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By

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ABSTRACT

The present investigation comprised exploratory prospective and retrospective studies of the relationships between cognitive functioning, Diabetes Self-Management Behaviour (DSMB) completion, and diabetes-related and general Quality of Life (QoL). A prospective study explored the relationships among these variables in a sample of 26 adults over the age of 40 with Type 2 Diabetes Mellitus (T2DM). Measures used included validated neuropsychological tests assessing multiple cognitive domains and abilities, three self-report measures of DSMB, and the Audit of Diabetes Dependent Quality of Life (ADDQoL). Increased performance on a phonemic verbal fluency task was significantly related to better DSMB behaviour completion ($r = .577$, $p = .002$, $r^2 = .333$). There were many significant relationships between a self-report measure of executive functioning and DSMB completion. Processing speed and objective and self-report measures of executive functioning correlated significantly with general QoL. An archival study investigated these relationships using data from the Health and Retirement Study (HRS). The Telephone Interview for Cognitive Status (TICS) assessed cognitive functioning, and measures of DSMB completion and impact of diabetes on life from the 2003 HRS diabetes survey were used to assess DSMB completion and QoL outcome variables in a sample of 776 community dwelling adults with T2DM. Cognitive functioning as measured by the TICS did not account for significantly more variance and did not significantly predict DSMB completion over and above demographic and health-related variables for any of the domains of DSMB completion. Cognitive functioning and a total score of difficulty with DSMB completion accounted for significantly more variance in diabetes impact over and above demographic and health-related variables when A1C was ($F(2, 503) = 9.846$, $p < .001$) and was not ($F(2, 700) = 13.282$, $p < .001$) included in the model. However, cognitive functioning was not a significant predictor of diabetes impact in either model. Difficulty with DSMB completion was a significant predictor in both models and thus accounted for most of the increase in variance explained above and beyond that explained by the demographic and health-related variables. The implications of the results for future studies of the relationships between cognitive functioning, DSMB completion, and QoL are discussed, as well as the strengths and limitations of the prospective and archival studies.

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LIST OF ABBREVIATIONS

Alzheimer's Disease (AD)
Audit of Diabetes Dependent Quality of Life (ADDQoL)
Behavioral Rating Inventory of Executive Functions – Adult Version (BRIEF-A)
Body Mass Index (BMI)
Calibrated Neuropsychological Normative System (CNNS)
Charlson Comorbidity Index (CCI)
Colour Word (CW)
Delis-Kaplan Executive Function System (D-KEFS)
Depression Anxiety Stress Scale – Short-form (DASS-21)
Diabetes Self-Management Behaviour (DSMB)
Diabetes Self-Management Questionnaire (DSMQ)
Diabetes-Related Quality of Life (DRQoL)
Executive Interview 25 (EXIT25)
Frontal Assessment Battery (FAB)
General Quality of Life (GQoL)
Geriatric Depression Scale - Short-Form (GDS-SF)
Health and Retirement Study (HRS)
Hopkins Adult Reading Test–A (HART–A)
Major Depressive Disorder (MDD)
Mild Cognitive Impairment (MCI)
Mini-Mental State Exam (MMSE)
Montreal Cognitive Assessment (MoCA)
Multiple Regression Analysis (MRA)
Quality of Life (QoL)
Rapid Estimate of Adult Literacy in Medicine – Short Form (REALM-SF)
Repeatable Battery of the Assessment of Neuropsychological Status (RBANS)
Rey Auditory Verbal Learning test (RAVLT)
Self-Care Inventory – Revised (SCI-R)
Self-Management Profile for Type 2 Diabetes (SMP-T2D)
Socioeconomic Status (SES)
Statistical Package for the Social Sciences (SPSS)
Summary of Diabetes Self-Care Activities (SDSCA)
Telephone Interview for Cognitive Status (TICS)
Trail Making Test (TMT)
Total Illness Burden Index (TIBI)
Type 1 Diabetes Mellitus (T1DM)
Type 2 Diabetes Mellitus (T2DM)
Vascular Cognitive Impairment (VCI)

CHAPTER I

INTRODUCTION AND REVIEW OF THE LITERATURE

Type 2 Diabetes Mellitus (T2DM) is a chronic disease affecting primarily adults and older adults (Government of Canada, 2011). Given the chronicity of the disease and the daily management required to stave off the complications of the disease, T2DM treatment regimens include a number of Diabetes Self-Management Behaviours (DSMB). These DSMB need to be completed independently by the individual with T2DM while under the supervision of a physician and ideally, but not always, a diabetes treatment team (Bailey & Kodack, 2011). The DSMB include taking medication (pills and/or insulin), blood glucose monitoring, following a healthy diet, maintaining physical activity, executing regular foot care, and attending follow-up appointments. The goal of these behaviours is to achieve good control of the disease as measured by A1C levels (the three month average measure of blood glucose levels) and the postponement or prevention of disease complications (Mulcahy et al., 2003).

Adherence to T2DM treatment regimens is notoriously poor (Ahola & Groop, 2013; Bailey & Kodack, 2011; Gillani, 2012) due to the many barriers to adherence, for instance medication costs, diabetes knowledge and health literacy levels, and mental health (Emery et al., 2010). A new barrier that has emerged in the past decade that has not received the same level of empirical investigation as other barriers is poor cognitive functioning (Primozic et al., 2012). It is now known that, on average, groups of individuals with T2DM have small to moderate deficits in all studied cognitive abilities and domains when they are compared to groups of individuals without T2DM (Monette et al., 2014; Palta et al., 2014; van den Berg et al., 2009).

The first goal of the present investigation was to determine the relationship between cognitive functioning and DSMB completion. The second goal of the current study was to determine the impact of cognitive functioning and DSMB completion on diabetes-related quality of life (QoL). The answers to these questions from the current investigation and from the research literature can be used to improve T2DM management and improve QoL in individuals with T2DM.

The following sections review the previous literature that is most relevant to these two questions. The review of the literature will encompass a brief description of T2DM, a review of the most up to date findings on cognitive functioning in T2DM, definitions and descriptions of adherence and barriers to the completion of DSMB, previous work on the relation between cognitive functioning and DSMB completion and between DSMB completion and QoL, and will conclude with a description of the present study.

Description of T2DM

T2DM is a chronic metabolic disorder characterized by hyperglycemia (elevated blood glucose levels, Codario, 2010). Hyperglycemia results from a gradual process in which the body becomes incapable of absorbing glucose due to body tissues becoming insulin resistant. At first, the body can maintain fasting blood glucose levels in the normal or non-diabetes range (4.0 to 6.0 mmol/l) by producing insulin in excess (hyperinsulinemia). When the pancreatic cells become exhausted and die and can no longer produce insulin in excess, glucose intolerance (pre-diabetes) develops. At this point fasting blood glucose ranges from 6.1 to 7.9 mmol/l. T2DM is diagnosed when fasting blood glucose levels surpass 7.9 mmol/l (Codario, 2010).

The development of T2DM is related to increasing age, poor diet, physical inactivity, and obesity (Pradhan, 2007). There is also evidence for a genetic predisposition towards T2DM (Moore & Florez, 2008). However, a complete understanding of the gene-environment and gene-gene interactions does not yet exist (Herder & Roden, 2011). At least 36 diabetes-associated genes have been identified; yet, only ~10% of the heritability of T2DM can be explained (Herder & Roden, 2011). Prevalence rates of diabetes across ethnicities (gene-environment interaction) vary with some as low as 1% in rural Asian populations and some as high as 30-50% in Pima Indian and Polynesian populations (Moore & Florez, 2008). The child of a parent with diabetes has a 40% chance of developing diabetes compared to a population risk of approximately 7%; if both parents have diabetes the chances increase to 70% (Moore & Florez, 2008).

T2DM is a progressive chronic disease that leads to complications resulting in end organ damage, such as peripheral and central neuropathy often resulting in amputation of the lower limbs due to infection; nephropathy (kidney damage); retinopathy, in which the small blood vessels of the retina become damaged, leading to visual impairment and blindness; and cerebrovascular and cardiovascular disease, including atherosclerosis, heart attack, and stroke (Brands et al., 2007, Emery-Tiburcio et al., 2015). T2DM is often comorbid with obesity, dyslipidemia, and hypertension and it leads to excess disability and early mortality (Palta et al., 2014).

The purpose of the treatment of T2DM is to keep blood glucose levels within the optimal range to prevent or slow down the complications of diabetes through the completion of DSMB. At first, T2DM can be managed with lifestyle modifications, namely, changing diet, increasing physical activity, and reducing or eliminating unhealthy behaviours such as smoking. As the disease progresses, oral hypoglycemic medications and eventually insulin injections may be required to maintain target blood glucose levels and stave off complications (Brands et al., 2007).

Throughout the world, approximately 366 million people have been diagnosed with diabetes; estimates put this number at 552 million by 2030 (Whiting et al., 2011). In Canada the prevalence of diabetes in adults over the age of 20 is 8.7%, representing 1 in 11 Canadians (Government of Canada, 2011). The greatest increase in the prevalence of diabetes occurs after the age of 40; with prevalence rates of at least 20% for every age group older than 65 years of age (Government of Canada, 2011). Approximately 90% of individuals with diabetes have T2DM, and this percentage increases in older age groups. Ontario has the third highest prevalence of diabetes compared to all other provinces and territories and is surpassed only by Nova Scotia and Newfoundland. In addition, more than 50% of individuals living with diabetes in Canada are of working age (between 25 and 64 years of age, Government of Canada, 2011).

Cognitive Functioning in T2DM

T2DM is associated with increased risk of vascular dementia, Alzheimer's Disease (AD), and accelerated rate of cognitive decline in older adults (Palta et al., 2014). Munshi and colleagues (2006) reported that cognitive dysfunction (poor performance on neuropsychological measures when compared to normative samples with similar demographic characteristics) is present in 30-40% of individuals who have diabetes and are more than 70 years of age. Estimates indicate that 6 to 13% of all cases of dementia can be attributed to diabetes (Biessels et al., 2008; Koekkoek et al., 2015). An early systematic review showed a 1.2 to 2.3 times greater risk for AD and a 2.2 to 3.4 times greater risk for vascular dementia in individuals with diabetes when compared to individuals without diabetes (Cukierman et al., 2005). A more recent meta-analysis confirmed these rates showing a 1.46 (95% CI: 1.20-1.77) times greater risk of developing AD and a 2.48 (95% CI: 2.08-2.96) times greater risk of developing vascular dementia in individuals with diabetes when compared to individuals without diabetes (Cheng et al., 2012).

Vascular Cognitive Impairment and T2DM. Cognitive dysfunction that is associated with or caused by vascular risk factors has been called vascular cognitive impairment (VCI, Hachinski et al., 2006; Vasquez & Zakzanis, 2015). VCI ranges in severity from unnoticed cognitive changes, to mild cognitive impairment, to dementia, and can occur in isolation or along with AD pathology (Hachinski et al., 2006; Vasquez & Zakzanis, 2015). Vascular risk factors include T2DM, hypertension, dyslipidemia, obesity, and cerebrovascular incidents (Hachinski et al., 2006; van den Berg et al., 2009). Some vascular risk factors (including T2DM) are treatable; treatment of vascular risk factors is thought to prevent or postpone VCI and exacerbation of AD pathology by VCI comorbidity (Hachinski et al., 2006). The numerous vascular risk factors often co-occur and have overlapping consequences such as atherosclerosis; however, these risk factors also show differences in the end organ damage caused, age of onset, and initial damage at time of diagnosis (van den Berg et al., 2009)

A review by van den Berg and colleagues (2009) looked at the effects of T2DM, impaired glucose metabolism, hypertension, dyslipidemia, and obesity on cognitive functioning. T2DM and hypertension were the vascular risk factors with the most consistent associations with cognitive dysfunction, with 67% of studies reviewed for T2DM and 71% of studies reviewed for hypertension showing cognitive dysfunction in groups of individuals with each condition (van den Berg et al., 2009). Results were less consistent for other risk factors with individuals with impaired glucose metabolism showing decline in 12.5% of studies, individuals with obesity showing decline in 50% of studies, and those with dyslipidemia showing decline in 40% of studies reviewed (van den Berg et al., 2009). The most commonly affected cognitive domains across vascular risk factors were memory, processing speed, and cognitive flexibility; however, the most commonly affected domains were also the most commonly assessed domains, suggesting a broader sampling a cognitive domains assessed is likely required (van den Berg et al., 2009). Importantly, studies controlling for the effects of individual vascular risk factors (e.g., dyslipidemia, obesity, and hypertension) on each of the studied risk factors (e.g., T2DM) did not produce statistically significant differences in affected cognitive domains from studies that did not control for the effects of individual risk factors and effect sizes for impairment remained similar across risk factors (van den Berg et al., 2009).

VCI as a whole causes impairment in all cognitive domains; however, the greatest impairments are seen in executive functioning and processing speed (Vasquez & Zakzanis, 2015) and more specifically with shifting abilities (Hachinski et al., 2006). The work of Hachinski and colleagues and of Vasquez and Zakzanis shows some overlap with the findings of van den Berg and colleagues (2009) in the areas of processing speed, cognitive flexibility/shifting, and executive functioning.

Metabolic syndrome is the name given to the presence of three or more of the following vascular risk factors: abdominal obesity, elevated diastolic blood pressure, elevated systolic blood pressure, elevated glucose levels, elevated cholesterol levels, and elevated triglyceride levels (Falkowski et al., 2014). A study investigating the effects of metabolic syndrome status on executive functioning abilities found that metabolic syndrome was significantly associated with worse executive functions; however, this association only accounted for 1% of variance after controlling for age, education, gender, and ethnicity (Falkowski et al., 2014). Most importantly, this study only found that the presence (≥3 components) or absence (≤2 components) of metabolic syndrome predicted executive functioning abilities and the authors did not find additive effects of more metabolic syndrome components being associated with worse executive functioning as they had hypothesized (Falkowski et al., 2014). These findings fit with the findings of van den Berg and colleagues (2009), who concluded that having diagnoses of multiple risk factors does not necessarily lead to greater cognitive impairment overall than does having a diagnosis of a single risk factor.

Neuropsychological findings in T2DM. Neuropsychological findings specific to T2DM will be reviewed within the context of the above discussion. A review (van den Berg et al., 2009) and meta-analyses (Kinga & Szamosközi, 2014; Monette et al., 2014; Palta et al., 2014; Vincent & Hall, 2015) have provided good summaries of the neuropsychological effects of T2DM.

In the van den Berg and colleagues (2009) review, cognitive functioning was classified by cognitive domains. Studies reviewed assessing these domains showed impairments in individuals with T2DM in 63% of studies assessing processing speed, 50% assessing attention, 44% assessing memory, 38% assessing cognitive flexibility, 33% assessing language, 31% assessing general intelligence, and 22% assessing perception and construction. Median Cohen's *d* for the most commonly affected domains were -0.4 for processing speed, -0.5 for attention, and -0.3 for memory (van den Berg et al., 2009).

These authors noted that cross sectional studies with older adults tended to have larger effect sizes (van den Berg et al., 2009). On the other hand, adjusting for risk factors other than age did not significantly change the findings. A recent longitudinal study showed that cognitive decline was 19% greater over the 20 years of the study in those with T2DM compared to those without T2DM (Rawlings et al., 2014). T2DM on average sped cognitive aging by five years; in other words, a person who was 65 years-old with T2DM would be expected to have the same level of cognitive functioning as a person who was 70 years-old without T2DM (Rawlings et al., 2014).

In their meta-analysis Palta and colleagues (2014) included 24 studies published between 1995 and 2013 and these authors also classified cognitive functioning by cognitive domains. Small to moderate statistically significant deficits were found in every classified cognitive domain in individuals with T2DM when compared to controls without T2DM. Specifically, using the author's cognitive classification, the largest deficits in mean effect sizes were found in motor functions (d = -0.36), followed by processing speed (d = -0.33), executive functions (d = -0.33), verbal memory (d = -0.28), visual memory (d = -0.26), and attention/concentration (d = -0.19).

Monette and colleagues (2014) included 25 studies published between 2000 and 2013 in their meta-analysis and classified cognitive functioning more specifically by cognitive abilities. Results were similar to Palta and colleagues (2014) in that all classified cognitive abilities showed statistically significant small to moderate deficits in individuals with T2DM compared to controls without T2DM. The largest mean effect sizes were reported for processing speed measured with tasks with motor demands (-0.37), and for divided attention/shifting (-0.36, Monette et al., 2014). Median effect sizes equivalent to those reported by van den Berg and colleagues (2009) were calculated for cognitive domains and yielded Cohen's *d*s of -0.42 for processing speed, -0.36 for attention, and -0.28 for memory (Monette et al., 2014).

Vincent and Hall (2015) completed a meta-analysis specifically of executive functioning in individuals with and without T2DM. The authors included 60 studies published between 1984 and 2013. Again, all effect sizes were statistically significant and small to moderate in magnitude (Vincent & Hall, 2015). The executive functioning composite had a small effect size (d = -0.25). Effect sizes were calculated for individual components of executive functioning as classified by the authors. The letter fluency (d = -0.38), attention (d = -0.38), shifting (d = -0.36), and inhibition (d = -0.32) effect sizes were larger than the executive functioning composite effect size and the categorical fluency (d = -0.16) and working memory (d = -0.13) effect sizes were smaller in magnitude than the executive functioning composite.

A fourth meta-analysis by Kinga and Szamosközi (2014) reviewed nine studies published between 1993 and 2009. The magnitude of effect sizes for this meta-analysis ranged from small to large for classified cognitive domains. However, this meta-analysis was of adults age 18-65 and included studies with individuals with T1DM and T2DM. Thus, the results of this meta-analysis are not directly comparable to the other three meta-analyses reviewed above.

Effect sizes for memory and processing speed were similar across all studies where these were reported (Monette et al., 2014, Palta et al., 2014; van den Berg et al., 2009). Attention showed a larger median effect size in the van den Berg et al. (2009) study (-0.5), a smaller mean effect size in the Palta et al. (2014) study (-0.19), an intermediate median effect size in the Monette et al. (2014) study (-0.36), and an intermediate mean effect size in the Vincent and Hall (2015) study (-0.38). This difference in effect sizes for attention has two potential sources. First, the van den Berg et al. study only reported median effect sizes, the Palta et al. and the Vincent and Hall studies only reported mean effect sizes, and the Monette et al. study reported both mean and median effect sizes. The different statistics used could have contributed to the difference in attention effect sizes across these three studies and are not directly comparable values.

Second, the three studies differed in terms of whether tests were classified by domain or by ability. In the Monette et al. (2014) study the mean effect size for the attention domain was -0.29 as compared to the mean effect size for the same domain from Palta and colleagues (2014, d = -0.19) and from Vincent and Hall (2015, d = -0.38). However, differences in mean effect sizes emerged among attention abilities in the Monette et al. study (divided attention/shifting d = -0.36, focused attention d = -0.15, and selective attention d = -0.33). Divided attention/shifting, often considered to be part of the executive functioning domain (Falkowski et al., 2014), had an effect size close to that reported for the entire executive functioning domain in the Palta et al. study (d = -0.33) and was identical to the shifting effect size reported by Vincent and Hall (d = -0.36). Further, the attention effect size from Vincent and Hall was likely inflated due to the inclusion of the Digit Symbol Substitution Test (DSST) in the calculation of this effect size. The DSST is a processing speed measure with high motor demands that measures divided attention (Strauss et al., 2006). Thus, divided attention/shifting is the most consistently reported impaired component of executive functioning in individuals with diabetes as it is in individuals with other vascular risk factors (van den Berg et al., 2009) and in VCI (Hachinski et al., 2006). As such, in the present study the cognitive abilities of processing speed and shifting/cognitive flexibility were measured by more than one neuropsychological test and the other cognitive abilities were measured by at least one measure.

The American Diabetes Association standards of medical care for diabetes recommend that cognitive screening should be done for all individuals diagnosed with diabetes and that there should be ongoing cognitive assessment in individuals with poor glycemic control and poor diabetes self-management (ADA, 2013). This is recommended as it is not T2DM itself that causes cognitive decline but the quality of glycemic control, the duration of diabetes, and the presence of complications (all indicators of a more advanced disease process) that lead to cognitive decline in T2DM (Rawlings et al., 2014). Therefore, better glycemic control achieved through performing DSMB should minimize cognitive functioning deficits and decline in individuals with T2DM. Unfortunately, adherence and self-care in T2DM as related to performing DSMB is generally poor as will be reviewed in the following section.

Adherence, Self-Care, and DSMB

Definitions and Statistics. Adherence is typically defined by “the extent to which a person’s actions and behaviour coincides with advice or instruction from a health care provider intended to prevent, monitor, or ameliorate a disorder” (p. 3, Christensen, 2004). In the context of T2DM, adherence is measured by achieving target A1C levels (usually $\leq$ 7%) and through the completion of DSMB (Bailey & Kodack, 2011).

The above definition is too simplistic (Emery et al., 2010). Walker & Usher (2003) provide a more comprehensive definition of adherence by distinguishing conditions under which the behaviour recommended by a healthcare provider is completed by an individual with T2DM. First, the individual must be aware of the provider recommendation. If the individual fails to complete the behaviour because they are not aware of the provider recommendation this is a knowledge deficit that needs to be corrected as opposed to a failure to adhere to the provider recommendation. Second, if the individual is aware of the provider recommendation, does not agree with it, but still completes the behaviour, this is categorized as compliance, which is different than adherence because the individual is passively following the instructions of the healthcare provider. Lastly, if the individual is aware of the provider recommendation, agrees with it, and completes the behaviour this can be categorized as adherence; and similarly, if the individual is aware of the provider recommendation, agrees with it, but fails to complete the behaviour, then this can be categorized as non-adherence or failure to adhere (Walker & Usher, 2003). This model of adherence recognizes that the individual with T2DM has an active role in completing their recommended DSMB, and ideally there is a collaborative relationship between the healthcare provider and the individual with T2DM (Emery et al., 2010).

Self-care and self-management are often used interchangeably to refer to behaviours necessary for T2DM treatment adherence (Bailey & Kodack, 2011). However, self-care is a broader concept that includes DSMB along with self-monitoring and symptom management completed by the individual with T2DM (Caro-Bautista et al., 2014). Self-care behaviours include DSMB (blood glucose monitoring, medication and/or insulin taking, physical activity, diet, foot care), but also problem solving when blood glucose is not in range, reducing diabetes complications, and living with diabetes (diabetes-related QoL); self-report can be utilized to measure all of these domains (Mulcahy et al., 2003). Good self-care helps protect against diabetes complications; the individual with T2DM must actively manage their diabetes through DSMB with the goal of achieving target blood glucose and A1C levels (Schmitt et al., 2013). Therefore, self-care is the ongoing day-to-day management of T2DM that requires intact knowledge and skills, motivation, mood, and DSMB completion (Feil et al., 2012).

Adherence in T2DM is notoriously poor with only slightly more than half of individuals achieving a target A1C of less than 7.0% (Bailey & Kodack, 2011; Hunter, 2016). Only 7 to 25% of people with diabetes fully adhere to all aspects of their treatment regimen, i.e., complete all their DSMB (Gillani, 2012). Similarly, Ahola & Groop (2013) reported that only 39% of individuals with T2DM achieve “complete success” in at least 2/3 of their self-management behaviour domains as per their provider recommendations. Failures to adhere to diet recommendations occur in 40-60% of individuals with diabetes, failures to complete recommended glucose monitoring occur in 30-80% of individuals with diabetes, and failures to adhere to physical activity recommendations occur in 70-80% of individuals with diabetes (Gillani, 2012). Adherence to medication recommendations is usually better than to diet and physical activity recommendations (Ahola & Groop, 2013). These poor rates of DSMB completion can be better understood with the consideration that estimates place the total time required to execute all DSMB as directed by healthcare providers at up to 2 hours per day for the average adult with T2DM (Gonzalez et al., 2016). Overall, adherence in T2DM is found to be poorest for females, people with comorbid depression, those with negative attitudes towards insulin, and those with lower general and diabetes specific education (Emery et al., 2010).

Barriers to the completion of DSMB. The major goal of diabetes education and the role of the healthcare provider are to facilitate the ability of individuals with T2DM to carry out their DSMB behaviours and empower them to take responsibility for their DSMB in order to complete them independently (Caro-Bautista et al., 2014; Compeán-Ortiz et al., 2010). Barriers to diabetes self-care hinder the independent decision-making and independent execution of agreed upon DSMB and treatment goals and affect treatment adherence (Caro-Bautista et al., 2014). Barriers to completion of DSMB belong to three major categories: individual or patient factors, provider or treatment factors, and environmental or system level factors.

Individual or patient level factors. Individual or patient level factors include knowledge and skill (Ahola & Groop, 2013; Bailey & Kodack, 2011; Emery et al., 2010). Lack of knowledge is seen as a barrier. However, good levels of knowledge do not in and of themselves guarantee adherence to DSMB as more knowledge has been shown to lead to more flexibility in performance of DSMB (Ahola & Groop, 2013). This greater flexibility in performance of DSMB behaviours due to increased knowledge has been shown to sometimes lead to failures to reach A1C goals (Ahola & Groop, 2013). Health beliefs, including feeling as though the disease is not severe or a lack of faith in the efficacy of the treatment regimen, lead to poor adherence (Ahola & Groop, 2013; Bailey & Kodack, 2011; Castellon et al., 2009; Emery et al., 2010; Gonzalez et al., 2016). Poor self-efficacy, coping, and problem solving skills, lack of empowerment, and an external health locus of control also lead to poor adherence (Ahola & Groop, 2013; Bailey & Kodack, 2011; Emery et al., 2010; Gonzalez et al., 2016). Poor health literacy leads to poorer adherence (Ahola & Groop, 2013; Bailey & Kodack, 2011; Castellon et al., 2009; Emery et al., 2010). Cultural factors including ethnicity and religious beliefs have differing effects on adherence (Emery et al., 2010; Gonzalez et al., 2016). Psychological factors such as depression, anxiety, substance abuse, or severe mental illness all hinder adherence (Ahola & Groop, 2013; Bailey & Kodack, 2011; Castellon et al., 2009, de Groot et al., 2016). Finally, cognitive impairment has been shown to be a barrier to DSMB completion (Ahola & Groop, 2013; Bailey & Kodack, 2011; Castellon et al., 2009; Emery et al., 2010). These authors refer specifically to dementia as a barrier, but specific characterizations of the impact of cognitive abilities on DSMB are scarce in the literature. The few studies that have been completed will be discussed in the next section.

Provider or treatment factors. In addition to these factors at the individual level, a host of other factors can impact adherence. Treatment regimen factors that adversely affect adherence include more complex treatment regimens, more frequent medication dosages, and more severe medication side effects (Bailey & Kodack, 2011; Castellon et al., 2009). Provider factors that influence adherence include interaction and communication style of the healthcare provider (Ahola & Groop, 2013; Castellon et al., 2009; Emery et al., 2010). Ratings of quality of physician communication and their level of participatory decision making with patients were found to predict DSMB completion in individuals with diabetes after controlling for sociodemographic and disease variables (Heisler et al., 2002).

Environmental or system level factors. Environmental or system level factors include cost of the medication, availability of care, distance to the physician's office, interference of the treatment regimen with lifestyle and other duties, and access to social support (Ahola & Groop, 2013; Bailey & Kodack, 2011; Castellon et al., 2009; Emery et al., 2010; Gonzalez et al., 2016). Human factors can also become barriers, including poor labelling and packaging of medications and reading levels of instructions above the comprehension of the individual with T2DM (Castellon et al., 2009).

All three levels of barriers interact together and the same individual with T2DM can show difficulties with adherence for reasons that change across time (Castellon et al., 2009). As the current investigation was an exploratory study most concerned with the relationship between DSMB completion and cognitive functioning, only individual level factors were considered in the present investigation. Individual level factors that are most likely to affect the relationship between DSMB completion and cognitive functioning were exclusion criteria in the present study where possible (e.g. diagnoses of dementia, severe mental illness, chronic diseases not typically comorbid with T2DM). When it was not possible to exclude individual level factors, these factors were analysed to determine their impact on DSMB completion.

DSMB and Cognitive Functioning

Due to the chronicity of T2DM, most of the DSMB are expected to be performed independently by the individual with T2DM, with the healthcare provider available to facilitate understanding on a limited basis. Therefore the impact of cognitive functioning on the daily management of T2DM must be known (Compeán-Ortiz et al., 2010). Conceptually, there is a reciprocal relationship between DSMB completion and cognitive functioning (Feil et al., 2012; Umegaki et al., 2013) wherein cognitive impairment (due to T2DM or some other disease process) can begin to interfere with the individual's ability to complete their DSMB and adhere to their treatment regimen. Once this happens, there is likely to be poorer T2DM control, which would increase the risk of diabetes complications and further cognitive decline (Feil et al., 2012). This cycle would continue leading to more severe cognitive decline unless an intervention is carried out to compensate for the cognitive deficits (Compeán-Ortiz et al., 2010; Monette, 2012; Primozic et al., 2012).

Completing DSMB is difficult for cognitively intact individuals (Feil et al., 2012) as seen by the statistics discussed above (Ahola & Groop, 2013; Gillani, 2012). In addition, specific cognitive deficits predict DSMB completion over and above measures of health literacy typically used in the T2DM adherence literature (Ross et al., 2010). Most health behaviour models for the management of chronic illnesses do not incorporate the possible effects of cognitive deficits on performance of health behaviours (Hall et al., 2006). Cognitive deficits can potentially influence the accuracy of health beliefs, the ability to assimilate new information to change beliefs, and the ability to problem solve situations according to one's health beliefs (Castellon et al., 2009). As such, cognitive deficits and decline, not only frank cognitive impairment or dementia, are barriers to the completion of DSMB (Feil et al., 2012).

The cognitive changes seen in normal aging can serve to inform the difficulties individuals with T2DM might have completing their DSMB due to the profile of cognitive deficits in T2DM being qualitatively similar to that of normal aging (van den Berg et al., 2009). The pattern of cognitive deficits seen in those with T2DM is often characterized as accelerated aging (Okereke et al., 2008). Normal aging generally leads to slowed processing speed, difficulty with divided attention, changes in working memory, executive function abilities, efficiency of information retrieval, and prospective memory (Castellon et al., 2009). Due to the changes in cognition that occur as humans age, older adults might not have the memory and organizational skills necessary for complex treatment regimens requiring multiple coordinated behaviours and goal management (i.e., DSMB, Emery et al., 2010). Retrospective memory for instructions on how to take medications and prospective memory for when to take them have been shown to affect treatment adherence in older adults, with poorer abilities in these areas leading to nonadherence (Castellon et al., 2009).

Previous studies of the effect of cognitive functioning on DSMB completion. Few studies have investigated the relationship between DSMB and cognitive impairment (Feil et al., 2009; Feil et al., 2012; Sinclair et al., 2000) or the relationship between DSMB and cognitive abilities (Asimakopoulou & Hampson, 2002; Compeán-Ortiz et al., 2010; Gatlin & Insel, 2015; Primozic et al., 2012; Rosen et al., 2003; Thabit et al., 2009); and existing studies also have found conflicting results. Each of these studies will be discussed in turn and were used to inform the design of the current investigation.

The first study identified on the subject looked at the capabilities of individuals with diabetes (most had T2DM) to complete DSMB and other related behaviours (Sinclair et al., 2000). The Mini-Mental State Exam (MMSE) was used to measure cognitive functioning. The MMSE is a measure of cognitive functioning used to screen for the presence of dementia; scores below 23 out of a possible 30 indicate the possibility of dementia (Folstein et al., 1975). In the Sinclair and colleagues study, 113 individuals with MMSE scores ≤ 23 were compared to 283 individuals with MMSE ≥24. Those with poorer cognitive functioning were statistically significantly less likely to be solely responsible for their medication intake and blood glucose monitoring, to attend a specialized diabetes clinic, to have adequate diabetes knowledge, and to complete their activities of daily living. They were also statistically significantly more likely than those with higher cognitive function to have been hospitalized in the last year, to have received help with personal care, to have had a needs assessment completed in the past year, and to be living in a long-term care home (Sinclair et al., 2000). This study did not evaluate the ability of individuals to complete their DSMB, only if they were completing them independently or not given their cognitive status. The study also used a cognitive screening measure to obtain an estimate of current cognitive status rather than evaluating multiple cognitive domains or abilities.

Asimakopoulou & Hampson (2002) reported selected findings from an unpublished study where they explored the relationships between measures of cognitive functioning and self-reported DSMB completion in 51 individuals with T2DM and no dementia. No data were reported; only a description of findings was provided. Multiple Regression Analysis (MRA) controlling for age, premorbid IQ, and depression found that better completion of diet DSMB was predicted by better scores on the modified Wisconsin Card Sorting Test, a measure of executive functioning, and that better physical activity DSMB was predicted by better performance on a serial subtraction task, a measure of working memory. After reporting that above findings, these authors concluded that overall the cognitive deficits present in T2DM when there is no dementia present were unlikely to affect completion of DSMB (Asimakopoulou & Hampson, 2002). It is difficult to know how the authors reached this conclusion given what was reported.

Rosen and colleagues (2003) investigated the relationship between cognitive abilities and adherence to Metformin (the most commonly used oral hypoglycemic medication) in 79 individuals with T2DM attending a VA primary care clinic. Microelectronic Event Monitoring Systems were used to assess medication intake for a 4-week period and the MMSE, Trail Making Test A & B, Stroop, Digit Span, Digit Symbol, and Grooved Pegboard cognitive tests were administered. Only the Stroop word score (a measure of processing speed), time to completion of Trails B (a measure of visual scanning, processing speed, and shifting), and age were significantly correlated with medication adherence. Stepwise Regression showed that age accounted for 9.8% of the variance in medication adherence and time to completion of Trails B accounted for an additional 9.1% of variance (R^2 change from age only). A second Stepwise Regression showed that number of Stroop words read accounted for an additional 8% of variance (R^2 change from age only, Rosen et al.). There were no significant correlations between neuropsychological measures and A1C, and MMSE score accounted for 13.3% of the variance in missed appointments (Rosen et al., 2003). This study provides some indication that processing speed and shifting are important for medication adherence; however, medication taking was the only domain of DSMB included in the study.

Thabit and colleagues (2009) assessed the relationship between executive dysfunction and DSMB completion in 50 older adults with T2DM. They assessed executive dysfunction using two measures, the Frontal Assessment Battery (FAB) and the Executive Interview 25 (EXIT25). They assessed global cognitive functioning using the MMSE, a measure wherein performance on memory and orientation items accounts for most of the score. A total score from a measure of DSMB correlated significantly with the EXIT25 (r = -0.3 p <.05) and the MMSE (r = 0.5 p<.05), but not with the FAB (r = 0.2 p = 0.14). DSMB completion was significantly worse for those who scored below the cut-off for impairment on both the EXIT25 and the FAB. The correlation between MMSE and DSMB completion remained significant when the variance accounted for by FAB scores was removed (r = 0.36, p < 0.05), which suggests that overall cognitive functioning has an effect on DSMB completion greater than that caused by executive dysfunction alone (Thabit et al., 2009). Conversely, these authors also concluded that a MMSE score within normal limits does not preclude executive dysfunction that can impact DSMB completion and that executive deficits in individuals with T2DM can be missed if they are not assessed directly (Thabit et al., 2009).

Compeán-Ortiz and colleagues (2010) investigated the relationship of memory abilities and DSMB completion in 105 younger Mexican adults ages 30 to 55 years with T2DM. They excluded individuals with an MMSE score under 23. They administered a Spanish measure of DSMB and the Spanish version of the Wechsler Memory Scale, yielding scores of immediate verbal and visual recall and delayed visual and verbal recognition and recall. After accounting for diabetes education and knowledge, delayed verbal recognition, immediate visual recall, and delayed visual recall were significantly related to blood glucose monitoring accounting for 9.4%, 14.2%, and 11.1% of the variance, respectively. Immediate visual recall and delayed visual recall were significantly related to diet DSMB accounting for 8.5% and 7.6% of the variance respectively. All other memory scores were reportedly not significantly related to blood glucose monitoring or diet, and none of the memory scores were significantly related to physical activity or medication DSMB after accounting for prior diabetes education and knowledge (Compeán-Ortiz et al., 2010). This study is important because the authors demonstrated that memory abilities are related to blood glucose monitoring and diet DSMB in younger adults who scored above the cut-off score for dementia on a cognitive screening measure.

Feil and colleagues (2012) investigated the relationship of cognitive functioning with diabetes comorbidity and DSMB in a community sample of 1398 older adults. Cognitive functioning was measured using the Telephone Interview for Cognitive Status (adapted from the MMSE). More severe cognitive impairment was significantly related to poorer DSMB completion and the relationship became stronger as diabetes comorbidities increased. Cognitive impairment affected physical activity DSMB most strongly followed by diet DSMB. These two domains were also the most affected when diabetes comorbidities increased (Feil et al., 2012). These findings remained significant after controlling for functional status, duration of diabetes, treatment modality, and demographic characteristics (Feil et al., 2012). This study was the first to show the relationship between cognitive functioning and DSMB in a large sample of community dwelling older adults. A study by the same group also showed a significant relationship between cognitive impairment (measured using the Cognitive Abilities Screening Instrument) and poorer DSMB completion in 51 male veteran outpatients (Feil et al., 2009).

Primozic and colleagues (2012) investigated the relationship between cognitive abilities and DSMB using the Repeatable Battery of the Assessment of Neuropsychological Status (RBANS) to measure immediate and delayed memory, attention, language, and visuospatial/constructional abilities; the Tower of London to measure the executive functions of planning, problem solving, and working memory, and the Stroop test to measure processing speed and cognitive flexibility in 98 adults with T2DM over the age of 40. Simple regression analysis showed a significant relationship between a total score for DSMB and body mass index (BMI), depression symptoms, total score on the RBANS, immediate memory, visuospatial/constructional abilities, attention, and planning and problem solving. There were no significant associations between the total score for DSMB and age, A1C, duration of diabetes, diabetes-related distress (proxy measure for QoL), working memory, processing speed, cognitive flexibility, language, and delayed memory (Primozic et al., 2012).

Multiple regression analysis (MRA, Primozic et al., 2012) showed that better problem solving, lower BMI, female sex, and absence of depression predicted better total DSMB scores ($R^2 = 0.37$, $p < 0.001$). The RBANS total ($\beta = 0.33$, $p < 0.006$, $R^2 = 0.40$, $p < 0.001$) and attention domain ($\beta = 0.28$, $p < 0.015$, $R^2 = 0.39$, $p < 0.001$) scores significantly predicted total DSMB scores when these scores were used in the regression model in place of planning and problem solving. Visuospatial/constructional abilities and immediate memory scores did not significantly predict total DSMB when they were inserted into the model and delayed memory and language scores were not tested due to not being significant in the simple regression analyses (Primozic et al., 2012). This study is important because the relationships between DSMB and multiple cognitive abilities across all cognitive domains in relation to demographic and disease variables were analysed.

Finally, Gatlin and Insel (2015) investigated the relationship between working memory as measured by the Working Memory Index of the WAIS-III and executive functioning as measured by the EXIT25 in a sample of 67 adults with T2DM. These authors assessed global cognitive functioning using the MMSE. Participants with a score ≤ 23 on the MMSE were excluded from the study. Self-care was measured by the Self-Care Inventory – Revised (SCI-R), a 25-item self-report measure, which included medication, blood glucose, diet, and exercise DSMB domains, along with question assessing preventative and routine aspects of self-care (Gatlin & Insel, 2015). Scores on the Exit25 and the SCI-R were significantly correlated ($r = -0.31$, $p < .01$). However, there was no significant correlation between the Working Memory Index and the SCI-R ($r = 0.01$, $p > .05$).

Overall significant relationships were found between DSMB completion and cognitive impairment in all three studies in which only global cognitive impairment was measured (Feil et al., 2009; Feil et al., 2012; Sinclair et al., 2000). Executive dysfunction in the presence of a normal range score on the MMSE was noted (Gatlin & Insel, 2015; Thabit et al., 2009) to impact DSMB completion and self-care. Immediate memory, visuospatial/constructional abilities, attention, and planning and problem solving

(Primozic et al., 2012) were significantly correlated with DSMB completion total scores, although immediate memory and visuospatial/constructional abilities were not independent predictors of DSMB completion in the MRA analyses.

For specific DSMB domains, previous studies indicated that diet DSMB completion is impacted by memory abilities (Compeán-Ortiz et al., 2010) and executive functioning (Asimakopoulou & Hampson, 2002). Memory abilities were also related to blood glucose monitoring DSMB completion (Compeán-Ortiz et al., 2010). Processing speed and shifting abilities were related to successful medication adherence (Rosen et al., 2003). Physical activity DSMB completion was impacted by working memory abilities (Asimakopoulou & Hampson, 2002). However, all the studies investigating the impact of cognitive abilities on DSMB completion also have reported nonsignificant associations with many cognitive abilities (Asimakopoulou & Hampson, 2002; Compeán-Ortiz et al., 2010; Primozic et al., 2012; Rosen et al, 2003; Thabit et al.,2009) and no clear pattern of deficits has emerged; therefore, the effects of cognitive abilities on the completion of DSMB remain to be fully determined.

DSMB and QoL

Good quality of life (QoL) is an essential (Gonzalez et al., 2016) and sometimes overlooked (Cochran & Conn, 2008) treatment outcome in T2DM, even though it is a core outcome of DSMB education (Mulcahy et al., 2003). To aid in the development of a measure of QoL, the World Health Organization developed the following consensus definition of QoL by international expert review:

> individuals' perception of their position in life in the context of the culture and value system in which they live and in relation to their goals, expectations, standards and concerns. It is a broad ranging concept

> affected in a complex way by the persons' physical health, psychological state, level of independence, social relationships and their relationship to salient features of their environment (The WHOQOL Group, 1995, p. 1405).

QoL in individuals with T2DM is often defined in relation to which aspects of well-being and life quality are being considered (Cochran & Conn, 2008). General QoL usually queries overall well-being across many psychosocial functioning domains. The construct of health QoL encompasses the impact of overall health status on QoL and well-being. Related to health QoL, diabetes specific QoL measures the impact of diabetes on QoL and well-being (Ostini et al., 2012). General QoL in T2DM is diminished when compared to those without T2DM (Cochran & Conn, 2008; Emery-Tiburcio et al., 2015). This is evidenced by the higher prevalence of Major Depressive Disorder (MDD) in individuals with T2DM (15-20%) compared to those in the general population (2-9%, Gonzalez et al., 2007). Untreated depression affects DSMB completion and has also been associated with higher risks of mortality and dementia in those with T2DM when compared to those with T2DM and no depression (Kirkman et al., 2012; Primozic et al., 2012). In addition, treatment of depression symptoms alone does not usually lead to an increase in DSMB completion (Gonzalez et al., 2016; Hunter, 2016). Poor general and diabetes-related QoL have been shown to negatively impact DSMB completion (Cochran & Conn, 2008; Primozic et al., 2012). Likewise, learning how to complete DSMB and performing the behaviours increases QoL (Cochran & Conn, 2008), possibly because individuals with T2DM feel better physically when they exercise and follow a recommended healthy diet and do not experience the unpleasant physical side effects of hyperglycemia. Performing DSMB can also increase self-efficacy with regard to the individual's ability to manage their T2DM and thus may lead to a positive effect on general QoL and overall well-being (Cochran & Conn, 2008).

Depression is important to consider because it directly affects completion of DSMB and QoL (de Groot et al., 2016). Lin and colleagues (2004) studied the relationship between MDD and DSMB completion in 4463 individuals with diabetes (95.6% had T2DM). These authors found that MDD was associated with poorer completion of self-initiated behaviours that are difficult to maintain (e.g., physical activity, diet, and medication intake) but not with more preventive time-limited behaviours (e.g., blood glucose monitoring, foot inspections, and follow-up appointments, Lin et al.). Gonzalez and colleagues (2007) investigated the relationship of MDD and subclinical depression to DSMB completion in 879 adults with T2DM attending a primary care clinic. These authors found that those meeting criteria for MDD reported almost a full additional day of nonadherence to diet, physical activity, and blood glucose monitoring over the past week compared to individuals who did not meet criteria for MDD. Importantly, they found that depression symptom severity (a continuous measure) was a better predictor of the completion of all DSMB, with the exception of blood glucose monitoring, than meeting criteria for MDD (a dichotomous measure). Only MDD, and not depression symptoms, was significantly associated with decreased blood glucose monitoring (Gonzalez et al., 2007). The results of this study and subsequent replications (Gonzalez et al., 2016) indicate the importance of assessing current depression symptom severity and not just current or past diagnoses of MDD.

There is a paucity of evidence on the impact of cognitive functioning and DSMB completion on QoL. Cognitive abilities, completion of DSMB, and level of QoL are all reciprocally interrelated (Cochran & Conn, 2008; Feil et al., 2012; Primozic et al., 2012; Umegaki et al., 2013) and causation can only be fully established through longitudinal models. Given these relationships any one of these three constructs could have been chosen as an outcome under evaluation in the present study. The most interesting of these outcomes that encompasses all of these relationships is the effect of cognitive abilities and DSMB on QoL, as achieving better QoL and elucidating the barriers to achieving better QoL in T2DM are important clinical and humanistic goals. Rodriguez-Pascual and colleagues (2011) found a significant relationship between health-related QoL and cognitive impairment, depression symptoms, and functional deficits in individuals with T2DM. More severe cognitive impairment, depression symptoms, and functional deficits predicted worse perceived QoL. However, DSMBs were not assessed specifically, and there was no significant relationship between QoL and A1C (Rodriguez-Pascual et al., 2011).

Present Study

The present study was an exploratory investigation of two main questions. The first was the relationship between cognitive abilities/cognitive functioning and DSMB completion. That is, is cognitive functioning related to successful DSMB completion and which cognitive abilities are most related to successful DSMB completion? The second research question investigated the best predictors of diabetes specific QoL and the impact of diabetes on the lives of individuals with T2DM. These research questions were answered with two datasets. One was collected specifically for this dissertation, hereinafter referred to as “the prospective study,” and the second was an archival dataset from the U.S. Health and Retirement Study (HRS, 2006), hereinafter referred to as “the archival study.”

The prospective study. The first research question was exploratory as previous research had found some significant relationships, but no patterns have emerged that allowed for strong specific directional *a priori* hypotheses. Anticipated results were that individuals with T2DM with weaker cognitive abilities (compared to norms and others in the sample) would have lower reported DSMB completion. The relationship of DSMB completion with demographic (social determinants of health) and disease variables in the prospective study sample was also analysed.

Multiple measures of the cognitive abilities most likely to show deficits in those with T2DM (i.e., processing speed and cognitive flexibility/switching) along with at least one other measure of major cognitive abilities shown to be impaired in those with T2DM (i.e., overall cognitive functioning, memory, attention, working memory, and verbal fluency) were included. A questionnaire querying executive functioning through behaviours was included as it is important to assess executive functions using multiple modalities as objective neuropsychological tests of executive functioning do not always correlate well with observed behaviour (Strauss et al., 2006). Multiple measures of DSMB were used in order to gain more reliable measurement of all domains. Younger adults were included in the sample given the findings of Compeán-Ortiz and colleagues (2010) indicating that younger adults showed deficits in memory abilities that impacted their DSMB completion. Measures of depression, anxiety, and stress symptoms, premorbid cognitive functioning, as well as information on demographic variables, disease variables, and comorbidities, were recorded.

The second research question sought to determine the best predictors of diabetes-related QoL in individuals with T2DM. Choice of measured predictors was informed by previous theory regarding individual barriers to good management of diabetes, including disease, demographic, and depression symptom variables. The size of the collected sample did not permit the investigation of these predictive relationships; however; the relationship of cognitive abilities, DSMB completion, and chosen predictor variables with diabetes-related QoL were investigated using correlational and group difference methods.

The archival study. The measures used to answer the first and second research questions were different for the archival study and were restricted by the measures chosen for inclusion in the Health and Retirement Study (HRS, 2006). For the first exploratory research question, a total score on a screening measure of cognitive functioning was used to predict DSMB completion. Feil and colleagues (2012) used the HRS data to answer this first research question by constructing tertiles for cognitive functioning and dichotomizing DSMB completion as is common in epidemiological research (Bennette & Vickers, 2012). The current archival study analysed these data using statistical analyses more common in psychological research. The current archival study also included younger individuals with T2DM in the analysis given the findings of Compeán-Ortiz and colleagues (2010). Feil and colleagues excluded younger individuals with T2DM from their analyses.

The archival study sought to answer the second research question in the same manner as the prospective study, by determining the best predictors of diabetes-related

QoL. The outcome measure was a questionnaire about the impact of diabetes in the participant’s life from the HRS diabetes dataset. Disease, demographic, and depression symptom variables comparable to those from the prospective study were entered in the first step of the model. DSMB and cognitive functioning were entered in the second step of the model.

CHAPTER II
PROSPECTIVE STUDY METHOD

Participants and Procedures

This was a prospective cross-sectional exploratory study. Participants were adults with T2DM recruited from multiple outpatient and community centres specializing in the treatment of individuals with T2DM in the Windsor community. Windsor-Essex Community Health Centre sites in Windsor and Leamington, Hôtel-Dieu Grace Healthcare bariatric clinic, Windsor Regional Hospital diabetes clinic, Endocrinologist offices in Windsor, the Windsor Family Health Team, the Windsor-Essex branch of Diabetes Canada, the Erie St. Clair Local Health Integration Network, Life After Fifty, the Windsor-Essex Medical Society, City Centre Health Care, and the University of Windsor Participant Pool were contacted by the researcher for the purposes of recruitment. All of these organizations agreed to post or circulate the study flyer except for the Windsor Regional Hospital and City Centre Health Care. The study flyer was also posted at the University of Windsor and circulated on social media. Participants were given $20 and had their parking costs reimbursed as part of their participation in the study.

Inclusion criteria for the prospective study consisted of: (a) 40 years of age or older, (b) at least a grade 8 education, (c) English proficiency sufficient to understand instructions and complete the tests and questionnaires, (d) diagnosis of T2DM for at least 1 year, and (e) access to current medication(s) list and most recent A1C level to bring in for the testing appointment. Exclusion criteria for the prospective study were as follows: (a) diagnoses of diabetes other than T2DM (i.e. T1DM or gestational diabetes), (b) previous diagnosis of dementia, (c) history of neurological disease, including moderate to severe traumatic brain injury, (d) history of severe mental illness requiring hospitalization, (e) current substance abuse or history of severe substance abuse, (f) other serious diagnosed chronic diseases that are not typically comorbid with T2DM, including genetic/congenital disorders, severe respiratory diseases, cancers not in complete remission, etc., and (g) hearing or vision problems that cannot be corrected with aids and that would have an effect on the standardized administration of the neuropsychological measures.

Thirty-one individuals responded to the advertisement and 26 were recruited and completed the study. The five volunteers who did not complete the study were excluded due to a diagnosis of dementia (*n* = 2), history of severe mental illness requiring hospitalization (*n* = 1), diagnosis of T1DM (*n* = 1), and diabetes duration of less than one year (*n* = 1). Participants were recruited from Windsor-Essex Community Health Centre sites (*n* = 20), from an endocrinologist office (*n* = 2), from the flyers posted at the University of Windsor (*n* = 2), from the Windsor Family Health Team (*n* = 1), and from the Hôtel-Dieu Grace Healthcare bariatric clinic (*n* = 1).

Consent to the blood glucose test and the assessment was obtained upon first meeting with each participant. Once consent to participate in the study was obtained, the participant tested their blood glucose using a glucometer and testing strips provided by the researcher to minimize measurement error. The participant was able to use a personally-owned lancet if available; otherwise one was provided by the researcher. The researcher recorded the blood glucose level immediately preceding the assessment. If the blood glucose level was at or below 4.0 mmol/l, the assessment stopped, and the participant was directed to follow their regular procedure for treating hypoglycemia. No participants had blood glucose below 4.0 mmol/l at the outset of the study and all participants left the testing appointment without medical incidents of any kind.

The demographic questionnaire was then completed in interview format with the participant. Following this, the neuropsychological tests were administered followed by the diabetes self-management behaviour questionnaires, the diabetes-related QoL questionnaire, and the mood questionnaires. While the participant was completing the assessment an informant completed an informant version of the diabetes self-management questionnaires. This only occurred for participants who were accompanied by a spouse or caregiver who was knowledgeable about the diabetes management regimen of the participant and who gave consent to allow the informant to complete the questionnaire. All procedures in the present study were approved by the University of Windsor Research Ethics Board (REB# 15-134).

Measures

All measures are discussed in the order of administration by the examiner during the assessment, unless otherwise specified. All measures were chosen for appropriateness of use with the participants to be included in the study.

Demographic questionnaire and Charlson Comorbidity Index. The demographic questionnaire, which included questions to permit completion of the Charlson comorbidity index, took approximately 20 minutes and was completed as an intake interview with the participant in order for the researcher to clarify any responses and increase accuracy of the collected information (see Appendix 1). The demographic questionnaire included questions about age, gender, ethnicity, birth place, years in Canada if not originally from Canada, primary language, English fluency, highest education level attained, number of years of English education completed, current occupation, current marital status and living arrangements, smoking status, amount of alcohol consumed on average, most recent measures of height and weight in order to calculate body mass index, current treatment modality (diet and exercise, oral hyperglycemic medications, insulin, or some combination) and complete medication list, duration of diabetes in years, presence of diabetes complications, presence of psychiatric diagnoses or treatment, whether there was hospitalization within the last year, and whether or not they had received the “Master Your Health” program or any other diabetes education program.

The Charlson Comorbidity Index (CCI) was developed to estimate prognostic comorbidity in longitudinal studies (Charlson et al. 1987). It has been found to reliably predict mortality, length of hospital stay, and post-operative complications (Deyo et al. 1992). The present study used the CCI to enable calculation of a summary score of comorbid conditions present along with T2DM to be used as a potential covariate in the statistical analyses. The CCI includes a list of 16 comorbid medical conditions that are assigned a weight of 1, 2, 3, or 6 corresponding to increased adjusted relative risk. The weighted values are added to obtain a total comorbidity score. Some medical conditions queried on the CCI were exclusion criteria for study participation and thus were not present in study participants: dementia, connective tissue disease, leukemia, malignant lymphoma, solid benign tumours and metastatic tumours, and AIDS. Medical conditions that were queried along with the demographic questionnaire during the intake interview included myocardial infarction, congestive heart failure, peripheral vascular disease, cerebrovascular disease, peptic ulcer disease, moderate to severe chronic kidney disease, hemiplegia, liver disease, and chronic obstructive pulmonary disease. Diabetes, although queried by the CCI, was not included in the total comorbidity score unless the participant reported diabetes complications other than neuropathy. If a participant reported presence of neuropathy this was classified as peripheral vascular disease. The maximum score possible on this modified version of the CCI was 15.

Neuropsychological measures and questionnaires. The neuropsychological measures included in the present study were selected as measures of the cognitive abilities most often affected in those with T2DM according to the meta-analyses and the systematic review discussed above (Kinga & Szamosközi, 2014; Monette et al., 2014; Palta et al., 2014; van den Berg et al., 2009; Vincent & Hall, 2015). These measures are also the measures that would be most likely to detect cognitive deficits in those with T2DM (Hachinski et al., 2006; Palta et al., 2014). The cognitive ability(ies) measured by each included neuropsychological test score are stated as each measure is discussed below in accordance with classifications provided in Strauss et al. (2006) and summarized in Table 1.

The Montreal Cognitive Assessment (MoCA) was developed to be a cognitive screening test for Mild Cognitive Impairment (MCI, Nasreddine et al., 2005). The items on the test measure immediate and delayed memory, executive, visuospatial, language, attention, and orientation abilities with a total score out of 30 indicating current level of cognitive functioning (Nasreddine et al., 2005). The MoCA was found to be more sensitive than the Mini-Mental State Examination (MMSE) for detecting MCI (90% versus 18%) and Alzheimer’s Disease (AD) (100% versus 78%). Specificity of the MoCA was high at 87% (Nasreddine et al., 2005). The MoCA places higher demands on executive functioning abilities than the MMSE, and this is important as executive functions are the priority for assessment in individuals with T2DM (Hachinski et al., 2006). Administration of the MoCA takes approximately 10 minutes. A score of ≤ 25 indicates possible MCI or AD. Internal consistency of the MoCA is good (Cronbach Alpha = 0.83) and test-retest reliability over an average of 35 days had a correlation of 0.92 (Nasreddine et al., 2005).

Index scores for the MoCA have been developed recently as an added aid in determining conversion from intact cognition to MCI or AD (Julayanont et al., 2014). Possible index scores are the Memory Index Score, calculated by adding the number of words recalled in free (given a weight of 3), cued (given a weight of 2), and multiple choice (given a weight of 1) recall, with a score ranging from 0 to 15; the Executive Index Score, calculated by adding the raw scores from the Trail Making Test part B, clock drawing, digit span forward and backward, A tapping, serial-7 subtraction, letter fluency, and abstraction items, and producing a score ranging from 0 to 13; the Visuospatial Index Score, calculated by adding the raw scores of the cube copy, clock drawing, and naming items, producing a score ranging from 0 to 7; the Language Index Score, calculated by adding the raw scores for naming, sentence repetition, and letter fluency, producing a score ranging from 0 to 6; the Attention Index Score, calculated by adding the raw scores for digit span forward and backward, vigilance (tapping when the letter A appeared in a string of letters read aloud), serial-7 subtraction, sentence repetition, and both immediate recall trial words, producing a score ranging from 0 to 18; and, lastly, the Orientation Index Score, ranging from 0 to 6, is calculated by summing the orientation items from the MoCA (Julayanont et al., 2014). All indices along with the total MoCA score were good statistically significant predictors of conversion from intact cognition to MCI and AD with the exception of the Language Index Score (Julayanont et al., 2014).

The Rey Auditory Verbal Learning test (RAVLT) is a list learning task that measures immediate memory, total learning, recall after a distracter task, recall after a 20 minute delay, and recognition. Administration took approximately 10-15 minutes excluding the 20 minute delay. A list of 15 words was read aloud at the rate of one per second. The participant was asked to repeat as many words as they could remember in any order. This was done four more times with a fixed order of presentation for the 15 words for a total of five learning trials. A second list of 15 new words was then presented and the participant was asked to recall as many words as they could in any order from the second list. Immediately following this the participant was asked to recall as many words as they could from the list that was presented five times. After a 20 minute delay the participant was asked to recall the words a final time. They were then presented with a recognition task consisting of a list of 50 words containing the 30 words they had seen from the two lists as well as 20 new words that were phonemically or semantically similar to the words they had been presented with previously (Strauss et al., 2006).

The Geffen norms from Strauss et al. (2006, pp. 795-6) were used as these encompassed the entire age range of participants in the present study. These norms are age and gender corrected as no age corrected only norms could be found for this task. The mean number of words recalled and pooled standard deviations were calculated for each age group collapsing across gender and the resulting means and standard deviations were used to norm the raw scores on this task. Cronbach alpha was high for the total score (*r* = .90), test-retest reliability at one year was 0.60 for the fifth learning trial and 0.70 for delayed recall, and delayed recall scores have high correlations with total learning scores (*r* > .75; Strauss et al., 2006). The Palta and colleagues (2014) meta-analysis found larger effect sizes for the RAVLT as compared to the California Verbal Learning Test and a memory test should be included in assessment of individuals with T2DM (Hachinski et al., 2006).

The Trail Making Test measures processing speed (Part A) and cognitive flexibility/shifting (Part B), the cognitive abilities most severely affected by T2DM (Monette et al., 2014). Administration took approximately 5 minutes unless there were severe impairments on the task. The participant was asked to connect numbers from 1 to 25 that were randomly placed on the page in ascending order (Part A) and then connect numbers and letters in the same fashion, alternating between the two (Part B, Strauss et al., 2006). The time to completion raw score for parts A and B were converted to a T-score adjusted for age according to norms from the CNNS (Schretlen et al., 2010). Test-retest reliability was adequate in most healthy and clinical populations evaluated (Strauss et al., 2006). Part A and Part B were moderately correlated (*r* = .31), which suggests the two parts measure similar although somewhat different abilities (Strauss et al., 2006).

The Salthouse Perceptual Comparison Test is a comparison task that can be used as a measure of processing speed (Schretlen et al., 2010). The task is timed and sensitive to mild difficulties with processing speed. The task also has a low motor demand, only requiring the participant to make same or different judgments and indicating their response by writing “S” or “D.” This was valuable to the present study as individuals with T2DM are more impaired on tasks of processing speed with motor task demands (more representative of psychomotor efficiency) versus orally presented processing speed tasks (more representative of central processing speed, Monette et al., 2014). There were four conditions, two letter conditions, one with 3 letters and one with 6 letters, each completed for 30 seconds, and two pattern conditions, one with 3 line patterns and one with 6 line patterns, each completed for 30 seconds. The score was the number of correct responses achieved in each of the 30 second trials. The raw scores were converted to a T-score adjusted for age according to norms from the Calibrated Neuropsychological Normative System (CNNS, Schretlen et al., 2010).

The Digit Span test was used to measure attention (digit span forward) and working memory (digit span backwards, Schretlen et al., 2010). Participants heard a string of digits of increasing length over several trials and they were required to repeat them exactly as heard (forward) or in reverse order (backward). The scores were the longest digit string recalled for each condition. The raw scores were converted to a T-score adjusted for age according to norms from the CNNS (Schretlen et al., 2010).

The Color-Word Interference Test from the Delis-Kaplan Executive Function System (D-KEFS, Delis et al., 2001) was used to measure processing speed (trial 1 & 2), inhibition (trial 3), and inhibition and switching (trial 4), all abilities moderately affected by T2DM (Monette et al., 2014). Trial 1 required participants to name the colour of ink patches as quickly as possible. Trial 2 required participants to read colour words printed in black ink as quickly as possible. Trial 3 required participants to name the colour of ink a colour name was printed in as quickly as possible; the colour name did not match the colour of ink. Trial 4 required participants to complete the same task as trial 3 in addition to reading the colour word of items contained inside a box, but continuing to name the colour ink for items not contained inside a box. Time to completion was the raw score for all 4 trials. The raw scores were converted to a scaled score adjusted for age according to norms from the D-KEFS (Delis et al., 2001).

The verbal fluency task used the letters F, A, and S to measure phonemic fluency and the category animals to measure semantic fluency; both abilities are components of executive functioning. The participant was asked to name as many words as they could in one minute that begin with the letter F, then A, then S. They could not name proper names of people, places, or things and they could not name the same word with a different ending. They were then asked to name as many animals as they could in one minute (Strauss et al., 2006). Tombaugh and colleagues (1999) reported high internal consistency ($\alpha = .83$) and acceptable test-retest reliability over a 5.6 year re-test period ($r = .74$). They also reported that animals named had a correlation of .52 with FAS scores. The norms from Tombaugh et al. were used in the present study. These norms were age and education corrected as no age corrected only norms could be found for this task. The mean number of words named and pooled standard deviations were calculated for each age group collapsing across education levels and the resulting means and standard deviations were used to norm the raw scores on this task.

The Hopkins Adult Reading Test–A (HART–A) is a list of 34 irregularly pronounced words and a single letter that can be used as an estimate of premorbid intellectual abilities (Schretlen et al., 2009). The participant was asked to read the 35 items aloud and was given credit for each item correctly read and pronounced. Cronbach alpha for the HART-A was high at .93 and the correlation of the short-form HART-A to the 70 word long-form HART was .98 (Schretlen et al., 2009). Test-retest reliability over a 4-6 year period was high at .94. The raw score was converted to an age corrected Full-Scale IQ score as per norms from the CNNS (Schretlen et al., 2010).

The Rapid Estimate of Adult Literacy in Medicine – Short Form (REALM-SF) was used to estimate health literacy, a possible covariate in analysis of the relation between cognitive abilities and DSMB (Emery et al., 2010). The REALM-SF is a seven item list of medically related words that provides an estimated grade level of reading for health literacy based on how many of the seven words are read and pronounced correctly (0 words < 3rd grade, 1-3 words = 4th - 6th grade, 4-6 words = 7th - 8th grade, and 7 words > 9th grade, Arozullah et al., 2007). The REALM-SF and the long-form 66 item REALM correlated highly with each other at 0.94 and had excellent agreement between assigned grade-levels (Arozullah et al., 2007). The REALM-SF correlated highly with the Wide Range Achievement Test – Revised total index score at 0.83 (Arozullah et al., 2007). The validation sample included ethnic minorities and older adults. The HART-A and the REALM-SF took approximately 10 minutes to administer.

The Behavioral Rating Inventory of Executive Functions – Adult Version (BRIEF-A) was included as it is a standardized self-report inventory of behaviours related to executive functioning, the cognitive domain that should be assessed most thoroughly in individuals with T2DM (Hachinski et al., 2006). Executive functioning is a broad category of cognitive abilities that organize and direct the domains of cognitive functioning, emotional responses, and behaviour (Roth et al., 2005). The BRIEF-A contains a number of scales that query different aspects of executive functioning, including Inhibition, Shifting, Emotional Control, Initiation, Working Memory, Planning/Organizing, Organization of Materials, Self-Monitoring, and Task Monitoring

(Roth et al., 2005). These scales were combined to form three summary indices, the Behavioural Regulation Index, the Metacognition Index, and the Global Executive Composite. The BRIEF-A has 75 items and higher scores indicate more difficulties with executive functioning. It took 10-15 minutes to complete. The BRIEF-A has excellent internal consistency (Cronbach α ranging from .93 to .96 for the three major indices and from .73 to .90 for the individual clinical scales) and test-retest reliability for an average one month interval (ranging from r = .93 to .94 for the three major indices and from .82 to .93 for the individual clinical scales, Roth et al.). Expert consensus was used to assess content validity, and convergent and divergent validity was good (Roth et al., 2005).

Table 1
Summary of neuropsychological test scores and measured cognitive abilities and domains in the present study

Measure	Score	Cognitive Ability	Domain
MoCA	Total score	N/A	Overall cognitive functioning (this is a screener for MCI)
RAVLT	Trial 1 total words recalled	Working memory	Executive functioning
	Total number of words recalled after five learning trials	Learning and immediate recall	Memory
	Total number of words recalled after a distractor task (trial 6)	Immediate recall after distractor	Memory
	Total number of words recalled after a 20 minute delay (trial 7)	Delayed recall	Memory
	List A recognition total number of words	Recognition	Memory

Trail Making Test	Part A total time to completion	Processing Speed	Processing Speed
	Part B total time to completion	Cognitive flexibility/shifting	Executive functioning
Salthouse Perceptual Comparison Test	Number of correct responses in 60 seconds (letters)	Processing Speed	Processing Speed
	Number of correct responses in 60 seconds (patterns)	Processing Speed	Processing Speed
Digit Span Test	Longest digit sequence recalled forward	Attention	Attention
	Longest digit sequence recalled backward	Working Memory	Executive functioning
Color-Word Interference Test	Trial 1 time to completion	Processing Speed	Processing Speed
	Trial 2 time to completion	Processing Speed	Processing Speed
	Trial 3 time to completion	Inhibition	Executive functioning
	Trial 4 time to completion	Inhibition/Shifting	Executive functioning
FAS and Animals verbal fluency	Total number of words named for F, A, and S trials	Phonemic verbal fluency	Executive functioning
	Total number of animals named	Semantic verbal fluency	Executive functioning

DSMB measures. Three measures of DSMB were used in the present study: the Self-Management Profile for Type 2 Diabetes (SMP-T2D), the Summary of Diabetes Self-Care Activities (SDSCA), and the Diabetes Self-Management Questionnaire (DSMQ), see Appendix 2). These three measures of DSMB were used as each measure includes unique domains of DSMB including the domains shown to be negatively impacted by cognitive deficits discussed earlier. The three measures also use different approaches to asking about DSMB. In addition, combining scores that measure the same DSMB domains across measures allowed for a more reliable estimate of each of the behaviours each domain measures. Each of the three measures will now be discussed. Scores from each measure and how they were averaged for the data analysis are summarized in Table 2.

The Self-Management Profile for Type 2 Diabetes (SMP-T2D) is a 12-item scale and required 3-5 minutes to complete. It measures four dimensions of diabetes self-management: blood glucose monitoring, medication taking, healthy eating, and engaging in physical activity (Peyrot et al., 2012). Four scores are produced; there is no summary score for the scale (Peyrot et al., 2012) Participants were asked to indicate completion of behaviours over the past week. The questions on the SMP-T2D are asked in a way that queries the number of days participants missed completing DSMB, instead of asking them to report a lack of compliance in completing required behaviours with the assumption that participants would be more likely to report the former over the latter (Peyrot et al., 2012).

Content validity of the SMP-T2D was assessed by literature review, interviews with 49 individuals with T2DM, an expert panel composed of experts in epidemiology and diabetes care, and a pilot study with a sample of 83 individuals with T2DM (Peyrot et al., 2012). Criterion validity was poor with correlations between the four content areas and A1C falling between -.03 and .07 (Peyrot et al., 2012). This is not unusual. A1C is the “Gold Standard” measure for diabetes management. However A1C, because blood glucose levels are variable in T2DM, is known to correlate poorly with other indicators of diabetes management, such as self-reported DSMB and random and fasting blood glucose levels (Walker & Usher, 2003). Construct validity was good with all convergent and divergent a priori hypotheses being supported at statistically significant levels. Cronbach's alpha was high with a median of .80 and a range of .71 to .87 across content areas. Test-retest reliability was good for a 1 week interval (r = .83, Peyrot et al., 2012). The SMP-T2D was found to be the psychometrically strongest DSMB measure in a recent review of DSMB measures (Caro-Bautista et al., 2014).

The Summary of Diabetes Self-Care Activities (SDSCA) is an 11-item scale with 6 supplemental scale items. It took 6-8 minutes to complete. It is the most widely used measure of DSMB in the literature (Schmitt et al., 2013). The five core self-management domains are diet (which has a general diet subscale and a specific diet subscale), exercise, blood glucose testing, foot care, and smoking. Smoking was queried during the intake interview; therefore this item was omitted from the questionnaire. The supplemental domain used in the present study is medication taking (Toobert et al., 2000). Participants were asked to report on how many of the past 7 days they completed the queried behaviours. Toobert and colleagues reported numerical psychometric properties for an earlier version of the scale, but not for the revised version that will be employed in the current study. They reported that the items of the revised scale were chosen because they showed consistent mean values across studies, lack of ceiling or floor effects, temporal stability, internal consistency, predictive validity, sensitivity to change, ease of scoring, and ease of interpretation (Toobert et al., 2000).

Caro-Bautista and colleagues (2014) reviewed the first version of the SDSCA and found the measure to have good content validity, intermediate internal consistency, and poor criterion and test-retest reliability. As with the SMP-T2D, the poor criterion validity was due to limitations in A1C as "Gold Standard" comparison criterion measure (Schmitt et al., 2013). The revised version of the SDSCA was the only DSMB measure to meet all the criteria for recommended use in another review of DSMB measures (Eigenmann et al., 2009). Schmitt and colleagues reported a Cronbach alpha of .63 for the revised version of the SDSCA. The Cronbach alphas for two of the four diet items representing the general diet subscale, and for the exercise, blood glucose testing, and foot care domains ranged from .69 to .88. The two other diet items representing the specific diet subscale had a Cronbach alpha of .15 (Schmitt et al., 2013). As such, the current study only used the two general diet subscale items leading to a final scale of 10 items (8 core [smoking item also omitted] and 2 supplemental). Schmitt and colleagues also reported adequate test-retest reliability. In the present study the SDSCA produced five scores; there is no summary score for the SDSCA.

The Diabetes Self-Management Questionnaire (DSMQ) is a 16 item scale that took 4-6 minutes to complete (Schmitt et al., 2013). Participants were asked to rate on a 4-point scale how much each of the 16 statements related to self-care activities applied to them when thinking back over the past 8 weeks. The DSMQ measures four domains: glucose management (includes medication and blood glucose monitoring), dietary control, physical activity, and health care use (attending diabetes-related medical appointments). The DSMQ was developed specifically to be correlated with A1C level, the "Gold Standard" criterion measure (Schmitt et al., 2013). All 16 items on the DSMQ negatively correlated with A1C indicating lower A1C when better diabetes self-care was reported, as would be expected. Fourteen of the 16 items had statistically significant correlations with A1C level (mean $r = -.23$, $SD = 0.09$, range = -.09 to -.38). Cronbach alpha for the overall scale was .84, and ranged from .6 to .77 for individual subscales (Schmitt et al., 2013).

The DSMQ provided five scores, one for each of the four domains and a total score for the measure. Exploratory and confirmatory factor analyses confirmed the four factor structure of the DSMQ (Schmitt et al., 2013). The authors suggested that the significant correlation of the DSMQ total score with A1C ($r = -0.38$, $p < 0.001$), in contrast to the lack of significant associations of the SDSCA and the DSMQ with A1C, was due to differences in conceptualization of DSMB among the three measures and to differences in the time frame participants were asked to address. The DSMQ included questions about self-care behaviours and about attending medical appointments as opposed to only questions about self-management behaviours as the other two measures did. The queried timeframe of the DSMQ was eight weeks versus one week for the SDSCA and SMP-T2D. These differences allowed for a more reliable estimate of self-care behaviours and for a better predictor of A1C levels (Schmitt et al., 2013).

Participants were asked to bring to the assessment a spouse or caregiver who was knowledgeable about the participant's diabetes treatment regimen. The spouse or caregiver completed a modified and combined version of the DSMB measures (see Appendix 2) while the participant was completing the assessment. There were only seven informants in the present study. All informants were spouses of the participants. Given the small number of informants and high incidence of missing data due to "don't know" responses, informant data were not analysed in the present study.

Table 2

Summary of DSMB scores provided by each measure and used in the analyses

Measure	Domain Score
SMP-T2D	Medication
	Blood glucose monitoring
	Diet
	Physical Activity
SDSCA	Medication
	Blood glucose testing
	General diet
	Exercise
	Foot care
DSMQ	Medication
	Blood glucose monitoring
	Diet
	Physical activity
	Healthcare use
	Total Score
Average score used in analysis	**DSMB measures included in average score**
DSMB Medication	SMP-T2D and SDSCA medication scores; DSMQ medication excluded (Cronbach's α=.876)
DSMB Blood Glucose	SMP-T2D, SDSCA, and DSMQ blood glucose monitoring scores (Cronbach's α=.881)
DSMB Diet	SMP-T2D and DSMQ diet scores; SDSCA diet excluded (Cronbach's α=.756)
DSMB Exercise	SMP-T2D, SDSCA, and DSMQ exercise scores (Cronbach's α=.913)
SDSCA Foot Care	Not an average score
DSMQ Healthcare Use	Not an average score
DSMQ Total Score	Not an average score

Note. Average scores were calculated in the following way: First, individual scores from each DSMB measure were converted to z-scores; Second, the mean of z-scores for each average DSMB score was calculated; Finally, this score was converted to a t-score for ease of interpretation; DSMQ medication was excluded from the Medication average score due to poor internal consistency (Cronbach's α=.664 when included). SDSCA diet was excluded from Diet average score due to poor internal consistency (Cronbach's α=.553 when included)

Diabetes-related Quality of Life measure. The Audit of Diabetes Dependent Quality of Life (ADDQoL) was developed to measure overall QoL and the impact of diabetes on QoL. The ADDQoL allowed participants to indicate the impact of their diabetes on 19 aspects of life, to indicate whether the impact is positive or negative, as well as to indicate the perceived importance of each of the QoL aspects. It took approximately 10 minutes to complete. There was one general item that queried current QoL and 19 subsequent items that queried various life domains and the impact of diabetes on these domains, including leisure, work, relationships, self-image, finances, and independence (Bradley & Speight, 2002). The newest version of the ADDQoL19, which was used in the present study, included simplified instructions, questions, and wording (Bradley, 2012). The ADDQoL19 was chosen as it is a well validated measure of the impact of diabetes on QoL across multiple relevant life domains (Ostini et al., 2012). In addition, diabetes specific QoL measures have been found to be more valid and reliable measures of QoL in individuals with diabetes when compared to general and health-related QoL measures (El Achhab et al., 2008).

Ostini and colleagues (2014) reported that three reviews have found that the ADDQoL is a reliable instrument with good face and content validity. In their study, using the Multitrait-Multimethod approach, they reported that the ADDQoL19 has good construct validity; a priori hypotheses were supported and analyses demonstrated convergent and divergent validity (Ostini et al., 2014). Internal consistency of items was very high (α = .95, Ostini et al., 2014).

Mood measures. Measures of depression symptoms were given to participants as depression symptoms have been shown to impact DSMB completion (Lin et al., 2004) and continuous measures of depression symptoms capturing subclinical symptom levels have been shown to better predict the impact of depression on DSMB completion than a diagnosis of MDD (Gonzalez et al., 2016).

The Geriatric Depression Scale - Short-Form (GDS-SF) is a 15 item screening measure for depression symptoms in older adults that employs a yes/no answer format that is easier for those with cognitive deficits, lower education, or less proficiency with English to understand and complete (Edelstein et al., 2010). The participant was asked to indicate if they had experienced symptoms of depression in the past week. The GDS-SF took 5-7 minutes to complete. The GDS-SF has high internal consistency ($\alpha = .88$). The correlation between the GDS-SF and the 30 item long-form is .89 and the two measures have similar sensitivity and specificity (Edelstein et al., 2010). The raw scores were converted to a T-score adjusted for age according to norms from the CNNS (Schretlen et al. 2010).

The Depression Anxiety Stress Scale – Short-form (DASS-21) is a 21 item screening measure for depression, anxiety, and stress symptoms (Lovibond & Lovibond, 1995). It was beneficial to measure anxiety and stress symptoms in the current study as individuals with T2DM experience higher levels of anxiety and stress than those without T2DM (de Groot et al., 2016; Emery-Tiburcio et al., 2015) and these symptoms could impact DSMB completion and diabetes-related QoL. The participant was asked to rate how much each statement has applied to them in the past week on a 4-point scale (0-3). The DASS-21 took approximately 8 minutes to complete. The 42 item long-form of the DASS has strong psychometric properties (Carmin & Ownby, 2010). The DASS-21 has been found to have good internal consistency, excellent convergent validity, and good discriminant validity (Carmin & Ownby, 2010). The raw scores were converted to a z-score according to norms from the DASS manual (Lovibond & Lovibond, 1995).

Both the GDS-SF and the DASS-21 were used in the present study as neither measure was originally developed and validated to assess mood symptoms for the entire age range of participants in the present study, although, subsequent studies have shown that the GDS-SF can be used with younger adults (Rule et al., 1989; Sivrioglu et al., 2009) and that the DASS-21 can be used with older adults (Gloster et al., 2008). Differences in depression symptom levels reported using both measures were investigated.

Analyses

Descriptive statistics were reported based on raw scores for all data and age-corrected standardized scores for the neuropsychological and mood measures based on the norms described above for each measure. Normed age-corrected scores from the neuropsychological measures were used in all analyses to minimize error as the sample was not large enough to use covariates. The REALM-SF was not included in the analyses as all but two participants had a medical literacy level of equal to or greater than a Grade 9 level. The other two participants had a medical literacy level equivalent to a Grade 8 reading level. None of the measures used in the study required a reading level greater than Grade 8. All variables for which paired t-tests and repeated measures ANOVAs were done were recoded if the variables were not measured on the same scale. Associations between the demographic and disease variables and the DSMB and QoL scores were analysed and reported along with the descriptive statistics for these variables.

The first research question was answered by analysing the Pearson *r* correlations between all measures of cognitive functioning and the average DSMB scores. The second research question was answered by analysing the Pearson *r* correlations between diabetes-related and general QoL and all measures of cognitive functioning and the average DSMB scores. The potential difference between the two measures of depression symptoms was analysed. Lastly, additional exploratory analyses were completed to investigate potential differences on the three measures of processing speed administered in the study and also potential differences between the objective neuropsychological tests and the self-report behavioural data provided by the BRIEF. Measures of effect size (r^2, Cohen's d, ω^2) were calculated and reported where appropriate.

Assumptions and missing data. The statistical assumptions for t-tests, ANOVAs, and correlations were evaluated. There were no outliers (defined as a z-score greater or lesser than 3.29, Tabachnick & Fidell, 2007) on most variables used in the analysis. The MoCA Orientation scale had two extreme scores (both $z = -3.397$) and the DSMQ Healthcare Use score had one extreme score ($z = -3.965$). However in both instances, these outliers did not represent actual extreme values in the population. For the MoCA Orientation scale, the outliers are individuals who scored 5/6 whereas every other participant scored 6/6. For the DSMQ Healthcare Use score, the outlier reported relatively lower health-care use than the rest of the participants in the sample. Most participants scored 10/10 for health care use, the outlier scored 5.56/10. Ceiling effects for both of these variables are concordant with the sample in the present study having been drawn from healthy community dwelling adults attending their maintenance medical appointments. Given this, the outliers were not removed from the analyses.

Normality was investigated using multiple methods which included inspection of histograms, use of the Shapiro-Wilks test, and inspection of skewness and kurtosis values. All variables in the analyses satisfied the assumption of normality except for the MoCA Orientation scale and the DSMQ Healthcare Use score. Both variables had elevated negative skew (greater than |2|) and positive kurtosis (greater than |3|). These violations are due to the ceiling effects discussed above and thus the variables were not transformed. Interpretation of significant findings involving these two variables took into account the fact that these variables contain outliers and were not normally distributed.

Bivariate scatter plots were inspected for every pair of variables for which Pearson *r* correlations coefficients were calculated. The linearity and homoscedasticity assumptions were satisfied for all correlations in the analysis based on acceptably linear and homoscedastic patterns in the scatter plots. Levene's test was used to evaluate the homogeneity of variances assumption for the independent t-tests and the one-way ANOVAs. For the independent t-tests, if Levene's test was significant, the equal variance not assumed *t* statistic was reported and interpreted where necessary. For the one-way ANOVAs, Levene's test was not significant for all ANOVAs except for the Employment Status ANOVA with DSMB Exercise and Diabetes-related QoL as the dependent variables. However, in both instances, the largest variance was less than four times larger than the smallest variance. Mauchly's test of sphericity was not significant for all repeated measures ANOVAs except for the one with medication as the outcome variable. For this test, the Greenhouse-Geisser corrected statistic was interpreted.

Three participants had scores missing from one or two of the three DSMB measures that comprised the average DSMB scores. Two participants were missing scores for the SDSCA and DSMQ medication score and one participant was missing a score for the DSMQ blood glucose score. For these three participants, the average DSMB score was calculated from the one or two available scores. One participant who did not take medication had missing data for all three DSMB measures for the medication score. Thus, all analyses involving the DSMB Medication score have a sample size of 25 participants. These were the only missing data in the prospective study. All statistical analyses were completed using the Statistical Package for the Social Sciences (SPSS) version 22.

CHAPTER III
PROSPECTIVE STUDY RESULTS

Descriptive statistics were calculated for all demographic, health, and diabetes-related variables, as well as, all neuropsychological, DSMB, Mood, and QoL measures. These are reported first. Next, relationships between the demographic, health, diabetes-related variables, and mood measures with the measures of DSMB and QoL were evaluated. Following this, correlations between the neuropsychological measures and the DSMB measures were calculated to answer the first research question. Correlations between the DSMB and neuropsychological measures and the QoL measures were then calculated to answer the second research question. Next, comparisons of scores on the depression and processing speed measures were done to answer questions about the possible differences due to the age of the participants for the depression measures and to the differing motor demands of the processing speed measures. Finally, additional exploratory analyses were conducted comparing scores on self-report and performance based neuropsychological measures of processing speed.

Descriptive Statistics

The descriptive statistics for the demographic, health, and diabetes-related variables for the 26 participants are found in Table 3. All data were self-reported except for BMI, most recent A1C, medications taken, and pre-testing blood glucose. BMI was calculated from self-reported most recent height and weight measurements. All but two participants completed high school. The study sample overall was highly educated and overwhelmingly of white race and Canadian ethnicity. On average the sample had a BMI classified in the obese range, low levels of reported current and chronic pain, low levels of comorbid conditions as measured by the CCI, A1C levels slightly above the 7% target range, and pre-testing blood glucose in the hyperglycemic range.

Table 3

Descriptive statistics for demographic, health, and diabetes-related variables (N=26)

Variable	N(%)[a]	Mean (SD)	Min-Max
Demographic			
Age		62.12 (12.599)	41-83
Years of Education		14.46 (2.642)	9-22
Female Gender	11(42.3)		
Ethnicity [b]			
White or Canadian	25(96.2)		
Eastern European	1(3.8)		
Birthplace[b]			
Canada	25(96.2)		
Eastern Europe	1(3.8)		
Language spoken day-to-day[b]			
English	25(96.2)		
French, but fluent in English	1(3.8)		
Employed			
Yes	9(34.6)		
No	3(11.5)		
Retired	14(53.8)		
Partnered			
Single, Divorced, or Widowed	9(34.6)		
Married or Cohabitating	17(65.4)		
Informant Present	7(26.9)		
Health and diabetes-related			
Smokes Cigarettes[b]	2(7.7)		
Drinks Alcohol	11(42.3)		
BMI (kg/m^2)		33.700 (6.648)	19.0-44.9
Current Pain 0-9 scale[c]		1.63 (2.287)	0-7
Chronic Pain 0-9 scale[c]		2.00 (2.884)	0-9
Total score on CCI[c]		1.08 (1.294)	0-4
Previous Psychiatric Dx[b]	4(15.4)		
Hospitalized Past Year[b]	3(11.5)		
Past Diabetes Education[b]	26(100)		
Diabetes Duration in years		13.04 (10.204)	1-36
Most Recent A1C (%)[c]		7.185 (1.225)	5.0-10.6
Hospitalized for Hypo[b]	1(3.8)		
Reported T2DM Complication	7(26.9)		
Treatment Modality			
Diet & Exercise	3(11.5)		
Medication only	9(34.6)		
Medication & Insulin	14(53.8)		

Other Medication			
High Cholesterol	21(80.8)		
Hypertension	24(92.3)		
Hypothyroid	7(26.9)		
Cardiovascular	5(19.2)		
Elevated Uric Acid	2(7.7)		
Acid Reflux	7(26.9)		
Arthritis	3(11.5)		
HRT	1(3.8)		
Fibromyalgia	2(7.7)		
Anxiety	1(3.8)		
Depression	5(19.2)		
Aspirin 81mg	12(46.2)		
Blood Glucose Pre-Testing (mmol/l)[c]		10.131 (3.491)	5.2-18.6

Note. BMI: Body Mass Index; CCI: Charlson Comorbidity Index; DASS: Depression Anxiety Stress Scale; Dx: Diagnosis; GDS: Geriatric Depression Scale; Hypo: Hypoglycemia; HRT: Hormone Replacement Therapy

[a]All percentages indicate a yes response or the response is included in the variable label unless otherwise indicated or there are multiple groups

[b]Not enough variability in answers to perform analyses for associations with DSMB and QoL

[c]Higher scores indicate worse symptoms, worse diabetes control, or greater comorbidity

Table 4 contains the average raw and normed scores for all neuropsychological tests administered. The estimated Full-Scale IQ of the sample based on the Hopkins Adult Reading Test (HART) was in the high average range. Twelve participants scored below the cut-off on the Montreal Cognitive Assessment (MoCA), indicating possible cognitive impairment. However, all mean scores on all neuropsychological tests were in the average range as per the age-corrected norms except for the majority of the memory measures from the Rey Auditory Verbal Learning Test (RAVLT), which were in the low average range. The norms used for the RAVLT in the present study could have underestimated the performance of participants on this measure as compared to other available norms (Strauss et al, 2006); however, the norms used in the present study were the only norms that encompassed the entire age range of participants recruited in the study. Thus, the sample on average is cognitively intact based on their performance on the objective neuropsychological measures.

The participants reported difficulties with executive functioning that fell within the low average range for most indices of the Behavioral Rating Inventory of Executive Functions (BRIEF) in contrast to their average range performance on the objective measures of executive functioning. The proportion of participants that scored below 1.5 standard deviations from the mean varied by measure, was generally low overall (less than 15% of the sample for the majority of scores), and was highest for the RAVLT and BRIEF scores.

Table 4
Descriptive statistics for neuropsychological measures and questionnaires (N=26)

Test	Mean(SD)[a]	Sample Min-Max	Test Min-Max	Mean (SD)[b]	N(%) of people 1.5 SD below the mean
MoCA					
Total Score	24.769 (2.717)	18-30	0-30		12 (46.2)
Memory Index	11.192 (2.638)	6-15	0-15		
Executive Index	11.038 (1.661)	7-13	0-13		
Visuospatial Index	6.038 (0.916)	4-7	0-7		
Language Index	4.885 (1.107)	3-6	0-6		
Attention Index	16.115 (1.840)	12-18	0-18		
Orientation Index	5.923 (0.272)	5-6	0-6		
RAVLT					
Trial 1	4.192 (1.415)	0-7	0-15	-0.973 (1.024)	6 (23.1)
Trial 5	9.038 (2.705)	3-14	0-15	-0.817 (1.245)	9 (34.6)
Total Learning	36.077 (9.952)	18-57	0-75	-0.966 (1.093)	9 (34.6)

List B	4.115 (1.840)	1-8	0-15	-0.535 (1.219)	7 (26.9)
Trial 6	7.077 (3.224)	1-12	0-15	-0.700 (1.363)	7 (26.9)
Trial 7	6.385 (2.872)	1-12	0-15	-0.811 (0.912)	7 (26.9)
Recognition Hits	11.731 (2.376)	6-15	0-15	-0.142 (1.053)	3 (11.5)
Salthouse					
Letter	25.731 (6.792)	14-40	0-64	48.692 (10.810)	2 (7.7)
Pattern	35.769 (9.066)	21-53	0-64	52.192 (11.795)	3 (11.5)
Total	61.500 (15.321)	36-93	0-128	49.808 (11.541)	3 (11.5)
TMT A[c]	39.485 (15.512)	17.370-92.160	0-300	46.962 (9.374)	3 (11.5)
TMT B[c]	90.434 (35.272)	32.750-207.580	0-300	49.346 (9.604)	3 (11.5)
Longest Digit Span					
Forward	5.962 (1.113)	5-9	0-9	45.808 (8.971)	0 (0)
Backward	4.346 (1.263)	2-7	0-8	44.308 (10.921)	5 (19.2)
Total	10.308 (1.934)	8-15	0-17	44.077 (9.125)	4 (15.4)
D-KEFS Colour-Word					
Condition 1[c]	31.692 (5.485)	23.110-42.440	0-90	10.269 (2.393)	0 (0)
Condition 2[c]	23.532 (3.797)	18.000-33.330	0-90	10.423 (2.452)	1 (3.8)
Condition 3[c]	64.897 (15.375)	42.620-107.870	0-180	10.308 (2.936)	3 (11.5)
Condition 4[c]	76.509 (24.055)	41.600-148.280	0-180	9.577 (3.580)	3 (11.5)
F A S Total	34.231 (11.931)	15-58	0- No Max.	-0.463 (1.107)	4 (15.4)
Animals Total	19.077 (5.699)	9-31	0- No Max.	0.203 (1.299)	4 (15.4)
HART-A	24.654 (5.314)	11-34	0-35	116.000 (10.092)	0 (0.000)
BRIEF					

Inhibit[d]	11.846 (2.588)	8-17	8-24	53.692 (8.615)	4 (15.4)
Shift[d]	10.423 (2.469)	6-15	6-18	60.192 (11.154)	11 (42.3)
Emotional Control[d]	16.654 (4.390)	10-27	10-30	58.538 (12.166)	9 (34.6)
Self-Monitor[d]	9.769 (2.388)	6-15	6-18	55.231 (11.119)	4 (15.4)
Initiate[d]	14.154 (3.484)	8-21	8-24	61.500 (12.744)	11 (42.3)
Working Memory[d]	13.808 (3.175)	9-20	8-24	62.000 (12.060)	10 (38.5)
Plan/Organize[d]	15.615 (4.158)	10-27	10-30	57.038 (12.472)	8 (30.8)
Task Monitor[d]	10.192 (2.433)	6-15	6-18	58.462 (11.951)	7 (26.9)
Organization of Materials[d]	12.692 (4.231)	8-22	8-24	53.500 (13.453)	5 (19.2)
Behaviour Regulation[d]	48.692 (9.303)	30-70	30-90	58.423 (10.871)	6 (23.1)
Metacognition[d]	66.462 (15.039)	42-104	40-120	61.500 (15.895)	7 (26.9)
Global Executive Composite[d]	115.154 (22.632)	72-158	70-210	59.808 (11.696)	8 (30.8)

Note. BRIEF: Behavioral Rating Inventory of Executive Functions; D-KEFS: Delis-Kaplan Executive Function System; HART-A: Hopkins Adult Reading Test–A; MoCA: Montreal Cognitive Assessment; RAVLT: Rey Auditory Verbal Learning Test; TMT: Trail Making Test
[a]Raw scores
[b]Normed scores
[c]Higher raw scores indicate worse performance
[d]Higher raw and normed scores indicate worse self-rated performance

Table 5 contains the average scores on all measures of Diabetes Self-Management Behaviours (DSMB). Reported completion of DSMB was highest for medication taking and healthcare use, followed by blood glucose testing and dietary control. Reported completion was lowest on average for exercise and foot care. There were significant differences between reported blood glucose testing (p = .037) and exercise (p < .001) DSMB completion across the three measures of DSMB (see Table 5). There were significant differences between medication (*t(22)* = 2.545, *p* = .018, *d* = .531) and blood glucose (*t(25)* = -2.296, *p* = .024, *d* = .470) on the SDSCA and SMP-T2D. Participants reported significantly higher medication taking on the SDSCA compared to the SMP-T2D and the reverse for blood glucose testing with significantly higher reported DSMB completion on the SMP-T2D compared to the SDSCA.

Table 5
Descriptive statistics for DSMB (N=26)

	SDSCA		SMP-T2D		DSMQ			
	Mean(SD)	Min-Max	Mean(SD)	Min-Max	Mean(SD)	Min-Max	F(*df*)	*p*
Medication	9.658 (.641) [a]	7.86-10	9.257 (1.245) [b]	5.71-10	8.913 (2.336) [a]	0-10	1.628[c] (*1.196, 26.308*)	.208
Blood Glucose	6.566 (3.458)	0-10	7.857 (3.435)	0-10	7.111 (2.740) [b]	1.11-10	3.536 (*2, 48*)	.037
Diet	7.006 (2.250)	0-10	6.154 (2.807)	0-10	6.026 (1.875)	2.50-10	1.869 *(2, 50)*	.165
Exercise	4.506(3.527)	0-10	3.828 (2.709)	0-10	6.368 (3.072)	0-10	19.312 (*2, 50*)	<.001
Foot Care	4.121 (3.448)	0-10						
HealthCare Use					9.530 (1.002)	5.56-10		
Total Score					7.360 (1.319)	4.62-10		

Notes. Diabetes Self-Management Behaviour (DSMB) scores are out of 10; SDSCA: Summary of Diabetes Self-Care Activities; SMP-T2D: Self-Management Profile for Type 2 Diabetes; DSMQ: Diabetes Self-Management Questionnaire
[a]N=23
[b]N=25
[c] Greenhouse-Geisser correction applied

Table 6 contains the descriptive statistics for the Audit of Diabetes Dependent Quality of Life (ADDQoL), the Depression Anxiety Stress Scale (DASS-21), and the Geriatric Depression Scale (GDS-SF). Average diabetes-related quality of life (DRQoL) showed a slightly negative impact of diabetes on QoL with a mean level of DRQoL of 8.539. No impact of diabetes on QOL is equivalent to a score of 9 on the ADDQoL. The mean general quality of life (GQoL) for the sample was good at 5.269. The midpoint of 4 represents neither good nor bad GQoL on the ADDQoL.

The mean score on the GDS-SF was below the cut-off of 5 indicating that on average the participants did not report elevated symptoms of depression on this measure. The mean scores of the DASS-21 Depression and Anxiety scales were in the mild symptom range. The mean score of the DASS-21 Stress scale was in the normal range.

Table 6
Descriptive statistics for ADDQoL and Mood (N=26)

	Raw Mean (SD)	Sample Min-Max	Test Min-Max	Normed Mean(SD)
ADDQoL DRQoL	8.539 (1.096)	6.33-9.89	0-12	
ADDQoL GQoL	5.269 (.827)	4-7	0-7	
GDS[a]	4.461 (3.972)	0-14	0-15	62.846 (11.915)
DASS Depression[a]	11.153 (11.651)	0-42	0-42	.738 (1.651)
DASS Anxiety[a]	8.308 (6.757)	0-22	0-42	.695 (1.308)
DASS Stress[a]	10.769 (8.140)	0-28	0-42	.064 (1.041)

Notes. ADDQoL: Audit of Diabetes Dependent Quality of Life; DASS: Depression Anxiety Stress Scale; DRQoL: Diabetes-related Quality of Life; GDS: Geriatric Depression Scale; GQoL: General Quality of Life
[a]Higher scores indicate worse symptoms

Relationships Between DSMB and QoL with Demographics and Health Variables

Relationships between the demographic, health, diabetes-related variables, and mood with the DSMB and QoL measures can be found in Table 7. There were no significant relationships or differences between any DSMB or QoL measures and years of education, employment status, between participants who had informants come with them and those who did not, reported current and chronic pain, CCI score, and pre-testing blood glucose level.

The age of participants was significantly correlated with blood glucose testing ($r = .446$, $p = .023$, $r^2 = .199$) with blood glucose DSBM completion increasing with increasing age. Participants differed significantly on blood glucose testing ($t(15.767) = 2.164$, $p = .046$, $d = .958$), healthcare use ($t(10.658) = 2.252$, $p = .046$, $d = 1.080$), and total ($t(24) = 2.629$, $p = .015$, $d = 1.085$) DSMB completion by gender. For all three behaviours the men performed their DSMBs significantly more often than the women. Participants who were in a domestic partnership completed their foot care DSMB significantly more often than participants who did not report having romantic partners ($t(24) = 2.304$, $p = .030$, $d = .989$). Participants who drank alcohol at least once a month had significantly worse foot care DSMB completion than participants who did not drink alcohol ($t(22.154) = -2.357$, $p = .028$, $d = .989$). Total DSMB completion scores were significantly correlated with BMI ($r = -.488$, $p = .011$, $r^2 = .238$). As BMI increased, total DSMB completion decreased.

Geriatric Depression Scale scores correlated significantly with exercise ($r = -.399$, $p = .043$, $r^2 = .159$) and total ($r = -.419$, $p = .033$, $r^2 = .176$) DSMB completion, as well as with general QoL ($r = -.758$, $p < .001$, $r^2 = .575$). Higher reported depression symptoms on the GDS-SF were significantly related to lower exercise and total DSMB behaviour completion and lower general QoL. DASS-21 Depression scores were significantly correlated with general QoL ($r = -.682$, $p < .001$, $r^2 = .465$). As reported depression symptoms increased general QoL decreased. DASS-21 anxiety scores were significantly correlated with blood glucose DSMB completion (r = .409, p = .038, r^2 = .167), as well as with diabetes-related (r = -.430, p = .029, r^2 = .185) and general QoL (r = -.466, p = .016, r^2 = .217). Participants with higher reported anxiety symptoms were more likely to have higher blood glucose DSMB completion and significantly lower diabetes-related and general QoL. DASS-21 Stress scores were significantly correlated with general QoL (r = -.589, p = .002, r^2 = .347). Participants with higher reported stress symptoms were more likely to have significantly lower general QoL.

Diabetes duration was significantly correlated with exercise (r = -.412, p = .036, r^2 = .170) and foot care DSMB completion (r = .419 , p = .033, r^2 = .176), as well as with diabetes-related QoL (r = -.391, p = .048, r^2 = .153). Exercise DSMB completion and diabetes-related QoL decreased as diabetes duration increased, whereas foot care DSMB completion increased as diabetes duration increased. Most recent A1C level was significantly correlated with diet DSMB completion (r = -.450, p = .021, r^2 = .203) and general QoL (r = -.410, p = .037, r^2 = .168). As A1C level increased, diet DSMB completion and general QoL significantly decreased. Participants with reported diabetes complications significantly differed on healthcare use DSMB completion ($t(18)$ = 2.480, p = .023, d = .684) and on general QoL ($t(24)$ = -2.236, p = .035, d = -1.029). Participants with complications reported significantly higher healthcare use and significantly lower general QoL. Treatment modality was significantly related to blood glucose ($F(2,23)$ = 4.603, p = .021, ω^2 =.247), diet ($F(2,23)$ = 8.609, p = .002, ω^2 =.393), and exercise ($F(2,23)$ = 5.152, p = .014, ω^2 =.271) DSMB completion, as well as general QoL ($F(2,23)$ = 5.156, p = .014, ω^2 =.271). Blood glucose DSMB completion was highest for participants taking both medication and insulin, followed by those using diet and exercise to treat their T2DM, and was lowest for individuals who only take medication. Diet DSMB completion was highest for participants using diet and exercise to treat their T2DM, followed by those who only take medication, and was lowest for individuals taking both medication and insulin. Exercise DSMB completion was highest for participants using diet and exercise to treat their T2DM, followed by those who only take medication, and was lowest for individuals taking both medication and insulin. Finally, general QoL was highest for participants using diet and exercise to treat their T2DM, followed by those who only take medication, and was lowest for individuals taking both medication and insulin.

Table 7
Significant relationships and differences between demographic, health, diabetes-related, and mood variables and DSMB and QoL (N=26)

Variable	1[a]	2	3	4	5	6	7	8	9
Demographic									
Age		*							
Years of Education									
Female Gender		*[b]				*[b]	*		
Employed									
Yes									
No									
Retired									
Partnered									
Single, Divorced, or Widowed					*				
Married or Cohabitating									
Informant Present									
Health and diabetes-related									
Drinks Alcohol					*[b]				
BMI							*		
Current Pain[c]									
Chronic Pain[c]									
Score on CCI[c]									
GDS[c]				*			*		**
DASS Depression[c]									**
DASS Anxiety[c]		*						*	*
DASS Stress[c]									**
Diabetes Duration				*	*			*	

Most Recent A1C[c]			*						*
Reported T2DM Complication						*[b]			*
Treatment Modality		*	**	*					*
Diet & Exercise									
Medication only									
Medication & Insulin									
Blood Glucose Pre-Testing (mmol/l)[c]									

Note. Continuous variables are correlations with DSMB and QoL; Dichotomous variables are independent t-tests with DSMB and QoL; Categorical variables with more than 2 groups are One-way ANOVA with DSMB and QoL; The Ethnicity, Birthplace, Language spoken day-to-day, Smokes Cigarettes, Previous Psychiatric Diagnosis, Hospitalized Past Year, Past Diabetes Education, and Hospitalized for Hypoglycemia variables were not included in the analyses as there is not sufficient variability to permit reliable comparisons; 1: DSMB Medication; 2: DSMB Blood Glucose; 3: DSMB Diet; 4: DSMB Exercise; 5: SDSCA Foot Care; 6: DSMQ Healthcare Use; 7: DSMQ Total Score; 8: ADDQoL Diabetes-related QoL; 9: ADDQoL General QoL; BMI: Body Mass Index; CCI: Charlson Comorbidity Index; DASS: Depression Anxiety Stress Scale; GDS: Geriatric Depression Scale

[a]N=25

[b]Equal variances not assumed t-value interpreted

[c]Higher scores indicate worse symptoms, worse diabetes control, or greater comorbidity

*p <.05

**p <.01

Correlations Between Neuropsychological Measures and DSMB

The correlations between DSMB and the neuropsychological measures calculated to answer the first research question can be found in Table 8. Medication DSMB completion was significantly correlated with the BRIEF Initiate (r = -.639, p = .001, r^2 = .408) and Metacognition (r = -.400, p = .047, r^2 = .160) scales. Increasing difficulties with initiation and metacognition were significantly related to decreasing medication DSMB completion. Blood glucose DSMB completion was significantly correlated with FAS total score (r = .577, p = .002, r^2 = .333) and the BRIEF Inhibit (r = .449, p = .021, r^2 = .202), Emotional Control (r = .459, p = .018, r^2 = .211), and Behaviour Regulation (r = .413, p = .036, r^2 = .171) scales. Better performance on the FAS was significantly related to increased blood glucose DSMB completion. Increasing difficulties with inhibition, emotional control, and behaviour regulation were significantly related to greater blood glucose DSMB completion. Diet DSMB completion was significantly correlated with BRIEF Emotional Control (r = -.436, p = .026, r^2 = .190), Self-Monitor (r = -.439, p = .025, r^2 = .193), Initiate (r = -.440, p = .025, r^2 = .194), and Behaviour Regulation (r = -.425, p = .031, r^2 = .181) scales. Increasing difficulties with emotional control, self-monitoring, initiation, and behaviour regulation were significantly related to decreasing diet DSMB completion. There were no significant correlations between Exercise and Foot Care DSMB completion and the neuropsychological measures. Healthcare Use DSMB completion was significantly correlated with the MoCA Orientation score (r = .515, p = .007, r^2 = .265). Increasing Healthcare Use was significantly related to better orientation MoCA scores. Total DSMB completion was significantly correlated to BRIEF Plan/Organize (r = -.422, p = .032, r^2 = .178) and Metacognition (r = -.421, p = .032, r^2 = .177) scales. Increasing difficulties with planning, organizing, and metacognition were significantly related to decreasing total DSMB completion.

Correlations of Neuropsychological Measures and DSMB with QoL

The correlations between DSMB and neuropsychological measures with Diabetes-Related and General QoL that were calculated to answer the second research question can be found in Table 8. Regarding the correlations between DSMB and QoL, Blood Glucose DSMB completion was significantly correlated to Diabetes-Related QoL (r = -.514, p = .007, r^2 = .264). Increasing blood glucose DSMB completion was significantly related to decreasing diabetes-related QoL. Total DSMB completion was significantly correlated with General QoL (r = .418, p = .034, r^2 = .175). Increasing total DSMB completion was significantly related to increasing general QoL.

As for the correlations between the neuropsychological measures and the QoL, Diabetes-Related QoL correlated significantly with recognition memory on the RAVLT (r = .493, p = .011, r^2 = .243). Higher scores on recognition memory were significantly related to higher levels of diabetes-related QoL. General QoL correlated significantly with TMT A (r = .460, p = .018, r^2 = .212), TMT B (r = .562, p = .003, r^2 = .316), and D-KEFS Colour-Word Trial 1 (r = .528, p = .006, r^2 = .279) scores. Better performance on all three neuropsychological measures was significantly related to better general QoL. Finally, General QoL correlated significantly with all but one of the scales of the BRIEF (Shift: r = -.470, p = .015, r^2 = .221; Emotional Control: r = -.555, p = .003, r^2 = .308; Self-Monitor: r = -.594, p = .001, r^2 = .353; Initiate: r = -.450, p = .021, r^2 = .202; Working Memory: r = -.565, p = .003, r^2 = .319; Plan/Organize: r = -.451, p = .021, r^2 = .203; Task Monitor: r = -.563, p = .003, r^2 = .317; Organization of Materials: r = -.487, p = .012, r^2 = .237; Behavioural Regulation: r = -.618, p = .001, r^2 = .382; Metacognition: r = -.643, p < .001, r^2 = .413; and Global Executive Composite: r = -.635, p < .001, r^2 = .403). Increasing reported difficulties with abilities measured by each scale were significantly related to poorer general QoL. Overall, reported general QoL decreased in the presence of poorer processing speed and executive functioning abilities.

Table 8
Pearson r correlations between neuropsychological measures, DSMB, and QoL (N=26)

	DSMB Medication[a]	DSMB Blood Glucose	DSMB Diet	DSMB Exercise	SDSCA Foot Care	DSMQ Healthcare Use	DSMQ Total Score	ADDQoL DRQoL	ADDQoL GQoL
ADDQoL									
DRQoL	-.174	-.514**	.112	.152	.081	.240	.024	1	.317
GQoL	.212	-.079	.352	.300	.277	.159	.418*	.317	1
MoCA									
Total Score	-.060	.324	-.249	-.019	-.166	.203	.169	-.082	.082
Memory Index	.149	.204	-.188	.083	-.131	.120	.103	-.169	-.153
Executive Index	-.269	.229	-.279	-.229	-.328	.038	-.072	-.036	.021

Visuospatial Index	-.219	.343	-.063	-.071	-.251	.214	.198	-.142	.197
Language Index	.189	.319	-.132	.060	-.035	.109	.189	.077	.166
Attention Index	.043	.291	-.107	.057	-.055	.223	.242	.126	.163
Orientation Index	-.175	-.208	-.083	.014	-.288	.515**	.198	.349	-.082
RAVLT									
Trial 1	.261	.146	.078	.180	.018	-.353	.100	-.257	-.159
Trial 5	.082	.098	-.255	.115	-.160	.082	.148	.112	.094
Total Learning	-.006	.183	-.305	.134	-.150	-.074	.152	.113	.171
List B	-.113	.194	-.200	.034	-.102	-.159	-.033	-.082	.086
Trial 6	-.086	-.050	-.210	.172	-.257	.118	.131	.245	.127
Trial 7	.015	-.049	-.126	.236	-.121	.099	.216	.261	.217
Recognition Hits	.040	-.131	-.107	.039	.268	.195	.153	.493*	.226
Salthouse									
Letter	-.033	.378	-.143	-.140	-.099	-.018	.033	.132	.184
Pattern	-.024	.103	-.209	.059	-.158	.158	.122	.250	.220
Total	.002	.257	-.163	-.038	-.139	.053	.095	.187	.215
TMT A	.175	.174	.201	.029	-.118	-.106	.101	-.008	.460*
TMT B	-.047	.120	-.009	.176	.094	-.006	.189	.213	.562**
Longest Digit Span									
Forward	.000	.181	.085	-.083	-.219	.088	.201	-.041	.293
Backward	-.086	.065	-.096	.159	.058	.156	.176	.149	.088
Total	-.125	.152	-.011	.009	-.064	.174	.211	.085	.209
D-KEFS Colour-Word									
Condition 1	.263	.303	-.082	.112	.127	.055	.256	.193	.528**
Condition 2	.147	.205	.012	.041	.113	-.115	.067	.072	.158
Condition 3	-.178	.215	-.023	.130	-.226	-.160	-.107	.080	.080
Condition 4	-.252	.091	-.221	.025	-.226	.079	-.022	.042	.108
F A S Total	.059	.577**	-.189	-.016	-.018	-.101	.071	-.143	.114
Animals Total	.116	.379	-.205	-.193	-.153	-.215	-.028	.023	.040
HART-A	-.033	.190	-.284	-.196	.077	-.176	-.234	.007	.000
BRIEF									
Inhibit	.237	.449*	-.259	.153	-.034	.086	.158	-.195	-.257
Shift	-.216	-.075	-.157	-.294	-.154	-.341	-.386	-.070	-.470*
Emotional Control	-.072	.459*	-.436*	-.376	-.082	-.244	-.335	-.208	-.555**
Self-Monitor	-.264	.245	-.439*	-.275	-.075	-.090	-.386	-.229	-.594**
Initiate	-.639**	.150	-.440*	-.383	-.196	.061	-.313	-.020	-.450*
Working Memory	.011	-.011	.014	.046	.122	-.254	-.252	-.099	-.565**
Plan/Organize	-.380	.026	-.223	-.197	-.289	-.308	-.422*	-.076	-.451*
Task Monitor	-.225	.244	-.130	-.049	-.174	-.267	-.226	-.238	-.563**
Organization of Materials	-.225	.073	-.321	-.160	-.115	-.081	-.285	-.198	-.487*
Behaviour	-.100	.413*	-.425*	-.294	-.110	-.214	-.316	-.245	-.618**

Regulation									
Metacognition	-.400*	.093	-.381	-.196	-.214	-.180	-.421*	-.074	-.643**
Global Executive Composite	-.260	.245	-.351	-.244	-.143	-.213	-.361	-.202	-.635**

Note: DRQoL: Diabetes-related Quality of Life; GQoL: General Quality of Life
[a]N=25
*p <.05
**p <.01

Comparisons of Depression Measures

The comparison of the two depression symptom measures used in the present study can be found in Table 9. The difference between the GDS-SF and the DASS-21 depression scores was not significant when comparing non-age-corrected GDS-SF scores to the DASS-21 depression scores, which do not have age-corrected norms (see Table 9). However, when the age-corrected GDS-SF scores were compared to the non-age-corrected DASS-21 depression scores the difference became statistically significant (see Table 9) with participants reporting significantly higher levels of depression symptoms on the GDS-SF when compared to the DASS-21. The magnitude of the difference was moderate (d = .484).

Table 9
Comparison of depression measure scores

		t(25)	*p*	Cohen's *d*
GDS –DASS Depression	Age corrected GDS	2.467	.021	0.484
	Non-age-corrected GDS	1.946	.063	0.381

Note. DASS: Depression Anxiety Stress Scale; GDS: Geriatric Depression Scale

Comparisons of Processing Speed Measures

Participants' scores on the measures of processing speed were compared due to the differing motor and visual scanning task demands of the processing speed tasks. TMT A has the greatest motor and visual scanning task demands, followed by the Salthouse Letter test. C-W Trial 2 has no motor component and requires the least amount of visual scanning compared to the TMT A and the Salthouse Letter test. The TMT A, the Salthouse Letter, and the C-W Trial 2 tests all use letters or words as the test stimuli. Participants performed progressively worse on the measures of processing speed as motor and visual scanning demands increased (see means in Table 10). However, the difference was only statistically significant when comparing the most demanding task (TMT A) to the least demanding task (CW Trial 2). The magnitude of the difference was moderate (d = -.487).

Table 10
Comparisons of processing speed measures with differing motor and visual scanning demands

	$t(25)$	p	Cohen's d
TMT A - Salthouse Letter	-0.929	0.362	-0.182
TMT A - CW Trial 2	-2.467	0.021	-0.487
Salthouse Letter - CW Trial 2	-1.586	0.125	-0.311
Test	Mean (SD)		
TMT A	46.962 (9.374)		
Salthouse Letter	48.692 (10.810)		
CW Trial 2	51.519 (8.213)		

Note. CW: Colour Word; TMT: Trail Making Test

Comparisons of Self-report and Performance Based Neuropsychological Measures

Self-report BRIEF scores were compared to the performance based neuropsychological tests that measure equivalent cognitive abilities. For all comparisons, participants scored lower on the self-report BRIEF measures compared to their scores on the performance based neuropsychological measures (see means in Table 11). However, the differences were only statistically significant for both shifting ability comparisons (see Table 11). The magnitude of the shifting ability differences was moderate to large (see Cohen's d values in Table 11).

Table 11

Exploratory comparisons of BRIEF scores to corresponding cognitive abilities

	t(25)	*p*	Cohen's *d*
CW Trial 3 - BRIEF Inhibit	1.584	0.126	0.311
CW Trial 4 - BRIEF Shift	2.719	0.012	0.533
TMT B - BRIEF Shift	3.578	0.001	0.702
RAVLT Trial 1 - BRIEF Working Memory	0.696	0.493	0.137
LDSB - BRIEF Working Memory	1.959	0.061	0.384

Test	Mean (SD)
BRIEF Inhibit	46.308 (8.615)
CW Trial 3	51.192 (9.744)
BRIEF Shift	39.808 (11.154)
CW Trial 4	48.721 (11.993)
TMT B	49.346 (9.604)
BRIEF Working Memory	38.000 (12.060)
RAVLT Trial 1	40.268 (10.245)
LDSB	44.308 (10.921)

Note. BRIEF scores were reverse scored so that higher scores indicated better performance; Means and SD were reported as T-scores; BRIEF: Behavioral Rating Inventory of Executive Functions; CW: Colour Word; LDSB: Longest Digit Span Backwards; RAVLT: Rey Auditory Verbal Learning Test; TMT: Trail Making Test

CHAPTER IV
PROSPECTIVE STUDY DISCUSSION

The prospective study sought first to determine the relationship between cognitive abilities and DSMB completion and second to determine the relationship between cognitive functioning and DSMB completion with diabetes-related and general QoL. Due to the small sample size, these relationships were investigated using univariate statistics within the context of the prospective study being an exploratory study. Scores on the DSMB measures will be discussed first. Next, the correlations between DSMB and the neuropsychological measures answering the first research question and the correlations between DSMB and the neuropsychological measures with diabetes-related and general QoL answering the second research question will be discussed. Finally, the results encompassing the depression measures, the processing speed tests, and the objective and self-report measures of executive functioning will be discussed. Study strengths and limitations will conclude the prospective study discussion. Future directions are discussed throughout where relevant.

DSMB Measures

Reported completion of DSMB in this study was highest for medication taking and healthcare use, followed by blood glucose testing and dietary control. Reported completion was lowest on average for exercise and foot care. These results are in line with reported rates of completion of each domain of DSMB in the literature where medication adherence is highest, followed by blood glucose testing, dietary control, physical activity, and foot-care (Ahola & Groop, 2013; Gillani, 2012; Gonzalez et al., 2016). However, the percentage of the sample reporting successfully completing their DSMB is higher than what has been reported in the literature (Ahola & Groop, 2013;

Gillani, 2012; Gonzalez et al., 2016). The reported healthcare use was high in this study compared to reported rates in the literature (Gillani, 2012). This is likely an artifact of the sample having been recruited from the offices where they attend their healthcare appointments.

The questions on the SDSCA ask on how many of the past 7 days DSMB were completed whereas the SMP-T2D asks on how many of the past 7 days the participant missed completing their DSMB with the assumption that individuals are more likely to report missing the completion of their DSMB due to difficulties rather than report a lack of compliance in completing their required behaviours (Peyrot et al., 2012). In the present study, this assumption held true for medication, diet, and exercise DSMB where reported rates of DSMB completion were higher on the SDSCA as compared to the SMP-T2D, although the differences were only statistically significant for medication DSMB completion. The assumption was not supported for blood glucose DSMB completion. Reported rates of blood glucose DSMB completion were statistically significantly higher on the SMP-T2D as compared to the SDSCA.

To the best of the researcher's knowledge this was the first study to use multiple validated self-report measures of DSMB completion to investigate the relationships between DSMB completion and cognitive functioning. The finding of significant differences in self-reported DSMB completion across measures purporting to measure the same behaviours across the same time span (for SDSCA and SMP-T2D) in the same individual is noteworthy. In the present study, order effects and fatigue cannot be ruled out as the explanations for these significant differences; however, future research should investigate these differences. If the differences in self-reported DSMB completion across measures are replicated, self-report measures of DSMB will need to be revised to gain a more reliable measurement of self-reported DSMB completion.

Correlations Between Neuropsychological Measures and DSMB

There were only two statistically significant relationships between DSMB completion and the objective neuropsychological measures. First, there was a significant relationship between phonemic verbal fluency and blood glucose DSMB completion with higher scores on FAS correlating with increased blood glucose DSMB completion. Phonemic verbal fluency is a measure of executive functioning (Strauss et al., 2006) that is sensitive to the cognitive dysfunction present in T2DM (Wong et al., 2014). This is the first study reporting a specific relationship between phonemic verbal fluency and blood glucose DSMB completion; however, other studies have linked better executive functioning to increased DSMB completion in those with T2DM (Asimakopoulou & Hampson, 2002; Gatlin & Insel, 2015; Primozic et al., 2012; Rosen et al., 2003; Thabit et al., 2009).

Second, there was a significant relationship between the MoCA Orientation Index and healthcare use DSMB completion. Better orientation was correlated with greater use of healthcare. Although being properly oriented to date and location is certainly necessary to attend healthcare appointments, this finding is likely an artifact of the ceiling effects in the data of both of these non-normally distributed variables. The individuals in the sample of the prospective study were relatively healthy community dwelling volunteers who were recruited while they were attending their healthcare appointments. Thus, the ceiling effects on the MoCA Orientation Index and the healthcare use DSMB completion measures are to be expected.

There were many statistically significant relationships between the BRIEF (a self-report measure of executive functioning) and DSMB behaviour completion. Increased medication DSMB completion was significantly related to lower reported difficulties with metacognition and specifically with initiation. The component abilities of metacognition-- initiation, working memory, planning, organization, and task monitoring-- are all required in order to successfully manage taking medication, especially when there are multiple medications that need to be taken at different times during the day (Emery et al., 2015; Koekkoek et al., 2015; Tomlin & Asimakopoulou, 2014; Wasserman et al., 2015). Increased diet DSMB completion was significantly related to lower reported difficulties with behaviour regulation and specifically with emotional control and self-monitoring. Disruptions in behaviour regulation, especially in emotional control, have been found to heavily influence diet DSMB completion, especially in those with depression and eating disorders (de Groot et al., 2016; Gonzalez et al., 2016).

Increased blood glucose DSMB completion was significantly related to increasing difficulties with behavioural regulation and specifically with inhibition and emotional control. This finding seems contradictory; however, given that those with T2DM do not test their blood glucose as frequently when they have good A1C levels and do not take insulin (SMBG International Working Group, 2008), it is possible that individuals with poorer disease management (higher A1C values and requiring insulin), possibly due to poorer behavioural regulation, are testing their blood glucose more often than those with better disease management. There was a positive correlation between A1C level and blood glucose DSMB completion in the present study indicating that participants with higher A1C levels (worse glycemic control) reported increased blood glucose DSMB completion, although the correlation was not statistically significant ($r = .179$, $p > .05$). However, there was a statistically significant difference between individuals managing their T2DM with insulin and those using only medication or diet and exercise ($t(24) = 2.861$, $p = .009$, $d = 1.171$) with those taking insulin reporting significantly greater blood glucose DSMB completion. Finally, increased total DSMB completion was significantly related to lower reported difficulties with metacognition and specifically with planning and organization. As with medication DSMB completion, the component abilities of metacognition are all required in order to successfully complete all DSMB (Emery et al., 2015; Koekkoek et al., 2015; Tomlin & Asimakopoulou, 2014; Wasserman et al., 2015).

To the best of the researcher's knowledge, the present investigation was the first study to use a self-report measure of executive functioning to investigate the relationship between executive functioning abilities and DSMB completion. Given that executive functioning abilities are essential to successful DSMB completion (Vincent & Hall, 2015; Wasserman et al., 2015), and the limits of standardized performance-based neuropsychological tests of executive functioning in predicting behaviour and functional outcomes such as DSMB completion (Chaytor et al., 2006), the inclusion of self-report measures of executive functioning in investigations of DSMB completion should occur much more frequently. Further, standardized performance based measures of executive functioning almost exclusively measure the metacognitive aspects of executive functioning, whereas the BRIEF measures the behaviour regulatory and emotional control aspects of executive functioning in addition to the metacognitive aspects (Roth et al., 2005). Given the relationships between behaviour regulation and emotional control and DSMB completion in the present study and the higher prevalence of depression and anxiety in those with T2DM (de Groot et al, 2016), it will be necessary in future studies to assess both the metacognitive and behavioral regulatory aspects of executive functioning to gain a complete understanding of the effects of executive dysfunction on DSMB completion.

The validated BRIEF scales are based on self-reported difficulties completing concrete behaviours as opposed to the abstract deficits measured by objective neuropsychological tests (Roth et al., 2005). Clinicians working with individuals with diabetes who have difficulties completing their DSMB could use their patient's self-reported difficulties from the BRIEF scales as a starting point to develop individually tailored interventions to increase DSMB completion. These kinds of individually tailored patient-centered interventions have been found to be the most effective in increasing DSMB completion (Johnson & Marrero, 2016). Psychologists are well trained to develop and deliver these interventions provided they receive training in the disease process and psychosocial and cognitive effects of diabetes. This training is becoming increasingly available (Hunter, 2016).

The majority of the correlations between the neuropsychological measures and DSMB completion were not significant in the present study. First and foremost, this is due to the small sample size and low power to detect significant relationships. However beyond this limitation, every study investigating the relationships between cognitive functioning and DSMB completion in individuals without dementia has reported null findings (Asimakopoulou & Hampson, 2002; Compeán-Ortiz et al., 2010; Gatlin & Insel, 2015; Primozic et al., 2012; Rosen et al., 2003; Thabit et al., 2009). The review and meta-analyses of cognitive functioning in individuals with T2DM (Monette et al., 2014; Palta et al., 2014; van den Berg et al., 2009; Vincent & Hall, 2015) have reliably found cognitive deficits in individuals with T2DM in all cognitive abilities and domains ranging from .20 - .45 standard deviations units. Impairments in the completion of complex daily activities such as DSMB completion are not usually expected until an individual's cognitive impairments are approximately 1.5 standard deviations below the mean (Albert et al., 2011). Further, individuals with T2DM with small decrements in cognitive functioning within the range found in the meta-analyses of cognitive functioning in T2DM are not likely to have new difficulties with DSMB completion due to these cognitive deficits (Koekkoek et al., 2015). Cognitive impairment is not likely to produce changes or increasing difficulties in DSMB completion until it reaches the level of mild cognitive impairment or dementia (Koekkoek et al., 2015). This does not preclude the existence of difficulties with DSMB completion from relative weaknesses in cognitive functioning that have existed over the lifetime of the individual; however, these difficulties would be a target for individually tailored interventions and these idiosyncratic difficulties would likely be masked in group-based quantitative analyses. This assumption requires further research using qualitative methods.

The majority of participants in the present study scored above the threshold for cognitive impairment (1.5 standard deviations below the mean) on the neuropsychological measures (Table 4) and overall all scores on the neuropsychological tests were in the low average to average range. The sample size in the present study precludes the investigation of comparisons of DSMB completion of the individuals who scored above 1.5 standard deviations below the mean to those who scored 1.5 standard deviations below the mean. Future investigations should endeavour to do this given the many null findings in studies where participants do not have cognitive deficits at the level of dementia. The threshold of the level of cognitive deficits needed to impact DSMB completion must be identified in addition to the cognitive abilities and domains that most impact DSMB completion. Finally, the majority of significant relationships between the neuropsychological measures and DSMB completion came from the BRIEF scores. The largest proportion of individuals who scored in the range suggestive of possible cognitive impairment occurred on the BRIEF scales (Table 4). This finding provides preliminary evidence that the relationships between executive functioning and DSMB completion may only be present when deficits are greater on average than the .20 -.45 standard deviations below the mean that are observed in the T2DM population as a whole.

Correlations of Neuropsychological, DSMB, and Mood Measures with QoL

Neuropsychological measures and QoL. Better scores on TMT A, TMT B, and D-KEFS Colour-Word Trial 1 were significantly related to increasing general QoL. Increasing reported difficulties with all but one of the executive functioning abilities measured by the BRIEF scales was significantly related to poorer general QoL. Thus, general QoL was negatively impacted by poorer processing speed and executive functioning abilities. This finding is concerning as processing speed and executive functioning, especially shifting abilities measured by the TMT B, are the cognitive abilities with the greatest magnitude of impairment in the T2DM population (Monette et al., 2014; Vincent & Hall, 2015). However; to the best of the researcher's knowledge, this is the first study to investigate the relationships between cognitive functioning and general and diabetes-related QoL in individuals with T2DM using a large number of neuropsychological tests. Further research on these relationships and their impact on DSMB completion is needed.

DSMB, Mood, and QoL. More total DSMB completion was significantly related to better general QoL. This relationship is well established in the literature (Cochran & Conn, 2008; Gonzalez et al., 2016; Hunter, 2016). Increasing blood glucose DSMB completion was significantly correlated to decreasing diabetes-related QoL. Increased blood glucose testing has been shown to negatively impact QoL (Gonder-Frederick et al., 2016; Simon et al., 2008). Elevated depression symptom scores were significantly related to decreased exercise DSMB completion and general QoL. These relationships are also well established in the literature (Cochran & Conn, 2008; de Groot et al, 2016; Gonzalez et al., 2016).

Increased anxiety symptoms were significantly correlated to increased blood glucose DSMB completion and decreased diabetes-related and general QoL. As above, increased blood glucose testing has also been shown to increase anxiety symptoms (Gonder-Frederick et al., 2016; Simon et al., 2008). There is a 20% increase in the incidence of anxiety disorders in people with diabetes compared to those without diabetes; however, there have been no studies of routine screening for anxiety disorders in healthcare settings for patients with diabetes (de Groot et al., 2016). In the present study, 14 (53.8%) participants had anxiety symptoms in the normal range, 2 (7.7%) participants had anxiety symptoms in the mild range, 5 (19.2%) participants had anxiety symptoms in the moderate range, 3 (11.5%) participants had anxiety symptoms in the severe range, and 2 (7.7%) participants had anxiety symptoms in the extremely severe range as measured by the DASS-21. Anxiety symptoms are not equivalent to anxiety disorders; a diagnostic assessment would be required to diagnose an anxiety disorder. However, 38.4% of participants in the current study who were community dwelling volunteers reported moderate to extremely severe levels of anxiety symptoms. Four of the seven anxiety items of the DASS-21 query somatic symptoms that commonly occur in individuals with T2DM. This could be leading to an overestimation of anxiety symptoms in these individuals as measured by the DASS-21. Nevertheless, routine screenings of anxiety symptoms should be done in individuals with T2DM. Especially because individuals with anxiety and depression tend to believe that completing their DSMB will negatively impact their QoL (de Groot et al., 2016). This belief has been shown to be false as DSMB education and completion increase QoL (Cochran & Conn, 2008).

General QoL was measured using a single item measured on a 7-point Likert scale as this is how this construct is measured on the ADDQoL. Any findings in the present study relating to general QoL must be replicated using a validated measure of general QoL. It would also likely prove fruitful to investigate these relationships using a measure of health-related QoL that is not specific to diabetes given that many individuals with T2DM have medical comorbidities that could impact their health-related QoL.

Comparisons of Depression Measures

Scores on the two depression measures used in the current study were not significantly different when non-age-corrected scores were compared. However, when the age-corrected scores on the GDS-SF were compared to the non-age-corrected scores of the DASS-21, there was a significant difference in reported depression symptoms, with participants reporting significantly more depression symptoms on the GDS-SF as compared to the DASS-21. The GDS-SF was developed to assess depression symptoms in older adults (Edelstein et al., 2010) and given the significant differences may be more appropriate to use as a screening measure for depression symptoms in older adults with T2DM. The GDS-SF and DASS-21 contain equivalent numbers of items querying the somatic symptoms of depression. In individuals with T2DM it is essential to query whether self-reported symptoms on a depression screening measure are due to depression or are due to T2DM. This must be done as part of a diagnostic evaluation and cannot be determined solely from responses to a self-report depression screening measure (de Groot et al., 2016).

Comparisons of Processing Speed Measures

Participant's scores on three measures of processing speed were compared. Participant's performance worsened as motor and visual scanning task demands of the processing speed measures increased. The differences in performance were only significant for the task with the greatest motor and visual scanning task demands (TMT A) as compared to the task with the least motor and visual scanning task demands (C-W Trial 2). There were no significant differences between these two measures and the Salthouse Letter test, the measure with intermediate motor and visual scanning task demands.

This finding is salient for a couple of reasons. First, processing speed deficits are common in individuals with T2DM and processing speed tasks with motor demands show a larger magnitude of impairment than processing speed tasks with oral task demands (Monette et al, 2014). This is likely due to deficits in psychomotor efficiency caused by the peripheral neurological changes common in those with T2DM impacting performance on processing speed tasks with higher motor demands (Awad et al., 2004).

Greater visual scanning demands could also impact performance on processing tasks in individuals with T2DM who have impaired vision due to retinopathy (Awad et al., 2004). These conflations of processing speed with psychomotor efficiency and visual scanning may lead to overestimated processing speed deficits in individuals with T2DM. This is problematic as peripheral and central neurological changes due to T2DM may not co-occur in the same individual (Manschot et al., 2008). Second, the TMT A is a commonly used measure of processing speed in clinical neuropsychological assessments (Strauss et al., 2006). If the TMT A is used as the only measure of processing speed in a neuropsychological assessment of an individual with T2DM, processing speed deficits may be overestimated especially if the person has peripheral nerve damage due to diabetes complications. For these reasons, performance on measures of processing speed with differing motor and visual scanning task demands warrants further study in individuals with T2DM to determine the magnitude of these differences. This research could inform test selection for neuropsychological assessment with individuals with T2DM. For now, clinicians should strive whenever possible to administer more than one measure of processing speed with differing task demands when assessing individuals with T2DM.

Comparisons of Self-report and Performance Based Neuropsychological Measures

Comparisons were made between the self-report BRIEF scores and the performance based neuropsychological tests that measure the same cognitive abilities. For all comparisons, participants scores were lower on the self-report BRIEF measures compared to their scores on the performance based neuropsychological measures. However, the only statistically significant differences were for both shifting ability comparisons. This is important because shifting abilities have some of the largest magnitudes of impairments relative to other cognitive abilities in individuals with T2DM (Monette et al., 2014; Vincent & Hall, 2015) and participants' self-reported difficulties with shifting abilities exceeded those measured by the objective measures in the present study. The meaning and mechanisms of these differences in self-report and objective measures of shifting abilities and executive functioning more broadly in individuals with T2DM requires further study.

Individuals with T2DM are self-reporting difficulties with executive functioning that may not be detected with objective neuropsychological tests, and the effects of these impairments on DSMB completion may be missed when working clinically with individuals with T2DM. This has the potential to impact diabetes management outcomes given the many significant correlations of BRIEF scale scores with DSMB completion and QoL in the present study. In addition, setting aside the assumption that the self-report measure is detecting deficits that the objective test may be missing, the situation remains that individuals with T2DM are reporting difficulties with executive functioning on self-report measures that correlate with DSMB completion. These difficulties could be improved through interventions that psychologists are well suited to develop and provide (Hunter, 2016). These interventions could increase DSMB completion in these individuals either directly by improving their executive functioning abilities or accommodating their executive functioning deficits, or indirectly by improving individual's self-efficacy and mood, both factors that can impact DSMB completion (de Groot et al., 2016; Gonzalez et al., 2016).

Strengths and limitations

This study has many strengths. To the best of the knowledge of the researcher, this was the first study to use multiple self-report measures of DSMB completion to investigate relationships with cognitive functioning and QoL and the relationships between self-reported completion on each of the DSMB measures. This was also the first study to assess the relationship between self-reported executive functioning abilities and DSMB completion, between self-reported depression symptoms on the GDS-SF and the DASS-21, and between cognitive functioning using a large number of neuropsychological tests and diabetes-related and general QoL in a T2DM sample.

The greatest limitation of the present study was the small sample size. The sample was also predominantly of white race and Canadian ethnicity, well-educated, and consisted mostly of volunteers recruited while attending their healthcare appointments. Thus, the sample as a whole had low average to average cognitive functioning, and reported higher levels of DSMB completion and QoL than would be expected from the T2DM population as whole (Ahola & Groop, 2013; Gillani, 2012; Gonzalez et al., 2016). This combined with the low power due to the small sample size likely resulted in under-detection of relationships between cognitive functioning, DSMB completion, and QoL.

This was an exploratory study and any significant relationships found must be replicated in future studies using larger samples and multivariate statistics to gain a more complete understanding of the relationships investigated in the present study. Given the small sample size, the relationships between cognitive functioning, DSMB completion, and QoL could not be investigated further by taking into account the effects of demographic, health, and diabetes-related variables other than age. However, in their review, van den Berg et al., (2009) reported that adjusting for risk factors other than age did not significantly change the results for the cognitive deficits found in individuals with T2DM. Further investigations are required to determine if this would be the case for the relationships between cognitive functioning, DSMB completion, and QoL. Age-corrected normed scores on the neuropsychological measures were used in the analyses to adjust for the effects of age on cognitive functioning. Not all tests were normed using the same normative sample and thus this could have led to differences in the corrections for age across neuropsychological measures. However, this is what is done in clinical settings and tests that were co-normed from the CNNS were used where possible in the present study.

CHAPTER V
ARCHIVAL STUDY METHOD

Participants and Procedures

The participants in the archival study came from the Health and Retirement Study (HRS) Core 2002 survey and the follow-up 2003 diabetes study (HRS, 2006). The HRS is an American national survey completed longitudinally. Prevalence rates of T2DM in Americans are comparable to those of Canadians (Canadian Institute for Health Information, 2015). Beginning in 1992, participants in the HRS have been surveyed every two years. A new cohort is added every six years; four cohorts have been added along with the original 1992 cohort. The survey is sponsored by the National Institute on Aging and managed by the University of Michigan. As of 2007, the survey was representative of the entire US population born before 1948 with a sample of more than 30 000 participants, although Americans of African and Latin descent/ethnicity were oversampled. Interviews were done with participants every two years in-person or over the phone. Participants over the age of 80 were given priority for in-person interviews. Interviews could be done with informants for participants who were unwilling or unable to complete the interview but consented to having an informant, usually a spouse or daughter, complete the interview on their behalf. Approximately 10% of the sample had informants who completed the interviews on behalf of the participant. The study collected detailed information on physical and mental health and demographic information, including entire surveys on economic, employment, marital, and family status and history, retirement planning, and use and access to public and private support systems available to older adults in the United States (further information is available at http://hrsonline.isr.umich.edu/).

In October 2003, a survey was sent in the mail to 2 350 participants who reported having diabetes in the HRS 2002 core survey. This survey queried self-reported information on diabetes treatment, self-management behaviours, and coping with living with diabetes. Participants were also asked to return a blood spot that would measure A1C. In total, 1 901 (80.894% response rate) and 1 233 (64.861% response rate) completed the survey and returned the A1C measure, respectively. The sample size for the present study was determined by the number of participants who met the inclusion and exclusion criteria for the study.

Inclusion criteria for the archival study consisted of: (a) 40 years of age or older, (b) diagnosis of T2DM for at least 1 year, (c) completion of the cognitive functioning, DSMB, and Impact of Diabetes in Life measures. Exclusion criteria for the archival study were as follows: (a) diagnoses of diabetes other than T2DM (i.e., T1DM or gestational diabetes) or if type of diabetes was unknown; (b) previous diagnosis of dementia or a score on the cognitive functioning measure that would be indicative of possible dementia; (c) not residing in the community; (d) an informant completed the interview from the 2002 core study, as there is no cognitive functioning data for participants; (e) an informant completed the 2003 diabetes survey. The inclusion and exclusion criteria for the archival study were less stringent than for the prospective study due to the larger sample size of the archival study, the greater availability of covariate variables, and the nature of the comorbidity measure included in the Diabetes study.

Of the 1901 individuals with T2DM that completed the 2003 diabetes survey individuals without T2DM (unknown: n = 248, T1DM: n = 50), with diabetes duration for less than one year (n = 17), that did not live in the community (n = 29), that had an informant complete the interview (n = 144), who had a previous diagnosis of dementia (n = 21), for whom there was no TICS total score (n = 494), with a score on the TICS indicating a possible dementia (≤ 8, n = 9), who had an informant complete the diabetes survey (n = 56), who did not complete the Impact of Diabetes in Life measure (n = 22) or who answered 5 or fewer questions on the Impact of Diabetes in Life measure (n = 24), and who did not complete any of the 4 DSMB outcome measures (n = 11) were excluded. After the inclusion and exclusion criteria were applied the number of individuals eligible for participation in the current study was 776 for the analyses without A1C and 565 for the analyses with A1C.

Measures

The most appropriate available measures present in the HRS datasets were chosen to parallel as closely as possible the measures in the prospective study.

Demographic and disease variables and the Total Illness Burden Index. The demographic and disease variables included in the analyses as covariates were age in years at the time of data collection, gender, race (white, black, other), annual household income, years of education, length of diabetes duration in years, previous completion of a diabetes education program, A1C level, type of diabetes treatment regimen (diet/exercise, oral medication, insulin, or oral medication and insulin), depression symptom level, body mass index, a diagnosis of elevated cholesterol, and score on the Total Illness Burden Index (TIBI).

The TIBI is an imputed variable representing a score of diseases comorbid with diabetes in 15 domains including organ systems affected by diabetes complications (Greenfield, et al. 1995). The TIBI is scaled from 0 to 100. Higher scores indicated greater severity of comorbidities. The measure was developed to be used in studies with functional status and quality of life outcomes as most measures of comorbidity are used to estimate mortality (Greenfield, et al., 1995). The 15 domains covered by the TIBI include: hearing loss, hypertension, nonspecific bowel disease, genitourinary problems, gastrointestinal autonomic neuropathy, foot disease, lower gastrointestinal disease, upper gastrointestinal disease, musculoskeletal problems, vision problems, congestive heart failure, chronic obstructive pulmonary disease, ischemic heart disease, renal disease, and neurological problems.

Cognitive functioning measure. Cognitive functioning was measured in the 2002 core survey using an abbreviated version of the Telephone Interview for Cognitive Status (TICS, Brandt et al., 1988, Breitner et al., 1995). The TICS was developed from the Mini-Mental State Examination (MMSE) to be used in telephone surveys to screen for cognitive impairment. The modified version used in the HRS has been shown to have good psychometric properties, including strong internal and construct validity (Ofstedal et al., 2006). The maximum achievable score was 35 with higher scores indicating better cognitive functioning. The total score was composed of immediate recall (max. 10 points), delayed recalled (max. 10 points), serial 7s (max. 5 points), counting backwards (max. 2 points), orientation (max. 4 points), and naming (max. 4 points).

DSMB measure. There were two DSMB measures present in the HRS 2003 diabetes study dataset. The first was based on the Summary of Diabetes Self-Care Activities (SDSCA, Schmitt et al., 2013; Toobert et al., 2000) described above in the DSMB measures section of the prospective study. Only the domains of medication/insulin intake, diet, and blood glucose testing were included in the HRS diabetes dataset and in the analyses in the current archival study. The average score for medication/insulin intake was used in the analyses. If there was only one score for either medication or insulin intake, this single score was used in the analyses in place of an average score. The second measure was adapted from the Diabetes Care Profile (Fitzgerald et al., 1996). Five items asked about DSMB completed over the past six months in the domains of medication taking, engaging in exercise, following a prescribed diet, measuring blood glucose levels, and checking feet. Participants were asked to rate: "Over the past six months, how difficult has it been to do each of the following exactly as the doctor who takes care of your diabetes suggested?" Each domain was measured on a Likert scale ranging from 1 to 5, with 1 = so difficult that I could not do it at all, and 5 = not difficult, I got it exactly right. A mean total score on this scale was used in the present study with higher scores indicating less difficulty with DSMB completion. Internal consistency for the total score was found to be adequate (α = .71, Heisler et al., 2007).

Impact of Diabetes in Life measure. This measure was developed specifically for use in the HRS 2003 diabetes study based on theoretical models for factors influencing diabetes treatment behaviours and attitudes (Heisler et al., 2007). It is a measure of the impact of diabetes on the life of the participant, in both functional and emotional domains. The questionnaire asked: "Which of the following diabetes issues are currently a problem for you?" Each question was measured on a Likert scale ranging from 1 to 5, with 1 = not a problem, and 5 = serious problem. A mean total score on this scale was used in the present study with higher scores indicating greater impact of diabetes on the participant's life. There were 10 items that asked about finding money to pay for medications, keeping up with commitments at work or at home, having goals for diabetes care, feeling discouraged by the diabetes treatment plan, coping with diabetes complications, restrictions on eating, uncomfortable interactions with family and friends, feeling overwhelmed by the diabetes treatment regimen, and worrying about low blood sugar and future diabetes complications.

Depression measure. The measure of depression symptoms present in the dataset was administered at the same time as the TICS. The measure is an 8-item questionnaire based on the 20-item Center for Epidemiologic Studies Depression Scale. Higher scores indicated greater severity of depression symptoms. The 8-item measure was found to be a valid single-factor measure of depression symptoms in older adults (Karim et al., 2014). The questionnaire queried yes/no responses to feeling depressed, happy (reverse scored), lonely, and sad, feeling like they could not get going, feeling that everything done is effortful, that sleep was restless, and that life was enjoyed (reversed scored) over the past week.

Analyses

Descriptive statistics were reported for all variables in the analysis along with Pearson *r* correlations between the DSMB subscales and total score and the TICS score, between the TICS score and the Impact of Diabetes in Life score, and between the DSMB subscales and total score and the Impact of Diabetes in Life score.

The first research question was answered using hierarchical MRAs to determine the relationship between each of the DSMB measures and cognitive functioning while accounting for variables known to be related to DSMB completion. The first step included demographic and disease variables that correlated significantly with each of the outcomes. The second step included the TICS score. The outcomes were medication, diet, blood glucose, or total DSMB completion. There were a total of six hierarchical MRAs done to answer the first research question, one with medication DSMB as the outcome, one with blood glucose DSMB as the outcome, two with diet DSMB as the outcome with and without A1C, and two with total DSMB as the outcome with and without A1C. The second research question also used hierarchical MRA to determine what predicts the impact of diabetes on life in individuals with T2DM. The first step included demographic and disease variables that correlated significantly with the outcome. The second step included the TICS score and the DSMB total score. The outcome was the Impact of Diabetes in Life measure. Two hierarchical MRAs were run to answer the second research question with and without A1C as a step one variable.

Missing data and dummy coding. There were missing data on many of the step 1 variables in the analyses. The data were not missing completely at random and thus imputing missing values would have biased the parameter estimates. A1C was the only continuous covariate with a large proportion of missing data. Separate hierarchical MRAs were done with and without A1C in step 1 for outcome variables that included A1C as a step 1 variable. Household income values were missing for 29.8% of the sample and diabetes duration values were missing for 14.9% of the sample. These variables were thus categorized in order to preserve as much data as possible. Household income was categorized as <20th percentile (below the poverty line for most households), >20th but < 50th, >50th percentile, and missing according to 2002 U.S. Census Bureau data for household income Table A-2 (https://www.census.gov/data/tables/2016/demo/income-poverty/p60-256.html). This was done given that individuals under the poverty line would be most likely to struggle financially and thus have household income possibly impact DSMB completion, followed by those between the 20th and 50th percentiles, as compared to individuals with household incomes above the 50th percentile. Diabetes duration was categorized as ≤ 5 years, ≥6 to ≤ 15 years, ≥ 16 years, and missing based on two studies showing that diabetes knowledge significantly differed for those with duration of ≤ 5 years compared to those with a duration of ≥6 years (Kassahun et al., 2016) and that individuals with diabetes durations of greater than >15 years have significantly higher risks of cardiovascular complications (Shah et al., 2010), both factors that could impact DSMB completion.

The remaining variables with missing data were missing values in small proportions (0.5 to 5.4%). Missing values were estimated based on the category those with missing values were most likely to belong to given base rates in the population and in the sample. For diabetes education, 42 individuals (5.4%) with missing values were assumed to have completed diabetes education. For diabetes treatment modality, 11 individuals (1.4%) with missing values were assumed to be taking only medication for their diabetes treatment management. For smoking status, 4 individuals (0.5%) with missing values were assumed to be non-smokers. For BMI, 7 individuals (0.9%) were missing values. The missing values all came from women in the sample, thus the median BMI for women in the sample (28.350) was substituted for the missing values for these participants. Finally for cholesterol level, 35 individuals (4.5%) with missing values were assumed to have elevated levels of cholesterol.

Each of the 8 hierarchical MRAs was run with and without the replaced missing values. There were no significant differences when replaced missing values were used as compared to running the analyses with list-wise case deletion except for when the cholesterol level variable was included in the analyses. As such, the 35 individuals with missing data on the cholesterol variable were excluded from the analyses as there was no other way to estimate missing values that would not bias the data. For all other variables with missing data, the missing values were replaced as described above for all analyses in an effort to preserve as much data as possible.

For the total DSMB and Diabetes Impact outcomes, some individuals did not complete every item that made up the total score for each measure. If individuals completed less than 60% of the items they were excluded from the study as described above. In order to preserve data and include individuals in the analyses who completed at least 60% of the items but had missing values on some items (n = 206 for total DSMB and n = 51 for diabetes impact); a mean score of completed items was calculated and then multiplied by 5 for the total DSMB scores and by 10 for the diabetes impact score. This resulted in a total score equivalent across all participants included in the analyses even if they had not answered every item on the total DSMB or diabetes impact measures.

Categorical step 1 variables were dummy coded to allow for inclusion as predictors in the hierarchical MRAs. Race was coded with white race as the baseline. There was one dummy coded variable comparing white individuals to black individuals and another variable comparing white individuals to individuals with an “other” race. Male gender was the baseline for the gender dummy coded variable. Household income was coded with income $>50^{th}$ as the baseline. There were three dummy coded variables: one comparing $<20^{th}$ percentile income to the $>50^{th}$ percentile income, one comparing $>20^{th}$ but $<50^{th}$ percentile income to the $>50^{th}$ percentile income, and one comparing individuals with missing values on household income to those with $>50^{th}$ percentile income. Not having received diabetes education was the baseline for the diabetes education dummy coded variable. Diabetes treatment modality was coded with those being treated with diet and exercise only as the baseline. There were three dummy coded variables: one comparing those taking medication only to those being treated with diet and exercise only, one comparing those taking insulin only to those being treated with diet and exercise only, and one comparing those taking both medication and insulin to those being treated with diet and exercise only. Diabetes duration was coded with those with a duration of ≥6 to ≤ 15 years as the baseline. There were three dummy coded variables: one comparing those with a duration of ≤ 5 years to those with a duration of ≥6 to ≤ 15 years, one comparing those with a duration of ≥ 16 years to those with a duration of ≥6 to ≤ 15 years, and one comparing those with missing values to those with a duration of ≥6 to ≤ 15 years. Being a non-smoker was the baseline for the smoking status dummy coded variable.

Assumptions and outliers. The assumptions of hierarchical MRA were evaluated for each of the 8 hierarchical MRAs completed in the present study. The assumptions of adequate sample size, linearity, absence of multicollinearity, and independence of errors were met for all 8 of the hierarchical MRAs. Univariate normality (skewness values greater than ± 2 and kurtosis values ± 3) and thus the assumption of normally distributed residuals was violated for the medication DSMB and Diabetes Impact hierarchical MRAs. Univariate normality was attained for the diet, blood glucose, and total DSMB completion outcomes. The multivariate residuals histograms approached, but did not completely fit the normal distribution. There were no influential observations in any of the 8 hierarchical MRAs as all Cook's distance's values were <.1. The number of outliers on Y (standardized residuals > |2.5|) ranged from 3 to 28 across the 8 hierarchical MRAs and the number of outliers on X (Mahalanobis distance with p = .001 cut-off) ranged from 1 to 29 across the 8 hierarchical MRAs. The assumption of homoscedasticity was violated for all 8 hierarchical MRAs. As such, outliers were left in the analyses and bootstrapping (simple sampling, 1000 samples, bias-corrected and accelerated 95% CI) was done for all 8 of the hierarchical MRAs. Results were reported for all 8 hierarchical MRAs with and without bootstrapping. Only the bootstrapped results were interpreted. All statistical analyses were completed using SPSS version 22.

CHAPTER VI
ARCHIVAL STUDY RESULTS

Descriptive statistics were calculated for all demographic and disease related variables included in the analyses, as well as, for the TICS, DSMB, and Diabetes Impact measures. These are reported first. Next, Pearson *r* correlations between the TICS and the DSMB measures, between the DSMB measures and the Diabetes Impact measure, and between the Diabetes Impact measure and the TICS are reported. Finally, the six hierarchical MRAs with DSMB measures as the outcome are reported to answer the first research question and the two hierarchical MRAs with Diabetes Impact as the outcome measure are reported to answer the second research question.

Descriptive Statistics

Descriptive statistics for the sample are reported in Table 12. On average, participants in the sample were older and had completed at least a grade 12 education. The participants in the sample reported few depression symptoms. The average BMI was in the overweight range and the average A1C value was just over the 7% target value. Significant relationships of the demographic and disease-related variables with the DSMB measures and the diabetes impact measure are also reported in Table 12. Only variables with significant relationships with study outcome variables were included in step one of the hierarchical MRAs for a particular outcome. For medication DSMB, the variables included in step one were: age, years of education, race, household income and smoking status. For blood glucose DSMB, the variables included in step one were: gender, smoking status, diabetes education, and treatment modality. For diet DSMB, the variables included in step one were: age, depression symptoms, BMI, TIBI, and elevated cholesterol with and without A1C. For total DSMB, the variables included in step one were: depression symptoms, BMI, and TIBI with and without A1C. Finally for diabetes impact, the variables included in step one were: age, years of education, gender, race, depression symptoms, BMI, TIBI, diabetes education, diabetes duration, elevated cholesterol, and treatment modality with and without A1C. Although these variables had significant zero order correlations with the outcome variable in each of the respective MRAs where they were included as predictors in step 1, these variables were not always significant predictors of the outcome variable when all variables were included in the model (see Tables 16, 18, 20, 22, 24, 26, 28, 30).

Table 12

Descriptive statistics for demographic and disease-related variables (N=776)[a]

Variable	N(%)[b]	Mean (SD)	Min-Max	1	2	3	4	5
Demographic								
Age		72.707 (6.147)	45-95	*		*		*
Years of Education		12.077 (3.030)	0-17	*				*
Female Gender	389(50.01)				*			*
Race								
White	653(84.1)			*				*
Black	99(12.8)							
Other	24(3.1)							
Household Income								
<20th percentile	213(27.4)							
>20th to < 50th	197(25.4)			*				
>50th percentile	135(17.4)							
Missing	231(29.8)							
Disease-related								
Smokes Cigarettes	45(5.8)			*	*			
Depression Symptoms[c]		1.530 (1.892)	0-8			*	*	*
BMI		29.085 (5.334)	17.90-53.30			*	*	*
Score on TIBI[c]		33.931 (18.174)	0-89.90			*	*	*
Past Diabetes Education	414(53.4)				*			*
Diabetes Duration								
≤ 5 years	197(25.4)							
≥6 to ≤ 15 years	243(31.3)							*
≥ 16 years	220 (28.4)							
Missing	116(14.9)							
A1C (N=565)[c]		7.084 (1.157)	4.80-15.20			*	*	*

Elevated Cholesterol (N=741)	455(61.4)			*		*
Treatment Modality						
Diet & Exercise	76(9.8)					
Medication only	521(67.1)		*			*
Insulin only	97(12.5)					
Medication & Insulin	82(10.6)					

Note. Continuous variables are correlations with DSMB and Diabetes Impact; Dichotomous variables are independent t-tests with DSMB and Diabetes Impact; Categorical variables with more than 2 groups are One-way ANOVA with DSMB and Diabetes Impact; 1: DSMB Medication; 2: DSMB Blood Glucose; 3: DSMB Diet; 4: DSMB Total; 5: Diabetes Impact; BMI: Body Mass Index; TIBI: Total Illness Burden Index

[a] N=776 unless otherwise indicated

[b]All percentages indicate a yes response or the response is included in the variable label unless otherwise indicated or there are multiple groups

[c]Higher scores indicate worse symptoms, worse diabetes control, or greater comorbidity

*p <.05

Descriptive statistics for the TICS, DSMB, and Diabetes Impact measures can be found in Table 13. On average, participants reported completing their medication DSMB most often, followed by blood glucose and diet DSMB, which were reportedly completed at roughly the same frequency. Reported difficulty with total DSMB completion was low with the average score indicating that participants managed to complete their DSMB as recommended by their healthcare practioners without difficulty most of the time. Average reported diabetes impact on life was quite low, with 156 (20.1%) reporting no diabetes impact. In total, 96.4% of participants scored 20 or less out of 40 on the measure.

Table 13

Descriptive statistics for TICS, DSMB, and Diabetes Impact

	N	Mean (SD)	Sample Min-Max	Test Min-Max
TICS	776	22.254 (4.565)	10-35	0-35
Medication DSMB	689	6.719 (1.066)	1-7	1-7
Blood Glucose DSMB	683	5.697 (2.110)	1-7	1-7
Diet DSMB	729	5.646 (1.588)	1-7	1-7
Total DSMB	750	20.934 (2.846)	10-25	5-25
Diabetes Impact[a]	776	5.992 (6.609)	0-40	0-40

Notes. DSMB: Diabetes Self-Management Behaviour; TICS: Telephone Interview for Cognitive Status

[a]Higher scores indicate worse impact.

Correlations between the TICS, DSMB, and Diabetes Impact

The correlations between the TICS, DSMB, and diabetes impact can be found in Table 14. The TICS total score was significantly correlated with medication DSMB. Higher scores on the TICS were significantly related to increased reported medication DSMB completion. There were no other significant correlations between the TICS and DSMB or diabetes impact. Diabetes impact was significantly correlated with medication, diet, and difficulty with total DSMB completion. Increasing impact of diabetes on life was significantly related to lower medication and diet DSMB completion and with more reported difficulty with total DSMB completion. Although these correlations were statistically significant, the proportion of variance accounted for by these correlations was low ranging from 0.6 to 7.2%.

Table 14
Pearson r correlations between DSMB, TICS, and Diabetes Impact

	DSMB Medication	DSMB Blood Glucose	DSMB Diet	DSMB Total	Diabetes Impact
TICS					
R	.100**	-.041	-.057	.021	-.070
P	.008	.289	.125	.571	.051
N	689	683	729	750	776
r^2	.010	.002	.003	.000	.005
Diabetes Impact					
R	-.079*	-.026	-.254**	-.269**	
P	.038	.491	<.001	<.001	
N	689	683	729	750	
r^2	.006	.001	.065	.072	

Note: TICS: Telephone Interview for Cognitive Status
*p <.05
**p <.01

DSMB Analyses Answering the First Research Question

Medication DSMB. The model including age, education, race, household income, and smoking status in step one and cognitive functioning in step two accounted for 5% of the variance in medication DSMB completion (see Table 15). Cognitive functioning did not account for significantly more variance than the step one variables ($F(1, 679)$ = .l36, p = .713). Age, education, and black race (as compared to the baseline of white race) were significant predictors of medication DSMB completion in step one (see Table 16). Age and black race remained significant predictors of medication DSMB completion in step two; however, education was no longer a significant predictor in step two. Cognitive functioning was not a significant predictor of medication DSMB completion.

Table 15

Model Summary

					Change Statistics				
Model	R	R^2	Adj. R^2	Std. Error of the Est.	R^2 Change	F Change	*df1*	*df2*	Sig. F Change
Step 1	0.222	.049	.038	1.046	.049	4.409	8	680	<.001
Step 2	0.222	.050	.037	1.046	.001	.136	1	679	.713

Note. Adj: Adjusted; Est: Estimate; Sig: Significance; Std: Standard

Table 16

Model Coefficients with Bootstrapping (n=689)

Coefficients								Bootstrapped Coefficients				
											BCa 95% CI	
Model	B	Std. Error	β	t	Sig.	*r*	Sig.	Bias	Std. Error	Sig.	Lower	Upper
1												
(Constant)	7.716	.522		14.793	<.001			-.008	.585	.001	6.636	8.823
Age	-.017	.007	-.100	-2.578	.010			.000	.008	.035	-.034	-.001
Education	.029	.013	.084	2.201	.028			.001	.013	.032	.006	.057
Black Race	-.455	.122	-.144	-3.741	<.001			-.003	.175	.013	-.838	-.115
Other Race	.129	.229	.021	.563	.573			.002	.081	.106	-.048	.292
Household Income <20th Percentile	-.138	.123	-.057	-1.121	.263			.005	.113	.218	-.357	.103
Household Income >20th to < 50th Percentile	.051	.124	.021	.415	.679			.002	.089	.556	-.119	.222
Household Income Missing	-.070	.121	-.030	-.580	.562			.003	.109	.511	-.286	.157
Smoking	.142	.176	.030	.806	.420			.005	.080	.082	-.024	.318
2												
(Constant)	7.621	.582		13.083	<.001			-.004	.677	.001	6.304	9.008
Age	-.017	.007	-.097	-2.442	.015	-.100	.009	.000	.008	.048	-.035	.000
Education	.027	.015	.077	1.831	.067	.133	.003	.001	.014	.064	.000	.058
Black Race	-.446	.124	-.141	-3.599	<.001	-.148	<.001	-.003	.175	.014	-.840	-.084
Other Race	.135	.230	.022	.589	.556	.040	.293	.002	.086	.105	-.037	.315
Household Income <20th Percentile	-.136	.123	-.057	-1.110	.268	-.604	.095	.005	.114	.230	-.363	.108
Household Income >20th to < 50th Percentile	.051	.124	.021	.415	.679	.074	.052	.002	.090	.551	-.122	.223
Household Income Missing	-.069	.121	-.030	-.570	.569	-.045	.241	.002	.108	.514	-.279	.157
Smoking	.148	.177	.032	.837	.403	.037	.334	.006	.084	.075	-.016	.336
TICS	.004	.010	.016	.369	.713	.100	.008	.000	.011	.747	-.017	.026

Note. BCa 95% CI: Bias-Corrected and Accelerated 95% Confidence Interval; Sig. Significance; Std: Standard; TICS: Telephone Interview for Cognitive Status

Blood Glucose DSMB. The model including gender, diabetes education, treatment modality, and smoking status in step one and cognitive functioning in step two accounted for 4.3% of the variance in blood glucose DSMB completion (see Table 17). Cognitive functioning did not account for significantly more variance than the step one variables (*F(1, 675)* = 1.296, *p* = .255). Diabetes education, taking insulin only or both medication and insulin (as compared to a baseline of diet and exercise only) for diabetes treatment, and smoking status were significant predictors of blood glucose DSMB completion in step one (see Table 18). All significant predictors in step one remained significant in step two. Cognitive functioning was not a significant predictor of blood glucose DSMB completion.

Table 17
Model Summary

					Change Statistics				
Model	R	R^2	Adj. R^2	Std. Error of the Est.	R^2 Change	F Change	*df1*	*df2*	Sig. F Change
Step 1	0.202	.041	.032	2.075	.041	4.816	6	676	<.001
Step 2	0.207	.043	.033	2.075	.002	1.296	1	675	.255

Note. Adj: Adjusted; Est: Estimate; Sig: Significance; Std: Standard

Table 18

Model Coefficients with Bootstrapping (n=683)

Coefficients								Bootstrapped Coefficients				
Model	B	Std. Error	β	t	Sig.	*r*	Sig.	Bias	Std. Error	Sig.	BCa 95% CI Lower	BCa 95% CI Upper
1												
(Constant)	4.917	.286		17.176	<.001			.008	.320	.001	4.221	5.565
Gender	.310	.159	.074	1.949	.052			.000	.162	.066	-.006	.654
Diabetes Education	.422	.161	.100	2.616	.009			-.002	.167	.020	.092	.723
Treatment Modality: Meds Only	.352	.276	.079	1.278	.202			-.009	.311	.242	-.219	.984
Treatment Modality: Insulin Only	.867	.335	.142	2.585	.010			-.002	.334	.014	.216	1.557
Treatment Modality: Meds and Insulin	.824	.356	.119	2.311	.021			-.024	.352	.012	.136	1.464
Smoking	-.820	.347	-.089	-2.359	.019			.015	.407	.036	-1.595	-.024
2												
(Constant)	5.379	.497		10.825	<.001			.005	.494	.001	4.390	6.354
Gender	.304	.159	.072	1.908	.057	.081	.035	-.001	.162	.071	-.012	.644
Diabetes Education	.433	.162	.102	2.679	.008	.166	.002	-.002	.167	.011	.098	.735
Treatment Modality: Meds Only	.329	.276	.074	1.189	.235	-.066	.086	-.009	.309	.275	-.242	.936
Treatment Modality: Insulin Only	.830	.337	.136	2.465	.014	.092	.017	-.002	.336	.020	.193	1.519
Treatment Modality: Meds and Insulin	.791	.358	.114	2.211	.027	.060	.115	-.024	.352	.019	.123	1.418
Smoking	-.858	.349	-.093	-2.458	.014	-.095	.013	.016	.410	.028	-1.643	-.045
TICS	-.020	.017	-.043	-1.138	.255	-.041	.289	.000	.017	.243	-.057	.016

Note. BCa 95% CI: Bias-Corrected and Accelerated 95% Confidence Interval; Sig. Significance; Std: Standard; TICS: Telephone Interview for Cognitive Status

Diet DSMB. The model including age, BMI, TIBI, depression symptoms, and cholesterol in step one and cognitive functioning in step two accounted for 11.2% of the variance in diet DSMB completion (see Table 19). Cognitive functioning did not account for significantly more variance than the step one variables ($F(1, 691) = 2.563$, $p = .110$). Age and TIBI were significant predictors of diet DSMB completion in step one (see Table 20). All significant predictors in step one remained significant in step two. Cognitive functioning was not a significant predictor of diet DSMB completion.

Table 19
Model Summary

Model	R	R^2	Adj. R^2	Std. Error of the Est.	Change Statistics: R^2 Change	F Change	*df1*	*df2*	Sig. F Change
Step 1	0.329	.108	.102	1.487	.108	16.822	5	692	<.001
Step 2	0.334	.112	.104	1.486	.003	2.563	1	691	.110

Note. Adj: Adjusted; Est: Estimate; Sig: Significance; Std: Standard

Table 20
Model Coefficients with Bootstrapping (n=698)

Model	Coefficients: B	Std. Error	β	t	Sig.	*r*	Sig.	Bootstrapped Coefficients: Bias	Std. Error	Sig.	BCa 95% CI Lower	BCa 95% CI Upper
1												
(Constant)	4.621	.883		5.234	<.001			.069	.885	.001	2.869	6.504
Age	.032	.010	.119	3.161	.002			-.001	.010	.002	.012	.049
BMI	-.018	.012	-.061	-1.469	.142			-.001	.012	.147	-.041	.004
TIBI	-.018	.004	-.214	-5.001	<.001			.000	.004	.001	-.025	-.011
Depression	-.060	.032	-.071	-1.901	.058			.000	.037	.105	-.129	.008
Cholesterol	-.100	.120	-.031	-.838	.402			-.003	.120	.402	-.327	.135
2												
(Constant)	5.324	.985		5.404	<.001			.075	1.016	.001	3.140	7.508
Age	.029	.010	.107	2.798	.005	.173	<.001	-.001	.011	.006	.009	.047
BMI	-.018	.012	-.062	-1.495	.135	-.205	<.001	-.001	.012	.144	-.041	.004
TIBI	-.019	.004	-.220	-5.131	<.001	-.288	<.001	.000	.004	.001	-.026	-.011
Depression	-.066	.032	-.078	-2.070	.039	-.147	<.001	.000	.037	.076	-.137	.005
Cholesterol	-.077	.120	-.024	-.639	.523	-.103	.006	-.003	.121	.510	-.313	.171
TICS	-.020	.013	-.060	-1.601	.110	-.052	.172	.000	.014	.134	-.047	.008

Note. BCa 95% CI: Bias-Corrected and Accelerated 95% Confidence Interval; BMI: Body Mass Index; Sig. Significance; Std: Standard; TIBI: Total Illness Burden Index; TICS: Telephone Interview for Cognitive Status

Diet DSMB with A1C. The model including age, BMI, TIBI, depression symptoms, cholesterol, A1C in step one and cognitive functioning in step two accounted for 12.6% of the variance in diet DSMB completion (see Table 21). Cognitive functioning did not account for significantly more variance than the step one variables ($F(1, 511) = .277$, $p = .599$). Age, TIBI, and A1C were significant predictors of diet DSMB completion in step one (see Table 22). All significant predictors in step one remained significant in step two. Depression symptoms became a significant predictor in step 2. Cognitive functioning was not a significant predictor of diet DSMB completion.

Adding A1C to the model accounted for an additional 1.4% of the variance in diet DSMB completion.

Table 21
Model Summary

					Change Statistics				
Model	R	R^2	Adj. R^2	Std. Error of the Est.	R^2 Change	F Change	*df1*	*df2*	Sig. F Change
Step 1	0.354	.125	.115	1.440	.125	12.197	6	512	<.001
Step 2	0.354	.126	.114	1.441	.001	.277	1	511	.599

Note. Adj: Adjusted; Est: Estimate; Sig: Significance; Std: Standard

Table 22
Model Coefficients with Bootstrapping (n=519)

Coefficients								Bootstrapped Coefficients				
											BCa 95% CI	
Model	B	Std. Error	β	t	Sig.	*r*	Sig.	Bias	Std. Error	Sig.	Lower	Upper
1												
(Constant)	5.588	1.110		5.035	<.001			-.006	1.061	.001	3.447	7.720
Age	.031	.012	.114	2.632	.009			.000	.011	.009	.005	.055
BMI	-.007	.014	-.025	-.520	.603			.000	.014	.616	-.034	.020
TIBI	-.018	.004	-.221	-4.449	<.001			.000	.004	.001	-.027	-.010
Depression	-.066	.037	-.078	-1.793	.074			.000	.043	.132	-.144	.016
Cholesterol	-.127	.135	-.040	-.941	.347			.005	.138	.345	-.403	.174
A1C	-.175	.055	-.131	-3.149	.002			-.002	.065	.007	-.308	-.052
2												
(Constant)	5.921	1.279		4.631	<.001			.019	1.269	.001	3.345	8.540
Age	.030	.012	.108	2.386	.017	.165	<.001	.000	.012	.016	.004	.054
BMI	-.008	.014	-.027	-.553	.580	-.188	<.001	.000	.014	.590	-.035	.019
TIBI	-.018	.004	-.223	-4.475	<.001	-.293	<.001	.000	.004	.001	-.027	-.010
Depression	-.068	.037	-.080	-1.828	.068	-.155	<.001	.000	.043	.128	-.145	.015
Cholesterol	-.119	.136	-.038	-.870	.385	-.102	.021	.005	.142	.381	-.407	.195
A1C	-.175	.055	-.132	-3.162	.002	-.159	<.001	-.002	.065	.007	-.309	-.053
TICS	-.008	.015	-.023	-.526	.599	-.019	.666	-.001	.016	.643	-.037	.020

Note. BCa 95% CI: Bias-Corrected and Accelerated 95% Confidence Interval; BMI: Body Mass Index; Sig. Significance; Std: Standard; TIBI: Total Illness Burden Index; TICS: Telephone Interview for Cognitive Status

Total DSMB. The model including BMI, TIBI, and depression symptoms in step one and cognitive functioning in step two accounted for 8.9% of the variance in difficulty with total DSMB completion (see Table 23). Cognitive functioning did not account for significantly more variance than the step one variables ($F(1, 745)$ = .024, p = .877). TIBI was the only significant predictor of difficulty with total DSMB completion in step one (see Table 24). TIBI remained a significant predictor in step two. Cognitive functioning was not a significant predictor of difficulty with total DSMB completion.

Table 23
Model Summary

					Change Statistics				
Model	R	R^2	Adj. R^2	Std. Error of the Est.	R^2 Change	F Change	*df1*	*df2*	Sig. F Change
Step 1	0.298	.089	.085	2.723	.089	24.214	3	746	<.001
Step 2	0.298	.089	.084	2.724	.001	.024	1	745	.877

Note. Adj: Adjusted; Est: Estimate; Sig: Significance; Std: Standard

Table 24
Model Coefficients with Bootstrapping (n=750)

Coefficients								Bootstrapped Coefficients				
											BCa 95% CI	
Model	B	Std. Error	β	t	Sig.	*r*	Sig.	Bias	Std. Error	Sig.	Lower	Upper
1												
(Constant)	22.701	.552		41.100	<.001			-.006	.532	.001	21.517	23.714
BMI	-.006	.021	-.012	-.314	.753			.000	.020	.746	-.040	.032
TIBI	-.044	.006	-.280	-6.990	<.001			.000	.006	.001	-.056	-.032
Depression	-.056	.054	-.038	-1.035	.301			-.001	.060	.352	-.170	.062
2												
(Constant)	22.776	.735		30.976	<.001			-.003	.762	.001	21.140	24.264
BMI	-.006	.021	-.012	-.307	.759	-.138	<.001	.000	.020	.753	-.042	.033
TIBI	-.044	.006	-.280	-6.984	<.001	-.295	<.001	.000	.006	.001	-.057	-.032
Depression	-.057	.055	-.038	-1.046	.296	-.166	.001	-.001	.061	.350	-.170	.062
TICS	-.003	.022	-.005	-.155	.877	.021	.571	.000	.023	.881	-.046	.043

Note. BCa 95% CI: Bias-Corrected and Accelerated 95% Confidence Interval; BMI: Body Mass Index; Sig. Significance; Std: Standard; TIBI: Total Illness Burden Index; TICS: Telephone Interview for Cognitive Status

Total DSMB with A1C. The model including BMI, TIBI, depression symptoms, and A1C in step one and cognitive functioning in step two accounted for 11.7 % of the variance in difficulty with total DSMB completion (see Table 25). Cognitive functioning did not account for significantly more variance than the step one variables ($F(1, 537)$ = .033, p = .856). TIBI was the only significant predictor of difficulty with total DSMB completion in step one (see Table 26). TIBI remained a significant predictor in step two. Cognitive functioning was not a significant predictor of difficulty with total DSMB completion. Adding A1C to the model accounted for an additional 2.8% of the variance in difficulty with total DSMB completion.

Table 25
Model Summary

					Change Statistics				
Model	R	R^2	Adj. R^2	Std. Error of the Est.	R^2 Change	F Change	*df1*	*df2*	Sig. F Change
Step 1	0.342	.117	.110	2.634	.117	17.765	4	538	<.001
Step 2	0.342	.117	.109	2.637	.001	.033	1	537	.856

Note. Adj: Adjusted; Est: Estimate; Sig: Significance; Std: Standard

Table 26
Model Coefficients with Bootstrapping (n=543)

Coefficients								Bootstrapped Coefficients				
											BCa 95% CI	
Model	B	Std. Error	β	t	Sig.	*r*	Sig.	Bias	Std. Error	Sig.	Lower	Upper
1												
(Constant)	23.741	.921		25.772	<.001			.001	.940	.001	21.835	25.637
BMI	.006	.023	.011	.251	.802			.000	.022	.780	-.037	.049
TIBI	-.048	.007	-.315	-6.730	<.001			.000	.007	.001	-.061	-.033
Depression	-.076	.064	-.050	-1.188	.235			-.001	.074	.302	-.220	.071
A1C	-.178	.097	-.074	-1.829	.068			.000	.110	.102	-.385	.035
2												
(Constant)	23.855	1.114		21.410	<.001			.001	1.190	.001	21.421	26.291
BMI	.006	.023	.012	.254	.800	-.142	.001	-.001	.022	.783	-.038	.049
TIBI	-.048	.007	-.315	-6.726	<.001	-.329	<.001	.000	.007	.001	-.061	-.033
Depression	-.078	.065	-.051	-1.200	.231	-.141	.001	-.001	.075	.310	-.219	.066
A1C	-.179	.097	-.075	-1.834	.067	-.101	.018	.000	.110	.103	-.387	.031
TICS	-.005	.026	-.007	-.182	.856	.027	.537	.000	.027	.870	-.057	.050

Note. BCa 95% CI: Bias-Corrected and Accelerated 95% Confidence Interval; BMI: Body Mass Index; Sig. Significance; Std: Standard; TIBI: Total Illness Burden Index; TICS: Telephone Interview for Cognitive Status

Diabetes Impact Analyses Answering the Second Research Question

Diabetes Impact. The model including age, education, race, gender, diabetes education, treatment modality, diabetes duration, BMI, TIBI, depression, and cholesterol in step one and cognitive functioning and difficulty with total DSMB completion in step two accounted for 25.1% of the variance in diabetes impact (see Table 27). Cognitive functioning and difficulty with total DSMB completion accounted for significantly more variance over and above step one variables ($F(2, 700) = 13.282$, $p < .001$). Age, taking medication only (as compared to a baseline of diet and exercise only) for diabetes treatment, TIBI, and depression symptoms were significant predictors of diabetes impact in step one (see Table 28). All significant predictors in step one remained significant in step two. In addition, taking insulin only (as compared to a baseline of diet and exercise only) for diabetes treatment became significant in step two. Cognitive functioning was not a significant predictor of diabetes impact; however, difficulty with total DSMB completion was a significant predictor of diabetes impact. For every one standard deviation decrease on the measure of total DSMB completion there was a 0.179 standard deviation increase in diabetes impact. Recalling that higher DSMB scores mean less difficulty with DSMB completion, this means that less difficulty with DSMB completion was associated with less impact of the diabetes of the individual’s life.

Table 27
Model Summary

					Change Statistics				
Model	R	R^2	Adj. R^2	Std. Error of the Est.	R^2 Change	F Change	*df1*	*df2*	Sig. F Change
Step 1	0.472	.223	.205	5.919	.223	12.592	16	702	<.001
Step 2	0.501	.251	.232	5.818	.028	13.282	2	700	<.001

Note. Adj: Adjusted; Est: Estimate; Sig: Significance; Std: Standard

Table 28
Model Coefficients with Bootstrapping (n=719)

Coefficients								Bootstrapped Coefficients				
											BCa 95% CI	
Model	B	Std. Error	B	t	Sig.	*r*	Sig.	Bias	Std. Error	Sig.	Lower	Upper
1												
(Constant)	12.206	3.737		3.266	.001			.121	3.910	.001	3.726	19.978
Age	-.143	.040	-.128	-3.553	<.001			-.001	.040	.001	-.219	-.064
Education	-.102	.077	-.047	-1.331	.184			-.003	.089	.255	-.268	.052
Black Race	.076	.687	.004	.111	.912			-.011	.877	.926	-1.586	1.799
Other Race	2.901	1.268	.077	2.287	.022			-.093	2.012	.150	-.777	6.611
Gender	.336	.459	.025	.733	.464			.006	.456	.471	-.537	1.196
Diabetes Education	.708	.453	.053	1.564	.118			-.005	.472	.135	-.294	1.640
Treatment Modality:	1.403	.802	.099	1.749	.081			-.042	.593	.021	.259	2.427

Meds Only												
Treatment Modality: Insulin Only	1.670	1.039	.084	1.608	.108			-.047	.966	.093	-.291	3.404
Treatment Modality: Meds and Insulin	1.563	1.079	.072	1.449	.148			-.013	.943	.105	-.272	3.420
Diabetes Duration: ≤5years	-.253	.604	-.017	-.419	.675			-.001	.538	.635	-1.340	.772
Diabetes Duration: ≥16 years	.734	.587	.050	1.251	.211			.017	.615	.239	-.443	1.906
Diabetes Duration: Missing	-.031	.720	-.002	-.043	.966			-.016	.715	.974	-1.463	1.260
BMI	-.054	.048	-.044	-1.116	.265			.000	.050	.267	-.149	.046
TIBI	.103	.015	.285	6.923	<.001			.000	.016	.001	.072	.133
Depression	.717	.126	.203	5.677	<.001			.003	.158	.001	.402	1.023
Cholesterol	.539	.477	.040	1.129	.259			.010	.460	.250	-.289	1.461
2												
(Constant)	21.881	4.325		5.059	<.001			.077	4.356	.001	12.899	30.349
Age	-.141	.040	-.126	-3.484	.001	-.161	<.001	-.001	.039	.001	-.214	-.062
Education	-.099	.082	-.045	-1.208	.228	-.100	.007	-.003	.095	.312	-.278	.064
Black Race	.083	.689	.004	.121	.904	.042	.260	-.009	.838	.917	-1.374	1.647
Other Race	2.664	1.250	.071	2.132	.033	.082	.021	-.094	2.093	.206	-1.380	6.456
Gender	.507	.454	.038	1.116	.265	.097	.010	.008	.446	.267	-.344	1.392
Diabetes Education	.773	.445	.058	1.734	.083	.069	.065	-.003	.463	.099	-.220	1.713
Treatment Modality: Meds Only	1.442	.789	.101	1.828	.068	-.045	.233	-.043	.621	.021	.222	2.553
Treatment Modality: Insulin Only	2.015	1.025	.101	1.966	.050	.098	.009	-.058	.965	.034	.138	3.730
Treatment Modality: Meds and Insulin	1.676	1.062	.077	1.579	.115	.089	.018	-.025	.946	.088	-.195	3.531
Diabetes Duration: ≤5years	-.234	.593	-.015	-.394	.694	-.111	.003	-.009	.533	.653	-1.263	.747
Diabetes Duration: ≥16 years	.908	.578	.062	1.571	.117	.088	.018	.021	.603	.136	-.279	2.125
Diabetes Duration: Missing	-.302	.709	-.016	-.426	.670	.030	.416	-.016	.709	.681	-1.739	1.024
BMI	-.055	.047	-.045	-1.174	.241	.158	<.001	.000	.049	.247	-.151	.040
TIBI	.083	.015	.230	5.481	<.001	.379	<.001	.000	.016	.001	.052	.114
Depression	.680	.125	.192	5.447	<.001	.305	<.001	.002	.158	.001	.369	.991
Cholesterol	.583	.470	.043	1.242	.215	.136	<.001	.012	.458	.210	-.261	1.538
TICS	-.023	.055	-.016	-.423	.673	-.069	.066	.000	.058	.651	-.138	.097
Total DSMB	-.419	.082	-.179	-5.125	<.001	-.270	<.001	.002	.083	.001	-.581	-.257

Note. BCa 95% CI: Bias-Corrected and Accelerated 95% Confidence Interval; BMI: Body Mass Index; DSMB: Diabetes Self-Management Behaviour; Sig. Significance; Std: Standard; TIBI: Total Illness Burden Index; TICS: Telephone Interview for Cognitive Status

Diabetes Impact with A1C. The model including age, education, race, gender, diabetes education, treatment modality, diabetes duration, BMI, TIBI, depression, cholesterol, and A1C in step one and cognitive functioning and difficulty with total DSMB completion in step two accounted for 29.5% of the variance in diabetes impact (see Table 29). Cognitive functioning and difficulty with total DSMB completion accounted for significantly more variance over and above step one variables ($F(2, 503)$ = 9.846, $p < .001$). Age, education, other race (as compared to the baseline of white race), diabetes education, taking medication only (as compared to a baseline of diet and exercise only) for diabetes treatment, TIBI, and depression symptoms were significant predictors of diabetes impact in step one (see Table 30). All significant predictors in step one remained significant in step two. Cognitive functioning was not a significant predictor of diabetes impact; however, difficulty with total DSMB completion was a significant predictor of diabetes impact. For every one standard deviation decrease on the measure of total DSMB completion there was a 0.172 standard deviation increase in diabetes impact. Recalling that higher DSMB scores mean less difficulty with DSMB completion, this means that less difficulty with DSMB completion was associated with less impact of the diabetes of the individual's life. Adding A1C to the model accounted for an additional 4.4% of the variance in diabetes impact.

Table 29
Model Summary

					Change Statistics				
Model	R	R^2	Adj. R^2	Std. Error of the Est.	R^2 Change	F Change	*df1*	*df2*	Sig. F Change
Step 1	.517	.268	.243	5.728	.268	10.858	17	505	<.001
Step 2	.543	.295	.269	5.630	.028	9.846	2	503	<.001

Note. Adj: Adjusted; Est: Estimate; Sig: Significance; Std: Standard

Table 30

Model Coefficients with Bootstrapping (n=523)

Coefficients								Bootstrapped Coefficients				
											BCa 95% CI	
Model	B	Std. Error	β	t	Sig.	*r*	Sig.	Bias	Std. Error	Sig.	Lower	Upper
1												
(Constant)	17.670	4.788		3.691	<.001			.137	5.231	.002	7.672	27.831
Age	-.195	.049	-.165	-4.018	<.001			.000	.050	.001	-.288	-.094
Education	-.232	.089	-.104	-2.592	.010			-.006	.103	.034	-.444	-.046
Black Race	-.512	.895	-.023	-.572	.567			.044	1.173	.647	-2.635	2.040
Other Race	5.543	1.524	.141	3.637	<.001			.109	2.838	.049	-.044	11.559
Gender	-.178	.523	-.014	-.340	.734			-.016	.513	.733	-1.208	.712
Diabetes Education	1.109	.520	.084	2.134	.033			-.019	.512	.036	.129	2.066
Treatment Modality: Meds Only	1.410	.904	.098	1.559	.120			-.012	.680	.042	.058	2.638
Treatment Modality: Insulin Only	1.180	1.236	.055	.955	.340			-.008	1.209	.325	-.996	3.497
Treatment Modality: Meds and Insulin	.600	1.249	.027	.481	.631			.008	1.137	.587	-1.646	3.056
Diabetes Duration: ≤5years	-.483	.682	-.032	-.708	.479			.012	.598	.430	-1.707	.739
Diabetes Duration: ≥16 years	.529	.672	.036	.787	.432			.012	.718	.449	-.802	2.070
Diabetes Duration: Missing	-.901	.821	-.047	-1.097	.273			-.001	.768	.250	-2.402	.604
BMI	-.088	.055	-.073	-1.600	.110			-.003	.058	.137	-.206	.016
TIBI	.107	.017	.303	6.336	<.001			.000	.018	.001	.074	.143
Depression	.812	.150	.224	5.431	<.001			.008	.210	.001	.390	1.246
Cholesterol	.372	.551	.027	.675	.500			.033	.543	.487	-.738	1.655
A1C	.158	.228	.028	.692	.489			-.005	.214	.449	-.276	.556
2												
(Constant)	29.927	5.624		5.322	<.001			.346	5.892	.001	18.427	41.564
Age	-.209	.050	-.177	-4.203	<.001	-.189	<.001	.000	.048	.001	-.295	-.111
Education	-.195	.094	-.088	-2.072	.039	-.140	.001	-.003	.106	.070	-.426	.006
Black Race	-.640	.893	-.028	-.716	.474	.019	.669	.030	1.100	.536	-2.673	1.655
Other Race	5.583	1.499	.142	3.724	<.001	.150	.001	.106	2.869	.045	-.152	11.991
Gender	.055	.518	.004	.106	.915	.071	.103	-.005	.505	.905	-1.021	.992
Diabetes Education	1.105	.511	.084	2.163	.031	.104	.017	-.020	.498	.031	.129	2.000
Treatment Modality: Meds Only	1.474	.889	.103	1.658	.098	-.019	.662	-.008	.707	.034	.040	2.761
Treatment Modality: Insulin Only	1.686	1.221	.078	1.380	.168	.089	.041	.003	1.225	.174	-.574	4.020
Treatment Modality: Meds and Insulin	.670	1.228	.030	.545	.586	.080	.067	.017	1.101	.539	-1.585	3.021
Diabetes Duration:	-.466	.672	-.031	-.693	.489	-.115	.009	.018	.587	.430	-1.641	.739

≤5years												
Diabetes Duration: ≥16 years	.657	.662	.044	.993	.321	.091	.037	.013	.707	.344	-.658	2.214
Diabetes Duration: Missing	-1.232	.811	-.064	-1.520	.129	-.018	.682	-.019	.775	.120	-2.737	.199
BMI	-.086	.054	-.071	-1.586	.113	.165	<.001	-.003	.057	.140	-.199	.018
TIBI	.085	.017	.241	4.896	<.001	.375	<.001	-.001	.018	.001	.050	.119
Depression	.749	.148	.206	5.071	<.001	.328	<.001	.007	.209	.003	.343	1.184
Cholesterol	.497	.544	.037	.915	.361	.111	.011	.025	.555	.368	-.667	1.774
A1C	.050	.225	.009	.223	.824	.092	.035	-.006	.226	.819	-.388	.447
TICS	-.083	.066	-.056	-1.273	.203	-.085	.051	-.002	.070	.230	-.215	.049
Total DSMB	-.407	.096	-.172	-4.232	<.001	-.278	<.001	-.006	.103	.001	-.608	-.225

Note. BCa 95% CI: Bias-Corrected and Accelerated 95% Confidence Interval; BMI: Body Mass Index; DSMB: Diabetes Self-Management Behaviour; Sig. Significance; Std: Standard; TIBI: Total Illness Burden Index; TICS: Telephone Interview for Cognitive Status

CHAPTER VII
ARCHIVAL STUDY DISCUSSION

The archival study sought first to determine the relationship between cognitive functioning and DSMB completion and second to determine the relationship between cognitive functioning and DSMB completion and the impact of diabetes on the life of the individual. These relationships were investigated using hierarchical multiple regression analysis. Overall performance of the sample on the measures of DSMB completion and diabetes impact will be discussed first. Next, the analyses with DSMB completion as the outcome answering the first research question will be discussed followed by the analyses with diabetes impact as the outcome measure answering the second research question. Study strengths and limitations will conclude the archival study discussion. Future directions are discussed throughout where relevant.

DSMB Completion and Diabetes Impact

DSMB completion was highest for medication DSMB followed by blood glucose and diet DSMB. This corresponds to completion patterns reported by other studies, where medication DSMB completion is highest followed by the other domains of DSMB (Ahola & Groop, 2013; Gonzalez et al., 2016). Average reported difficulty with total DSMB completion was low which corresponds to the high rates of DSMB completion of the participants in this sample. Average reported diabetes impact on life was very low, with 20% of the sample reporting no impact of diabetes on life and 97% of participants reporting half of the maximum possible impact of diabetes on their lives. These reported rates of the impact of diabetes on life are lower than what is generally reported (Debono & Cachia, 2007); however, this is difficult to assess as the measure of diabetes impact on life used in the archival study was developed specifically for the HRS survey and evaluations of the validity and reliability, as well as, average performance on the measure have not occurred.

Relationships Between Cognitive Functioning and DSMB Completion

Cognitive functioning as measured by the TICS was not a significant predictor of completion for medication, blood glucose, and diet DSMB or for the total difficulty with DSMB completion both when A1C was included as a variable in the model and when it was not. Rosen and colleagues (2003) also failed to find any relationship between a cognitive screening measure (MMSE) and DSMB completion. Similarly, there was no relationship between the MoCA total score and DSMB completion in the prospective study. Thabit and colleagues (2009) did report a significant relationship between increased MMSE scores and increased total DSMB completion. All other previous studies did not include a cognitive screening measure, only used the screening measure as an exclusion criterion, or included individuals with dementia. Overall, investigating the relationship between cognitive functioning and DSMB completion using only a cognitive screening measure appears to be of limited utility, and studies should strive to include validated neuropsychological measures of multiple cognitive domains and abilities.

Feil and colleagues (2012) found that lower cognitive functioning as measured by the TICS was significantly related to more difficulty with exercise and diet DSMB completion. They did not find any significant associations between the TICS and difficulty with blood glucose or foot care DSMB completion and they did not investigate the relationships between the TICS and difficulty with medication DSMB completion due to high ceiling effects on this variable indicating very low levels of difficulty with medication DSMB completion (Feil et al., 2012). Feil and colleagues dichotomized the individual components of the difficulty with DSMB completion total score that was used in the present study and they did not analyse the medication, blood glucose, and diet DSMB completion measures that are based on the SDSCA as was done in the present study. Further, these authors made no mention of missing data or how these were handled in their analyses (Feil et al., 2012). This makes unclear what their findings are based on given the high levels of missing data in the HRS datasets and their reported sample size of 1398 as compared to the maximum sample size of 776 in the present study. This sample size of 776 included replacement of missing data as described in the data analyses section. Therefore, the results of the present study and those of Feil and colleagues are not directly comparable even though the analyses in both studies were completed with the same dataset.

Relationships of Cognitive Functioning and DSMB Completion with Diabetes Impact

Cognitive functioning and difficulty with total DSMB completion together accounted for significantly more variance over and above demographic and health-related variables when A1C was included in the model and also when it was not. However, cognitive functioning was not a significant independent predictor of diabetes impact in either model. Difficulty with total DSMB completion was a significant predictor of diabetes impact in both models and accounted for the significant increase in R^2. Increased reported impact of diabetes on life lead to a significant increase in reported difficulty with total DSMB completion. It is no surprise that more difficulty with DSMB completion could lead to a greater perceived impact of diabetes on the individual's life (Gonzalez et al., 2016).

Strengths and Limitations

The archival study was completed with a large nationally representative sample of Americans with T2DM (HRS, 2006). There was no relationship between cognitive functioning and DSMB completion. One reason for this is the TICS is a screening measure that is not sensitive to the cognitive deficits most often found in those without T2DM (Tomlin & Sinclair, 2016). There is no measure of processing speed on the TICS and the only component of executive functioning that is assessed is working memory. Working memory is only marginally impaired in individuals with T2DM (Monette et al., 2014, Vincent & Hall, 2015). Executive deficits in individuals with T2DM can be missed if they are not assessed directly (Thabit et al., 2009). Thus, had validated neuropsychological measures of multiple cognitive domains and abilities been used, there may have been significant relationships between cognitive functioning and DSMB completion. The use of these measures is not feasible in large studies where data is collected over the phone as was done in the HRS study.

The DSMB measures in the archival study were adapted from validated measures, but their use in survey format has not been validated. The total DSMB score was a measure of difficulty with DSMB completion and not a measure of actual DSMB completion. In addition, the impact of diabetes on life measure was developed for the HRS study and has not been validated. There was a lot of missing data in the present study and the data were not missing completely at random; however, efforts were made to preserve as much data as possible without introducing bias. Survey methodology is not the optimal way to collect data on DSMB completion, especially given that this area of study is still in its infancy.

The TICS data was gathered months before the DSMB completion and impact of diabetes on life data. Cognitive functioning of participants could have changed during this time. The medication, blood glucose, and diet DSMB completion measures asked about completion within the last seven days. DSMB completion at the time the TICS data were collected could have been different than what was reported in the survey. This limitation also applies to the impact of diabetes on life measure which asked about current impact. For cross-sectional investigations, all data should be collected within a short time span as was done in the prospective study.

CHAPTER VIII
GENERAL DISCUSSION

The general discussion will address future directions in the research of the relationships between cognitive functioning and DSMB completion as these pertain to interventions needed to address the impact of cognitive functioning on DSMB completion, a holistic model that considers the multiple barriers to successful DSMB completion, and methodological recommendations for future studies in this area.

Interventions Needed Based on Relationships of Cognitive Functioning and DSMB

The importance of recognizing the impact of cognitive functioning on DSMB completion and T2DM treatment outcomes is steadily increasing (Kirkman et al., 2012; Primozic et al., 2012; Vincent & Hall, 2016, Wong et al., 2014) and many authors have pointed to the shortcomings of the current model of diabetes education and treatment (Ahola & Groop, 2013; Gillani, 2012; Gonzalez et la., 2016; Tomlin & Asimakopoulou, 2014, West et al., 2016). The model of simply using didactic instruction to teach those with T2DM how to complete their medication, blood glucose, diet, and physical activity DSMB is insufficient for successful completion of these behaviours (Gillani, 2012; West et al., 2016). Individuals with T2DM need to be taught problem-solving skills, goal setting, and behavioural regulation strategies (Gonzalez et al., 2016; Gillani, 2012). In addition, behaviour change interventions need to be incorporated into diabetes education and treatment to increase the rates of DSMB completion (Tomlin & Asimakopoulou, 2014). More attention must also be paid to the aspects of motivation, self-efficacy, and mental health that affect DSMB completion and QoL (Hunter 2016, Tomlin & Sinclair, 2016). Finally, the effects of cognitive deficits on DSMB completion must be taken into account and alleviated or accommodated through cognitive interventions (Compeán-Ortiz et al., 2010; Gatlin & Insel, 2015; Monette, 2012; Primozic et al., 2012; Wasserman et al., 2015)

Psychologists and neuropsychologists are well trained to provide these types of interventions and adjuncts to diabetes treatment education that have been recommended to improve DSMB completion and T2DM treatment outcomes (Fisher et al., 2005; Hunter, 2016; Johnson & Marrero, 2016). However, psychologists and neuropsychologists do not typically receive training in the disease process, psychosocial, and cognitive aspects of T2DM that they would need to develop and deliver these interventions (Hunter, 2016; Johnson & Marrero, 2016). This is changing now with the American Psychological Association offering certifications and continuing education programs specific to working with individuals with diabetes (Hunter, 2016).

Many studies have shown the effectiveness of psychological interventions to increase DSMB completion including problem-solving therapy, cognitive behavioural therapy, motivational interviewing, patient empowerment, and family therapy (Fisher et al., 2005; Gonzalez et al., 2016; Hunter, 2016). However, the majority of individuals with T2DM do not have access to these interventions either because they are not part of their routine T2DM treatment regimens, there are not enough service providers offering these interventions, and these interventions often require out-of-pocket payment (Hunter, 2016).

There are currently no validated cognitive interventions designed to help individuals with T2DM increase their DSMB completion by accommodating weaknesses in cognitive functioning with strategies that are used in cognitive rehabilitation with other patient groups. This is largely due to the lack of research on the links between cognitive functioning and DSMB completion (Bruce, 2015; Wasserman et al., 2015) and the fact that neuropsychologists do not typically receive specific training to work with individuals with T2DM. As a result, any recommendations made to improve or accommodate cognitive functioning deficits in individuals with T2DM with regards to their DSMB completion are made based on clinical experience but have not been researched or validated (Bruce, 2015; Koekkoek et al., 2015; Wasserman et al., 2015).

There is a large need for the development and validation of interventions that seek to improve or accommodate cognitive deficits in individuals with T2DM in order to increase DSMB completion, improve A1C, and delay or prevent diabetes complications including cognitive impairment and dementia (Koekkoek et al., 2015; Wasserman et al., 2015). Existing well validated cognitive interventions such as Goal Management Training (Levine et al., 2012) or the Memory and Aging Program (Wiegand et al., 2013) could be adapted to make use of the strategies and skills from these interventions specifically to increase DSMB completion through compensatory behaviours.

A Holistic Model Addressing All Barriers to DSMB Completion

The prospective and archival studies focused on barriers at the individual level as cognitive deficits represent an individual level barrier to DSMB completion and diabetes treatment adherence (Ahola & Groop, 2013; Bailey & Kodack, 2011; Emery et al., 2010). However, there are barriers to DSMB completion at the treatment level and at the environment level (Ahola & Groop, 2013; Bailey & Kodack, 2011; Castellon et al., 2009).

The Social Ecological model provides an excellent theoretical backdrop for DSMB completion and T2DM treatment regimens (Fisher et al., 2005; Johnson &

Marrero, 2016). The Social Ecological model acknowledges that behaviour (i.e. DSMB) has multiple causes and the individual with T2DM has individual characteristics that determine their likelihood of completing their DSMB; however, there are many other factors outside of the control of the individual that contribute to their successful DSMB completion (Fisher et al., 2005). Factors external to the individual include the people around them and their interpersonal relationships (family, friends, peers, co-workers); their community (healthcare setting, media, institutional regulations); and the larger society (culture, economic and educational policies, provincial and federal policies and regulations, Fisher et al., 2005; Gillani, 2012; Johnson & Marrero, 2016). All of these factors interact and contribute to facilitating or hindering DSMB completion (Fisher et al., 2005; Johnson & Marrero, 2016).

Psychologists usually intervene at the individual and interpersonal level and not as much at the community and societal level (Johnson & Marrero, 2016). The interventions discussed in the previous section take into consideration many individual level factors that are neglected by the traditional medical model (Johnson & Marrero, 2016). Interpersonal, community, and societal level factors would also influence the effectiveness of these interventions. A particular individual with T2DM could not reasonably be expected to successfully complete their DSMB if there were many interpersonal, community, and societal factors external to them hindering their treatment management and self-care activities (Fisher et al., 2005). For example, at the interpersonal level, intrusive involvement by others such as spouses or other caregivers that is controlling in nature can hinder DSMB completion and T2DM treatment adherence (Weibe et al. 2016). At the community level, diet and exercise DSMB completion is more difficult if the person lives in an area where access to healthy foods and safe settings to exercise are limited (Fisher et al., 2005).

At the societal level, medication and blood glucose DSMB completion could be hindered in individuals of lower SES who may not be able to pay for their medications, needles, insulin, test strips, and lancets (Gonzalez et al., 2016). In Canada, despite having universal healthcare, 57% of individuals with diabetes report that they do not complete their medication and blood glucose DSMB as recommended by their healthcare practitioners because they cannot afford their medications and supplies (Diabetes Canada). In Ontario, individuals without private coverage for prescription medications must pay a deductible equivalent to 4% of their income before they can have their medication and insulin costs covered. In addition, needles and lancets are not covered by this plan and must be paid for out-of-pocket by individuals under the age of 65 (Government of Ontario). In the United States, where many individuals, especially those with lower SES, do not have any healthcare insurance, the societal level barrier of the cost of medications and supplies to treat T2DM could be expected to have an even greater impact than described above. Given the poorer diabetes treatment outcomes for those of lower education (Emery et al., 2010; Gonder-Frederick et al., 2016; Gonzalez et al., 2016), SES (Bailey & Kodack, 2011; Bruce, 2015; Gillani, 2012; Gonder-Frederick et al., 2016; Gonzalez et al., 2016; Johnson & Marrero, 2016; Weibe et al. 2016), and with minority status be it ethnic (Bailey & Kodack, 2011; Gonder-Frederick et al., 2016; Gonzalez et al., 2016; Hunter, 2016; Kirkman et al., 2012; Weibe et al., 2016), disability (de Groot et al., 2016; Emery et al., 2010; Gillani, 2012), or gender (Emery et al., 2010; Gillani, 2012), societal level factors impact greatly on DSMB completion and successful treatment outcomes cannot be achieved for all individuals with T2DM while systemic inequalities exist.

Psychologists could become more involved in shaping policies at the community and societal level to decrease barriers to DSMB completion in addition to the work done at the individual and interpersonal levels (Johnson & Marrero, 2016). If they do not, successes made at the individual and interpersonal levels will continue to be undermined by barriers at the community and societal levels and the most vulnerable individuals with T2DM will continue to have poorer DSMB completion, T2DM treatment outcomes, and QoL (de Groot et al., 2016). Psychologists and other healthcare practitioners should work collaboratively with individuals with T2DM to establish shared treatment goals and empower individuals to identify and remove or alleviate barriers to DSMB completion at all levels whenever possible (Ahola & Groop, 2013; Fisher et al., 2005; Gillani, 2012; Gonzalez et al., 2016; Hunter, 2016; Johnson & Marrero, 2016; Kirkman et al., 2012; Weibe et al., 2016). There should also be more studies of the societal barriers and their impact on DSMB completion and T2DM treatment adherence in order to provide evidence for policy changes that could reduce or eliminate these barriers (Fisher et al., 2015; Gillani, 2012; Johnson & Marrero, 2016; Weibe et al., 2016).

Future Methodological Directions

Much more research is needed to determine the nature and shape of the relationships between cognitive functioning and DSMB completion (Tomlin & Sinclair, 2016). The relationships between cognitive functioning, DSMB completion, and diabetes-related and general QoL require further investigation as this was the first study to explicitly investigate these relationships with several measured cognitive abilities and domains. For the most part, studies investigating the relationships between cognitive functioning and DSMB completion have relied on self-report measures of DSMB completion. Given the general shortcomings of self-report data leading to possible inaccurate reporting due to social desirability, errors in recall, or lack of insight (Caro-Bautista et al., 2014) and the differences in reporting found in the prospective study across DMSB completion measures completed by the same individual in the same time span, methods other than self-report should be employed in future studies. Other methods of assessing medication DSMB include pill counts, pharmacy refill records, and electronic pill bottle caps that make use of Microelectronic Event Monitoring Systems (Gonzalez et al., 2016; Mulcahy et al., 2003; Rosen et al., 2003). Blood glucose DSMB could be measured using log books tracking testing and blood glucose levels or by downloading blood glucose testing readings directly from an individual's glucometer (Gonzalez et al., 2016; Gonder-Frederick et al., 2016; Mulcahy et al., 2003). Exercise DSMB could be measured using a pedometer or any of the number of exercise tracking technologies that have been developed recently and are becoming widely available (Gonzalez et al., 2016; Gonder-Frederick et al., 2016). Finally, diet DSMB could be measured using food diaries-- either paper-pencil or more sophisticated electronic ones (Gonzalez et al., 2016; Gonder-Frederick et al., 2016; Mulcahy et al., 2003).

There have been no longitudinal studies of the effects of cognitive functioning on DSMB completion. Longitudinal methods will be required to assess the dynamic nature of DSMB completion (Castellon et al., 2009) and to investigate the interacting effects of barriers to DSMB completion at the individual, interpersonal, community, and societal level (Johnson & Marrero, 2016). In addition, more studies of the top-down influences of community and societal barriers on the interpersonal and individual barriers are required to influence policy in order to ensure that all individuals with T2DM have the opportunity and resources to successfully complete their DSMB and manage their T2DM.

In vivo studies of DSMB completion are required. A single study has investigated the relationship between a sham insulin injection skills test and performance on the Clock Drawing Test and the MMSE (Trimble et al., 2005). Poorer performance on the Clock Drawing Test was significantly associated with increased likelihood of making serious errors on the sham insulin injection task ($p = .01$) in a sample of 30 older adults. However, there was no significant association between performance on the task and performance on the MMSE ($p > .05$, Trimble et al., 2005). Future studies should investigate the relationships of multiple cognitive domains and abilities with in-lab performance on ecologically valid DSMB tasks such as the sham insulin injection task used by Trimble et al. and with other tasks necessary for successful DSMB completion. This methodology would be especially important to assess diabetes-related problem solving skills such as adjusting insulin doses in response to high or low blood sugar and changes in physical activity (Hills-Briggs et al., 2007; Mulcahy et al., 2003).

These in-vivo studies would also serve the function of providing pilot data for the development of interventions to accommodate the effects of changes in cognitive functioning on the completion of DSMB. The goal of these interventions would be to increase and maintain successful DSMB completion in the face of cognitive deficits or declining cognitive functioning (Monette, 2012; Primozic et al., 2012). Finally, once the relationships between cognitive functioning and DSMB have been further elucidated, interventions should be developed and validated to counter the impacts of cognitive functioning on DSMB completion and T2DM adherence. This will require the continued efforts to train psychologists and neuropsychologists in the disease processes, psychosocial, and cognitive aspects of T2DM (Hunter, 2016).

Conclusion

The present investigation sought to determine the impact of cognitive functioning on DSMB completion and diabetes-related and general QoL. In the prospective study, executive functioning objectively measured by phonemic verbal fluency and measured using self-report was significantly related to DSMB completion. Objective measures of processing speed and executive functioning along with self-report measures of executive functioning were significantly related to general QoL. In the archival study cognitive functioning as measured by the TICS was not significantly related to DSMB completion or impact of diabetes on life.

Much more research with varied methodologies is needed to conclusively determine the relationships between cognitive functioning, DSMB completion, and QoL. Future research is also needed to develop, validate, and implement interventions that can remove or accommodate the impact of cognitive deficits on DSMB completion in order to allow individuals with T2DM to continue to successfully manage the disease and prevent or delay further complications and cognitive impairment. Finally, further research is needed to address barriers to DSMB completion and T2DM treatment adherence at the individual, interpersonal, community, and societal levels in order to improve the overall poor levels of T2DM treatment adherence in the T2DM population as whole.

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APPENDICES

Appendix 1

Demographic Questionnaire/ Interview

Participant ID:_____________

Date (MM/DD/YYYY): ________________ D.O.B. (MM/DD/YYYY): ________________

Age: ___________

Gender: Man Woman Other: _________________ Prefer Not To Answer

Ethnicity: ____

Birth Place (City, Province, Country):

____

If NOT born in Canada, how many years have you lived in Canada?: _______

Primary language spoken day-to-day: ____

Fluent in English if primary language is not English: Yes No

Highest Education level attained (Years of education): __________________________________

Number of years of education in English: __________________________

Are you employed?:

Yes No Other:________________________

If yes, what is your occupation? ________

If no, when was the last time you worked? ________________________

Current Marital Status:

a) Single, never married
b) Married

c) Cohabiting
d) Divorced or separated
e) Widowed or widower
f) Other (please specify): ________________________

With whom do you live currently? (alone, spouse, other):

____

Do you smoke?: Yes No

If YES, on average, how many Cigarettes do you smoke per DAY: _______

Do you drink alcohol?: Yes No

If YES, on average how many drinks do you have per WEEK: ___________

Height: _______________

Weight: _______________

What is your currently prescribed T2DM treatment regimen?:

a) Diet & exercise only
b) Oral hypoglycemic medications: (types and dose)
c) Insulin (types and dose):
d) Oral hypoglycemic medications and insulin

Please provide us with your current, most up-to-date medication list:

Medication Name	Dose	Frequency

What was your most recent A1C?: __________%

When was it measured?: __________________

When were you diagnosed with diabetes? (years since diagnosis): ______________

Do you have any complications from your diabetes?: Yes No

If YES, what complications do you have: __________________

Have you ever received a psychiatric diagnosis?: Yes No

Have you ever taken medication for your mood or received psychotherapy?:

Yes No

If YES, please specify: ____

Have you been hospitalized in the PAST YEAR (Circle one)?: Yes No

If YES, how many times in the past year: ________________

If YES, for what reason: ________________________

Have you ever been hospitalized specifically for hypoglycemia?: Yes No

Have you received the "Master Your Health" program?:

Yes No

Have you received any other diabetes education programs?:

Yes No

If YES, please specify the program: _____________________________

What is your current level of pain from 0-9, 0 being no pain and 9 being the most pain you have ever had? ___________

What is your chronic level of pain on average from 0-9, 0 being no pain and 9 being the most pain you have ever had? ___________

Do you take medication for of the following health conditions:

High Blood Pressure	Yes	No
High Cholesterol	Yes	No
Hypothyroidism	Yes	No

(circle point value for endorsement):

a) Myocardial Infarction (heart attack, 1 point)
b) Congestive Heart Failure (1 point)
c) Peripheral Vascular Disease (blood clots in legs, neuropathy, 1 point)
d) Cerebrovascular Disease (stroke, TIA, aneurysm, bleed, 1point)
e) Peptic Ulcer Disease (acid reflux, 1 point)
f) Diabetes Mellitus with end-organ damage (1 point)
g) Moderate to Severe Chronic Kidney Disease (2 points)
h) Hemiplegia (paralysis, 2 points)
i) Liver Disease (mild, 1 point)
j) Liver Disease (moderate to severe, 3 points)
k) Chronic Obstructive Pulmonary Disease (1 point)

Pre-testing glucometer reading: ______mmol/l

Completion date of the testing appointment if hypoglycemia was reported (MM/DD/YYYY): ______________________ or

did not participate after hypoglycemia was reported or

Not Applicable (No hypoglycemia)

Informant Measures Completed? Yes No

If yes, relationship of informant to participant: _________________________

Appendix 2

Participant ID:_____________

Date (MM/DD/YYYY): ________________

Diabetes Self-Management Behaviour Questionnaire

The questions below ask you about your diabetes self-care activities during **the past 7 days**. If you were sick[1] during the past 7 days, please think back to the last 7 days that you were not sick.

Diet

How many of the last SEVEN DAYS have you followed a healthful eating plan?

0 1 2 3 4 5 6 7

On average, over the past month, how many DAYS PER WEEK have you followed your eating plan?

0 1 2 3 4 5 6 7

Exercise

On how many of the last SEVEN DAYS did you participate in at least 30 minutes of physical activity? (Total minutes of continuous activity, including walking).

0 1 2 3 4 5 6 7

On how many of the last SEVEN DAYS did you participate in a specific exercise session (such as swimming, walking, biking) other than what you do around the house or as part of your work?

0 1 2 3 4 5 6 7

Blood Sugar Testing

On how many of the last SEVEN DAYS did you test your blood sugar?

0 1 2 3 4 5 6 7

On how many of the last SEVEN DAYS did you test your blood sugar the number of times recommended by your health care provider?

0 1 2 3 4 5 6 7

Foot Care

On how many of the last SEVEN DAYS did you check your feet?

0 1 2 3 4 5 6 7

On how many of the last SEVEN DAYS did you inspect the inside of your shoes?

[1] In diabetes treatment regimens "sick days" represent the presence of any acute illness that can affect blood glucose levels and requires changes to the routine treatment regimen.

0 1 2 3 4 5 6 7

Medications

On how many of the last SEVEN DAYS did you take your recommended insulin injections?

0 1 2 3 4 5 6 7 N/A

On how many of the last SEVEN DAYS did you take your recommended number of diabetes pills?

0 1 2 3 4 5 6 7 N/A

Please answer the following questions as accurately as possible based on how you managed your diabetes.

How many days during the past week (last 7 days) …

1. …did you miss taking your diabetes medications as prescribed?

   0 1 2 3 4 5 6 7

2. …did you miss monitoring your blood sugar?

   0 1 2 3 4 5 6 7

3. …did you eat foods not healthy for your diabetes?

   0 1 2 3 4 5 6 7

4. …did you eat more food than you were supposed to?

   0 1 2 3 4 5 6 7

5. …did you do at least some light physical activity (such as walking, light gardening)?

   0 1 2 3 4 5 6 7

6. …did you do at least 30 minutes of moderate physical activity (such as pushing a vacuum cleaner, riding a bicycle, playing golf)?

   0 1 2 3 4 5 6 7

7. …did you do at least 20 minutes of vigorous physical activity (such as running or participating in strenuous sports)?

   0 1 2 3 4 5 6 7

8. During the past week, how much difficulty did you have with **(0= no difficulty, 7= the most difficulty you have ever had):**

   a. Monitoring your blood sugar?

      0 1 2 3 4 5 6 7

   b. Giving yourself your diabetes medications as your doctor instructed?

      0 1 2 3 4 5 6 7

c. Managing your weight?

0 1 2 3 4 5 6 7

d. Periods of uncontrolled eating?

0 1 2 3 4 5 6 7

e. Feeling hungry?

0 1 2 3 4 5 6 7

f. Food cravings?

0 1 2 3 4 5 6 7

g. Being physically active?

0 1 2 3 4 5 6 7

h. Coping with frustration and worry related to your diabetes?

0 1 2 3 4 5 6 7

9. During the past week (last 7 days), how frustrated have you been with trying to manage your diabetes **(0= no frustration, 7= the most frustration you have ever had)**?

0 1 2 3 4 5 6 7

10. During the past week (last 7 days), how worried have you been about your future health because of your diabetes **(0= no worry, 7= the most worry you have ever had)**?

0 1 2 3 4 5 6 7

11. Overall, how confident have you felt during the past week (last 7 days) about being able to manage your diabetes **(0= no confidence, 7= the most confidence you have ever had)**?

0 1 2 3 4 5 6 7

12. How important is it for you right now to **(0= not important, 7= the most important it has ever been)**:

a. monitor your blood sugar?

0 1 2 3 4 5 6 7

b. take your diabetes medications as your doctor instructed?

0 1 2 3 4 5 6 7

c. manage your weight?

0 1 2 3 4 5 6 7

d. manage your diet?

0 1 2 3 4 5 6 7

e. manage your physical activity?

0 1 2 3 4 5 6 7

f. manage frustration and worry related to your diabetes?

0 1 2 3 4 5 6 7

The following statements describe self-care activities related to your diabetes. Thinking about your self-care over the **last 8 weeks**, please specify the extent to which each statement applies to you on a 1-4 scale with 1= does not apply to me and 4= applies to me very much. If a question asks about a self-care activity that is not part of your diabetes treatment, please circle the N/A option.

1. I check my blood sugar levels with care and attention.

1 2 3 4 N/A

2. The food I choose to eat makes it easy to achieve optimal blood sugar levels

1 2 3 4

3. I keep all doctors' appointments recommended for my diabetes treatment.

1 2 3 4

4. I take my diabetes medication (e. g. insulin, tablets) as prescribed.

1 2 3 4 N/A

5. Occasionally I eat lots of sweets or other foods rich in carbohydrates.

1 2 3 4

6. I record my blood sugar levels regularly

1 2 3 4 N/A

7. I tend to avoid diabetes-related doctors' appointments

1 2 3 4

8. I do regular physical activity to achieve optimal blood sugar levels.

1 2 3 4

9. I strictly follow the dietary recommendations given by my doctor or diabetes specialist.

1 2 3 4

10. I do not check my blood sugar levels frequently enough as would be required for achieving good blood glucose control.

1 2 3 4 N/A

11. I avoid physical activity, although it would improve my diabetes.

1 2 3 4

12. I tend to forget to take or skip my diabetes medication (e. g. insulin, tablets).

1 2 3 4 N/A

13. Sometimes I have real 'food binges' (not triggered by hypoglycemia).

1 2 3 4

14. Regarding my diabetes care, I should see my medical practitioner(s) more often.

1 2 3 4

15. I tend to skip planned physical activity.

1 2 3 4

16. My diabetes self-care is poor.

1 2 3 4

Participant ID:_____________

Date (MM/DD/YYYY): ________________

Diabetes Self-Management Behaviour Questionnaire (Informant)

Please think of the individual you care for or live with who has diabetes and answer the following questions as accurately as possible.

The questions below ask you about the diabetes self-care activities of the person with diabetes you care for or live with during **the past 7 days**. If they were sick during the past 7 days, please think back to the last 7 days that they were not sick.

Diet

How many of the last SEVEN DAYS have they followed a healthful eating plan?

0 1 2 3 4 5 6 7 DK

On average, over the past month, how many DAYS PER WEEK have they followed their eating plan?

0 1 2 3 4 5 6 7 DK

How many days during the past week (last 7 days) did they eat foods not healthy for diabetes?

0 1 2 3 4 5 6 7 DK

During the past week (last 7 days), how many days did they eat more food than they were supposed to?

0 1 2 3 4 5 6 7 DK

Exercise

How many days during the past week (last 7 days), did they do at least some light physical activity (such as walking, light gardening)?

0 1 2 3 4 5 6 7 DK

How many days during the past week (last 7 days), did they do at least 30 minutes of moderate physical activity (such as pushing a vacuum cleaner, riding a bicycle, playing golf)?

0 1 2 3 4 5 6 7 DK

How many days during the past week (last 7 days), did they do at least 20 minutes of vigorous physical activity (such as running or participating in strenuous sports)?

0 1 2 3 4 5 6 7 DK

Blood Sugar Testing

On how many of the last SEVEN DAYS did they test their blood sugar?

0 1 2 3 4 5 6 7 DK

On how many of the last SEVEN DAYS did they test their blood sugar the number of times recommended by their health care provider?

0 1 2 3 4 5 6 7 DK

How many days during the past week (last 7 days) did they miss monitoring their blood sugar?

0 1 2 3 4 5 6 7 DK

Medications

On how many of the last SEVEN DAYS did they take their recommended insulin injections?

0 1 2 3 4 5 6 7 N/A

On how many of the last SEVEN DAYS did they take their recommended number of diabetes pills?

0 1 2 3 4 5 6 7 N/A

How many days during the past week (last 7 days) did they miss taking their diabetes medications as prescribed?

0 1 2 3 4 5 6 7 N/A

1. Which of the following has their health care team (doctor, nurse, dietitian, or diabetes educator) advised them to do?

Please check all that apply:

____ a. Follow a low-fat eating plan

____ b. Follow a complex carbohydrate diet

____ c. Reduce the number of calories they eat to lose weight

____ d. Eat lots of food high in dietary fiber

____ e. Eat lots (at least 5 servings per day) of fruits and vegetables

____ f. Eat very few sweets (for example: desserts, non-diet sodas, candy bars)

____ g. Other (specify): ____

____ h. They have not been given any advice about their diet by their health care team.

2. Which of the following has their health care team (doctor, nurse, dietitian or diabetes educator) advised them to do?

Please check all that apply:

____ a. Get low level exercise (such as walking) on a daily basis.

____ b. Exercise continuously for at least 20 minutes at least 3 times a week.

____ c. Fit exercise into their daily routine (for example, take stairs instead of elevators, park a block away and walk, etc.)

____ d. Engage in a specific amount, type, duration and level of exercise.

____ e. Other (specify): ____

____ f. They have not been given any advice about exercise by their health care team.

3. Which of the following has their health care team (doctor, nurse, dietitian, or diabetes educator) advised them to do?

Please check all that apply:

____ a. Test their blood sugar using a drop of blood from their finger and a color chart.

____ b. Test their blood sugar using a machine to read the results.

____ c. Test their urine for sugar.

____ d. Other (specify): ____

____ e. They have not been given any advice either about testing their blood or urine sugar level by their health care team.

4. Which of the following medications for their diabetes has their doctor prescribed?

Please check all that apply.

____ a. An insulin shot 1 or 2 times a day.

____ b. An insulin shot 3 or more times a day.

____ c. Diabetes pills to control their blood sugar level.

____ d. Other (specify): ____

____ e. They have not been prescribed either insulin or pills for their diabetes.

The following statements describe self-care activities related to the person with diabetes. Thinking of self-care over the **last 8 weeks**, please specify the extent to which each statement applies to this person on a 1-4 scale with 1= does not apply to them and 4= applies to them very much. If you are not sure that they complete (or do not complete) the self-care activity, please circle the do not know (DK) option.

1. They check their blood sugar levels with care and attention.

1 2 3 4 DK

2. The food they choose to eat makes it easy to achieve optimal blood sugar levels

1 2 3 4 DK

3. They keep all doctors' appointments recommended for their diabetes treatment.

1 2 3 4 DK

4. They take their diabetes medication (e. g. insulin, tablets) as prescribed.

1 2 3 4 DK

5. Occasionally they eat lots of sweets or other foods rich in carbohydrates.

1 2 3 4 DK

6. They record their blood sugar levels regularly

1 2 3 4 DK

7. They tend to avoid diabetes-related doctors' appointments

1 2 3 4 DK

8. They do regular physical activity to achieve optimal blood sugar levels.

1 2 3 4 DK

9. They strictly follow the dietary recommendations given by their doctor or diabetes specialist.

1 2 3 4 DK

10. They do not check their blood sugar levels frequently enough as would be required for achieving good blood glucose control.

1 2 3 4 DK

11. They avoid physical activity, although it would improve their diabetes.

1 2 3 4 DK

12. They tend to forget to take or skip their diabetes medication (e. g. insulin, tablets).

1 2 3 4 DK

13. Sometimes they have real 'food binges' (not triggered by hypoglycemia).

1 2 3 4 DK

14. Regarding their diabetes care, they should see their medical practitioner(s) more often.

1 2 3 4 DK

15. They tend to skip planned physical activity.

1 2 3 4 DK

16. Their diabetes self-care is poor.

1 2 3 4 DK

VITA AUCTORIS

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