications.

Over 1,400 subjects,aged 13 to 39 years, participated in the study. The subjects were divided into 2 groups: 1) the primary prevention group, which had little or no complications, to assess if intensive therapy would prevent development of complications and 2) the secondary intervention group which had minimal development of complications, to assess if intensive therapy would delay progression of complications. No patients with advanced complications were included.

Conventional therapy consisted of 1 or 2 insulin injections per day plus appropriate glucose monitoring, diet and exercise counselling, and clinic visits every 3 months. The goal of conventional therapy was to maintain "clinical well-being" (9). Intensive therapy involved 3 or more injections of insulin per day, frequent diet and exercise counselling, frequent glucose monitoring (at least 4 times per day) and frequent interaction with members of the patient's management team including weekly phone contact and monthly clinic visits. The goal of intensive therapy was normalization of blood glucose (9).

Metabolic control was measured by the use of average preprandial(ac)blood glucose and by hemoglobin A1c (HbA1c). HbA1c reflects glycemic control over a 2 to 3 month period. The target levels that were sought with intensive therapy were : Average ac blood glucose of 6.1 mmol/L and average HbA1c of less than or equal to the upper limit of normal= 6.05%.

The principal outcome measure was retinopathy. Nephropathy, neuropathy, and macrovascular events, as well as psychological factors were also evaluated.

The DCCT did not achieve the metabolic goals it had sought(1) but instead achieved a mean ± SD blood glucose of 8.6 ± 1.7 mmol/L with intensive therapy vs. 12.8 ± 3.1 mmol/L with conventional therapy and a reduction of HbA1c from approximately 9% at baseline to 7% with intensive therapy (1). Although the DCCT did not achieve glycemic normalization, the significant reduction in mean blood glucose and HbA1c had profound effects on the development and progression of the microvascular complications of diabetes. As illustrated in Table 1, retinopathy, nephropathy,and neuropathy were all favourably influenced by intensive therapy.

Table 1: Reduction of Complications (DCCT)

	Risk reduction % (95%CI)
Retinopathy primary prevention	76 (62-85)
Retinopathy secondary prevention	54 (39-66)
Microalbuminuria (≥40mg/24h)	39 (21-52)
Albuminuria (≥300mg/24h)	54 (19-74)
Clinical neuropathy	60 (38-74)

Zinman B: Intensive Diabetes Management, 1996. Unpublished.

The benefits of intensive therapy were so striking that an independent committee officially terminated the study one year earlier than scheduled (9).

As in the words of DCCT chair, Oscar B.Crofford, MD, intensive therapy is "not just more insulin" (9). It also entails frequent self-monitoring of blood glucose, proper diet and exercise, and support of a skilled professional team. This is very important to keep in mind and because of this distinction, many professionals prefer the term "intensive diabetes management" instead of "intensive insulin therapy."

Unfortunately, intensive therapy was also associated with two major undesirable outcomes. These included an increased risk of severe hypoglycemia as previously mentioned and a tendency to gain weight (10). Severe hypoglycemia, defined as *hypoglycemic reactions requiring the assistance of another person,* was increased 3-fold with intensive therapy compared to conventional

therapy. To be more precise, there were 62 severe hypoglycemic episodes per 100 patient-years with intensive therapy compared to only 19 such episodes per 100 patient-years with conventional therapy (1). After 5 years, intensively treated subjects gained a mean of 4.04 Kg for males and 3.25 Kg for females in body weight compared with conventional therapy (10). This finding could not be explained by an increase in caloric intake since there were no differences with respect to caloric intake between the two groups (10). This may suggest other mechanisms for the weight gain seen with intensive therapy including decreased glucosuria (10) and overtreatment of hypoglycemia (11).

However, based on the results of the DCCT, published in 1993, the DCCT study group, the American Diabetes Association, and other organizations concerned with the management of diabetes concluded that intensive therapy, with a goal of achieving glucose levels as close to normal as possible, should be employed in most patients with insulin-dependent diabetes mellitus.

2.2 Dietary Strategies

Successful implementation of intensive therapy requires careful attention to meal planning. Several approaches can be used in prescribing the meal plan including the exchange system and carbohydrate counting. Table 2 Summarizes some common dietary strategies that are utilized in intensive management.

Table 2: Dietary Strategies Used In Intensive Management

System	Advantages	Disadvantages
Healthy Food Choices (similar to Canada's Food Guide)	Simple concepts.	May not be precise enough for fine adjustments to premeal insulin.
Exchange System	Allows for broader nutritional issues.	Complex, extensive teaching required.
Modified Exchanges or "Interchanges"	Simplifies exchanges by considering starch, milk, and fruit as equivalent.	Poor tool for limiting fat and calories.
Total Available Glucose (TAG)	Most precise approach for estimating meal-related insulin demands.	Complex, requires calculations.
Carbohydrate Gram Counting	Simple to teach and learn.	Poor tool for limiting fat and calories.

Adapted from Brackenbridge, B: Diabetes Reviews, 1994 (22).

The two most popular approaches are the Exchange System and Carbohydrate Gram Counting(referred to as Carbohydrate Counting).

a) The Exchange System

Recognizing the difficulty in dietary management and the need to simplify and standardize diets, a joint committee of the American Diabetes Association, the American Dietetic Association, and the Diabetes Section of the U.S. Public Health Service in 1950

developed a system for simplifying meal planning by using food exchange lists. This was considered a great step forward because it meant that a person with diabetes no longer had to weigh out portions of food, and a larger variety of foods could be included in the person's diet. The exchange system remained unchanged until 1977 (27 years later), when it was revised primarily to divide the meat and milk exchange groups into high fat, moderate fat, and low fat groups. It was revised again in 1985(12). The American version of the exchange system(13)is in the form of "exchange lists." These are lists of foods in various food categories. The Canadian version of the exchange system(14)is "The Good Health Eating Guide." The Good Health Eating Guide is an educational tool designed to include 6 food groups (starch, protein, milk, fruits & vegetables, fats and an "extras" group). Under each food category there are lists of foods and portion sizes that constitute an "exchange." Some differences between the two systems exist as follows: the American system further subdivides each food category. For example, the meat group is divided into very lean, lean, medium fat, and high fat lists. The Canadian system has all five groups and the extra group on one sheet and does not subdivide the groups.

The system is designed such that the amount, or portion, of each exchangeable food in a single category contains approximately the same amount of carbohydrate, protein, or fat. For example: a starch exchange will contain 3g of protein, trace fat and approximately 15g carbohydrate.

The weakness of this system lies in the fact that it is very rigid and the calculation of carbohydrate is awkward since it only gives approximations.

In 1992, the Canadian Diabetes Association published a position statement on the role of dietary sugars in diabetes mellitus(15). The position states that in the context of a healthy diet, sugars can be substituted for other carbohydrates without any adverse effects on blood glucose control. This conclusion was reached by examining a number of studies. Bantle et al.,1993(16) were able to show no deleterious effects on blood glucose control when up to 19% of energy was supplied as sucrose, as part of a mixed meal, to type II subjects with diabetes. As well, sucrose as part of a snack was shown not to have any detrimental effects on blood glucose levels compared to carbohydrates of other sources(17) or to snacks sweetened with aspartame(18) in patients with type I diabetes. Based on this information, the National Nutrition Committee (NNC) of the Canadian Diabetes Association released the revised Good Health Eating Guide Kit for people with diabetes (14) on September 16, 1994. The new guide includes a seventh food group: the *sucrose* group and allows for up to 10% of energy as sucrose in a mixed meal.

The exchange system may be too complex for most patients. Some studies have looked at the exchange system versus "simplified or liberalized" diet approaches. Abraira et al.,1980 (19) compared the use of a "liberalized" dietary approach with the single restriction of simple sugars versus a calorically defined approach based on the American Diabetes Association Exchange System on 30 adult outpatients with type I diabetes over a 2 year period. They found no significant differences between the two groups in terms of body weight, caloric intake, food consumption and distribution patterns. Gallagher et al.,1984 (20) found similar results as Abraira in a 4 year study with 51 lean adult male outpatients with type II diabetes mellitus.

b) Carbohydrate Counting

A dietary strategy that appears to be more flexible and less rigid is carbohydrate counting. Carbohydrate counting as a meal planning approach for people with diabetes has been used for many years in Europe and at some centres in the United States. Renewed interest in this approach occurred after DCCT publications featured this approach as one of the 4 dietary strategies used in the DCCT (21).

Carbohydrate counting is thus gaining in popularity especially in the area of intensive diabetes management. It is based on the premise that carbohydrate is the main determinant of meal-related (or Regular) insulin demands. Between 90% and 100% of digestible dietary carbohydrate enters the blood stream as glucose within approximately 1½ hours of ingestion (22). Although, a portion of calories from protein and fat are metabolized to glucose, they yield much less glucose overall than does an equal quantity of carbohydrate. As well, the glucose released by the metabolism of fat and protein does not appear in the blood stream in the immediate post-prandial period. For these reasons, protein and fat normally contribute relatively little to both meal-related insulin demands and the calculation of mealtime boluses (22).

The insulin demand created by a meal or snack can thus be closely approximated by simply counting the grams of carbohydrate it contains.

According to Brackenbridge(22), this approach is more precise, less time consuming, easier to teach, and less limiting than traditional meal plans based on the exchange system.

There are two types of approaches that employ carbohydrate counting. These can be defined as the ***consistent*** approach and the ***variable*** approach. With the *consistent approach*, patients are taught to maintain a consistent intake of carbohydrate per meal, making insulin adjustments for food intake unnecessary. With the *variable approach*, carbohydrate is counted qualitatively with a scale from 1 to 5 where 3 is "usual" or quantitatively (in grams). With the quantitative aspect of the variable approach a **ratio** is determined by the physician whereby Regular insulin (or short-acting insulin) is usually prescribed as **x units per 10 to 15 grams** of carbohydrate per meal. To summarize, the main difference of the *consistent* versus the *variable* approach is that the latter (variable approach) is based on adjusting insulin to lifestyle rather than vise versa as in the case of the "consistent" approach. The consistent approach is the "carbohydrate counting" approach that is described in the "Good Health Eating Guide" of The Canadian Diabetes Association (14).

Carbohydrate Counting was one of 4 dietary strategies used in the DCCT (2), however, the DCCT used the "consistent" approach and a comparison was not made among the strategies utilized.

In 1987, Chantelau et al.(23) looked at a "simplified" approach versus the exchange system in 50 insulin-dependent subjects undergoing intensive insulin therapy. The "simplified" approach involved quantifying carbohydrate only, as 12g portions or "bread-equivalent units." These were balanced quantitatively against insulin dosages taking physical activity and other factors into account. Total energy, protein and fat were not quantitatively prescribed. The two groups were as follows: traditional or exchange-type meal plan with traditional insulin therapy (**group 1**) versus a simplified diet similar to the

carbohydrate consistent approach with intensive insulin therapy (group 2). Subjects acted as their own controls. The study showed no change in eating habits, body weight, body mass index, or serum lipids in the "simplified" group. Furthermore, there was an improvement in metabolic control using the "simplified" strategy. The authors thus concluded that a simplified diet prescription does not hinder diabetes control in the setting of intensified insulin therapy. However, the weakness of this study lies in the fact that the insulin treatment may have been a confounding variable. That is, the authors compared two different insulin treatments with two different dietary strategies. This could have been resolved by keeping the insulin constant or performing an analysis of covariance (ANCOVA) in order to "remove" the influence of insulin.

No other published studies to date have compared carbohydrate counting with the exchange system. As well, no other studies, to our knowledge, have looked at the variable carbohydrate approach versus the exchange system in the context of intensive diabetes management.

As mentioned previously, diet remains an obstacle in the self-management of diabetes. Moreover, people with diabetes have to feel confident or have a high sense of self-efficacy with respect to their ability to follow their meal plan or to co-ordinate their insulin with food intake as in the case of carbohydrate counting. Psycho-social aspects such as self-efficacy and quality of life may provide answers as to why certain self-care behaviours such as diet continue to be barriers to appropriate self-care management.

3. Self-Efficacy

3.1 Self-Efficacy Theory

"Efficacy" is an individual's objective ability to perform a specific behaviour. Efficacy can be measured by observing whether or not an individual actually exhibits the behaviour. "Perceived self-efficacy" is an individual's judgment of his ability to do the behaviour. Thus, efficacy is an objective measure of performance while perceived self-efficacy is a judgment individuals make about their ability to do the behaviour. "Self-efficacy" is usually used to mean "perceived self-efficacy" since an individual's perception is implied in most contexts in which the concept is used (24).

Self-efficacy is an important link between knowing what to do and actually doing it (24). Many instances exist in health education where simply providing health information, and increasing an individual's desire to do a particular behaviour, do not lead to behaviour change. Individuals need to feel they are capable of performing a task before they are likely to attempt it (24).

Self-efficacy theory suggests people's beliefs in their abilities to perform specific behaviours influence: 1) their choice of behaviour and the situation which will be avoided or attempted 2) the effort they will spend in attempting a specific task. More energy is often devoted to a task that will be successful 3) how long a person will persist with a task, even when facing difficulties; and 4) emotional reaction such as anxiety, since negative emotions may be aroused when an individual is confronted with the threat of failure. Knowing what to do and believing one can do it are not the only determinants of behaviour. A person also must know how to do it (skills) and want to do the behaviour (incentives). Thus, health education programs must include knowledge of what to do, skills to do it, and incentives for doing it (24).

There are 4 ways people develop their sense of self-efficacy. These 4 ways are as follows:

Performance Accomplishments

An individual actually performs the task. This provides the best indication of the ability to do a task.

Vicarious Experience

Watching others perform a task without adverse consequences can generate expectations in individuals that they also will be able to perform the activity. However, this is less dependable than direct experience of performing the behaviour.

Verbal Persuasion

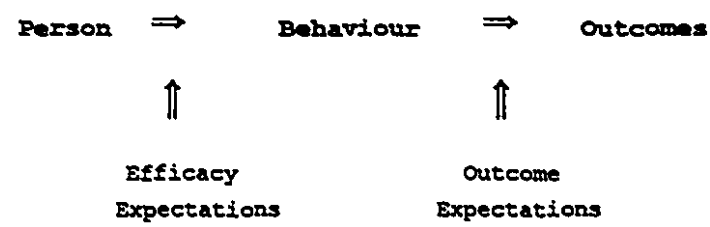
Individuals can be convinced through others telling them they can do it. This is not as strong as the previous ways and it often depends on the credibility of the persuader.

Emotional Arousal

Self-efficacy can be affected by stressful or taxing circumstances that produce emotional arousal. For example, if an individual has a strong fear of failure, he/she may be too anxious to attempt a new behaviour.

The relationship between self-efficacy and behaviour is depicted in Figure 1.

Figure 1
Schematic representation of the theory of self-efficacy and its relationship to behaviour



From Bandura A. Self-efficacy: Toward a unifying theory of behaviour change. Psychol Rev 1977; 84(2):193 in Lawrence and McLeroy (24).

The diagram clearly illustrates the important distinction between ***efficacy expectations or sense of self-efficacy*** and ***outcome expectations***. The expectation that behaviour will or will not be related to the outcome and the value of the outcome to the individual constitute an outcome expectation (25). This may be clarified by the following example:

> Someone believes that eating low fat food products will result in weight loss (behaviour is related to outcome) and it is important to the individual that she loses weight (value). Therefore, the relationship of behaviour to outcome and the value of the outcome constitute this individual's "outcome expectation" which appears to be positive.

When studies have made both self-efficacy and outcome expectations operational, self-efficacy was found to be more important than outcome expectations in predicting behaviour(26,27).

Self-efficacy is also related to a specific behavioural task. According to Bandura(24), no global sense of self-efficacy exists. A global sense of self-efficacy probably involves self-esteem, self-confidence, or some other general factor. Self-efficacy differs from self-esteem since self-esteem focuses on self-worth rather than on performance. Self-efficacy differs from self-confidence since self-confidence incorporates ideas about control over the outcomes of behaviour rather than control over behaviour itself (24). The word "confidence" is often used, for convenience, in contexts that imply self-efficacy. However, the distinction, as described above, should be kept in mind.

Self-efficacy is also *situation specific*. This may be clarified with the following example:

> **One may feel confident (high self-efficacy) that he can follow his diet when he is <u>at home</u> but NOT feel confident(low self-efficacy) in following his diet when he is <u>at a party</u>.**

Another important aspect of self-efficacy for health educators involves its predictive capability. Determining how one perceives the ability to perform a behaviour in a certain situation indicates the likelihood of one actually performing the behaviour, given proper incentives. *"If you think you can, and you want to, you probably will"* (24).

3.2 Applications of Self-Efficacy in Diabetes Mellitus

Two reported studies operationalized the concept of self-efficacy for individuals with diabetes: Crabtree, 1986, as referenced in Hurley (25), found that self-efficacy predicted diabetes behaviours of adults who self-managed their disorder. Grossman, Brink and Hauser, 1987 (28) developed a scale for use with children and found that self-efficacy of adolescent girls was correlated with their metabolic state. Since the publication of these studies, several studies have looked at the link between self-efficacy and diabetes self-care behaviour. In 1989, Kingery and Glasgow (29) evaluated self-efficacy and outcome expectations in the self-regulation of 127 adult outpatients with non-insulin-dependent diabetes mellitus and found that self-efficacy and outcome expectations were strong predictors of self-care in the diabetes exercise regimen but weaker predictors in the dietary and glucose testing areas. In 1990, Hurley (25) developed a self-efficacy scale for adults with insulin-dependent diabetes mellitus that was adapted from Crabtree's scale. She utilized the scale in 1992 (30) with 142 adults with insulin-dependent diabetes mellitus in order to evaluate the ability of self-efficacy to predict self-care behaviour. The results were positive in that self-efficacy did predict behaviour up to one month and this led the authors to conclude that self-efficacy, being so predictive of behaviour, should be used to evaluate intervention strategies. Since this conclusion was published, only one study to date (31) has used self-efficacy as an evaluation tool. This study evaluated the self-efficacy of 19 adults with insulin and non-insulin- dependent diabetes mellitus before and after a diabetes nutrition education class. The results of this study indicated an increase in self-efficacy following the class. As well, subjects who lived with others had

a higher sense of self-efficacy than those who lived alone. Subjects with IDDM for more than 10 years had a higher sense of self-efficacy than those with IDDM for less than 10 years and people with NIDDM for less than 10 years had a higher sense of self-efficacy than those with IDDM for less than 10 years.

4. Quality of Life

It has become increasingly accepted in both medical and psychiatric literature that a more comprehensive evaluation of the quality of life, including the subjective experience of the patient, is necessary to determine the impact of the disease (32).

Quality of life assessments, as suggested by Spitzer in Mayou et al.(33) should include the following 5 health related dimensions: physical functioning, social functioning, emotional/mental state, burden of symptoms, and the perception of well-being.

Mayou et al, 1990 (33) assessed the quality of life of 57 adults with insulin-dependent diabetes mellitus and found that some disruption of work and social life was related to diabetes. However, Tebbi et al.,1990 (34) found that vocational adjustment of young adults with IDDM did not differ from that of healthy controls. Rodin, 1990 (32) found that with increasing complications in 158 adults with IDDM there was an increase in depressive symptoms as was assessed using the Beck Depressive Inventory. As well, he found that the depressive symptoms were more profound in those individuals who felt unsupported.

In 1988, the DCCT study group developed a specific quality of life scale, the Diabetes Quality of Life Scale or DQOL (35) that was used to measure the impact that intensive therapy had on the quality of life of their subjects. With respect to quality of life, they found that there was no difference between the conventionally treated group and the intensive group. Therefore, they concluded that intensive therapy does not affect quality of life any differently than conventional therapy.

It seems evident that quality of life has emerged as an important measure for evaluating the effects of alternative medical treatment strategies. According to Testa and Simonson, 1996 (36) quality of life can be altered by both the immediate effects and the longer-term consequences of treatment, especially in the case of chronic diseases. Glasgow and Osteen,1992 (5) suggest that quality of life is an understudied and very important outcome in the evaluation of diabetes treatment strategies. They recommend using specific and general quality of life scales **together** in order to obtain a better picture of the quality of life. They suggest the Medical Outcomes Survey (MOS) (37) for a general scale and the DQOL for a specific scale. The use of these two scales **together** was validated by Jacobson et al. in 1994(38).

Understanding the psycho-social factors such as self-efficacy and quality of life is very important in the development, execution, and evaluation of treatment and educational strategies.

People living with diabetes have to have a high sense of self-efficacy in order to carry out a number of self-care behaviours effectively so that they will be able to acheive better metabolic control and improved quality of life. However, this is not possible without appropriate patient education.

5. Education in Diabetes

The importance of education was first recognized by Dr. Elliot P. Joslin, a diabetes specialist, who stated within two years of the introduction of insulin, that every insulin treated patient had to be properly educated to carry out his treatment (39).

According to Assal et al.,1985 (39), it appears essentially useless to conduct research projects designed to evaluate new diabetes therapies and insulin treatment strategies on anyone other than well trained patients with diabetes. Several studies (40,41,42)have assessed the impact of diabetes education on metabolic control and some studies have also looked at the impact of diabetes education on psycho-social factors such as self-efficacy (41,42). These studies have generally found positive results. However, according to Glasgow and Osteen,1992 (5), psycho-social factors such as self-efficacy and quality of life have received little research attention in the assessment of diabetes treatment and educational strategies. As well, several authors point out that knowledge is either not or is only weakly associated with other outcomes (43,44,45,46). Glasgow and Osteen,1992 (5) suggest measuring the knowledge of practical, applied skills such as making appropriate food choices or adjusting insulin dosages rather than knowledge of abstract concepts.

Similarly, as indicated in several studies(2,46,47), education and training of the patient are essential for the prevention of acute complications such as severe hypoglycemia and ketoacidosis.

PART II. RESEARCH DESIGN

1. Study Design

The study design is a randomized, counter-balanced, repeated measures, prospective study that lasted for approximately one year. The study involved measuring metabolic and psycho-social factors (dependent variables) via lab tests, glucose meter readings, food records and questionnaires before and after each of 3 protocols or approaches (independent variable). The adherence to the protocols was also evaluated.

2. Study Sample

In order to have an 80% chance of detecting a 1% difference in glycated hemoglobin, we would require a sample of 19 individuals.

Twenty one adult outpatients who were followed at the Metabolic Day Centre (MDC) of the Royal Victoria Hospital and who met inclusion criteria participated in the study. Fifteen subjects completed the entire study.

All subjects completed all 3 protocols consecutively in random order. Each protocol was 3.5 months in duration and consisted of monthly clinic visits to the MDC and weekly contact by telephone. The following describes inclusion and exclusion criteria:

Inclusion:

- Ages 18-65, Males and Females.
- *Multiple Daily Injections (MDI) for at least 2 to 3 months prior to the study.
- Self-monitoring of blood glucose (SMBG) of at least 2 to 3 times per day prior to the study.
- BMI less than or equal to 30.
- Provision of Informed Consent.

Exclusion:

- Pregnancy.
- Advanced Complications.
- Hypoglycemia Unawareness.

*** MDI refers to 3 injections of short-acting or Regular insulin per day (i.e. before each meal) and 1 intermediate or long-acting insulin such as NPH or Ultralente respectively. Usually NPH is given at bedtime or HS and Ultralente at supper.**

3. Methodology

The study was divided into the following periods: baseline (or pre-study), beginning of protocol (first 4 weeks)), Middle of protocol (next 4 weeks), End of protocol (next 6 weeks) and end of study (about 10.5 months from baseline). Figure 2 is a schematic representation of the study design. The visits, highlighted in **bold** numbers represent the following: baseline (visit 1) and the end of each protocol (visits 4, 7, and 10). All subjects were seen individually during their clinical visits. The order of the actual protocols (A, B, or C) vary per subject since the study was randomized. Six possible combinations of the order existed. These were placed in a container and an "order" was randomly chosen for each subject. The order chosen was <u>NOT</u> placed back into the container until all possibilities were

exhausted. The process was then repeated. The **X's** in Figure 2 indicate what was completed at each visit.

Fig. 2: Schematic Representation of the Study Design

	PROTOCOL									
	1				2			3		
Visits:	1	2	3	4	5	6	7	8	9	10
Questionnaires										
Descriptive	X									
Self-efficacy	X			X	X		X	X		X
Quality of Life	X			X	X		X	X		X
Approach	X			X	X		X	X		X
Knowledge	X									X
Food Records										
7 days	X									
4 days		X	X	X	X	X	X	X	X	X
Lab Tests & Physical Examination	X			X			X			X
Teaching	X	X	X	X		X	X	X	X	X	X

The following describes what was completed at each visit:

Baseline: 7 day food records, questionnaires (quality of life, self-efficacy, approach assessment or stress and perceived complexity of each approach, and knowledge of various aspects of diabetes), log sheets, glucose meter readings,*physical examination and lab tests.

Beginning of Protocol: Questionnaires (quality of life, self-efficacy, approach assessment), 4 day food records, log sheets and glucose meter readings, *physical examination and lab tests.

Middle of protocol: 4 day food records, log sheets and glucose meter readings.

End of protocol: Questionnaires (quality of life, self-efficacy, approach assessment), 4 day food records, log sheets and glucose meter readings, *physical examination and lab tests.

After each subject completed all 3 protocols, at the end of study, the following was completed: questionnaires (quality of life, self-efficacy, approach assessment and knowledge), 4 day food records, log sheets and glucose meter readings, *physical examination and lab tests.

In order to facilitate compliance and assure organization, each subject was provided with a binder where they kept their questionnaires, log sheets, food records, their original consent forms, and a "reminders" form (as shown in Appendix A-1) where important information was recorded such as: contact telephone numbers, next appointment dates, and a list of things to bring and to do for their next appointment. As well, the last section of the binder contained educational material on topics such as treatment of hypo and hyper glycemia, exercise, alcohol use, sick day management, and travelling across time zones. This educational material was developed in Nova Scotia (48).

* **The physical examination was performed by the physician.**

4. Description of Outcome Measures

4.1 Metabolic Outcomes

a) Glycated Hemoglobin

Glycated hemoglobin (GHb) is a general term for glucose bound non-enzymatically to hemoglobin with a ketoamine structure (49). The term "glycated hemoglobin" refers to a series of minor hemoglobin components that are linked with various sugars (49). The reaction between glucose and hemoglobin A (HbA) is an example of non-enzymatic glycation, which is slow, continuous, and irreversible(49). Therefore, GHb is useful as a measure of long term blood glucose control, with poorer control being manifested as higher GHb levels. It represents the average blood glucose control over a period of 2 to 3 months. It can be taken any time of the day, without regard to food intake or blood glucose at the time of testing (49). The upper limit of normal at the Royal Victoria Hospital is 8.5%. The target level set out by the Canadian Diabetes Association Advisory Board (6)is less than 110% of the upper limit of normal or in the case of the Royal Victoria Hospital, a GHb of less than 9.4%. The DCCT showed that GHb was highly predictive of risk for development and /or progression of microvascular and neuropathic complications (1).

The laboratory of the Royal Victoria Hospital measured glycated hemoglobin (GHb)or HbA1. This was the method used until January, 1996 when the laboratory began assessing HbA1c. However, in order to be consistent, we had the RVH laboratory perform GHb measurements on our samples even after January, 1996. HbA1c is a specific glycated hemoglobin that is an adduct of glucose attached to the beta-terminal valine residue of HbA. Table 3

describes the various terminology associated with GHb. Therefore, GHb is non-specific attachment of various sugars whereas HbA1c is specific attachment of glucose to the hemoglobin molecule. HbA1c is the form of GHb that has been studied most extensively and was the first species found to be increased in individuals with diabetes (49).

Table 3: Glycated Hemoglobin Terminology

HbA The major form of hemoglobin, a native unmodified tetramer consisting of two alpha and two beta chains.
GHb A general term for glucose bound nonenzymatically to hemoglobin with a ketoamine structure.
HbA1 GHb species that are more negatively charged forms of HbA, detected by cation-exchange chromatographic and electrophoretic methods, which include HbA1a, HbA1b, HbA1c, also called the "fast" hemoglobins.
HbA1c A specific GHb that is an adduct of glucose attached to the valine residue of HbA.
Total GHb A term used to describe all GHb species as measured by affinity chromatographic methods.

Goldstein, D. Clinical Diabetes,1995 (49).

b) Preprandial (ac) Blood Glucose

Preprandial blood glucose was assessed using the Companion 2 glucose meter, provided free of charge to all subjects, by Medisense Inc. Subjects were also provided with test strips, free of charge, for the duration of the study and were asked to monitor their blood glucose at least 4 times per day (before each

meal and at bedtime) and to record their results in the log sheets, as described in section 4.3 C and as shown in Appendix A-2. Subjects tested their blood glucose by placing a small drop of blood on a test strip already inserted into the meter which gave a reading of the sample within 20 seconds. The Companion 2 glucose meter has the capacity to hold the last 125 glucose values by date and time of day. These values were accessed from the memory of the meter by "downloading" the meter onto a computer program, Medisense Precision Link+ 1.0, 1995 supplied by Medisense Inc. The target preprandial blood glucose sought was 4 to 7 mmol/L, as set out by the Canadian Diabetes Association Advisory Board (6).

C) Lipid Profile

Lipid Profile assessments included: Total cholesterol, LDL cholesterol, HDL cholesterol, and Triglycerides. This assessment was performed by the laboratory of the Royal Victoria Hospital. Total cholesterol was assessed via the Beck-Man Method, HDL via a Precipitate Total, Triglycerides via the Lipase-Glycerol Method and LDL was derived using the following formula (7):

LDL= Total Cholesterol-(HDL + TG/2.2)

The target levels that were sought are levels set out by the Canadian Diabetes Association Advisory Board and are as follows:

Total Cholesterol	<5.2 mmol/L
LDL	<3.4 mmol/L
HDL	>1.1 mmol/L
Triglycerides	<1.7 mmol/L

d) Body Weight and BMI

Subjects were weighed at each monthly clinic visit (without shoes) using an electronic scale at the MDC. The weights were recorded in kilograms in the patient's chart. Height was obtained through medical charts and body mass index(BMI)was calculated as weight in Kg divided by height in meters squared or W/H^2.

e) Hypoglycemic Episodes

The frequency of Severe hypoglycemic reactions ,defined as ***hypoglycemic reactions requiring the assistance of another person*** were determined and reported in the results section. As well, non-severe hypoglycemic reactions were also determined by examining meter memories. There is no agreed upon blood glucose value for defining hypoglycemia (7). We chose a blood glucose value of less than 4 mmol/L as indicative of hypoglycemia. The results obtained are reported as mean and total hypoglycemic episodes per Protocol and Time in the results section.

4.2 Psycho-Social Outcomes

Psycho-social factors (self-efficacy, quality of life and stress) were assessed using the questionnaires (Appendix B-1,B-2,B-3) described below. Questionnaires were completed before (blue color coded) and after (pink color coded) each protocol. They were available in both French and English. The questionnaires were coded as described below. The coding was only for the purpose of analysis and did not appear on the questionnaires given to subjects. Questionnaire reliability was determined by conducting Cronbach's coefficient alpha analysis. This is used to estimate internal-consistency reliability. Internal-consistency

reliability assures that each item of a subscale measures what it is intended to reflect or belong to.

a) Self-Efficacy

i.The Insulin Management Self-Efficacy Scale

The same self-efficacy questionnaire, as shown in Appendix B-1, was given to the subjects before and after each protocol. It was adapted from Hurley's Insulin Management Self-Efficacy Scale or IMSES (25). In all, we adapted two questions (numbers 23,29) and added 5 new questions (numbers 24,25,32,33,35). We believe that one item in Hurley's scale (number 18) or number 21 in our scale was originally misclassified as belonging to the "diet" subscale. We felt that it was more consistent with the "insulin" subscale.

The questionnaire consists of 54 questions that are grouped according to the following subscales and total scale:

Subscales	Our Scale	Hurley's
General Scale	6 items	6 items
Diet Scale	10 items	7 items
Insulin Scale	13 items	11 items
Total Scale	**33 items**	**28 items**

The first 21 questions of the questionnaire (1a to 7c) are classified as "outcome expectations." These were questions we developed for the purpose of the study. The distinction between self-efficacy and outcome expectations has already been described in the literature review section regarding self-efficacy theory.

Subjects were asked to respond to each question on a likert-rating scale ranging from 1 to 6 with 1 being "strongly agree" and 6 being "strongly disagree." The questions with an **asterix**(Appendix B-1) were reverse-scored in order to be consistent with the original scale, where a ***higher score indicates a higher sense of self-efficacy***. The questions that are **circled**(Appendix B-1)are questions we added and the subscale is indicated for each question: **G** for general, **D** for diet, **I** for insulin and **other** if the question is not part of any subscale but part of the total score.

a) Questionnaire Reliability

The baseline self-efficacy questionnaires of 19 subjects were used to determine internal-consistency reliability. Internal-consistency reliability is considered acceptable when Cronbach's alpha is .5 or above(37). Table 15, in the results section shows Cronbach's alpha of our scale in comparison to the Insulin Management Self-Efficacy Scale or Hurley's Scale.

b) Quality of Life

As recommended by Glasgow et al.,1992 (5), we decided to use a general quality of life questionnaire: The Medical Outcomes Survey or MOS Short-Form General Health Survey (37) and a specific quality of life questionnaire: The Diabetes Quality of Life or DQOL measure from the Diabetes Control and Complications Trial (35).

i.The Medical Outcomes Survey (MOS)

The MOS consists of 22 items or questions that are grouped according to the following subscales:

Health Perceptions	5 items
Physical Functioning	6 items
Role Functioning	2 items
Mental Health	5 items
Pain	1 item
Social Functioning	1 item

The description of each subscale is outlined in Table 4 and the actual questionnaire that was utilized is shown in Appendix B-2. Questions indicated by an **asterix** were reverse-scored in order to be consistent with the original scale where a ***higher score (expressed as a percentage) indicates a better quality of life.*** The subscale that each question belongs to is indicated. Please note that the asterixes and indications of subscales did not appear on the questionnaires given to the subjects. This questionnaire was attached to the DQOL.

Table 4: Definition of Health Concepts of the Medical Outcomes Survey

Measure	Definition
Physical Functioning	Extent to which health interferes with a variety of activities (e.g. sports, carrying groceries, climbing stairs, and walking).
Role Functioning	Extent to which health interferes with usual daily activities such as work, housework, or school.
Social Functioning	Extent to which health interferes with normal social activities such as visiting with friends during the past month.
Mental Health	General mood or affect, including depression, anxiety, and psychological well-being during past month.
Health Perceptions	Overall ratings of current health in general.
Pain	Extent of bodily pain in past 4 weeks.

Stewart et al. Medical Care, 1988 (37).

a) Questionnaire Reliability

The baseline quality of life (MOS) questionnaires of 19 subjects were used in the analysis of internal-consistency reliability, as measured by Cronbach's alpha as previously described.

Table 18, in the results section, shows Cronbach's alpha of our sample compared with the MOS.

ii. The Diabetes Quality of Life (DQOL) Scale

The Diabetes Quality of Life Scale or DQOL was originally designed for use with both adolescents and adults in the DCCT. The items do not identify specific types of treatment so that it is applicable to patients using different methods of diabetes management(35). It consists of 46 items or questions that are grouped into four primary subscales and a total scale as follows:

Satisfaction	15 items
Impact	20 items
Worry: Diabetes Related	4 items
Worry: Social/Vocational	7 items
DQOL Total	**46 items**

Appendix B-2 outlines the questionnaire. Items with an **asterix** were reverse-scored in order to be consistent with the original scale where a ***lower score indicates a higher quality of life***. The DQOL can be considered as a battery of related subscales. Each subscale assesses quality of life from a different vantage point. Patient satisfaction with him or her self is assessed with the "Satisfaction" subscale, impact generated by diabetes is assessed by the "Impact " subscale, and worry about anticipated effects of diabetes is assessed with the "Worry" subscales. Responses to questions are made with a 5-point Likert scale. Satisfaction is rated from 1 (very satisfied) to 5 (very dissatisfied). Impact and worry scales are rated from 1 (no impact and never worried) to 5 (always impacted and always worried). Unlike other quality of life measures, the DQOL includes worry scales because concerns or worries have been described as an important way that diabetes can influence the patient and the family (35).

a) Questionnaire Reliability

The baseline quality of life (DQOL) questionnaires of 19 subjects were used in the analysis of internal-consistency reliability, as measured by Cronbach's alpha as previously described.

Table 19, in the results section depicts the Cronbach's alpha of our sample and that of the DCCT which used the Diabetes Quality of Life Scale(DQOL).

c) Stress and Perceived Complexity

i. The Approach Assessment Questionnaire

This was a questionnaire we developed in order to assess the impact of each treatment approach or protocol. We wanted to be able to assess the level of stress and perceived complexity of each approach.

The questionnaire consists of 12 items or questions that are grouped into the following subscales and total scale:

Stress	10 Items
Perceived Complexity	2 Items
Total Scale	**12 Items**

The questionnaire is outlined in Appendix B-3.

The questions are rated by a Likert scale from 1 to 5, where 1 indicates (**no stress** or **not complex**) and 5 indicates (**very stressed** or **very complex**).

a) Questionnaire Reliability

The baseline approach assessment questionnaires of 19 subjects were used in the analysis of internal-consistency reliability, as measured by Cronbach's alpha as previously described.

Table 24, in the results section shows the Cronbach's alpha for this measure based upon our study sample.

4.3 Other Assessment Tools

a) Knowledge Questionnaire

The knowledge questionnaire that we used was adapted from The Diabetes Information Test, the knowledge test developed for use in the DCCT (50). Appendix B-4 outlines this questionnaire.

It consists of 44 items or questions that are grouped into the following subscales and total scale :

General	6 items
Exercise	2 items
Insulin	12 items
Illness	2 items
Diet	11 items
Alcohol	1 item
Hypoglycemia	6 items
Hyperglycemia	2 items
Complications	2 items
Total Scale	**44 items**

Each subject received a knowledge questionnaire at baseline (pre-study) and at the termination of the study (approximately 10.5 months later). The subjects received a score as a percentage. ***A higher score indicates higher knowledge levels.***

b) Descriptive Questionnaire

An information gathering form was used by the investigator to help gather pertinent data from each subject's medical chart including levels of complications. The levels of complications were determined by a form (Appendix A-9) that contained codes for each level of each complication. The Descriptive Questionnaire (as shown in Appendix B-6),composed of 10 items or questions, was given to each subject at baseline to complete. This questionnaire was used to assess previous contact with a dietitian, social support, technical skills and educational level.

c) Log Sheets

The majority of the work for the subjects involved keeping daily detailed log sheets throughout the study. An example of the log sheets used with a description of each component is shown in Appendix A-2. Subjects had to record the results of their self-monitoring of blood glucose (SMBG) before each meal and at bed time, their insulin dosage and type of insulin given, their food intake, activity level, and stress level. Food intake was estimated by each subject by either using a "qualitative" scale from 1 to 5 (where 3 is the individual's "usual" intake) or in terms of **grams** of carbohydrate (for protocol 3 only). Activity and stress levels were also estimated using the scale from 1 to 5. The scale is very subjective since **"usual"** depends on the

individual. For example, a "usual" activity level or a score of 3 for one person may be considered extreme or a score of 5 for another individual. These sheets were examined by the investigators, primarily the physicians, since clinical decisions for insulin dose adjustments, were based on these sheets. As well, log sheets were compared to food records and to the Insulin Adjustment Guides(Appendix A-6) of each protocol in order to assess adherence to each protocol. This process for assuring adherence will be described in more detail later.

d) Food Records

Subjects were asked to keep a 7 day food record at baseline (pre-study) and 4 day food records each month. A sample of the form provided is shown in Appendix A-3. Subjects were asked to record everything they ate and drank, the type of meal, and the time of day. The food records were analyzed using the CBORD Nutrient Analysis Program for energy and carbohydrate content. The results of the analysis were recorded on a special form developed to help gather this information (see Appendix A-4). The primary purpose of the food records was to help in the assessment of adherence to each protocol (specifically Protocol C) and to assess the impact of each protocol on food intake, particularly energy and carbohydrate intake. The results of this assessment are described later.

5. Description of the 3 Approaches or Protocols

After visiting several centres in the Montreal area, namely: Hôtel-Dieu Hospital, Nôtre-Dame Hospital, St.Luc Hospital, Cité de la Santé de Laval and The Montreal General Hospital, the approach that was most commonly used with patients on intensive

insulin therapy was similar to our Protocol C which utilizes the carbohydrate counting dietary strategy based on the *variable approach*. Several centres in Ontario (e.g. Mount Sinai, TRIDEC) also utilise an approach similar to Protocol C. However, the predominant approach used at The Royal Victoria Hospital and some centres in Ontario (e.g. Kingston General Hospital, Hôtel-Dieu Hospital) is similar to Protocol A based on the exchange system dietary strategy. An approach similar to Protocol B is used with some patients at the Royal Victoria Hospital. Therefore, 3 approaches were determined as being predominately utilized with subjects with type I diabetes on intensive insulin therapy or multiple daily injections of insulin (MDI). These approaches were refined and are described below. The 3 treatment approaches that were evaluated in this study were named: Protocol A, Protocol B, and Protocol C. Subjects were provided with a description of each protocol (Appendix A-5), Insulin Adjustment Guides (Appendix A-6), and Basal Insulin Adjustment Guides (Appendix A-7). All the material was available in both French and English.

5.1 Protocol A

Protocol A is considered to be the least flexible of the 3 protocols in terms of self-adjustments of insulin and most rigid in terms of dietary adherence. It consists of a fixed diet based on the exchange system, as previously described and fixed insulin dosages. The diet was developed by the dietitian in accordance with the subjects usual intake as evaluated from the 7 day or baseline food record. The insulin dosages were set by the physician in accordance with lifestyle and metabolic goals. Subjects were advised not to adjust their insulin dosages based on diet or activity but were able to adjust according to their

preprandial blood glucose levels using a sliding scale (Appendix A-6). In order to compensate for changes in activity, subjects were able to adjust their diet. Subjects were also able to adjust their "basal" (longer-acting insulin) and their "usual" dose of Regular insulin, that was set by the physician, based on a 1 week review of their glycemic control as outlined in the *Basal Dose Adjustment Guides* (Appendix A-7).

5.2 Protocol B

Protocol B is considered flexible. It is similar to Protocol A in that it is based on a fixed diet and fixed insulin dosages for most days, but with a greater flexibility in diet compared to Protocol A. Besides adjusting for glycemic control, subjects were also encouraged to adjust their insulin in accordance to dietary intake (as assessed on a scale of 1 to 5- as previously described) and activity level (as assessed on a scale of 1 to 5- as previously described). Subjects were also able to adjust their "basal" or longer-acting insulin dose and their "usual" dose of Regular insulin as described previously.

5.3 Protocol C

Protocol C is considered to be the most flexible approach. It is the approach most centres are beginning to use in their intensive management programs. It is NOT based on a fixed diet or on fixed insulin dosages. The dietary strategy that is used with this approach is "Carbohydrate Counting" based on the "quantitative variable system" where Regular insulin is expressed as **x units per 10 grams of carbohydrate.** This has been described earlier and should be distinguished from Carbohydrate Counting based on the "consistent approach." With the quantitative variable

approach, the physician prescribes a ratio of Regular insulin per 10 grams of carbohydrate for each meal based on each patient's individual needs. For example, one patient may have a ratio of 1 unit/10g carbohydrate for breakfast while another patient might have 2 units/10g of carbohydrate for breakfast. The ratios may also differ among meals. With this approach, subjects are also encouraged to adjust their insulin based on glycemic control and activity level.

In order to facilitate carbohydrate counting, we developed a booklet (Appendix A-8) that was adapted from "Les Glucides", developed by Hélène Langelier, a Dietitian at Hôtel-Dieu Hospital. This booklet is now available for use by other centres. To date, over 20 centres across Canada have received this booklet. As well, the average carbohydrate content of foods was given using a booklet entitled "Eat well, Live well" that was developed by Francine Emmian,P.Dt., a Dietitian at the Royal Victoria Hospital. This booklet is based on the exchange system of the Good Health Eating Guide.

6. Assessments of Adherence

In order to assess adherence to the study and to the protocols (particularly Protocol C), we performed two analyses:
1) assessment of accuracy of self-monitoring of blood glucose reporting and 2) assessment of accuracy of carbohydrate counting.

6.1 Accuracy of Self-Monitoring of Blood Glucose Reporting

This assessment was performed on 19 subjects within the first 3.5 months of the study. The objective was: to determine the frequency of monitoring & accuracy of self-reporting blood glucose results. As well, we wanted to determine if there were any predictors of accuracy: previous metabolic control (GHb),

self-efficacy, quality of life or stress. The methodology involved comparing the glucose values that were written in the log sheets with those obtained by "downloading" the memory of the meters. Accuracy was defined as ***a discrepancy less than or equal to 15%*** between log sheet values and meter values. The results are described in the results section. Two abstracts (Appendix C-1) of this analysis were written and accepted. The English version was accepted for publication in the May, 1996 Supplement Issue of *Diabetes*, a publication of the American Diabetes Association and the French version was accepted for an oral presentation at L'ACFAS, 1996.

6.2 Accuracy of Carbohydrate Counting

This assessment was performed on 10 subjects who had completed Protocol C. The objective of this analysis was: to determine the accuracy of counting carbohydrate and to determine if there were any predictors of accuracy such as: previous metabolic control (GHb), self-efficacy, quality of life, stress, accuracy of SMBG reporting.

The methodology of this analysis involved comparing the grams of carbohydrate for each meal and snack written in the log sheets with those analyzed from the food records using the CBORD Nutritional Analysis Program. Accuracy was defined as a ***discrepancy of less than or equal to 10 grams of carbohydrate per meal*** between log sheet values and food record values.

An abstract written from this analysis (Appendix C-2) was accepted as a poster presentation by The Canadian Diabetes Association, Diabetes Educators' Section for September 25-28, 1996, Regina, Saskatchewan.

7. Statistical Analyses

Statistical analyses were performed using the Statistical Program for Social Sciences (SPSS) for Windows, SPSS Inc. Chicago, 1994.

Reliability (internal consistency) of questionnaire subscales and total scores were assessed using Cronbach's coefficient alpha.

One-Way Analysis of Variance (ANOVA) was used to assess differences by ***Protocol*** (for protocol effect) and by ***Time*** (for study effect) for the metabolic and psycho-social outcome measures. Where differences were found, post-hoc analysis using Tukey's HSD was performed to determine where the differences were.

Relationships among psycho-social and metabolic variables were assessed using Pearson product moment correlational analysis.

Accuracy of carbohydrate counting was determined using Pearson product moment correlational analysis. As well, One-Way Analysis of Variance was used to assess differences among "groupings" of subjects. These "groupings" were determined from the results obtained. For example, subjects were grouped as either ***Accurate*** or ***Inaccurate***. Descriptive statistics (frequencies) were used to assess the percentage of accurate values with respect to SMBG reporting. One-Way Analysis of Variance was also used to assess differences among "groupings" of subjects. Subjects were grouped as: ***Very Accurate, Fairly Accurate,*** *and* ***Inaccurate***.

All analyses assumed a significance level of alpha= 0.05. Trends were reported if $p<0.50$.

PART III. RESULTS

1. Characteristics of the Study Sample

Originally, we had 21 participants in the study. Six subjects either dropped out or were excluded from the study. Reasons for dropping out or for being excluded from the study are presented in Table 5. A subject with an eating disorder was undergoing psychological treatment. However, she was not able to maintain food records and was anxious about being weighed so she decided to drop out of the study. This occurred within the first couple of months of the study. Another subject dropped out early on because he was unable to keep appointments secondary to a hectic schedule as a pharmaceutical representative. The other subjects left the study or were excluded later on, either in the middle or close to the end of the study. One subject actually completed the entire study. However, she developed hyperthyroidism during the study and was thus excluded from the analyses. The subjects identified with an asterix were discovered to be ***inaccurate*** in their self-reporting of blood glucose results. One of these subjects was confronted and as a result dropped out of the study. The other one dropped out of the study secondary to a busy schedule.

Table 5: Characteristics of Drop-outs or Exclusions

Number		6
Sex (M/F)		2/4
Reasons	n=1:	moved to another city.
	n=1:	had an eating disorder.
	*n=1:	was "too" busy with family matters.
	n=1:	was excluded because she developed hyperthyroidism.
	*n=1:	was excluded because he was not adhering to the study.
	n=1:	dropped-out on the basis that he could not keep appointments.
Education		Majority (n=5) completed University
Duration of diabetes		10 to 30 years
Baseline GHb (%)		10.4 to 13.7

* Later analysis revealed that these subjects were inaccurate in their reporting of SMBG results.

The Characteristics of the final sample of 15 subjects is shown in Table 6. None of the subjects were newly diagnosed since the minimum duration of diabetes was 8 years. As a group, they were knowledgeable about diabetes (mean score= 81%). Prior to the study, the majority of subjects(n=11) were following a treatment approach similar to Protocol A or with even less self-adjustments of insulin than what was indicated by Protocol A. The majority (n=13) had more than one session with a Dietitian prior to entering the study. As well, the majority of subjects (n=13) had seen a Dietitian less than 1 year (n=6) or between 1 to 5 (n=7) years ago.

The subjects were well educated since the majority (n=11) had completed University. The majority (n=12) were also employed. Only 3 subjects lived alone. The rest(n=12) lived with either their parents, spouses or many other people. The majority of subjects (n=10) felt that their loved ones were very supportive with respect to their diabetes. The majority of the subjects(n=13) also felt that their loved ones were either moderately (n=7) or very (n=6)supportive with respect to their meal plan and the majority of subjects (n=13) described their life as being either very hectic(n=8) or slightly hectic(n=5).

Table 6: Characteristics of the Final Sample

Age(Mean ± SE)	38 ± 2.75 (23 to 59) years
Sex (M/F)	6/9
Duration of Diabetes (Mean ± SE)	Mean= 18.1 ± 1.5 (8 to 28) years
Education	Majority (n=11) completed University (3 of whom have obtained Masters degrees)
Marital Status (by end of study)	4= single, 7= married, 4=divorced or separated
Knowledge of Diabetes (Mean ± SD)	Mean baseline score : 81% ± 12.1
Prior Insulin Regimen	n=10: 3 regular and 1 long acting n=4: 2 regular and 2 long acting n=1: 2 regular and 1 long acting
Prior Adjustment Regimen	Majority (n=11)were on protocol A or less
Weight Status	Baseline: Mean=67.7 Kg (48.4 to 91.2)
Mean Height	165.7 cm
BMI	Baseline: Mean= 24.7 (20 to 31.5)
Smoking Status	Majority(n=10) never smoked

2. Metabolic Control

2.1 Glycated Hemoglobin

A positive correlation was obtained with *duration of diabetes* and GHb at the end of each protocol(r=.40,p<0.01). As well, a One-Way Analysis of Variance(ANOVA)indicated a trend(p=0.36) between *duration of diabetes* and baseline metabolic control(GHb) where subjects with a longer duration (>10 years) of diabetes had worse control compared to those with a shorter duration of diabetes (<10 years). No significant associations were observed with psycho-social variables.

There were no statistically significant differences, in mean glycated hemoglobin levels, among the protocols and by time(Table 7). There was a trend (p=0.19) indicating an initial decrease with study initiation that increased with time. However, GHb remained lower compared to baseline (p<0.10).

Table 7 : Mean (%) Glycated Hemoglobin (GHb) by Protocol and Time(months)

Protocol	Mean ± SE	Range	
		Min	Max
A	9.67 ± .31	7.0	11.5
B	9.45 ± .44	7.2	13.4
C	10.21 ± .43	7.5	13.0
Time (months)			
0	10.94 ± .64	7.2	15.0
4	9.63 ± .44	7.2	13.4
7	9.69 ± .42	7.0	13.1
10	10.0 ± .36	7.4	13.0

Data are means ± SE and Range.

Table 8 shows the mean changes in glycated hemoglobin (GHb) for each protocol and for each time interval during the study. The biggest decrease appears to be with Protocol B. However, this was not statistically significant.

Table 8 : Mean changes (%) in Glycated Hemoglobin (GHb) by Protocol and Time (months)

Protocol	Mean ± SE	Range	
		Min	Max
A	- .27 ± .56	-6.5	2.1
B	- .82 ± .63	-6.6	2.9
C	.14 ± .63	-5.7	3.3
Time (months)			
4	-1.3 ± .76	-6.6	2.9
7	.05 ± .47	-3.7	3.3
10	.31 ± .47	-2.8	.8

Data are Means ± SE and Range.

Glycated hemoglobin or HbA1 was grouped according to the following levels of control (6): Optimal= < 110%, Sub-Optimal= 110-140% and Compromised=>140% control. These levels indicate the percentage of the upper limit of normal and are depicted by Time (Fig.3) and by Protocol(Fig.4). With respect to the effect of time, it is clear to see that the majority of subjects (n=12) began the study with either Sub-Optimal (n=6) or Compromised (n=6) control. However, the majority of subjects (n=10) ended the study (at 42 weeks) with Sub-Optimal control and only 1 subject ended with Compromised control. This finding is clinically significant although not statistically significant. As well, Protocol B resulted with the most subjects(n=8) achieving Optimal control. This was also not significant.

Figure 3: Metabolic Control: Study Eff ect

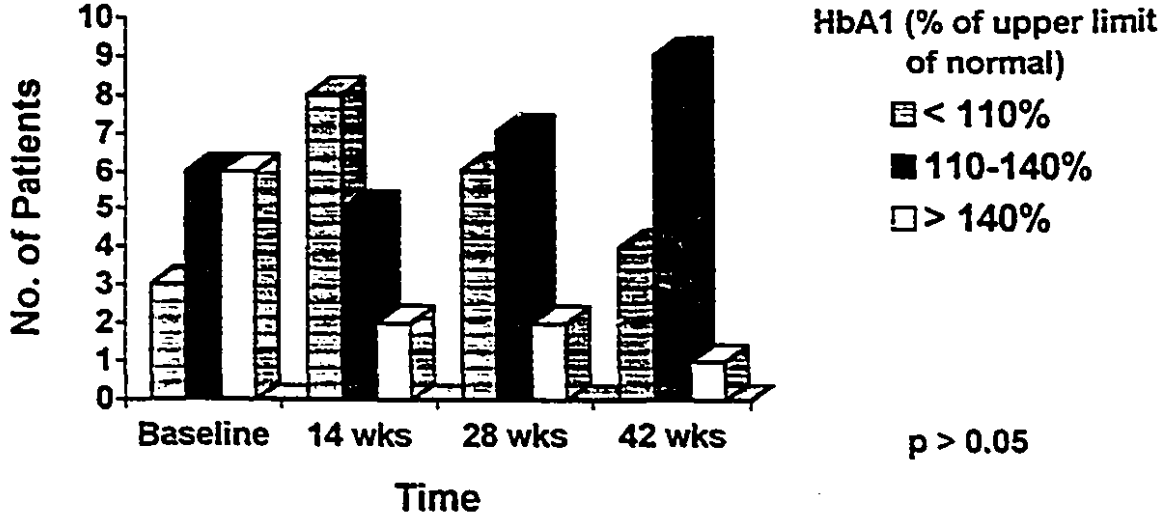
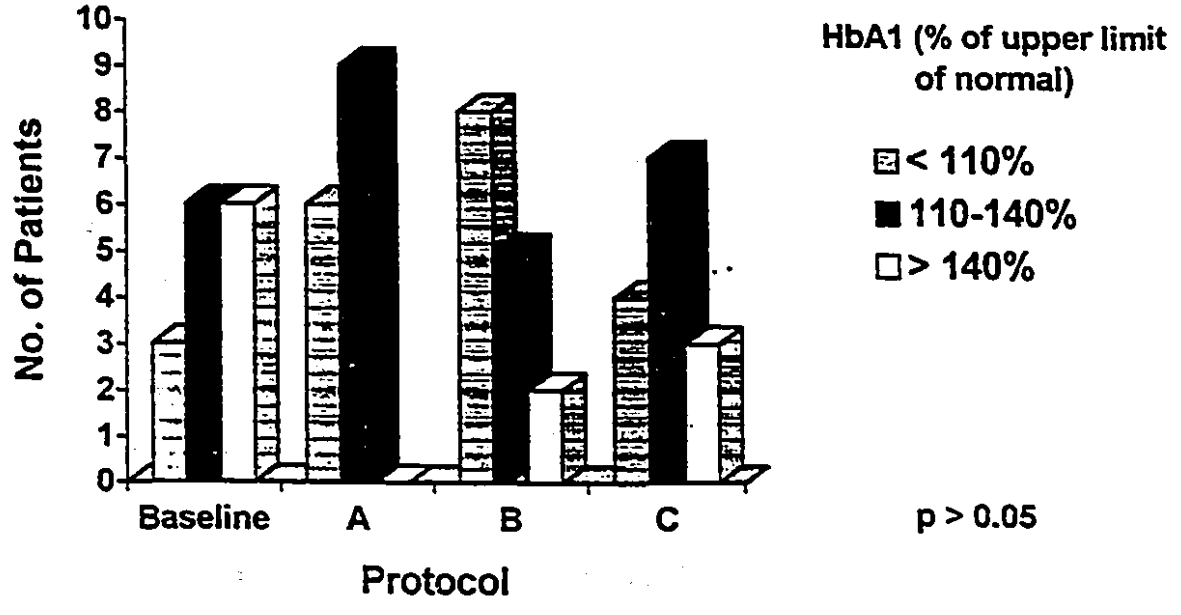


Figure 4: Metabolic Control: Protocol Effect



2.2 Preprandial (ac) Blood Glucose

The mean preprandial blood glucose,as reported on the log sheets (Table 9) and as assessed from the meter memory (Table 10) is depicted by Protocol and Time. A trend($p=0.19$), similar to that observed with the glycated hemoglobin results, was also observed with preprandial blood glucose as determined from the meter memories. The initial improvement with study initiation did not persist and again, there was a rising trend at the end of the study. However, as with glycated hemoglobin, there was an improvement compared to baseline. A significant correlation ($r=0.39$, $p<0.05$) between preprandial blood glucose and glycated hemoglobin was obtained. As well, a significant correlation ($r=0.91$, $p=0.000$) was obtained between log sheet values and meter values. The mean meter value of 9.75 was significantly ($p<0.05$) greater than the mean log sheet value of 9.50 as determined via a two-tailed paired t-test. This difference, however, is not considered to be "clinically significant."

Table 9 : Mean Preprandial Blood Glucose (log sheets) by Protocol and Time(months)

Protocol	Mean ± SE	Range	
		Min	Max
A	9.57 ± .40	7.26	12.7
B	9.18 ± .34	7.67	11.5
C	9.52 ± .59	7.42	13.3
Time (months)			
0	9.25 ± .61	7.35	13.6
4	9.12 ± .46	7.26	13.3
7	9.42 ± .39	7.42	12.1
10	9.74 ± .49	7.83	13.3

Data are Means ± SE and Range. Blood glucose values are reported in mmol/L.

Table 10: Mean Preprandial Blood Glucose(meter) by Protocol and Time(months)

Protocol	Mean ± SE	Range	
		Min	Max
A	9.81 ± .40	7.10	12.1
B	9.48 ± .35	7.90	11.8
C	9.60 ± .54	7.60	13.2
Time(months)			
0	11.3 ± 1.2	9.59	13.6
4	9.23 ± .42	7.10	12.8
7	9.62 ± .39	7.90	11.8
10	10.1 ± 1.7	8.02	13.2

Data are Means ± SE and Range. Blood glucose values are reported in mmol/L.

2.3 Lipid Profile

Table 11 shows the mean lipid profile by Protocol and Time (months). There were no significant differences among the protocols or by time.

Table 11: Mean Total Lipid Profile (mmol/L) by Protocol and Time (months)

	Protocol		
	A	B	C
Cholesterol	4.84 ± .18 (3.93 to 5.91)	4.85 ± .21 (3.27 to 5.82)	4.96 ± .27 (3.68 to 7.1)
LDL	2.92 ± .18 (1.52 to 3.68)	2.96 ± .20 (1.75 to 3.88)	3.08 ± .27 (1.33 to 5.42)
HDL	1.51 ± .11 (.94 to 2.16)	1.40 ± .07 (1.05 to 1.79)	1.48 ± .09 (1.04 to 2.20)
Triglycerides	1.00 ± .14 (.53 to 1.96)	1.07 ± .16 (.19 to 2.52)	.83 ± .13 (.15 to 1.83)

	Time			
	0	4	7	10
Cholesterol	5.06 ±.21 (3.88 to 6.26)	4.85 ±.22 (3.27 to 5.91)	4.91 ± .24 (3.83 to7.12)	4.90 ± .27 (4.00 to 6.22)
LDL	3.20 ± .20 (1.70 to 4.37)	3.00 ± .21 (1.33 to 3.88)	2.98 ± .25 (1.5 to 5.42)	2.97 ± .19 (1.85 to 3.96)
HDL	1.42 ± .11 (.87 to 2.02)	1.51 ± .09 (1.05 to 2.20)	1.43 ± .08 (1.05 to 2.12)	1.44 ±.10 (.94 to 2.16)
Triglycerides	.97 ± .17 (.48 to 2.39)	.78 ±.13 (.15 to 1.78)	1.08 ± .16 (.38 to 2.52)	1.05 ± .13 (.61 to 1.87)

Data are Means ± SE and (Range).

2.4 Weight

Table 12 shows the mean weight (Kg) by Protocol and Time (months). The mean changes in weight (Kg) by Protocol and Time (months) are shown in Table 13. The weights appear to be stable throughout each protocol, including Protocol C, and throughout the study in general (i.e. with time).

Table 12: Mean Weight (Kg) by Protocol and Time (months)

Protocol	Mean ± SE	Range	
		Min	Max
A	68.2 ± 2.77	48.5	88.7
B	68.1 ± 3.04	47.5	87.3
C	67.4 ± 3.20	46.8	86.5
Time (months)			
0	67.7 ± 3.00	48.4	91.2
4	67.5 ± 2.85	48.8	87.3
7	68.3 ± 3.10	46.8	88.7
10	68.0 ± 3.02	48.5	86.5

Data are Means ± SE and Range. The results represent values at the end of a protocol.

Table 13: Mean Changes in Weight (Kg) by Protocol and Time(months)

Protocol	Mean ± SE	Range	
		Min	Max
A	.42 ± .46	-2.5	3.0
B	.24 ± .47	-3.9	3.0
C	-.44 ± .47	-2.2	3.8
Time (months)			
4	-.23 ± .46	-3.9	3.0
7	.82 ± .46	-2.0	3.8
10	-.31 ± .45	-2.5	2.6

Data are Means ± SE and Range.

2.5 Hypoglycemic Episodes

There were 3 episodes of severe hypoglycemia in 15 patients or 20 episodes per 100 patient-years. Table 14 summarizes the mean and total episodes of hypoglycemic reactions per Protocol and Time. There were no statistically significant differences among the protocols or with time.

Table 14: Mean and Total Hypoglycemic Episodes by Protocol and Time (months)

Protocol	Mean ± SD	Total
A	24.6 ± 20	369
B	26.6 ± 19	346
C	28.0 ± 25	365
Time (months)		
4	29.2 ± 22	410
7	27.3 ± 22	382
10	22.2 ± 19	288

Data are Means ± SD. Data are expressed in mmol/L. Hypoglycemia is defined as a blood glucose value of less than 4 mmol/L.

3. Psycho-Social Factors

3.1 Self-Efficacy

Table 15 shows the internal consistency results. The Cronbach's alpha(a) ranged from (.75 to .86)with the total scale achieving (.86). The mean self-efficacy scores before and after each protocol are shown in Table 16. Table 17 depicts the scores by time. There were no significant differences among the protocols. There was a general trend ($p=0.22$) indicating an increase with study initiation that appears to deteriorate by 7 months. However, self-efficacy appears to remain higher compared to baseline. There was a positive correlation ($r=0.31$, $p<0.05$)

between *duration of diabetes*, grouped as: >20 years, 10-20 years, and <10years, and self-efficacy with respect to insulin. This association was confirmed by an ANOVA indicating a trend(p=0.06) that shows subjects who had a longer duration of diabetes had a higher self-efficacy with respect to adjusting insulin than those with a shorter duration of diabetes.

Table 15 : Cronbach's Alpha of the Sample versus the Insulin Management Self-Efficacy Scale

Scale	Sample		Hurley's	
	Items	Cronbach's a	Items	Cronbach's a
General	6	.75	6	.68
Diet	10	.82	7	.78
Insulin	14	.76	11	.68
Total	**33**	**.86**	**28**	**.82**

Table 16: Mean Scores of the Insulin Management Self-Efficacy Before and After Each Protocol

Scale	Protocol					
	A		B		C	
	Before	After	Before	After	Before	After
Diet	4.44 ±.18 (3.2 to 5.1)	4.55 ±.14 (3.3 to 5.3)	4.56 ± .14 (3.3 to 5.1)	4.40 ±+.1 (3.3 to 5.1)	4.49 ±.17 (2.8 to 5.1)	4.36 ±.18 (2.8 to 5.4)
Insulin	4.31 ±.11 (3.2 to 4.8)	4.33 ±.13 (3.1to5.2)	4.31 ±.12 (3.2to4.9)	4.30 ±.11 (3.2 to 4.9)	4.44 ± .08 (3.8to4.8)	4.08+.19 (2.1to4.9)
General	5.36 ±.15 (4.3to6.0)	5.47 ±.13 (4.3to6.0)	5.30 ±.19 (4.2to6.0)	5.31 ±.13 (4.2to 6.0)	5.46 ±.13 (4.3 to 6.0)	5.28 ±.15 (4.2 to6.0)
Total	4.31 ±.10 (3.5to4.9)	4.43 ±.10 (3.5to5.0)	4.38 ± .11 (3.4to5.1)	4.32 ±.08 (3.8to4.8)	4.43 ±.09 (3.8to5.1)	4.45 ±.17 (3.4to6.3)

Table 17: Mean Scores of the Insulin Management Self-Efficacy by Time (months)

Scale	Time (months)			
	0	4	7	10
Diet	4.36±.20 (2.8to5.1)	4.59±.20 (2.8 to 5.4)	4.41±.13 (3.3to5.1)	4.47±.10 (3.6to5.0)
Insulin	4.29±.12 (3.1to4.8)	4.25±.13 (3.3to5.2)	4.26±.15 (3.2to4.8)	4.30±.12 (3.1to4.8)
General	5.27±.17 (4.2to6.0)	5.41±.16 (4.2to6.0)	5.15±.17 (4.3to6.0)	5.28± 15 (4.3to6.0)
Total	4.29±.11 (3.4to4.9)	4.60±.17 (3.4 to6.3)	4.34±.10 (3.5to4.8)	4.31±.09 (3.5to4.7)

Data are Means ± SE and (Range). A higher score= higher self-efficacy , maximum=6.0. The scores represent values at the end of a protocol.

3.2 Quality of Life

Tables 18 and 19 show the internal consistency results of the MOS and DQOL respectively. The Cronbach's alpha (a) of the MOS ranged from (.72 to 1.0) and for the DQOL (.80 to .94) with the DQOL total scale achieving (.94). The mean quality of life scores (as percentages) are shown for each subscale of the Medical Outcomes Survey (MOS) before and after each protocol in Table 20 and by time(months)in Table 21. There were no significant differences noted by protocol or by time. The mean quality of life scores for the Diabetes Quality of Life (DQOL) questionnaire are shown in Table 22 before and after each protocol and in Table 23 by time (months).

Table 18 : Cronbach's Alpha of the Sample versus the Medical Outcomes Survey

Scale	Sample		MOS	
	Items	Cronbach's a	Items	Cronbach's a
Physical Functioning	6	.72	6	.86
Role Functioning	2	1.0	2	.92
Social Functioning	1	---	1	---
Mental Health	5	.81	5	.88
Health Perceptions	5	.64	5	.87
Pain	1	---	1	---

Table 19: Cronbach's Alpha of the Sample versus the Diabetes Quality of Life Scale

Scale	Sample		DQOL	
	Items	Cronbach's a	Items	Cronbach's a
Satisfaction	15	.89	15	.88
Impact	20	.85	20	.77
Worry: Diabetes	4	.80	4	.67
Worry: Social	7	.92	7	.83
DQOL Total	**46**	**.94**	**46**	**.92**

Table 20: Mean Scores(%) of the Medical Outcomes Survey Before and After Each Protocol

Scale	Protocol					
	A		B		C	
	Before	After	Before	After	Before	After
Health	56.7±2.3 (40to70)	54.6±1.6 (44to68)	60.5±2.8 (48to84)	59.9±2.9 (48to93)	58.7±2.0 (44to68)	60.0±2.1 (52to84)
Mental	69.1±1.2 (57to77)	69.1±1.2 (60to77)	68.6± 1.6 (57to77)	70.0± 1.3 (60to77)	70.4±1.3 (60to80)	70.4±1.4 (60to77)
Pain	41.3±5.3 (20to80)	45.3±7.7 (20to100)	41.4±6.4 (20to80)	32.9±5.0 (20to60)	34.2±5.3 (20to80)	33.3±4.2 (20to80)
Physical	97.2±1.4 (83to100)	97.0±1.4 (83to100)	95.2±2.8 (67to100)	96.3±1.9 (67to10)	94.8±2.8 (77to100)	96.0±1.8 (77to100)
Role	94.4± 4.5 (33to100)	100± 0.0	100± 0	98.9±1.1 (83to100)	97.8±2.2 (67to100)	97.8±2.2 (67to100)
Social	98.9+1.1 (83to100)	97.8+1.5 (83to100)	95.2+2.7 (67to100)	96.7+3.3 (50to100)	95.5+3.4 (50to100)	98.9+1.1 (83to100)

Data are Means ± SE and (Range). A higher score indicates a better quality of life, maximum=100%.

Table 21: Mean Scores(%)of the Medical Outcomes Survey by Time(months)

Scale	Time (months)			
	0	4	7	10
Health	56.8± 2.4 (40to72)	59.3± 2.3 (52to84)	56± 2.0 (44to68)	59.2± 2.7 (52to93)
Mental Health	69.7±1.0 (60to77)	69.8±1.4 (60to77)	69.3±1.5 (60to77)	70.4±.97 (63to77)
Pain	40.0±6.2 (20to80)	41.3±6.6 (20to100)	40.0±6.5 (20to100)	30.0+4.1 (20to60)
Physical Function	94.0± 3.0 (67to100)	95.9±1.8 (77to100)	95.9±1.7 (83to100)	97.4±1.6 (77to100)
Role Function	93.3±4.8 (33to100)	97.8± 2.2 (67to100)	98.9± 1.1 (83to100)	100± 0.0
Social Function	91.1± 3.9 (50to100)	97.8± 1.5 (83to100)	96.7± 3.3 (50to100)	98.9± 1.1 (83to100)

Data are Means ± SE and (Range). A higher score indicates a better qualtity of life, maximum=100%. The scores represent values at the end of a protocol.

Table 22: Mean Scores of the Diabetes Quality of Life Scale Before and After Each Protocol

Scale	Protocol					
	A		B		C	
	Before	After	Before	After	Before	After
Impact	1.9±.09 (1.4to2.7)	1.8±.09 (1.3to2.8)	1.9±.14 (1.3to3.0)	1.8± .1 (1.4to2.9)	1.8±.09 (1.4to2.5)	1.8±.09 (1.3to2.5)
Satisfaction	2.2±.13 (1.3to3.3)	2.1±.18 (1.3to3.5)	2.1±.16 (1.3to3.1)	2.0±.13 (1.3to3.0)	2.1±.18 (1.2to4.1)	2.0±.11 (1.4to3.0)
Worry: Diabetes	2.0±.21 (1to4)	1.8±. 21 (1.3to4.3)	2.1±.20 (1.3to3.8)	1.9±.17 (1.3to3.8	1.9±.20 (1to4)	1.8±.12 (1.3to2.8)
Worry: Social	2.5±.44 (1.3to6.7)	2.1±.36 (1.0to5.3)	2.0±.31 (1to5)	2.2±.31 (1.0to5.0)	2.2±.34 (1to5)	1.7±.21 (1.0to4.1)
Total	2.1±.12 (.4to3.5)	2.0±.13 (1.3to3.2)	2.0±.15 (1.3to3.4)	1.9±.13 (1.3to3.3)	1.9±.10 (1.4to2.5)	1.8±.11 (1.3to3.0)

Data are Means ± SE and (Range). A lower score indicates a better quality of life, minimum=1.0.

Table 23: Mean Scores (%)of the Diabetes Quality of Life Scale by Time(months)

Scale	Time (months)			
	0	4	7	10
Impact	1.9±.09 (1.5to2.5)	1.8±.09 (1.3to2.5)	1.8±.10 (1.5to2.9)	1.9±.09 (1.4to2.8)
Satisfaction	2.2±.19 (1.3to4.1)	1.9±.12 (1.3to2.7)	2.2±.13 (1.4to3.0)	2.1±.16 (1.3to3.5)
Worry: Diabetes	1.9±.21 (1.0to4.0)	1.8±.14 (1.3to2.8)	1.9±.18 (1.3to3.8)	1.8±.20 (1.3to4.3)
Worry:Social	2.1±.26 (1.0to5.0)	1.8±.22 (1.0to4.1)	2.4±.38 (1.0to5.3)	1.8±.28 (1.0to4.7)
DQOL Total	2.0±.10 (1.4to2.5)	1.8±.11 (1.3to3.0)	2.0±.12 (1.5to3.3)	1.9±.13 (1.3to3.2)

Data are Means ± SE and (Range). A lower score indicates a better quality of life, minimum=1.0. The scores represent values at the end of a protocol.

3.3 Stress and Perceived Complexity

Table 24 shows the internal consistency results. The Cronbach's alpha (a) achieved ranged from (.80 to.88) with the scale total achieving (.88). Table 25 shows the mean approach scores for each subscale and total scale before and after each protocol. There was a statistically significant ($P<0.0001$) increase in perceived complexity as subjects progressed from Protocols A to C with the difference being between Protocol A and C. However, stress was not statistically significant. The mean approach scores by time are outlined in Table 26. No significant differences were observed with time.

Table 24 : Cronbach's Alpha of the Approach Questionnaire

Scale	Items	Cronbach's a
Complexity	2	.80
Stress	10	.87
Total	12	.88

Table 25: Mean Approach Scores Before and After Each Protocol

Scale	Protocol					
	A		B		C	
	Before	After	Before	After	Before	After
Stress	2.38±.16 (1.3to3.7)	2.06±.12 (1.1to2.8)	2.26±.17 (1.1to3.5)	2.11±.21 (1.3to3.8)	2.38±.19 (1.1to3.5)	2.27±.19 (1.0to3.6)
Complexity	*1.47±.16 (1to3)	**1.27±.11 (1to2)	1.93±.24 (1to4)	**1.23±.10 (1to2)	*2.57±.30 (1to5)	**2.20±.20 (1to3)
Total	2.23±.15 (1.3to3.6)	1.93±.10 (1.1to2.6)	2.21±.15 (1.3to3.4)	1.97±.18 (1.2to3.5)	2.41±.19 (1.3to3.8)	2.25±.18 (1.2to3.4)

Data are Means ± SE and (Range). A lower score is associated with less stress and complexity, minimum=1.0. *P<0.001(differences were between A and C), **P<0.0001(differences were between A and C ; B and C).

Table 26: Mean Approach Scores by Time (months)

Scale	Time (months)			
	0	4	7	10
Stress	2.47±.19 (1.1to3.7)	2.19±.23 (1.1to3.8)	2.22±.13 (1.5to.3.2)	2.03±.15 (1.0to2.8)
Complexity	2.37±.26 (1.0to5.0)	1.63±.16 (1.0to3.0)	1.57±.19 (1.0to3.0)	1.50±.18 (1.0to3.0)
Total	2.45±.18 (1.3to3.8)	2.11±.20 (1.1to3.5)	2.13 ±.14 (1.4to3.2)	1.95±.14 (1.2to2.7)

Data are Means ± SE and (Range). The scores represent values the end of a protocol.

4. Knowledge Questionnaire

Table 27 shows the mean scores for each subscale and total scale before and after the study. There was a statistically significant ($p<0.05$) increase in the ***total score*** following the study. As well, There was an overall increase for all the scales post-study with the exception of alcohol and general scales; however, this was not statistically significant.

Table 27: Mean Knowledge Scores (%) Before and After the Study

Scale	Score (%)	
	Before	After
General	88 ± 14	85 ± 16
Diet	75 ± 18	85 ± 12
Insulin	85 ± 18	93 ± 14
Alcohol	50 ± 52	38 ± 50
Exercise	96 ± 13	100 ± 0
Hyperglycemia	86 ± 23	90 ± 27
Hypoglycemia	81 ± 21	89 ± 13
Illness	71 ± 26	72 ± 36
Complications	93 ± 18	94 ± 17
TOTAL	***81 ± 12**	***88 ± 6**

Data are Means ± SD. *P<0.05. A higher score is an indication of higher knowledge levels, maximum=100%. Scores were obtained at baseline or prior to the study (Before) and at the end of the study at about 10.5 months (After).

5. Food Records

Table 28 outlines the mean energy intakes by Protocol and Time. No statistically significant differences were found for protocol or time. However, there was a trend (p=0.21) indicating a higher energy consumption with Protocols B and C. The mean carbohydrate intakes by Protocol and Time are outlined in Table 29. No statistically significant differences were found for protocol or time. A trend (p=.44) was also observed indicating a higher carbohydrate consumption with protocols B and C. As well, a trend (p=.29) indicating a decrease in carbohydrate intake with time was observed.

Table 28: Mean Energy Intakes by Protocol and Time (months)

Protocol	Mean ± SE	Range	
		Min	Max
A	1449.1 ± 84.1	977	2081
B	1672.8 ± 94.1	1121	2569
C	1609.0 ± 93.9	1142	2212
Time (months)			
0	1721.6 ± 121.0	1167	2924
4	1610.9 ± 71.6	1042	2047
7	1558.3 ± 111.6	977	2569
10	1558.1 ± 95.4	1142	2212

Data are Means ± SE and Range. Data are expressed as Kilocalories.

Table 29: Carbohydrate Intakes by Protocol and Time (months)

Protocol	Mean ± SE	Range	
		Min	Max
A	182 ± 11.6	100	251
B	202 ± 11.7	126	296
C	196 ± 10.0	135	243
Time (months)			
0	218 ± 17.2	135	366
4	204 ± 8.8	127	245
7	186 ± 14.4	100	296
10	189 ± 9.2	135	243

Data are Means ± SE and Range. Data are expressed as grams.

6. Adherence to Regimen

6.1 SMBG Reporting Accuracy Assessment

The mean Frequency of monitoring was 3.5 times/day with a range of 2.4 to 4 times per day. 2081 paired results were obtained. Of these, 71.7% were identical. That is, 71.1% of the values recorded in the log sheets and obtained from the meter were 100% identical. 7.4% of the values were within 15% discrepancy. These values, that were either identical or were within 15% discrepancy, were considered as ***clinically acceptable.***

21% of the values were considered as being ***"clinically different."*** These are values that would have a significant impact on the physician's clinical decisions. These differences included the following: values that were **greater than 15% discrepancy** (8.7%) **omissions** or values that were in the meter but not written in the log sheets (4.6%)and **additions** or values written in the log sheets but were not in the meter (7.5%). From the results obtained, the subjects were then classified as follows: ***Very Accurate*** (n=10). These were subjects who had greater than 90% of their values as "clinically acceptable." ***Fairly Accurate*** (n=5). These were subjects who had 50 to 89% of their values as "clinically acceptable." ***Inaccurate*** (n=4). These were subjects who had less than 50% of their values as "clinically acceptable." There was a statistically significant difference ($p<0.05$) between the *very accurate* and *inaccurate* groups. The *fairly accurate* group had mostly <u>omissions or additions</u> whereas the *inaccurate* group had values that were mostly <u>above 15% discrepancy</u>. Subjects who were *very accurate* were more satisfied with themselves($p<0.05$) and had a better diabetes-specific quality of life ($p<0.01$), as assessed using the Diabetes Quality of Life questionnaire. They were also more confident in their ability to adjust their insulin ($p<0.05$), as assessed using the Self-Efficacy questionnaire compared to those who were *inaccurate*. This is outlined in Tables 30 and 31. No statistically significant differences were observed between metabolic control and accuracy.

Table 30: Mean Diabetes Quality of Life Scores by Levels of Accuracy in SMBG Reporting

Subscales	Groups		
	Very Accurate	Fairly Accurate	Inaccurate
Satisfaction	*1.96 ± .38	2.21 ± .71	*2.93 ± .85
Impact	1.94 ± .37	2.06 ± .45	2.15 ± .34
Worry: Diabetes	1.75 ± .72	1.70 ± .21	2.56 ± 1.1
Worry: Social	1.93 ± .71	1.97 ± .53	3.08 ± 1.8
DQOL Total Score	**1.94 ±.31	**2.06 ± .46	**2.84 ± .65

Data are Means ± SD. *p<0.05(differences were between *Very Accurate* and *Inaccurate* groups) and **p<0.01(differences were between *Very Accurate* and *Inaccurate; Fairly Accurate* and *Inaccurate* groups). A lower score indicates a better quality of life, minimum=1.0.

Table 31: Mean Insulin Management Self-Efficacy Scale Scores by Levels of Accuracy in SMBG Reporting

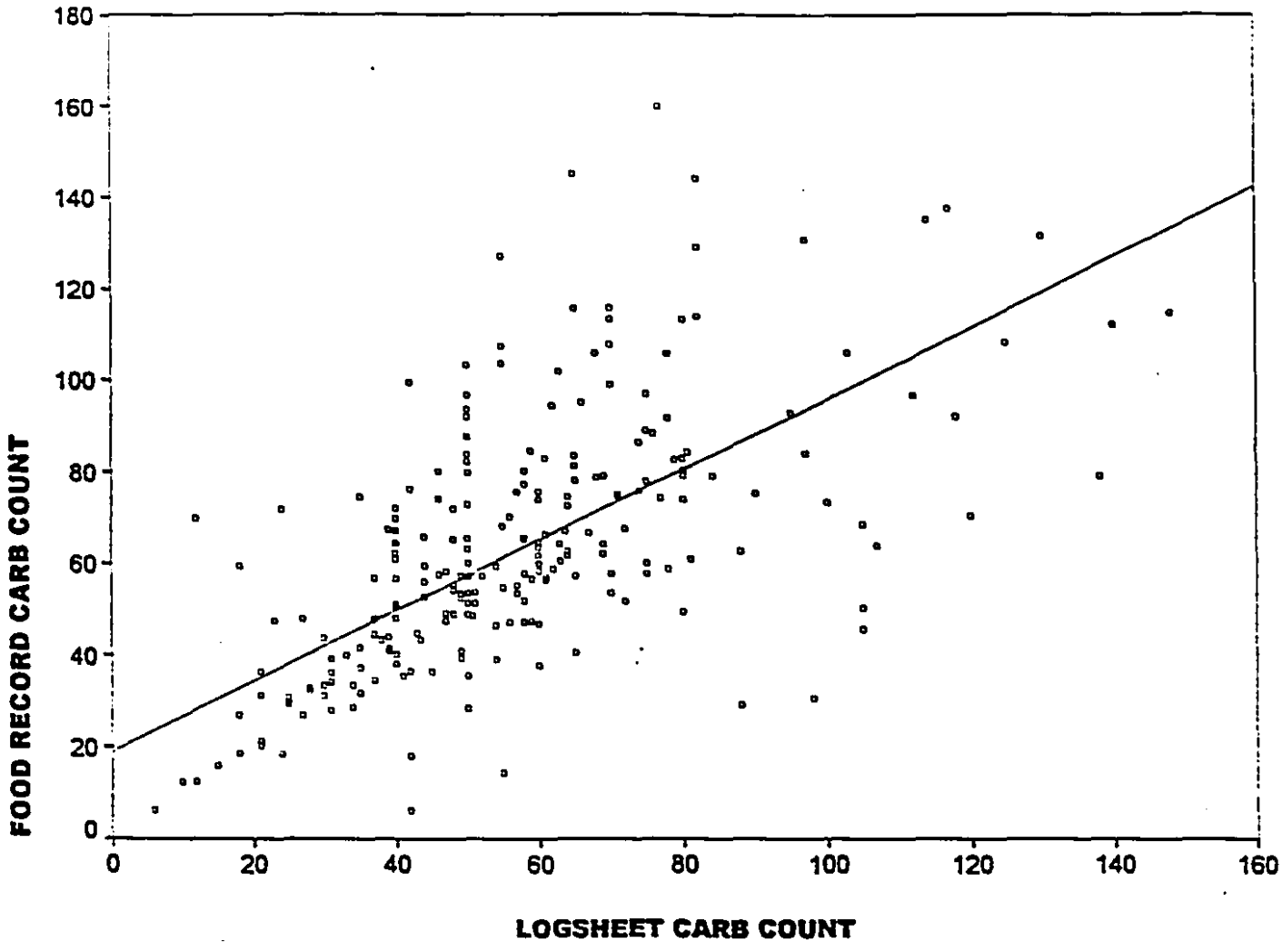
Subscales	Groups		
	Very Accurate	Fairly Accurate	Inaccurate
General	5.25 ±.65	5.41 ±.71	4.25 ± 2.3
Insulin	*5.43 ± .62	5.02 ± .79	*4.54 ± 1.2
Diet	5.13 ± .55	5.04 ±.61	4.23 ± 1.2
Total	4.54 ± .95	4.49 ± .80	3.97 ± 1.6

Data are Means ± SD. *p<0.05. A higher score indicates a higher self-efficacy, maximum=6.0.

6.2 Carbohydrate Counting Accuracy

287 paired values were obtained and a significant correlation (r= 0.68, p<0.0001) was obtained between the log sheet values and the food record values. This is depicted in Fig 5. 51% of the values were within 10 grams carbohydrate and 70% were within 11 to 20 grams carbohydrate. Subjects were grouped as follows: **Accurate** (n=6), where their median value had a discrepancy of less than or equal to 10 grams of carbohydrate or as **Inaccurate** (n=4), where their median value had a discrepancy of greater than 10 grams of carbohydrate. Accuracy in carbohydrate counting was significantly (p=0.01) associated with accuracy in SMBG reporting. There was a trend(p=0.41) indicating better metabolic control at baseline in subjects who were *accurate* (mean GHb=9.06%)compared to those who were *inaccurate*(mean GHb=10.4%).

Figure 5: Carbohydrate Count Accuracy



r = 0.68

PART IV. DISCUSSION

Since the publication of the DCCT results in 1993, intensive management is the treatment approach that is being advocated as the treatment of choice for people with type I diabetes. However, there is no standard educational approach that is being used in intensive management; therefore, the aim of our study was to assess three educational strategies that are utilized in intensive management with a goal of determining which one would produce the most favourable results with respect to metabolic control and quality of life. The three strategies differed with respect to flexibility in adjusting insulin and the way that the insulin was adjusted, primarily, for food intake.

The difference that was observed to be statistically significant among the three approaches was with respect to perceived complexity, indicating that perceived complexity increased as subjects progressed from Protocols A to C. This finding is contrary to other studies that define the exchange system as "complex"(19,20,23) and carbohydrate counting as "simplified"(19,23). These studies, however, did not assess stress levels or perceptions of complexity. The subjects in our study were not adjusting intensively prior to the study. The majority, as forementioned, were using an approach similar to Protocol A but with even less adjustments than what was indicated by Protocol A. Therefore, the introduction of a totally new approach, especially carbohydrate counting (Protocol C) may have caused some "anxiety" which is understandable. However, although subjects found protocols B and C more complex compared to Protocol A, this did not appear to cause them more stress since there were no statistically significant differences observed with stress. Furthermore, the majority of subjects(n=12) decided to

continue with Protocol B and 3 subjects decided to continue with Protocol C at the end of the study. No one went back to Protocol A. This may be an indication that individuals prefer treatment approaches that allow for more flexibility and control. Moreover, despite this perception of Protocol C as complex, they were able to follow Protocol C as indicated by the fact that the majority of the subjects were considered to be ***accurate*** in their ability to calculate carbohydrate.

Subjects that were found to be ***accurate*** in their ability to calculate carbohydrate were also ***very accurate*** with their reporting of SMBG results. As well, there was a trend indicating better baseline metabolic control (GHb) in those subjects who were accurate compared to those who were inaccurate in calculating carbohydrate.

With respect to our assessment of accuracy in SMBG reporting, we were surprised to find that 21% of the values were considered to be clinically significant inaccuracies. Other studies have found worse results than ours when subjects were unaware of the memory capacity of their meter (52,53,54) and better results when subjects were aware of the memory (55). However, no study to date has looked at accuracy in the context of intensive diabetes management. Despite, the level of inaccuracies, we did not find any difference with respect to metabolic control. Other studies(52,55,56)have also made this observation. Subjects who were ***very accurate*** in their SMBG reporting were also more satisfied with themselves and had a better overall diabetes-specific quality of life compared to subjects who were classified as ***inaccurate***. Furthermore, they were more confident in adjusting their insulin compared to those classified as ***inaccurate***.

There were no statistically significant differences among the protocols with respect to metabolic control. However, this may be due to a lack of power secondary to a small sample size. With 15 subjects, a difference in glycated hemoglobin of at least 1.4% had to be attained. In order to observe a difference of 1%, we required 23 subjects. In the DCCT(1), it was noted that for every difference of 1% in glycated hemoglobin, there was a 45% reduction in chronic complications. This finding is contrary to our initial hypothesis where we expected to find improved metabolic control with Protocol C. There was a *clinically significant* difference of 1.3% in glycated hemoglobin with initiation of the study. However, the initial improvement was not maintained, although, the control achieved during the study remained better than what it was at baseline where the majority of the subjects had either sub-optimal or compromised control. At the end of the study only one subject had compromised control. Our results concur with the DCCT (1) whose subjects were highly selected and Haakens et al.,1995(51) whose subjects and study conditions were more similar to ours.

There were no statistically significant differences among the 3 protocols in terms of self-efficacy and quality of life. This finding is contrary to our initial hypothesis where we expected to find an improved quality of life with Protocol C. There was a trend indicating an initial improvement in self-efficacy with study initiation that eroded at approximately 7 months. This may have educational implications. Perhaps educational strategies need to be modified so that methods that increase self-efficacy can be utilized or additional "booster" sessions may be needed every 3 months.

The non-significant findings with respect to the psycho-social variables can not be attributed to the reliability of our instruments. The results of our internal consistency analyses show that our questionnaires were very reliable measures of what they intended to measure. The Cronbach's alpha for the scale total in the self-efficacy questionnaire of (.86) revealed that our reliability estimate surpassed the reliability estimate achieved by Hurley (25). Furthermore, our scores indicate that the scale is a reliable measure for individuals undergoing intensive diabetes management. The Cronbach's alpha for the scale totals of the approach questionnaire (0.88) and the DQOL(0.94)revealed that our scales achieved a reliability estimate considered adequate(25).

Unlike the DCCT (10) and other studies (51), we did not find an increase in weight with intensive management. We were also surprised not to find an increase in weight with Protocol C since this was the most flexible approach with respect to diet. This assumption is supported by the fact that the energy intake for this protocol was not statistically different from the others.

With respect to energy intake, there appears to be a mean decrease in energy consumption during the study compared to baseline. This decrease in energy consumption may be due to better metabolic control resulting in decreased glucosuria, therefore, resulting in lower energy needs. The renal threshold for glucose being greater than 10 mmol/L may help to support this assumption since the mean preprandial blood glucose at baseline(as assessed by the meter memory) is 11.3 mmol/L and is lower throughout the study period (9.23 to 10.1 mmol/L). Although individual food records have not yet been assessed for the possibility of under reporting, overall we feel that we were

able to obtain an accurate reflection of the mean energy intake for the group. Our goal was to obtain 36 days of dietary intake data, as measured using four day food records, per individual.

In order to estimate energy consumption so that the individual and group intake is within 10% of the usual intake, 31 days would be needed for an individual but only 3 days for a group (57). We achieved an average of 28 days per individual (78% of the goal) and a total of 398 days for the group. Furthermore, we feel confident that, as a group, our results regarding energy intake are reliable since our sample of individuals are non-obese adults living in an industrialized country. Schoeller, 1990 (58) states in his review regarding the accuracy of self-reported energy intakes that "although many studies have indicated under reporting of dietary intake, reasonably accurate results have been reported among non-obese adult subjects in industrialized countries." An in depth analysis of the food records will be done in the near future and individual records will be excluded if there appears to be under reporting. This will be verified by comparing the reported energy intake with the individual's Basal Metabolic Rate (BMR) calculation as outlined by Bingham, 1994(59) and Goldberg et al., 1991 (60). The "cut-off" value that will be required for 15 subjects, with 95% confidence, for 4 days would be 1.41 and for 28 days it would be 1.43 (60). Therefore, if the reported intake is less than 1.43 times the calculated BMR for an average of 28 days per individual, we will exclude the individual from the analysis. However, we must also keep in mind that there are numerous limitations with current nutrient analysis programs and this usually results in "educated guessing" for some food combinations by the person(s) entering the data. Therefore, it is recommended that we exercise caution in being "quick to blame" the individual for under reporting. Furthermore, we can not rely

on either subjective measures, such as food records, or objective measures alone. Subjective and objective measures must be used together in order to obtain a better understanding and a more complete picture of what is going on. We feel that by using objective along with subjective measures in our study, we are able to substantiate our results.

Our findings with respect to hypoglycemic episodes are different from those observed in the DCCT with intensive management(1). The frequency of severe hypoglycemic episodes in our study was 20 episodes per 100 patient-years, which is similar to what the DCCT observed in their control group which was 19 episodes per 100 patient-years(1). Perhaps, this is due to the fact that the level of glycemic control that we achieved was not as good as that achieved by the DCCT thus resulting in less episodes of severe hypoglycemia since better control is associated with a greater incidence in hypoglycemic episodes (1). As well, there were no differences among the three approaches with respect to non-severe or mild hypoglycemic reactions.

The main strength of this study is its design. It was a counter-balanced, randomized, within subjects, prospective study using human subjects who were "free-living". This is perhaps one of the strongest designs. By having subjects as there own controls, we minimized differences due to individual variability. With randomization, we helped to control for a possible "carry-over" effect that would likely result if only one order was followed. Since this was a long-term prospective study, we were able to realistically assess changes over time. As well, since subjects were free-living, the results have direct application to "real life." However, the purpose of the study was to help guide future care in the area of intensive management. Therefore, the

results should only be generalized to centres and subjects who are undergoing (or planning to undergo) intensive management.

The main **limitation or weakness** of the study is its "lack of power" as previously mentioned. A statistical analysis that would be most appropriate for this type of study design, and would also be more powerful, is a "repeated measures ANOVA." We decided not to use a repeated measures ANOVA since the main limitation of this analysis is that it can not account for "missing" data and therefore it discards the entire subject from the analysis even if only a small portion of the data is missing. Therefore, we did not feel that we would have gained more power by using a repeated measures ANOVA. For this reason and since we wanted to be consistent with our use of statistics, we decided to perform ***all*** of our analyses dealing with the determination of a Protocol and Time effect using a one way ANOVA.

The significance or potential impact of the study was that it would: 1) help guide future care at the Royal Victoria Hospital and possibly other centres that have initiated or are planning to initiate intensive management programs; 2)help elucidate the best educational approach; 3)help guide in the development of educational material for "intensive management"; 4) help in the development of a computerized "self-care" package for people with type I diabetes.

With respect to guiding future care, this study has already had a great impact on the delivery of care for patients with type I diabetes at the Royal Victoria Hospital. There are now two other options that are being offered to patients (namely, Protocols B and C). Protocol B appears to be in greater demand. As well, Protocol B will be used in another study that will be done by a

group from Nôtre Dame Hospital in conjunction with Université de Montréal.

It appears from our results that all three approaches are equally good educational approaches with respect to metabolic control and quality of life.

Since intensive management is a relatively new area, there is not a lot of educational material available in this area. The booklet that we developed for counting carbohydrate content has already been distributed to over 20 centres in Canada and has recently been requested by several others. Our log sheet and insulin adjustment guides are also in great demand by other individuals and centres.

The vast amount of data that we have with respect to log sheets and records from the meter memory will help in the development of a computerized "self-care" package. We are beginning to work with a statistician on the development of this program.

PART V. CONCLUSION

Contrary to our initial hypothesis, Protocol C did not appear to offer any advantages in terms of metabolic control or psycho-social adaptation compared to Protocols A & B. Perhaps, more time is needed to adapt with an approach such as Protocol C. This requires further investigation. The fact that there was no statistically significant difference among the protocols with respect to metabolic control and quality of life, indicates that any of the three approaches can be utilized by patients undergoing intensive management. However, the fact that the majority (n=12) of the subjects continued with Protocol B and no one went back to Protocol A is an indication that there is a preference for strategies that offer more flexibility with respect to adjusting insulin. Moreover, since Protocol C did not appear to be better than Protocols A and B, individuals who are not willing or ready to undertake carbohydrate counting strategies need not be excluded from participating in intensive management programs. Centres that offer intensive management programs should, therefore, not only offer carbohydrate counting as a dietary strategy but should also consider using other approaches that still quantify food intake and allow for flexibility with insulin adjustments.

Health care practitioners are encouraged to utilize the memory capacity of patients' glucose meters in order to make clinical decisions. Accuracy in SMBG reporting may help screen for individuals who may be less satisfied with their diabetes, less confident in their ability to adjust their insulin and not ready for carbohydrate counting strategies. Educational efforts could be allocated more efficiently. As well, educational strategies to increase self-efficacy may be warranted in this population.

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APPENDIX A
Forms

Participant:_____

Study Number:_____

IMPORTANT REMINDERS

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YOUR NEXT VISIT IS:

FOR NEXT VISIT BRING:

OTHER THINGS TO DO:

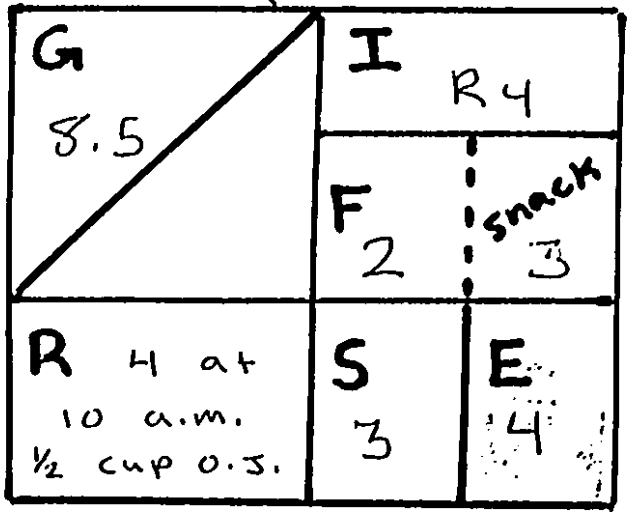
UMBER_____

EXAMPLE

Protocol # _____

A-2

Day	Breakfast time: _____	Lunch time: _____	Dinner time: _____	Bed Time time: _____	Comments
Monday	G / I / F / R / S / E	G / I / F / R / S / E	G / I / F / R / S / E	G / I / F / R / S / E	
Tuesday					
Wednesday					
Thursday					
Friday					
Saturday					
Sunday					



GUIDE

I= Amount & Type of Insulin.

F= Amount of Food on a Scale from 1 to 5 OR Grams (g) of Carbohydrate for Protocol # 3 Only.

Snack: Amount on Scale 1 to 5 OR Grams (g) Carbohydrate for Protocol # 3 Only.

S= Level of Stress on a Scale from 1 to 5.

E= Level of Exercise or Activity on Scale from 1 to 5.

G= Blood Glucose Values

before meals / after meals

R= Low Blood Sugar Reaction. (write sugar value, time of reaction & how you treated it)

SCALE

1= Much Less than Usual

2= Less than Usual

3= Usual

4= More than Usual

5= Much More than Usual

PROTOCOL # —

NUMBER_____

A-2

Comments

Day	Breakfast time: _____				Lunch time: _____				Dinner time: _____				Bed Time time: _____			
	G	I			G	I			G	I			G	I		
			F				F				F				F	
Monday	R	S	E		R	S	E		R	S	E		R	S	E	
	G	I			G	I			G	I			G	I		
			F				F				F				F	
Tuesday	R	S	E		R	S	E		R	S	E		R	S	E	
	G	I			G	I			G	I			G	I		
			F				F				F				F	
Wednesday	R	S	E		R	S	E		R	S	E		R	S		E
	G	I			G	I			G	I			G	I		
			F				F				F				F	
Thursday	R	S	E		R	S	E		R	S	E		R	S		E
	G	I			G	I			G	I			G	I		
			F				F				F				F	
Friday	R	S	E		R	S	E		R	S	E		R	S		E
	G	I			G	I			G	I			G	I		
			F				F				F				F	
Saturday	R	S	E		R	S	E		R	S	E		R	S	E	
	G	I			G	I			G	I			G	I		
			F				F				F				F	
Sunday	R	S	E		R	S	E		R	S	E		R	S		E

·:ord all food and fluids that you eat and drink, at the time you consume them or as soon as possible
ter. Please indicate the time of day. Specify the quantity of each portion in terms of ounces, cup
unit. Indicate method of cooking and all sauces,gravies and dressing used.
ill this diary for _____ consecutive days.

A-3

DATE: _____				DATE: _____			
TIME	MEAL	TYPE OF FOOD	AMOUNT	TIME	MEAL	TYPE OF FOOD	AMOUNT

Food record data

PROTOCOL:		breakfast		am snack		lunch		pm snack		supper		hs snack	
PT #	date	carb	kcal	carb	kcal	carb	kcal	carb	kcal	carb	kcal	carb	kcal

BASELINE

MIDDLE

END

Protocol # 1:

Please follow the meal plan that was provided for you by the Dietitian/Investigator.

Please follow the insulin dosages that were originally perscribed to you by the physician.

Only adjust your insulin if you have low blood sugars (less than 3) or high blood sugars (over 10). Please see **Insulin Adjustment** section of your booklet for how to adjust.

You can also make adjustments with your diet if your blood sugars are very low (less than 3-see **treatment for hypoglycemia**) or very high (over 14- see **treatment for hyperglycemia**).

You can also make **adjustments with your diet** if you have a change of activity (see **Exercise Guidelines** in your booklet).

If your sugars remain abnormal, please call the study team as soon as possible so we can help you adjust your dose.

Protocol #2:

Please follow the meal plan that was provided for you by the Dietitian Investigator.

Please follow the insulin dosages that were originally perscribed to you by the physician unless changes are necessary (see **Below**).

Adjust your insulin according to your blood sugars before your meals. If you will have a change in your food intake (based on the scale from 1 to 5), or If you will have a change in your activity level (based on scale of 1to 5 or according to level of activity -see **Insulin Adjustment Guidelines for Exercise**). Please see **Insulin Adjustment** section of your booklet for how to make these adjustments.

Adjust your basal or planned dose of insulin according to your blood sugars. Please see **Insulin Adjustments For Planned dose** section of your booklet on how to adjust your basal or planned dose.

You can make minor adjustments with your diet if your blood sugars are very low (less than 3-see **treatment for hypoglycemia**) or very high (over 14- see **treatment for hyperglycemia**).

You can make minor **adjustments with your diet** according to your blood sugars (as mentioned above) or if you have a change of activity (see **Exercise Guidelines** in your booklet).

If your sugars remain abnormal, please call the study team as soon as possible so we can help you adjust your dose.

Protocol #3:

Please follow the carbohydrate meal planning approach that was taught to you by the Dietitian/ Investigator.

Please follow the Insulin Ratios for your Regular Insulin and your Dose of Insulin for (N,L or U) that was originally perscribed to you by the physician unless changes are necessary (see **Below**).

Set your Insulin dose for **Regular Insulin** according to the **TOTAL** grams of carbohydrate you consume per meal.

Adjust your insulin ratio for regular insulin according to your blood sugars before meals or according to your activity level (based on scale form 1 to 5). Please see **Insulin Adjustment** section of your booklet for how to adjust.

Adjust your basal or planned dose of insulin according to your blood sugars. Please see **Insulin Adjustment For Planned Dose** section of your booklet on how to adjust your basal or planned dose.

You can make minor adjustments with your diet if your blood sugars are very low (less than 3-see **treatment for hypoglycemia**) or very high (over 14- see **treatment for hyperglycemia**).

You can make minor **adjustments with your diet** if you have a change of activity (see **Exercise Guidelines** in your booklet).

If your sugars remain abnormal, please call the study team as soon as possible so we can help you adjust your dose.

INSULIN ADJUSTMENTS GUIDE FOR PROTOCOL # 1

If your sugars (before meals) are:

	Breakfast	Lunch	Supper	Bedtime
Greater than 14	R ____	R____	R_____	____
10.1 - 14	R ____	R____	R_____	____
3 - 10 (usual)	**R ____**	**R____**	**R_____**	**____**
Less than 3	R ____	R____	R_____	____

The above adjustments are an <u>immediate adjustment</u> with R (regular insulin).

If your sugars remain abnormal, call the study team as soon as possible to help you adjust your insulin.

INSULIN ADJUSTMENTS GUIDE FOR PROTOCOL #2

Administer your insulin dose according to your <u>blood sugars before your meal as</u> follows:

	Breakfast	Lunch	Supper	Bedtime
Less than 3.3	R____	R____	R _____	____
3 - 4.9	R____	R____	R _____	____
5 - 7	R____	R____	R _____	____
7.1 - 9	R____	R____	R _____	____
9.1 - 11	R____	R____	R _____	____
11.1 - 14	R____	R____	R_____	____
Greater than 14	R____	R____	R _____	____

If there is a **<u>change in your food intake</u>** as assessed on a scale of 1 - 5:

For 1	R____	R____	R _____	____
For 2	R____	R____	R _____	____
For 3	**R____**	**R____**	**R _____**	**____**
For 4	R____	R____	R_____	____
or 5	R____	R____	R_____	____

If there is a **<u>change in your activity</u>** adjust as follows according to the scale from 1 - 5. Change insulin <u>prior to or within 2 hours</u> of activity:

For 1	R____	R____	R____	____
For 2 or 3	**R____**	**R____**	**R____**	**____**
For 4	R____	R____	R____	____
For 5	R____	R____	R____	____

Also see **Guidelines for Adjusting Insulin for Exercise** in booklet for more details.

INSULIN ADJUSTMENT GUIDE FOR PROTOCOL # 3

Set your R insulin dose based on the **TOTAL** grams of CHO per meal.

Your insulin ratio **PER 10 grams of carbohydrate is** as follows:

	Breakfast	Lunch	Supper	Bedtime
	R ____	R____	R_____	____

Change your R insulin dose according to your **blood sugars before meals** as follows:

Greater than 14	R ____	R____	R_____	____
10.1 - 14	R ____	R____	R_____	____
3 - 10 (usual)	**R ____**	**R____**	**R_____**	____
Less than 3	R ____	R____	R_____	____

Change your R insulin dose prior to or within 2 hours of activity as assessed on scale of 1 - 5 :

For 1	**R_____**	**R_____**	**R_____**	**_____**
For 2 or 3	**R_____**	**R_____**	**R_____**	**_____**
For 4	**R_____**	**R_____**	**R_____**	**_____**
For 5	**R_____**	**R_____**	**R_____**	**_____**

ADJUSTMENTS OF THE BASAL OR PLANNED DOSE OF REGULAR OR ULTRALENTE INSULINS

You may change your regular insulin before meals or your Ultralente insulin before supper if your blood sugars have been as follows (see **BELOW**) for an average of 7 days:

If before breakfast your blood sugars have been:

Less than 4 or 1 NIGHT reaction	Decrease Ultralente at supper by	_____
4.1 -7.0	**DO NOT CHANGE**	
Greater than 7.0	Increase Ultralente at supper by	_____

If before lunch your blood sugars have been:

Less than 4 or 1 MORNING reaction	Decrease breakfast Regular by	_____
Greater than 7.0	Increase breakfast Regular by	_____

If before supper your blood sugars have been:

Less than 4 or 1 AFTERNOON reaction	Decrease lunch Regular by	_____
Greater than 7.0	Increase lunch Regular by	_____

If before bed your blood sugars have been:

Less than 4 or 1 evening reaction	Decrease supper Regular by	_____
Greater than 7.0	Increase supper Regular by	_____

If you experience a hypoglycemic reaction 2 days in a row, decrease the insulin causing the reaction by 2 units:

TIME OF REACTIONS		**ACTION**
Between:	breakfast & lunch	Decrease R breakfast by 2
	lunch & supper	Decrease R lunch by 2
	supper & bedtime	Decrease R supper by 2
	bedtime & breakfast	Decrease N bedtime by 2

ADJUSTMENTS OF THE BASAL OR PLANNED DOSE OF REGULAR OR NPH INSULINS

You may change your regular insulin before meals or your NPH insulin before bedtime if your blood sugars have been as follows (see **BELOW**) for an average of 7 days.

If **before breakfast your blood sugars have been**:

Less than 4 or 1 NIGHT reaction	Decrease NPH at bedtime by	_____
4.1 -6.9	DO NOT CHANGE	
Greater than 7.0	Increase NPH at bedtime by	_____

If before lunch your blood sugars have been:

Less than 4 or 1 MORNING reaction	Decrease breakfast Regular by	_____
Greater than 7.0	Increase breakfast Regular by	_____

If before supper your blood sugars have been:

Less than 4 or 1 AFTERNOON reaction	Decrease lunch Regular by	_____
Greater than 7.9	Increase lunch Regular by	_____

If before bed your blood sugars have been:

Less than 4 or 1 evening reaction	Decrease supper Regular by	_____
Greater than 7.0	Increase supper Regular by	_____

If you experience a hypoglycemic reaction 2 days in a row, decrease the insulin causing the reaction by 2 units:

TIME OF REACTIONS	ACTION
Between: breakfast & lunch	Decrease R breakfast by 2
lunch & supper	Decrease R lunch by 2
supper & bedtime	Decrease R supper by 2
bedtime & breakfast	Decrease N bedtime by 2

Food	Amount	Wt.	CHO(g)
Peas, fresh	250 ml	153	12
Peas, green (small),boiled	250 ml	169	26
Peas, green (small), frozen	250 ml	169	24
Peas, green (small),canned	250 ml	180	23
Pepper, green, cooked	1	73	3
Pepper, green, fresh	1	74	4
Potato flakes, dried	250 ml	222	33
Potatoes, scalloped	250 ml	259	33
Potato, baked, without peel	1	159	34
Potato, baked, with peel	1	206	52
Potato,(fries), frozen	10	50	18
Potato, peeled before cooking	1	135	27
Potato,mashed with milk&butter	250 ml	222	37
Potato, hash brown	250 ml	165	12
Radish, fresh	10	45	2
Rutabaga, boiled	250 ml	180	14
Tomato, fresh (medium)	1	123	5
Tomatoes,whole, canned	250 ml	254	11
Tomato paste	50 ml	53	5
Tomato sauce	50 ml	52	4
Tomato juice	250 ml	256	11
Zucchini	250 ml	190	7
Legumes			
Beans, white,cooked	250 ml	189	47
Beans, lima, dry, cooked	250 ml	199	41
Beans, red, cooked	250 ml	187	43
Lentils, cooked	250 ml	209	42
Chick peas, boiled	250 ml	173	47
Soya beans, cooked	250 ml	182	18
Tofu (7cm x 6cm x 2cm)	1	89	2
Fruits			
Apricots	1	36	4
Apricots, whole, in syrup	250 ml	273	59
Apricots ,dried, cooked	250 ml	264	56
Apricots, dried, not cooked ½	10	35	22
Pineapple,cons in water	250 ml	260	22
Pineapple,cons thick syrup	1	64	13
Pineapple cubes	250 ml	164	20
Avocado (Florida)	1	304	27
Banana	1	114	27
Blueberries	250 ml	153	22
Cranberries, whole	250 ml	100	13
Cherries (sweet)	250 ml	153	25
Lemon, without peel	1	84	6
Dates	250 ml	168	138
Figs (dried)	1	19	12
Strawberries, frozen	250 ml	157	14
Strawberries, fresh	250 ml	157	11
Raspberries, fresh	250 ml	130	15
Fruit cocktail, in water	250 ml	259	22
Fruit cocktail, in juice	250 ml	262	31
Fruit cocktail, in syrup	250 ml	269	51
Kiwi, fresh (large)	1	91	14
Mango, fresh, peeled	1	176	30
Water melon (piece)	1	368	26
Honeydew melon (piece)	1	129	12
Mulberries, fresh	250 ml	152	19
Nectarine, fresh, peeled	1	136	16
Orange, fresh, peeled	1	131	15
Grapefruit, white or pink ½	1	118	10
Papaya, fresh, peeled	1	311	31
Pears, canned in their juice	250 ml	262	34
Pears, canned in syrup	250 ml	269	52
Pear, fresh, with peel	1	169	26
Apple, fresh, with peel	1	138	21

Food	Amount	Wt.	CHO(g)
Apple, pureed, unsweetened	250 ml	256	29
Prunes, dried, not cooked	3	25	15
Prunes, dried, cooked	250 ml	224	63
Prunes, fresh	1	66	9
Peaches, canned in water	250 ml	256	16
Peaches, canned in their juice	250 ml	262	30
Peaches, canned in syrup	250 ml	270	54
Peach, fresh, whole, peeled	1	87	10
Raisins	250 ml	174	138
Grapes, fresh	250 ml	169	30
Rhubarbe,fresh,cubed	250 ml	129	6
Tangerine/mandarine in syrup	250 ml	266	43
Tangerine/mandarine, fresh	1	84	9
Desserts			
Cakes			
White cake, ready 1/26x23cm	1pc	71	45
Anglefood cake 1/12x25cm	1pc	53	31
Devil's food cake, icing	1pc	69	40
Cheese cake 1/12x23cm	1pc	92	28
White cake, icing	1pc	114	70
Boston cake	1pc	69	34
Carrot cake, cheese icing	1pc	60	30
Fruit cake, 4x7 5x2cm	1pc	60	36
Yellow cake, chocolate icing	1pc	75	45
Sponge cake	1pc	44	24
Pastries			
Donut (yeast)	1	42	16
Donut,cake	1	43	22
Date square	1	90	45
Chocolate eclair, cream puff	1	100	23
Muffin ,corn	1	40	20
Muffin,blueberry or bran	1	40	17
Danish	1	65	30
Pies			
Lemon meringue pie 1/6	1pc	140	53
Blueberry pie (2 crusts) 1/6	1pc	158	55
Cherry pie (2 crusts) 1/6	1pc	158	61
Custard pie 1/6	1pc	152	36
Apple pie (2 crusts) 1/6	1pc	158	60
Peach pie (2 crusts) 1/6	1pc	158	60
Raisin pie (2 crusts) 1/6	1pc	158	68
Sweets			
Peanuts,chocolate covered	15	30	12
Candies, hard	6	30	29
Jelly beans	10	30	28
Caramels or chocolates	3	30	23
Brown sugar	15 ml	9	9
Brown sugar	250 ml	232	224
Baker's chocolate,bitter (square)	1	28	8
Baker's chocolate,sweet (square)	1	28	16
Jam	15 ml	20	14
Popsicle	1	85	16
Marshmallow	4	28	23
Jujubes	5	30	26
Mints	60 ml	28	25
Chewing gum	1	4	4
Molasses	15 ml	21	14
Honey	15 ml	21	17
Licorice	3	33	24
Maple syrup	15 ml	20	13
Chocolate syrup	15 ml	19	11
Table syrup	15 ml	21	16
Sugar, white, granulated	250 ml	211	210
Sugar, white, granulated	5 ml	5	5
Chocolate bar, milk	1	30	17

Metabolic Day Center of the Royal Victoria Hospital

Carbohydrate-Counting Boo...

Use this booklet to calculate the amount of carbohydrate at each meal Inject the quantity of Regular insulin that is necessary for that meal, using the insulin-carbohydrate ratio suggested by your physician for that meal.

A snack containing 20g of carbohydrate or less during the day does not require an injection.

A snack containing 30g of carbohydrate or less at bedtime does not require an injection.

Inject your insulin 15 to 30 minutes before your meal.

Example:

$$\frac{\text{Total grams of carbohydrate in the meal}}{10\text{ g of carbohydrate}} \times \text{Insulin ratio}$$

250 ml Orange Juice	26g
2 Slices of whole wheat bread	24g
Margarine	0g
30 ml of Peanut Butter	6g
250 ml of 2% Milk	12g
TOTAL	68g

$$68\text{ g} \times \frac{1.2\text{ units insulin}}{10\text{ g of carbohydrate}} = 8.16\text{ unités}$$

Therefore, inject 8 units of insulin.

Developed by: Maria Kalergis, Dietitian

Adapted from "Les Glucides" developed by Hélène Langelier, Dietitian at the Centre de Recherche de l'Hôtel-Dieu de Montréal.

Food	Amount	Wt	CHO(g)
Cereal Products			
Arrowroot cookies (small)	2	13	9
Fig cookies	2	28	21
Chocolate chip cookies	2	22	15
Oatmeal & raisin cookies	2	26	19
Oreo cookies	2	20	14
Pecan cookies (Whippet)	1	17	12
Melba toast	1	4	3
Soda crackers	4	11	8
Graham wafers plain	1	27	9
Graham wafers buckwheat	1	27	6
All Bran cereal	125 ml	30	13
Bran Buds cereal	175 ml	30	19
Bran Flakes cereal	325 ml	30	19
Cheerios cereal	325 ml	30	25
Cinnamon harvest crunch cereal	80 ml	30	17
Cream of wheat (dry)	45 ml	30	21
Oatmeal, instant (dry)	80 ml	30	17
Just Right cereal	160 ml	30	23
Pep cereal	160 ml	30	22
Rice Krispies cereal	250 ml	30	25
Shredded Wheat cereal	160 ml	30	21
Shredded cereal	160 ml	30	22
Special K cereal	300 ml	30	23
Whole wheat flour	250 ml	127	90
All purpose flour	250 ml	133	101
Cake flour	250 ml	114	91
Wheat germ	15 ml	7	3
Rice, white short grain	250 ml	185	45
Rice, white long grain	250 ml	169	39
Rice, brown	250 ml	180	46
Wheat bran	15 ml	3	2

N B Cereals high in fibre. It is very important to always subtract the dietary fibre from the Total carbohydrate. Fibre is not absorbed, therefore does not require insulin

Food	Amount	Wt	CHO(g)
Bread			
Bagel	1	68	38
Bread crumbs	250 ml	100	78
Croissant	1	57	27
English muffin	1	57	27
6 grain bread	1sl	25	12
Raisin bread	1sl	25	13
White bread	1sl	28	14
Cracked wheat bread	1sl	25	12
Whole wheat bread	1sl	25	12
Rye, or Viennese bread	1sl	20	11
Italian bread	1sl	30	17
Pita bread	1	60	33
Hamburger bun	1	60	32
Hot dog bun	1	50	27
Bread, small crust	1sl	50	30
Pasta			
Macaroni (enriched cooked)	250 ml	148	34
Egg noodles (cooked)	250 ml	169	39
Noodles chow mein (canned)	250 ml	47	27
Spaghetti (enriched cooked)	250 ml	148	34
Grains			
Pumpkin & squash (seeds)	125 ml	73	13
Sesame (butter)	15 ml	14	3
Sesame (seeds) ,dried	125 ml	79	7
Sunflower (seeds), dried	125 ml	76	14

Food	Amount	Wt.	CHO(g)
Nuts			
Almonds (whole, skinless)	125 ml	75	15
Peanuts (roasted in oil)	125 ml	77	14
Peanut Butter	15 ml	16	3
Cashews (roasted)	125 ml	69	20
Dried sweet coconut	125 ml	49	23
Walnuts	125 ml	53	10
Brazil Nuts	125 ml	74	11
Mixed nuts (dried roasted)	125 ml	72	18
Mixed nuts (roasted in oil)	125 ml	75	16
Pistachios (dried roasted)	125 ml	68	19
Pecan halves	125 ml	57	10
Beverages			
Beer	341 ml	343	13
Beer (light)	341 ml	343	6
Cola	280 ml	292	30
Gingerale	280 ml	289	25
Tonic Water (sweetened)	280 ml	289	25
Iced tea (powder)	250 ml	273	23
Red or white wine(dry)	100 ml	100	1
Sweet wine	100 ml	101	12
Juice			
Apricot juice, canned	250 ml	265	38
Pineapple juice, canned	250 ml	264	36
Orange juice, unsweetened	250 ml	263	26
Cranberry juice	250 ml	267	40
Lemonade	250 ml	258	17
Lemonade, frozen concentrate	250 ml	262	30
Grapefruit juice	250 ml	261	24
Apple juice	250 ml	262	31
Prune juice	250 ml	270	47
Grape juice, sweetened frozen	250 ml	264	34
Soups			
Cream of mushroom with milk	250 ml	262	16
Cream of chicken with milk	250 ml	262	16
Chicken noodle	250 ml	267	8
Tomato & vegetable soup	250 ml	267	11
Beef & noodle (canned)	250 ml	258	9
Clam chowder soup (white)	250 ml	262	18
Clam chowder soup (red)	250 ml	258	13
Onion soup	250 ml	260	5
Minestrone	250 ml	255	12
Pea soup with ham	250 ml	267	30
Vegetable soup	250 ml	255	13
Tomato soup with water	250 ml	258	18
Tomato soup with milk	250 ml	262	24
Milk Products			
Coffee whitener	5 ml	2	1
Cream for coffee (15 ml)	15 ml	15	0
Cream for coffee (250 ml)	250 ml	253	7
Ice cream, vanilla	125 ml	78	17
Sour cream (15 ml)	15 ml	15	0
Sour cream (250 ml)	250 ml	253	11
Whip cream (15 ml)	15 ml	15	0
Whip cream (250 ml)	250 ml	251	5
Cheese Blue (piece)	1	45	0
Cheese Brick (piece)	1	45	0
Cheese Brie (piece)	1	45	0
Cheese Camembert (piece)	1	45	0
Cheese Cheddar (piece)	1	45	0
Cheese Cottage	250 ml	239	9
Cheese Feta (piece)	1	45	2

Food	Amount	Wt.	CHO(g)
Cheese spread	15 ml	15	1
Cheese Mozzarella	1	45	1
Cheese Parmesan	15 ml	5	0
Cheese Ricotta (piece)	1	45	2
Cheese Swiss (piece)	1	45	2
Soya milk	250 ml	254	5
Milk(whole, 2%, 1%, skim)	250 ml	258	12
Ice milk, vanilla (soft icecream)	125 ml	92	20
Pudding, rice & raisin	125 ml	140	37
Pudding,chocolate,canned	125 ml	132	28
Pudding, vanilla, canned	125 ml	132	31
Pudding, tapioca	125 ml	87	15
Sorbet , orange	125 ml	102	31
Yogurt, with fruits	125 ml	125	23
Yogurt, plain	125 ml	125	9
Fats			
Butter	15 ml	15	0
Corn oil	15 ml	14	0
Soya oil	15 ml	14	0
Sunflower oil	15 ml	14	0
Margarine	15 ml	14	0
Fastfood			
Bg Mac	1	200	39
Cherry pie	1	88	32
Apple pie	1	85	29
Ice cream cone	1	4	3
Chips	10	20	10
Hamburger (Whopper)	1	265	42
Chocolate milkshake	1	291	65
Vanilla milkshake	1	291	60
McNuggets	6	109	14
Egg McMuffin	1	138	31
Pop corn	250 ml	8	6
Pretzels, sticks	5	15	11
Sauces			
Mayonnaise	15 ml	14	0
Salad dressing (mayonnaise)	15 ml	15	4
French or Italian dressing	15 ml	16	2
Thousand Islands dressing	15 ml	16	4
Meat			
Lamb (cutlette)	1po	87	0
Lamb (leg, broiled))	2po	87	0
Beef (roast)	2po	87	0
Turkey (white or brown)	2po	86	0
Ham	1po	27	0
Egg (medium)	1	46	0
Pork (bacon,grilled)	1po	23	0
Pork (ribs, medium size)	2	70	0
Pork (chops, grilled)	1	87	0
Chicken with skin(½ breast)	1	98	0
Chicken without skin	4po	92	0
Veal (cutlette)	1po	92	0
Seafood			
Crab, canned	150 ml	86	0
Shrimps, canned ,medium	28	90	0
Shrimps,breaded,fried,large	11	88	0
Halibut (piece)	1	92	0
Lobster, canned	150 ml	92	0
Oysters,raw (small)	9	90	3
Cod, fresh (piece)	1	88	0
Fishsticks, breaded, frozen	3	90	6
Scallops, steamed	7	90	3

Food	Amount	Wt.	CHO(g)
Sardines, canned, (medium)	7	84	0
Salmon, canned	150 ml	95	0
Salmon, fresh (piece)	1	92	0
Sole, grilled (filet)	1	90	0
Tuna, canned	125 ml	85	0
Trout, grilled (piece)	1	93	0
Mixed Foods			
Beef stew, canned	250 ml	259	18
Chili con carne without beans	250 ml	269	16
Chili con carne with beans	250 ml	269	32
Chop suey with meat	250 ml	264	13
Chicken chow mein without noodle, canned	250 ml	264	19
Pork & beans, canned	250 ml	267	52
Macaroni with cheese	250 ml	211	42
Meatloaf 10x8x1 cm	1sl	73	3
Pizza 1/8 by 35 cm diameter	1sl	65	1
Chicken pot pie	1	232	42
Shepherd's pie	250 ml	265	23
Quiche Lorraine 1/8x20 cm	1pc	176	29
Spaghetti with meat sauce	250 ml	262	41
Meat pie 1/8 x 23 cm	1pc	139	32
Vegetables			
Artichoke (medium)	1	300	12
Asparagus (sticks)	4	60	3
Egg plant, boiled, cubes	250 ml	101	7
Beets, diced	250 ml	180	12
Broccoli, boiled	250 ml	184	9
Broccoli, fresh (stem)	1	151	8
Carrots, boiled	250 ml	165	17
Carrots, fresh(19 cm)	1	72	7
Mushrooms, canned	250 ml	165	8
Mushrooms, fresh	250 ml	74	3
Brussel sprouts, boiled	250 ml	165	14
Red cabbage, fresh	250 ml	74	5
Cabbage, boiled	250 ml	158	4
Cabbage, fresh	250 ml	74	4
Coleslaw	250 ml	127	16
Cauliflower, fresh or cooked	250 ml	131	6
Sour croute	250 ml	249	11
Pumpkin, canned	250 ml	259	21
Cucumber, fresh	250 ml	111	3
Winter squash, cooked (cubes)	250 ml	217	19
Celery, fresh, diced	250 ml	127	5
Spinach, boiled	250 ml	190	7
Spinach, fresh	250 ml	59	2
Beans,yellow/green boiled	250 ml	132	10
Beans, yellow/green,canned	250 ml	144	6
Bean sprouts, fresh	250 ml	131	5
Vegetable juice	250 ml	256	12
Lettuce	250 ml	59	2
Mixed vegetables, frozen	250 ml	172	23
Mixed vegetables, canned	250 ml	172	16
Marinated, mixed, sweetened	1	10	3
Marinated in dill (10 cm)	1	136	3
Corn, sweet (cob)	1	77	19
Corn, sweet,creamed,canned	250 ml	270	49
Corn, sweet, whole, canned	250 ml	173	32
Turnip, boiled, pureed, strained	250 ml	243	12
Turnip, raw, cubes	250 ml	137	9
Onion, minced, boiled	250 ml	222	14
Onion, minced, fresh	250 ml	169	12
Olives, black (large)	5	20	0
Olives, green (medium)	5	20	0
Parsnip, boiled	250 ml	165	32
Sweet potatoes, pureed	250 ml	340	84

RETINOPATHY (Add date of assessment)

100. not yet assessed
101. Normal retina
102. Background retinopathy
103. Pre-proliferative retinopathy
104. Proliferative retinopathy
105. Proliferative - stable post laser
106. Macular edema
107. Blindness of one eye
108. Bilateral blindness
199. Other : please specify

NEPHROPATHY (Add date of assessment)

100. not yet assessed
101. No microalbuminuria/proteinuria
102. Microalbuminuria > 15 mg/day
103. Proteinuria 0.1-0.5 g/day
104. Proteinuria 0.5-1.0 g/day
105. Proteinuria 1.0-3.0 g/day
106. Proteinuria > 3.0 g/day
107. Mild renal insufficiency
108. Hemodialysis
109. Peritoneal dialysis
110. Renal transplantation
199. Other : please specify

EUROPATHY : (Add date of assessment)

00. not yet assessed
01. Absence of neuropathy
02. Asymptomatic peripheral polyneuropathy
03. Symptomatic peripheral polyneuropathy
04. Severe peripheral polyneuropathy
05. Autonomic neuropathy
06. Gastroparesis
99. Other : please specify

HYPERTENSION (Add date of assessment)

100. not yet assessed
101. no hypertension
102. Mild untreated hypertension
103. Moderate/severe untreated hypertension
104. Treated, controlled hypertension
105. Treated, uncontrolled hypertension
199. Other : please specify

CORONARY ARTERY DISEASE
(Add date of assessment)

100. not yet assessed
101. No evidence of CAD
102. Angina
103. Past MI, no angina
104. Past MI, angina
105. Post coronary artery bypass, no angina
107. Post coronary artery bypass, angina
199. Other : please specify

SMOKING (Add date of assessment)

100. Smoking status not known
101. Never smoked
102. Ex-smoker (< 2 years)
103. Ex-smoker (> 2 years)
104. Smokes < 0.5 ppd
105. Smokes 0.5-1.5 ppd
106. Smokes 1.5-2.5 ppd
107. Smokes > 2.5 ppd
108. Cigar or pipe
199. Other : please specify

FERTILITY (Add date of assessment)
(Add GxPyAz)
100. Not known
101. Fertile
102. Oral contraceptives
103. Barrier (condom or diaphragm)
104. Intrauterine device
105. Surgical sterility
106. Post-menopause
199. Other : please specify

APPENDIX B
Questionnaires

INSULIN MANAGEMENT DIABETES SELF-EFFICACY SCALE

Number_____ **Protocol#**_____

This survey asks you to rate your degree of confidence for being able to carry out your diabetes-related activities. Please write the date that you actually completed the survey.

Date_____

The following statements describe what some people believe about their ability to take care of their diabetes. After reading each statement, **circle the number** that best expresses your beliefs. **Please answer each statement.** There are no right or wrong answers. If a question does not apply to you, please write **NA** (not applicable) beside the question.

Circle: **1** if you **strongly agree** with the statement,

2 if you **moderately agree** with the statement,

3 if you **slightly agree** with the statement,

4 if you **slightly disagree** with the statement,

5 if you **moderately disagree** with the statement,

6 if you **strongly disagree** with the statement,

Please answer each statement according to the protocol you <u>have just completed.</u>

INSULIN MANAGEMENT DIABETES SELF-EFFICACY SCALE

Number_____ **Protocol#**_____

This survey asks you to rate your degree of confidence for being able to carry out your diabetes-related activities. Please write the date that you actually completed the survey.

Date_____

The following statements describe what some people believe about their ability to take care of their diabetes. After reading each statement, **circle the number** that best expresses your beliefs. **Please answer each statement.** There are no right or wrong answers. If a question does not apply to you, please write NA (not applicable) beside the question.

Circle: **1** if you **strongly agree** with the statement,

2 if you **moderately agree** with the statement,

3 if you **slightly agree** with the statement,

4 if you **slightly disagree** with the statement,

5 if you **moderately disagree** with the statement,

6 if you **strongly disagree** with the statement,

Please answer each statement according to the protocol you <u>will be completing</u>.

	1 Strongly Agree	2	3	4	5	6 Strongly Disagree
* 1 a. Following my diabetes protocol is important to me.	1	2	3	4	5	6
b. Following my diabetes protocol will improve my overall well-being.	1	2	3	4	5	6
c. Following my diabetes protocol will lead to better blood sugar control.	1	2	3	4	5	6
* 2 a. Following my diabetes protocol even when my daily routine changes is important to me.	1	2	3	4	5	6
b. Following my diabetes protocol even when my daily routine changes will improve my overall well-being.	1	2	3	4	5	6
c. Following my diabetes protocol even when my daily routine changes will lead to better blood sugar control.	1	2	3	4	5	6
* 3 a. Adjusting my insulin as recommended is important to me.	1	2	3	4	5	6
b. Adjusting my insulin as recommended will improve my overall well-being.	1	2	3	4	5	6
c. Adjusting my insulin as recommended will lead to better blood sugar control.	1	2	3	4	5	6
* 4 a. Adjusting my insulin even when my daily routine changes is important to me.	1	2	3	4	5	6
b. Adjusting my insulin even when my daily routine changes will improve my overall well-being.	1	2	3	4	5	6
c. Adjusting my insulin even when my daily routine changes will lead to better blood sugar control.	1	2	3	4	5	6

Key

* = Reverse-scored

(= Diet questions

Other = Not part of any scale but part of TOTAL

Subscales

G = General

D = Diet

I = Insulin

	1 Strongly Agree	2	3	4	5	6 Strongly Disagree
5 a. Following my diet is important to me.	1	2	3	4	5	6
b. Following my diet will improve my overall well-being.	1	2	3	4	5	6
c. Following my diet will lead to better blood sugar control.	1	2	3	4	5	6
6 a. Following my diet even when my daily routine changes is important to me.	1	2	3	4	5	6
b. Following my diet even when my daily routine changes improve my overall well-being.	1	2	3	4	5	6
c. Following my diet even when my daily routine changes will lead to better blood sugar control.	1	2	3	4	5	6
7 a. Treating my low blood sugar reaction as recommended is important to me.	1	2	3	4	5	6
b. Treating my low blood sugar reaction as recommended will improve my overall well-being.	1	2	3	4	5	6
c. Treating my low blood sugar reaction as recommended will lead to better blood sugar control.	1	2	3	4	5	6

Do you feel confident in being able to do the following:

8. I can carry out practically all of the self-care activites in my daily diabetes routine.	1	2	3	4	5	6
9. I am confident in my ability to manage my diabetes.	1	2	3	4	5	6

Do you feel confident in being able to do the following:

	1 Strongly Agree	2	3	4	5	6 Strongly Disagreee
C **10.** I feel unsure about having to use what I know about diabetes self-treatment every day.	1	2	3	4	5	6
C **11.** I don't think I can follow my diabetes routines every single day.	1	2	3	4	5	6
* C **12.** I can eat my meals at the same time every day.	1	2	3	4	5	6
* C **13.** I can stay on my diabetic diet when I eat in familiar places away from home(such as at a friend's house).	1	2	3	4	5	6
* C **14.** I can stay on my diabetic diet when I eat in unfamiliar places.	1	2	3	4	5	6
C **15.** I'm not sure I'll be able to stay on my diabetic diet when the people around me don't know that I have diabetes.	1	2	3	4	5	6
C **16.** I'm not sure I'll be able to follow my diabetic diet every day.	1	2	3	4	5	6
* D **17.** I can correctly exchange one food for another in the same food group.	1	2	3	4	5	6
* C **18.** When I go to parties, I can follow my diet plan.	1	2	3	4	5	6
I **19.** I cannot test my blood when I am away from home.	1	2	3	4	5	6
* I **20.** I can recognize when my blood sugar is too high.	1	2	3	4	5	6
I **21.** When I feel sick, I can test my blood sugar more than I routinely do.	1	2	3	4	5	6

Do you feel confident in being able to do the following:

	1 Strongly Agree	2	3	4	5	6 Strongly Disagree
22. I can take my insulin using the recommended procedure.	1	2	3	4	5	6
23. I can adjust my insulin according to my blood sugar result as recommended .	1	2	3	4	5	6
24. I can adjust my insulin according to my food intake as recommended.	1	2	3	4	5	6
25. I can adjust my food intake according to my blood sugar results as recommended.	1	2	3	4	5	6
26. I may have difficulty taking my insulin when away from home.	1	2	3	4	5	6
27. I'm not sure I can figure out what to do about my insulin dose when changes occur in my usual routine.	1	2	3	4	5	6
28 I can figure out when to call my doctor about problems with my feet.	1	2	3	4	5	6
29. I can take care of my feet as recommended.	1	2	3	4	5	6
30. I can exercise several times a week.	1	2	3	4	5	6
31. I cannot exercise unless I feel like exercising.	1	2	3	4	5	6

Do you feel confident in being able to do the following:

	1 Strongly Agree	2	3	4	5	6 Strongly Disagree
32. I can adjust my insulin as recommended when I exercise.	1	2	3	4	5	6
33. I can adjust my food intake as recommended when I exercise.	1	2	3	4	5	6
34. I can do what was recommended to prevent low blood sugar reactions when I exercise.	1	2	3	4	5	6
35. I can figure out what self-treatment to administer when my blood sugar gets lower than it should be.	1	2	3	4	5	6
36. I can figure out what self-treatment to administer when my blood sugar gets higher than it should be.	1	2	3	4	5	6
37. I'm not sure I can recognize when my blood sugar is low.	1	2	3	4	5	6
38. I'm not sure I can adjust my diabetes self-treatments if I get a cold or the flu.	1	2	3	4	5	6
39. I can fit my diabetes self-treatment routine into my usual life style.	1	2	3	4	5	6
40. I think I can follow my diabetes plan even when my daily routine changes.	1	2	3	4	5	6

Do you have any **comments** you wish to add about confidence in your ability to self-manage your diabetes?

Quality of Life Assessment Form

Number_____ Protocol #_____
Date _____

The following questions will help to give us some indication of how your diabetes affects your daily life. This is very important to us since diabetes affects many aspects of daily living. Please answer all questions. If a question does not apply to you, please write NA (not apllicable) beside it.

General Assessment

1. In general, would you say your health is: **(Circle One)**

   1. Excellent
   2. Very Good
   3. Good
   4. Fair
   5. Poor

2. How much bodily pain have you had during the past 4 weeks? **(Circle One)**

   1. None
   2. Very Mild
   3. Mild
   4. Moderate
   5. Severe

3. For how long (if at all) has your health limited you in each of the following activities? **(Check One Box on Each Line)**

	Limited more than 3 months	Limited for 3 months or less	Not limited at all
a. The kinds or amounts of vigorous activities you can do, like lifting heavy objects, running or participating in strenuous sports.	☐	☐	☐
b. The kinds or amounts of moderate activities you can do, like moving a table, carrying groceries or bowling.	☐	☐	☐
c. Walking uphill or climbing a few flights of stairs.	☐	☐	☐

	Limited more than 3 months	Limited for 3 months or less	Not limited at all
d. Bending, lifting or stooping	☐	☐	☐
e. Walking one block	☐	☐	☐
f. Eating, dressing, bathing, or using the toilet.	☐	☐	☐

4. Does your health keep you from working at a job, doing work around the house or going to school? **(Circle One)**

Role Functioning

1. Yes, for more than 3 months
2. Yes, for 3 months or less
3. No

5. Have you been unable to do certain kinds or amounts of work, housework or schoolwork because of your health? **(Circle One)**

1. Yes, for more than 3 months
2. Yes, for 3 months or less
3. No

For each of the following questions, please check the box for the one answer that comes closest to the way you have been feeling during the past month. (Check One Box on Each Line).

Social Functioning

	All of the Time	Most of the Time	A Good Bit of Time	Some of the time	A Little of the Time	None of the Time
6. How much of the time, during the past month, has your health limited your social activities (like visiting with friends or close relatives?)	☐	☐	☐	☐	☐	☐

Mental Health

	All of the Time	Most of the Time	A Good Bit of Time	Some of the time	A Little of the Time	None of the Time
7. How much of the time, during the past month, have you been a very nervous person?	☐	☐	☐	☐	☐	☐
8. During the past month, how much of the time have you felt calm and peaceful?	☐	☐	☐	☐	☐	☐
9. How much of the time, during the past month have you felt downhearted and blue?	☐	☐	☐	☐	☐	☐
10. During the past month, how much time have you been a happy person?	☐	☐	☐	☐	☐	☐
11. How often, during the past month, have you felt so down in the dumps that nothing could cheeer you up?	☐	☐	☐	☐	☐	☐

12. Please check the box that best describes whether each of the following statements is true or false for you. **(Check One Box on Each Line).**

Health perceptions

	Definitely True	Mostly True	Not Sure	Mostly False	Definitely False
a. I am somewhat ill	☐	☐	☐	☐	☐
b. I am as healthy as anybody I know	☐	☐	☐	☐	☐
c. My health is excellent	☐	☐	☐	☐	☐
d. I have been feeling bad lately	☐	☐	☐	☐	☐

Diabetes-Specific Assessment

Satisfaction	1 Very Satisfied	2	3	4	5 Very Dissatisfied
1. How satisfied are you with the amount of time it takes to manage your diabetes?	1	2	3	4	5
2. How satisfied are you with the amount of time you spend getting checkups?	1	2	3	4	5
3. How satisfied are you with the time it takes to determine your sugar level?	1	2	3	4	5
4. How satisfied are you with your current treatment?	1	2	3	4	5
5. How satisfied are you with the flexibility you have in your diet?	1	2	3	4	5
6. How satisfied are you with the demands your diabetes is placing on your family?	1	2	3	4	5
7. How satisfied are you with your knowledge about diabetes?	1	2	3	4	5
8. How satisfied are you with your sleep?	1	2	3	4	5
9. How satisfied are you with your social relationships and friendships?	1	2	3	4	5
10. How satisfied are you with your sex life?	1	2	3	4	5
11. How satisfied are you with your work, school, and household activities?	1	2	3	4	5

	1 Very Satisfied	2	3	4	5 Very Dissatisfied
12. How satisfied are you with the appearance of your body?	1	2	3	4	5
13. How satisfied are you with the time you spend exercising?	1	2	3	4	5
14. How satisfied are you with your leisure time?	1	2	3	4	5
15. How satisfied are you with life in general?	1	2	3	4	5
Impact	**1** **Never**	**2**	**3**	**4**	**5** **Always**
1. How often do you feel pain associated with the treatment for your diabetes?	1	2	3	4	5
2. How often are you embarrassed by having to deal with your diabetes in public?	1	2	3	4	5
3. How often do you have low blood sugar?	1	2	3	4	5
4. How often do you feel physically ill because of your diabetes?	1	2	3	4	5
5. How often does your diabetes interfere with your family life?	1	2	3	4	5
6. How often do you have a bad night's sleep?	1	2	3	4	5
7. How often do you find your diabetes limiting your social relationships & frienships?	1	2	3	4	5
8. How often do you feel good about yourself?	1	2	3	4	5
9. How often do you feel restricted by your diet?	1	2	3	4	5

	1 Never	2	3	4	5 Always
10. How often does your diabetes interfere with your sex life?	1	2	3	4	5
11. How often does your diabetes keep you from driving a car or using a machine (e.g., a typewriter)?	1	2	3	4	5
12. How often does your diabetes interfere with your exercising?	1	2	3	4	5
13. How often do you miss work, school, or household duties because of your diabetes?	1	2	3	4	5
14. How often do you find yourself explaining what it means to have diabetes?	1	2	3	4	5
15. How often do you find that your diabetes interrupts your leisure-time activities?	1	2	3	4	5
16. How often do you tell others about your diabetes?	1	2	3	4	5
17. How often are you teased because you have diabetes?	1	2	3	4	5
18. How often do you feel that because of your diabetes you go to the bathroom more than others?	1	2	3	4	5
19. How often do you find that you eat something you shouldn't rather than tell someone that you have diabetes?	1	2	3	4	5
20. How often do you hide from others the fact that you arehaving an insulin reaction?	1	2	3	4	5
21. How often do you worry about your children having diabetes.	1	2	3	4	5

Worry: Social/Vocational	1 Never	2	3	4	5 Always
1. How often do you worry about whether you will get married?	1	2	3	4	5
2. How often do you worry about whether you will have children?	1	2	3	4	5
3. How often do you worry about whether you will not get a job you want?	1	2	3	4	5
4. How often do you worry about whether you will be denied insurance?	1	2	3	4	5
5. How often do you worry about whether you will be able to complete your education?	1	2	3	4	5
6. How often do you worry about whether you will miss work?	1	2	3	4	5
7. How often do you worry about whether you will take a vacation or a trip?	1	2	3	4	5

Worry: Diabetes Related	1 Never	2	3	4	5 Always
1. How often do you worry about whether you will pass out?	1	2	3	4	5
2. How often do you worry that your body looks different because you have diabetes?	1	2	3	4	5
3. How often do you worry that you will get complications from your diabetes?	1	2	3	4	5
4. How often do you worry about whether someone will not go out with you because you have diabetes?	1	2	3	4	5

Do you have any comments you wish to add about the quality of your life in general:

APPROACH ASSESSMENT

Number _____ Protocol #_____
Date _____

The following questions will help us understand how you feel about your diabetes treatment protocol or approach. Read the questions carefully and **circle your response.** If the question does not apply to you, write NA (not applicable) beside the question number.

STRESS

1. Overall, within the past month, how would you rate your level of stress?

1	2	3	4	5
Not Stressed	A Little Stressed	Somewhat Stressed	Moderately Stressed	Very Stressed

2. How much does your present protocol influence your level of stress?

1	2	3	4	5
Not Stressed	A Little Stressed	Somewhat Stressed	Moderately Stressed	Very Stressed

3. How much does adjusting insulin for diet influence your level of stress?

1	2	3	4	5
No Influence	Little Influence	Some Influence	Moderate Influence	Great Influence

4. How much does adjusting insulin according to your blood sugar results influence your level of stress?

1	2	3	4	5
No Influence	Little Influence	Some Influence	Moderate Influence	Great Influence

5. How much does adjusting insulin for exercise influence your level of stress?

1	2	3	4	5
No Influence	Little Influence	Some Influence	Moderate Influence	Great Influence

6. When you feel stressed, does it influence what you eat?

1	2	3	4	5
No Influence	Little Influence	Some Influence	Moderate Influence	Great Influence

7. How much does following your diet according to your protocol influence your level of stress?

1	2	3	4	5
No Influence	Little Influence	Some Influence	Moderate Influence	Great Influence

8. How much does adjusting your diet according to your blood sugar results influence your level of stress?

1	2	3	4	5
No Influence	Little Influence	Some Influence	Moderate Influence	Great Influence

9. How much does adjusting diet for exercise influence your level of stress?

1	2	3	4	5
No Influence	Little Influence	Some Influence	Moderate Influence	Great Influence

10. How much does treating your low blood sugar reactions influence your level of stress?

1	2	3	4	5
No Influence	Little Influence	Some Influence	Moderate Influence	Great Influence

PERCEIVED COMPLEXITY

11. How complex would you say your present diet is?

1	2	3	4	5
Not Complex	A Little Complex	Somewhat Complex	Moderately Complex	Very Complex

12. How complex would you say your present approach or protocol is?

1	2	3	4	5
Not Complex	A Little Complex	Somewhat Complex	Moderately Complex	Very Complex

Please provide any additional comments you might have about your present approach protocol in general:

DIABETES INFORMATION TEST

DIRECTIONS: Read each item and decide which choice **BEST** completes the statement or answers the question. Indicate your answer by circling the appropriate letter.

General

1. The usual cause of diabetes is:

   a). eating too much sugar and other sweet foods.
   b). lack of effective insulin in the body.
   c). failure of the kidneys to control sugar in the urine.
   d). I don't know.

2. Glycosylated hemoglobin (A1C hemoglobin or HBA1c) is a laboratory test that gives an indication of the:

   a). changes in the walls of blood vessels.
   b). average blood sugar level over 2-3 months.
   c). level of fat in the blood.
   d). I don't know.

3. The best laboratory test for diagnosing diabetes is the:

   a). urine test for sugar.
   b). urine test for ketones.
   c). blood test for sugar.
   d). I don't know.

4. In untreated diabetes the blood sugar is usually:

   a). normal.
   b). increased.
   c). decreased.
   d). I don't know.

5. Diabetes is an inherited disease. The diabetes is usually inherited from:

   a). the mother.
   b). the father.
   c). both the mother and father.
   d). I don't know.

6. The best way to assess your day-to day diabetes control is:

   a). a written record of blood sugar tests at home.
   b). random urine test results.
   c). a single blood sugar test at the hospital.
   d). I don't know

Exercise

7. When a person with Type I (insulin-dependent) diabetes increases his play or work, he should do the following changes to avoid low blood sugar. Use:

   a). the same amount of insulin with additional food.
   b). more insulin with less food.
   c). no insulin with the same amount of food.
   d). I don't know.

8. The general effect of exercise is to:

   a). lower the blood sugar level.
   b). raise the blood sugar level.
   c). increase sugar in the urine.
   d). I don't know.

Insulin

9. Insulin causes blood sugar to.

   a). increase.
   b). decrease.
   c). neither increase or decrease.
   d). I don't know.

10. Regular insulin lasts about:

   a). 6-hours.
   b). 12- hours.
   c). 24-hours.
   d). I don't know.

11. Regular insulin peaks at about:

   a). 2-4 hours.
   b). 8 hours.
   c). 1 hour.
   d). I don't know.

12. Lente and NPH insulins last about:

a). 6-hours.
b). 16-hours.
c). 36-hours.
d). I don't know.

13. Lente and NPH insulins peak at about:

a). 2-4 hours.
b). 6-10 hours.
c). 20 hours.
d). I don't know.

14. Ultralente insulin lasts about:

a). 24-hours.
b). 12-hours.
c). 8-hours.
d). I don't know.

15. Ultralent insulin peaks at about:

a). 6-hours.
b). 12-16-hours.
c). 2-4 hours.
d). I don't know.

16. Which blood sugar test is MOST helpful to decide if a change is needed in the Regular insulin taken in the morning?

a). breakfast.
b). lunch.
c). supper.
d). I don't know.

17. To decide if a change is needed in Ultralente insulin at supper or NPH insulin taken at bed time, which blood sugar test is MOST helpful?

a). breakfast.
b). supper
c). evening snack (before bed).
d). I don't know.

18. To decide if a change is needed in Regular insulin taken before supper, which blood sugar test is MOST helpful?

    a). breakfast.
    b). supper.
    c). evening snack (before bed).
    d). I don't know.

19. When blood sugar is being controlled by long-acting insulin, a bedtime snack:

    a). is important
    b). is not important.
    c). should be taken from the "extra" exchange list.
    d). I don't know.

20. To decide if a change is needed in NPH or Lente insulin taken before breakfast, the blood test MOST helpful is:

    a). breakfast.
    b). supper.
    c). evening snack (before bed).
    d). I don't know.

Illness

21. When a person with Type I (insulin-dependent) diabetes becomes ill, she will frequently require:

    a). more insulin.
    b). less insulin.
    c). no insulin.
    d). I don't know.

22. When a person with Type I diabetes is sick:

    a). carbohydrate intake should be sharply restricted.
    b). foods other than carbohydrate should be increased.
    c). carbohydrate intake in some form should be continued.
    d). I don't know.

Diet

23. Which of the following statements is correct?

    a). One cup of milk may be exchanged for four ounces of cheese.
    b). One ounce of beef may be exchanged for one ounce of cream cheese.
    c). One egg may be exchanged for one ounce of Canadian bacon.
    d). I don't know.

24. One bread exchange contains about:

    a). 15 grams of carbohydrate.
    b). 10 grams of carbohydrate.
    c). 20 grams of carbohydrate.
    d). I don't know

25. One fruit exchange contains about:

    a). 10 grams of carbohydrate.
    b). 15 grams of carbohydrate.
    c). 5 grams of carbohydrate.
    d). I don't know.

26. One fat exchange contains about:

    a). 20 grams of carbohydrate.
    b). 30 grams of carbohydrate.
    c). 0 grams of carbohydrate.
    d). I don't know.

27. Which nutrient has the GREATEST effect on blood sugars:

    a). Fat
    b). Carbohydrate.
    c). Protein.
    d). I don't know.

28. The bread exchange list contains foods high in carbohydrate. One slice of bread may be exchanged for:

    a). 1/2 cup cornflakes.
    b). 6 graham crackers.
    c). 1 small potato.
    d). I don't know.

29. One orange may be exchanged for

a). 1 banana (medium size)
b). 1 cup of orange juice
c). 1 small apple
d). I don't know

30. The meal plan used in diabetes management:

a). is unlike the ordinary American diet.
b). could be the basis for an excellent family meal plan.
c). is too high in fat for general use.
d). I don't know.

31. The type of food highest in calories per gram is:

a). carbohydrate.
b). protein.
c). fat.
d). I don't know.

32. The main sources of carbohydrate in the diabetes meal plan are:

a). fats and oils.
b). vegetables.
c). breads and cereals.
d). I don't know.

33. Foods which may be used as "extras" on a diabetes exchange meal plan are:

a). foods labeled "dietetic" or "diabetic".
b). foods which contain 20 calories per serving or less.
c). alcoholic beverages.
d). I don't know.

Alcohol

34. The general effect of alcohol is to:

a). increase blood sugar
b). decrease the body's response to hypoglycemia.
c). not effect blood sugar.
d). I don't know.

Hypoglycemia

35. Insulin reaction or shock is caused by

    a). an imbalance of insulin and blood sugar.
    b). too much food and not enough insulin.
    c). too little exercise.
    d). I don't know

36. When a person with diabetes has an insulin reaction, the amount of sugar in the blood is:

    a). not important
    b). usually high
    c). usually low
    d). I don't know.

37. The best way to treat a hypoglycemic reaction is by having:

    a). a chocolate bar.
    b). 1/2 cup of orange juice.
    c). 1 cup of orange juice with 2 teaspoons of sugar.
    d). I don't know

38. In case of SEVERE hypoglycemic reactions, everyone with diabetes should have:

    a). a bottle of regular coke in the house.
    b). glucagon.
    c). liquid glucose or glucose gel.
    d). I don't know.

39. The action of glucagon is to:

    a). raise the blood sugar.
    b). lower the blood sugar.
    c). neutralize insulin.
    d). I don't know

40. Food eaten by a person to treat an insulin reaction should be:
    a). subtracted from the next meal.
    b). subtracted from the evening snack.
    c). taken in addition to the total food allowance.
    d). I don't know.

Hyperglycemia

41. The presence of sugar and ketones in the urine usually is:

a). a warning sign of an insulin reaction.
b). a warning sign of ketoacidosis.
c). not important.
d). I don't know.

42. When a person with diabetes develops ketoacidosis, she may experience:

a). sweating and convulsions.
b). rapid onset coma.
c). thirst and excessive urination.
d). I don't know.

Complications

43. Large blood vessel damage (arteriosclerosis) is:

a). a special problem seen only in diabetes.
b). a common problem seen earlier in people with diabetes than in the general population.
c). responsible for eye complications.
d). I don't know.

44. Small blood vessel disease in persons with diabetes is most readily recognized in the:

a). feet and legs.
b). brain.
c). eyes and kidneys.
d). I don't know.

DESCRIPTIVE QUESTIONNAIRE

Number_____

Date_____

The following questions will help us with our data analysis. Please answer all the questions.

1. How frequently have you seen a Dietitian in your life. **(Circle One)**

   a. No previous counselling by a Dietitian
   b. One session with a Dietitian
   c. More than one session with a Dietitian
   d. Other (specify)_____

2. What best describes the last time you saw a Dietitian. **(Circle One)**

   a. Never
   b. Less than 1 year ago
   c. 1-5 years ago
   d. 5-10 years ago
   e. Other (specify) _____

3. What best describes your living situation. **(Circle One)**

   a. Live alone
   b. Live with parents
   c. Live with spouse or one good adult friend
   d. Live with one adult and one or a few children
   e. Live with many people

4. How would you describe the support loved ones give you with respect to your diabetes. **(Circle One)**

1	2	3	4	5
Very Supportive	Moderately Supportive	Somewhat Supportive	Moderately Unsupportive	Very Unsupportive

5. How would you describe the support loved ones give you with respect to your meal plan. **(Circle One)**

1	2	3	4	5
Very Supportive	Moderately Supportive	Somewhat Supportive	Moderately Unsupportive	Very Unsupportive

6. How many of the following items have you used. **(Circle all that are true)**
   a. A Computer
   b. A VCR
   c. An Alarm Clock
   d. A Calculator
   f. None of the above

7. How many of the following items have you programmed. **Ex:** You have set the VCR to record a future program. **(Circle all that are true)**
   a. A Computer
   b. A VCR
   c. An Alarm Clock
   d. A Microwave Oven
   f. None of the above

8. What is the highest level of education that you have completed.

   _____

9. What do you do for a living. **(give your job title).**

   _____

10. How hectic would you describe your life to be. **(Circle One)**

    a. Very hectic
    b. Slightly hectic
    c. Neither hectic or calm
    d. Slightly calm
    e. Very calm

THANK YOU

APPENDIX C
Abstracts

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Accuracy of Carbohydrate Counting In Subjects Undergoing Intensive Diabetes Management

Carbohydrate (CHO) counting is a dietary strategy often utilized in intensive management. Since units of Regular insulin are often based on grams of CHO to be consumed (usually as units/10g CHO), accuracy is very important. The objectives of this study were: to assess accuracy of CHO counting and to determine predictors of accuracy (glycated hemoglobin , self-efficacy, quality of life, accuracy in self-monitoring of blood glucose (SMBG) reporting as assessed using Medisense companion 2 glucose meters equipped with memory). Ten subjects, who were part of a study comparing different methods of adjusting insulin dosages to food intake, were asked to complete 4 day food records at Times: 0, 2 and 4 months. They kept detailed log sheets where they recorded grams of CHO per meal and snack. Log sheet values were compared with values obtained from food records. There was a significant correlation between log sheet values and food record values ($r=0.68$, $p< 0.01$). Of the 287 values generated, 51% were within 10g & 70% were within 20g CHO. Accuracy of CHO counting was associated with accuracy in SMBG reporting ($p<0.0001$). No other significant associations were found. Accuracy in SMBG reporting may be a useful predictor of the patient's ability to accomplish carbohydrate counting strategies.