STRESS, APPRAISAL, AUTONOMOUS SUPPORT AND COPING: AN INTEGRATIVE PERSPECTIVE OF ADULT TYPE 2 DIABETES MANAGEMENT IN NEWFOUNDLAND AND LABRADOR

by

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ABSTRACT

In the present study, data was collected from 165 adult type 2 diabetes patients in Newfoundland and Labrador to understand their psychosocial behaviour associated with blood glucose (*HbA1c*). Patient characteristics and the effect of four types of psychosocial behaviour on *HbA1c* are examined. A high prevalence of poor glycemic control is found in the participants having $BMI \geq 35$. The participants with higher stress have a negative appraisal of diabetes. The highly stressed group has a tendency to use emotion-oriented coping and to have a poor perception of autonomous supportiveness.

Two path models are developed conducting regressions analyses. The first one shows that stress, appraisal and coping can explain 7.4% of the variance in *HbA1c*. The second path model shows that appraisal plays a role of mediator and can explain 5.8% of the variance in *HbA1c*. Finally, 50.4% of the variance in stress can be explained by appraisal, coping and autonomous perception.

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List of Symbols and Acronyms

Symbol/Acronym	Description
ADS	Appraisal of Diabetes Scale
BMI	Body Mass index
CCHS	Canadian Community Health Survey
CDA	Canadian Diabetes Association
CISS	Coping Inventory of Stressful Situations
HbA1c	A measure of glycated haemoglobin
HCCQ	Health Care Climate Questionnaire
HREA	Health Research Ethics Authority
HRQOL	Health Related Quality of Life
ILI	Intensive Lifestyle Intervention
NPHS	National Population Health Survey
PAID	Problem Areas in Diabetes
SDT	Self-Determination Theory
TMSC	Transactional Model of Stress and Coping
WHO	World Health Organization

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1 Chapter 1

Introduction

1.1 General

In the 20th century, significant improvements in nutrition and living conditions in industrialized/developed countries led to a decline in the level of major infectious diseases and the emergence of a number of chronic conditions (Yarnell and O'Reilly, 2013). Diabetes is one of the chronic non-communicable diseases that causes personal suffering together with immense family and societal burden, while posing a major threat to the health care system. Current estimates show that diabetes is the sixth leading cause of death in Canada (Statistics Canada, 2013). The International Diabetes Federation estimates that approximately 285 million people worldwide have diabetes, which is projected to increase to 438 million by 2030 (Wellsource, 2013). In recent years, the World Health Organization (2009) recognized diabetes as a highly prevalent chronic metabolic condition and a major cause of substantial morbidity and mortality, which is treatable but not curable. Diabetes is classified into four types: (i) type 1 diabetes primarily develops during childhood or adolescence, (ii) type 2 diabetes mainly develops in adults, (iii) gestational diabetes occurs temporarily during pregnancy, and (iv) miscellaneous type includes unusual or rare inherited/acquired causes of diabetes. A subtype of diabetes is the Latent Autoimmune Diabetes of Adulthood (LADA) which has features in common with both type 1 and type 2, and is sometimes refer to as type 1.5.

The present study is focused on type 2 diabetes. In type 2 diabetes, patients' blood glucose level is chronically elevated because the pancreas is no longer able to produce enough insulin or the body does not properly use the insulin it makes. As a result, glucose builds up in the bloodstream

instead of being used as energy. Approximately 90–95% of the diagnosed cases of diabetes are type 2 (Shah et al., 2012).

Type 2 diabetes has a steeply rising trend with age and is highly prevalent in the obese population. The risk of developing type 2 diabetes increases with Body Mass Index (BMI) (Colditz et al., 1990; Must et al., 1999). Compared with normal-weight adults, obese populations have a 3–7 times higher risk of developing type 2 diabetes, which could rise to 20 times if the *BMI* is greater than 35 (Mokdad et al., 2003; Field et al., 2001). Moreover, type 2 diabetes is strongly associated with a number of microvascular and macrovascular complications, which decrease the quality of life and could lead to premature mortality (Sikdar et al., 2010). Jeerakathil et al. (2007) showed that type 2 diabetes patients might have a two-fold increased risk of stroke within the first 5 years of diagnosis as compared with the general population. It has been estimated that type 2 diabetes related complications could reduce life expectancy up to 10 years (Department of Health, UK, 2001). Type 2 diabetes related complications may begin 5–6 years before diagnosis and the actual onset of diabetes might occur ten years or more before clinical diagnosis (Harris et al., 1992).

Previous studies such as the Diabetes Control and Complications Trial Research Group (DCCT) (1993) showed that patients who maintained *HbA1c* (a measure of glycated haemoglobin to get an overall picture of blood sugar level) close to the normal level have significantly fewer clinical complications such as retinopathy, neuropathy and nephropathy. Moreover, research work for decades on type 2 diabetes convincingly demonstrates that better *HBA1c* is associated with improved quality of life, better long-term health outcomes and healthy aging. Therefore, maintaining the glucose level as close to a normal level as possible is very important.

1.2 Rationale and Scope

Over the last several decades, the prevalence of diabetes in Canada has increased dramatically. According to the Canadian Diabetes Association (CDA, 2014b), 11 million Canadians are living with diabetes or prediabetes—among them three million are diagnosed with type 2 diabetes. Type 2 diabetes is one of the fastest growing diseases in Canada—more than 60,000 new cases yearly. The CDA (2012) reported that 52,000 people in Newfoundland and Labrador have diabetes, which is the highest diabetes prevalence in Canada—9.3% in 2012 and projected to 14.4% by 2020, while in Canada the prevalence was 7.6% in 2012 and projected to be 10.8% by 2020. The prevalence is even higher in seniors (65 years plus) in Newfoundland and Labrador than other provinces—19.7% in Newfoundland and Labrador while 14.6% in Canada (Statistics Canada, 2005). Such a high prevalence and rapidly increasing rate are alarming to the health care systems of the province and also a burden to society and families. It is estimated that the direct and indirect costs to the government of Newfoundland and Labrador associated with diabetes is currently over $254 million per year, which might increase to over $322 million per year by 2020 if appropriate actions are not taken. In 2016, approximately 179,000 people living in Newfoundland and Labrador (35% of the population) were living with diabetes or prediabetes (CDA, 2016). Moreover, insulin pumps and their supplies are generally expensive. Therefore, the CDA recommended that the government of Newfoundland and Labrador establish a provincial diabetes program to address these issues. The CDA also recommended healthy lifestyle tips as the first step to fight against or live with diabetes.

The success of clinical treatments and lifestyle interventions for type 2 diabetes management depends on adherence to daily treatment regimens and maintaining better physical and mental health over a long period of time. As diabetes is a long-term chronic condition, managing physical

and mental health over a prolonged period of time is very difficult. It has been recognized that more than 50% of diabetes patients do not achieve optimal glycaemic control, despite the availability of advanced treatment. Therefore, a large multi-national program DAWN (Diabetes Attitudes, Wishes and Needs) has been initiated to examine psychosocial factors influencing self-management which might be potential barriers to glycemic control (DAWN, 2014).

Despite the many studies available in the literature on type 2 diabetes to identify its cause, prevention, control and management, the exact causes are still not clear. There is still a huge lack of understanding of the interaction between psychosocial factors and their effects on diabetes management. The importance of psychosocial factors in patient care, in general, was identified several decades ago (e.g. Engel, 1977). The Canadian Diabetes Association (2014b) recognized that symptoms of depression affect at least 30% of diabetic patients, and depression and stress are interrelated. Chronic emotional stress is considered a significant risk factor for the development of depression among diabetes patients (Pouwer et al., 2010). Existing evidence suggests that the suffering caused by diabetes might exacerbate emotional stress, depression and *HbA1c*. Diabetic patients with emotional stress are less adherent to medical care and suffer a higher level of complications (Piette et al., 2004). Therefore, in recent decades diabetes-related stress has received significant attention by many researchers around the world. According to the American Diabetes Association (2013), the blood sugar level of a diabetic patient could be increased significantly by stress. On the other hand, diabetes itself could be a stressor and can create stress (Lloyd et al., 2005). It is hypothesized that, if the diabetes-related stress could be managed, a patient might better control *HbA1c* at the targeted level. However, a question is: how stress is related to other psychosocial factors that affect *HbA1c* management.

The management of stress depends on how the patient reacts to a stressor. Lazarus and Folkman (1984) suggested that patients' reaction to a stressor can be represented by cognitive appraisal. Under a stressful situation, a patient reacts in two different ways: (i) gets threatened (i.e. negative appraisal) and (ii) seeks resources to minimize the stress (i.e. positive appraisal). Carey et al. (1991) showed that the appraisal influences psychosocial adjustment and glycemic control (maintaining low *HbA1c*). Among different psychosocial adjustments, appraisal might influence the coping strategies a patient uses to overcome a stressful situation, which play a major role in physical and psychological well-being (Macrodimitris and Endler, 2001; Shah et al., 2012). Endler and Parker (1990) identified three general types of coping: (i) task-oriented effort to solve the problem, (ii) emotion-oriented reaction to reduce stress, and (iii) avoidance-oriented coping to distract or divert the stress.

Healthcare providers might play an important role in the stress management of a diabetes patient. This could be assessed from the patients' perceptions of whether the system is autonomy supportive (Williams et al., 1998a). A good perception could change the motivation to develop competence, which eventually plays a significant role in *HbA1c* control (Williams et al., 2004).

1.3 Purpose of Study and Objectives

Previous studies suggest that psychosocial behaviour needs to be studied properly to understand diabetes management strategies. Although the prevalence of diabetes is highest in Newfoundland and Labrador in Canada, problem-specific data has not been collected on this population. The existing studies available in the literature are based on secondary data (Sikdar et al., 2010; Roche and Wang, 2014). The aim of the present study is to identify whether and what psychosocial factors influence the diabetes patients in Newfoundland and Labrador with regards to maintaining an optimal glucose control. In order to identify these factors, following a review of the literature, four

psychosocial factors—stress, appraisal, coping and perception of autonomous health care supports—are considered in this study.

The main objective of this study is to identify any relationships between patient characteristics (e.g. age, *BMI*), psychosocial variables and blood glucose level. To achieve this objective the following steps have been taken:

i. Characterize stress level and its variation among the patients;
ii. Identify how patients differ in their thoughts and feelings about having diabetes and its relation to diabetes control;
iii. Identify the type of coping strategies the patients follow to deal with this chronic disease;
iv. Evaluate the effectiveness of health care providers' support in the development of autonomy or self-confidence such that effective diabetes control strategies are utilized; and
v. Identify any confounding effects of some socio-demographic, lifestyle, self-care and clinical variables on stress, appraisal, coping styles and autonomy supportiveness and thus on glycemic control.

A cross-sectional study is conducted, which involves primary data collection together with a comprehensive statistical analysis. The hypotheses of this study are that in the study population:

- Diabetes-related stress is a factor associated with poor glycemic control as evidenced by higher levels of *HbA1c*;
- Patients' appraisal affects stress and coping styles and eventually elevation of *HbA1c level*;
- Patients' capacity to internalize the autonomy support into their motivation system improves patients' appraisal, coping styles and thus controls *HbA1c*;

- Coping styles (task, emotion and avoidance) modify the diabetes-related stress;
- There is a pathway between stress, patients' appraisal, autonomy support, coping and *HbA1c*, which can be determined through regression analysis of the data.

1.4 Organization of the thesis

The thesis consists of six chapters. The outline is as follows:

- Chapter 1 highlights the background, scope and objectives of the research.
- Chapter 2 contains a comprehensive literature review, primarily focused on the effects of psychosocial behaviour on type 2 diabetes management.
- Chapter 3 presents the research methods, which include the design of the present cross-sectional study.
- Chapter 4 presents the statistical analysis of data. In addition to descriptive statistics, inferential analysis results are included in this chapter.
- Chapter 5 contains the discussion of the results. The similarities and differences between the present study and other studies are discussed in this chapter. The limitations and potential application of the present research are also highlighted.
- Chapter 6 presents the conclusions. Some recommendations for future studies are also included in this chapter.

1.5 Major contributions

A major contribution of this study involves primary data collection on psychosocial behaviour of type 2 diabetes patients in Newfoundland and Labrador. To the best of the author's knowledge, this is the first time; a set of problem-focused data on type 2 diabetes patients has been collected on this population. Through conducting statistical analyses, some additional aspects of the psychosocial behaviour of the participants in Newfoundland and Labrador, as compared to other studies, have been identified.

2 Chapter 2

Literature Review

2.1 Introduction

The International Diabetes Federation estimated that more than 415 million adults globally were diagnosed with diabetes in 2015. This has been projected to increase to 642 million by 2040. Moreover, approximately 1 in 2 (46%) patients with diabetes is currently clinically undiagnosed. As discussed in Chapter 1 there are mainly three types of diabetes. Among them, type 2 diabetes is the focus of the present study. There are many risk factors associated with type 2 diabetes, such as family history, overweight, poor diet, physical inactivity, age and ethnicity. Recent studies also suggest that diabetes and mental health are interrelated (DAWN, 2014). The psychological behaviour of diabetes patients could significantly influence glycemic management (Shah et al., 2012). While a wide range of studies related to type 2 diabetes is available, the literature review presented in this chapter is mainly focused on the effects of psychological behaviour on diabetes management.

2.2 Current state of type 2 diabetes management

In order to understand the complex mechanism of type 2 diabetes and combat this exponentially growing chronic disease, multidimensional research programs have been initiated in the past. Similarly, to provide better care, multifactorial approaches have been used in recent years, instead of relying simply on the biomedical model of health. The research findings are also regularly incorporated in clinical practice guidelines—for example, the Clinical and Scientific Section of the Canadian Diabetes Association has updated the recommendations for diabetes care every 5 years, since 1992.

In recent decades, a large number of clinical and public health studies have followed an epidemiological approach to understand the determinants and distribution of bio-psychosocial aspects of patients' chronic conditions to a higher degree. Bio-psychological research has broadened its concern to include the biology, psychology (e.g. thoughts, emotions, and behaviours) and social (e.g. socio-economical, socio-environmental, and cultural) aspects of diseases, in contrast to only one of the three aspects of the disease. Santrock (2007) stated that health might be better understood if the bio-psychological factors are included rather than dealing with purely the biological issues. In a study on a Canadian population, Bryant et al. (2010) stated that "the mechanisms by which type 2 diabetes comes about are not well understood." Therefore, to understand the entirety of diabetes a wide range of research is essential.

Knowler et al. (2002) showed that changes in lifestyle have a significant positive impact both on type 2 diabetes incidence and management—approximately twice as effective as metformin (an oral diabetes medicine). However, the cost involves in training for lifestyle change could be high; therefore, the socio-economic condition plays a major role. Haggerty et al. (2003) showed that effective treatments are available for both the physical and mental health aspects of diabetes, but they are often provided separately, which is inefficient and inconvenient as this ignores the interaction between these two aspects of the condition. They hypothesized that, because of this non-interactive treatment, the success in *HbA1c* control is relatively low with medical treatments only. Elaine et al. (2010) conducted a meta-analysis to identify effective psychosocial interventions that could improve the physical and mental health of diabetes patients. They identified positive implications of combined physical and mental health interventions and coordination of care, and suggested that an integrated approach would be more efficient to understanding the different aspects of diabetes and thus enhance diabetes management.

Depressive disorder is highly prevalent in diabetic patients (30%) as compared to people without diabetes (Anderson et al., 2001; Ali et al., 2006; Barnard et al., 2006). However, depression might come from many different sources, such as stressful life events, poor control of diabetes, duration of diabetes and limited social support (Robinson et al., 2013). Some of the factors related to development of depression, which in turn affect diabetes management, are shown in Fig. 2.1.

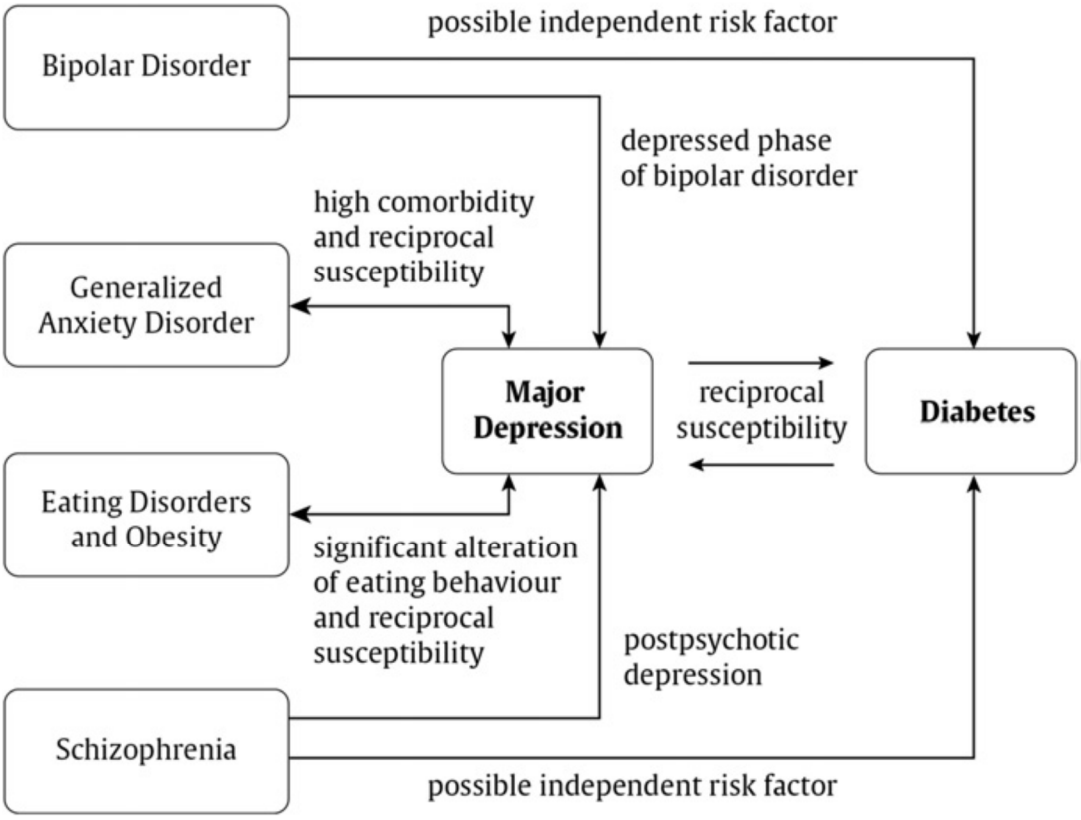

Fig. 2.1: Interplay between patient characteristics, depression and diabetes (after Robinson et al., 2013)

Shah et al. (2012) showed that the patients having high diabetes related stress have a negative appraisal of the disease. Once they apprise negatively, they try to use avoidance-oriented coping and passive recognition, which in turn increase depression.

2.3 Psychosocial factors

There are many psychosocial aspects that could be related to diabetes management. However, in the present study, four psychosocial factors, namely stress, appraisal, coping and autonomy perception of health care supports, are considered. In the following sections, the literature review on these four factors is presented.

2.3.1 Diabetes related stress

Stress has been considered one of the key psychosocial factors that affects many chronic diseases. It is now well accepted that stress and illness are interrelated, and stress level varies with pre-existing vulnerability factors (Cohen & Edwards, 1989; Cohen & Wills, 1985; Kessler & McLeod, 1985), such as person's early experience as explained by Bowlby (1969) in the attachment theory, differences in social support systems, skills, attitudes, beliefs, and personal characteristics. Persons exposed to stress tend to engage in poor health practice that can manifest a disease state (Cohen & Williamson, 1988; WHO, 2000).

The relationship between stress and diabetes has been recognized in previous research but its complexity and directionality are not resolved yet. Stress itself could be a cause of the onset of diabetes; on the other hand, management of and adherence to diabetes care are often difficult which also create stress in patients with diabetes (e.g. Polonsky et al., 1995; Welch et al., 1997; Lloyd et al., 2005). Lloyd et al. (2005) mentioned that patients with type 2 diabetes may experience different types of stress with different levels of severity that could affect glucose control to different degrees. Although stress might come from different sources, diabetes related stress is a kind of stress that arises from regular diabetes management activities (e.g. hospital visit, glucose monitoring, eating recommended diet, physical activities) over a long period of time and worrying about the development of diabetes related complications that might exacerbate emotional stress and affect

self-care behaviour and thereby glucose levels (DCDT, 1993; Polonsky et al., 1995; Welch et al., 1997; Lloyed et al., 2005).

Previous studies also found that the stressful condition is a triggering factor of diabetes or at least a possible cause of increasing the risk of developing diabetes (Vialettes et al., 1989; Kawakami et al., 1999; Pouwer et al., 2010). Pouwer et al., (2010) reviewed a number of prospective epidemiological studies that investigated the associations between different forms of emotional stress and the development of type 2 diabetes mellitus. The gender based studies show that men are more vulnerable to stress: men are twice likely to develop diabetes compared to women (Rod et al., 2009; Kato et al., 2009). Toshihiro et al. (2008) found that stress in daily life is associated with an increased risk for the development of type 2 diabetes. Moreover, Surwit et al. (2002), Raikkonen et al. (2003), Zhang et al. (2006) found that the persons who reported a high level of stress and high hostility were more likely to have higher insulin resistance levels.

Over the last few decades, several studies also documented that the majority of patients with diabetes have elevated rates of depression and stress (Polonsky et al., 1999; Anderson et al., 2001; Lloyd et al. 2005; Shah et al., 2008; DAWN, 2014). The CDA (2014) recognized that depression is highly prevalent in diabetes patients and these symptoms affect at least 30% of them. Patients with depressive symptoms reported significantly more diabetes related stress than their counterparts (Shah et al., 2012; Gruen, 1993; Tennant, 2002). Pouwer et al. (2010) mentioned that the combination of these two interrelated factors (i.e. stress and depression) results in poor health outcomes in patients with type 2 diabetes. Roche and Wang (2014) showed that early diabetes diagnosed males and females are more stressful (59.4% male and 68.3% female) than their late diagnosed counterparts (49.9% male and 62.9% female), which might be interpreted as the diagnosed patients are more stressful than non-diagnosed. In other words, if a person knows that

s/he has diabetes, the person could be worried about maintaining glucose levels, which could increase diabetes related stress. Piette et al. (2004) documented that diabetes patients with emotional stress are less adherent to medical care and suffer a higher level of complications. On the other hand, Polonsky et al. (1995) showed that diabetes related emotional stress is different from general emotional stress, and it should be assessed differently.

Stressful experience might affect diabetes management both through physiological and psychological mechanisms, although it is very difficult to separate them. For example, one of the symptoms of type 2 diabetes is mood swings, which are considered the result of sugar imbalance. On the other hand, when the blood sugar drops the mood can swing to an irritable condition until energy stores are replenished with food. This physiological change that occurs in patient affects them emotionally and the body's response creates stress. This stress comes from biological sources through the metabolic disorder. On the other hand, management and adherence to diabetes are often difficult which can affect patients' behaviour and create stress. Lloyed et al. (2005) differentiated these mechanisms into physiological and behavioral pathways. Whatever mechanisms stress follows or whatever sources the stress comes from, it disturbs glucose metabolism (Cox et al., 1984).

Although this transactional relationship between stress and diabetes has long been considered as an important issue, the research is still ongoing because the relationship between stress and *HbA1c* with other psychosocial variables is not fully understood. For example, patients can perceive stress in different ways which can make for differences in glucose control. In recent years, the influence of stressful experiences on diabetes patients has been identified as one of the major areas of research to improve diabetes management (Surwit et al., 2002; DeVries et al., 2004; DAWN, 2014). A number of studies show that diabetes-related stress could affect self-care behaviour (e.g.

Polonsky et al., 1995; Welch et al., 1997). Lloyd et al. (2005) conducted a comprehensive review of available research to show the link between stress and diabetes through psychological mechanisms and via behaviour. They suggested three useful approaches to manage stress: (i) changing stress producing situations, (ii) changing physiological response and (iii) de-emphasizing the stress with destruction. Lloyd et al. (2005) also mentioned that the link between stress and diabetes is more evident in smaller in-depth studies as compared to large studies using self-report checklists.

In summary, although stress and diabetes are found to be associated, care must be taken during the interpretation of the results. Various factors, such as the focus of study and measurement tools, are different in the studies available in the literature and therefore all the information from different studies could not be easily placed in a common framework to generate solid conclusions.

2.3.2 Appraisal of diabetes

The current models of stress emphasize the mediating role of the appraisal process in the stress–health relationship. The appraisal is a cognitive evaluative process that assesses the meaningfulness and relevance of perceptual and/or emotional schematic experience and determines the significance of that experience for his/her well-being. Previous researchers identified two components of appraisals: namely primary and secondary (e.g. Lazarus & Folkman, 1984). Generally, the initial cognitive appraisals progress from primary to secondary. In the primary appraisal, the person evaluates the potential threat of confronting a situation; while in the secondary appraisal, the person evaluates their own capacity to alter this situation and manage their emotional reactions. Both components eventually generate the preparation, facilitation, and support for problem-solving and active coping. Based on this concept, an empirical framework, named as the 'transactional model of stress and coping (TMSC),' was developed by Lazarus and

Folkman (1984) for assessing the processes of coping with stressful events. This model was also used by others (e.g. Honey et al., 2003) for different forms of depression such as post-partum depression. The TMSC has empirical evidence that appraisal of a stressor evaluates psychosocial outcomes of a stressor (e.g. diabetes) more accurately than does the stressor itself. The model explains the concept of appraisal as a cognitive evaluative process which leads individuals to perceive a given situation in different ways.

In the case of diabetes, the way a person appraises his/her diabetes is likely to influence their overall morale or psychological adjustment. Based on this hypothesis, Carey et al. (1991) conducted a study and developed a psychometrically sound validated questionnaire for diabetic patients, named the 'Appraisal of Diabetes Scale (ADS)' to measure patients' primary and secondary appraisal processes; whether they appraise it positively or negatively. The ADS can measures patients' positive/negative cognitive feelings and attitudes. The purpose of their study was to identify empirical evidence of potential relationships between stress and appraisal during the course of the diabetes. It is shown that the appraisal has moderate and significant effects on diabetes control. Macrodimitris and Endler (2001) also examined some aspects of appraisal and showed that type 2 diabetes perceived control moderates the relationships between depression, coping and metabolic control.

To the knowledge of this author, this empirical evidence is used only by Shah et al. (2012), who examined the effects of stress and appraisal on *HbA1c* and found a significant relationship between these variables. They found that the appraisal has some effects on stress and also on coping styles. It has been shown that patients' appraisal plays a mediating role between stress and coping. Patients who appraise diabetes negatively are very upset about their diabetes and fail to use

problem focus coping. Further investigation is required to understand the complex relationship(s) between these variables and their effects on *HBA1c*.

2.3.3 Coping strategies

Another important psychosocial aspect related to chronic disease is coping styles which explains how people react to various difficult, stressful or upsetting situations (Boekaerts and Roder, 1999; De Ridder, 1997). Several studies suggested that the coping strategies could be used to deal with some issues, such as stress and depression, related to chronic illness through psychological adjustment (Aldwin, 1994; Endler et al., 1998; Reid et al., 1994; Taylor, 1999). The American Association of Diabetes Educators has recently endorsed healthy coping as one of the key self-care behaviours for patients with diabetes. Conway and Terry (1992) found that the choice of an appropriate problem-focused coping style can control diabetes. Some studies (e.g. Maes et al., 1996; Smari and Valtysdottir, 1997) show a strong relationship between glycemic control and problem-focused reaction. More specifically, they found some positive correlations between emotional and avoidance-oriented coping and high blood glucose levels. While there are some contradictory results about the role of emotion and avoidance-oriented coping on glucose levels (e.g. Hanson et al., 1989; Smari and Valtysdottir, 1997), recent studies (Shah et al., 2012) suggest that negative emotions could be one of the causes of difficulties a patient faces in controlling blood glucose. Shah et al. (2012) also found that there are some direct significant effects of passive resignation, avoidance and diabetes integration on diabetes-related stress, which also support the findings of Welch et al. (1997). Fisher et al. (2007) conducted a comprehensive systematic review of the studies available in literature to assess the effects of healthy coping in diabetes management and then identified some effective or promising interventions. It has been suggested that diabetes self-management education, together with supportive interventions, can lead towards healthy

coping. The group of individuals with poor coping is less likely to use a problem-focused approach to cope with their disease. Kroese et al. (2013) also showed that intervention is a promising approach for the development of proactive coping skills and self-care behavior in diabetes patients.

2.3.4 Perceived autonomy support

The long-term persistence and adherence to medicine and a healthy lifestyle are equally important in controlling *HbA1c*. While there might be adequate treatment and appropriate diabetes management strategies available, proper motivation and support from the health care providers are required for better outcomes. This could be assessed from patients' perceptions of whether the system is autonomy supportive (Williams et al., 1998a, Williams et al., 2009). Autonomy is a concept that is derived from the self-determination theory of motivation (SDT). The SDT suggests that autonomy support from others helps motivate the patients to change their health behaviour. The SDT focused on the individual's inherent growth tendencies and their innate psychological needs using intrinsic and extrinsic motivations and identifies three basic innate needs namely competence, relatedness and autonomy. Koestner et al. (2008) showed that autonomous motivation performs much better than controlled motivation in reaching a goal. Williams et al. (1998a) found some empirical evidence of SDT in diabetic patients. Patient's perception of autonomy support from the health care providers is an extrinsic factor that changes autonomy motivation to develop competence, which eventually plays a significant moderate role on *HbA1c* control. Williams et al. (2004) conducted a longitudinal study to test the SDT process with type 2 diabetes patients. It has been shown that patients having enhanced autonomous motivation and perceived competence can better manage their glucose level. Klein et al. (2004) reviewed several papers and identified a number of behaviour change techniques which could be facilitated in office practice that are

helpful for weight management and thus on diabetes control. They also tried to investigate whether the autonomy support from care providers has an important role in the behaviour change process.

Yamakawa and Makimoto (2008) conducted an exploratory qualitative study to investigate the effects of positive/negative experience or perception among diabetes patients who received regular care. It was observed that the patient who received intervention from the care providers and had a positive experience and perception of the disease coped well with diabetes and eventually benefited in *HbA1c* management. Raaijmakers et al. (2014) conducted a cross sectional study and showed that perceived autonomy support correlates positively with self-management skills, which improves the health-related quality of life (*HRQOL*). The effect of autonomous supportiveness is a relatively unexplored area, and the author of the present study believes that further investigation is required in this area for development of better glucose management strategies.

Autonomy-supportive communication from care providers facilitates patients with more self-determined motivation and perceived competence, and thereby more long-lasting behavioral change. Previous studies show that a higher level of autonomy support, in contrast to a controlling style communication, has some positive influence on long-term chronic disease management and self-regulated behavior, such as smoking cessation, weight loss, glucose control, and adherence to medication (Williams et al., 1996; Williams et al., 1998b; Williams et al., 1998a, Williams et al., 1999; Williams et al., 2002; Williams et al., 2011; Ng et al., 2012).

2.4 Additional Factors

Previous research shows that in addition to psychosocial factors, as described above, a number of other factors influence type 2 diabetes management. These factors can be categorized into the following four groups:

a) Socio-demographic factors (e.g. age, sex, marital status, education, occupation),

b) Lifestyle factors (e.g. smoking, alcohol consumption, recreational drugs),

c) Self-care behaviour (e.g. exercise, blood glucose monitoring, diet), and

d) Clinical factors (treatment strategies, oral medication, insulin and pump).

Although the effects of these factors on type 2 diabetes are described under different headings in the following sections, for clarity, these factors are interrelated and might have combined effects on diabetes management.

2.4.1 Socio-demographic factors

A wide variety of socio-demographic factors might directly or indirectly influence diabetes management. Some of the key factors are discussed below.

2.4.1.1 Age

Type 2 diabetes in adult populations has been found in a wide range of age—even in a person under 20 years of age. However, most of the adults are diagnosed with type 2 diabetes at the age of 40 or more. In Canada, diabetes screening is recommended every three years after the age of 40. Therefore, there might be some clinically undiagnosed diabetes patients. Harris et al. (1992) reported that type 2 diabetes might be undiagnosed for 9–12 years, which could cause additional complications. A study on 466 diabetes patients in Newfoundland and Labrador conducted by

Roche and Wang (2014) shows that 74.2% of patients were diagnosed late. They also found that the percentage of late diagnosis is higher in male (78.9%) than female (68.5%) patients.

2.4.1.2 Duration of diabetes

The duration of diabetes also affects glycemic management. The risk of depression increases with the duration of diabetes, which in turn affects diabetes management (Robinson et al., 2013). As the increase in insulin resistance and decline in beta cell function are the two main problem in type 2 diabetes patients, glucose management likely worsens over time (Turner et al., 1999), and therefore treatment should be dynamic as the therapeutic requirements increase with duration of disease (Harper et al., 2013). Polonsky et al. (1995), however, showed that older patients reported no serious diabetes-related problems, which indicates that the patients might adapt to the disease with age or duration of diabetes.

2.4.1.3 Gender

In general, males differ from females not only biologically but also in attitudes, expectations and social supports, which could be related to diabetes management. Women normally view type 2 diabetes as having negative effects on their life and worry about the complications related to this disease (Fitzgerald et al., 1995), while the men are worried about the limitations the disease might impose (Jonsson et al., 2000) although they believe it is a controllable disease (Brown et al., 2000). Men show lower diabetes related stress than women (Rubin et al., 2006). Women reported that they receive higher levels of support from the health care team and see the benefit of self-management; however, men reported a lower expectation of the benefit from self-management (Gucciardi et al., 2008). A study on a German population shows a gender difference in the association of adherence and poor glycaemic control: poor glycaemic control was found in 37% in men and 19% in women who reported non-adherence to medication (Raum et al. 2012). Huxley

et al. (2006) showed a 50% higher risk of death from coronary heart disease associated with type 2 diabetes in women than that of in men.

2.4.1.4 Marital status

A married individual can get support from his/her partner to enhance the capacity to manage long-lasting chronic diseases such as type 2 diabetes and can maintain better physical and mental health than unmarried or widowed counterparts. However, very few studies have been done with specific focus on the effect of marital status on type 2 diabetes management, although in many studies, marital status has been considered as a confounder. Cornelis et al. (2014) showed that not being married, and more specifically widowers, have a high risk of type 2 diabetes, which might be due to unfavorable changes in lifestyle, diet and adiposity.

2.4.1.5 Socio-economic status

Socio-economic status (SES)—an individual's position relative to other people in the society—has some link to type 2 diabetes, especially in high income countries (Robbins et al., 2005; Kumari et al., 2004; Cox et al., 2007; Maty et al., 2010; Agardh et al. 2007 & 2011, Ross et al., 2010; Sacerdote et al., 2012). The SES includes three indicators, namely education level, income and occupation, which are interrelated but not interchangeable. A case-cohort study in eight European countries showed that the low SES group had a higher prevalence of type 2 diabetes (Sacerdote, et al., 2012). This study also showed that there might be an inverse relationship between education and type 2 diabetes. The relationship between SES and type 2 diabetes management is more complex, because SES does not have a direct biological effect on diabetes. However, it has indirect effects on diabetes management through changing lifestyle, behaviour, access to health care services and taking advantage of health information. Adults with high educational level are more receptive to diabetes management massages from heath care providers than their counterparts.

Bryant et al. (2010) conducted a two-pronged study on the issue of the incidence and management of type 2 diabetes. In the first prong, they analyzed two large data sets from the Canadian Community Health Survey (CCHS) and National Population Health Survey (NPHS) and identified risk factors of developing type 2 diabetes. The CCHS data shows that having type 2 diabetes is strongly related to income and these differences increase with age. The low-income older Canadians are twice as likely to have type 2 diabetes compared to wealthy older Canadians. The analysis of NPHS data shows that poverty increases the risk of developing type 2 diabetes by 24% over a two year period. Moreover, those who have been living longer often in poverty over the 12 year study period show 41% greater chance of developing type 2 diabetes. In the second prong of their study, Bryant et al. (2010) studied the effects of low income on the day-to-day lives of people trying to manage their type 2 diabetes by interviewing 60 patients in Toronto. Thematic analyses demonstrate the importance of the social determinants; and more specifically, insufficient income, inadequate and/or insecure housing and food insecurity are identified as key barriers to the effective management of type 2 diabetes. It was concluded that besides individual based risk factors, policy changes that secure adequate income, affordable and stable housing, and easy access to the medications and supplies are also required for better diabetes management.

Based on a study on a population of Alberta, Rabi et al. (2006) showed that a low income population has a higher prevalence of diabetes and diabetes related complications. Even within the single payer health care system, low income individuals commonly visit their family physicians while the high income people prefer to go to speciality care (Dunlop et al., 2000). Dinca-Panaitescua et al. (2011) showed that type 2 diabetes is strongly related to income, age, education, overweight and lack of physical activity. Wamala et al. (1999) found that among Swedish women those who had lower education were 2.3 times more likely to develop diabetes.

Diabetes is not a disease of a particular profession; however, some associations between occupation and the development/management of type 2 diabetes have been observed. Gan et al. (2015) showed a high prevalence of type 2 diabetes in the shift workers, especially in men. Trief et al. (1999) found that work is not a significant predictor of *HbAlc*; however, psychosocial adaptation could be a significant predictor of positive appraisal and diabetes-related satisfaction. Moreover, diabetes-related quality of life is influenced by involvement with co-workers. A qualitative study revealed that occupation could influence self-management of type 2 diabetes—for example, taking insulin or eating doctor recommended food in public places (Pyatak, 2011). Hwang and Bugeja (2000) conducted a study on homeless diabetic patients and found that three quarters of the participants could not maintain their diabetes properly because of the diet at shelters, access to medications and supplies, co-ordination of medications with meals, alcohol consumption, drug use and mental-health problems.

2.4.1.6 Environmental factors

Frank and McCarthy (2016) identified a number of potential environmental perpetrators that could affect lifestyle, such as physical inactivity and eating habits, and thereby glucose management (Fig. 2). Environmental exposures could disturb cellular and physiological processes in type 2 diabetes patients through active, reactive or modulation of genome functions. Many factors, other than those listed in Fig. 2, could act as confounding, bias or reverse causality, which create difficulties in interpreting observational study data. In addition, they identified that inherited DNA could be a cause of variation in type 2 diabetes.

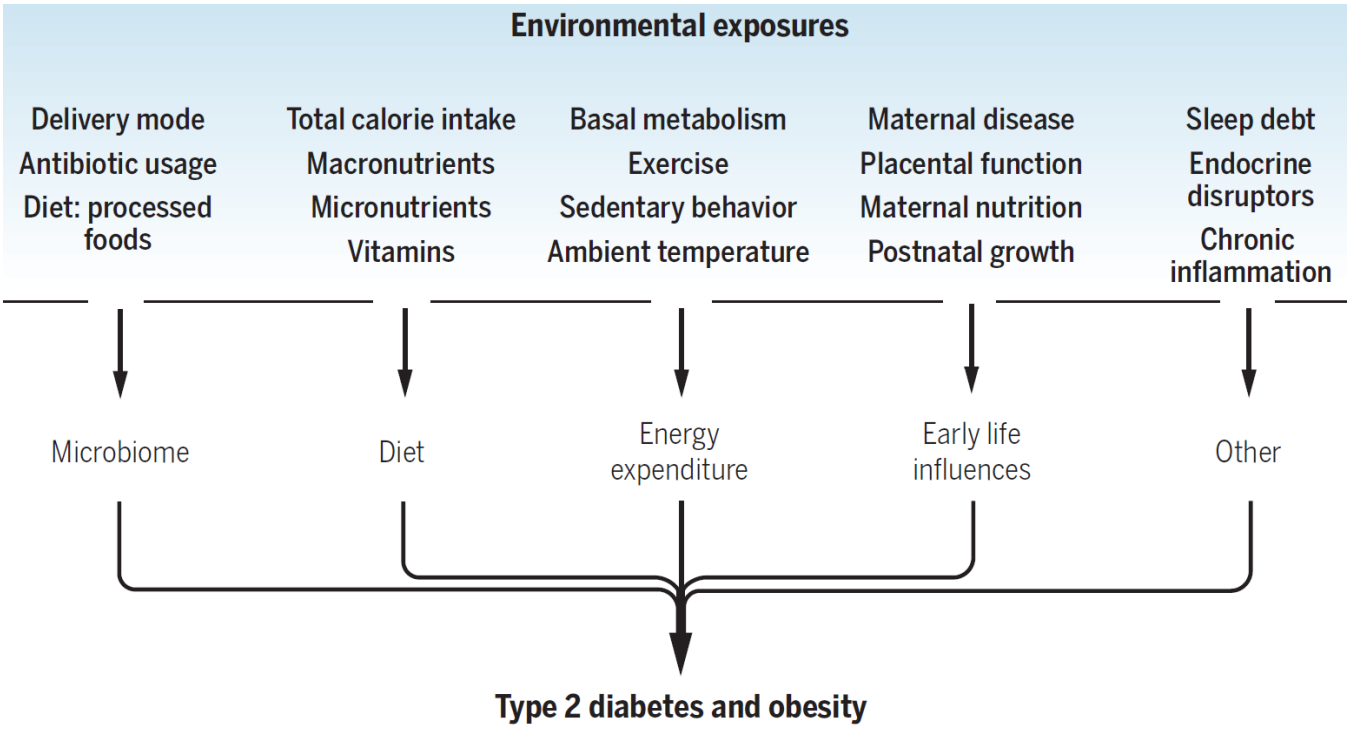

Fig. 2.2: Environmental exposures and mechanisms implicated in the development of type 2 diabetes and obesity (after Frank and MaCarthy, 2016)

2.4.1.7 Weight management

Approximately 80 to 90% of people with type 2 diabetes are overweight or obese, and the individuals with a higher BMI and diabetes have an increased risk of overall mortality (Wing, 2000; Wharton et al., 2013). However, it should be noted that not all overweight people become diabetic. Obesity complicates the management of type 2 diabetes by increasing insulin resistance and blood glucose concentration (Maggio & Pi-Sunyer, 1997). Klein et al. (2004) provided some specific recommendations for better management of weight, diet and physical activities. They discussed that weight management through lifestyle modification (diet/exercise) has a significant positive impact on both prevention and management of type 2 diabetes. Torgerson et al. (2004) mentioned that an initial 5% reduction of body weight significantly improves diabetes management by enhancing insulin action and decreasing fasting blood glucose concentrations.

Long-time weight management is the hardest task for most of the patients (National Institutes of Health, 1998). It is possible if diet and physical activities are maintained for a prolonged period. However, most of the time, patients find this difficult and this results in poor compliance and adherence to these regimes (Miedema et al., 2015). Therefore, behaviour therapy has been suggested as an effective method to develop skills needed to control problematic eating and maintain physical activity (National Institutes of Health, 1998). Care providers and office facilities might play an important role in this aspect (Klein et al., 2004).

One of the largest and longest randomized evaluations of intensive lifestyle intervention (ILI) for weight reduction is the Look AHEAD (2014) trial, where it is has been shown that the weight loss could have many health benefits including prevention and resolution of type 2 diabetes. It has been shown that a modest weight loss of 5% to 10% improves glycemic control. However, obese patients with diabetes have greater difficulties with weight loss as compared to obese individuals without diabetes (Wing et al., 1987). Bariatric surgery is another alternative that can results in sustained body weight and better management of type 2 diabetes. However, in Canada, this surgery is reserved mainly for patients of Class-III obese ($BMI \geq 40$) or Class-II obese ($BMI = 35–39.9$) with an increased number of comorbidities (Lau, 2010). Based on the fact that there is a close association between diabetes and obesity, in recent years there is a growing trend to combat these two epidemics in a common framework under the name of "diabesity."

2.4.1.8 Other factors

In addition to the above mentioned factors, many other personal behaviours might be changed due to diabetes, which in turn affect diabetes management. As they are not the main focus of the present study, a brief discussion is provided in this section. Moderate alcohol consumption shows as high as a 30% reduced risk of type 2 diabetes (Carlsson et al., 2005). Roche and Wang (2014) showed

a low smoking prevalence in males with diabetes; however, the smoking prevalence did not vary in females with or without diabetes. They also showed that the patients who have been diagnosed with diabetes at the early stage of the disease show fewer comorbidities than those in the late diagnosed group. Exercise with diet has been considered the most effective way to reduce the risk of diabetes and other diseases. Early studies show a low risk of diabetes in the active population. On the other hand, people with type 2 diabetes have a reduced exercise capacity. Schauer et al. (2009) showed that the patients with type 2 diabetes would significantly benefit from exercise; however, they are typically cardiovascularly unfit for a sufficient level of exercise and consequentially have a sedentary lifestyle that results in an increase in body weight and poor diabetes management.

2.5 Self-management education

Over the last decades, diabetes care has shifted towards multifaceted self-management education—a systematic intervention through patients' active participation. These programs combine psychological and behavioural interventions, and interactive and collaborative teaching that adapts to individual needs to increase capacity and confidence to self-manage their diabetes. A number of meta-analyses show that self-management education could reduce *HbA1c* by 0.36 to 0.81 (Bodenheimer et al., 2002; Chodosh et al., 2005; Minet et al., 2010). Jones et al. (2013) suggested that standardized instruments, such as the Problem Areas in Diabetes (PAID), could be used to assess patients' physiological behaviour. It has been suggested that a patient-centred learning approach could be the most effective behavioural intervention to empower individuals towards achievement of the goal, as shown in Fig. 2.3.

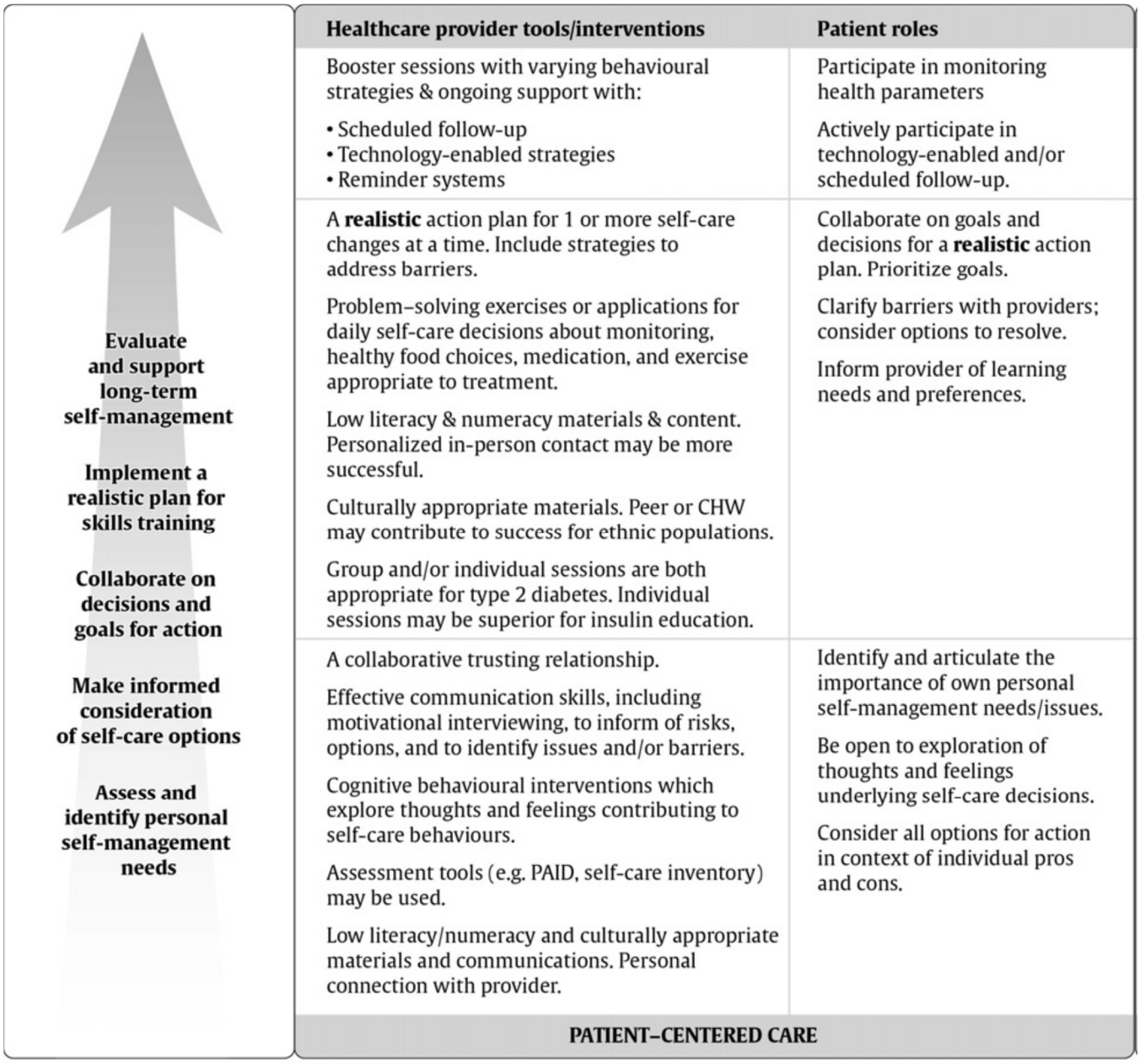

Fig. 2.3: Steps for successful development of self-management education for type 2 diabetes (after Jones et al., 2013)

2.6 Discussion of literature review

The literature review presented above critically examines the research findings of the effects of four psychosocial factors on glucose management. Among them, stress has been identified as one

of the key factors associated with diabetes. Stress has at least two effects: (i) it increases the risk of the onset of diabetes, and (ii) it has negative effects on glucose management (Delamater & Cox, 1994; Viner et al., 1996; Surwit et al., 2002; DeVries et al., 2004). The second one is the focus of the present study. The management of diabetes over a long period of time is a stressful experience, which might change the patients' physiological, psychological and behavioural characteristics. However, the present literature review examines mainly psychological and behavioural aspects. Previous studies suggest that stress may alter the form of day-to-day hassles and could add a new layer of complexity every day that could make diabetes management challenging (Lloyed et al., 2005). The improved capacity of a patient to accept these day-to-day hassles might reduce some of this stress. Still, the complex relationship between stress and glucose management is not fully understood, although some general trends have been identified.

Acceptance and adherence to regular diabetes management strategies is challenging and could be influenced by the patients' positive/negative appraisal. A positive appraisal results in better coping styles that improve diabetes management. On the other hand, a negative appraisal might result in poor glucose management (Shah et al., 2012).

Perceived autonomous support from health care providers might alter patients' appraisal. Previous studies show that patients who perceived more autonomy support from caregivers had developed better self-management skills. However, some contradictory results were also found in relation to autonomy support and psychosocial and biological outcomes of diabetes self-management. For example, Raaijmakers et al. (2014) data shows no significant association between perceived autonomy support and *HRQOL*; however, Williams et al. (1998a) showed a positive association with self-management. Moreover, they recognized that the relationship between self-management and *HRQOL* is confounded by other variables, which could be the reason for not showing any

direct relationship. Overall, the present literature search shows that few studies have been conducted in this area, and therefore, more studies are required. If autonomy support is positively associated with glucose control, health care professionals can be trained to be more autonomy-supportive to increase autonomous perception in patients such that patients can accept diabetes positively. This might empower them to be more self-determined and accepting of healthy lifestyles for better diabetes management.

From the literature review it is also found that demography, genetics and environment could play a role in diabetes management. A very limited number of studies are found on the population of persons with diabetes in Newfoundland and Labrador, although the prevalence rate of diabetes is the highest of all Canadian provinces. The review of previous studies shows that various measurement tools have been used in the past to assess the same variable and therefore the findings from different studies could not be placed in a common framework for analysis. Most of the studies are cross-sectional in nature, which might be due to limited resources including cost and time. Well-designed cohort studies might better explain the mechanisms, or at least could validate the findings of cross-sectional studies.

Previous studies show that glucose management over a long period of time is a very complex phenomenon associated with many factors, and therefore no simple or single solution could be provided. Therefore, in order to proceed further, the present study has been started with a conceptual model shown in Fig. 2.4 to relate psychosocial factors with *HbA1c* management. It is hypothesized that autonomous support could positively influence both stress and appraisal.

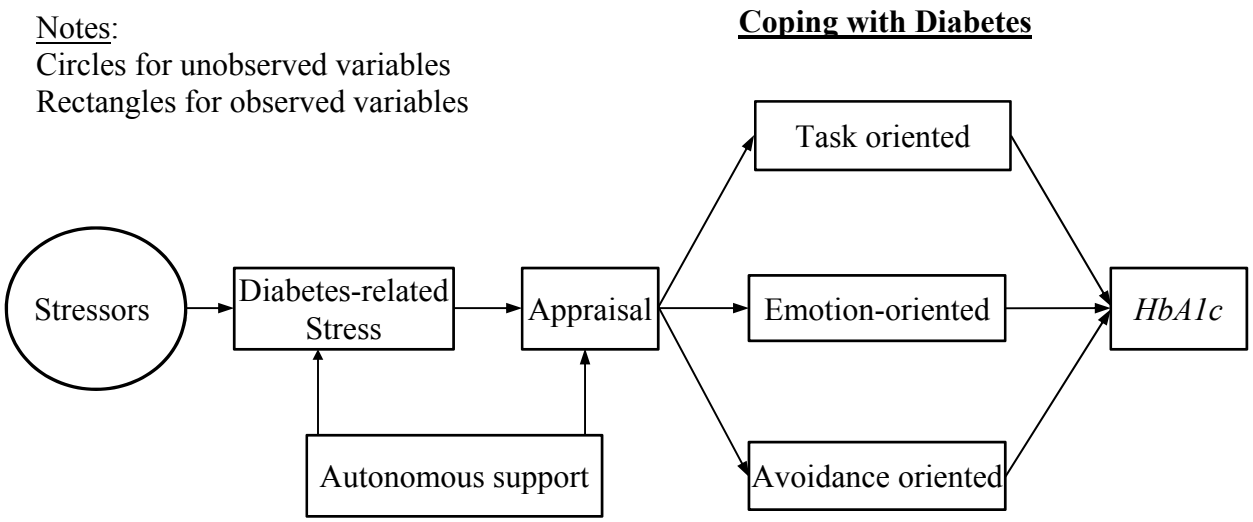

Fig. 2.4: Possible relationship between key psychosocial variables and *HbA1c*

3 Chapter 3

Materials and Method

3.1 Introduction

A cross-sectional study design is used in the present study. Based on a questionnaire survey and electronic health record, the data on patient characteristics and psychosocial exposures has been obtained. While there are some inherent limitations of the cross-sectional study over other study designs, it is a suitable method for estimating the prevalence of behaviour or disease in a population (Sedgwick, 2014). The author of this thesis is the principal investigator of this research project. The research has been supervised by experts having a wide range of experience in this area including an internal medicine physician specializing in diabetes, a biostatistician and a community medicine physician.

3.2 Participants

The present study has been conducted on type 2 diabetes patients in Newfoundland and Labrador, Canada.

3.2.1 Inclusion/exclusion criteria

Inclusion/exclusion criteria have been established for the selection of the study sample and also for generalization to the study/target population. The inclusion criteria are: age $\geq$ 18 years, diagnosed type 2 diabetes at least one year before recruitment for this study, living in Newfoundland and Labrador. It is assumed that the effects of psychosocial variables may be

properly identified if the patient has experienced or lived with his/her diabetes at least for a period of one year.

The exclusion criteria involve those having learning disabilities, any previously diagnosed psychological disorder, language (English) barrier, unable to communicate properly or failed to fill out the questionnaires, have no record of *HbA1c* level in the past six months at the time of the survey.

3.3 Sampling method and patient recruitment process

In this cross-sectional survey, demographic, psychological, social and clinical information on adult type 2 diabetes patients was collected from the patients during their appointment with the specialist Dr. Sahar Iqbal at the St. Clare's Mercy Hospital and Major's Path Clinic of the Eastern Health Outpatients Services. The author understands that most people with type 2 diabetes are treated by family physicians. Therefore, the results presented in this study can only be generalized to the patients followed by specialists. The eligible patients were recruited from these two clinics, based on above inclusion criteria. The study sample comprised of consecutive outpatients who came to these clinics, satisfied the inclusion criteria, were willing to volunteer to participate in this study and agreed to sign the Health Research Ethics Authority (HREA) approved consent form. The Eastern Health outpatient lists of these two clinics are considered as the sample frame to recruit the study sample. The study participants were recruited during the two weekly clinics at the St. Clare's Mercy Hospital and one bi-weekly clinic at Major's Path.

To recruit eligible patients, a study-design poster, attached in Appendix A, was placed on the noticeboard in St. Clare's Mercy Hospital and Major's Path Clinic of the Eastern Health Outpatients Services (Medicine Department), with permission. As shown, the poster explains the

context of the survey and provides contact information for the first contact person (Dr. Sahar Iqbal). The poster was also available at her clinics and she helped with arranging the survey process. During the appointment time, the patients were asked whether s/he would be willing to participate in the study. The first contact person kept participants' information with a study-specific identification number.

In the second step of the patient recruitment process, the principal investigator (PI) (the author of this thesis) met the participants. The PI again explained the purpose of the study. Although participation was completely voluntary, the participants had to sign the HREA approved consent form, attached in Appendix B, before s/he proceeded to fill out the study questionnaires.

The primary data was collected using a set of predetermined self-administered validated questionnaires and the personal data form of this study (Appendix C). After getting consent, the PI gave these questionnaires to the participant in a closed envelope provided by the Division of Community Health and Humanities, Faculty of Medicine, Memorial University. A quiet/private place was provided in the clinic to fill out the questionnaires. The study questionnaires were completed by the participants, and for most of the cases it took approximately 20–30 minutes. The PI was available to answer any questions or concerns. The completed questionnaires were returned to the PI in the same envelope with an ID number given by the first contact person. The PI kept all envelopes with completed questionnaires in a locked cabinet located in the office for this study in St. Clair's Mercy Hospital. The patient recruitment process had to be continued for the period of 18 months to get the targeted number as discussed in the following sections.

3.4 Data collection instruments

The main interest of the present cross-sectional survey is to investigate the effects of four psychosocial factors namely stress, appraisal, coping styles and autonomy supportiveness as

independent variables. The following four sets of standardized questionnaires were selected to collect the information for these variables from the study participants. Other information (e.g. demographic and lifestyle behaviour) was collected using a data extraction form, which was developed based on previous studies (Anderson et al., 2001; Fisher et al., 2007; Shah et al., 2012). Clinical information was provided by Dr. Sahar Iqbal from the patients' health record.

3.4.1 Data extraction form

The patient characteristics were collected using the present study-designed data extraction form, as attached in Appendix C. The following information was collected:

a) *Socio-demographic*: (i) age, (ii) sex, (iii) marital status, (iv) education, (v) occupation and (vi) income. In order to make it simple and effective, some of these have been categorized into groups: for example, occupations have been categorized based on the National Occupational Classification, NOC-2011 (2012).

b) *Lifestyle*: (i) smoking, (ii) recreational drugs and (iii) alcohol consumption status.

c) *Self-care behaviour*: (i) exercise frequency and duration, (ii) frequency of blood glucose check at home, and (iii) adherence to doctors' recommended diet.

d) *Clinical*: treatment strategies—for example, oral medication, insulin and pump.

3.4.2 Data retrieved from health record

Information on four variables was retrieved from the participants' health record through the first contact person using the participants' identification number: height and weight (or *BMI*), number of co-morbidities, duration of diabetes and *HbA1c* level. To count the total number of co-morbidities, diabetes was excluded from the list of comorbid conditions as it is the index/primary condition of the present study. Using the height and weight, the value of body mass

index (*BMI*) is calculated as *BMI* = mass in kilograms/(height in meters) ^{2}. Although the unit of *BMI* is kg/m^2, simply the number, without the unit, is used in the following sections by current convention. *HbA1c* level is considered as an outcome variable. Note that, the blood glucose level can be measured in different ways; however, the *HbA1c* test is considered as one of the best methods. In this test, the amount of glucose attached to haemoglobin is measured. A higher *HbA1c* means higher glucose in the blood. Unlike glucose in the blood, which fluctuates rapidly, the *HbA1c* level changes slowly approximately over a 10–week period and therefore this test is considered a better quality control test. The *HbA1c* was also considered as a reliable measurement for glucose in different studies (Shah et al., 2012; Williams et al., 2004). In the present study, the *HbA1c* is considered as the primary clinical health outcome of the patient.

3.4.3 Standard questionnaires

The following four validated self-administered standardized questionnaires were used to collect psychosocial information from each participant.

3.4.3.1 Problem Areas in Diabetes Questionnaire (PAID)

Several instruments have been used for the measurement of stress to examine a potential association between stress and glucose control. For example, a number of studies (e.g. Surwit et al., 2002) used the Perceived Stress Scale, PSS (Cohen et al., 1983). The PSS assesses the level of stress of an individual under unpredictable, uncontrollable and overwhelming situations. Rod et al. (2009) used a study developed questionnaire to measure the intensity and frequency of stress. The ATT39, a 39-item self-report measure developed by Dunn et al. (1986), has also been used by some researchers (e.g. Shah et al., 2012). The original questionnaire on stress with diabetes (QSD) is comprised of 90 items (Duran et al., 1995). The time taken to complete this questionnaire ranges

between 15 to 20 minutes (Achhab et al., 2008). The revised form of this questionnaire (QSD-R) is a 45-item questionnaire that defines eight stress scales (Herschbach et al., 1997). It can assess eight types/sources of stress. The diabetes distress scale (DDS), a 17-item questionnaire, was developed by Polonsky et al. (2005), and can assess four types of distress namely emotional burden, physician-related distress, regimen-related distress, and interpersonal distress.

In the present study, the Problem Areas in Diabetes Questionnaire (PAID) (Polonsky et al., 1995), which can assess diabetes-specific emotional distress, is used. Among some other questionnaires, this one has been specially designed to help clinicians identify patients' diabetes-related stress and formulate treatment interventions. Moreover, this questionnaire is currently recommended by a number of guidelines—for example, in the Canadian Diabetes Association 2013 Clinical Practice Guidelines for the prevention and management of diabetes in Canada (Jones et al., 2013), as shown in Fig. 2.3. This measure covers possible negative emotions in diabetes patients, for example "feeling alone with diabetes." Note that, a number of researchers have validated the PAID scales (e.g. Welch et al., 1997) and it is widely accepted by the scientific community and has generated many research papers available in the literature. This is relatively shorter than other instruments—a 20-item self-report questionnaire on a 5-point Likertscale (0–4). The sores are added and then multiplied by 1.25 to generate a total PAID score that ranges between 0 and 100. A higher score represents higher diabetes related distress. A diabetes-related emotional distress level has been categorized into three groups based on PAID scores: (i) low (score 0–10), (ii) moderate (score 11–39) and (iii) high (score ≥ 40) (Petraityte et al. 2015). A PAID score equal to or greater than 40 indicates that the patient has "emotional burnout" and may need special attention (DAWN, 2014).

Previous studies show that PAID has a consistently high internal reliability (i.e. Cronbach's alpha = 0.90), and strong correlations with other psychosocial variables such as emotional distress,

depression, diabetes self-care behaviours, coping strategies and health beliefs. It also represents a statistically significant predictor of glycaemic control in some studies (Polonsky et al., 2015).

The PAID was originally developed in US English, but has later been translated into Spanish, Japanese, Dutch, German, Chinese, Croatian, Danish, and Portuguese. Based on a cross-sectional study, Welch et al. (2003) showed that PAID is unrelated to the duration of diabetes, education, ethnicity, and gender. Also, based on 7 longitudinal studies where this instrument has been used, Welch et al. (1997) showed that diabetes treatment and interventions reduce PAID scores with time.

3.4.3.2 Appraisal of Diabetes Scale (ADS)

Similar to stress, various instruments have been developed and used in the past to assess appraisal. A comprehensive discussion and comparative study of the available tools are available in Carry et al. (1991). In the present study, the Appraisal of Diabetes Scale (ADS), developed by Carey et al. (1991), has been used (Appendix C). They examined the psychometric properties of this questionnaire and also validated it for the relationship between appraisal scores with other variables including: (a) diabetic regimen adherence, (b) glycemic control, (c) health beliefs related to diabetes, (d) stress, and (e) psychological adjustment. The ADS was developed based on the TMSC model (Lazarus & Folkman, 1984) and the research conducted by Gong-Guy and Hammen (1980) and Hammen and Mayol (1982). The ADS is a seven-item self-reported scale which measures both primary and secondary appraisals of diabetes. Total ADS score can be obtained by reversing items #2 and 6 and then summing up the score of each item. The range of ADS scores varies between 7 and 35, and the higher total score the greater the negative appraisal and the smaller the total score the more positive appraisal strategies. Thus, a lower score is better for diabetes management. The ADS has several important practical strengths (Carey et al., 1991). To

determine whether ADS scores are depend on insulin-dependent status, *t*-tests were conducted and observed no significant difference between insulin-dependent ($M = 18.5$; $SD = 4.0$) and non-insulin dependent subjects ($M = 19.0$, $SD = 3.9$; $t(187) = 0\ .849$, $p > 0.35$]. It is also easy to score and interpret because it inquires only the diabetes-related information. As this questionnaire is very simple, it can be quickly completed by the participants (less than 5 minutes, Achhab et al., 2008), and easily administered by a nonprofessional. The ADS has been used to measure patients' cognitive feelings about their well-being after being diagnosed with type 2 diabetes.

The ADS has also been used to assess psychosocial adaptation to family and work environments in relation to glycaemic control (Trief et al., 1998; Trief et al., 1999). It has been translated into different languages such as Korean and Japanese to measure coping strategies (Lee et al., 2015; Hara et al., 2011).

3.4.3.3 Coping Inventory of Stressful Situations (CISS)

Coping is one of the key factors that has been considered in health studies for assessing the impact of stress on health and well-being. A number of instruments have been developed to measure coping strategies in stressful situations. Welch (1994) developed a 21-item Diabetes Coping Measure (DCM) instrument that includes four subscales: tackling spirit, avoidance, passive resignation, and diabetes integration. A number of authors have used the DCM for assessment of coping in type 2 diabetes patients (Huang et al., 2009; Shah et al., 2012).

In this study, the Coping Inventory of Stressful Situations (CISS), developed by Endler and Parker (1990), has been used. This instrument has also been used to measure coping in diabetes patients (Sultan & Heurtier-Hartemann, 2001). The CISS is a self-report measure on a 5-point Likert scale (1–5) attempting to index the different coping strategies that people may use in stressful situations. This scale has been found to have high internal consistency and reliability, and been validated for

different populations. This is a 48-item self-report measure which was developed to assess mainly three coping styles. Firstly, *Task-Oriented Coping* refers to adaptively utilizing problem solving techniques to address stressful situations, with higher scores being associated with greater attempts to apply specific solutions to a stressor. Secondly, *Emotion-oriented Coping* refers to maladaptive dealing with an ongoing stressor in a passive and overly emotional or ruminative manner, with higher scores being associated with lack of acknowledgement of emotions or feelings. Finally, *Avoidance-oriented Coping* refers to denial or avoidance of a stressor. Each of the coping subscales is developed based on 16 items. Scores of each subscale range from 16 to 80, a higher score on any of these mechanisms indicates greater attempts to apply that coping mechanism to overcome the stress (Endler & Parker, 1990).

3.4.3.4 Health Care Climate Questionnaire (HCCQ)

Patient-centered physician communication could play a significant role in improved diabetes management. After diagnosis, the psychological behaviour of a type 2 diabetes patient might significantly change which might result in stress, emotion, anxiety, uncertainty and fear. A limited number of standardized measures of patient-centered communication have been developed in the past, which include the Behavior Change Counseling Index (BECCI) (Lane et al., 2005) and the Motivational Interviewing Treatment Integrity Scale (Moyers et al., 2005). Although the purpose of these instruments is to modify health behaviors, they have been designed primarily to assess physician communication practices, rather than for evaluation of the patients' perspective. Therefore, they may not be suitable for evaluating patients' perceived autonomy support from their care providers that helps in decision-making, quality of life and selection of coping strategies.

To assess diabetic patients' perceptions of the degree to which the health care providers were autonomy supportive, the Health Care Climate Questionnaire (*HCCQ*) has been used prominently

not only for type 2 diabetes but also for other chronic diseases (Williams et al., 2006; Shumway et al., 2015). The present study used the *HCCQ* to assess patients' perceived autonomy support from their health care providers. It assesses the distinction between patients' autonomous versus controlled perception they received from their health care providers. This is a 15-item questionnaire to measure perceived autonomy support on a 7-point Likert scale (1–7). To calculate the HCCQ scores, first reverse the scores in item number 13 and then average all scores. Higher average scores represent a higher level of perceived autonomy support. The HCCQ has been validated and the scores used as a motivational predictor for different types of health issues including smoking cessation (Williams et al., 1999), weight-loss programs (Williams et al., 1996) and diabetes (Williams et al., 1998a). More specifically, Williams et al. (1998a) found that perceived autonomy supports significantly predict the reduction in *HbA1c*, and this prediction is independent of treatment strategies.

3.5 Sample size calculation

Fitzner and Heckinger (2010) discussed various considerations for the calculation of sample size, particularly in diabetes research, and showed that it depends upon the objectives of the study. The main objectives of the proposed research are to find the relationship(s) between diabetes-related stress, appraisal, coping styles, autonomy supportiveness and *HbA1c* through multiple regression analysis. The number of variables and their prevalence influence the sample size.

3.5.1 Variables

In order to achieve the objectives, the following 6 variables namely (i) *PAID* score, (ii) *ADS* score (iii) Task-oriented coping score (iv) Emotion-oriented coping score, (v) Avoidance-oriented coping score, (vi) Autonomy supportiveness score, are extracted from the four sets of validated

standard questionnaires. These 6 variables are considered as primary independent research variables. Moreover, 12 other variables namely (i) age, (ii) sex, (iii) marital status, (iv) education, (v) occupation/income, (vi) smoking, (vii) alcohol, (viii) BMI, (ix) duration of diabetes, (x) number of comorbidities, (xi) types of treatment strategies received from physician and (xii) exercise, were extracted from the study-developed data extraction form and patients' health record. These 12 variables are considered as co-variables/control variables. The level of *HbA1c* is considered as the outcome (dependent) variable. Based on previous studies as discussed above, it is assumed that these variables might provide sufficient evidence to achieve the objectives of the proposed research through identifying their direct, indirect and confounding relationship(s) to *HbA1c* management.

3.5.2 Method used in sample size calculation

To calculate the minimum sample size for research where multiple correlation and regression analysis are to be performed, the following parameters are required: (i) anticipated effect size (R^2), (ii) desired statistical power (1-β), (iii) the total number of predictors (N), and (iv) type-1 error probability level (α). In general, the effect size of 0.02, 0.15 and 0.3 is considered as small, medium and large, respectively (Hinton, 2014). Cochran and Conn (2008) showed an effect size of approximately 0.3 in people with diabetes who experienced improved quality of life from diabetes self-management training programs. Shah et al. (2012) also used $R^2 = 0.3$ to calculate sample size for their study. Based on these studies, the value of $R^2 = 0.3$ is used in the present study. The desired statistical power of 0.8 is used. In order to calculate the sample size, the above mentioned 18 variables are considered as predictor variables and *HbA1c* as the dependent variable. Now, using $R^2 = 0.3$, $\beta = 0.2$ (statistical power = 0.8), $N = 18$ predictors (6 primary research and 12

control variables) and $\alpha = 0.05$, the minimum required sample size is calculated as 42 using the G*Power software (Faul et al., 2009).

In general, the required sample size is higher for a lower prevalence rate (Dell et al., 2002). In the present study, diabetes related stress is considered as the main predictor variable for *HbA1c* management. As discussed in Chapter 2, Roche and Wang (2014) showed that 49.9–68.3% of patients with diabetes experience stress in Newfoundland and Labrador. The CDA (2014) reported that depression is more common in people with diabetes as compared to the general population and it affects at least 30% of diabetic patients. It has also been stated that depression may develop in diabetes patients because of stress and anxiety. Based on Anderson et al. (2001), Shah et al. (2008) calculated the sample size using a prevalence of 25%. Therefore, based on these studies, a prevalence rate of 30% is used in the present study to calculate the sample size.

Dividing the above calculated value by the prevalence (0.3) the minimum required sample size of 140 (= 42/0.3) is obtained. Finally, using a conservative rate of attrition of 10%, a total of 154 (= 1.1×140) patients were targeted for the proposed study.

3.6 Ethical Considerations

Ethical approval involved a two-step process. Firstly, an application was submitted for ethics review to the Health Research Ethics Board (HREB)-General Research of Newfoundland and Labrador. The HREB approval is provided in Appendix D. After HREB approval, another application was submitted to the Research Proposal Approval Committee (RPAC) for organizational review and approval, because the study was conducted at the Major's Path Clinic and St. Clare's Mercy Hospital, and therefore resource utilization and allocation needed to be

approved. The RPAC approval is also provided in Appendix D. Both applications were submitted with the approval of supervisory committee members.

The data collection was performed in the diabetic clinics at the Major's Path and in the medicine outpatient clinic at the St. Clare's Mercy Hospital, depending upon the patients' appointment with the specialist Dr. Sahar Iqbal. To maintain privacy, a quiet and private environment was provided within the centers and there was only one patient at a time.

Patients' identifiable information was separated from demographic, clinical and psychosocial data and kept in a locked cabinet in the office dedicated for this research to maintain confidentiality. Only the identification number was used to link the data and statistical analysis. That means, after data preparation, no personal information was used and the data was handled only by identification number. Therefore, a high level of patient confidentiality was maintained.

Patients were informed that they have the right not to provide access to their data and to withdraw from the study at any time, without prejudice to their medical care, and that they are not obliged to state the reasons. However, no request for withdrawal was received.

Potential risks associated with participation in the study were unlikely or of low risk. There was no physical risk as the patients were not asked to perform any physical tasks as part of the data collection process. However, the participants were asked to provide information about their physical and mental well-being and demographic data. It might upset some participants to think about their poor health or other problems, which could be the cause of some psychological risk.

In order to minimize such risks several approaches were taken. Sufficient time was given if any question(s) upset them. The participants were also free to refuse to respond to any question that might result in psychological disturbance. It was also planned that if required, s/he would be

referred to a psychologist or to the supervisor of the applicant (Dr. Sahar Iqbal), who is a specialist in internal medicine. Fortunately, this did not happen in the present study.

The collected information is protected from unauthorized access and disclosure. The following three methods of protection were applied: (i) *Organizational security*: the data has been used only by the applicant and her supervisory committee members. Confidentiality agreement forms have been signed by these users. (ii) *Physical security*: the office room dedicated to this study at the St. Clare's Mercy Hospital is a locked room. All the information has been stored in a locked filing cabinet. In addition, after-office hour security was also available at the St. Clare's Mercy Hospital. (iii) *Technical security*: All the data is stored and the analyses are performed using a dedicated personal computer in this office. The analysis of data and report/technical writing have been done using this computer. This computer is password protected, and has firewalls and network security.

The supervisor, Dr. Sahar Iqbal, will retain the copies of the essential documents for a period of at least 5 years or longer as required by HREA. The essential documents include the signed consent form, completed questionnaires and all electronic data, enrolment history, approvals and all related correspondence.

The outcome of the results is presented in this M.Sc. thesis in the Division of Community Health and Humanities Faculty of Medicine at Memorial University of Newfoundland. It is also planned that the results will be published as technical papers in conferences/journals. Participant identifications will be completely eliminated and the results will be presented in anonymized form only mentioning that the data has been collected from Newfoundland and Labrador. During the interview, the principal investigator's contact information has been given such that the participants can borrow the thesis following Memorial University protocol or can get any clarification of the technical papers, if interested.

3.7 Statistical Methods used for data analysis

The statistical analyses have been primarily carried out using the IBM SPSS Statistics 24 (SPSS, 2016) software; however, in some cases Microsoft Excel has been used for further interpretation and plotting of results.

After receiving self-administered data using the four standard questionnaires and one study-specific data form, some additional information about the participant was collected from their electronic medical records which includes recent *HbA1c*, height and weight or *BMI*, year of diagnosis, and number of comorbidities. All the raw data (socio-demographic, life style, clinical, self-care, health record and psychosocial) have been properly arranged and entered into SPSS anonymously using a study-specific patient identification number. The raw data has been double checked before being entered into SPSS.

After entering the data into SPSS, the variables were categorized as nominal, ordinal and scale variables, depending upon their nature, for selection of appropriate statistical analysis methods. Before conducting any inferential statistical analysis, an exploratory data analysis has been performed to examine whether there were any issues in the data, such as outliers, non-normal distributions, problems with coding, missing values, and/or errors in entering the data. Microsoft Excel was frequently used, in addition to SPSS, for an in depth understating of the data using graphical and tabular representations.

As the psychosocial responses were obtained through four sets of standard Likert-type questionnaires, the summated scores were calculated using the recommended procedure described previously for each questionnaire. To calculate PAID scores, the suggested procedure given by Polonsky et al. (1995) was followed. As no recommendation has been given for missing data interpretation, if anyone missed two or less items, they have been replaced by an average value

(i.e. 2). To calculate ADS scores, the suggested procedure given by Carey et al. (1991) was followed. For missing data interpretation, a similar procedure, as described above for PAID, has been followed. If a participant did not respond to one question, it was replaced by an average value (i.e. 3). To obtain CISS scores for the three subscales (i.e. task, emotion and avoidance) and also the diversion and distraction subscales for avoidance, the procedure recommended in the CISS-Adult manual was followed (Endler & Parker, 1990). As per the recommendations, the raw score for each sub-scale was converted to a *T*-score using the procedure recommended in the CISS-Adult profile form developed by Endler and Parker, (1990a). Note that, as this is a linear *T*-score, the variables that are not normally distributed in the raw data will continue to be non-normally distributed after the transformation (Endler & Parker, 1990a). Moreover, the obtained *T*-score, which is a standardized scaled score with a mean of 50 and standard deviation of 10, represents the CISS score. The CISS-Adult questionnaire also includes a table, which could be directly used to obtain the T-score for a given raw score. If there were some missing or ambiguous data, it was replaced by 3 as per CISS manual.

To calculate autonomy supportive scores, the procedure recommended by Williams and his co-workers at the University of Rochester was followed (HCCQ, 2017). For missing data, if a participant did not respond to two or fewer items, the value was replaced by the average scale (i.e. 4).

Dummy variables were created for the categorical variables such as marital status, education, occupation, income, doctor recommended diet, exercise duration, smoking status and number of co-morbidities. These dummy variables were used in the regression analysis as control variables.

As summated scores for the four sets of questionnaires were used in inferential statistics, internal consistency of response was checked using Cronbach's α coefficient. The α value of each CISS scale was calculated based on the raw score (before converting to *T*-scores).

A comprehensive statistical analysis was performed after scoring, creating dummy variables, computing new variables and checking the internal consistency for summated scores. The descriptive analysis was performed to characterize the study sample and get a clear picture of participant demographics, life styles, clinical, self-care, psychosocial information and diabetes level.

As the present study is based on a cross-sectional survey method, information is obtained only at a single point in time. Therefore, the prevalence ratios are calculated for a number of variables as suggested by Szklo and Nieto (2014). In addition, to compare the response in different groups, cross-tabulation and Chi-square tests for categorical variables and independent sample t-test for continuous variables have been performed.

Hierarchical multiple regression analyses are performed using the enter method considering *HBA1c* as a dependent variable. The confounder/covariates for the analysis are chosen carefully from demographic, lifestyle, clinical and self-care variables. A *p*-value less than 0.05 is considered as statistically significant. A correlation matrix is developed for all predictor variables and data is checked for multi-collinearity, linearity and homoscedasticity. Note that, the multi-collinearity effect is significant if the correlation coefficient is greater than 0.7 (Daniel & Cross, 2013), which has not been observed in the present study. Moreover, based on correlation coefficients, the key independent variables are identified. Finally, two path models are developed conducting a comprehensive regression analysis.

3.8 Summary

In addition to medical treatment, the management of type 2 diabetes could be significantly influenced by patient characteristics and psychosocial factors. The details of the primary data collection for the cross-sectional survey method used in the present study is presented in this chapter. A total of 165 diabetes patients participated in this study—all of them are adults from Newfoundland and Labrador, who visited two clinics in St. John's during 2015–2016. The data was collected using four sets of standard questionnaires on psychosocial variables, one study-specific form and health records. A brief summary of the methods used for analysis of data is also presented in this chapter. Further details of analysis, results and discussion are provided in the following two chapters.

4 Chapter 4

Analysis of Data and Results

4.1 Introduction

A detailed analysis of the data is presented in this chapter. The statistical analyses have been carried out using SPSS software (IBM SPSS Statistics, Version 24). The data collection of the present study took about 18 months—from September 2015 to February 2017.

A total of 265 patients were invited to participate and, among them, 171 filled out the questionnaires. Based on this, a response rate for the study was calculated as 65% (= 171/265). After the collection of information from the heath care record, it has been found that 7 of them had a different type of diabetes (type 1 or LADA type). This data has been removed during the analysis, and therefore 165 participants have type 2 diabetes. Among this 165, some of them did not complete all of the questionnaires. Excluding them, the total number of participants is over 140, the required sample size.

4.2 Data arrangement for categorical variables

As mentioned in Section 3.4, patient information was collected from three different sources: (i) the data extraction form developed for this study, (ii) data retrieved from the electronic health record and (iii) four sets of standard questionnaires. A number of variables obtained from the first two approaches are categorical variables (Table 4.1). For statistical analysis of these variables, a reference category is required to be selected to define dummy variables. The third column of Table 4.1 shows the "reference category" used in the present study, where 0 represents the reference

category and ≥ 1 is for other categories. For simplification and a better interpretation of the response, some of the categories have been combined. Merging groups of small numbers into a relatively large number helped make data more representative. For example, in the occupation classification, the first nine categories are combined to form a "working and study group" of 48.7%, as each category in this group has a very small percentage (e.g. Natural and Applied Sciences & Related occupation is only 0.7%). The basis for the new categorization is shown in the fourth column of Table 4.1.

4.3 Descriptive statistics of categorical variables

Table 4.1 shows the sample characteristics. The number of female participants are ~ 4% higher than male. Approximately half of the participants (47.4%) have education up to high school or below while 52.5% have post-secondary education and above. Approximately half of the participants are employed in different sectors (49.7%), while the other half are retired or unemployed (50.3%). Approximately one-third of the participants are retired (35.1%). Two-thirds of the participants are either married or in common-law relation (66.6%), while the remaining one-third are currently without a partner. About two-thirds of the participants (62.7%) are in the low income category having an annual income equal to or less than $40,000, while only ~ 9% have an income more than $80,000 per annum.

About one-third of the population (35.4%) never smoked, while 54.3% quit smoking. Only 10.4% are currently smoking. More than two-thirds of the population (69.6%) do not consume any alcohol. Only 2.7% are taking some recreational drugs.

Table 4.1: Demographic and baseline characteristics of study population

Variables	Percentage	Revised category[§]	Comments
Gender (*N* = 165)			
Male	47.9%	0	-
Female	52.1%	1	-
Education (*N* = 158)			
Reading level grade 8 or higher	25.9%	0	High school or below
High school diploma	21.5%		
Some post-secondary	13.9%	1	Post-secondary education and above
College or trade certification	32.3%		
University degree	6.3%		
Occupation classification (*N* = 151)			
Management	7.3%	0	Employed
Business, Finance & Admin.	12.6%		
Natural & Applied Sciences	2.0%		
Health	11.9%		
Social Science, Education & Govt.	2.6%		
Sales & Service Occupations	4.6%		
Transport, Equipment Operators	6.6%		
Processing, Manuf. & Utility	2.0%		
Retired	35.1%	1	-
Unemployed	15.2%	2	-

Variables	Percentage	Revised category[§]	Comments
Marital status (*N* = 165)			
Single	11.5%		
Widowed	12.1%	0	Without partner
Divorced	9.7%		
Married	62.4%	1	With partner
Common law	4.2%		
Income (*N* = 145)			
≤ 20,000	25.5%	0	Low income
21,000 - 40,000	37.2%		
41,000 - 60,000	20.0%	1	Middle to high income
61,000 - 80,000	8.3%		
81,000 - 100,000	4.8%		
≥ 101,000	4.1%		
Smoking status (*N* = 164)			
Never smoked	35.4%	0	No smoking history
Current smoker	10.4%	1	Smoking history
Past smoker	54.3%		
Alcohol consumption status (*N* = 158)			
No	69.6%	0	-
Yes	30.4%	1	-

Variables	Percentage	Revised category[§]	Comments
Recreational Drugs (*N* = 149)			
No	97.3%	0	-
Yes	2.7%	1	-
Exercise (*N* = 160)			
No	44.4%	0	-
Yes	55.6%	1	-
Exercise duration (*N* = 81)			
15 minutes	24.7%	0	≤30 minutes
30 minutes	43.2%		
45 minutes	4.9%	1	> 30 minutes
1 hour	27.2%		
Diet frequency in a week (*N* = 93)			
Somewhat strict	47.3%		
Sometimes	37.6%	0	Flexible dieting
Rarely	2.2%		
Very strict	12.9%	1	Strict dieting
Exercise frequency in a week (*N* = 77)			
≤ 3	48.1%	0	-
4–7	51.9%	1	-

Variables	Percentage	Revised category[§]	Comments
Recommended diet (*N* = 160)			
No	31.9%	0	-
Yes	68.1%	1	-
Checking blood glucose (*N* = 163)			
No	9.8%	0	-
Yes	90.2%	1	-
Number of comorbidities (*N* = 149)			
≤ 3	45.6%	0	-
4–8	54.4%	1	-
Diabetes centre visit (*N* = 128)			
Weekly	1.6%		
Bi-weekly	0.8%	0	Centre visit
Monthly	20.3%		
Rarely	28.9%		
Never	48.4%	1	No centre visit
Diet (*N* = 152)			
No	20.4%	0	-
Yes	79.6%	1	-
Oral medication (*N* = 138)			
No	31.9%	0	-
Yes	68.1%	1	-

Variables	Percentage	Revised category[§]	Comments
Insulin (*N* = 134)			
No	39.6%	0	-
Yes	60.4%	1	-
Pump (*N* = 114)			
No	95.6%	0	-
Yes	4.4%	1	-

Notes: [§] 0 in column 3 is "reference category"

In terms of maintaining fitness, 55.6% of the participants exercise, and approximately two-thirds of them (24.7% + 43.2% = 67.9%) exercise equal to or less than 30 minutes per week. Only 12.9% strictly maintain the recommended diet, although about half of the participants (47.3%) somewhat follow strict dieting.

In terms of medical history, 90.2% of the participants check their blood glucose level at home. About half of the participants (48.4%) never visit diabetes education centres. In order to control their diabetes, 68.1% of the participants take oral medicine and 60.4% of the participants are on insulin, while 33% take both. Also, 4.4% of the participants are using insulin pumps.

4.4 Descriptive statistics of continuous variables

In addition to the categorical variables listed in Table 4.1, several continuous variables were obtained from the data extraction form and health record. Table 4.2 shows the descriptive statistics of these variables.

A comparative analysis to investigate gender-based difference was carried out. No significant difference in the mean age of male and female participants is found (t = -0.722, p = 0.471). The average age at diagnosis of diabetes was about 50 years, and there is no significant difference between male and female age at diagnoses (t = -0.826, p = 0.410). Almost two-thirds of the patients (66%) were diagnosed with diabetes at the age between 40 and 60 years (69.6% for males and 63.1% for females). The mean duration of diabetes of the male and female participants is 11.9 and 11.7 years, respectively. An independent t-test showed no significant difference between these two groups (t = 0.240, p = 0.811). The mean *BMI* of the male and female participants is 35.5 and 36.2, respectively; however, a t-test shows that the difference is not statistically significant (t = -0.601, p = 0.549). Finally, the mean *HbA1c* in the male and female participants is 7.98 and 7.66, respectively. Again, a t-test shows no significant difference in *HbA1c* between these two groups (t = 1.328, p = 0.186). Among the variables shown in Table 4.2, the p-value in the t-test is the lowest in *HbA1c* between male and female, although it is not statistically significant. Further analysis for this variable is performed in the following sections.

4.5 Descriptive statistics of variables from standard questionnaires

The descriptive statistics of all the measures within the 4 sets of questionnaires are shown in Table 4.3. The scoring procedure has been described in Sections 3.4.3 and 0, and the possible range is shown in the fourth column of Table 4.3. In addition, analyses are performed for males and females separately. Table 4.3 shows a good (α = 0.8–0.9) to excellent ($\alpha \geq 0.9$) overall reliability coefficient for all the measures, including the response of male and female participants separately. The values of α in the present study are higher than the α obtained during the development of the questionnaires, as shown in the square bracket in the fifth column of Table 4.3.

Table 4.2: Descriptive statistics of the continuous variables

Variables	***M* (*SD*)**	***t***	***p-value***
Age			
Overall (*N* = 165)	61.8 (11.8)		
Male (*N* = 79)	61.1 (11.8)	-0.722	0.471
Female (*N* = 86)	62.4 (11.9)		
Age at diagnosis			
Overall (*N* = 163)	49.9 (11.5)		
Male (*N* = 79)	49.2 (11.2)	-0.826	0.410
Female (*N* = 84)	50.7 (11.8)		
Duration of diabetes			
Overall (*N* = 163)	11.8 (6.6)		
Male (*N* = 79)	11.9 (5.2)	0.240	0.811
Female (*N* = 84)	11.7 (7.6)		
BMI			
Overall (*N* = 160)	35.9 (8.3)		
Male (*N* = 77)	35.5 (7.8)	-0.601	0.549
Female (*N* = 83)	36.2 (8.9)		
HbA1c			
Overall (*N* = 165)	7.81 (1.52)		
Male (*N* = 79)	7.98 (1.42)	1.328	0.186
Female (*N* = 86)	7.66 (1.60)		

Table 4.3: Descriptive statistics for PAID, ADS, HCCQ and CISS Scales

Variables	*N*	Mean score (SD)	Possible range	Reliability coefficient (α)
PAID	144	30.14 (21.28)		0.94 [0.95[§§]]
PAID_male	71	27.06 (19.25)	0–100	0.93
PAID_female	73	33.13 (22.83)		0.95
ADS	163	18.65 (4.85)		0.80 [0.73[†]]
ADS_male	77	18.42 (4.96)	7–35	0.82
ADS_female	86	18.86 (4.77)		0.79
HCCQ	161	5.93 (1.05)		0.95 [0.80[††]]
HCCQ_male	77	6.00 (1.00)	1–7	0.94
HCCQ_female	84	5.88 (1.09)		0.96
Task	148	42.53 (13.12)		0.94
Task_male	72	45.58 (12.44)	16–80	0.92 [0.90[§]]
Task_female	76	39.63 (13.16)		0.95 [0.87[§]]
Emotion	146	48.10 (11.88)		0.91
Emotion_ male	72	49.49 (12.43)	16–80	0.92 [0.9[§]]
Emotion_female	74	46.76 (11.24)		0.91 [0.9[§]]
Avoidance	147	50.43 (12.66)		0.88
Avoidance_ male	71	54.09 (12.09)	16–80	0.87 [0.81[§]]
Avoidance_female	76	47.00 (12.28)		0.89 [0.82[§]]
Distraction	149	50.77 (12.00)		0.81
Distraction_ male	72	53.47 (12.25)	8–40	0.83 [0.72[§]]

Variables	*N*	Mean score (SD)	Possible range	Reliability coefficient (α)
Distraction_female	77	48.25 (11.26)		0.80 [0.72[§]]
Diversion	150	48.73 (12.60)		0.84
Diversion_ male	72	52.43 (11.49)	5–25	0.77 [0.74[§]]
Diversion_female	78	45.32 (12.69)		0.88 [0.78[§]]

[§] α values of Endler and Parker (1999) to develop CISS questionnaires

[§§] α values of Polonsky et al. (1995) to develop PAID questionnaires

[†] α values of Carey et al. (1991) to develop ADS questionnaires

[††] α values of Williams et al. (1998) to develop HCCQ questionnaires (5 items)

4.6 Diabetes and obesity

In order to investigate the relationship between obesity and glycemic control, the *BMI* of the study population is divided into five groups, as shown in Table 4.4, based on the World Health Organization (WHO, 1997) classification. Table 4.4 shows that more than 70% of the participants (overall 74.5%, male 75.7%, and female 73.5%) are obese ($BMI \geq 30$). Although the sample has been selected simply by targeting type 2 diabetes patients, without setting any inclusion/exclusion criteria for *BMI*, it shows a significantly high prevalence of obesity in the diabetes patients participating in the present study. In the present study, the number of obese participants ($BMI \geq 30$) was 10.9 times that of normal weight participants ($BMI \leq 24.99$).

Table 4.4: Categorization of *BMI* of the participants

	Normal ***BMI* ≤ 24.99**	**Overweight (*BMI* ≥ 25)**			
		Pre-obese 25–29.99	**Obese *BMI* ≥ 30**		
			Class-I obese 30–34.99	**Class-II obese 35–39.99**	**Class-III obese ≥ 40**
Overall (*N*=160)	6.9% (11)	18.8% (30)	26.3% (42)	21.3% (34)	26.9% (43)
Male (*N* = 78)	6.4% (5)	17.9% (14)	29.5% (23)	21.8% (17)	24.4% (19)
Female (*N* = 83)	7.2% (6)	19.3% (16)	24.1% (20)	20.5% (17)	28.9% (24)

Note: (i) values in the parenthesis show the number of participants in the group

(ii) *BMI* ≥ 35 is called as "highly obese" in this study

The condition of diabetes is classified into two groups: (i) well-controlled (*HbA1c* ≤ 7%) and (ii) poorly-controlled (*HbA1c* > 7%) (Kassaian et al., 2012). Table 4.5 shows that approximately two-thirds of the participants are in the poorly controlled group. The prevalence of poor glycemic control is higher in males (69.6%) than females (58.1%), with a prevalence ratio (*PR*) of 1.197.

Table 4.5: Categorization of patients based on glycemic control

	***HbA1c* ≤ 7 Well-controlled**	***HbA1c* > 7 Poorly-controlled**
Overall (*N* = 165)	36.4% (60)	63.6% (105)
Male (*N* = 79)	30.4% (24)	69.6% (55)
Female (*N* = 86)	41.9% (36)	58.1% (50)

Note: values in parenthesis show the number of participants in the group

A Chi-square test shows that there is an association between gender and diabetic condition. (PR = 1.197, $\chi^2(1) = 2.345$, $p = 0.126$). The 95% confidence interval of PR is 0.951–1.508.

To identify any relation between glycemic control and body weight, *BMI* has been divided into two groups: $BMI < 35$ and $BMI \geq 35$. Table 4.6 shows *HbA1c* (well- and poorly-controlled) in these two groups. The Chi-square test at the level of 95% confidence shows a significant difference between the participants having a $BMI \geq 35$ (Obesity Class-II and -III) and poorly *HbA1c* control ($HbA1c > 7$) and their counterparts ($\chi^2(1) = 3.896$, $p = 0.048$). Moreover, the prevalence risk (*PR*) is 1.258 and the range is 1.002–1.579 (i.e. > 1.0) with a 95% confidence interval. Therefore, it can be concluded that the patients with a $BMI \geq 35$ might have poor glycemic control and the difference from their counterparts is statistically significant.

Table 4.6: Glycemic control between two *BMI* groups

	***HbA1c* ≤ 7**	***HbA1c* > 7**	**Total**
***BMI* < 35**	35 (21.9%)	48 (30.0%)	83 (51.9%)
***BMI* ≥ 35**	21 (13.1%)	56 (35.0%)	77 (48.1%)
Total	56 (35%)	104 (65%)	160 (100%)

In summary, the study population has a high prevalence of obesity. Among the obese patients, two-thirds or more have poor glycemic control. This is more pronounced in males than females. A critical examination shows that obese participants ($BMI \geq 35$) have less control of their diabetes.

4.7 Stress in diabetes patients

The term "emotional burnout" is used to describe the mental state that could be caused by excessive and prolonged stress. In a type 2 diabetes patient, if the *PAID* score is 40 or higher, it is considered to be at the level of emotional burnout. In the present study, out of 144 patients, 47 are at the level of emotional burnout. In the emotional burnout group, 89.4% of patients have poor glycemic control (*HbA1c* > 7.0), while in the low to moderate stress group (i.e. *PAID* score less than 40), 55.6% of patients have poor glycemic control.

A prevalence ratio (*PR*) of 1.605 is obtained considering stress (burnout) as the prevalence factor and *HbA1c* (*HbA1c* ≤ 7 vs *HbA1c* > 7) as the outcome. A Chi-square test shows that the calculated *PR* is statistically significant ($\chi^2(1) = 16.17$, $p < 0.001$ and $1.275 \leq PR \leq 2.02$ for a 95% confidence interval). Therefore, it can be concluded that the emotional burnout group has poor glycemic control compared to the patients without emotional burnout, and this is statistically significant.

Table 4.7: Glycemic control in diabetes related stress groups

	***HbA1c* ≤ 7**	***HbA1c* > 7**	**Total**
***PAID* < 40**	43 (29.9%)	54 (37.5%)	97 (67.4%)
***PAID* ≥ 40**	5 (3.5%)	42 (29.2%)	47 (32.6%)
Total	48 (33.3%)	96 (66.7%)	144 (100%)

The present study shows that, 42 participants (i.e. 29.2% of the total participants) have poor control in *HbA1c* and high stress. Among these 42 patients, 66.7% ($N = 28$) have *PAID* score between 40

and 60. The *PAID* score of the other 33.3% (N = 14) is greater than 60 with a maximum of 95. These participants might have severe emotional burnout and require special attention.

Out of the 5 patients who had $PAID > 40$ and $HbA1c \leq 7$, two patients had severe emotional burnout (*PAID* = 67.5 and 75).

4.8 Independent *t*-tests for measured variables

In the previous sections, based on *HbA1c*, the participants have been divided into two groups—$HbA1c \leq 7.0$ in the well-controlled group and $HbA1c > 7.0$ in the poorly-controlled group. Table 4.8 shows the independent *t*-test results of the measured variables between these two groups. The mean of the *PAID* (i.e. stress) and *ADS* (i.e. appraisal) scores is higher in the poorly-controlled group than in the well-controlled group. This difference is statistically significant ($p \leq 0.05$). Note that, a high *PAID* or *ADS* score represents poor diabetes management. The *Task* score in the poorly-controlled group is slightly higher than in the well-controlled group; however, it is not statistically significant. All the other subscales of the *CISS* (*Emotion*, *Avoidance*, *Distraction* and *Diversion*) show higher scores in the poorly-controlled group than their counterpart. Among these subscales, the difference between the mean in these two groups is considerably higher only in the emotion subscale, but this difference is not statistically significant (p = 0.166). No significant difference is found in the mean of the *HCCQ* score (i.e. the perception of health care support).

In summary, Table 4.8 shows a direct relation between *HbA1c* in the well- versus poorly-controlled groups and two other variables namely stress and appraisal. However, the other factors listed in Table 4.1 to Table 4.8 might have some direct or indirect influence on glycemic control. Therefore, the data has been further analyzed developing a correlation matrix and conducting multi-level regression for path analysis.

4.9 Correlations among patient characteristics and study scales

Table 4.9 shows the correlation matrix between the measured variables, some of the main patient characteristics and *HbA1c*. Not listed in Table 4.9, there is a strong correlation between age and four variables, the Pearson correlation coefficients (r) are -0.234**, 0.329** and -0.196* for *BMI*, duration of diabetes and *HbA1c*, respectively.

Diabetes related stress (*PAID*) is not related to age in this study population (r = -0.084, $p > 0.1$). A relatively small positive correlation exists between stress and *BMI* (r = 0.158, p = 0.063), and stress and the duration of diabetes (r = 0.136, p = 0.106). *PAID* is moderately correlated with *HbA1c* (r = 0.232, p = 0.005). Appraisal (*ADS*) is negatively correlated to age (i.e. less negative appraisal in older participants). Moreover, it has a moderate positive correlation with *HbA1c* (r = 0.313, $p < 0.001$). Among the different types of coping strategies, emotion-oriented coping has a positive relation with the duration of diabetes; however, it is not statistically significant. Emotion-oriented coping has a moderate positive correlation with *HbA1c* (r = 0.176, p = 0.032). Avoidance and distraction oriented coping strategies might also influence *HbA1c* as they have a relatively high values of r. The perception of health care support (*HCCQ*) is negatively related to *HbA1c*; however, it is not statistically significant (r = -0.112, p = 0.156). The other coefficients listed in Table 4.9 are relatively small and are not statistically significant, which indicates that there might be some association but it may not have practical significance.

Table 4.8: Mean difference between well- and poorly-controlled groups in *PAID*, *ADS*, *HCCQ* and *CISS* scores

Variable score	**Well- vs poorly-controlled[§]**	***N***	***M***	***SD***	***t***	***df***	***p***
PAID	Well	37	21.82	17.29	-3.259[a]	88.11[a]	.002
	Poorly	85	34.03	22.49			
ADS	Well	37	17.51	4.44	-2.919	120	.004
	Poorly	85	20.14	4.63			
Task	Well	37	41.22	12.11	-0.780	120	.437
	Poorly	85	43.26	13.78			
Emotion	Well	37	46.51	12.13	-1.395	120	.166
	Poorly	85	49.84	12.07			
Avoidance	Well	37	49.95	12.67	-0.339	120	.736
	Poorly	85	50.78	12.36			
Distraction	Well	37	49.76	12.10	-0.767	120	.445
	Poorly	85	51.54	11.69			
Diversion	Well	37	47.73	11.44	-0.384	120	.702
	Poorly	85	48.65	12.42			
HCCQ	Well	37	5.94	0.80	-0.040	120	.968
	Poorly	85	5.94	1.03			

[a]The *t* and *df* were adjusted because variances are not equal

[§] Well-controlled: $HbA1c \leq 7.0$; Poorly-controlled: $HbA1c > 7.0$

Table 4.9: Correlations among patient characteristics and study scales

Variable	*Age*	*BMI*	*Duration of diabetes*	*HbA1c*
PAID	-.084	.158§	.136§	.232**
ADS	-.121	.087	.088	.313**
Task	-.080	-.024	-.017	.042
Emotion	-.014	.088	.081	.176*
Avoidance	.038	-.042	.025	.123
Distraction	.024	.049	.035	.144§
Diversion	.064	-.102	-.002	.096
HCCQ	.100	.054	.028	-.112

***$p < 0.001$; **$p < 0.01$; *$0.01 < p < 0.05$; §$0.05 < p < 0.1$

Table 4.10 shows the correlation among the measured variables. The *PAID* score is significantly positively correlated with *ADS*, *Emotion* and *Distraction* and negatively with *HCCQ* and *Diversion*. An insignificant correlation coefficient is found between *PAID* and *Task* scores. Strong positive correlations between *PAID* and *ADS* ($r = 0.719$) and *PAID* and *Emotion* ($r = 0.542$) suggest that the patients suffering from stress are more likely to appraise the disease negatively and try to adopt emotion-oriented coping. Among these patients, the high stress group has a high negative perception about the care providers ($r = -0.300$). A strong correlation between *ADS* and *Emotion* ($r = 0.562$) suggests that negatively appraised patients have a tendency to use emotion-oriented coping. These patients also have a negative perception about the care providers (r = -

0.317). The task-oriented coping does not show a statistically significant correlation with *PAID*, *ADS* or *HCCQ*. However, it has a strong correlation with avoidance-oriented coping ($r = 0.519$). *Avoidance* is strongly related to *Task* and *Emotion* ($r = 0.519$ and $r = 0.463$, respectively). The r values in the last two rows of Table 4.6 show that the patients with distraction oriented coping use emotion more than task-oriented coping ($r = 0.617$ and $r = 0.287$, respectively); however, an opposite trend is found in the diversion oriented group ($r = 0.175$ in *Emotion* and $r = 0.568$ in *Task*).

Table 4.10: Correlation among *PAID*, *ADS*, *HCCQ* and *CISS* scales

Variables	1	2	3	4	5	6	6.1	6.2
1. PAID	1.00							
2. ADS	0.719**	1.00						
3. HCCQ	-0.300**	-0.317**	1.00					
4. Task	-0.015	-0.008	0.122	1.00				
5. Emotion	0.542**	0.562**	-.185*	0.106	1.00			
6. Avoidance	0.099	0.077	0.007	0.519**	0.463**	1.00		
6.1 Distraction	0.259**	0.229*	-0.083	0.287*	0.617**	-	1.00	
6.2 Diversion	-0.112	-0.098	0.092	0.568**	0.175*	-	0.493**	1.00

**$p < 0.01$; *$0.01 < p < 0.05$

4.10 Path analysis

The aim of the present study is to identify relationships that might exist between psychosocial variables, patient characteristics and glycemic control. In the previous sections, the bivariate analyses show the correlation between the variables. In order to develop a combined model, the

key variables that influence *HbA1c* are identified though path analysis using hierarchical multiple regressions (enter method). Based on a critical evaluation of correlations among the variables and a number of trials with several combinations, two path models are proposed.

4.10.1 Model-I

The present study has been initiated based on a hypothesis that, in addition to patient characteristics, the perception of the health care system could influence the psychosocial behaviour, which in turn might affect glycemic management of type 2 diabetes patients. Following this hypothesis, the first path model, shown in Fig. 4.1, is developed to predict coping strategies and its effects on diabetes management. As identified in the previous sections stress, appraisal and emotion-oriented coping are the major factors related to *HbA1c*. As the other variables might also influence *HbA1c*, the patient characteristics, as listed in the first column of Table 4.11, are entered in the first block of hierarchical regression analyses.

First, the hierarchical regression analysis (enter method) is performed for appraisal (*ADS*) against stress (*PAID*), keeping patient characteristics in the first block and *PAID* in the second block. The key output of this analysis is shown in Table 4.11. It is found that patient characteristics can explain 5.6% ($R^2 = 0.056$) of the variance in appraisal with $p = 0.244$. Analyses are also performed with different combinations of variables, as listed in Table 4.1, for patient characteristics in the first block; however, no significant increase in R^2 or decrease in p-value is found. Note, however, that the p-value in the regression analysis for patient characteristics depends on the outcome variable, as shown later. In this analysis, *PAID* can explain an additional 38.3% of the variance in appraisal ($p < 0.001$). Note that, the p-values of R^2 change statistics are reported for the path model analysis. In other words, although R^2 in the first block with patient characteristics is not significant, in the second block the increase in R^2 with *PAID* is statistically significant.

As shown in Fig. 2.4, it has been hypothesized that autonomous support could influence both stress and appraisal. Therefore, *PAID* and *ADS* scores are regressed against the *HCCQ* score separately while controlling for patient characteristics (Fig. 4.1). The patient characteristics can explain 9.3% of the variance of *PAID* ($R^2 = 0.093$, $p = 0.030$). When *HCCQ* scores are added in the second block, R^2 increased by 0.072 ($p < 0.001$), which implies that *HCCQ* can explain an additional 7.2% of the variance in stress. Similarly, when patient characteristics are controlled, *HCCQ* can explain 4.6% of the variance in the *ADS* score ($p = 0.004$).

In the next steps, again controlling for the above patient characteristics, regression analysis is performed defining the three coping variables separately as dependent variables. Patient characteristics can explain 4.4% of the variance in *Task* ($p = 0.409$). When *ADS* is added in the second block, the value of R^2 does not increase ($\Delta R^2 = 0.0004$). This implies that appraisal cannot explain the task-oriented coping in this study sample. Moreover, these results are not statistically significant ($p = 0.787$). A similar pattern is found for avoidance: *ADS* can only explain 0.5% of the variance of avoidance-oriented coping when controlling for patient characteristics—R^2 increases from 0.040 to 0.045 and $p > 0.05$. In the case of emotion-oriented coping, patient characteristics gives $R^2 = 0.066$ ($p = 0.147$), which increases to $R^2 = 0.271$ ($p < 0.001$) when *ADS* is added in the second block. This indicates that 27.1% of the variance in emotion-oriented coping could be explained using appraisal. It is also found that the avoidance-oriented coping can also explain 14.3% of variance in emotion-oriented coping ($p < 0.001$). However, task-oriented coping does not show any statistically significant effect on emotion-oriented coping when patient characteristics are controlled.

In the last step, each coping strategy is used separately to predict *HbA1c*. When *HbA1c* is considered as the dependent variable, patient characteristics can explain 15.3% of the variance in

HbA1c, and this is statistically significant ($p < 0.001$). When the emotion-oriented coping is added, the change in R^2 is 0.021 ($p = 0.047$). In other words, emotion-oriented coping can explain significantly 2.1% of the variance in *HbA1c*. Similarly, the avoidance-oriented coping can explain 1.7% of the variance in *HbA1c* with $p = 0.079$. However, the task-oriented coping does not show any statistically significant increase in R^2 from the values obtained for patient characteristics ($\Delta R^2 = 0.001$, $p = 0.682$).

As patient characteristics can significantly predict *HbA1c* ($p < 0.05$), the key variables influencing the results are further investigated. Table 4.12 shows the summary of the first step of regression analysis when *HbA1c* is the dependent variable and emotion-oriented coping is in the second block of regression analysis as the independent variable. As shown in Table 4.12, among the patient characteristics considered in the regression analysis, age, education, marital status and duration of diabetes have statistically significant relationships with *HbA1c* ($0.01 < p < 0.05$).

Finally, a regression analysis is performed for *HbA1c* with patient characteristics in first block and *PAID*, *HCCQ*, *ADS*, *Task*, *Emotion* and *Avoidance* in the second block. It is found that R^2 increases from 0.153 ($p < 0.001$) to 0.228 ($p = 0.030$) when the second block is added. This implies that stress, autonomous perception, appraisal and coping can explain 7.4% of the variance in *HbA1c*. The final model, with all the variables, has $F(13,151) = 3.421$ and $p < 0.001$.

The path analysis suggests that the patients with high stress have a negative appraisal of diabetes. As they appraise negatively, they try to use primarily emotion-oriented coping such as “become upset” or “get angry.” This might again increase the stress and thereby *HbA1c*.

Notes:
i) Patients' characteristics are controlled in each step of regression analysis
ii) ***p<0.001; **p<0.01; *0.01<p<0.05; §0.05<p<0.1
iii) Solid lines for significant effect and dashed lines for insignificant effects

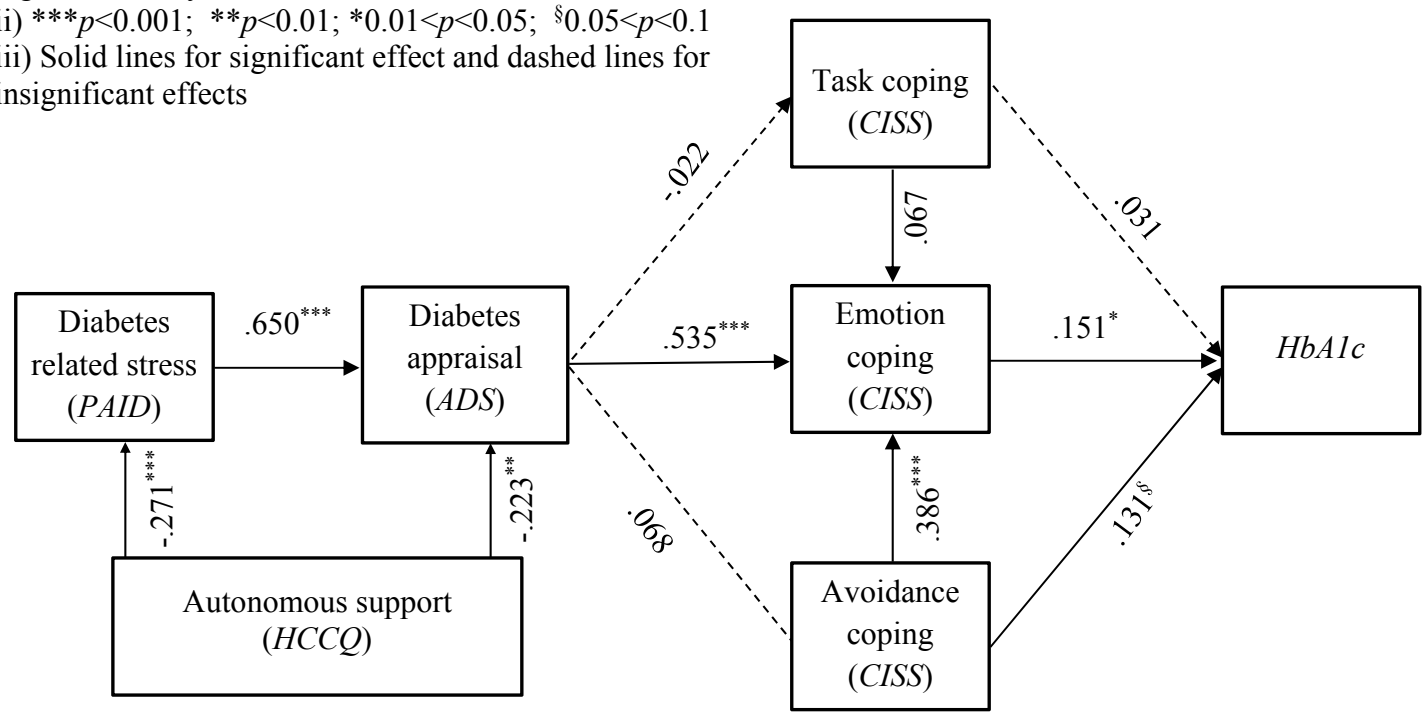

Fig. 4.1: Path Model-I to predict *HbA1c*

Table 4.11: Regression analysis results for predicting appraisal of diabetes for Model -1

Variable	B †	SE B ‡	β§	p	Tolerance
Block 1					
Age	-.064	.036	-.157	.073	.799
BMI	.849	.625	.109	.176	.937
Education[a]	.661	.835	.067	.430	.837
Income[b]	-.958	.960	-.090	.320	.735
Marital status[c]	-.038	.860	-.004	.965	.846
Duration of Diabetes	.112	.062	.151	.072	.862
Comorbidities[d]	-.089	.824	-.009	.914	.915
Block 2					
PAID	.158	.015	.650	.000***	.907

† Unstandardized partial regression coefficient

‡ Standard error of B

§ Standardized regression coefficient

[a] Reference category: up to high school diploma

[b] Reference category: ≤$40,000 per annum

[c] Reference category: single, widowed or divorced

[d] Reference category: ≤ 3 comorbidities

***$p < 0.001$; **$p < 0.01$; *$0.01 < p < 0.05$; §$0.05 < p < 0.1$

Table 4.12: Regression analysis results for predicting *HbA1c* of diabetes for Model -1

Variable	B †	SE B ‡	β§	p	Tolerance
Block 1					
Age	-.026	.011	-.198	.015*	.791
BMI	.221	.187	.090	.238	.937
Education[a]	.611	.250	.197	.015*	.837
Income[b]	-.113	.287	-.034	.695	.725
Marital status[c]	-.503	.257	-.156	.050*	.846
Duration of Diabetes	.056	.018	.241	.003*	.862
Comorbidities[d]	-.328	.246	-.102	.184	.915
Block 2					
Emotion	.021	.010	.151	.047*	.934

† Unstandardized partial regression coefficient

‡ Standard error of B

§ Standardized regression coefficient

[a] Reference category: up to high school diploma

[b] Reference category: ≤ $40,000 per annum

[c] Reference category: single, widowed or divorced

[d] Reference category: ≤ 3 comorbidities

***$p < 0.001$; **$p < 0.01$; *$0.01 < p < 0.05$; §$0.05 < p < 0.1$

4.10.2 Model-II

Figure 4.2 shows the second path model. In this model, mediator variables are identified first, based on two levels of linear regression analysis. In the first step, a dependent variable is regressed against two predictor variables individually and then, in the second step, the regression analysis is performed combining these two predictors. For example, Table 4.13 shows that *HbA1c* is strongly related to *PAID* and *ADS* individually with a high level of statistical significance (see β and *p* values). However, when the regression is performed with both of these predictors, the β value of *PAID* significantly decreases and it becomes statistically insignificant ($p = 0.775$). This indicates that *ADS* is a mediator between *PAID* and *HbA1c*. Therefore, in the path model, there is no need to show the direct effect of *PAID* on *HbA1c*. A similar analysis is performed for the other variables to identify the mediators. As shown in the last row, *PAID* acts as a mediator between *HCCQ* and *ADS*. However, in the combined regression analysis, the *p*-value for *HCCQ* increases above the level of significance ($p = 0.08$). Therefore, a Sobel test is performed which gives $z = -3.761$ and $p < .001$, which confirms that *PAID* is a mediator between *HCCQ* and *ADS*.

Similar to Model-I, as discussed in Section 4.10.1, hierarchical regression analyses are performed for Model II, keeping patient characteristics in the first block as control variables and entering predictor variable(s) in the second block.

Firstly, stress is regressed against autonomous perception. Patient characteristics can explain 9.3% of the variance in stress (*PAID*) ($R^2 = 0.093$, $p = 0.030$). Autonomous perception (*HCCQ*) can explain an additional 7.2% of the variance in *PAID* ($R^2 = 0.164$, $p < 0.001$).

Secondly, appraisal (*ADS*) is regressed against stress (*PAID*). Patient characteristics can explain 5.6% of the variance in *ADS* ($R^2 = 0.056$, $p = 0.244$), while *PAID* can explain an additional 38.3% of the variance in *ADS* ($\Delta R^2 = 0.383$, $p < 0.001$).

Table 4.13: Identification of mediators for Model-II

Dependent Variables	Predictors	Individual		Combined		Comment
		β	*p*	β	*p*	
HbA1c	*PAID*	0.232	0.005	0.034	0.775	*ADS* is a mediator
	ADS	0.313	< 0.001	0.268	0.025	
HbA1c	*Emotion*	0.176	0.034	-0.007	0.940	*ADS* is a mediator
	ADS	0.313	< 0.001	0.315	0.002	
ADS	*HCCQ*	-0.240	0.02	-0.107	0.08	*PAID* is a mediator
	PAID	0.729	< 0.001	0.695	< 0.001	

As identified, *ADS* also plays the role of mediator between *Emotion* and *HbA1c*. In the next step, *ADS* is a dependent variable and *Emotion* is a predictor. It demonstrates that, $R^2 = 0.056$ ($p = 0.244$) for patient characteristics, and $\Delta R^2 = 0.273$ ($p < 0.001$) when *Emotion* is added in the second block of the regression analysis. This indicates that emotion-oriented coping can explain 27.3% of the variance in the level of appraisal. When both *PAID* and *Emotion* are added in the second block, with patient characteristics in the first block, it is found that these two variables can jointly explain 50.4% of the variance in appraisal ($p < 0.001$).

The task- and avoidance-oriented copings do not have a significant effect on appraisal or *HbA1c* (β is relatively small and $p > 0.05$). However, for completeness, the effects of these variables are shown by dashed lines in Fig. 4.2.

In the last step, a regression analysis is performed for *HbA1c* against *ADS*, controlling for patient characteristics. In this case, patient characteristics can explain 15.3% ($R^2 = 0.153$, $p < 0.001$) and *ADS* can explain an additional 5.8% ($\Delta R^2 = 0.058$, $p < 0.001$) of the variance in *HbA1c*.

Finally, a regression analysis is performed for *HbA1c* with patient characteristics in first block and *PAID*, *HCCQ*, *ADS*, *Task*, *Emotion* and *Avoidance* in the second block (full model). This analysis shows that R^2 increases from 0.153 ($p < 0.001$) to 0.228 ($p = 0.030$) when the second block is added. This implies that, regression analysis without a path model, can explain 7.4% of the variance in *HbA1c* by stress, autonomous perception, appraisal and coping.

Therefore, it can be concluded that when an appropriate path is defined identifying appropriate mediators, only appraisal can explain 5.8% of the variance in *HbA1c*, while all the variables together can explain 7.4%. These analyses also explain the importance of mediators in the path analysis.

Although appraisal could explain ~ 6% of the variance in *HbA1c*, given the clinical and economic burden with diabetes and considering the fact that these patients are under a specialist treatment, this findings might have a significant impact on diabetes management.

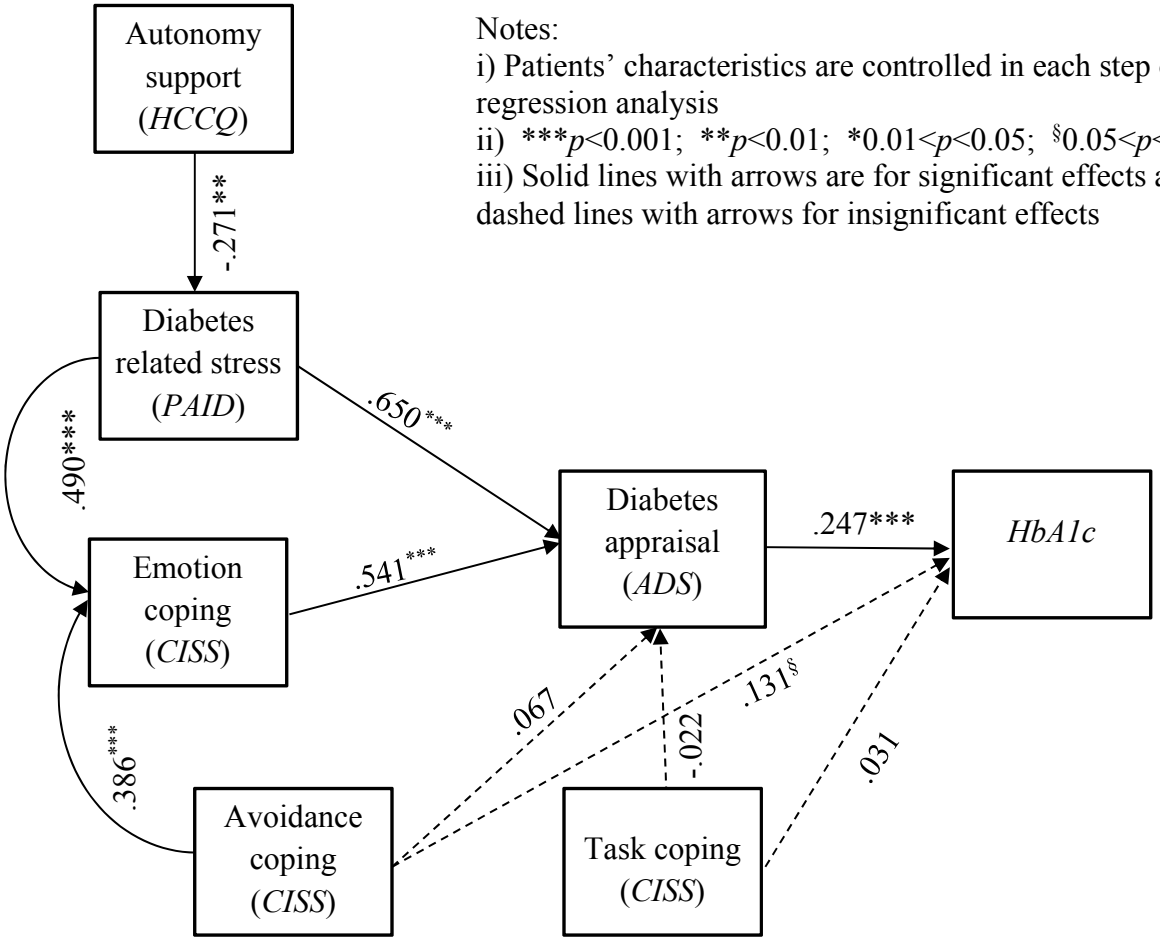

Fig. 4.2: Path Model-II to predict *HbA1c*

4.10.3 Relationship between psychosocial variables

To examine the relation among the psychosocial variables, the *PAID* score has been considered as the dependent variable. Similar to path analysis, a hierarchical regression analysis is performed entering patient characteristics in the first, autonomous perception in the second, appraisal in the third, and coping in the last block. Table 4.14 shows the summary of the regression analysis. Patient characteristics can explain 9.3% of the variance in stress ($F(7,157) = 2.293$, $p < 0.030$). Autonomous perception, appraisal and coping can explain additional 7.2%, 31.4% and 2.5% of the variance in stress, respectively; and all of them are statistically significant, as shown by the *p*-values in the last column of Table 4.14. The predictors listed in the first column of Table 4.14 can jointly explain a total of 50.4% of the variance in stress ($p < 0.001$).

A regression analysis was also performed entering patient characteristics in the first block and all the other predictors (autonomous perception, appraisal and coping) in the second block. In this analysis, autonomous perception, appraisal and coping can explain 50.4% of the variance in stress ($p < 0.001$).

Table 4.14: Regression analysis results for relationships between psychosocial variables

Predictor(s)	ΔR^2	*p*-value for ΔR^2
Patient characteristics	0.093	0.03
Autonomous perception (*HCCQ*)	0.072	< 0.001
Appraisal (*ADS*)	0.314	< 0.001
Coping strategies (*Task*, *Emotion*, *Avoidance*)	0.025	0.05

Note: Stress (*PAID*) is dependent variable

5 Chapter 5

Discussion

Despite the availability of and access to advanced clinical treatment and facilities, more than 50% of type 2 diabetes patients cannot maintain *HbA1c* below 7.0, even in developed countries. In recent years, the psychosocial behaviour of the patient is considered as one of the potential causes of this poor glycemic control. Overall, the results presented in Chapter 4 support the study hypothesis that psychosocial factors influence diabetes management. Although some of the aspects described above have been explored in previous studies, to the author's knowledge, this is the first study where problem specific data has been collected on diabetes patients in Newfoundland and Labrador, Canada, with a conjecture that the response of these patients might be different because of several reasons, such as the high prevalence of obesity in this province in Canada.

5.1 Patient characteristics

In the study sample, males and females are almost evenly distributed (47.9% and 52.1%, respectively), and there is no significant difference between their mean age (61 and 62 years, respectively). Both males and females were diagnosed with diabetes at the mean age of ~ 49 years and have lived with diabetes for a mean of ~ 11–12 years.

Age has a negative correlation with *HbA1c* (β = -.198, p = 0.015, see Table 4.12), which implies that older participants have better control in *HbA1c*. A similar trend has been shown in a study sample in Paris, France, although it was not statistically significant (β = -.074, $p > 0.05$) (Sultan et al. 2001). However, one should carefully interpret this relationship because the age of onset of type 2 diabetes varies widely (M = 49.9, SD = 11.5 years, see Table 4.2). Therefore, for a given age, the duration of having diabetes is not same. A positive correlation is found between the duration of diabetes and *HbA1c* (β = .241, p = 0.003, see Table 4.12).

Poor control of blood glucose (*HbA1c* > 7.0) is found in 63.6% of patients—higher in men (69.6%) than women (58.1%). This finding justifies the necessity of this type of research to identify other factors, such as psychosocial factors, which could be the potential cause of difficulties in diabetes management, although the patients receive appropriate clinical treatment. The percentage of poorly controlled diabetes patients found in this study is higher than the values reported in previous studies—for example, DAWN (2001) reported about 50% of patients remained poorly controlled. Therefore, although the participants of the present study were under a specialist's care and may not represent general diabetes patients, it is worth examining the reasons behind the higher percentage of poorly controlled diabetes patients in Newfoundland and Labrador.

A joint report from the Public Health Agency of Canada and the Canadian Institute for Health Information showed that obesity in Canada roughly doubled between 1981 and 2009 (PHAC & CIHI, 2011). One in four adult Canadians is obese (*BMI* ≥ 30) and more than 59% are overweight (*BMI* ≥ 25). Across the different regions in Canada, the highest prevalence of obesity has been found in Newfoundland and Labrador (27.7%). It is generally considered that obesity is a strong factor in the development of type 2 diabetes.

Ford et al. (1997) showed that the risk of diabetes might increase between 4.5% and 9% for every kilogram increase in body weight. Previous studies also show that 60–90% of type 2 diabetes patients are obese (Stumvoll et al., 2005; Halpern et al., 2005). This is in-line with the present study: 74.5% of the participants in the present study are obese (*BMI* ≥ 30).

Previous studies show that adults with a *BMI*≥35 are 20 times more likely to develop diabetes than normal-weight persons with *BMI* < 25 (Klein et al. 2004; Mokdad et al. 2001; Field et al. 2001). In the present study, although the *BMI* of the participants during the development of diabetes is

not known, in the current sample, the number of obese participants ($BMI \geq 30$) is 10.9 times that of the normal-weight participants.

Excess body weight is currently considered as one of the potential risk factors for development of type 2 diabetes (Golay and Ybarra 2005; Klein et al. 2004; Mokdad et al. 2001; Field et al. 2001). The present study shows that body weight is also affects diabetes management—the percentage of patients having poor control of *HbA1c* (> 7.0) is higher in highly obese patients ($BMI \geq 35$) than their counterparts. The present cross-sectional study does not provide any directionality—whether high obesity causes poor glycemic control or vice versa. However, this finding supports the recent health care concern with "diabesity"—diabetes plus obesity (Norris, 2005).

In the regression analysis, a statistically significant relationship between *BMI* and *HbA1c* is not found. However, when participants are categorized into two groups ($BMI < 35$ and $BMI \geq 35$), a significant difference is found: the $BMI \geq 35$ group has poor glycemic control as compared to the $BMI < 35$ group. A potential reason could be: the $BMI \geq 35$ group might have a sedentary lifestyle and an insufficient level of exercise because they might be cardiovascularly unfit, as mentioned by Schauer et al. (2009).

The present study shows poorer glycemic control in the higher educated participants than the participants who have up to high school diploma ($\beta = .197$, $p = 0.015$, see Table 4.12). A study on a population in Newfoundland and Labrador shows that the participants with low education levels, especially females, were likely to be diagnosed early with diabetes (Roche and Wang, 2014). One of the potential reasons behind this early diagnosis is that the individuals with low education levels might visit physicians more frequently than highly educated people (Bertakis et al., 2000). The patients with lower education levels reported visiting frequently for physical examination and counseling and also a better response to diabetes-specific communications with the care providers

(Piette et al., 2003). These factors might influence *HbA1c*, although in general, the risk of the development of diabetes is high in the individuals with low education levels.

Marital status influences glycemic control. The patients who are married or have common law partner show a better control in *HbA1c* than the group of single, widowed or divorced participants. This could be due to unfavorable changes in lifestyle, diet and adiposity in the patients not being married, and more specifically widowhood (Cornelis et al., 2014).

5.2 Psychosocial behaviour

Four sets of standard questionnaires are used to understand the psychosocial behaviour of diabetes patients. The diabetes related stress, appraisal of diabetes, coping styles used to manage the disease and the perception of the health care providers are evaluated using the response to these questionnaires. A good to excellent reliability for all the measures was found (Cronbach α is greater than 0.8), which is similar and, in some cases, higher than the values of α reported during the development of these questionnaires.

The diabetes related stress is not strongly related to age in this study population (r = -0.084, p > 0.1). A strong negative correlation between stress and age has been reported in some previous studies (Sultan et al. 2001; Welch et al., 2003; Shah et al. 2012). Some positive correlations exist between stress and *BMI* (r = 0.158, p = 0.06), and stress and the duration of diabetes (r = 0.136, p = 0.10) (Table 4.11). A strong positive correlation between stress and *HbA1c* is in line with previous studies (Polonsky et al. 1995; Sultan et al., 2001; Shah et al. 2012). Appraisal (*ADS*) is negatively correlated to age but it is not statistically significant. However, appraisal has a strong positive correlation with *HbA1c*. These trends are consistent with Shah et al. (2012).

Diabetes related stress, measured by the *PAID* score, is an important factor that contributes to glycemic control. While this general conclusion has been drawn by a number of researchers, the

present study reveals some additional facts in the study sample in Newfoundland and Labrador. Identifying the highly stressed participants using emotional burnout (*PAID* score greater than 40), it is found that overall 32.6% (47 out of 144) of patients suffer from emotional burnout. Among the emotional burnout patients, 89.4% cannot maintain *HbA1c* below 7.0, which indicates that diabetes related stress might be a barrier for glycemic control. It is to be noted that the participants in the present study were recruited from two speciality clinics. Some of them, especially the obese participants, might have to go through lifestyle interventions and medical treatments including surgery. Their unsuccessful attempts may have led to high stress, as observed in this study sample. A strong positive relation is found between stress and appraisal—the higher the stress the higher the negative appraisal of diabetes. The path analysis (Model-II) shows that appraisal plays a role of mediator in the relationship between diabetes related stress and *HbA1c*. When the role of appraisal on coping strategies is examined using Model-I, it is found that appraisal has a direct effect on emotion-oriented coping. Note that, Shah et al. (2012), who measured stress using *ATT39* (Dunn et al., 1986) and appraisal using *ADS* (Carey et al. 1991), showed that appraisal works as a mediator between stress and Diabetes Coping Measure, *DCM* (Welch, 1994). In the path analysis, after controlling for patient characteristics, *PAID* could explain 38.3% of variance in appraisal in the present study, while *ATT39* could explain 24% of the variance in appraisal in Shah et al. (2012). Appraisal is significantly related to emotion-oriented coping. No significant relationship is found between appraisal and task-oriented (i.e. problem-focused) or avoidance-oriented coping. It is to be noted here that Shah et al. (2012) showed a statistically significant relation between appraisal and problem-focused coping. However, the authors raised some concerns about the measurement of problem-focused coping using the DCM, because the reliability coefficient for this subscale was very low (0.56). However, in the present study, CISS gives an excellent reliability coefficient

(0.94). This study sample shows that there is no direct relation between appraisal and task-oriented coping. Similarly, no direct relation is found between appraisal and avoidance-oriented copings.

The positive correlation between *Task* and *Avoidance* is in line with previous studies on diabetes (Sultan et al., 2001) and Endler and Parker (1990), who developed the CISS questionnaires to identify coping strategies in stressful situations based on data collected on undergraduate students. *Avoidance* is strongly related to *Task* and *Emotion* ($r = 0.519$ and $r = 0.463$, respectively), which is again in line with other studies (Sultan et al. 2001; Endler and Parker 1990). *Distraction*, which is a subscale of *Avoidance*, is more strongly related to *Emotion* than *Task*. On the other hand, the other subscale of *Avoidance* (i.e. social *Diversion*) is highly correlated to *Task* compared to *Emotion* (Table 4.10).

The present study sample shows no significant difference in the perception of health care providers between well- and poorly-controlled groups. However, it is to be noted that these patients are under the Canada's Universal Health-Care System, where the patients do not have to pay directly for most health care services, which is covered by universal public health insurance. The response could be different in different health care systems, especially where the patients have to pay directly for services.

5.3 Potential application

The path analysis using hierarchical multiple regressions shows that appraisal can explain a major portion of the variance in *HbA1c* that has been identified using the measurements for stress, appraisal, coping and perception of health care. In terms of application of the present research, a routine screening of appraisal in type 2 diabetes patients could be performed at specialist clinics using the easy-to-administer instrument, the Appraisal of Diabetes Scale (ADS), which is simply a 7-item questionnaire. Then the patients with $BMI \geq 35$, poorly-controlled diabetes and high *ADS*

score might be considered for special care. Finally, if required, the emotional burnout of a patient could also be assessed using the Problem Areas in Diabetes Questionnaire—which is again an easy-to-administer 20-item questionnaire.

It is to be noted here that Welch et al. (1997) suggested that the patients having emotional burnout and poor control of *HbA1c* need special attention, and in some cases, might have to be referred to a mental health specialist to overcome stress related problems.

5.4 Limitations of the study

Although the results presented in the previous sections reveal some useful information about the management of type 2 diabetes in the patients in Newfoundland and Labrador, a number of limitations of this study need to be mentioned.

Study design

The present study is based on a cross-sectional survey method, which provides the information at a point in time. However, the management of diabetes should reflect long-term performance, not only after diagnosis but also before diagnosis and even before the development of diabetes. Therefore, the present cross-sectional design could not capture causal interpretations of the association between the study variables. For example, a group of patients were past smokers; however, the effects of quitting smoking could not be identified in this study. A longitudinal design with study focused variables would provide further information.

Sample selection

The study samples were selected at the two clinics in St. John's: the St. Clare's Mercy Hospital and Major Path Clinic. This sample may not be fully representative of diabetes patients in Newfoundland and Labrador. The participants are selected from the patients who came to visit the specialist. As the type 2 diabetes is a primary care disease that is primarily treated by family

physicians, the present study sample from speciality clinics cannot be generalized to all diabetes patients in Newfoundland. Although these patients came from all over the province, the distribution of the patients—for example, urban or rural—were not investigated.

Data collection

The patient characteristics were obtained using a study-designed data extraction from (Appendix C). This questionnaire was developed based on the general trends of data presented in previous studies. However, after analyzing the data, it is recognized that some of the questions could be modified for better data collection. As an example, a very small percentage of participants falls within some listed occupations (e.g. Natural and Applied Science). It might be better if the occupations were divided into three simple categories: employed, unemployed and retired. On the other hand, more detailed information on some variables would provide richer data. For example, as mentioned in Section 5.1, the participants without a partner show a poor control in glucose. If the duration of living without a partner in the widowed and divorced groups was known, it might provide further information on the effect of loss of the partner on glucose management.

The results presented above are based on self-reported data, which are prone to recall bias. Moreover, the response might be influenced by the patient's condition during the completion of the questionnaires, not only related to diabetes but also other physical and mental conditions.

The four sets of standard questionnaires used in this study to measure the psychosocial variables have been developed from and validated on different populations. However, there are a number questionnaires available to measure these psychosocial variables. The effectiveness of these questionnaires on this population has not been investigated by comparing the performance of different measuring tools. Any inherent limitations of these questionnaires might exist in the results presented above. In terms of the dependent variable, the most recent value of *HbA1c*

obtained from patients' health record is used. It would be better if an average value of *HbA1c* for a period of time is used.

Statistical analysis

As shown in Table 4.1, the response rate to some questions related to patient characteristics is low when compared to the questionnaires for psychosocial variables. Among them, the low response rate in exercise and diet related questions, is notable. These two factors might have a significant influence on glucose management, and therefore a better method for collection of these data is necessary. In the present study, a number of small groups were merged to create categorical variables for regression analysis. Although collected, a number patient characteristics (except for those listed in the Block 1 of Table 4.11) were not considered in the regression analysis. These factors might have some influence on glucose management.

Comorbidity might have a significant influence on stress and *HbA1c*. In the present study, only the number of comorbidities is known. If the type and level of comorbid disease were known, it could be used for better indexing—for example, using the Charlson Comorbidity Index (Carlson et al., 1987).

Finally, two path models were developed from regression analysis. Additional relationships might exist in this data, which requires further analysis.

6 Chapter 6

Conclusions and Recommendations for Future Studies

The rapidly growing number of type 2 diabetes patients over the last few decades is a significant concern to the patients, family members, society, health care providers and governments. In general, the prevalence of diabetes is higher in developed countries than developing countries. In Canada, the highest prevalence of type 2 diabetes has been reported in the Newfoundland and Labrador. It has also been reported in previous studies that diabetes and its related complications could be the major causes of reduced quality of life and mortality. Every year, a significant amount of the health care budget in developed countries is devoted to combating this chronic condition and its related complications.

Although type 2 diabetes is treatable/manageable, unfortunately more than 50% of patients are not on target, even in developed countries, despite easy access to health care. Therefore, in recent years, the research focus has shifted to include the psychosocial behaviours of type 2 diabetes patients, as they pertain to adherence to medical treatment and lifestyle adjustments (i.e. diet, exercise) over a long period.

6.1 Conclusions

In the present study, the psychosocial behaviour of type 2 diabetes patients in Newfoundland and Labrador is investigated in relation to glycemic control. A total of 165 patients completed four sets of standardized questionnaires, which provide study-focused psychosocial behaviour. The data collected using a study-designed data extraction form gives patient characteristics. Finally, the clinical behaviour (e.g. blood glucose level, *HbA1c*, *BMI*) was collected from the patients' electronic health record. A comprehensive statistical analysis is performed to interpret the data. Two path models have been proposed to show the relationship between *HbA1c* and psychosocial

variables. The following conclusions can be drawn about diabetic patients presenting to the specialty clinics for management of type 2 diabetes.

i. More than 70% of patients in the study sample are obese ($BMI \geq 30$), while only 11% of the participants have normal body weight ($BMI < 25$). This implies that the prevalence of obesity might be very high in type 2 diabetes patients in Newfoundland and Labrador.

ii. Highly obese patients might have difficulties with blood glucose control. Obese Class-II and –III patients ($BMI \geq 35$) show a higher prevalence of poor glycemic control ($HbA1c > 7$) than the patients with a $BMI < 35$, and this difference is statistically significant. However, no linear relationship is found between blood glucose control and *BMI* with a sufficient level of statistical significance.

iii. Approximately one-third of the patients suffer from emotional burnout due to diabetes related stress (*PAID* score greater than 40). Among them, 89% of patients have poor glycemic management and one-third might have severe burnout (*PAID* score between 60 and 95). The prevalence ratio of poor glycemic control in the burnout group as compared to low to moderate stress group is 1.61, which is statistically significant.

iv. Autonomous supportiveness has considerable effects on stress and appraisal in type 2 diabetes patients: a better autonomous perception reduces the stress and leads to a positive appraisal of diabetes.

v. The path Model-I shows that there is a strong relationship between diabetes related stress, autonomous perception of care providers, appraisal of diabetes and emotion-oriented coping. These four factors can explain 7.4% of the variance in *HbA1c*.

vi. The second path model (Model-II) shows that appraisal of diabetes acts as a mediator between stress and *HbA1c* and also between emotion-oriented coping and *HbA1c*.

Moreover, stress acts as a mediator between appraisal and patients' autonomous perception. Therefore, simply by appraisal 5.9% of the variance of *HbA1c* could be explained.

vii. In the relationship between psychosocial factors, autonomous perception, appraisal and coping can explain 49.8% of the variance in stress.

viii. The patient characteristics also influence *HbA1c*. The regression analysis shows that duration of diabetes, education and marital status have statistically significant effects on *HbA1c*. An increase in duration of diabetes increases *HbA1c*. The married and common law partner group has better control of *HbA1c* than the group including single, widowed or divorced participants. Higher educated participants have poor glycemic control as compared to the participants who have up to high school diploma.

Finally, the independent variables considered in this study are the attributes or characteristics of these type 2 diabetes patients. Therefore, the findings may not represent direct cause–effect relationships for glycemic control. However, this study would be very useful for development of strategies to deal with the burden of type 2 diabetes in Newfoundland and Labrador.

6.2 Recommendations for future studies

A number of factors that could influence blood glucose in type 2 diabetes patients in Newfoundland and Labrador have been investigated in the present cross-sectional study. The following are some of the areas which could be studied further.

a) Multi-center, if possible multinational, joint research programs are recommended. Such studies could identify whether there are differences in patients' responses at different locations, and if so, whether the difference is related to patient characteristics and/or available health care support, including medical insurance and the role of care providers.

Comparison of patients' performance at different locations might help identify ways to improve diabetes management strategies.

b) A similar type of study, as presented in this thesis, could be performed on type 1 diabetes. This type of study will reveal whether glucose management issues are dependent on the type of diabetes. If so, different strategies should be adopted for these two groups of patients.

c) Studies on lifestyle adjustment interventions would be useful. Identification of appropriate interventions, such as physical exercise and diet, might help in the development of improved guidelines for glucose management and increase public awareness.

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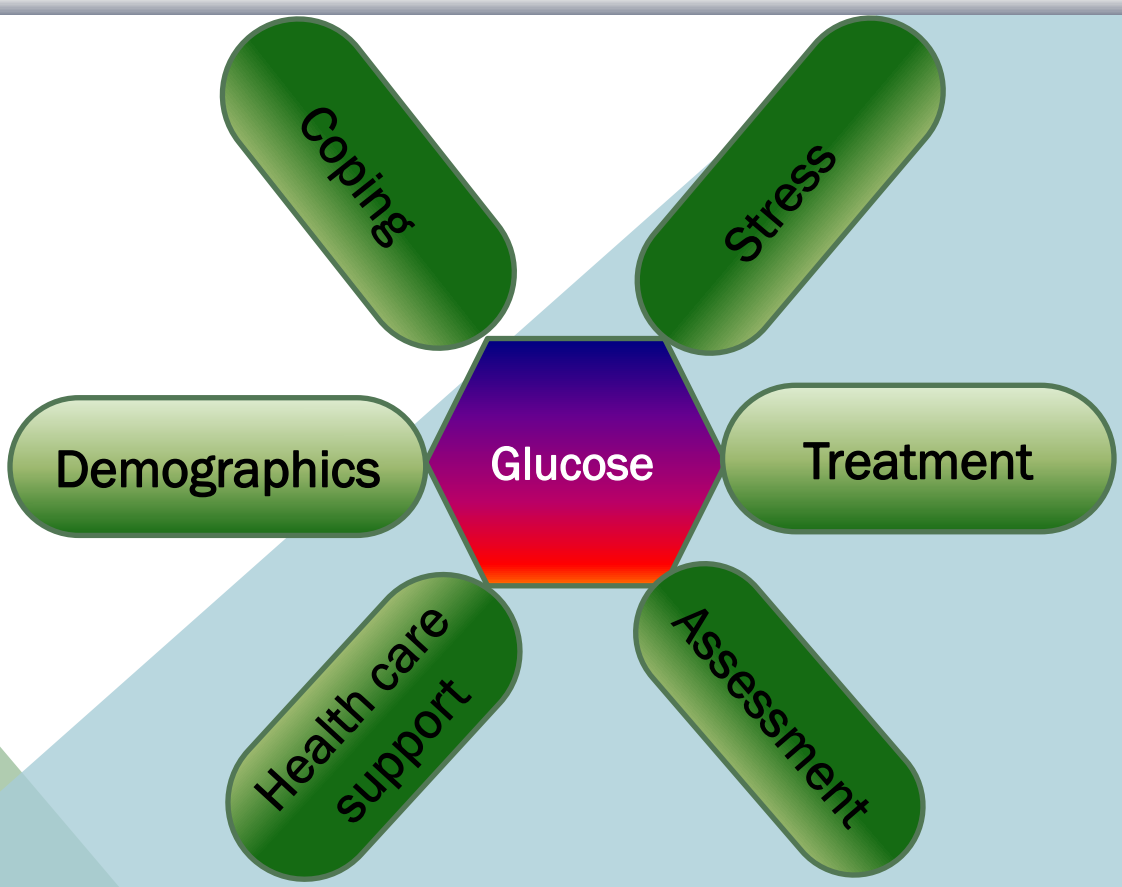
Appendix-A

Poster for Patient Recruitment

Effects of Psychosocial and Clinical Factors on Type 2 Diabetes Control

We invite you to take part in a research study identifying psychosocial and clinical factors affecting diabetes control



Please Contact:
Dr. Sahar Iqbal Tel. 709-777-5976 St. Clare's

A Study with Dr. Sahar Iqbal, Diabetes Specialist, supervising Krishna Roy, graduate Student, in the Division of Community Health and Humanities, MUN.

Appendix-B

Consent to Take Part in Research

How to Use the Consent Template

- Read the General Consent Guidelines found on the HREA website

Instructions

Red Font:
When developing your consent from this template, pay special attention to areas that are red font. These areas are intended to be tailored to specifically describe your research project and provide direction on what information is to be provided in each section and how it should be presented. They are included as part of standard format to ensure that these elements are considered in the development of your consent form.

Red Italicized Font:
The areas that are red italicized font are optional elements and may not apply to your study. They should be modified or deleted as needed.

After modifying these areas, font color should be changed to black, and *italics* replaced with regular font so that all text is in regular font (except **headings** which should always be bolded black font).

Bold Font:
The **bold** areas are standard language and should not be modified. However, when developing your consent form, the bold font should be replaced with regular font for the text in these sections. The headings are to remain in bold as per the format of the entire consent form. .

Please delete this page from your consent document before submitting it for review to the ethics committee.

CHECKLIST

This checklist is to be completed and submitted with this consent form.
It is to be removed from the final version of the consent document.

☒ Most recent version of consent template (June 2014) has been used
☒ Footer includes consent version, study name, line for patient initials
☒ Font size no less than 12 [except for footer]
☒ Left justification of text
☒ Grade 9 or lower reading level. Assessed reading level is: _____8_____
☒ Accepted definitions for specialized terms used where applicable
☒ Plain language principles used for study specific wording – no jargon, no acronyms, short words, short sentences, active voice and, where appropriate, bulleted lists

Standard, required wording (in bold type) has been used in the following sections:

	Yes	**No**	
Introduction	☒	☐	
Benefits (Q6)	☒	☐	
Liability Statement (Q7)	☒	☐	
Privacy and confidentiality (Q8)	☒	☐	
Questions or problem (Q9)	☒	☐	
Signature page	☒	☐	
Signature page for minor/assenting participants if applicable	☐	☐	**NA**

If you have answered No to any of the above, please give the rationale for these changes below:

TCPS2 guidelines provide a list of the information required for informed consent. Please refer to TCPS2, Chapter 3, available at: http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter3-chapitre3/.

The HREB Policy Manual provides detailed information on specific consent issues including: consent to research in emergency health situations; the use of substitute decision makers; assent for children; research involving special populations (children, cognitively impaired); managing consent in situations of difficult power relationships; and community consent to research involving Aboriginal communities. Please refer to the HREB Policy Manual on the HREA website: www.hrea.ca

Community Health and Humanities
Faculty of Medicine
Memorial University of Newfoundland
Health Sciences Centre
St. John's, NL Canada, A1B 3V6

Consent to Take Part in Research

TITLE: Effects of Psychosocial and Clinical Factors on Diabetes Management

INVESTIGATOR(S): Krishna Roy & Dr. Sahar Iqbal

You have been invited to take part in a research study. Taking part in this study is voluntary. It is up to you to decide whether to be in the study or not. You can decide not to take part in the study. If you decide to take part, you are free to leave at any time. This will not affect your usual health care/normal treatment.

Before you decide, you need to understand what the study is for, what risks you might take and what benefits you might receive. This consent form explains the study.

Please read this carefully. Take as much time as you like. If you like, take it home to think about for a while. Mark anything you do not understand, or want explained better. After you have read it, please ask questions about anything that is not clear.

The researchers will:

- discuss the study with you
- answer your questions
- keep confidential any information which could identify you personally
- be available during the study to deal with problems and answer questions

1. Introduction/Background:

Type 2 Diabetes in the Newfoundland and Labrador population is the highest in Canada. Many complications can happen if a patient cannot manage and control diabetes. We noticed that more than 50% of patients did not do well on medicine alone. We want to identify whether psychosocial factors are also important to bring diabetes under control.

2. Purpose of study:

The purpose of this research is to find the factors influencing diabetes management. We think patient's level of stress, self-confidence and coping skills might be related to diabetes control.

3. Description of the study procedures:

If you decide to take part in this study all you have to do is to fill out four sets of self-reported questionnaires and one personal data form related to your diabetes management. After you completed the questionnaires please return to Dr. Iqbal. No other visits are needed.

4. Length of time:

It will take approximately 30 minutes to complete the questionnaires and personal data form.

5. Possible risks and discomforts:

The study does not pose any significant risk. If you get emotionally upset while completing the questionnaires, you can take time or refuse to answer those questions. Although it is not expected, if required, the emotionally distressed patients will be referred to the hospital or community based services (The START Clinic–Eastern Health, Tel: (709) 777-5390).

6. Benefits:

The study will help diabetes patients like you in general but it may not help you directly.

7. Liability statement:

Signing this form gives the researchers your consent to be in this study. It tells us that you understand the information about the research study. When you sign this form, you do not give up your legal rights. Researchers or agencies involved in this research study still have their legal and professional responsibilities.

8. What about my privacy and confidentiality?

Protecting your privacy is an important part of this study. Every effort to protect your privacy will be made. However it cannot be guaranteed. For example we may be required by law to allow access to research records.

When you sign this consent form you give us permission to

- Collect information from you
- Collect information from your health record
- Share information with the people conducting the study
- Share information with the people responsible for protecting your safety

Access to records

The members of the research team will see health and study records that identify you by name. Other people may need to look at your health records and the study records that identify you by name. This might include the research ethics board. You may ask to see the list of these people. They can look at your records only when supervised by a member of the research team.

Use of your study information

The research team will collect and use only the information they need for this research study.

This information will include your

- Information in 4 sets of standard questionnaires and 1 personal data form —will be collected from you.
- Glucose level, age at the time of diagnosis of diabetes, height and weight, and other chronic diseases —will be collected from your health record.

Your name and contact information will be kept secure by the research team in Newfoundland and Labrador. It will not be shared with others without your permission. Your name will not appear in any report or article published as a result of this study.

Information collected for this study will be kept for five years.

If you decide to withdraw from the study, the information collected up to that time will be destroyed.

Information collected and used by the research team will be stored at the St. Clare's Mercy Hospital. Dr. Sahar Iqbal is the person responsible for keeping it secure.

Your access to records

You may ask the principal investigator (Krishna Roy) to see the information that has been collected about you.

9. Questions or problems:

If you have any questions about taking part in this study, you can meet with the investigator who is in charge of the study at this institution. That person is:

Krishna Rani Roy (Principal Investigator) & Dr. Sahar Iqbal (Supervisor)
Room S-114, Morrissey Wing, St. Clare's Mercy Hospital, Tel. 709-777-5976

Or you can talk to someone who is not involved with the study at all, but can advise you on your rights as a participant in a research study. This person can be reached through:
Ethics Office
Health Research Ethics Authority
709-777-6974 or by email at info@hrea.ca

After signing this consent you will be given a copy.

Signature Page

Study title: Effects of Psychosocial and Clinical Factors on Diabetes Control

Name of principal investigator: Krishna Rani Roy

To be filled out and signed by the participant:

	Please check as appropriate:	
I have read the consent.	Yes { }	No { }
I have had the opportunity to ask questions/to discuss this study.	Yes { }	No { }
I have received satisfactory answers to all of my questions.	Yes { }	No { }
I have received enough information about the study.	Yes { }	No { }
I have spoken to Krishna Roy (PI) and he/she has answered my questions	Yes { }	No { }
I understand that I am free to withdraw from the study • at any time • without having to give a reason • without affecting my future care	Yes { }	No { }
I understand that it is my choice to be in the study and that I may not benefit.	Yes { }	No { }
I understand how my privacy is protected and my records kept confidential	Yes { }	No { }
I agree that the study doctor or investigator may read the parts of my hospital records which are relevant to the study.	Yes { }	No { }
I agree to take part in this study.	Yes { }	No { }

_____ _____ _____ _

Signature of participant Name printed Year Month Day

<u>To be signed by the investigator or person obtaining consent</u>

I have explained this study to the best of my ability. I invited questions and gave answers. I believe that the participant fully understands what is involved in being in the study, any potential risks of the study and that he or she has freely chosen to be in the study.

_____Krishan Roy_____-___ _____

Signature of investigator Name printed Year Month Day

Telephone number: _____709-777-5976_____

Appendix-C

Questionnaires for Data Collection

Serial No.

Personal data Form

Effect of Psychosocial and Clinical Factors on Diabetes Control

Socio-demographic Information

Gender: ☐ Male ☐ Female

Age:

Education: ☐ Reading level grade eight or higher, ☐ High school diploma,

☐ Some post-secondary, ☐ College or trade certification, ☐ University degree

☐ Others (specify) _____

Occupation: ☐ Management Occupations, ☐ Business, Finance and Administrative occupations,

☐ Natural and Applied Sciences and Related Occupations, ☐ Health Occupations,

☐ Occupations in Social Science, Education, Government Services,

☐ Occupations in Art, Culture, Recreation and Sport,

☐ Sales and Service Occupations, ☐ Transport and Equipment Operators and Related Occupation, ☐ Occupations Unique to Primary Industry,

☐ Occupations Unique to Processing, Manufacturing and Utility, ☐ Retired,

☐ Student, ☐ without work, ☐ Others (specify) _____

Marital status: ☐ Single ☐ Married ☐ Widowed ☐ Divorced ☐ Common law

☐ Others (Specify) ___

Income: ☐ ≤20,000 ☐ 21,000 - 40,000 ☐ 41,000 - 60,000

☐ 61,000 - 80.000 ☐ 81,000 - 100.000 ☐ ≥101,000

Lifestyle information

Smoking: ☐ Current smoker ☐ Past smoker ☐ Never smoked

If smoke, how often you smoke in a week _____

Alcohol: ☐ Yes ☐ No

If consume alcohol, how often you consume in a week _____

Recreational Drugs: ☐ Yes ☐ No

Self-care behaviour

Do you exercise? ☐ Yes ☐ No

If yes, how many times in a week _____

Each time how long do you exercise? ☐ 15 minutes ☐ 30 minutes ☐ 45 minutes ☐ 1 hour

Do you follow doctor recommended diet? ☐ Yes ☐ No

If yes, how strictly you follow the diet restriction: ☐ Very strict, ☐ somewhat strict,

☐ Sometimes, ☐ Rarely

Do you check blood glucose at home? ☐ Yes ☐ No

If yes, how often in a week (specify approximate number)_____

Do you visit to diabetes centre? ☐ Weekly ☐ Bi-weekly ☐ monthly

☐ Rarely ☐ Never

Which of the following doctor recommended you to follow to manage your diabetes (select all those that apply)?

☐ Diet ☐ Exercise ☐ Oral medication

☐ Insulin ☐ pump ☐ Others_____ (Specify)

Problem Areas in Diabetes Questionnaire (PAID)

DAWN
Diabetes Attitudes Wishes & Needs

INSTRUCTIONS: Which of the following diabetes issues are currently a problem for you?
Circle the number that gives the best answer for you. Please provide an answer for each question. Please bring the completed form with you to your next consultation where it will form the basis for a dialogue about how you are coping with your diabetes

Patient name: Completion date: Interview date:

	Not a problem	Major problem	Moderate problem	Somewhat serious problem	Serious problem
1. Not having clear and concrete goals for your diabetes care?	0	1	2	3	4
2. Feeling discouraged with your diabetes treatment plan?	0	1	2	3	4
3. Feeling scared when you think about living with diabetes?	0	1	2	3	4
4. Uncomfortable social situations related to your diabetes care (e.g., people telling you what to eat)?	0	1	2	3	4
5. Feelings of deprivation regarding food and meals?	0	1	2	3	4
6. Feeling depressed when you think about living with diabetes?	0	1	2	3	4
7. Not knowing if your mood or feelings are related to your diabetes?	0	1	2	3	4
8. Feeling overwhelmed by your diabetes?	0	1	2	3	4
9. Worrying about low blood sugar reactions?	0	1	2	3	4
10. Feeling angry when you think about living with diabetes?	0	1	2	3	4
11. Feeling constantly concerned about food and eating?	0	1	2	3	4
12. Worrying about the future and the possibility of serious complications?	0	1	2	3	4
13. Feelings of guilt or anxiety when you get off track with your diabetes management?	0	1	2	3	4
14. Not “accepting” your diabetes?	0	1	2	3	4
15. Feeling unsatisfied with your diabetes physician?	0	1	2	3	4
16. Feeling that diabetes is taking up too much of your mental and physical energy every day?	0	1	2	3	4
17. Feeling alone with your diabetes?	0	1	2	3	4
18. Feeling that your friends and family are not supportive of your diabetes management efforts?	0	1	2	3	4
19. Coping with complications of diabetes?	0	1	2	3	4
20. Feeling “burned out” by the constant effort needed to manage diabetes?	0	1	2	3	4

Serial No.

Appraisal of Diabetes Scale

People differ in their thoughts and feelings about having diabetes. We would like to know how you feel about having diabetes. Therefore, please circle the answer to each question which is closest to the way *you* feel. Please give your honest feelings - *we are interested in how you feel*, not what your doctor or family may think.

1 How upsetting is having diabetes for you?

1	**2**	**3**	**4**	**5**
Not at All	Slightly upsetting	Moderately upsetting	Very upsetting	Extremely upsetting

2 How much control over your diabetes do you have?

1	**2**	**3**	**4**	**5**
Not at All	Slight amount	Moderate amount	Large amount	Total amount

3 How much uncertainty do you currently experience in your life as a result of being diabetic?

1	**2**	**3**	**4**	**5**
None at all	Slight amount	Moderate amount	Large amount	Extremely large amount

4 How likely is your diabetes to worsen over the next several years? (Try to give an estimate based on your personal feeling rather than based on a rational judgement.)

1	**2**	**3**	**4**	**5**
Not likely at all	Slightly likely	Moderately likely	Very likely	Extremely likely

5 Do you believe that achieving good diabetic control is due to your efforts as compared to factors which are beyond your control?

1	**2**	**3**	**4**	**5**
Totally because of me	Mostly because of me	Partly because of me and Partly because of others factors	Mostly because of other factors	Totally because of other factors

6 How effective are you in coping with your diabetes?

1	**2**	**3**	**4**	**5**
Not at All	Slightly effective	Moderately effective	Very effective	Extremely effective

7 To what degrees does your diabetes get in the way of your developing life goals?

1	**2**	**3**	**4**	**5**
Not at all	Slight amount	Moderate amount	Large amount	Extremely large amount

Serial No.

Health Care Climate Questionnaire

Perceived Autonomy Support

Please answer the questions below **regarding your overall relationships with your health care providers since you are diagnosed with diabetes.** They have different styles in dealing with patients. Your responses will be kept confidential, so none of them will know your responses. Please be honest and candid. Choose your answers using the scale below for each question by circle a number from 1 to 7 for each item.

1	2	3	4	5	6	7
Strongly disagree	Moderately disagree	Slightly disagree	Neutral	Slightly agree	Moderately agree	Strongly agree

1. I feel that my health care providers have provided me choices and options about my health.	1	2	3	4	5	6	7
2. I feel my health care providers understand how I see things with respect to my health.	1	2	3	4	5	6	7
3. I am able to be open with my health care providers about my health.	1	2	3	4	5	6	7
4. My health care providers convey confidence in my ability to make changes regarding my health.	1	2	3	4	5	6	7
5. I feel that my health care providers accept me whether I follow their recommendations or not.	1	2	3	4	5	6	7
6. My health care providers have made sure I really understand my health risk behaviors and the benefits of changing these behaviors without pressuring me to do so.	1	2	3	4	5	6	7
7. My health care providers encourage me to ask questions.	1	2	3	4	5	6	7
8. I feel a lot of trust in my health care providers.	1	2	3	4	5	6	7
9. My health care providers' answers my questions related to my health fully and carefully.	1	2	3	4	5	6	7
10. My health care providers listen to how I would like to do things regarding my health.	1	2	3	4	5	6	7
11. My health care providers handle my emotions very well.	1	2	3	4	5	6	7
12. I feel that my health care providers care about me as a person.	1	2	3	4	5	6	7
13. I don't feel very good about the way my health care providers' talks to me about my health.	1	2	3	4	5	6	7
14. My health care providers try to understand how I see my health before suggesting any changes.	1	2	3	4	5	6	7
15. I feel able to share my feelings with my health care providers.	1	2	3	4	5	6	7

CISS-Adult by Norman S. Endler, Ph.D. F.R.S.C. & James D.A. Parker, Ph.D.

Serial No.

Instructions: The following are ways people react to various difficult, stressful, or upsetting situations. Please circle a number from 1 to 5 for each item. Indicate how much you engage in these types of activities when you encounter a difficult, stressful, or upsetting situation.

	Not at all				Very much
1. Schedule my time better	1	2	3	4	5
2. Focus on the problem and see how I can solve it	1	2	3	4	5
3. Think about the good times I've had	1	2	3	4	5
4. Try to be with other people	1	2	3	4	5
5. Blame myself for procrastinating	1	2	3	4	5
6. Do what I think best	1	2	3	4	5
7. Preoccupied with aches and pains	1	2	3	4	5
8. Blame myself for having gotten into this situation	1	2	3	4	5
9. Window shop	1	2	3	4	5
10. Outline my priorities	1	2	3	4	5
11. Try to go to sleep	1	2	3	4	5
12. Treat myself to a favorite food or snack	1	2	3	4	5
13. Feel anxious about not being able to cope	1	2	3	4	5
14. Become very tense	1	2	3	4	5
15. Think about how I have solved similar problems	1	2	3	4	5
16. Tell myself that it is really not happening to me	1	2	3	4	5
17. Blame myself for being too emotional about the situation	1	2	3	4	5
18. Go out for a snack or meal	1	2	3	4	5
19. Become very upset	1	2	3	4	5
20. Buy myself something	1	2	3	4	5
21. Determine a course of action and follow it	1	2	3	4	5
22. Blame myself for not knowing what to do	1	2	3	4	5
23. Go to a party	1	2	3	4	5
24. Work to understand the situation	1	2	3	4	5
25. "Freeze" and don't know what to do	1	2	3	4	5
26. Take corrective action immediately	1	2	3	4	5
27. Think about the event and learn from my mistake	1	2	3	4	5
28. Wish that I could change what had happened or how I felt	1	2	3	4	5
29. Visit a friend	1	2	3	4	5
30. Worry about what I am going to do	1	2	3	4	5
31. Spend time with a special person	1	2	3	4	5
32. Go for a walk	1	2	3	4	5
33. Tell myself that it will never happen again	1	2	3	4	5
34. Focus on my general inadequacies	1	2	3	4	5
35. Talk to someone whose advice I value	1	2	3	4	5
36. Analyze the problem before reacting	1	2	3	4	5
37. Phone a friend	1	2	3	4	5
38. Get angry	1	2	3	4	5
39. Adjust my priorities	1	2	3	4	5
40. See a movie	1	2	3	4	5
41. Get control of the situation	1	2	3	4	5
42. Make an extra effort to get things done	1	2	3	4	5
43. Come up with several different solutions to the problem	1	2	3	4	5
44. Take time off and get away from the situation	1	2	3	4	5
45. Take it out on other people	1	2	3	4	5
46. Use the situation to prove that I can do it	1	2	3	4	5
47. Try to be organized so I can be on top of the situation	1	2	3	4	5
48. Watch TV	1	2	3	4	5

Appendix-D

HREA and RPAC Approvals

NEWFOUNDLAND AND LABRADOR
HREB
HEALTH RESEARCH ETHICS BOARD

Ethics Office
Suite 200, Eastern Trust Building
95 Bonaventure Avenue
St. John's, NL
A1B 2X5

June 9, 2015

Ms Krishna Roy
C/o Dr Sahar Iqal
Room S-114, Morrissey Wing
St. Clare's Mercy Hosptial
154 LeMarchant Road
St. John's, NL

Dear Ms Roy:

Reference #15.112

RE:Stress, appraisal, autonomous support and coping: An integrative perspective of adult type 2 diabetes management in Newfoundland

This will acknowledge receipt of your correspondence.

This correspondence has been reviewed by the Chair under the direction of the Board. ***Full board approval*** of this research study is granted for one year effective **May 14, 2015.**

This is your ethics approval only. Organizational approval may also be required. It is your responsibility to seek the necessary organizational approval from the Regional Health Authority or other organization as appropriate. You can refer to the HREA website for further guidance on organizational approvals.

This is to confirm that the Health Research Ethics Board reviewed and approved or acknowledged the following documents (as indicated):

- Application, approved
- Consent form, approved
- Poster, approved
- Personal data form, approved
- CISS – Coping inventory for stressful situations, approved
- ADS – Appraisal of Diabetes Scale, approved
- PAID - Problem Areas I diabetes Questionnaire, approved
- HCCQ – Health Care Climate Questionnaire, approved
- Letter for Request for access to the patient data file, approved

MARK THE DATE

This approval will lapse on May 14, 2016. It is your responsibility to ensure that the Ethics Renewal form is forwarded to the HREB office prior to the renewal date; you may not receive a reminder. The Ethics Renewal form can be downloaded from the HREB website http://www.hrea.ca.

If you do not return the completed Ethics Renewal form prior to date of renewal:

- ***You will no longer have ethics approval***
- *You will be required to stop research activity immediately*
- *You may not be permitted to restart the study until you reapply for and receive approval to undertake the study again*
- *Lapse in ethics approval* ***may result in interruption or termination of funding***

You are solely responsible for providing a copy of this letter, along with your approved HREB application form; **to the Office of Research Services** should your research depend on funding administered through that office.

Modifications of the protocol/consent are not permitted without prior approval from the HREB. **Implementing changes without HREB approval may result in your ethics approval being revoked, meaning your research much stop**. Request for modification to the protocol/consent must be outlined on an amendment form (available on the HREA website) and submitted to the HREB for review.

The Health Research Ethics Board operates according to the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, the Health Research Ethics Authority Act and applicable laws and regulations.

You are responsible for the ethical conduct of this research, notwithstanding the approval of the HREB.

We wish you every success with your study.

Sincerely,

Dr Fern Brunger (Chair, Non-Clinical Trials Health Research Ethics Board)
Ms. Patricia Grainger (Vice-Chair, Non-Clinical Trials Health Research Ethics Board)

CC: S Iqbal