The Influence of Diabetes-Related Worry and Worry-Driven Behaviour on the Self-Management of Type 1 Diabetes Mellitus

by

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AUTHOR'S DECLARATION

I hereby declare that I am the sole author of this thesis. This is a true copy of the thesis, including any required final revisions, as accepted by my examiners.

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Abstract

Background. Type 1 diabetes mellitus (T1DM) requires the ongoing self-management of blood glucose to minimize the likelihood of serious morbidity and premature mortality. Adherence to clinical recommendations is challenging and is influenced by serious short-term complications of self-management (e.g., hypoglycemia, hyperglycemia) and long-term vascular pathology (e.g., eye disease, heart attack). Worry of hypoglycemia (WoH) and worry of vascular complications (WVC) are two cognitive and behavioural constructs that have important implications for blood glucose control. Although researchers have argued that avoidance behaviour explains the relationship between diabetes-related worry and blood glucose, data supporting this assertion is lacking. Furthermore, the impact of diabetes-related worry and worry-driven behaviour on important health-related quality of life (HRQoL) dimensions is unclear. The purpose of the present study was to provide the first test of this avoidance behaviour mediation hypothesis, and to examine the relationships between diabetes-related worry, avoidance behaviour and HRQoL (perceived impact; self-management satisfaction). Method. One hundred and fifty two individuals with T1DM completed a self-report questionnaire package, and 129 participants had blood glucose values (i.e., A1C) available for analysis. Results. Avoidance behaviour did not mediate the relationships between diabetes-related worry and blood glucose. However, WoH was associated with avoidance behaviour, which in turn, was associated with higher blood glucose levels. Hypoglycemia avoidance behaviour mediated the positive relationship between WoH and the perceived impact of having diabetes, and WVC and hyperglycemia avoidance behaviour were independently associated with the perceived impact of having diabetes. While WoH and WVC were associated with lower satisfaction with self-management practices, hypoglycemia subtle

avoidance behaviour, hyperglycemia avoidance behaviour, and complication vigilance/risk behaviour avoidance was associated with greater satisfaction. Discussion. In the majority of cases, the avoidance behaviour mediation hypotheses were not supported by these data. However, these results highlight the differential impact of diabetes-related worry and worry-driven behaviour on blood glucose and HRQoL among individuals with T1DM. Strengths and limitations of the present study are discussed, and directions for future research are offered.

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CHAPTER 1

Diabetes mellitus is a complex chronic medical condition that involves the dysregulation of blood glucose metabolism. As of 2005, it was estimated that 1.8 million Canadians have developed diabetes (Canadian Diabetes Association, 2008), and the World Health Organization projects that it will affect upwards of 370 million people worldwide by 2030 (Wild, Roglic, Green, Sicree & King, 2004).

1.1 Definitions of Diabetes

Type 1 diabetes mellitus (T1DM) accounts for 10% of all cases of diabetes. In this condition, the body's immune system attacks and destroys the ß-cells in the pancreas. These cells are responsible for the body's production of insulin (the hormone that facilitates the transfer of glucose from the blood plasma into the organs and tissues of the body). This ß-cell destruction results in insufficient insulin production, and leads to an inability of the body to metabolize carbohydrates and glucose that is ingested (Lawson & Muirhead, 2001). Eventually, a high level of unusable glucose in the blood results in cellular death, vascular damage, and organ failure. The management of T1DM requires repeated insulin injections and lifestyle modification involving dietary choice, physical activity, self-monitoring of blood glucose, and medication adherence. Prior to the discovery and administration of insulin in humans in 1922, individuals with T1DM typically did not live beyond adolescence (Cheng & Zinman, 2001). All deaths resulted from a metabolic condition called diabetic ketoacidosis (described below). However, with the advent of insulin therapy, a long and productive life can be achieved, particularly when coupled with appropriate behavioural management.

In contrast, Type 2 diabetes mellitus (T2DM) results from the cumulative effect of excessive energy intake coupled with insufficient energy expenditure among genetically

predisposed individuals. This imbalance increases the demand for insulin production by the pancreas to maintain a homeostatic state of blood glucose. Over time, the presence of copious amounts of insulin results in an irreversible cellular resistance to the insulin produced by the pancreas (Capes & Anand, 2001). Furthermore, chronic elevations in blood glucose are toxic, and destroy the pancreatic ß-cells resulting in a relative deficiency in insulin production. In essence, the pancreas produces less insulin; and the cells of the body are unable to effectively use the insulin that is produced. First line interventions include similar health behaviour change (i.e., dietary choice, physical activity). However, if unsuccessful at managing blood glucose, it is managed with medications that stimulate insulin production and/or sensitize the cells of the body to the insulin produced by the pancreas, and In later stages, individuals with T2DM may require intensive insulin therapy to maintain normal blood glucose levels.

Regardless of the underlying pathophysiology, individuals with diabetes are faced with significant biopsychosocial demands that impact the management of their disease (Delamater et al., 2001; Fisher, Delamater, Bertelson, & Kirkley, 1982; Petrie et al., 1996; Wysocki, Buckoloh, Lochrie, & Antal, 2005).

1.2 Self-Management and Disease-Related Complications

If individuals are unable to maintain normal blood glucose levels, they risk facing a myriad of complications that are dispersed over time. Some complications are relatively episodic and frequent, where others are cumulative and eventual. For example, in the short-term, individuals must manage the risk of acute episodes of excessively low blood glucose (i.e., hypoglycemia), and excessively high blood glucose (e.g., hyperglycemia; Booth, 2001; Yale, 2001). In the longer-term, individuals risk developing serious vascular pathology that can lead to blindness, renal failure, persistent neuropathic pain, myocardial infarctions (heart

attack), cerebral vascular accidents (stroke), or peripheral arterial disease. To gain a better appreciation for these short-term and long-term complications that range in severity from noxious yet benign, to potentially life threatening, a cursory review of these symptoms and states will be provided.

1.2.1 Hypoglycemia

Optimal blood glucose ranges from 4.0mmol/L – 7.0mmoL/L (CDA, 2008). Hypoglycemia is defined as a state of low plasma glucose concentration ($\leq$ 4.0mmol/L) that is accompanied by a host of aversive physical symptoms. Symptoms are divided into two categories and include adrenergic (i.e., trembling, heart palpitations, sweating, anxiety, hunger, nausea, or tingling) and transient neurological (i.e., impaired concentration, fatigue, confusion, weakness, drowsiness, vision changes, difficulty speaking, headache, dizziness, loss of consciousness, and seizures; Hepburn, 1994). In mild forms, individuals often become aware of these unpleasant adrenergic symptoms and are able to self-correct by administering oral carbohydrate (i.e., typically liquids containing glucose, such as juice or soda). In more extreme states, transient neurological symptoms develop and often require the assistance of others to correct. The results of several studies have shown that on average, mild episodes occur twice per week, and severe episodes occur once or twice per year (Pedersen-Bjergaard et al., 2004; Pramming, Thorsteinsson, Bendtson, & Binder, 1991). Furthermore, half of all instances of hypoglycemia occur nocturnally during sleep (Banarer & Cryer, 2003).

Unfortunately, as a consequence to intensive insulin therapy (i.e., multiple daily injections) and the strict glycemic control required to minimize the risk of long-term complications (discussed below), the frequency of hypoglycemic episodes increases three-fold compared to individuals on less intensive insulin regimens (DCCT, 1997). In fact, severe

hypoglycemia is the most common adverse event of intensive insulin therapy (Yale, 2001). It has been argued to be the greatest limiting factor to the maintenance of optimal glycemic control because it may trigger dangerous physiological states, excessive worry, and maladaptive avoidance behavior (Cryer, 2002; Cryer, 1999).

1.2.2 Hyperglycemia

In contrast, hyperglycemia is defined as a state of elevated plasma glucose concentration ($\geq$ 7.0mmol/L). It is accompanied by a different constellation of symptoms that include excessive thirst, excessive urination, fatigue, itchy skin; and over time, weight loss. In mild forms, individuals are often unaware of these elevations. In more flagrant episodes, individuals may self-detect these aforementioned symptoms. Hyperglycemia is managed by self-administering an injection of short-acting insulin to restore normal blood glucose levels. However, if untreated, extreme hyperglycemia can precipitate a state of diabetic ketoacidosis (DKA), which results in both the production of ketones and metabolic acidosis (Booth, 2001). DKA leads to excessive urination and loss of both fluid and electrolytes that can result in death. Repeated episodes of DKA may be evidence of poor metabolic control, which potentiates morbidity and premature mortality. Precipitants for DKA include infection, abdominal crises (e.g., gastrointestinal bleeding, pancreatitis), physical trauma (Ellermann et al., 1984; Wetterhall et al., 1992), and insulin omission (Levitsky et al., 1991). Prior to the discovery of insulin, heart attacks secondary to DKA were certain to be the cause of death in individuals with T1DM.

1.2.3 Microvascular and Macrovascular Complications

Over time, individuals with T1DM are at risk for developing a number of serious microvascular and macrovascular complications. Microvascular complications include

retinopathy (microaneurysms in the retina), nephropathy (persistently positive presence of albumin in the urine that represents kidney dysfunction), and neuropathy (disorders of the peripheral nerves). In turn, these complications each contribute to blindness, end-stage renal disease, sensory loss, persistent peripheral pain, and weakness. In contrast, macrovascular complications arise from an atherosclerotic process that leads to myocardial infarction (heart attack), cerebrovascular accident (stroke), and peripheral arterial disease (peripheral vascular damage of the arteries, veins, and lymph vessels). The predominant risk factors for the development of all vascular complications include chronic hyperglycemia, hyperinsulinemia (excess unusable insulin circulating in the blood plasma) and disruptions in lipoprotein metabolism (Jenkins et al., 2004). Several prospective studies have shown significant associations between mean blood glucose levels (i.e., $\geq$ 7.0%) and the risk of vascular complications (UK Prospective Diabetes Study, 1998; DCCT, 1995a; Strandl et al., 1996). Furthermore, reductions in mean blood glucose levels results in significant reductions in the relative risk of both vascular complications and premature mortality. Specifically, a 1.0% absolute reduction in mean blood glucose levels results in a 37% reduction in the risk for microvascular complications, a 14% reduction in the risk for myocardial infarctions, and fewer all-cause deaths (Skyler, 1996; Stratton et al., 2000). A more detailed review of the prevalence and pathophysiology of diabetes-related vascular complications is provided elsewhere (see Krentz, Clough & Byrne, 2007).

1.3 Temporal Distribution of Self-Management and Disease-Related Complications

Individuals with T1DM are faced with the possibility of experiencing both self-management-related complications (i.e., hypoglycemia, hyperglycemia, DKA), and disease-related complications (i.e., microvascular and macrovascular pathology). However, the

incidence and potential occurrence of these consequences are distributed across time. In the short-term (particularly for individuals with a less advanced stage of diabetes), they face the regular occurrence of self-management complications as a result of blood glucose dynamics that are influenced by insulin administration, dietary choice, and physical activity. Early on in the disease process, the likelihood of occurrence of serious vascular pathology is low. However, for individuals with a more advanced stage of diabetes, they may be forced to contend with the near-future occurrence of both self-management and disease-related complications.

1.4 Diabetes Self-Management Practices

To minimize the likelihood of experiencing these self-management and disease-related complications, individuals must adopt and maintain a number of adaptive health behaviours. These include appropriate dietary choice, regular physical activity, medication adherence, and frequent blood glucose self-monitoring. Furthermore, in the event of significant variations in blood glucose, individuals must learn how to appropriately manage acute episodes of both hypoglycemia and hyperglycemia to restore normal blood glucose levels.

Over the past two decades, dietary recommendations for individuals with T1DM have undergone considerable revision. In 1998, the Canadian Diabetes Association (CDA) published the first consensus statement on the clinical practice guidelines for the detection and management of diabetes in Canada (Meltzer et al., 1998). At that time, dietary recommendations focused on meal planning. The guiding principle of meal planning involved consuming meals that were composed of 55% carbohydrates and 30% fats. However, this approach fostered rigidity in dietary choices, placed considerable limitations on food selection, and required individuals to eat meals at set intervals.

In recent years, the American Diabetes Association (ADA) and CDA have shifted away from meal planning and recommend that individuals learn and practice carbohydrate counting (a process of counting the number of grams of carbohydrates consumed) to establish an appropriate carbohydrate-to-insulin ratio (i.e., x grams of carbohydrate: 1 unit of insulin) (ADA, 2009; CDA, 2008). This ratio is unique to each individual, reflects the idiosyncrasies in carbohydrate and glucose metabolism, and must take into consideration anticipated energy expenditure. Furthermore, individuals must learn how to adjust their ratio to account for unexpected events that influence blood glucose metabolism (e.g., times of increased physical activity, high stress, or physical illness). Carbohydrate counting engenders greater flexibility in both dietary choices and timing of meals (DAFNE Study Group, 2002; Tunbridge et al., 1991). In theory, individuals are able to eat most foods by adjusting the amount of insulin administered to counter balance any increases in carbohydrate consumption. However, this method requires individuals to measure and weigh their foods to determine accurate portion sizes, and to determine food constituents using commercially available reference materials (e.g., calorie, carbohydrate, and fat counting reference books). Although there are several advantages associated with the increased flexibility, the demands required to accurately determine the constituents of foods may serve as a barrier to the consistent practice of carbohydrate counting.

Regular physical activity is also a cornerstone for diabetes self-management. While physical activity has not been shown to improve glycemic control in individuals with T1DM (Laaksonen et al., 2000), it has been found to reduce the risk of morbidity and mortality by improving cardiorespiratory fitness (Moy et al., 1993). Currently, both the ADA and CDA recommend that individuals participate in 150 minutes per week of vigorous aerobic activity

(i.e., achieving ≥ 70% of individuals maximum heart rate; CDA, 2008; ADA, 2009). Depending on individuals' aerobic capacity, activities could include brisk walking, jogging, or swimming.

Since 1922, insulin has remained an absolute indication for the treatment of individuals with T1DM (Cheng & Zinman, 2001). Currently, the ADA and CDA recommend the use of both long-acting and short-acting insulins (ADA, 2009; CDA, 2008). Long acting insulin has duration of action of 18-20 hours after administration. It is intended to cover individuals' insulin requirements between meals (Cheng et al., 2001). In contrast, short-acting insulin has duration of action of 4-8 hours after administration. It is administered just prior to meals and is intended to cover the insulin requirements for foods that are consumed. Adherence to this long-acting and short-acting insulin regimen can effectively lower blood glucose concentrations, prevent or minimize hyperglycemia, and minimize the risk of both microvascular and macrovascular complications (DCCT, 1993). However, this regimen increases the risk of severe hypoglycemia (McCrimmon & Frier, 1994), and is associated with weight gain (DCCT, 1995b).

Self-monitoring of blood glucose is intended to provide cross-sectional data on plasma glucose concentration. This information is used to inform decisions about health behaviours to maintain or restore euglycemia (i.e., blood glucose homeostasis). The frequency of blood glucose self-monitoring is unique to each individual, but is typically practiced prior to meals or the administration of insulin, if one suspects they are at risk of significant high or low deviations in blood glucose, or when making behaviour choices that influence their blood glucose metabolism (ADA, 2009; CDA, 2008).

In the event that individuals believe they are experiencing high or low deviations in blood glucose (i.e., hypoglycemia or hyperglycemia), they are advised to check their blood glucose to obtain objective information (ADA, 2009; CDA, 2008). In the event of hypoglycemia, individuals must administer oral carbohydrate (e.g., juice, soda) to increase their blood glucose concentrations. In the event of hyperglycemia, individuals may administer an injection of short-acting insulin to reduce their blood glucose concentrations. Failure to obtain objective blood glucose data prior to making such behavioral adjustments could lead to more extreme deviations in blood glucose and place individuals in physically hazardous situations. For instance, administering oral carbohydrate in the absence of hypoglycemia could result in hyperglycemia and contribute to poor glycemic control. Likewise, administering insulin in the absence of hyperglycemia could result in severe hypoglycemia, seizures, or death.

In light of these onerous demands to achieve and maintain euglycemia, some individuals with T1DM have difficulty making or sustaining the necessary health behaviours. Failure to maintain this homeostasis increases the risk of developing both self-management and disease-related complications. Achieving and maintaining euglycemia has proven to be daunting for most, and has been shown to be the exception rather than the rule. For example, in the largest multi-site prospective study of diabetes and its complications (DCCT, 1993), only 5% of the participants attained blood glucose levels in the optimal range despite having received intensive insulin therapy. Therefore, despite its efficacy, the majority of individuals are unable to achieve and sustain the recommended level of glycemic control required to prevent or minimize the risk of significant morbidity and premature mortality. Consequently, efforts of the past two decades have been focused on understanding the biopsychosocial factors

that influence adherence to health behavior regimens. Identifying and addressing these factors will be imperative for both secondary and tertiary prevention.

1.5 Psychological Factors in the Management of Diabetes

Psychological factors have been argued to play a central role in how individuals adjust to, and subsequently adhere to diabetes self-management recommendations. In one prospective study, researchers reported that individuals with T1DM had a 27% probability of developing major depressive disorder within 10-years of being diagnosed (Kovacs et al., 1997). It has also been shown that depression is twice as common, and generalized anxiety disorder is three times more common, among patients with diabetes compared to the general population (Anderson et al., 2001; Grigsby et al., 2002). Furthermore, depression is associated with decreased adherence to both dietary recommendations and medications (Ciechanowski, Katon & Russo, 2000), and trait anxiety and diabetes-related psychological distress are associated with worse glycemic control (Niemcryk et al., 1990; Sultan et al., 2001). Therefore, individuals with T1DM may have a propensity for experiencing negative emotionality that may interfere with the consistent practice of adaptive self-management behaviours. Unfortunately, an inability to adhere to the complex self-management regimens increases the risk of experiencing significant self-management and disease-related complications. Consequently, researchers have begun to examine the specific role of diabetes-related worry in the self-management of T1DM.

Individuals with T1DM are faced with the possibility of experiencing significant variability in their blood glucose. Depending on their history and experience with these high and low deviations, individuals can become focused on the possibility of experiencing future episodes of hypoglycemia or medical complications. In such cases, these concerns may exert motivational influence on diabetes self-management practices. Worry of hypoglycemia and

worry of vascular complications are two conceptually related constructs that relate to temporally dispersed self-management and disease-related events, which have shown promise in understanding the motivations that influence self-management practices (Cox et al., 1987; Cryer, 1999; Taylor et al., 2005). In this next section, the empirical literature examining these constructs will be reviewed.

1.5.1 Worry of Hypoglycemia

Individuals with T1DM learn to recognize the symptoms of hypoglycemia (e.g., sweating, faintness, trembling, and tachycardia) so they can appropriately self-correct to restore or maintain normal blood glucose (Schachinger et al., 2005). Mild hypoglycemic episodes are merely unpleasant. However, more severe and prolonged periods of low blood glucose can precipitate transient neurological symptoms (e.g., disorientation, loss of consciousness, seizures, coma). Depending on the context in which they occur, individuals may be placed in socially, occupationally, or physically compromising or hazardous situations (Holmes, Hayford, Gonzalez, & Weydert, 1983; Holmes, Koepke, Thompson, Gyevs, & Weydert, 1984). For instance, in a recent survey of individuals with T1DM, 52% reported experiencing hypoglycemia while driving an automobile during the previous 12-months (Cox et al., 2009). Repeated exposure to severe hypoglycemia has also been shown to result in degrees of cognitive impairment (Hershey, Lillie, Sadler & White, 2004). In extreme cases, hypoglycemia can even result in death (Cryer, Davis & Shamoon, 2003). Not surprisingly, a history of severe hypoglycemia has been shown to activate worry about future hypoglycemic events (Gold, Frier, MacLeod, & Deary, 1997; Irvine, Cox, & Gonder-Frederick, 1992). Furthermore, worry of hypoglycemia is associated with both dispositional tendencies to be anxious (Polonsky, Davis, Jacobson, & Anderson, 1992), the experience of panic attacks

(Costea, Ionescu-Tirgovite, Chea, & Mincu, 1993), and may account for unique variance in important health and behavioural outcomes.

As a consequence of worry, researchers have argued that individuals become motivated to avoid hypoglycemia by maintaining higher blood glucose levels (Cryer, 1999; Irvine, Cox, & Gonder-Frederick, 1992; Lundkvist, Berne, Bolinder, & Johsson, 2005; Surwit et al., 1982). Intuitively, actions taken to avoid severe hypoglycemia seem sensible, at least in the short-term. However, over prolonged periods of time, maintaining higher blood glucose levels increases the risk of developing significant vascular complications. In fact, it has been shown that elevated mean blood glucose levels (i.e., $\geq$ 7.0%) are associated with significant increases in the risk of developing vascular complications (DCCT, 1995a; Standl et al., 1996, UKPDS, 1998). While concern of hypoglycemia may be justified in some circumstances (e.g., while driving a vehicle), persistent worry and the consistent practice of hypoglycemia avoidance behaviour may be a shortsighted response that poses significant long-term risks.

The hypothesis that worry motivates avoidance behaviour is plausible. However, in a recent review of the worry of hypoglycemia literature (Wild et al., 2007), data appears to be mixed. Though this worry-avoidance phenomenon has been described in case studies (e.g., Cox et al., 1990) and qualitative reports (Shiu & Wong, 2000), the empirical data suggest that the relationships between worry, avoidance behaviour, and blood glucose are more complex (Irvine et al., 1992).

The Hypoglycemia Fear Survey (HFS) was developed to measure this phenomenon (Cox, Irving, Gonder-Frederick, Nowacek & Butterfield, 1987). It is a 27-item measure that is composed of two factors that represent worry and avoidance behaviour. Although other measures have been developed to evaluate this construct in both children, and parent's of

children with T1DM (Kamps, Roberts & Varella, 2005), the HFS has remained the most consistently used measure among adults.

To date, seven studies have been published examining worry of hypoglycemia in adults with T1DM. In addition to the original validation study (Cox et al., 1987), only one study has examined the relationships between the HFS and metabolic parameters (e.g., mean blood glucose, blood glucose variability; Irvine, Cox & Gonder-Frederick, 1992). Two additional studies examined the relationships between the HFS and other psychological constructs (Costea et al., 1993; Polonsky et al., 1992), one study was qualitative in a sample of Chinese speaking participants (Shiu & Wong, 2000), and two studies provided reviews of the limited literature and directions for future research (Gonder-Frederick et al., 2002; Wild et al., 2007). The remainder of the published data on worry of hypoglycemia has focused on adolescents with T1DM, and parents of children or adolescents with T1DM (e.g., Barnard et al., 2010; Haugstvedt et al., 2010).

In one observational study of 69 patients with T1DM, researchers sought to examine the relationships between worry of hypoglycemia, hypoglycemia avoidance behaviour, and a variety of glycemic and health-related outcomes (Irvine, Cox & Gonder-Frederick, 1992). These researchers used a 2 x 2 design to categorize individuals into levels of risk for experiencing hypoglycemia. Risk level was determined by an individual's mean daily blood glucose (high versus low) and blood glucose variability (high versus low). The results revealed a significant main effect for worry; such that, individuals with low-mean blood glucose demonstrated the highest levels of worry. They also found a mean-by-variability interaction, with those in the low-mean high-variability group showing the highest level of worry, compared to both the low-mean low-variability and the high-mean high-variability groups.

These authors also found no significant mean differences across the groups in the HFS behaviour subscale. Furthermore, neither the mean blood glucose levels, nor daily blood glucose readings were significantly associated with either the worry or behaviour subscales. This latter finding is consistent with the results of the original validation study (Cox et al., 1987). Of note, participants of this study had relatively poor glycemic control (i.e., more prone to experiencing high blood glucose) and reported experiencing less than one hypoglycemic episode during the previous 12-month period. Consequently, their minimal experience with hypoglycemia likely contributed to the lack of significant associations between the worry and behaviour subscales, and mean blood glucose measures.

The underlying assumption in this literature is that avoidance behaviour mediates the relationship between worry and mean blood glucose. This assumption has been communicated in several publications reviewing the clinical challenges of hypoglycemia management (e.g., Banarer & Cryer, 2003; Cryer 2008a; Cryer 2008b; Cryer, Davis, Shamoon, 2003). Although worry of hypoglycemia appears to be relevant for certain subgroups of individuals with T1DM (e.g., those with low mean blood glucose levels with high variability), this avoidance behaviour mediation hypothesis has not been directly tested.

One possible reason for the lack of significant associations between worry of hypoglycemia, avoidance behaviour, and some blood glucose parameters relates to the structure of the behaviour subscale. Examination of items revealed that this subscale taps more than overt hypoglycemia avoidance. For instance, one of the items asks the frequency in which individuals carry fast acting sugar to be used in the event of experiencing hypoglycemia. While this product is intended to manage acute episodes of hypoglycemia, the act of carrying fast acting sugar, in and of itself, does not affect blood glucose. Rather, this sugar product would

need to be ingested for it to have a direct influence on blood sugar levels. Consequently, this behaviour subscale appears to tap a more heterogeneous sample of behaviours than previously thought.

Unfortunately, no published studies have adequately examined the component structure of the HFS to determine if the proposed two-component solution is indeed appropriate. In fact, in the original validation study (Cox et al., 1987), a factor analysis of the 27-item measure was conducted using a limited sample of 35 participants with T1DM. At minimum, it is recommended that researchers obtain a 5:1 participant to item ratio (Hatcher, 1994), with a 10:1 ratio being more advantageous (Nunnally, 1978). Most recently, Anderbro and colleagues (2008) conducted a principal components analysis of an abbreviated version of this measure that was translated to Swedish. Researchers have not adequately assessed the factorial validity of the HFS using the full English version. Although theoretically, the worry of hypoglycemia construct may be important to assess among particular subgroups of individuals with T1DM (e.g., those at a higher risk of experiencing hypoglycemia), the impact of worry on a variety of behavioural and metabolic indices is unclear.

1.5.2 Worry of Vascular Complications

For some, the experience of hypoglycemia may be sufficiently averse to motivate the avoidance of noxious or hazardous experiences. However, there are likely other times, or for other individuals, in which the concern of vascular complications may be more salient. It is plausible that the presence of worry that is focused on a more distal set of potential outcomes may motivate a different constellation of self-management behaviours.

Relative to the literature on worry of hypoglycemia, research examining the impact of worry of vascular complications is even more limited. Recently, Taylor and colleagues

developed and validated a new self-report measure to assess worry of vascular complications in patients with T1DM. Results of their validation study yielded a reliable and valid measure that assesses a unitary worry construct, and was found to account for unique variance in mean blood glucose levels above and beyond general negative affect and worry of hypoglycemia. Although worry of vascular complications is likely to have some shared variance with worry of hypoglycemia (i.e., these two constructs representing forms of negative affect), they reflect affective and behavioural reactions to potential outcomes or consequences that lie on two ends of a temporal continuum. All individuals with diabetes must regularly contend with acute episodes of hypoglycemia and hyperglycemia. However, over time and as diabetes progresses to more advanced stages, the potential for developing vascular complications may exert an increasing amount of motivational influence on current behaviour. Therefore, to appreciate how temporally distributed worries may motivate current self-management decisions, considering theories of intertemporal choice may have utility.

1.6 Intertemporal Choice Theory in the Self-Management of T1DM

Recent reports by the World Health Organization (2005) indicate that the majority of life-threatening diseases are chronic, rather than infectious in nature. Fortunately, individuals are able to influence the development and management of chronic diseases by adopting a host of health-protective behaviours (e.g., healthy dietary choice, regular physical activity, avoidance of harmful substances). However, the consistent practice of health behaviours necessitates that individuals recognize and appreciate that their current behaviour impacts their later health outcomes. For example, if individuals are unaware that regular exercise minimizes the risk of heart disease and other ailments, the likelihood of them exercising regularly for primary or secondary prevention is slim. Unfortunately, many health protective behaviours are

often associated with many immediate costs (e.g., inconvenience, discomfort, time), despite their cumulative future benefits (Hall & Fong, 2007). This temporal conundrum places the self-regulatory demand squarely between intention and behaviour, such that good intentions are not always translated into consistent behaviours. In support of this notion, a recent meta-analysis of the intention-behaviour literature found that medium to large increases in behaviour intention resulted in only small to medium changes in desired behaviour (Webb & Sheeran, 2006). Furthermore, several moderators of this association have been identified including past behaviour patterns, and the controllability of the behaviour. These findings suggest that health behaviours cannot be fully explained by intentions alone, and that the path from intention to behaviour is not uniform. To account for these imperfect relationships, researchers have turned their attention to temporal factors that influence our health choices.

Emerging from the behavioural economic literature, intertemporal choice theory provides a framework to deconstruct the decision making process (for reviews, see Berns, Laibson & Loewenstein, 2007). Intertemporal choices involve decisions with consequences that emerge over time. It has been argued that such choices are influenced by three specific mechanisms including, 1) the anticipation of a future event or outcome, 2) self-control to resist immediate temptation to implement future decisions, and 3) the mental representation used to construe the future outcome of our choices. I will briefly define each of these mechanisms, before illustrating their applications with both a general and a diabetes-specific example.

According to intertemporal choice theory, anticipation refers to the experience of waiting for an expected outcome. When we decide to engage in a specific behaviour, action, or event, there is often a lag between the time that our decision is made and the moment that we

execute our decision. This anticipatory period may also provoke affective responses such as excitement or dread.

Self-control refers to the ability to hold out for a delayed reward in the face of a more attractive immediate alternative (Mischel, Shoda & Rodriguez, 1989). Related to self-control, preference reversals occur when individuals succumb to an immediate temptation that derails their ability to hold out for a delayed reward (Baumeister & Heatherton, 1996; Berns et al., 2007).

Finally, mental representation relates to the mental heuristics used when making a decision. With greater temporal distance between events, we tend to construe events in more abstract ways (e.g., good vs. bad). With less temporal distance, we tend to construe events in more concrete and tangible terms (e.g., that outcome will be bad because of X factor or factors; Liberman, Sagristano, & Trope, 2002; Loewenstein, Brennan, & Volpp, 2008).

Each of the above concepts is relevant for the execution of decisions that we make. For instance, I have decided to attend a family reunion that is planned for this coming winter. Over the next few months, I experience feelings of dread in anticipation of my perpetual family dysfunction. However, despite this, I become acutely aware that my attendance would make my parents extremely happy. Although this awareness enhances my motivation and strengthens my decision to attend, I may experience second thoughts on my way to the reunion. Since a considerable amount of time has passed since my last encounter with my extended family, I have vague recollections that my previous experience was unpleasant. Alternatively, if I were unfortunate enough to have attended a family function in the recent past, I would be more likely to recall the details that were responsible for my negative experience (e.g., my uncle instigating a heated argument with my father relating to the outcome of the recent political

election). Consequently, my decision to attend the upcoming family reunion is influenced by my anticipation of the event, the extent to which I have self-control to override my drive to avoid the gathering, and the mental representations that I use to predict the outcome of the event (which are based on my previous experience).

In the context of T1DM, individuals are faced with making decisions about a variety of proximal and distal outcomes that influence their overall disease management. Despite having a desire to be healthy with good glycemic control, the decisions that some make, may at times, be inconsistent with their overarching goal. For example, an individual is planning to attend an after work social gathering at which his/her new boss will be in attendance. After learning of their attendance, the individual worries that he/she might experience a hypoglycemic episode while at the gathering that would negatively influence their new boss' first impression of them. Despite valuing their health, this individual decides to take less insulin before attending the event to minimize the likelihood of experiencing hypoglycemia. After all, they recall the last time this happened, and their co-workers thought they were intoxicated. The following day, this individual was mortified when having to interact with these colleagues at work. Although this person values their health and overall diabetes management, they worry about experiencing hypoglycemia in the presence of their new boss and colleagues. This provokes a momentary preference reversal: They become willing to omit part of their insulin dose to minimize the likelihood of being embarrassed from an episode of hypoglycemia. Their detailed recollection of the outcome of a similar experience strengthens their decision, despite the known risks associated the repeated occurrence of this behaviour.

A variety of potential outcomes associated with diabetes may influence self-management practices in a variety of ways. In the short-term, becoming symptomatic of

hypoglycemia or hyperglycemia may facilitate momentary cognitions about health that are more concrete, meaningful, and valued. In essence, the potential for experiencing significant variability in blood glucose may increase the perception of short-term threat. In contrast, the absence of physical symptoms associated with vascular complications may create a perception of increased temporal distance that results in cognitions about health that are highly abstract and have less motivational influence on current behaviour.

Interim Summary

At any given moment, individuals with T1DM make a series of decisions that influence their blood glucose management. In the short-term, they are faced with the self-management complications of hypoglycemia and hyperglycemia. In the long-term, and as diabetes advances, they risk the development of significant vascular complications. The experience of physical symptoms associated with blood glucose variability or medical complications may provide valuable information that influences how individuals construe and evaluate their health to inform their immediate decisions. When faced with such symptoms, momentary preference reversals may occur in response to their perception of threat. In the short-term, symptoms of hypoglycemia may motivate avoidance behaviour, which over time, may negatively impact glycemic control and increase the risk for vascular complications. In contrast, symptoms of vascular pathology (e.g., changes in vision, numbness or tingling in the extremities) may increase the salience of the threat of serious medical morbidity. Consequently, individuals may become increasingly motivated to avoid hyperglycemic states to improve their blood glucose management. Although this behavioural response is well intentioned, the outcome of undermanaged blood glucose may not be fully appreciated until a cascade of irreversible vascular damage has occurred (Begg & Schulzer, 2001; Steele, 2001).

Specific Aim 1. The primary aim of this dissertation is to test whether diabetes-related avoidance behavior mediates the relationships between diabetes-related worry (worry of hypoglycemia, worry of vascular complications) and blood glucose.

In the sections outlined above, the impact of diabetes-related worry and self-management behaviours on blood glucose is considered. However, in addition to metabolic parameters, diabetes-related worry and self-management behaviours have the potential to influence the quality of individuals' lives in a number of substantive ways. To understand their potential impact on important quality of life dimensions, a brief review of this literature will be provided to frame the secondary aim of this dissertation.

1.7 Quality of Life in T1DM

Quality of life (QoL) has been identified as an important variable for measurement in clinical investigations (Guyatt et al., 1989). It has been used to predict patient outcomes in clinical trials (e.g., McClellan, Anson, Birkeli & Tuttle, 1991; Ganz, Lee & Siau, 1991), and to evaluate the effectiveness of interventions (e.g., Gelber, Goldhirsch & Cavalli, 1991; Aulikki et al., 1991). Unfortunately, there is a lack of consensus on the definition of QoL (Gill & Feinstein, 1994), which is reflected in the various tools used in its measurement. Some operationalize QoL in more generic ways and use measures like the 36-item questionnaire from the Medical Outcomes Study (SF-36; Ware & Sherbourne, 1992), the Nottingham Health Profile (Hunt & McEwan, 1980), or the Sickness Impact Profile (Gilson et al., 1975). However, these measures tap constructs akin to health status or functional status, rather than the subjective elements of health implied by the term "quality". Adopting these generic approaches can be useful because it facilitates comparisons about health status across different populations and interventions (Patrick & Deyo, 1989). However, it has been argued that such

generic measures may not be sensitive to the nuances inherent in the experience of diabetes and its treatment (Hart et al., 2007).

In contrast, others operationalize QoL in disease-specific ways (i.e., Health Related Quality of Life; HRQoL) using measures developed and validated to capture the nuances of specific disease processes and their treatment (e.g., cancer, diabetes). This increased level of specificity may be advantageous because it provides more clinically relevant information about the effects of, and interventions for, certain diseases, and may be more sensitive to illness-specific interventions (Hart et al., 2007).

However, attempts to compare data across studies becomes challenging because researchers use terms such as QoL, HRQoL, health status, and functional status interchangeably (Fortin et al., 2004). Furthermore, researchers are often unclear about how such constructs are defined, and use a variety of self-report measures to capture seemingly homogeneous phenomena. When comparing the differences between QoL and HRQoL, the former not only encompasses health-related factors but may also include non-medical aspects such as employment, family relationships, and spirituality (Gill & Feinstein, 1994). Although reconciling some of these differences in the QoL literature is beyond the scope of this current study, it is necessary to provide brief comment on the challenges inherent in QoL assessment to determine what is most informative and empirically supported for individuals with T1DM. Specifically, a multi-dimensional approach to evaluating quality of life has been argued to be important (Rubin & Peyrot, 1999). This often includes aspects of health status, and diabetes-specific elements including the perceived impact of having diabetes, and satisfaction with self-management practices and outcomes (Hart et al., 2007).

With respect to the health status of individuals with T1DM, more intensive treatments have been found to delay the onset and progression of vascular complications (DCCT, 1993). For certain aspects of diabetes sequale (i.e., microvascular and macrovascular complications secondary to undermanaged managed blood glucose), health status or functional status may be important to assess. Using a cohort of 281 participants with T1DM, Hart and colleagues (2003) investigated the factors that influence health status in this population. The results of their study showed that the presence of hyperglycemic complaints (i.e., tiredness, weight loss, thirst, polyuria, polydipsia) and the presence of macrovascular complications (i.e., myocardial infarcts, cerebrovascular accidents) had the most profound negative impact on individuals' health status (i.e., both physical functioning and mental health status). Similar results have been reported elsewhere (e.g., Hahl, et al., 2002; Hart, Redkop, Bilo, Meyboom-de Jong, & Berg, 2007; Rubin & Peyrot, 1999). Not surprisingly, these data suggest that individuals may experience the greatest negative impact on their health status in the face of undermanaged diabetes, or as they become symptomatic of vascular complications.

For other aspects of diabetes that have more proximal effects (i.e., hypoglycemia, hyperglycemia), health or functional status may be less relevant. However, the perceived impact of having diabetes and satisfaction with self-management practices and outcomes are two HRQoL dimensions that are more germane to the experience of self-management complications. The researchers of the DCCT developed and validated the Diabetes Quality of Life Questionnaire to assess these dimensions. It is the most widely used measure of HRQoL in individuals with diabetes, and provides valuable information about the experiences of living with this disease. The perceived impact subscale captures the extent to which individuals are impacted by a variety of diabetes-related factors (e.g., "How often are you embarrassed by

having to deal with your diabetes in public?"; "How often does your diabetes interfere with your family life?"; "How often does diabetes interrupt your leisure activities?"). The self-management satisfaction subscale assesses how satisfied individuals are with a variety of self-management practices and outcomes (e.g., "How satisfied are you with the time it takes to determine your blood sugar levels"; "How satisfied are you with the flexibility that you have in your diet?"; "How satisfied are you with the burden your diabetes places on your family?").

In examining the available literature, researchers have shown that the presence and severity of psychiatric symptoms (measured by self-report) and the presence or history of psychiatric disorders (assessed by structured clinical interview) is associated with a greater perceived impact of having diabetes and lower satisfaction (Jacobson, de Groot, & Samson, 1997). Although these effects are independent of vascular complications, the mechanisms that account for these associations have not been delineated. However, in light of the onerous demands required to effectively self-manage blood glucose, the influence of self-management behaviours may be important to consider.

In light of the observed relationships between psychiatric phenomenon and HRQoL (Jacobson et al., 1997), it is plausible that diabetes-related worry may also share similar associations with these HRQoL dimensions. As described above, worry of hypoglycemia may motivate a series of avoidance behaviours (e.g., avoiding being alone, keeping higher blood sugar levels). While these strategies are purposeful, they may also be associated with a greater perceived impact by imposing restrictions in domains that are appreciated and valued (e.g., independence, health maintenance). Furthermore, these behaviours may help to explain the relationship between worry of hypoglycemia and perceived impact. However, since hypoglycemia avoidance behaviors are intended to avert short-term harm, they may also be

associated with increased self-management satisfaction, and may help to account for the relationship between worry and satisfaction.

Similarly, worry of vascular complications may motivate a different constellation of avoidance behaviors (e.g., avoiding eating out in restaurants, avoiding carbohydrates). Although these behaviours are intended to minimize the likelihood of experiencing disease-related complications, they may impose restrictions on activities in which individuals engage and value (e.g., eating in restaurants; freedom in dietary choices). Therefore, these worry-driven behaviors may help to explain the relationship between worry of vascular complications and perceived impact. However, in light of these self-imposed restrictions, it is likely that hyperglycemia avoidance behaviors are also associated with lower satisfaction, and may help to account of the relationship between worry and satisfaction.

To date, no studies have been published that evaluate the impact of diabetes-related worry and worry-driven behaviour on HRQoL in this population. Understanding these relationships and the potential mediating role of diabetes-related worry behavior may help to identify the mechanisms that influence HRQoL in this population.

Specific Aim 2. The second aim of this dissertation is to test whether diabetes-related avoidance behavior mediates the relationships between diabetes-related worry and HRQoL (perceived impact, self-management satisfaction).

1.8 Study Rationale

Researchers have shown that worry and other forms of negative emotionality are more common among individuals with diabetes compared to the general population. Specifically, it has been hypothesized that diabetes-related worry is likely to motivate a variety of behaviours

intended to minimize the likelihood of experiencing both the complications of self-management and disease-related complications.

Worry of hypoglycemia may motivate avoidance behaviours (e.g., keep my blood sugar higher when alone; keep my blood sugar higher when in a long meeting) that are intended to minimize the likelihood of experiencing hypoglycemia (e.g., Cox et al., 1987; Irvine et al., 1992; Wild et al., 2007). In the short-term, these behavioural responses may serve a harm-avoidance function; however, they may negatively impact blood glucose management and increase the risk of developing vascular complications. Furthermore, making behavioral adjustments (e.g., eating at the first sign of low blood sugar) in the absence of objective blood glucose data is ill advised. Over time, repeated and unnecessary corrections to blood glucose will contribute to worsening blood glucose control. Although hypoglycemia avoidance behaviours are the likely mechanism that explains the relationship between worry of hypoglycemia and blood glucose, researchers have not directly tested this assertion.

Extending this logic, worry of vascular complications may motivate a different set of avoidance behaviours (e.g., avoiding eating carbohydrates or high calorie foods, avoiding eating out in restaurants). These behaviours are intended to avert high deviations in blood glucose, which over time, may minimize the likelihood of developing vascular complications. However, no published studies have examined the nature and extent of vascular complication worry behaviours in this population. Although hyperglycemia avoidance behaviors may also help to explain the relationship between worry of vascular complications and blood glucose, this will also be the first study to test this hypothesis.

In the presence of worry, hypoglycemia avoidance behaviors are intended to manage the threat of experiencing hypoglycemia. These behaviors function to avert situations that are

perceived to be dangerous or life threatening. However, responding to perceived low deviations in blood glucose is likely to be associated with the perceived negative impact of having diabetes. In contrast, hypoglycemia avoidance behaviours may provide individuals with increased confidence in their ability to avoid hypoglycemia by ensuring higher mean blood glucose levels. Although in the short-term, worry may be associated with lower satisfaction, hypoglycemia avoidance behaviours may be associated with increased satisfaction, and may help to explain the relationship between worry of hypoglycemia and self-management satisfaction.

When practiced in moderation, hyperglycemia avoidance behaviours may reflect adaptive self-management practices. However, these behaviours may also occur at a cost. For instance, avoiding eating carbohydrates, and avoiding eating out in restaurants have the potential to pose restrictions on domains of life that are both appreciated and valued (e.g., freedom in dietary choices). Therefore, when practiced to extremes or without flexibility, hyperglycemia avoidance behaviors may be associated with the perceived negative impact of having diabetes, and decreased satisfaction with diabetes self-management practices. These behaviours may also help to account for the relationships between worry of vascular complications and HRQoL dimensions.

Considered together, diabetes self-management behaviours are imperative for the maintenance of blood glucose homeostasis. Depending on the context in which these behaviours are practiced, hypoglycemia avoidance behaviour and hyperglycemia avoidance behaviour may be important mechanisms that help to explain a variety of relationships between diabetes-related worry, blood glucose, and HRQoL outcomes.

1.9 Study Hypotheses

Hypothesis 1. Worry of hypoglycemia will be positively associated with both blood glucose level and hypoglycemia avoidance behaviour. Hypoglycemia avoidance behaviour will be positively associated with blood glucose level, and will mediate the relationship between worry of hypoglycemia and blood glucose level.

Hypothesis 2. Worry of vascular complications will be inversely associated with blood glucose level, and positively associated with hyperglycemia avoidance behaviour. Hyperglycemia avoidance behaviour will be inversely associated with blood glucose level, and will mediate the relationship between the worry of vascular complications and blood glucose level.

Hypothesis 3. Worry of hypoglycemia will be positively associated with both the perceived impact of having diabetes, and hypoglycemia avoidance behaviour. Hypoglycemia avoidance behaviour will be positively associated with perceived impact, and will mediate the relationship between worry of hypoglycemia and perceived impact.

Hypothesis 4. Worry of vascular complications will be positively associated with both the perceived impact of having diabetes, and hyperglycemia avoidance behaviour. Hyperglycemia avoidance behaviour will be positively associated with perceived impact, and will mediate the relationship between worry of vascular complications and perceived impact.

Hypothesis 5. Worry of hypoglycemia will be inversely associated with self-management satisfaction, and positively associated with hypoglycemia avoidance behaviour. Hypoglycemia avoidance behaviour will be positively associated with self-management satisfaction, and will mediate the relationship between worry of hypoglycemia and self-management satisfaction.

Hypothesis 6. Worry of vascular complications will be inversely associated with self-management satisfaction, and positively associated with hyperglycemia avoidance behaviour. Hyperglycemia avoidance behaviour will be inversely associated with self-management satisfaction, and will mediate the relationship between worry of vascular complications and self-management satisfaction.

CHAPTER 2

METHOD

2.1 *Study Design*

In this present study, a cross-sectional observational design was used. Data was collected from participants through surveys that were completed either online or by paper copy, following a regularly scheduled appointment with their endocrinologist.

2.2 Participants

A total of 231 individuals with T1DM were eligible to participate in this study, and were approached in one of three tertiary care clinics specializing in the treatment of diabetes: University Health Network (Toronto General Site), McMaster University Medical Centre, and Sunnybrook and Women's College Hospital. Individuals were eligible to participate if they had received a diagnosis of T1DM, were receiving intensive exogenous insulin therapy, and were $\geq$ 18-years-old. A total of 215 individuals (93%) provided informed consent to participate, and 152 (71%) completed a self-report questionnaire. Of those participants who completed the questionnaire package, 129 (84%) had recent A1C values available in their electronic medical records. Participants who represented a wide range of age, duration of illness, and presence of diabetes-related medical complications were sought to ensure adequate amounts of variance in these variables.

2.3 Measures

2.3.1 *Demographic Information.* Participants were asked to respond to a series of demographic questions that assessed information relating to sex, age, employment status, current relationship status, and education (see Table 1 of the Appendix). Information on

participant income was obtained by linking the first three digits of their postal code to a geographical information systems (GIS) database based on 2006 Canadian census data.

2.3.2 Health Information. Participant health information was obtained by review of electronic medical records. In cases where community-based physicians were treating participants for their diabetes, informed consent was obtained to collect this information. The following information was sought: 1) recent A1C as an index of glycemia (see below for a detailed description), 2) duration since diagnosis with T1DM, 3) nature of current insulin therapy, 4) presence of microvascular complications (e.g., retinopathy, neuropathy, nephropathy), 5) presence of macrovascular complications (e.g., coronary artery disease, cerebrovascular disease, peripheral arterial disease).

To ensure the completeness of these data, particularly in cases where health record data were missing, participants were asked to self-report on the presence of both microvascular and macrovascular complications using a yes/no dichotomous response option (i.e., "Have you ever received laser eye treatment for retinopathy?; Do you have kidney disease as a result of your diabetes?; Are you currently receiving hemodialysis treatment?; Do you have nerve disease as a result of your diabetes [i.e., pain or numbness in hands or feet]?; Have you experienced any ulcers on your hands or feet?; Have you received any amputations because of advanced nerve disease related to your diabetes?). Participants were also asked to report the number of severe hypoglycemic episodes that they have experienced in the past 12-months. Severe episodes of hypoglycemia were defined as a state of low blood sugar that required the assistance of others for resuscitation (i.e., "In the past 12-months, how many times has your blood sugar been so low that you needed help from someone else?"). This particular question has been employed by researchers to examine the frequency of severe hypoglycemia because objective measures of

this phenomenon have been lacking (e.g., Cox et al., 2009; Gonder-Frederick et al., 2006; Nordfeldt, & Jonsson, 2001). In the event of discrepancies between participant self-report and electronic medical record data, the information contained in the electronic medical records were be considered to be the more accurate of the two.

2.3.3 Glycemic Control (A1C). A1C is considered to be the "gold standard" measure of achieved glycemic control. It provides an index of the mean blood glucose levels over the previous 90-120 days. A1C is assessed through a blood sample that is analyzed in the laboratory. Over the 120-day life span of red blood cells, glucose molecules bind to hemoglobin to form glycated hemoglobin. A concentration of glycated hemoglobin in the red blood cells reflects the average level of glucose that the red blood cells have been exposed to during its lifespan; this glycated hemoglobin is then expressed as a percentage. For individuals with T1DM, it is recommended that A1C be assessed every 3 months (CDA, 2008). These data are then used to inform clinical decision-making regarding medication and lifestyle management. Higher A1C is indicative of worse glycemic control. Optimal A1C is considered to be $\leq$ 6%. Failure to maintain A1C $\leq$ 6% has been shown to increase the risk of developing microvascular and macrovascular pathology, and premature mortality (DCCT, 1993, 1997). For individuals with elevated A1C ($\geq$ 6%), a 1.0% absolute reduction results in a 37% reduction in the risk for microvascular complications, a 14% reduction in the risk for myocardial infarctions, and fewer all-cause deaths (Stratton et al., 2000). Therefore, routine and ongoing assessment of A1C is imperative to inform medical and self-management decision-making to promote optimal diabetes management.

2.3.4 Hypoglycemia Fear Survey (HFS; Cox et al., 1987). The HFS was developed to assess the presence of worry associated with the experience of hypoglycemia symptoms. This

measure consists of 27-items that span two domains that include worry related to the experience of hypoglycemia (e.g., "I worry about having a reaction while driving"), and behaviours intended to avoid hypoglycemia (e.g., "I avoid being alone when my sugar is likely to be low"). Participants are asked to respond to questions using a five-point Likert scale that ranges from 1 (never) to 5 (very often). Results of a validation study found the internal consistency of the worry subscale to be strong (Cronbach's $\alpha = .89$). The internal consistency of the behavior subscale was found to be moderate (Cronbach's $\alpha = .61$).

Consistent with the original validation study (see Cox et al., 1987), the reliability of the HFS worry subscale in this present study was found to be strong (α's =.89), and the behaviour subscale was found to be moderate (Cronbach's $\alpha = .62$). However, individual item analysis revealed that the behaviour subscale taps a heterogeneous sample of behaviours that individuals might engage in response to worry. Consequently, a principle components analysis (PCA) was performed on these behaviour items to determine the unique component structure in this sample. The results of this analysis are presented below.

2.3.5 Fear of Complications Questionnaire (FOCQ; Taylor, Crawford, & Gold, 2005). The FOCQ was developed to assess the presence of worry related to the development of vascular complications associated with T1DM. This scale consists of 15-items that load on a unitary factor that accounts for 56% of the total variance. Participants are asked to respond to questions using a four-point Likert scale that ranges from 1 (very or all the time) to 4 (not at all or never). Results from the initial validation study found the FOCQ to be internally consistent (Cronbach $\alpha = .94$). Furthermore, it was shown to have good construct validity by demonstrating its distinction from the HFS (described above). To evaluate the behaviours that individuals are motivated to engage in response to worry of vascular complications, a

behaviour subscale was constructed for use in this present study. Items were generated in consultation with diabetes healthcare professionals, and individuals with T1DM. Specifically, individuals were asked to provide a list of behaviors that individuals might engage in response to concerns about developing vascular complications. A total of 13 behaviour items were generated.

Consistent with the original validation study, the internal consistency reliability of the FOCQ worry subscale was found to be strong (α =.94; Taylor et al., 2005). The internal consistency of the behaviour subscale was found to be moderate (α = .64). Since the behaviour subscale was generated for use in this current study, a PCA was performed to examine its component structure. The results of this analysis are also presented below.

2.3.6 Diabetes Quality of Life (DQOL; Diabetes Control and Complications Trial, 1988). The DQOL was developed by investigators of the DCCT to assess the HRQoL of individuals with T1DM. Participants are asked to respond to 46-items that span five domains that include: 1) the perceived impact of having diabetes, 2) self-management satisfaction, 3) worry (social/vocational), 4) worry (illness-related), and 5) overall quality of life. However, to avoid criterion contamination, participants only completed the perceived impact and self-management satisfaction subscales. Participants are asked to respond to questions using a five-point Likert scale that ranges from 1 (very satisfied/no impact) to 5 (very dissatisfied/always impacted). The results of studies examining the psychometric properties of the DQOL have found good internal consistency (Cronbach's α's range from .66-.92), and excellent test-retest reliability with a mean inter-trial interval of nine days (*r*s = .78-.92). Further tests of construct validity were conducted using conceptually related measures of diabetes-related distress, and were found to be in the moderate range (*r*s ranging from .34-.60).

The internal consistency reliability of the perceived impact and self-management satisfaction subscales was found to be strong (α = .81 and .87, respectively), which are similar to those reported elsewhere (DCCT, 1988; Jacobson, de Groot, & Samson, 1994).

2.4 Procedure

Participants were recruited from three tertiary care clinics specializing in the treatment of diabetes including: University Health Network (Toronto General Site), McMaster University Medical Centre, and Sunnybrook and Women's College Hospital. Eligible individuals were approached in the clinic waiting rooms during their scheduled appointments with their endocrinologist. Study details were also advertised in designated areas around these three hospitals, and recruitment advertisements were placed in local diabetes newsletters. Interested parties who were not approached in clinic contacted the researchers by telephone or email to solicit further information about the study. Individuals were then mailed an information letter outlining the details of the study, and were asked to return their completed consent form to researchers by mail. Once informed consent was obtained, all participants were asked to complete a self-report questionnaire package either electronically (using their home computer) or by paper copy. If by paper copy, they were asked to return their completed questionnaire to researchers by mail using a self-addressed stamped envelope that was provided. Participants who failed to submit their completed surveys within 14-days were sent reminders by telephone or email.

Participants also provided written and informed consent for the researchers to collect specified health information from their electronic medical records (outlined above). This study received clearance by the research ethics boards at the University of Waterloo, University

Health Network, Hamilton Health Sciences Centre, and Sunnybrook and Women's College Hospital.

2.5 Data Analytic Plan

Prior to conducting the primary analyses (described below), the distribution of each variable was examined using Shapiro-Wilk's test for normality and examination of Q-Q plots. Non-normally distributed variables were mathematically transformed.

Principal components analysis (PCA) was used to examine the component structure of the HFS and FOCQ. PCA is used to identify linear components that exist within a data set, and to understand how particular items contribute to a given component (Field, 2000). It uses correlations among the variables to identify smaller sets of components that empirically summarize the data (Tabachnick & Fidell, 2007). PCA was selected over Exploratory Factor Analysis (EFA) because the latter is better suited for hypothesis generation, rather than describing patterns that exist among observed variables. Although EFA also results in clusters of variables (i.e., factors) that highly correlate with each other, it is used to develop theories about underlying processes (e.g., personality traits) that influence participants' responses to items that result in such factors (Tabachnick et al., 2007). The question of interest in this present study is how items on the diabetes-related worry scales relate to each other to form interpretable patterns. For this reason, PCA was selected for use in these analyses.

One major methodological consideration when performing a PCA involves determining the number of independent observations (i.e., sample size) required to obtain a component pattern that approximates the population pattern (Guadagnoli & Velicer, 1988). Based on the shrinkage concept in multiple regression, correlation coefficients become adequate estimators of the population correlation coefficient when sample sizes reach a minimum threshold. In the

case of PCA, some researchers argue for the use of absolute minimum sample sizes, whereas other researchers argue that participant to item ratios are more important. For instance, some support absolute minimum sample sizes as small as an *N* of 50 (Barrett & Kline, 1981) and as large as 400 (Aleamoni, 1976). However, in the case of participant to item ratios, some suggest a minimum of 5:1 (Gorsach, 1983; Hatcher, 1994), whereas others argue that a minimum of 10:1 is necessary (Nunnally, 1978, p.421). Based on a series of Monte Carlo simulation studies, larger ratios become underscored when items are found to have low to moderate component saturations (i.e., component loadings in the range of .40-.60; Guadagnoli et al., 1988). Conducting a PCA with an inadequate sample size results in random and non-replicable components (e.g., Aleamoni, 1976), unstable component structures (Cliff, 1970), and a lack of generalizability to the population of interest (MacCallum et al., 1999).

The HFS and FOCQ (described above) are the two measures that were subjected to PCA. Each scale contains 27-items, and 28-items, respectively. Depending on the recommendations employed, the minimum sample size required to produce stable component patterns may be 140 (assuming that strong component saturations are produced), with 280 being more advantageous. Since differentiating between types of diabetes-related worry behavior was of utmost concern, the PCAs were limited to the HFS and FOCQ behavior subscales. Although this assumes that diabetes-related worry is homogeneous (i.e., that worry items likely load onto a single component), this has typically been the case in prior studies conducted by proponents in this field (e.g., Cox et al., 1987; Irvine et al. 1992; Polonsky et al., 1992; Taylor et al., 2005). By limiting the PCA to these two behavior dimensions results in the inclusion of 10-items for the HFS and 13-items for the FOCQ. This conservative approach results in participant to item ratios of approximately 14:1 and 11:1 for the HFS and FOCQ

behaviour subscales, respectively. Consequently, this will maximize the ability to approximate the different types of diabetes-related worry behaviors practiced in the population, and will help to ensure stable and replicable component solutions.

In each of the PCAs (described below), examination of eigenvalues and Catell's scree test was used to determine the number of components in each analysis that was most appropriate to retain. The extracted components were then subjected to orthogonal rotation. The purpose of rotation is to facilitate the identification a component solution that is equal to the solution obtained during extraction, while providing the most parsimonious interpretation (DeCoster, 1998). Specifically, Varimax rotation was selected because it maximizes the dispersion of loadings within a given component (e.g., making high loadings following extraction higher after rotation) resulting in more interpretable component solutions.

To test the main hypotheses in this study, mediation analyses were performed using hierarchical multiple regression as outlined by Baron and Kenny (1986). According to this method, a mediating variable accounts for the relation, in whole or in part, between a predictor variable and a criterion. Statistical mediation is presumed if the following conditons are met: 1) variable A (predictor variable) is significantly associated with variable B (the hypothesized mediating variable); 2) variable B (the hypothesized mediator) is significantly associated with variable C (the criterion variable); 3) when these paths are controlled, a previously significant association between variable A (predictor variable) and variable C (the criterion variable) is attenuated or becomes non-significant. Subsequently, the presence of mediation can be tested statistically by using the Sobel Test or the bootstrap method (for reviews, see Preacher & Hayes, 2008). In this present study, the Sobel Test was used because it has been argued to provide the most conservative test of mediation.

CHAPTER 3

RESULTS

3.1 Demographics. A total of 231 individuals were invited to participate in this study. Of these individuals, 215 (93%) provided informed consent, and 152 (71%) completed and returned the study survey. Reasons for individuals declining participation included a lack of interest in participating in research studies, and a perceived lack of time to complete the study survey. Of those who agreed to participate, reasons for not returning the completed survey included participants having lost their login information for the online survey, having lost the paper copy of the survey, having forgotten to complete and/or return the survey, and a perceived lack of time to complete the survey.

Of the participants who completed the self-report questionnaires, 129 (84%) had an A1C values available in their medical record. There was a mean difference of 62.3 days (SD = 96.1) between the time that participants' completed their self-report questionnaires and their most recent A1C assessment. The mean age of study completers was 39.4 years (SD = 13.7), whereas the mean age of the non-completers was 34.0 years (SD = 13.3). This mean difference was statistically significant (t_{151} = -2.45, p < .02), indicating that the study completers were older than the study non-completers. Sixty-four percent of study completers were female, and the majority were Caucasian (90%), married (46.8%), had completed college/university (44.2%), and were employed Full-time (50.6%). Based on 2006 Canadian Census data, the mean household income of participants was $45,353 ($SD$ = $22,845). The mean difference in household income between study completers and non-completers was not statistically significant (t_{151} = 1.86, p < .07). Demographic characteristics are presented in Table 1.

Insert Table 1 about here.

3.2 Background Health Information. When available, A1C values were collected from the electronic medical records of all participats in this study. Alternatively, requests for A1C data were sent to any community-based physicians treating study participants for their diabetes. A total of 171 participants had A1C values available for collection. The mean A1C of study completers was 7.60 (SD = 1.13), and the mean A1C of non-completers was 7.72 (SD = 1.14). This difference was not statistically significant (t_{175} = .56, p = .58). The mean number of severe hypoglycemic episodes experienced during the previous 12-months was 1.43 (SD = 1.41). The mean number of vascular complications that participants had developed was .35 (SD = .67). Diabetes-related medical characteristics of the participants are presented in Table 2.

Insert Table 2 about here.

3.3 Distribution of Variables.

Shapiro-Wilk's test was calculated to evaluate the distribution of all variables. The Q-Q plots were also examined. The results Shapiro-Wilk's test are presented in Table 3.

Insert Table 3 about here.

The results of this analysis showed that all variables were non-normally distributed. The only exception was the DQOL satisfaction subscale. Skewed variables were subjected to one of two transformations. Since the self-reported number of hypoglycemic episodes and self-reported number of vascular complications variables each contained values of zero, these variables were subjected to square root transformations. The remianing non-normally distributed variables were logarithmically transformed. Following transformation, Shaprio-Wilk's test and Q-Q plots were re-examined. Analysis of these data showed that the variables used in the primary

analyses were corrected to normal or near-normal distributions. A1C, worry of hypoglycemia, and worry of vascular complications were normalized (Shapiro-Wilk = .98-.99, p = .05-.21). The distributions for hypoglycemia avoidance, hyperglycemia avoidance, and perceived impact were substantially improved (Shapiro-Wilk = .97-.98, p = .01-.03). The presence and history of self-management and disease-related complications was marginally improved (Shapiro-Wilk = .51-.85, p = .001). To ensure that the assumption of normally-distributed residuals was not violated in any of the regression models (described below), scatter-plots of the standardized predicted and observed values were examined. Standardized scores for the satisfaction subscale were used in subsequent analyses.

Outliers were identified using Tukey's box plot. First, outliers were individually examined to ensure the accuracy of data entry. Valid and extreme values were then Winsorized to the upper and lower quartiles. Given the relatively small sample size, this procedure was selected to preserve the maximum power in the analyses (Wilcox 1994). The following number of values were trimmed for each of the following variables: A1C (two extreme high values), HFS-Worry (eight extreme high values), HFS-Behaviour (one extreme high value), presence of vascular complications (seven extreme high values), and 12-month frequency of severe hypoglycemia (seven extreme high values).

3.4 Principal Components Analysis. As previously discussed, the behaviour subscale items for both the HFS and FOCQ tap a heterogeneous sample of worry behaviours. Since no published studies have adequatley evaluated the full English version of the HFS, and the FOCQ behaviour subscale represents a new dimension, PCA was used to examine their compoent structures.

3.4.1 HFS-Behaviour. Examination of the eigenvalues and Catell's scree test indicated that a 3-factor solution accounting for 55% of the total variance may be appropriate because three factors had eigenvalues greater than one (2.61, 1.67, 1.23). A 4-factor solution was also considered, which accounted for 64% of the total variance. However, two items cross-loaded onto more than one factor, and two factors were composed of only two items. Since this resulted in a less parsimonious solution, the 3-factor solution was retained. The scree plot for the HFS-behaviour subscale is presented in figure 1.

Insert figure 1 about here

Individually, the amount of variance (after rotation) accounted for by factors 1-3 were, 26.1%, 16.7%, and 12.3%, respectively. No items cross-loaded onto more than one factor, and there were no hyperplane items (i.e., items that failed to saliently load on at least one factor). The factor loadings and communalities (h^2) for the HFS Behaviour 3-factor solution are presented in Table 4.

Insert table 4 about here

Examination of the item content revealed three clusters of items that could be interpreted as hypoglycemia avoidance behaviours (Factor 1), hypoglycemia compensatory behaviours (Factor 2), and hypoglycemia subtle avoidance behaviours (Factor 3). These components are operationalized as follows: Hypoglycemia avoidance behaviors are proactive actions taken to prevent the experience of hypoglycemia (e.g., "keeping sugars higher when alone", "eating large snacks at bedtime"); hypoglyceia compensatory behaviors are reactive actions taken to minimize the likelihood of experiencing hypoglycemia when the risk appears to be imminent

(e.g., “eating something at the first sign of low blood sugar”, “reducing insulin when I think my sugar is low”); hypoglycemia subtle avoidance behaviors are proactive actions taken to enhance one’s preparedness for detecting and managing hypoglycemia (e.g., “checking blood sugars more frequently when in long meetings”, “carrying fast-acting sugar”).

3.4.2 FOCQ-Behaviour. For the FOCQ, examination of the eigenvalues and Catell’s scree test indicated that a 3-factor solution may also be appropriate because three factors had eigenvalues greater than one (2.82, 1.61, 1.22). This solution accounted for 43% of the total variance. Similarly, a 4-factor solution was also considered, which accounted for 53% of the total variance. However, two items cross-loaded onto more than one factor, and two factors were composed of only two items. Since this resulted in a less parsimonious solution, the 3-factor solution was retained. The scree plot for the FOCQ-behaviour dimension is presented in figure 2.

Insert figure 2 about here

Individually, the amount of variance (after rotation) accounted for by factors 1-3 were, 21.7%, 12.4%, and 9.36%, respectively. Once again, no items cross-loaded onto more than one factor, and there were no hyperplane items. The factor loadings and communalities (h^2) for the FOCQ Behaviour 3-factor solution are shown in Table 5.

Insert table 5 about here

Examination of the item content suggested three conceptual clusterings that represent complication vigilance/risk behavior avoidance (Factor 1), hyperglycmeia avoidance behavours with diet and exercise (Factor 2), and hyperglycemia compensatory/reassurance

behaviours (Factor 3). These components are operationalized as follows: Complication vigilance/risk behavior avoidance are proactive actions taken to either detect signs and syptoms of vascular pathology (e.g., "check my feet for blisters, sores, or redness") or avoid identified health risk behavior (i.e., alcohol consumption); hyperglycemia avoidance behaviour with diet and exercise are proactive actions taken relating to dietary choice and exercise that are intended to avoid hyperglycemia; hyperglycemia compensatory/reassurance behaviors are reactive actions taken either in response to hyperglycemia or that provide reassurance around diabetes self-management practices.

3.5 Relationships Between Diabetes-Related Worry and Worry Behaviours

To examine the bivariate relationships between diabetes-related worry and worry-driven behaviours, a series of Pearson correlations were calculated. These correlations are presented in Table 6.

Insert table 6 about here.

The results of these analyses showed that worry of hypoglycemia was significantly related to hypoglycemia avoidance behaviour ($r = .34$, $p < .001$), and hypoglycemia compensatory behaviour ($r = .21$, $p < .01$). However, worry of hypoglycemia was not significantly related to hypoglycemia subtle avoidance behaviours ($r = .12$, $p < .15$). In contrast, worry of vascular complications was significantly related to complication vigilance/risk behaviour avoidance ($r = .30$, $p < .001$). However, it was not significantly related to hyperglycemia avoidance behaviour with diet and exercise ($r = .09$, $p < .30$) or hyperglycemia compensatory/reassurance behaviour ($r = .07$, $p < .37$).

3.6 Diabetes-Related Worry, Avoidance Behaviour, and Glycemic Control

To test the first and second hypotheses that avoidance behaviour mediates the relationships between diabetes-related worry and glycemic control, a series of hierarchical multiple regressions were conducted. On the first step of each model, demographic variables (sex, age, income) that have previously been shown to account for significant proportions of variance in glycemic control were entered as control variables. Although including the duration since diagnosis with T1DM as a control variable was desired, this information was only available for 116 (76%) of participants. Therefore, this variable was excluded from the analyses to preserve statistical power. In the first models (model 1), the independent variables of interest (i.e., worry of hypoglycemia, worry of vascular complications) were each entered as predictors in separate models, and A1C was entered as the criterion. In the second models (model 2), the same independent variables (i.e., worry of hypoglycemia, worry of vascular complications) were each entered as predictors, and the hypothesized mediating variables (i.e., hypoglycemia avoidance behaviour, hyperglycemia avoidance behaviour) were entered as the criterion. In the third models (model 3), both the hypothesized mediating variables and independent variables were entered simultaneously on the second step, and A1C was entered as the criterion.

A schematic of the first hypothesis is presented in Figure 3.

Insert Figure 3 about here

The results from the first set of analyses showed that worry of hypoglycemia was not a significant predictor of A1C ($\beta = -.12$, $p < .19$). However, hypoglycemia avoidance behaviour was positively associated with A1C ($\beta = .22$, $p < .05$); such that, greater avoidance behaviour

was associated with worse glycemic control. Furthermore, worry of hypoglycemia was positively associated with hypoglycemia avoidance behaviour ($\beta = .37$, $p < .001$). Since the independent effect of worry of hypoglycemia on A1C was not statistically significant, there is no evidence of mediation. However, hypoglycemia avoidance behaviour is acting as a suppressor variable. This suggests that hypoglycemia avoidance behavior suppressed irrelevant variance in A1C. In turn, this enhanced the magnatude of the relationship between worry and A1C when avoidance behaviour was included in the model. Of note, age was inversely associated with hypoglycemia avoidance behaviour ($\beta = -.16$, $p < .05$), suggesting that avoidance behaviours are associated with younger age. While the association between age and avoidance behavior is statistically significant, it may not be clinically meaningful since this relationship could be confounded by other factors (e.g., health status). A summary of this mediation model is presented in Table 7.

Insert Table 7 about here

A schematic of the second hypothesis is presented in Figure 4.

Insert Figure 4 about here

The results of these analyses showed that worry of vascular complications was not a significant predictor of either A1C ($\beta = .14$, $p < .11$) or hyperglycemia avoidance behaviour ($\beta = .07$, $p < .43$). Furthermore, hyperglycemia avoidance behaviour was not a significant predictor of A1C ($\beta = -.16$, $p < .09$). Consequently, there is no evidence of statistical mediation. A summary of this mediation model is presenced in Table 8.

Insert Table 8 about here

3.7 Diabetes-Related Worry, Avoidance Behaviour, and Perceived Impact

To test the third and fourth hypotheses that avoidance behaviour mediates the relationships between diabetes-related worry and the perceived impact of having diabetes, a further series of hierarchical multiple regressions were performed. On the first step of each model, demographic variables (sex, age, income) were entered as control variables. According to the recommendations outlined by Rubin and Peyrot (1999), it is important to destinguish between objective health factors and subjective perceptions when evaluating HRQoL. Since health factors are likely to explain significant proportions of unique variance in HRQoL, the experience of severe hypoglycemic episodes during the previous 12-months, and the number of vascular complications that participants had developed were added as additional control variables on the second step of the models that use HRQoL constructs (i.e., perceived impact, self-management satisfaction) as the criterion. This will permit the determination of the unique influences of diabetes-related worry and avoidance behavior on these HRQoL dimensions.

In the first models (model 1), the independent variables of interest (i.e., worry of hypoglycemia, worry of vascular complications) were each entered as predictors in separate models, and perceived impact was entered as the criterion. In the second models (model 2), the same independent variables (i.e., worry of hypoglycemia, worry of vascular complications) were entered as predictors, and the hypothesized mediating variables (i.e., hypoglycemia avoidance behaviour, hyperglycemia avoidance behaviour) were entered as the criterion. In the third models (model 3), both the hypothesized mediating variables and independent variables were entered simultaneously, and perceived impact was entered as the criterion.

A schematic of the third hypothesis is presented in Figure 5.

Insert Figure 5 about here

The results of these analyses showed that worry of hypoglycemia was a significant predictor of perceived impact ($\beta = .52$, $p < .001$); such that greater worry was associated with a greater perceived impact of having diabetes. Furthermore, worry of hypoglycemia was positively associated with hypoglycemia avoidance behaviour ($\beta = .37$, $p < .001$). In turn, hypoglycemia avoidance behaviour was positively associated with perceived impact ($\beta = .21$, $p < .01$). The association between worry of hypoglycemia and perceived impact was partially accounted for by hypoglycemia avoidance behaviour, providing support for the mediation hypothesis (*Sobel* = 2.36, $p < .02$). A summary of this mediation model is presenced in Table 9.

Insert Table 9 about here

A schematic of the fourth hypothesis is presented in Figure 6.

Insert Figure 6 about here

The results of these analyses showed that worry of vascular complications was a significnat predictor of perceived impact ($\beta = .46$, $p < .001$); such that, greater worry was again associated with greater perceived impact. Although hyperglycemia avoidance behaviour was positively associated with perceived impact ($\beta = .18$, $p < .02$), the independent association between worry of vascular complications and hyperglycemia avoidance behaviour was not significant. Consequently, there is no evidence of mediation. It appears that age was the only significant predictor of hyperglycemia avoidance behaviour ($\beta = .29$, $p < .001$); with avoidance behaviours being associated with being older. A summary of this mediation model is presenced in Table 10.

Insert Table 10 about here

3.8 Diabetes-Related Worry, Avoidance Behaviour, and Self-Management Satisfaction

To test the fifth and sixth hypotheses that avoidance behaviour mediates the relationships between diabetes-related worry and self-management satisfaction, a similar series of hierarchical multiple regressions were performed (as outlined above). A schematic of the fifth hypothesis is presented in Figure 7.

Insert Figure 7 about here

The results of these analyses showed that worry of hypoglycemia was a significant predictor of self-management satisfaction ($\beta = -.17$, $p < .05$); such that, greater worry was associated with less satisfaction. Furthermore, worry of hypoglycemia was positively associated with hypoglycemia avoidance behaviour ($\beta = .37$, $p < .001$). However, since the independent association between hypoglycemia avoidance behaviour and self-management satisfaction was not significant ($\beta = -.11$, $p < .24$), there is no evidence of mediation. A summary of this mediation model is presenced in Table 11.

Insert Table 11 about here

A schematic of the sixth hypothesis is presented in Figure 8.

Insert Figure 8 about here

The results of these analyses showed that worry of vascular complications was a significant predictor of self-management satisfaction ($\beta = -.42$, $p < .001$); such that, greater worry was similarly associated with less satisfaction. Although hyperglycemia avoidance behaviour was positively associated with self-management satisfaction ($\beta = .16$, $p < .04$), the independent

association between worry of vascular complications and hyperglycemia avoidance behaviour was not significant ($\beta = .07$, $p < .43$). Consequently, there is no evidence of mediation. A summary of this mediation model is presenced in Table 12.

Insert Table 12 about here

3.9 Exploratory Analyses

In the primary analyses described above, the relationships between diabetes-related worry (i.e., worry of hypoglycemia, worry of vascular complications), avoidance behaviour, and glycemic control, and HRQoL, were considered. However, the consequence of severe hypoglycemia on the experience of worry of hypoglycemia and hypoglycemia avoidance behaviour in this sample is unclear. Furthermore, the impact of vascular complications on the experience of both worry of vascular complications and hyperglycemia avoidance behaviour is not known. In this next section, these questions were considered. It was anticipated that the recent experience of both episodes of severe hypoglycemia and vascular complications, will be positively associated with both avoidance behaviour and diabetes-realted worry. In turn, worry will be positively associated with avoidance behaviour. It is also anticipated that diabetes-related worry will mediate the relationships between self-management and disease-related complications (i.e., episodes of severe hypoglycemia, number of vascular complications) and avoidance behaviours.

3.9.1 Self-Management and Disease-Related Complications, Diabetes-Related Worry, and Avoidance Behaviour

To examine whether diabetes-related worry (i.e., worry of hypoglycemia, worry of vascular complications) mediates the relationships between self-management and disease-

related complications (i.e., episodes of severe hypoglycemia, the number of vascular complications) and avoidance behaviour, a similar set of hierarchical multiple regressions were conducted (as outlined above).

A schematic of the worry of hypoglycemia mediation model is presented in Figure 9.

Insert Figure 9 about here

The results of these analysis showed that a recent history of severe hypoglycemia was not a significant predictor of hypoglycemia avoidance behaviour ($\beta = .04$, $p < .63$). However, severe hypoglycemia was positively associated with worry ($\beta = .27$, $p < .001$), which in turn, was positively associated with hypoglycemia avoidance behaviour ($\beta = .38$, $p < .001$). Although there is no evidence of mediation, these findings suggest a particular sequence of events that may contribute to both worry and and avoidance behaviour. Further examination of bivariate correlations showed that severe hypoglycemia was unrelated to hypoglycemia compensatory behaviours ($r = .10$, $p < .21$), and subtle avoidance behaviours ($r = .07$, $p < .38$). A summary of this mediation model is presenced in Table 13.

Insert Table 13 about here

A schematic of the worry of vascular complications mediation model is presented in Figure 10.

Insert Figure 10 about here

The results of these analyses showed that the number of vascular complications was not a significant predictor of hyperglycemia avoidance behaviour ($\beta = .12$, $p < .19$). However, the number of vascular complications was positively associated with worry ($\beta = .26$, $p < .001$);

with more complications being associated with greater worry. Since the independent effects between vascular complications and avoidance behaviour, and between worry and hyperglycemia avoidance behaviour, were not significant, there is no evidence of mediation. Further examination of bivariate correlations showed that vascular complications was significantly associated with complication vigilance/risk behaviour avoidance ($r = .22$, $p < .01$), but was unrelated to hyperglycemia compensatory/reassurance behaviour ($r = .00$, $p < .99$). A summary of this mediation model is presenced in Table 14.

Insert Table 14 about here

3.9.2 Diabetes-Related Worry, Alternative Worry Behaviours, and Outcomes

As previously shown, the behaviour subscales of both the HFS and FOCQ tap a heterogeneous sample of worry behaviour. The results of the PCA described above showed that the HFS behaviour items measure hypoglycemia avoidance behaviours, hypoglycemia compensatory behaviours, and hypoglycemia subtle avoidance behaviours. Furthermore, it was also shown that the FOCQ behaviour items similarly measure complication vigilance/risk behaviour avoidance, hyperglycemia avoidance behaviour with diet and exercise, and hyperglycemia compensatory/reassurance behaviours. Since the primary analyses outlined above focused on avoidance behaviour as the primary mediating variable between diabetes-related worry and both glycemic control and quality of life outcomes, the relationships between the diabetes-related worry, alternative worry behaviours (e.g., subtle avoidance behaviours, complication vigilance/risk behaviour avoidance, compensatory/reassurance behaviours) and outcomes will now be considered. First, Pearson correlations were calculated to examine the bivariate relationships among the variables. The worry and behaviour constructs that were

significantly associated with the outcomes (A1C, HRQoL) were further examined in a similar series of mediation models.

The relationships between the diabetes-related worry, alternative worry behaviours, and A1C, are presented in Table 5.

Insert table 5 about here.

Examination of these correlations showed that none of these additional diabetes-related worry behaviours are significantly associated with A1C. Consequently, no further analyses were performed using A1C as a criterion variable.

The relationships between diabetes-related worry, alternative worry behaviours, and HRQoL (perceived impact, self-management satisfaction) are presented in Table 15.

Insert table 15 about here.

Examination of these correlations showed that hyperglycemia compensatory/reassurance behaviour was significantly associated with perceived impact ($r = .26$, $p < .01$). Furthermore, hypoglycemia subtle avoidance behaviour was significantly associated with self-management satisfaction ($r = .22$, $p < .01$). While these latter associations are statistically significant, caution must be exercised in their interpretation given the magnatude of their relationships.

For similar reasons outlined in the primary analyses, I then sought to determine whether these alternative worry behaviours mediate the relationships between the diabetes-related worry (i.e., worry of hypoglycemia, worry of vascular complications) and HRQoL (perceived impact; self-management satisfaction). Subsequent analyses were considered if the hypothesized predictor, mediator, and criterion were each related at the bivariate level. Based on these findings, no additional analyses were performed.

CHAPTER 4

DISCUSSION

The purpose of this present study was to examine the impact of diabetes-related worry and avoidance behaviours on glycemic control and HRQoL in adults with T1DM. First, PCA was used to examine the structure of diabetes-related worry behaviour in this population. Through primary analyses, we examined that extent to which diabetes-related avoidance behaviours (e.g., hypoglycemia avoidance, hyperglycemia avoidance) mediate the relationships between diabetes-related worry and a variety of outcomes including glycemic control (i.e., A1C), and HRQoL (i.e., perceived impact, self-management satisfaction). Through exploratory analyses, I then examined the extent to which diabetes-related worry mediates the relationships between self-management and disease-related complications and diabetes-related avoidance behaviours. In this next section, these results will be summarized and integrated with the available literature. A discussion of the strengths and limitations of the present study will follow, and directions for future research will be offered.

4.1 Diabetes-Related Worry Behaviours

Over the past few decades, researchers have asserted that worry of hypoglycemia adversely impacts blood glucose management (Cox et al., 1987; Wild et al., 2007); at least for certain subgroups of individuals with T1DM (Irvine et al., 1992). Although the experience of severe hypoglycemia may sensitize individuals to worry, and worry may motivate a variety of avoidance behaviours (Irvine, Cox, & Gonder-Frederick, 1992; Gonder-Frederick et al., 2006), researchers have not directly tested this mediation hypothesis. Rather, researchers and clinicians appear to have accepted this to be fact in the absence of supporting evidence. Contributing to this confusion, the mechanism(s) responsible for worsening glycemic control

have not been clearly delineated. Although researchers hypothesized that hypoglycemia avoidance behaviour is the likely culprit, the measure used to assess this construct taps more than overt avoidance behaviour. Recently, other researchers have turned their attention to worry of vascular complications as another diabetes-related worry construct that has the potential to influence diabetes self-management and outcomes (e.g., Taylor et al., 2005). Since the instrument used to measure this construct does not assess worry-driven behaviour, a worry of vascular complication behaviour subscale was generated for use in this current study. PCA was used to examine the component structure of these two behaviour dimensions, and the results of these analyses were incorporated into a series of mediation models.

The results of the first PCA revealed that the worry of hypoglycemia behaviour subscale is best be represented by a 3-factor solution, which accounts for 53% of the total variance. These items reflect facets of hypoglycemia avoidance behaviour (Factor 1), hypoglycemia compensatory behaviour (Factor 2), and hypoglycemia subtle avoidance behaviour (Factor 3). Although the authors of this 27-item measure conducted a factor analysis as part of the original validation study (Cox et al., 1987), their sample was limited to 35 participants rendering their findings unreliable. To date, only one other PCA has been reported using an abbreviated version of the measure that was translated to Swedish (Anderbro, Amsberg, Wredling, Lins, Adamson, et al., 2008).

The results of the second PCA revealed that the worry of vascular complications behaviour subscale is also best represented by a 3-factor solution, which accounts for 43% of the total variance. These items reflect facets of complication vigilance/risk behaviour avoidance (Factor 1), hyperglycemia avoidance behaviour with diet and exercise (Factor 2), hyperglycemia compensatory/reassurance behaviour (Factor 3). Since this behaviour subscale

was generated for use in this present study, this is the first examination of its component structure.

Although previous studies have explored the predictors and consequences of worry of hypoglycemia and worry of vascular complications (e.g., Gonder-Frederick et al., 2006; Irvine, Cox & Gonder-Frederick, 1992; Taylor et al., 2005), researchers have considered diabetes-related worry behaviour to be homogeneous. While the practice of some behaviours may be motivated by worry, the impact of these behaviours may be divergent. Differentiating between types of worry behaviour has important implications for both research and clinical practice. For instance, it is likely that overt avoidance behaviour may have a more proximal impact on blood glucose, which over time, may exert cumulative effects on glycemic control. This is evidenced by a significant positive correlation between hypoglycemia avoidance behaviour and A1C in the adjusted model (see Figure 3). However, while subtle avoidance behaviours may be adaptive for diabetes management, they do not directly impact blood glucose. For instance, fast-acting sugar will only impact blood glucose if the sugar is ingested. Therefore, this subtle avoidance strategy may be associated with other psychosocial outcomes (e.g., self-efficacy), rather than blood glucose. Previous researchers have failed to differentiate among different types of worry behaviour, which may have contributed to the inconsistent associations with blood glucose parameters reported in previous studies (e.g., Cox et al., 1987; Irvine et al., 1992).

4.2 Relationships Between Diabetes-Related Worry and Worry Behaviours

The results of a series of bivariate correlations showed that worry of hypoglycemia was significantly associated with both avoidance and compensatory behaviour. However, worry of hypoglycemia was not significantly related to subtle avoidance behaviour. This suggests that

greater worry is associated with the more frequent practice of behaviours intended to avoid states of hypoglycemia (e.g., "keeping my sugar higher when I will be alone for a while") or react when hypoglycemia appears to be imminent (e.g., "eating something as soon as I feel the first sign of low blood sugar"). However, worry of hypoglycemia is not related to the practice of subtle avoidance behaviour ("carrying fast acting sugar with me"), suggesting that factors other than worry may motivate such behaviours. For instance, carrying fast acting sugar, such as glucagon, is promoted as an adaptive strategy for diabetes self-management. It is plausible that individuals can be motivated to minimize the likelihood of experiencing hypoglycemia for reasons other than worry (e.g., inconvenience as a result of severe hypoglycemia).

In contrast, worry of vascular complications was positively associated with complication vigilance/risk behaviour avoidance. This suggests that worry is associated with the more frequent practice of behaviours intended to detect the signs and symptoms of vascular pathology (e.g., changes in visions, numbness or tingling in the extremities) and avoiding identified risk behaviours (e.g., alcohol consumption). However, the relationships between worry and both avoidance and compensatory behaviour were not statistically significant. Similarly, this lack of associations could mean that factors other than worry influence the practice of such behaviours.

For instance, experiencing an acute episode of hyperglycemia results in symptoms that include excessive urination, excessive thirst, fatigue, itchy skin, and over time, weight loss. Individuals may be motivated to avoid hyperglycemic states to eliminate these symptoms because they may be sufficiently averse in their own right. Acute episodes of hyperglycemia may, or may not, trigger worry about vascular pathology because for some, the consequences may be too far down stream. In other words, the consequence of developing vascular

complications may be too distal from the experience of hyperglycemia for it to sufficiently motivate avoidance or compensatory behaviours to maintain or restore euglycemia.

Interestingly, one of the strongest relationships was observed between worry of hypoglycemia and worry of vascular complications. This suggests that a general tendency to worry might underlie both of these constructs. In further support of this hypothesis, various vascular complication worry behaviours (e.g., complication vigilance/risk behaviour avoidance) were significantly associated with hypoglycemia worry behaviours (e.g., subtle avoidance behaviours, avoidance behaviour).

4.3 Diabetes-Related Worry and Glycemic Control

To date, the research examining the relationships between diabetes-related worry and glycemic control has been mixed. Some researchers have reported significant relationships between worry of hypoglycemia and a variety of indices including blood glucose variability and history of hypoglycemia (e.g., Gonder-Frederick et al., 2006; Irvine, Cox & Gonder-Frederick, 1992;). However, a relationship between worry and glycemic control (i.e., A1C) has not been shown (Cox et al., 1987; Irvine et al., 1992). Although researchers have hypothesized that worry motivates avoidance behaviour, which negatively influences glycemic control, no prior studies have tested this proposed mediation model. Furthermore, researchers have not considered a similar mediation model with the worry of vascular complications construct.

The results of a series of the analyses showed that hypoglycemia avoidance behaviour does not mediate the relationship between worry of hypoglycemia and A1C. However, in these analyses hypoglycemia avoidance behaviour is acting as a suppressor variable. For instance, the adjusted standardized ß-weight for the independent association between worry of hypoglycemia and A1C was not statistically significant (β = -.12, $p < .20$). However, when

hypoglycemia avoidance behaviour was included in the model, the direct effect of worry on A1C increased in magnitude and became statistically significant (β = -.20, p < .03). This suggests that hypoglycemia avoidance behavior suppressed irrelevant variance in A1C that strengthened its association with worry (Cohen, Cohen, West, & Aiken, 2003). Worry and avoidance behavior share variance with each other as evidenced by their significant relationship (β = .37, p < .001). Furthermore, the independent association between worry and A1C, and avoidance behavior and A1C are in the opposite direction. By failing to control for the variance in A1C accounted for by avoidance behavior, the relationship between worry and A1C was suppressed. The independent association between worry and A1C emerged only after controlling for avoidance behavior. In light of the inverse relationship between worry and A1C, it is possible that having a lower A1C increases the likelihood of experiencing hypoglycemia thereby increasing the degree to which individuals worry of hypoglycemia. The directionality of this association requires further examination using longitudinal research designs. Overall however, based on the guidelines outlined by Barron and Kenny (1986), the current data do not support the originally hypothesized mediation hypothesis. The findings instead suggest that to reveal the nature of the relationship between worry of hypoglycemia and A1C, it is important to account for the extent to which individuals engage in hypoglycemia avoidance behavior.

The results of our analyses also showed that hyperglycemia avoidance behaviour does not mediate the relationship between worry of vascular complications and A1C. In fact, the independent associations between worry and A1C, and avoidance behaviour and A1C, were not significant (p < .09). As described above, participants in this sample had reasonably well controlled blood glucose (mean A1C = 7.6). Although the results of exploratory analyses showed that the number of vascular complications accounted for 26% of the variance in worry,

the mean number of vascular complications among participants was .34 (SD = .67), and the modal number of complications that participants had developed was zero. Therefore, worry of vascular complications may not have been a particularly salient construct in this sample. However, if participants were more symptomatic of microvascular or macrovascular disease, we might expect the associations between worry, avoidance behaviour, and A1C to be more substantive.

In a related line of research in our laboratory, a propensity to experience anxiety (i.e., anxious temperament) was found to be inversely associated with A1C among individuals newly diagnosed with T2DM (Hall, Coons & Vallis, 2008; Hall, Rodin, Vallis & Perkins, 2009). This provides converging evidence that some manifestations of anxiety (i.e., worry of hypoglycemia, anxious temperament) are inversely associated with glycemic control among individuals with diabetes. Understanding the mechanisms responsible for these associations and outcomes will be important for future research.

Interim Summary

These findings suggest that the relationships between diabetes-related worry, avoidance behaviour, and glycemic control are complex. Although by definition, these data did not support the avoidance behaviour mediation hypotheses, they suggest that a series of related variables are associated with glycemic control. From the adjusted models, the experience of severe hypoglycemic episodes is associated with increased worry of hypoglycemia (β = .27, p < .001), which is associated with hypoglycemia avoidance behaviour (β = .37, p < .001). In turn, hypoglycemia avoidance behaviour is associated with worse glycemic control (β = .22, p < .05). Worry of hypoglycemia is only associated with worse glycemic control (β = -.20, p < .02) after controlling for hypoglycemia avoidance behavior, which is consistent with the

findings of previous research. Although the number of vascular complications was also associated with worry ($\beta = .26$, $p < .01$), there was no independent association between worry of vascular complications and either avoidance behaviour ($\beta = .07$, $p < .44$) or glycemic control ($\beta = .15$, $p < .10$).

4.4 Diabetes-Related Worry and Perceived Impact

Extending the mediation hypotheses considered above, it was hypothesized that diabetes-related avoidance behaviour would mediate the relationships between diabetes-related worry and HRQoL (i.e., perceived impact, self-management satisfaction). The results of analyses involving worry of hypoglycemia and perceived impact were supported by these data. Specifically, worry of hypoglycemia was associated with of the perceived negative impact of having diabetes, and accounted for 52% of the variance. Furthermore, avoidance behaviour was also associated with perceived impact, and partially accounted for the relationship between worry and perceived impact.

Individual item analysis of the perceived impact subscale revealed that items enquire about the frequency of occurrence of events including having low blood sugar, being embarrassed about having to manage diabetes in public, feeling physically ill, having a bad night's sleep, and experiencing limitations in social or occupational domains. Therefore, it is not surprising that worry of hypoglycemia shares such an appreciable relationship with this construct, and that behaviours intended to avoid the threat of hypoglycemia helps to explain this association.

These data also showed that hyperglycemia avoidance behaviour does not mediate the relationship between worry of vascular complications and perceived impact. Rather, worry of vascular complications and hyperglycemia avoidance behaviour are independently associated

with the perceived negative impact of having diabetes. However, there was no independent association between worry of vascular complications and avoidance behaviour. Furthermore, the results of exploratory analyses showed that hyperglycemia compensatory/reassurance behaviour was similarly associated with these negative perceptions.

It is logical that behaviours intended to avoid hyperglycemia that include avoiding eating out in restaurants, and avoiding eating carbohydrates and high calorie foods, may contribute to negative perceptions about having diabetes by the restrictions imposed on behaviors that are appreciated and valued (e.g., freedom in dietary choices). However, the association between worry of vascular complications and perceived impact is less intuitive.

Drawing from cognitive behavioural theories, worry is associated with a bias to perceive information more negatively. In a recent meta-analytic review, Bar-Haim and colleagues (2007) found that across studies and populations, anxiety is associated with a threat-related perceptual bias. This bias facilitates a process of hypervigilance toward threat in the environment (either external or internal), and may result in inaccurate conclusions being drawn about the nature and extent of potential threat. In this particular sample, the significant associations between worry and perceived impact could in part, be accounted for by an overactive threat-detection system. As individuals become increasingly worried of future vascular pathology, it is plausible that a negative perceptual bias becomes activated, which facilitates a selective focus on the negative aspects of living with diabetes.

4.5 Diabetes-Related Worry and Self-Management Satisfaction

These findings also showed that avoidance behaviour does not mediate the relationship between diabetes-related worry and self-management satisfaction. However, both worry of hypoglycemia and worry of vascular complications are associated with less satisfaction,

accounting for 17% and 42% of the variance, respectively. Interestingly, the difference in the magnitude of these effects is noteworthy. Severe hypoglycemia is an episodic and transient experience that, on average, occurs once or twice per year (Frier, 2008). In contrast, vascular complications represent irreversible medical conditions that contribute to blindness, renal failure, limb amputation, or other serious vascular events. Therefore, the gravity of these potential outcomes may help to explain why the independent association between worry of vascular complications and self-management satisfaction is considerably stronger than between worry of hypoglycemia and satisfaction.

Furthermore, the results of analyses showed that both hyperglycemia avoidance behaviour and hypoglycemia subtle avoidance behaviour were positively associated with self-management satisfaction. It is possible that the practice of such behaviours may serve an adaptive function that protects against dis- satisfaction with the outcome of diabetes self-management practices. For instance, behaviours such as avoiding eating carbohydrates that would increase blood glucose, carrying fast acting sugar, or checking blood glucose more frequently in certain situations, may help to empower individuals to adaptively respond to blood glucose deviations if, and when, they occur. Over time, and with repeated practice, they may facilitate a greater sense of diabetes-related self-efficacy and overall satisfaction. This self-efficacy hypothesis in patients with diabetes has been reported by other researchers (e.g., Grey et al., 2001; Rubin, Peyrot & Saudek, 1993), and has been similarly demonstrated among patients with other chronic diseases (e.g., Rea et al., 2004).

Interim Summary

The results of these analyses showed that diabetes-related worry is associated with the perceived impact of having diabetes and self-management satisfaction. Specifically,

hypoglycemia avoidance behaviour is an important mechanism that helps to explain the relationship between worry of hypoglycemia and perceived impact. Furthermore, worry of vascular complications and both hyperglycemia avoidance and compensatory/reassurance behaviours are similarly associated with the negative perceptions of the impact of having diabetes. However, hyperglycemia avoidance behaviour and hypoglycemia subtle avoidance behaviours are associated with greater satisfaction with self-management practices, suggesting that they may serve an adaptive function.

4.6 Distinctions Between Diabetes-Related Worry and HRQoL

Given the magnitude of the observed associations between diabetes-related worry, perceived impact, and self-management satisfaction, are these dimensions tapping into the same underlying construct? When the DQOL was developed, the researchers of the Diabetes Control and Complications Trial sought to capture the nuances of diabetes that appear to have the greatest impact on the quality of life experiences. The original scale was comprised of 5 subscales that include: 1) Impact of illness, 2) self-management satisfaction, 3) social/vocational worry, 4) diabetes-related worry, and 5) overall quality of life. The impact of illness and self-management satisfaction subscales were selected for use in this current study because they appeared to have the greatest potential to be impacted by diabetes-related worry and worry-driven behaviour. Although the DQOL contains a social and vocational worry subscale, items relate to worry about getting married, worry about whether or not individuals will have children, and worry about whether or not individuals will secure the job that they desire. For the diabetes-related worry subscale, items relate to worry about whether or not individuals will secure health insurance because of having diabetes, and worry about the appearance of one's body because of having diabetes. In addition, two additional items were

included that each assess worry about passing out, and worry about whether or not one will develop future complications. From the examination of these items, it seems that from early on, researchers appreciated that worry has the potential to impact the quality of life experiences for individuals with T1DM. However, the focus of the evaluation appears to have been on a heterogeneous sample of diabetes-related worries. Only two single items are vague approximations of the worry of hypoglycemia and worry of vascular complication constructs. However, these two particular items fail to capture the nature and extent of worry of both hypoglycemia and vascular complications, and do not begin to examine diabetes-related worry behaviours. Therefore, it appears that worry was conceptualized as an affective response that is central to the quality of life experiences of individuals with T1DM. However, worry of hypoglycemia, worry of vascular complications, and their associated worry behaviours, were peripheral to the conceptualization of HRQoL.

4.7 Age, Diabetes-Related Worry Behaviours, and Perceived Impact

Ancillary to the analyses described above, several interesting findings emerged involving age, avoidance behaviour, and perceived impact. First, age was inversely associated with hypoglycemia avoidance behaviours, and was positively associated with hyperglycemia avoidance behaviours. This suggests that the nature of avoidance behaviours may change as a function of increasing age. Specifically, as individuals age, they may be less likely to engage in hypoglycemia avoidance, and may be more likely to engage in hyperglycemia avoidance. Several potential explanations for these associations exist.

First, as individuals' age, the likelihood of developing vascular complications increases as a function of the advancing disease process. Consequently, individuals may become increasingly aware of the importance of effective diabetes self-management to minimize the

risk of vascular complications and premature mortality. As such, the motivation to avoid hypoglycemia may be overridden by a more salient concern of vascular complications.

Second, as individuals' age, the likelihood of having experienced episodes of severe hypoglycemia increases. In fact, individuals with T1DM experience one to two mild episodes per week, and one to two severe episodes per year (Frier, 2008). The nature and outcome of these glycemic deviations may influence the temporal dynamics of diabetes-related worry. Historically, if individuals have been successful at managing severe episodes of hypoglycemia, and averting dangerous or life-threatening outcomes (e.g., experiencing hypoglycemia while driving a vehicle), their worry may decrease as a function of their increased confidence in managing these events. However, if individuals have a history of experiencing dangerous or traumatic outcomes (e.g., seizures, hospitalizations) as a consequence of severe hypoglycemia, worry of hypoglycemia may remain salient.

In two related lines of research, it has been reported that individuals with T1DM are twice as likely to experience a "driving mishap" (i.e., motor vehicle collisions, traffic citations) compared to their non-diabetic spouses, and individuals with T2DM (Cox et al., 2001). The outcomes of these events likely influence a variety of both affective and behavioural responses. Others have shown that the perceived threat of death from an acute episode of hypoglycemia (e.g., following losses of consciousness or seizures) and worry about future episodes of hypoglycemia, are important contributing factors to the development of hypoglycemia-related posttraumatic stress symptoms (Myers et al., 2007). Under such conditions, individuals have been found to engage in significantly greater avoidant behaviour. This suggests that the outcomes of hypoglycemic episodes may be an important moderator of the association between age and avoidance behaviour. Although data in this current study failed to show a significant

relationship between severe hypoglycemia and avoidance behavior, hypoglycemia was positive associated with worry. Unfortunately, data in this present study were limited to the frequency of severe hypoglycemia. Consequently, examining the nature and outcomes of these experiences was not possible.

Finally, age was also inversely associated with the perceived impact of having diabetes, and accounted for approximately 20% of the variance. This suggests that as individuals' age, they are less likely to perceive the impact of having diabetes in social and occupational domains to be negative. It is possible that over time, individuals with diabetes become accustomed to the social experiences that have the potential to negatively impact one's life. For instance, several of the items on the perceived impact subscale assess elements of social interference (e.g., "How often are you embarrassed by having to deal with your diabetes in public?" "How often do you find yourself explaining what it means to have diabetes?"). With the increased experience that comes with navigating these sensitive social situations over time, it is possible that the perception of negative impact diminishes. However, the positive effect of age on perceived impact may not be uniform across all individuals. For instance, there may be subgroups of individuals for whom the perceptions of social interference may remain high across the lifespan. In a recent study, Di Battista and colleagues (2009) reported that social anxiety was positively associated with the perceived impact of having diabetes; such that greater social anxiety was associated with greater perceived impact. Although these researchers surveyed a sample of adolescents with T1DM, this study suggests that social anxiety may be an important moderator of the association between diabetes-related worry and perceived impact, and may be important to consider in future studies.

Interim Summary

In addition to the independent variables included in the above analyses, age was significantly associated with several outcomes, and sheds some light on the temporal dynamics of diabetes-related worry behaviour and HRQoL. Age was significantly associated with avoidance behaviour; however, the function of the avoidance may change across time. As individuals age, they may be less likely to practice hypoglycemia avoidance behaviour, and more likely to engage in hyperglycemia avoidance behaviour. Although we are unable to discern the motivations for these differences, this may relate to the decreasing temporal distance to the development of vascular complications. As individuals' age and diabetes advances, they are more likely to become symptomatic of vascular pathology. Therefore, individuals may become increasingly motivated to improve their glycemic control. Alternatively, as individuals age, the likelihood of experience other health problems increases. Therefore, the observed association between age and avoidance behaviour may be confounded by health status or the presence of other comorbid medical conditions. Although the cross sectional design of this current study prevents us from directly testing intertemporal choice theories, the associations between age and avoidance behaviour suggest that health-behaviour choices may be dynamic, and may be influenced by a variety of motivational and disease-related factors. Furthermore, age was inversely associated with perceived impact, suggesting that over time, some individuals may adjust to the perceived life interference imposed by diabetes self-management practices.

4.8 Strengths and Limitations

Data from this current study contribute to the psychosocial diabetes literature in a number of substantive ways. First, previous researchers have failed to differentiate between

diabetes-related worry behaviours. This was accomplished by subjecting the HFS behaviour subscale to a PCA. To date, researchers have not adequately assessed the component structure of the full English measure, let alone the behaviour dimension. This is also the first study to include a behaviour subscale to the FOCQ, which was similarly subjected to PCA.

Second, researchers have assumed that diabetes-related worry and worry-driven behaviours uniformly impact a variety of important health outcomes. However, only a few studies have been published that directly assessed the impact of diabetes-related worry and worry-driven behaviour on glycemic control (Cox et al., 1987; Irvine et al., 1992; Taylor et al., 2005). In a recent review of the worry of hypoglycemia literature, it was noted that researchers tend to selectively use the worry subscale only, and omit the behaviour subscale from analyses (Wild et al., 2007). These present findings suggest that assessing, and differentiating among different diabetes-related worry behaviours is indeed important in light of their unique associations with glycemic control, and HRQoL (perceived impact, self-management satisfaction).

Third, it has been assumed that avoidance behaviour mediates the relationship between worry of hypoglycemia and glycemic control (Cox et al., 1987; Cox et al., 2001; Irvine et al., 1992; Wild et al., 2007). Although intuitively this seems sensible, researchers have not directly tested this hypothesis, and the measure used to assess hypoglycemia avoidance captures more than simply avoidance behaviour. Furthermore, the worry of vascular complications behaviour subscale was constructed to capture similar heterogeneity. The results of our PCA confirm that diabetes-related worry behaviour is not homogenous. Rather, it is represented by a variety of behaviours that range from overt avoidance, compensatory, subtle avoidance, vigilance, and reassurance behaviours. Although each behaviour is intended to minimize the perils of both

hypoglycemia and vascular complications, the direct outcome of these behaviours is variable. These distinctions may appear to be semantic. However, they reflect important conceptual differences that influence how these constructs are both assessed and analyzed.

Fourth, these data suggest that not all diabetes-related worry behaviours are the same, and some may be more adaptive than others. As anticipated by researchers, overt avoidance behaviour appears to have the greatest impact on A1C. However, hypoglycemia avoidance and compensatory behaviours are associated with the negative perceptions of having diabetes, and may be detrimental to self-management satisfaction. In contrast, hypoglycemia subtle avoidance, hyperglycemia avoidance, and complication vigilance/risk behaviour avoidance are associated with greater self-management satisfaction. These findings have importance implications for both research and clinical practice.

Fifth, this is the first study to comprehensively examine the impact of temporally distributed diabetes-related worries and worry-driven behaviour on a variety of outcomes including glycemic control, and various HRQoL dimensions. Examining any one of these issues in isolation fails to account for the complexities inherent in the experience of living with T1DM.

Although qualities of this study help to ensure its contribution to the literature, this present study is not without its shortcomings. First and foremost, the cross sectional nature of these data limit the conclusions that can be drawn for several reasons. We are unable to examine the temporal dynamics of diabetes-related worry and worry-driven behaviour across time and disease progression. Given the complex nature of the relationships between diabetes-related worry, worry behaviour, and health outcomes, prospective examinations of these constructs will be paramount. Furthermore, we are unable to infer causality from these

observed associations. For instance, we found that worry of hypoglycemia and worry of vascular complications was associated with a variety of avoidance (overt and subtle), compensatory/reassurance, and vigilance/risk behaviour avoidance. However, it is plausible that diabetes-related worry behaviour creates a feedback loop through which the practice of worry behaviour maintains worry across time. In the anxiety disorders literature, this has been a well-documented phenomenon (for reviews, see Clark, 1999). To examine this possibility, studies employing longitudinal mediation models are needed (MacKinnon & Fairchild, 2009).

Second, A1C was used as the primary outcome measure of glycemia. Although A1C is considered to be the "gold standard" measure of achieved glycemic control, it provides a mean index of blood glucose. Consequently, it does not provide information on blood glucose variability. Irvine and colleagues (1992) have argued that individuals who are most susceptible to worry of hypoglycemia are individuals who experience a low mean blood glucose level, with a high degree of variability. This variability may contribute to a sense of unpredictability, and perhaps increases the likelihood of developing acute and significant glycemic deviations. Data on blood glucose variability would provide additional insight into the nature of the relationships between diabetes-related worry, worry behaviour, and health outcomes.

Third, for logistical reasons, we opted to collect A1C data from participant's existing medical records, rather than completing a separate blood draw for A1C analysis. Consequently, A1C values were not available for 23 participants. Factors that contributed to these missing data include the failure of participants' to complete their blood work in advance of their clinic appointments, and participants being treated for their diabetes outside of our three participating recruitment sites. Specifically, 11 participants were followed by community-based physicians

who required a fee in return for the release of participants' health information. Consequently, we were unable to collect these data.

Finally, the participants sampled in this current study had reasonably well controlled blood glucose. Therefore, this restricted the range in A1C values. Since the vast majority of participants in our sample were Caucasian, and the majority of which were free from vascular pathology, these findings may not be representative of all individuals living with T1DM. Rather, these results may only be applicable to Caucasian individuals with moderately well controlled blood glucose, who are relatively free from significant vascular complications.

4.9 Directions for Future Research

The results of this current study yield information that improves our understanding of the relationships between diabetes-related worry, worry-driven behaviour, and a variety of important health outcomes. However, future research is needed to address some important outstanding questions related to the nature and outcome of diabetes-related worry. While not exhaustive, the following section outlines some priorities for researchers.

First, all of the available research to date on diabetes-related worry has been cross-sectional. Therefore, we are unable to evaluate the temporal dynamics of diabetes-related worry and worry-driven behaviour. Understanding how these affective and behavioural experiences change across time and disease progression will be important to determine their cumulative impact on diabetes self-management practices and outcomes. This can be accomplished by using prospective research designs.

Second, A1C was used as our primary outcome of glycemia. However, this measure fails to capture variability in blood glucose. Since diabetes-related worry is likely to influence individuals' decisions about diabetes self-management practices at a momentary level,

examining worry, health behaviours, and glycemia using ecological momentary assessment (EMA) would be advisable. Technology such as continuous glucose monitoring systems, and Smartphone applications will enable researchers to examine these constructs in more sophisticated ways that increase the likelihood of deconstructing this complex biopsychosocial phenomena.

Third, the results of this current study only generalize to Caucasian individuals who have moderately well controlled diabetes. Therefore, researchers are encouraged to further explore the experience and outcome of diabetes-related worry with more ethnically diverse samples, and among individuals with more advanced, or less well controlled, T1DM.

Fourth, this is the second study that has examined the impact of worry of vascular complications on health outcomes in this population. To the best of my knowledge, this is also the first study to evaluate related worry-driven behaviour. Therefore, researchers would be advised to further explore these constructs, particularly among individuals who have developed more significant vascular pathology.

Fifth, this is the first study to conduct a PCA of the diabetes-related worry behaviour dimensions using an adequate sample size. These proposed component structures require confirmation using larger and more diverse samples of individuals with T1DM.

Finally, the results of our data suggest that the nature of diabetes-related avoidance behaviour changes as a function of increasing age. Furthermore, diabetes-related worry appears to influence the perceptions of the impact of having diabetes. To understand the conditions under which these relationships hold true, an examination of potential moderating variables is necessary. For instance, the outcome of severe hypoglycemic episodes that range from benign to life threatening will likely influence motivations to engage in hypoglycemia avoidance

behaviour. Furthermore, social anxiety has the potential to influence the perceived impact of having diabetes. These will be important variables to examine in future studies.

4.10 Conclusion

Individuals with T1DM are faced with experiencing short-term complications associated with blood glucose variability, and long-term vascular-mediated complications including blindness, renal failure, persistent pain, heart attack, or stroke. The self-management decisions that individuals make have the potential to influence these outcomes in both positive and negative ways. It has been hypothesized that affective experiences, such as diabetes-related worry, might influence such choices. Specifically, researchers have argued that worry of hypoglycemia negatively impacts glycemic control through an avoidance behaviour mechanism. In this present study, I sought to test this hypothesis. Furthermore, this avoidance behaviour mediation hypothesis was extended to include the distally focused worry of vascular complications, and included other important HRQoL dimensions.

By and large, the avoidance behaviour mediation hypotheses were not supported by these data. However, several insights into the relationships between diabetes-related worry, worry-driven behaviour, and HRQoL outcomes were realized. Although researchers have argued that worry of hypoglycemia negatively impacts glycemic control, worry was not independently associated with A1C. In fact, hypoglycemia avoidance behaviour was the only factor that was independently associated with worse glycemic control. However, avoidance behavior suppressed irrelevant variance in A1C, which enhanced the magnitude of the relationship between worry and A1C. Worry of vascular complications and hyperglycemia avoidance behaviour were both unrelated to A1C in this particular sample.

These findings suggest that diabetes-related worry shares a complex relationship with glycemic control. The results of subsequent analyses also showed that these factors are differentially associated with HRQoL outcomes. Hypoglycemia avoidance behaviour is associated with the perceived negative impact of having diabetes, and helps to explain the relationship between worry of hypoglycemia and perceived impact. Worry of vascular complications and hyperglycemia avoidance behaviour with diet and exercise were similarly associated with perceived impact; however, hyperglycemia avoidance behaviour and a variety of other worry-driven behaviours (e.g., hypoglycemia subtle avoidance, complication vigilance/risk behaviour avoidance) are associated with greater satisfaction with self-management practices and outcomes.

Ancillary to the primary analyses, these results suggest that the nature of avoidance behaviour is dynamic and may change as individuals' age. Specifically, it was observed that the practice of hypoglycemia avoidance behaviour is associated with being younger, and hyperglycemia avoidance behaviour was associated with being older. Although the specific mechanism(s) responsible for these associations cannot be elucidated from these data, a likely explanation involves the dynamics of the perceived temporal distance to the development of diabetes complications. As individuals age and diabetes advances, they may become less focused on the potential for experiencing hypoglycemia, and become more concerned with the possibility of developing significant vascular disease.

Considered together, these data suggest that the relationships between diabetes-related worry, worry-driven behaviour, and biopsychosocial outcomes are complex. Hypoglycemia avoidance behaviour is detrimental to blood glucose control, and diabetes-related worry and proactive avoidance behaviors are negatively associated with HRQoL. Clinically, this suggests

that diabetes-related worry and worry-driven behaviours are important constructs to assess in relation to both metabolic and psychosocial outcomes. Future research capitalizing on prospective designs is needed, and momentary assessment of psychological, behavioural, and metabolic constructs may be fruitful. The product of EMA will help to deconstruct the health decision-making process of individuals with T1DM. In turn, this will assist both researchers and clinicians in supporting individuals with T1DM to minimize the likelihood of significant medical morbidity and premature mortality.

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Appendix A: Figures

Figure 1 – HFS Behaviour Subscale Scree Plot

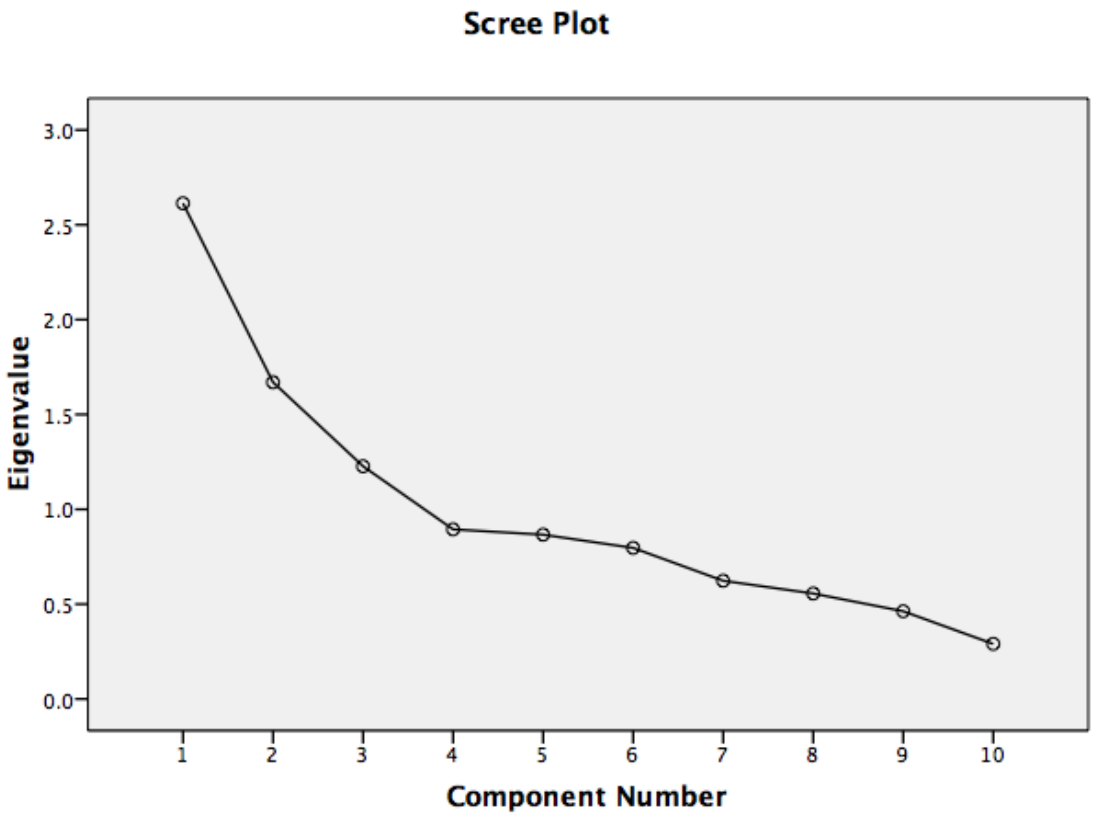


Figure 2 – FOCQ Behaviour Subscale Scree Plot

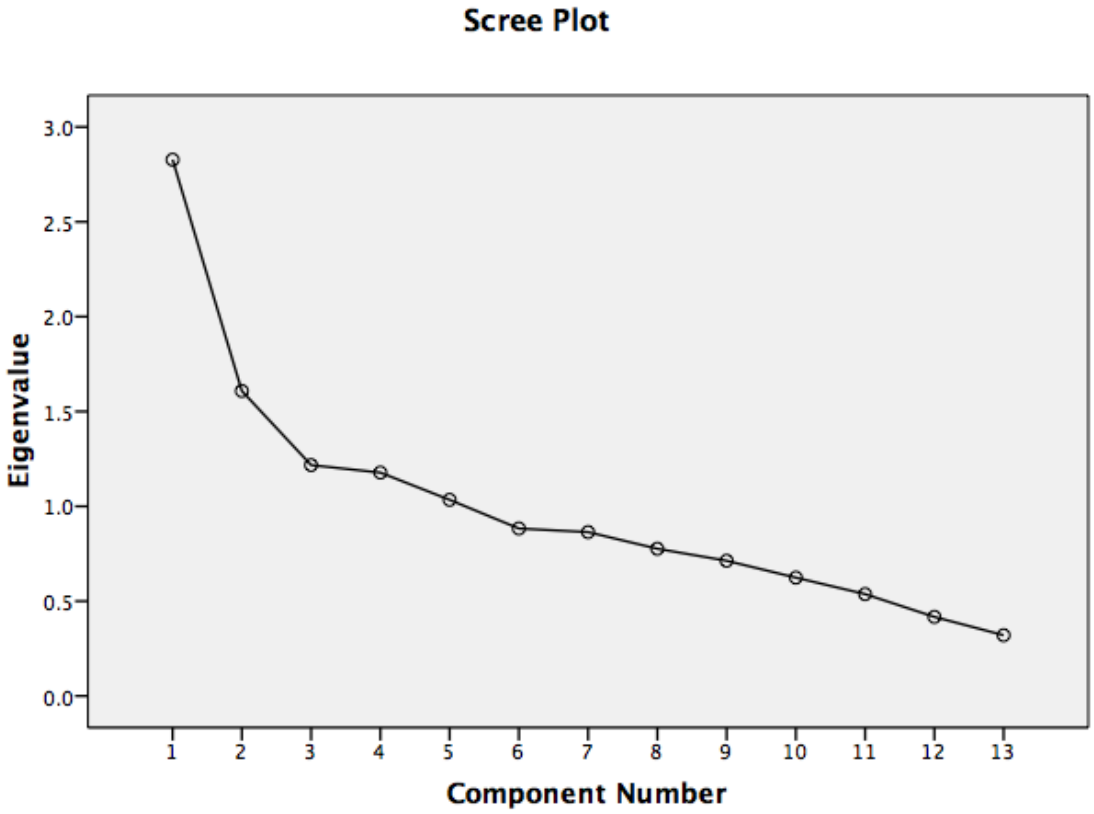
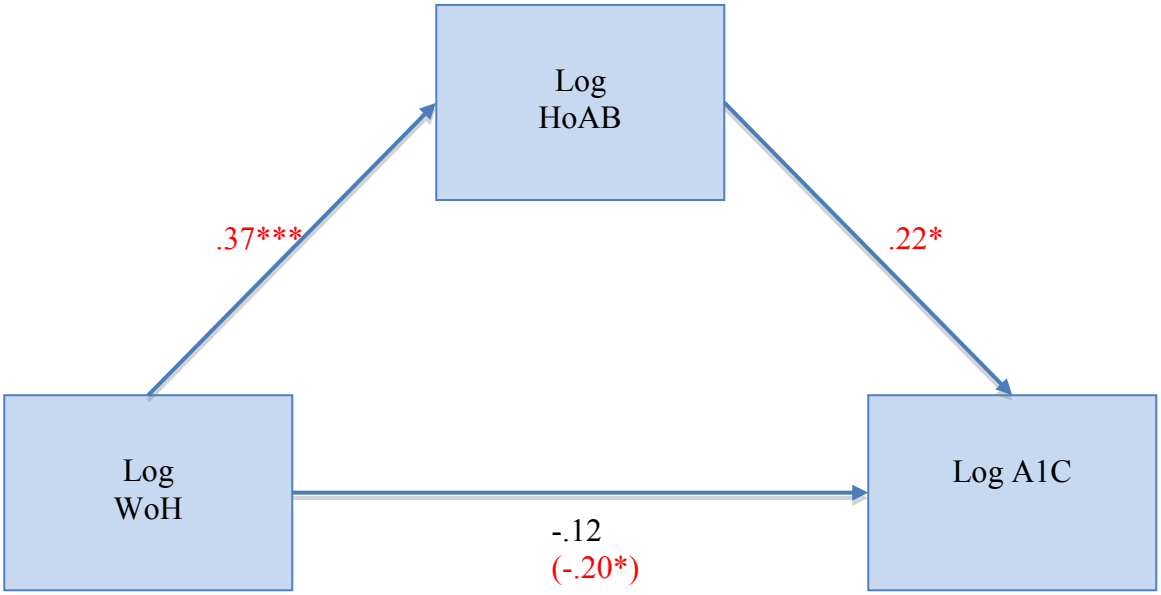
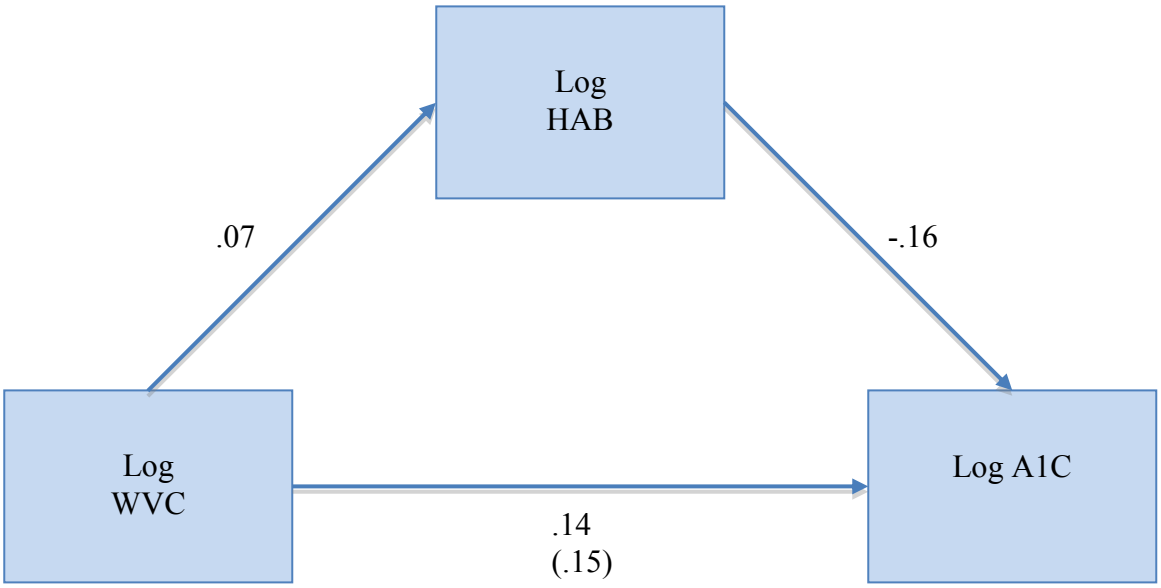


Figure 3 - Hypoglycemia Avoidance Behaviour Mediating the Relationship Between Worry of Hypoglycemia and A1C



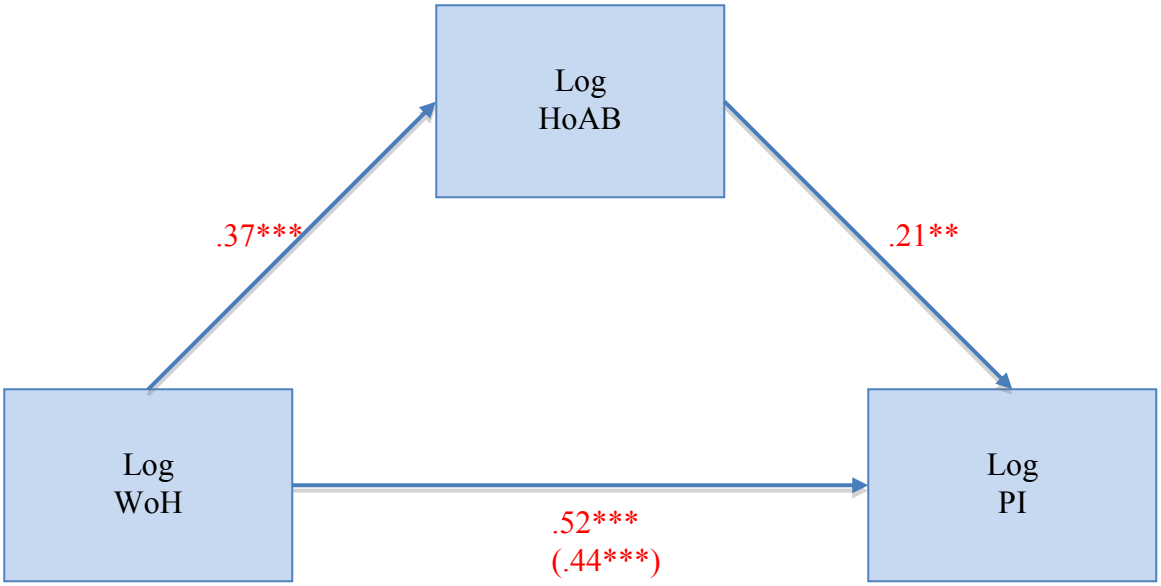
Note: WoH = Worry of Hypoglycemia; HoAB = Hypoglycemia Avoidance Behaviour; * p < .05; ** P < .01, ***p < .001; Multiple regression models are adjusted for age, education, and mean household income. Coefficients are standardized Beta weights.

Figure 4 - Hyperglycemia Avoidance Behaviour Mediating the Relationship Between Worry of Vascular Complications and A1C



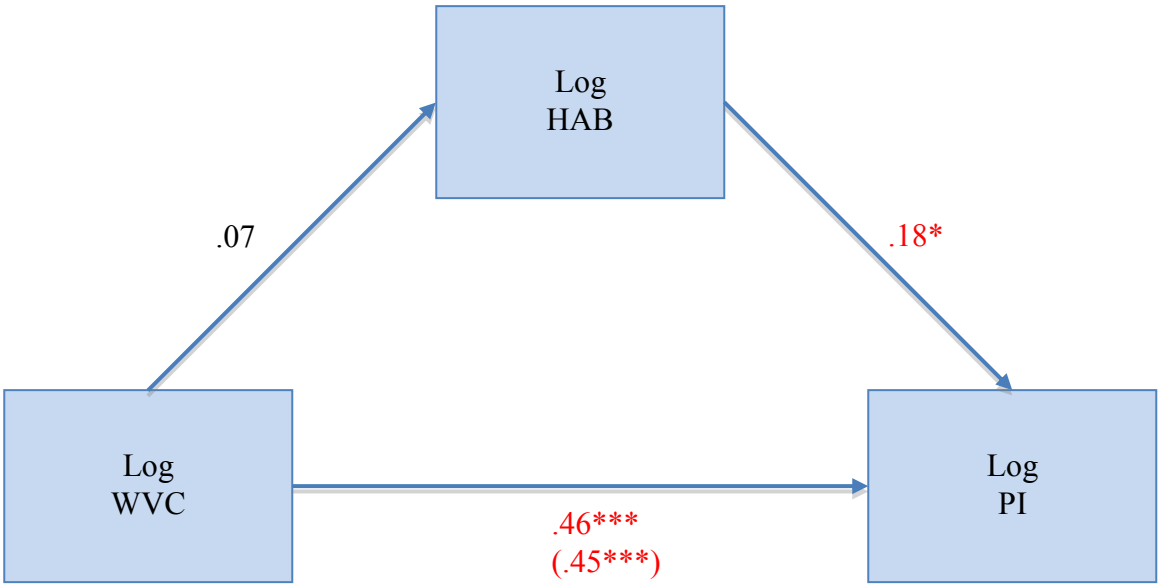
Note: WVC = Worry of Vascular Complications; HAB = Hyperglycemia Avoidance Behaviour with Diet and Exercise; * p < .05; ** p < .01; *** p < .001; Multiple regression models are adjusted for age, education, and mean household income. Coefficients are standardized Beta weights.

Figure 5 - Hypoglycemia Avoidance Behaviour Mediating the Relationship Between Worry of Hypoglycemia and Perceived Impact



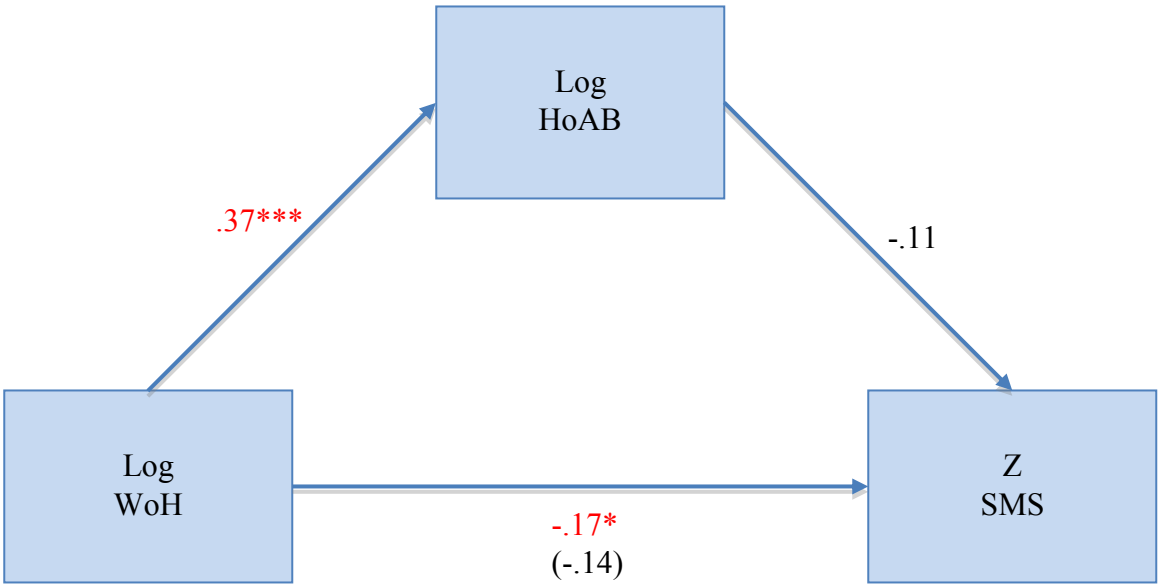
Note: WoH = Worry of Hypoglycemia; HoAB = Hypoglycemia Avoidance Behaviour; PI = Perceived Impact; * p < .05; ** p < .01; ***p < .001; Multiple regression models are adjusted for age, education, mean household income, 12-month Frequency of Severe Hypoglycemia, Presence of Vascular Complications. Coefficients are standardized Beta weights.

Figure 6 - Hyperglycemia Avoidance Behaviour Mediating the Relationship Between Worry of Vascular Complications and Perceived Impact



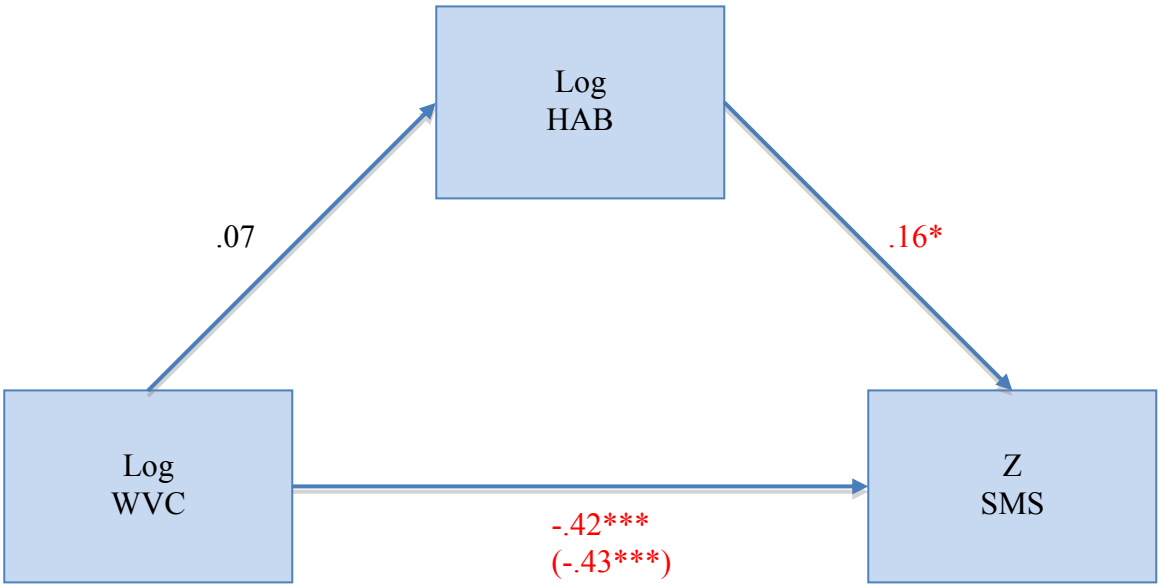
Note: WVC = Worry of Vascular Complications; HAB = Hyperglycemia Avoidance Behaviour with Diet and Exercise; PI = Perceived Impact; * p < .05; ** p < .01; ***p < .001; Multiple regression models are adjusted for age, education, mean household income, 12-month Frequency of Severe Hypoglycemia, Presence of Vascular Complications. Coefficients are standardized Beta weights.

Figure 7 - Hypoglycemia Avoidance Behaviour Mediating the Relationship Between Worry of Hypoglycemia and Self-Management Satisfaction



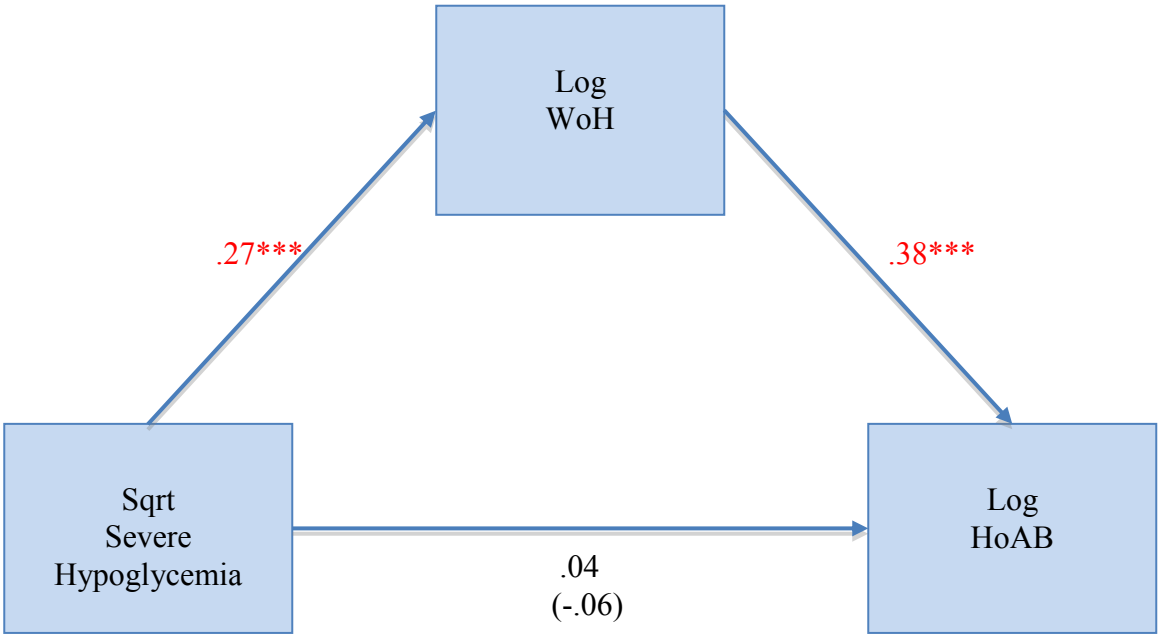
Note: WoH = Worry of Hypoglycemia; HoAB = Hypoglycemia Avoidance Behaviour; SMS = Self Management Satisfaction; * p < .05; ** p < .01; ***p < .001; Multiple regression models are adjusted for age, education, mean household income, 12-month Frequency of Severe Hypoglycemia, Presence of Vascular Complications. Coefficients are standardized Beta weights.

Figure 8 - Hyperglycemia Avoidance Behaviour Mediating the Relationship Between Worry of Vascular Complications and Self-Management Satisfaction



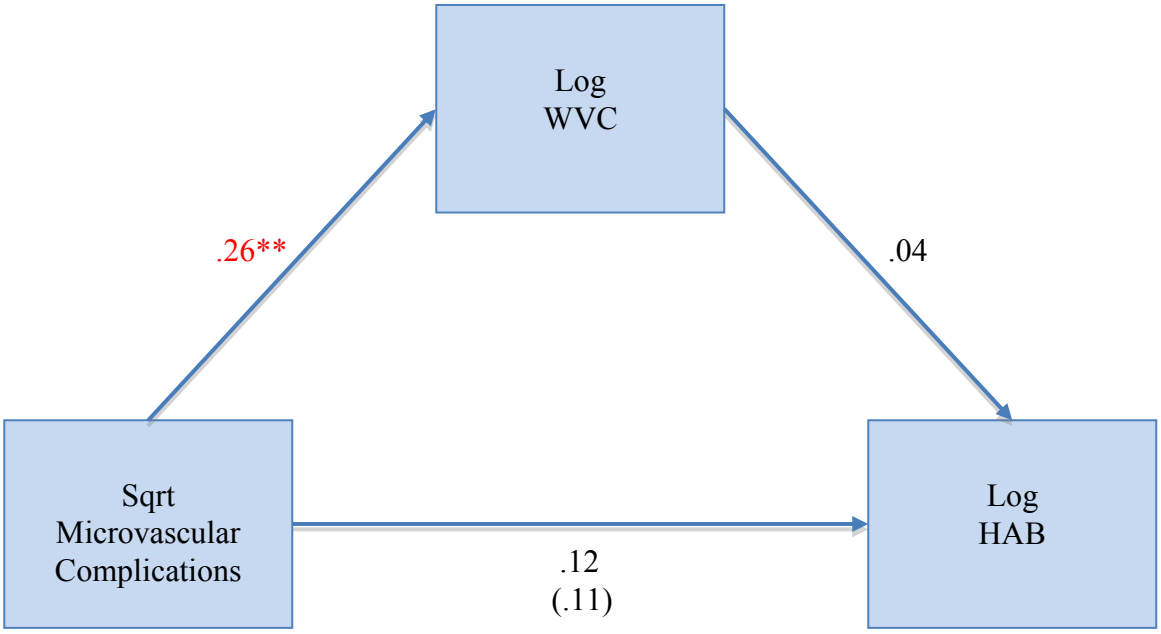
Note: WVC = Worry of Vascular Complications; HAB = Hyperglycemia Avoidance Behaviour with Diet and Exercise; SMS = Self-Management Satisfaction; * p < .05; ** p < .01; *** p < .001; Multiple regression models are adjusted for age, education, mean household income, 12-month Frequency of Severe Hypoglycemia, Presence of Vascular Complications. Coefficients are standardized Beta weights.

Figure 9 –Worry of Hypoglycemia Mediating the Relationship Between Severe Hypoglycemia and Hypoglycemia Avoidance Behaviour



Note: Severe Hypoglycemia = 12-month Frequency of Severe Hypoglycemia; WoH = Worry of Hypoglycemia; HoAB = Hypoglycemia Avoidance Behaviour; * p < .05; ** p < .01; ***p < .001; Multiple regression models are adjusted for age, education, and mean household income. Coefficients are standardized Beta weights.

Figure 10 - Worry of Vascular Complications Mediating the Relationship Between Presence of Vascular Complications and Hyperglycemia Avoidance Behaviour



Note: Microvascular Complications = Self-Reported Presence of Microvascular Complications; WVC = Worry of Vascular Complications; HAB = Hyperglycemia Avoidance Behaviour with Diet and Exercise; * p < .05; ** p < .01; *** p < .001; Multiple regression models are adjusted for age, education, and mean household income. Coefficients are standardized Beta weights.

Appendix B: Tables

Table 1 – Demographic Characteristics of Sample

		M	*SD* / %
Age (years)		39.4	13.7
Gender	Male		36 %
	Female		64 %
Ethnicity	Caucasian		90.0 %
	African American		2.0 %
	Asian		2.0 %
	Hispanic		1.0 %
	Other		5.0 %
Relationship Status	Single		27.3 %
	Dating/Partnered		19.5 %
	Married		46.8 %
	Separated/Divorced		6.5 %
Education	High School (some or completed)		14.9 %
	College/University (some)		18.8 %
	College/University (completed)		44.2 %
	Graduate Studies (some or completed)		22.1 %
Employment Status	Currently Unemployed		10.4 %
	Employed Part-Time		5.8 %
	Employed Full-Time		50.6 %
	Student		11.0 %
	Other		21.4 %
Household Income		$45,353	$22,845

Table 2 – Diabetes-Related Medical Characteristics

		M	*SD / n*
A1C		7.6%	1.13
Duration Since Diagnosis (Yrs)		18.6	12.3
Episodes of Severe Hypoglycemia (Past 12 months)		1.43	1.41
Lifetime Episodes of DKA		.58	.89
Vascular Complications	Retinopathy		15
	Nephropathy		5
	Neuropathy		32
	Coronary Artery Disease		0
	Cerebral Vascular Disease		0
	Peripheral Arterial Disease		0

Table 3 – Shapiro-Wilk Tests of Normality

Variable	Shapiro-Wilk Statistic	*p*
WoH	.93	.00
HoAB	.95	.00
HoCB	.98	.04
HSAB	.93	.00
WVC	.97	.02
HAB	.95	.00
HC/RB	.94	.00
CV/RBA	.98	.04
Impact	.94	.00
Satisfaction	.99	.63
A1C	.95	.00
Hypoglycemic Episodes	.81	.00
Complications	.57	.00

Note: WoH = Worry of Hypoglycemia; HoAB = Hypoglycemia Avoidance Behavior; HoCB = Hypoglycemia Compensatory Behavior; HSAB = Hypoglycemia Subtle Avoidance Behavior; WVC = Worry of Vascular Complications; HAB = Hyperglycemia Avoidance Behaviour with Diet and Exercise; HC/RB = Hyperglycemia Compensatory/Reassurance Behavior; CV/RBA = Complication Vigilance/Risk Behaviour Avoidance; Impact = Perceived Impact; Satisfaction = Self-Management Satisfaction; Hypoglycemic Episodes = 12-month Frequency of Severe Hypoglycemia; Complications = Number of Vascular Complications

Table 4 – HFS Behaviour 3-Factor Solution and Communalities

Item	F1	F2	F3	h^2
(4) I keep my sugar higher when I will be alone for a while.	.840*	.060	-.099	.719
(7) I keep my blood sugar higher when I plan to be in a long meeting or at a party	.807*	.227	.110	.716
(3) If test urine, I spill a little sugar to be on the safe side. If I test blood glucose, I run a little high to be on the safe side	.752*	-.086	.124	.589
(1) I eat large snacks at bedtime	.436*	.131	-.381	.352
(5) I eat something as soon as I feel the first sign of low blood sugar	-.216	.648*	.037	.467
(9) I avoid a lot of exercise when I think my sugar is low	.026	.627*	.408	.560
(6) I reduce my insulin when I think my sugar is too low	.272	.619*	-.093	.466
(2) I avoid being alone when my sugar is likely to be low	.332	.519*	-.115	.393
(8) I carry fast-acting sugar with me	-.018	-.153	.787*	.643
(10) I check my sugar often when I plan to be in a long meeting or go out to a party	.125	.311	.701*	.604

Note: *Salient factor loading ($\geq$ .40); F1 = Hypoglycemia Avoidance Behaviours; F2 = Hypoglycemia Compensatory Behaviours; F3 = Hypoglycemia Subtle Avoidance Behaviours

Table 5 – FOCQ Behaviour 3-Factor Solution and Communalities

Item	F1	F2	F3	h^2
(21) I check the feeling/sensation in my hands and feet	.778*	.206	.014	.648
(28) I check my feet for blisters, sores, or redness	.757*	.170	-.160	.627
(23) I check for changes in my eye sight	.712*	.107	.193	.555
(22) I check my blood pressure	.605*	-.152	.219	.437
(26) I avoid drinking alcohol that would increase my blood sugar	.460*	.197	-.130	.267
(27) I avoid eating carbohydrates to prevent high blood sugars	-.084	.738*	.110	.564
(16) I avoid eating high calorie foods to prevent high blood sugars	.245	.691*	-.018	.537
(25) I avoid eating out in restaurants to ensure that food is diabetic-friendly	.105	.564*	.007	.329
(17) I exercise when I think that my blood sugar is too high	.228	.519*	.001	.321
(24) I skip a meal if my blood sugar is too high	-.094	.331	.700*	.608
(18) I take more insulin than usual if my blood sugar is too high	.091	-.086	.535*	.302
(20) I ask to meet with my diabetes doctor more frequently than I need to	.138	-.178	.437*	.242
(19) I purposely keep my blood sugar lower when I am around people that could assist me	-.106	.188	.411*	.215

Note: *Salient factor loading (≥ .40); F1 = Complication Vigilance/Risk Behaviour Avoidance; F2 = Hyperglycemia Avoidance Behaviour with Diet and Exercise; F3 = Hyperglycemia Compensatory/Reassurance Behaviour

Table 6 – Correlations Between Diabetes-Related Worry and Worry Behaviours

	WoH	Hypoglycemia Avoidance Behaviour	Hypoglycemia Compensatory Behaviour	Hypoglycemia Subtle Avoidance Behaviour	WVC	Hyperglycemia Avoidance Behaviour with Diet/Exercise	Hyperglycemia Compensatory/ Reassurance Behaviour	Complication Vigilance/ Risk Behaviour Avoidance	A1C
WoH	1.00								
Hypoglycemia Avoidance Behaviour	.34***	1.00							
Hypoglycemia Compensatory Behaviour	.21**	.34***	1.00						
Hypoglycemia Subtle Avoidance Behaviour	.12	.05	.18*	1.00					
WVC	.33***	.21*	.04	.07	1.00				
Hyperglycemia Avoidance Behaviour with Diet/Exercise	.12	-.05	.05	.26**	.09	1.00			
Hyperglycemia Compensatory/ Reassurance Behaviour	.15	.19*	.28**	.28***	.07	.11	1.00		
Complication Vigilance/Risk Behaviour Avoidance	.08	-.05	.09	.34***	.30**	.34***	.08	1.00	
A1C	-.10	.14	-.16	-.14	.16	-.16	-.09	-.04	1.00

Note: * p < .05; ** p < .01; ***p < .01; WoH = Worry of Hypoglycemia; WVC = Worry of Vascular Complications; All variables are logarithmically transformed.

Table 7 –Hypoglycemia Avoidance Behaviour Mediating the Relationship Between Worry of Hypoglycemia and A1C

		Variable	*ß*	*p*	*F*	ΔR^2	Significance of ΔR^2
Model 1 – DV = logA1C							
	Step 1				1.95	.05	.13
		Sex	.18	.05			
		Age	-.13	.14			
		Income	.04	.63			
	Step 2				1.90	.02	.12
		logWoH	-.12	.19			
Model 2 – DV = logHoAB							
	Step 1				.91	.02	.44
		Sex	.05	.57			
		Age	-.13	.13			
		Income	-.02	.82			
	Step 2				6.20	.13	.000
		logWoH	.37	.00			
Model 3 – DV = logA1C							
	Step 1				1.95	.05	.13
		Sex	.18	.05			
		Age	-.13	.14			
		Income	.04	.63			
	Step 2				2.62	.05	.03
		logHoAB	.22	.04			
		logWoH	-.20	.02			

Note: WoH = log Worry of Hypoglycemia; HoAB = log Hypoglycemia Avoidance Behaviour.

Table 8 –Hyperglycemia Avoidance Behaviour Mediating the Relationship Between Worry of Vascular Complications and A1C

		Variable	*ß*	*p*	*F*	ΔR^2	Significance of ΔR^2
Model 1 – DV = logA1C							
	Step 1				1.98	.05	.12
		Sex	.18	.05			
		Age	-.13	.14			
		Income	.04	.60			
	Step 2				2.15	.02	.11
		logWVC	.14	.11			
Model 2 – DV = logHAB							
	Step 1				5.15	.10	.003
		Sex	-.07	.36			
		Age	.29	.001			
		Income	.08	.31			
	Step 2				4.01	.004	.43
		logWVC	.07	.43			
Model 3 – DV = logA1C							
	Step 1				1.98	.05	.12
		Sex	.18	.05			
		Age	-.13	.14			
		Income	.04	.60			
	Step 2				2.33	.04	.07
		logHAB	-.16	.09			
		logWVC	.15	.09			

Note: WVC = log Worry of Vascular Complications; HAB = log Hyperglycemia Avoidance Behaviour with Diet and Exercise.

Table 9 –Hypoglycemia Avoidance Behaviour Mediating the Relationship Between Worry of Hypoglycemia and Perceived Impact

		Variable	*ß*	*p*	*F*	ΔR^2	Significance of ΔR^2
Model 1 – DV = logPI							
	Step 1				.84	.02	.48
		Sex	.05	.60			
		Age	-.13	.13			
		Income	.02	.82			
	Step 2				1.57	.04	.08
		SqrtComplications	.12	.20			
		SqrtHypoglycemia	.15	.09			
	Step 3				8.95	.23	.000
		logWoH	.52	.00			
Model 2 – DV = logHoAB							
	Step 1				.91	.02	.44
		Sex	.05	.60			
		Age	-.13	.13			
		Income	-.02	.82			
	Step 2				6.20	.13	.000
		logWoH	.37	.00			
Model 3 – DV = logPI							
	Step 1				.84	.02	.48
		Sex	.05	.60			
		Age	-.13	.13			
		Income	.02	.82			
	Step 2				1.57	.04	.08
		SqrtComplications	.12	.20			
		SqrtHypoglycemia	.15	.09			
	Step 3				9.09	.27	.000
		logWoH	.44	.00			
		logHoAB	.21	.01			

Note: WoH = log Worry of Hypoglycemia; HoAB = log Hypoglycemia Avoidance Behaviour; PI = log Perceived Impact; Complications = Sqrt Number of Vascular Complications; Hypoglycemia = Sqrt 12-month Frequency of Severe Hypoglycemia.

Table 10 –Hyperglycemia Avoidance Behaviour Mediating the Relationship Between Worry of Vascular Complications and Perceived Impact

		Variable	*ß*	*p*	*F*	ΔR^2	Significance of ΔR^2
Model 1 – DV = logPI							
	Step 1				.85	.02	.47
		Sex	.05	.60			
		Age	-.13	.13			
		Income	.02	.82			
	Step 2				1.58	.04	.08
		SqrtComplications	.12	.20			
		SqrtHypoglycemia	.15	.09			
	Step 3				7.01	.18	.000
		logWVC	.46	.00			
Model 2 – DV = logHAB	Step 1				5.15	.10	.10
		Sex	-.07	.36			
		Age	.29	.001			
		Income	.08	.31			
	Step 2				4.01	.10	.43
		logWVC	.07	.43			
Model 3 – DV = logPI							
	Step 1				.85	.02	.47
		Sex	.05	.60			
		Age	-.13	.13			
		Income	.02	.82			
	Step 2				1.58	.04	.08
		SqrtComplications	.12	.20			
		SqrtHypoglycemia	.15	.09			
	Step 3				6.97	.21	.000
		logWVC	.45	.00			
		logHAB	.18	.02			

Note: WVC = log Worry of Vascular Complications; HAB = log Hyperglycemia Avoidance Behaviour with Diet and Exercise; PI = log Perceived Impact; Complications = Sqrt Number of Vascular Complications; Hypoglycemia = Sqrt 12-Month Frequency of Severe Hypoglycemia.

Table 11 –Hypoglycemia Avoidance Behaviour Mediating the Relationship Between Worry of Hypoglycemia and Self-Management Satisfaction

		Variable	*ß*	*p*	*F*	ΔR^2	Significance of ΔR^2
Model 1 – DV = zSMS							
	Step 1				1.70	.04	.17
		Sex	-.06	.48			
		Age	.12	.17			
		Income	.12	.15			
	Step 2				2.58	.05	.03
		SqrtComplications	-.25	.01			
		SqrtHypoglycemia	-.01	.92			
	Step 3				2.85	.03	.05
		logWoH	-.17	.05			
Model 2 – DV = logHoAB							
	Step 1				.91	.02	.44
		Sex	.05	.60			
		Age	-.13	.13			
		Income	-.02	.82			
	Step 2				6.20	.13	.000
		logWoH	.37	.00			
Model 3 – DV = zSMS							
	Step 1				1.70	.04	.17
		Sex	-.06	.48			
		Age	.12	.17			
		Income	.12	.15			
	Step 2				2.58	.05	.03
		SqrtComplications	-.25	.01			
		SqrtHypoglycemia	-.01	.92			
	Step 3				2.65	.04	.07
		logWoH	-.14	.15			
		logHoAB	-.11	.24			

Note: WoH = log Worry of Hypoglycemia; HoAB = log Hypoglycemia Avoidance Behaviour; SMS = z-Self-Management Satisfaction; Complications = Sqrt Number of Vascular Complications; Hypoglycemia = Sqrt 12-month Frequency of Severe Hypoglycemia.

Table 12 –Hyperglycemia Avoidance Behaviour Mediating the Relationship Between Worry of Vascular Complications and Self-Management Satisfaction

		Variable	*ß*	*p*	*F*	ΔR^2	Significance of ΔR^2
Model 1 – DV = zSMS							
	Step 1				1.72	.17	.04
		Sex	-.06	.48			
		Age	.12	.17			
		Income	.12	.15			
	Step 2				2.60	.09	.03
		SqrtComplications	-.25	.01			
		SqrtHypoglycemia	-.01	.92			
	Step 3				7.26	.25	.000
		logWVC	-.42	.00			
Model 2 – DV = logHAB							
	Step 1				5.15	.10	.002
		Sex	-.07	.36			
		Age	.29	.001			
		Income	.08	.31			
	Step 2				4.01	.004	.43
		logWVC	.07	.43			
Model 3 – DV = zSMS							
	Step 1				1.72	.17	.04
		Sex	-.06	.48			
		Age	.12	.17			
		Income	.12	.15			
	Step 2				2.60	.09	.03
		SqrtComplications	-.25	.01			
		SqrtHypoglycemia	-.01	.92			
	Step 3				6.97	.27	.000
		logWVC	-.43	.00			
		logHAB	.16	.04			

Note: WVC = log Worry of Vascular Complications; HAB = log Hyperglycemia Avoidance Behaviour with Diet and Exercise; SMS = z-Self-Management Satisfaction; Complications = Sqrt Number of Vascular Complications; Hypoglycemia = Sqrt 12-month Frequency of Severe Hypoglycemia.

Table 13 –Worry of Hypoglycemia Mediating the Relationship Between Severe Hypoglycemia and Hypoglycemia Avoidance Behaviour

		Variable	*ß*	*p*	*F*	ΔR^2	Significance of ΔR^2
Model 1 – DV = logHoAB							
	Step 1				.96	.02	.42
		Sex	.06	.51			
		Age	-.13	.13			
		Income	-.02	.78			
	Step 2				.77	.002	.63
		SqrtHypoglycemia	.04	.63			
Model 2 – DV = logWoH							
	Step 1				1.83	.04	.14
		Sex	.14	.09			
		Age	.09	.29			
		Income	.07	.40			
	Step 2				4.11	.07	.001
		SqrtHypoglycemia	.27	.00			
Model 3 – DV = logHoAB							
	Step 1				.96	.02	.42
		Sex	.06	.51			
		Age	-.13	.13			
		Income	-.02	.78			
	Step 2				4.71	.13	.000
		SqrtHypoglycemia	-.06	.48			
		logWoH	.38	.00			

Note: WoH = log Worry of Hypoglycemia; HoAB = log Hypoglycemia Avoidance Behaviour; Hypoglycemia = Sqrt 12-Month Frequency of Severe Hypoglycemia.

Table 14 –Worry of Vascular Complications Mediating the Relationship between Vascular Complications and Hyperglycemia Avoidance Behaviour

		Variable	*ß*	*p*	*F*	ΔR^2	Significance of ΔR^2
Model 1 – DV = logHAB							
	Step 1				5.06	.10	.002
		Sex	-.06	.43			
		Age	.28	.00			
		Income	.09	.28			
	Step 2				4.25	.01	.19
		SqrtComplications	.12	.19			
Model 2 – DV = logWVC							
	Step 1				2.73	.06	.46
		Sex	.22	.01			
		Age	.05	.54			
		Income	-.09	.30			
	Step 2				4.24	.11	.005
		SqrtComplications	.26	.00			
Model 3 – DV = logHAB							
	Step 1				5.06	.10	.002
		Sex	-.06	.43			
		Age	.28	.00			
		Income	.09	.28			
	Step 2				3.43	.01	.37
		SqrtComplications	.11	.25			
		logWVC	.04	.61			

Note: WVC = log Worry of Vascular Complications; HAB = log Hyperglycemia Avoidance Behaviour with Diet and Exercise; Complications = Sqrt Number of Vascular Complications.

Table 15 - Correlations between Worry Behaviour and Health Related Quality of Life Constructs

	Impact	Satisfaction	Hypoglycemia Avoidance Behaviour	Hypoglycemia Compensatory Behaviour	Hypoglycemia Subtle Avoidance Behaviour	Hyperglycemia Avoidance Behaviour with Diet/Exercise	Hyperglycemia Compensatory/ Reassurance Behaviour	Complication Vigilance/ Risk Behaviour Avoidance
Impact	1.00							
Satisfaction	-.53**	1.00						
Hypoglycemia Avoidance Behaviour	.38**	-.21**	1.00					
Hypoglycemia Compensatory Behaviour	.16	.10	.34**	1.00				
Hypoglycemia Subtle Avoidance Behaviour	.12	.22**	.05	.18*	1.00			
Hyperglycemia Avoidance Behaviour with Diet/Exercise	.19*	.13	-.05	.05	.26**	1.00		
Hyperglycemia Compensatory/ Reassurance Behaviour	.26**	.00	.19*	.28**	.28**	.11	1.00	
Complication Vigilance/ Risk Behaviour Avoidance	.03	.00	-.05	.10	.34**	.34**	.10	1.00

Note: * p < .05, ** p < .01; Impact = log Perceived Impact; Satisfaction = z-Self-Management Satisfaction. All remaining variables were logarithmically transformed.

Appendix C: Measures

Hypoglycemia Fear Survey

This survey is intended to find out more about how low blood sugar makes people feel and behave. Please answer the following questions as frankly as possible. Below is a list of things people with diabetes sometimes do in order to avoid low blood sugar. Read each item carefully. Circle one of the numbers to the right that best describes what you do during your daily routine to avoid low blood sugar.

		Never 1	Rarely 2	Sometimes 3	Often 4	Very Often 5
1.	Eat large snacks at bedtime	1	2	3	4	5
2.	Avoid being alone when my sugar is likely to be low	1	2	3	4	5
3.	If test urine, spill a little sugar to be on the safe side. If test blood glucose, run a little high to be on the safe side	1	2	3	4	5
4.	Keep my sugar higher when I will be alone for a while	1	2	3	4	5
5.	Eat something as soon as I feel the first sign of low blood sugar	1	2	3	4	5
6.	Reduce my medication (insulin/pills) when I think my sugar is too low	1	2	3	4	5
7.	Keep my blood sugar higher when I plan to be in a long meeting or at a party	1	2	3	4	5
8.	Carry fast-acting sugar with me	1	2	3	4	5
9.	Avoid a lot of exercise when I think my sugar is low	1	2	3	4	5
10.	Check my sugar often when I plan to be in a long meeting or go out to a party	1	2	3	4	5

Below is a list of concerns people with diabetes sometimes have. Please read each item carefully (please do not skip any). Circle one of the numbers to the right that best describes how often you worry about each item because of low blood sugar.

		Never 1	Rarely 2	Sometimes 3	Often 4	Very Often 5
11.	Not recognizing/realizing I am having a reaction	1	2	3	4	5
12.	Not having food, fruit, or juice with me	1	2	3	4	5
13.	Feeling dizzy or passing out in public	1	2	3	4	5
14.	Having a reaction while asleep	1	2	3	4	5
15.	Embarrassing myself or my friends/family in a social situation	1	2	3	4	5
16.	Having a reaction while alone	1	2	3	4	5
17.	Appearing stupid or drunk	1	2	3	4	5
18.	Losing control	1	2	3	4	5
19.	No one being around to help me during a reaction	1	2	3	4	5
20.	Having a reaction while driving	1	2	3	4	5
21.	Making a mistake or having an accident at work	1	2	3	4	5
22.	Getting a bad evaluation at work because of something that happens when my sugar is low	1	2	3	4	5
23.	Having seizures or convulsions	1	2	3	4	5
24.	Difficulty thinking clearly when responsible for others (children, elderly, etc.)	1	2	3	4	5
25.	Developing long-term complications from frequent low blood sugar	1	2	3	4	5
26.	Feeling lightheaded or faint	1	2	3	4	5
27.	Having an insulin reaction	1	2	3	4	5

Fear of Complications Questionnaire - Worry

This questionnaire is designed to help us understand how you feel about your diabetes and how it affects you, particularly in the long-term. Please answer the following questions as honestly as possible.

1.	I feel afraid of long-term complications of Diabetes	Very	Moderately	A little	Not at all
2.	I worry about losing my eyesight because of Diabetes	All the time	Frequently	Occasionally	Never
3.	I worry that having Diabetes increases my chances of heart disease	All the time	Frequently	Occasionally	Never
4.	I am afraid I will need a kidney transplant one day	Very	Moderately	A little	Not at all
5.	I am afraid of developing long-term complications as a result of frequent high blood sugars	All the time	Frequently	Occasionally	Never
6.	I am afraid that I may need kidney dialysis one day	Never	Occasionally	Frequently	All the time
7.	I am afraid that I will develop kidney problems on day	All the time	Frequently	Occasionally	Never
8.	How often do you think about long-term complications of Diabetes?	Never	Occasionally	Frequently	All the time
9.	I worry that I might be at a higher risk for having a stroke	All the time	Frequently	Occasionally	Never
10.	Do you ever worry about your future health?	Not at all	Occasionally	Frequently	All the time
11.	I worry that the Diabetes Specialist will find something wrong with my eyes	Not at all	Occasionally	Frequently	All the time
12.	Do you worry about future problems when your blood sugars are erratic?	Not at all	Occasionally	Frequently	All the time
13.	I am scared that Diabetes could affect my feet	Very	Moderately	A little	Not at all
14.	I am scared of having a heart attack in the future	Not at all	A little	Moderately	Very
15.	I worry about developing problems with circulation	Never	Occasionally	Frequently	All the time

Fear of Complications Questionnaire - Behaviour

These questions are designed to help understand the things that you do to avoid or prevent long-term complications of diabetes from high blood sugars. Please answer the following questions as honestly as possible.

1.	I avoid eating high calorie foods to prevent high blood sugars.	Always	Frequently	Occasionally	Never
2.	I exercise when I think that my blood sugar is too high.	Always	Frequently	Occasionally	Never
3.	I take more insulin than usual if my blood sugar is too high.	Never	Occasionally	Frequently	Always
4.	I purposely keep my blood sugar lower when I am around people that could assist me.	Never	Occasionally	Frequently	Always
5.	I ask to meet with my diabetes doctor more frequently than I need to.	Always	Frequently	Occasionally	Never
6.	I check the feeling/sensation in my hands and feet.	Never	Occasionally	Frequently	Always
7.	I check my blood pressure.	Always	Frequently	Occasionally	Never
8.	I check for changes in my eyesight.	Never	Occasionally	Frequently	Always
9.	I skip a meal if my blood sugar is too high.	Always	Frequently	Occasionally	Never
10.	I avoid eating out (e.g., restaurants) to ensure that food is diabetic-friendly.	Always	Frequently	Occasionally	Never
11.	I avoid drinking alcohol that would increase my blood sugar.	Never	Occasionally	Frequently	Always
12.	I avoid eating carbohydrates to prevent high blood sugars.	Always	Frequently	Occasionally	Never
13.	I check my feet for blisters, sores, or redness.	Never	Occasionally	Frequently	Always

Diabetes Quality of Life

The following questionnaire asks about how your diabetes has affected many different areas of your life. Please answer these questions as honestly as possible.

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

14.	How satisfied are you with your leisure time?	1	2	3	4	5
15.	How satisfied are you with life in general?	1	2	3	4	5
		No Impact or Never Worried				Always Impacted or Always Worried
	Impact	1	2	3	4	5
16.	How often do you feel pain associated with the treatment for your diabetes?	1	2	3	4	5
17.	How often are you embarrassed by having to deal with your diabetes in public?	1	2	3	4	5
18.	How often do you have low blood sugar?	1	2	3	4	5
19.	How often do you feel physically ill?	1	2	3	4	5
20.	How often does your diabetes interfere with your family life?	1	2	3	4	5
21.	How often do you have a bad night's sleep?	1	2	3	4	5
22.	How often do you find your diabetes limiting your social relationships and friendships?	1	2	3	4	5
23.	How often do you feel good about yourself?	1	2	3	4	5
24.	How often do you feel restricted by your diet?	1	2	3	4	5
25.	How often does your diabetes interfere with your sex life?	1	2	3	4	5
26.	How often does your diabetes keep you from driving a car or using other machines?	1	2	3	4	5
27.	How often does your diabetes interfere with your exercising?	1	2	3	4	5

28.	How often do you miss work, school, or household duties because of your diabetes?	1	2	3	4	5
29.	How often do you find yourself explaining what it means to have diabetes?	1	2	3	4	5
30.	How often do you find that your diabetes interrupts your leisure-time activities?	1	2	3	4	5
31.	How often do you tell others about your diabetes?	1	2	3	4	5
32.	How often are you teased because you have diabetes?	1	2	3	4	5
33.	How often do you feel that because of your diabetes you go to the bathroom more than others?	1	2	3	4	5
34.	How often do you find that you eat something you shouldn't rather than tell someone that you have diabetes?	1	2	3	4	5
35.	How often do you hide from others the fact that you are having an insulin reaction?	1	2	3	4	5