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Sedentary Behavior Associations with Cardiometabolic Risk and Depressive Symptoms in Overweight/Obese Type 2 Diabetics: Results from the CALM-D Trial

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UNIVERSITY OF MIAMI

SEDENTARY BEHAVIOR ASSOCIATIONS WITH CARDIOMETABOLIC RISK
AND DEPRESSIVE SYMPTOMS IN OVERWEIGHT/OBESE TYPE 2 DIABETICS:
RESULTS FROM THE CALM-D TRIAL

By

Carrie E. Brintz

A DISSERTATION

Submitted to the Faculty
of the University of Miami
in partial fulfillment of the requirements for
the degree of Doctor of Philosophy

Coral Gables, Florida

August 2016

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Sedentary Behavior Associations with Cardiometabolic Risk and Depressive Symptoms in Overweight/Obese Type 2 Diabetics: Results from the CALM-D Trial.

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Increased sedentary behavior has detrimental associations with cardiometabolic risk factors and depression, and has been associated with greater risk for cardiovascular disease and type 2 diabetes (T2DM), independent of engagement in moderate-vigorous physical activity (MVPA). There are limited studies of sedentary behavior in patients who already have T2DM. The aims of the study were to determine (1) whether a latent factor including self-reported daily sedentary time and daily average number of pedometer steps was associated with cardiometabolic risk factors and depressive symptoms in overweight/obese T2DM patients, and (2) whether a multi-component lifestyle intervention was successful at reducing sedentary time compared with standard care in overweight T2DM patients with significant depressive symptoms. A sample of 298 T2DM patients was recruited from Miami-area community health centers and by word-of-mouth. Participants were eligible if they were overweight/obese, had confirmed T2DM, and no evidence of CVD or renal disease. A medical history, psychosocial/behavioral measures, blood test, and pedometer data were collected. Sedentary time was self-reported with the Global Physical Activity Questionnaire (GPAQ). A subset of 111 participants with Beck Depression Inventory-II (BDI-II) total

scores >11 were randomized to receive either standard care or a 12-month, 17-session lifestyle intervention, and follow-up assessments were conducted 6 months and 12 months after baseline. At baseline, structural regressions indicated that a sedentary behavior factor was significantly, positively associated with waist circumference ($b = 4.47, p = .046$), adjusting for age and gender, but not when further adjusting for moderate-vigorous physical activity (MVPA). The sedentary behavior factor was significantly, positively associated with a composite cardiometabolic risk score ($b = .34, p = .049$), adjusting for age, gender, medication use and MVPA. It was not significantly associated with body mass index, hemoglobin A1c, or scores on the BDI-II. If correcting p -values for multiple comparisons, no associations were significant at $p < .05$. Structural regressions using latent growth modeling showed significant reductions in minutes/day of sedentary time on the GPAQ in the intervention group compared with standard care ($b = -6.54, p = .012$). Intervention participants decreased their sedentary time by an average of 5.15 minutes/month over 12 months ($p = .011$), whereas control participants increased their sedentary time by an average of 1.39 minutes/month ($p = .492$). This study found evidence of associations between sedentary time and measures of adiposity and composite cardiometabolic risk in overweight T2DM patients, but no associations with other selected cardiometabolic risk factors or depressive symptoms. It found that a lifestyle intervention successfully reduced self-reported sedentary time in overweight T2DM patients with depressive symptoms. Future studies should focus on the reliable measurement of sedentary time in T2DM patients and include longer follow-up periods in order to clarify if reductions in sedentary time can reduce cardiometabolic risk and depressive symptoms in T2DM patients.

TABLE OF CONTENTS

	Page
LIST OF FIGURES	iv
LIST OF TABLES	v
Chapter	
1 INTRODUCTION	1
Type 2 Diabetes	1
Sedentary Behavior	5
Population Trends in Sedentary Behavior	5
Sedentary Behavior and Cardiometabolic Health.....	8
Sedentary Behavior and Depression	12
Sedentary Behavior Interventions in Type 2 Diabetes	14
The Present Study	15
2 METHOD	17
Participants.....	17
Procedures.....	18
Measures	19
Statistical Analyses	22
3 RESULTS	25
Preliminary Analyses	25
Primary Analyses	26
4 DISCUSSION.....	29
Self-reported Sedentary Time in the Study Sample.....	30
Sedentary Behavior Latent Factor Associations	31
CALM-D Intervention Effects on Sedentary Time	33
Strengths and Limitations	34
Conclusions.....	35
REFERENCES	36
FIGURES.....	45
TABLES.....	47

LIST OF FIGURES

Figure 1	45
Figure 2	46

LIST OF TABLES

Table 1	47
Table 2	48
Table 3	49
Table 4	50
Table 5	51

Chapter 1

Introduction

Type 2 Diabetes

Diabetes mellitus (DM) affects over 25 million children and adults (8.3% of the United States population), and is the 7th leading cause of death in the U.S. Type 2 diabetes mellitus (T2DM), which is characterized by insulin resistance, hyperglycemia, and/or decreased secretion of insulin production by the pancreas, accounts for approximately 90% of cases of DM (ADA, 2010). T2DM results predominantly from lifestyle factors such as physical inactivity, a diet high in fat and sugar, smoking, which may result in overweight/obesity and high blood pressure, and having a family history of T2DM. T2DM is most prevalent in older adults, although the prevalence has increased in younger adults, likely as a result of higher rates of obesity in children and youth. When poorly controlled, T2DM can lead to microvascular complications such as neuropathy, retinopathy, and kidney failure. In addition, having T2DM increases risk for macrovascular complications such as heart disease and stroke, and ultimately premature mortality (ADA, 2013).

Sociodemographic factors such as ethnicity and socioeconomic status are associated with risk of developing T2DM and with diabetes-related outcomes. For example, Hispanics, blacks and Asians have higher rates of T2DM than non-Hispanic whites in the U.S. (Abate & Chandalia, 2003; Harris et al., 1998; Shai et al., 2006), and Hispanics are more likely than non-Hispanic whites to develop diabetes-related complications such as end-stage renal disease (Myers & Rodriguez, 2003). These ethnic disparities in T2DM rates and outcomes may be because of environmental, lifestyle,

genetic, and/or socioeconomic factors that are associated with certain ethnic groups (Abate & Chandalia, 2003; Shai et al., 2006). People of low socioeconomic status including lower income and educational attainment also have higher rates of T2DM (Agardh et al., 2011; Lee et al., 2011) and greater risk for poor T2DM outcomes such as having major kidney-related events (Jardine et al., 2012). In addition, having depression is both a risk factor for and a consequence of developing T2DM (Mezuk, Eaton, Albrecht, & Golden, 2008), and is associated with worse adherence to diabetes management recommendations (Egede, Ellis, & Grubaugh, 2009; Gonzalez et al., 2007; Lin et al., 2004) and less favorable diabetes-related outcomes (Egede, 2004; Lin et al., 2010).

The American Diabetes Association (ADA) has detailed a number of recommendations for the standard treatment and management of T2DM. The recommendation for glycemic control, or control of blood glucose levels in those with diabetes is achieving a level of glycated hemoglobin (HbA1c) less than 7%. Behavioral and pharmacological recommendations include taking oral medications and insulin therapy when appropriate, patient self-monitoring of blood glucose levels, pharmacological therapies to improve hypertension and dyslipidemia where needed, nutrition therapy to address individual nutrition needs and metabolic goals, increased physical activity (at least 150 minutes per week), and participation in diabetes self-management education (ADA, 2013). In particular, the ADA emphasizes the importance of weight loss for overweight and obese individuals with T2DM, as obesity complicates the management of T2DM and increases the risk for cardiovascular complications and mortality. Lifestyle recommendations for weight loss include a diet based on the ADA

and the American Heart Association (AHA) guidelines for reducing obesity-related comorbidities, as well as daily moderate-vigorous intensity aerobic physical activity (Klein, et al., 2004). In addition, the ADA recommends that psychosocial assessment and treatment be incorporated into routine diabetes care, emphasizing that psychosocial issues such as depression, anxiety, diabetes-related distress, illness attitudes, and social support can impair the patient's and family's ability to engage in diabetes self-care and result in worse health outcomes (ADA, 2013).

Because of the comprehensive, multifactorial nature of managing T2DM, a number of diabetes management interventions have focused on helping T2DM patients modify multiple aspects of their lifestyle as well as address emotional and motivational barriers to diabetes self-care. Multicomponent lifestyle modification interventions providing diabetes education and targeting improvements in both diet and physical activity have resulted in weight loss, improved glycemic control, reductions in the need for diabetes medications, and improved cardiovascular risk profiles compared with control conditions in T2DM patients (Cox et al., 2013). The Look AHEAD trial compared a 4-year intensive lifestyle modification program to diabetes support and education in 5,145 overweight and obese individuals with T2DM. The intervention, which focused on diet modification, increased physical activity, and behavioral change strategies, resulted in sustained improvements in weight, fitness, HbA1c, systolic blood pressure, and high-density lipoprotein cholesterol levels compared with the control condition at the 4-year follow up (Look AHEAD Research Group, 2010). Furthermore, while modest weight loss of 5-10% of body weight was associated with significant improvement in cardiovascular risk factors at 1-year in the Look AHEAD trial, even

greater weight losses were associated with greater cardiovascular risk improvements (Wing et al., 2011). However, there is little evidence that multicomponent lifestyle interventions reduce the incidence of cardiovascular events and mortality in T2DM patients, as 5-year results of two multicomponent trials (Cox et al., 2013; Simmons et al., 2012) and 10-year results of one trial (Look AHEAD Research Group, 2013) did not show significant reduction in cardiovascular burden or reduced cardiovascular mortality in their intervention groups compared with control groups.

Because individuals with T2DM and comorbid depression generally engage in worse diabetes self-care and have poorer outcomes than those without depression, psychological interventions have targeted T2DM patients with elevated levels of depression. These studies have consistently shown reductions in depressive symptoms, with a moderate overall effect size. Fewer psychological interventions targeting depressed individuals with T2DM have had significant effects on glycemic control, but those that did were more likely to include a diabetes self-management component in addition to psychotherapy, suggesting that treating depression alone without addressing diabetes self-care may not be sufficient for improving diabetes outcomes in these patients (Van der Feltz-Cornelis et al., 2010).

The components of T2DM management are multifaceted, involving intensive lifestyle modification, pharmacotherapy, and psychosocial intervention. A component of lifestyle that is recently becoming a public health concern, but has not been well addressed in T2DM is the effect of sedentary behavior on cardiometabolic health. Research is clear about the tremendous importance of increasing moderate-vigorous intensity physical activity (MVPA) and resistance training for the management of T2DM

and the prevention of disease. The ADA recommends that adults with T2DM engage in at least 150 minutes per week of moderate-intensity aerobic activity, 75 minutes per week of vigorous-intensity aerobic activity, or an equivalent combination of the two, as well as at least two days per week of resistance training (ADA, 2013). Yet, there is a growing body of evidence that excessive time spent in sedentary behaviors affects cardiometabolic health negatively, and through processes that are distinct from engaging in too little MVPA.

Sedentary Behavior

Sedentary behaviors are generally defined as behaviors resulting in little or no energy expenditure, usually in the range of 1.0-1.5 METs (multiples of the basal metabolic rate, which is the energy-cost of being at rest) and are typically characterized by sitting. Examples of sedentary behaviors include watching TV, time spent in automobiles, computer and video-game use, and sitting at work (Owen, Healy, Matthews, & Dunstan, 2010). Previous studies generally categorized people as sedentary if they did not engage in the recommended amounts of MVPA, characterized as activities resulting in energy expenditure in the range of 3.0-8.0 METs. However, researchers have begun to distinguish between sedentary behavior and light intensity activities that fall within the range of 1.5-3.0 METs.

Population Trends in Sedentary Behavior

Population-based studies of physical activity levels throughout the waking day indicate that many people spend the majority of their time in sedentary behaviors. Objectively measured accelerometer-derived data from the National Health and Nutrition Examination Survey (NHANES) indicated that overall, children and adults in the U.S.

spend 55 percent of their waking time (7.7 hours/day) in sedentary behaviors, and that sedentary behavior time begins to increase during adolescence and then again after 60 years of age (Matthews et al., 2008). The National Longitudinal Study of Adolescent Health, which followed adolescents in the U.S. into young adulthood, showed that not only were the majority of adolescents not achieving the recommended amount of physical activity each week, but that almost one quarter of adolescents spent more than the recommended amount of 14 hours maximum per week in screen time (TV/video viewing and computer/video game) and maintained this trend into adulthood. 17% of adolescents who achieved less than 14 hours of weekly screen time no longer achieved this in adulthood. Screen time did not include additional time that would be characterized as sedentary behavior, such as time spent sitting during school and work hours or while driving in automobiles (Gordon-Larson, Nelson, & Popkin, 2004). Accelerometer-derived activity in the Australian Diabetes, Obesity, and Lifestyle Study (AusDiab), a prospective study of 11,000 adults in Australia, indicated that during wearing time, a subsample of participants spent an average of 57% of time sedentary, 39% of time in light-intensity activity, and only 4% of time in MVPA. Sedentary time and light-intensity time were strongly inversely correlated, whereas sedentary time and MVPA time were weakly correlated, suggesting that time spent in light intensity activities that involve standing and/or ambulating may have more influence than MVPA on alterations in sedentary behavior (Healy et al., 2008). There is the potential for people to get the recommended daily amount of MVPA, but to be highly sedentary the rest of the day, a phenomenon that has been coined the “active couch potato” (Owen, Healy, Matthews, & Dunstan, 2010).

There is some evidence that sociodemographic and environmental factors contribute to sedentary behavior patterns. People reporting living in rural areas and having barriers to physical activity (e.g. cost, work commitments, neighborhood walkability) also report spending more time watching TV (Owen et al., 2011). According to a systematic review of studies examining sedentary behavior correlates (Rhodes, Mark, & Temmel, 2012), older age is associated with more TV viewing time, but less computer use. In addition, lower education and being unemployed are associated with more TV viewing. However, higher income has also been associated with more TV viewing. Associations of these variables with overall sitting time have been inconclusive. Marital status and gender do not appear to be associated with sedentary behavior, with the exception of men engaging in more video game time than women. Ethnicity is not associated with overall sitting time, but a number of studies have found that being African American is associated with more TV viewing time. Studies used primarily self-report measures of sedentary behavior. Overall, results of studies examining sociodemographic and environmental correlates of self-reported sedentary behavior have been somewhat inconclusive or dependent on the type of sedentary behavior (Rhodes, Mark, & Temmel, 2012).

Much is known about the beneficial and protective physiological processes that occur as a result of engaging in MVPA, and the public health guidelines regarding physical activity are well supported. Less is understood about what occurs during the large majority of people's daily lives while they engage in other incidental, routine, and /or sedentary activities (Hamilton, Healy, Dunstan, & Zderic, 2008). Research groups are studying the physiological, medical and public health impact of too much sitting, and the

evidence has begun to point to a unique inactivity physiology distinct from exercise physiology that may have dire consequences for health if not addressed further (Hamilton, Hamilton, & Zderic, 2007).

Sedentary Behavior and Cardiometabolic Health

It is not recent news that being sedentary may have negative consequences for health. Two London-based studies, conducted from 1949-1950 (Morris et al., 1953a) and from 1951-1952 (Morris et al., 1953b), found that over one year, incidence of coronary heart disease was higher in male drivers than in male conductors of the London Transport Executive, and higher in telephonists than in postmen in the London postal service. The primary difference between these groups was the level of physical activity required during the job, with conductors and postmen being consistently more active during the workday than drivers and telephonists, who were primarily sedentary. Since then, a growing number of studies have provided evidence that sedentary behavior is associated with worse cardiometabolic risk profiles and higher risk for cardiometabolic health conditions in adults. Importantly, these relationships exist independently of engagement in MVPA (Owen, Healy, Matthews, & Dunstan, 2010).

Prospective, longitudinal studies and meta-analyses have consistently found that spending more time watching TV and in overall sedentary behavior predicts higher incidence of CVD (Grøntved & Hu, 2011), T2DM (Hu et al., 2001; Hu, Li, Colditz, Willett, & Manson, 2003; Grøntved & Hu, 2011), CVD mortality, and pre-mature all-cause mortality (Dunstan et al., 2010; Katzmarzyk, Church, Craig, & Bouchard, 2009; Proper, Singh, Van Mechelen, & Chinapaw, 2011; Thorp, Owen, Neuhaus, & Dunstan, 2011; Wijndaele et al., 2011). Interestingly, all of the studies that found associations

between sedentary behavior and CVD/all-cause mortality found non-significant associations with mortality due to cancer.

Researchers are also interested in whether sedentary behavior is associated with known risk factors for T2DM and CVD. Data from the National Health and Nutrition Examination Survey (NHANES) showed a graded positive association between hours spent watching TV/videos or using a computer outside of work and prevalence of the metabolic syndrome, such that people who typically spent at least 4 hours per day in screen time were significantly more likely than those who spent less than 1 hour per day in screen time to have the metabolic syndrome (Ford, Kohl, Mokdad, & Ajani, 2011). The AusDiab study found that in adults without known diabetes, TV viewing time was positively associated with undiagnosed abnormal glucose metabolism (Dunstan et al., 2007) and likelihood of having the metabolic syndrome (Dunstan et al., 2005), and in women only, it was positively associated with 2-hour plasma glucose and fasting insulin (Dunstan et al., 2004), while adjusting for MVPA and waist circumference. Even amongst healthy Australian adults who met the public health guideline of 150 minutes/week of MVPA, there were dose-response associations of TV viewing time with waist circumference, systolic blood pressure, and 2-hour plasma glucose in men and women, and with fasting plasma glucose, triglycerides, and HDL-C in women only, and all associations were stronger in women than in men (Healy et al., 2008b). Longitudinal data from AusDiab showed that increased TV time over 5 years predicted adverse changes in waist circumference in both men and women, and adverse changes in blood pressure and a composite cardiometabolic risk score in women only (Owen, 2010). Other

longitudinal studies have found that more time spent watching TV predicts weight gain and obesity, particularly from adolescence to adulthood (Thorp et al., 2011).

Although TV/video viewing and computer use are commonly used proxies for sedentary behavior time and may provide useful information about domain-specific sedentary behaviors (Healy et al., 2011), total time spent sitting as well as objectively measured activity levels may more accurately represent an individual's overall inactivity. Wave 2 data from the AusDiab study included self-report measures of both TV viewing time and total sitting time, and found that total sitting time was a more consistent and significant predictor of biomarkers of metabolic health, including waist circumference, triglycerides, HDL-cholesterol, and fasting insulin (Thorp et al. 2010). Greater accelerometer-measured inactivity was also associated with higher waist circumference, higher triglycerides, and a higher overall metabolic risk score in the AusDiab study (Healy et al., 2008a). Objective accelerometer-measured sedentary time showed similar but stronger associations than previously found between self-reported sedentary time and 2-hour plasma glucose. Furthermore, accelerometer measured light intensity physical activity was negatively associated with 2-hour plasma glucose independently of MVPA, suggesting that replacing sedentary time with even light intensity activity could favorably influence metabolic risk factors (Healy et al., 2007). Indeed, increased breaks in sedentary time with even light intensity activity has been favorably associated with waist circumference, body mass index (BMI), triglycerides, and 2-hour plasma glucose, independent of accelerometer-measured sedentary time and MVPA (Healy et al., 2008b).

Accelerometer-derived data from 12,443 participants in the Hispanic Community Health Study/Study of Latinos (HCHS/SOL), a study of Hispanics/Latino adults in four

U.S. regions, showed that participants spent an average of 11.9 hours/day in sedentary behavior, and that greater sedentary time was associated with higher diastolic blood pressure, triglycerides, 2-hour glucose levels, fasting insulin, HOMA-Insulin Resistance (IR), and CRP, and lower HDL cholesterol. Associations with HDL-c, triglycerides, 2-hour glucose, and HOMA-IR remained significant when adjusting for moderate-vigorous physical activity, as well as within participants who met physical activity guidelines (Qi et al., 2015).

A number of mechanisms explaining the association between sedentary behavior and cardiometabolic health have been proposed, but still warrant further research. Sedentary behavior may result in decreased energy expenditure as well as increased energy consumption associated with increased snacking, which may promote weight gain and obesity (Thorp, Owen, Neuhaus, & Dunstan, 2011). Physical inactivity may also result in impaired carbohydrate metabolism and insulin resistance (Tremblay et al., 2010). As noted in the previous section, sedentary behavior has been associated with higher levels of fasting glucose, 2-hour plasma glucose, fasting insulin, and insulin resistance, a precursor of T2DM (DeFronzo, Bonadonna, & Ferrannini, 1992). Controlled experiments have shown that acute periods of physical inactivity in healthy subjects can result in the development of both insulin resistance and microvascular impairment (Hamburg et al., 2007). A small number of studies have found that sedentary behavior is associated with higher levels of adiposity-associated markers of inflammation, including leptin, TNF- α , IL-6 and c-reactive protein (CRP), with some associations only present in women (Allison et. al, 2012; Yates et al., 2012). Inflammation has been implicated in the

dysfunction of protective HDL particles (Onat & Hergenc, 2011) and the pathogenesis of CVD (Rikder, Hennekens, Buring, & Rifai, 2000).

There is some evidence that greater lipoprotein lipase (LPL) activity may result in lower risk for CHD in both humans and animals (Hamilton, Hamilton, & Zderic, 2004). Animal studies have found that the activity of LPL, an enzyme that is essential for the breakdown of triglycerides in circulating lipoproteins, is highly sensitive to physical activity and inactivity. During both acute and chronic periods of physical inactivity, there were robust reductions in muscle LPL activity in rats and mice (Hamilton, Hamilton, & Zderic, 2004). Furthermore, controlled experimental studies have shown a significant increase in circulating triglyceride levels in healthy subjects who undergo acute physical inactivity in the form of 1 to 7 days of bed rest (Saunders, Larouche, Colley, & Tremblay, 2012).

Sedentary Behavior and Depression

It has been well supported by the literature that depression is bi-directionally associated with T2DM (Mezuk, Eaton, Albrecht, & Golden, 2008). There is some evidence that sedentary behavior is associated with depressive symptoms. Two reviews of studies examining sedentary behavior and depression found mixed results depending on the measure of sedentary behavior used in the study. Greater TV viewing time was consistently linked with higher risk for depressive symptoms in cross-sectional studies, whereas computer time was inversely associated or had no association with depression (Teychenne, Ball, & Salmon, 2010; Rhodes, Mark, & Temmel, 2012). One cross-sectional study measuring total daily sitting time using objective accelerometer data found a positive association between sitting time and depressive symptoms in overweight

and obese women (Sanchez et al., 2008). Additionally, sedentary individuals who are older and of lower SES may be at greater risk for depressive symptoms (Arredondo et al., 2013).

There is a very limited body of longitudinal work examining the prospective association between sedentary behavior and depression, and existing studies used self-report measures of sedentary behavior. Furthermore, it is plausible that there is a bi-directional relationship between sedentary behavior and depression, but there is not enough research to confirm this. Data from the Nurse's Health Study showed that women with greater levels of TV viewing had a significantly greater risk of developing clinical depression over a 10-year follow-up (Lucas et al., 2011). The association between baseline TV viewing and incident clinical depression was not found in a 6-year prospective study of university graduates in Spain (Sanchez-Villegas et al., 2007). Teychenne, Abbott, Ball, and Salmon (2014) found that in socio-economically disadvantaged Australian women, baseline levels of sedentary behavior (TV viewing, computer use, overall sitting time and screen time) were not associated with depressive symptoms 3 years later, but baseline depressive symptoms were associated with more time spent TV viewing. Conversely, Brunet et al (2013) did not find an association between depressive symptoms and TV viewing 4 years later in young adults in Quebec, but did find an association with greater computer use in men only. Further longitudinal research with objective measures of sedentary time and with types of sedentary behavior other than TV viewing and screen time is needed to clarify the relationship between sedentary behavior and depression.

Sedentary Behavior Interventions in Type 2 Diabetes

Sedentary behavior is associated with T2DM and cardiometabolic risk factors associated with having T2DM. Numerous studies have examined the effects of lifestyle interventions on increasing physical activity in individuals with T2DM, a population that is at high risk for both microvascular and macro-vascular complications. Few studies have examined how a lifestyle intervention can impact the amount of time individuals with T2DM spend engaging in sedentary behavior. Two randomized-controlled cognitive-behavioral based pedometer interventions (De Greef, Deforche, Tudor-Locke, & De Bourdeaudhuij, 2010; De Greef et al., 2011) targeted physical activity and sedentary behavior in individuals with T2DM. The first pedometer-based intervention found that after a 12-week in-person intervention, participants significantly reduced their accelerometer-measured sedentary time, but the effects were not sustained 3 months post-intervention (De Greef, Deforche, Tudor-Locke, & De Bourdeaudhuij, 2010). The second pedometer-based intervention found that after a 24-week intervention consisting of one in-person session and 7 phone-support sessions, participants significantly reduced their accelerometer-measured and self-reported sedentary time, and the effects were sustained 6-months post-intervention (De Greef et al, 2011). However, it is unclear whether a reduction in sedentary behavior is associated with improvements in cardiometabolic health in T2DM patients.

The Diabetes Prevention Program (DPP) was a randomized, controlled trial in 3,234 overweight U.S. adults designed to compare a lifestyle intervention, metformin, and placebo in preventing or delaying T2DM onset in high-risk adults. Although the goals of the study were not primarily to reduce sedentary behavior, but rather to achieve

7% weight loss and 150 min/week of moderate intensity physical activity, data over 3.2 years of follow-up found that the lifestyle intervention was successful at reducing participants' self-reported TV-watching time and time sitting at work compared with the metformin and placebo groups. Furthermore, the study showed that across treatment arms, diabetes incidence increased by 3.4% for each additional hour spent watching TV, controlling for age, sex, treatment arm, and time-dependent leisure physical activity (Rockette-Wagner et al., 2015).

The Present Study

Sedentary behavior clearly has detrimental associations with cardiometabolic risk factors and health conditions such as T2DM. It may also be associated with depression, which is more prevalent in individuals with T2DM than in the general population and may have adverse effects on diabetes management and result in poorer diabetes outcomes. Few studies have examined sedentary behavior in T2DM patients, a high-risk population. The present study examined the associations of a latent factor of sedentary behavior, which included participant-reported, daily overall sedentary time and participant-reported daily average pedometer steps, with selected cardiometabolic risk factors and depressive symptom severity in overweight/obese individuals with T2DM. The study also examined whether the Community Approach to Lifestyle Modification for Diabetes (CALM-D) trial, a comprehensive lifestyle and psychosocial intervention for primarily minority, low SES, overweight/obese individuals with T2DM with significant depressive symptoms, was successful at reducing self-reported daily sedentary time compared with standard care. The CALM-D trial was designed primarily to examine the effects of the lifestyle intervention on weight, HbA1c, and depressive symptoms.

The following hypotheses were tested:

Specific Aim 1. To examine if a sedentary behavior latent factor with two indicators including self-reported sedentary time and number of pedometer steps was associated with a) BMI, waist circumference, HbA1c, and depressive symptom severity (Beck Depression Inventory II [BDI-II]), as these were the primary outcomes examined within the CALM-D trial (with the exception that weight was used to examine change in adiposity in the intervention study), and b) a composite cardiometabolic risk variable composed of systolic and diastolic blood pressure, HDL-cholesterol, triglycerides, waist circumference, and HbA1c, independently of self-reported time spent in moderate-vigorous physical activity.

Hypothesis 1a: Higher scores on a latent factor of sedentary behavior will be associated with greater cardiometabolic risk (i.e. higher values on all risk factors).

Hypothesis 1b: Higher scores on a latent factor of sedentary behavior will be associated with greater depressive symptom severity.

Hypothesis 1c: The associations in hypotheses 1a-1b will be independent of moderate-vigorous physical activity.

Specific Aim 2. To examine if change in self-reported sedentary time (excludes pedometer steps) over the 12-month study period varies as a function of randomization group, adjusting for age and gender.

Hypothesis 2: Change in sedentary time will vary as a function of randomization group, such that sedentary time will decrease significantly in the lifestyle intervention group compared with the standard care control group.

Chapter 2

Method

Participants

Baseline study participants were 298 adults aged 35-69 with self-reported T2DM who were recruited from Miami-area community health centers or referred by word-of-mouth. Baseline study participants were used in the analysis of specific aim 1. A subset of 111 baseline participants who were eligible for the full study were enrolled in a randomized-controlled trial evaluating a group lifestyle intervention entitled Community Approach to Lifestyle Modification for Diabetes (CALM-D) compared with standard care (SC). Randomized participants were used in the analysis of specific aim 2. The CALM-D program included structured diet, exercise, and coping skills training, with the goals of helping participants lose weight, increase physical activity, and improve stress management skills. Participants were eligible for the study if they were aged 18-70 years, overweight or obese (BMI values ≥ 27 kg/m²), with self-report of diabetes confirmed by fasting plasma glucose (FPG) ≥ 200 mg/dL (7 mmol/L) or impaired glucose tolerance (IGT) ≥ 200 mg/dL (11.2 mmol/L) 2-h after a 75-g oral glucose load, and significant depressive symptoms (BDI-II total score ≥ 11). Exclusionary criteria included evidence of CVD or renal disease (dialysis, urine dipstick protein +4, serum creatinine men: ≥ 1.5 mg/dl; women: ≥ 1.4 mg/dl), blood pressure $\geq 160/100$ mmHg, fasting triglycerides ≥ 600 mg/dl, HbA1c $\geq 11\%$ (97 mmol/mol), current use of medication for weight loss, bariatric surgery/bowel resection, inability to walk, severe mental illness, active suicidality, and any other limitation preventing full study participation. Non-depressed individuals with T2DM (i.e. Beck Depression Inventory-II [BDI-II] total score < 11)

were enrolled in the baseline examination, but had neither follow-up sessions nor randomization to the intervention.

Procedures

The study protocol, including the screening and full study informed consent forms, was approved by the University of Miami Human Subjects Research Office, Institutional Review Board, Medical Sciences Committee A. The study was registered in clinicaltrials.gov, identifier NCT01739205. At the screening session, participants completed screening informed consent, mental health screening, and a medical history form. For eligible participants, the full baseline examination consisted of demographic and psychosocial measures, a 2-hour oral glucose tolerance test (OGTT), anthropometry, blood-pressure, and urine and blood measures. Participants who were eligible for the full study and who provided informed consent were randomized to either the 12-month CALM-D intervention or the control condition using block randomization. All randomized participants received repeat psychosocial evaluations and medical testing at 6-months and 12-months post-baseline examination.

The CALM-D intervention consisted of 2 weekly sessions (1-hour each), followed by 2 weekly, then 4 bi-weekly, then 9 monthly group sessions (90 minutes each), for a total of 17 sessions. Session topics included relaxation exercises, eating less fat, tipping the calorie balance, being active, negative thoughts and emotions, challenging negative thoughts, medication adherence, managing stress, social support, problem solving, assertiveness, and staying motivated. Intervention participants were given a scale to monitor their weight, materials to monitor their diet and the type and number of minutes/day of physical activity, and a pedometer to monitor their daily steps.

Participants were also given goals of losing 7% of their body weight and engaging in 150 minutes of moderate-vigorous intensity physical activity, such as brisk walking, per week. Reducing sedentary behavior was not a specific goal of the intervention, but the session about physical activity addressed strategies to decrease inactivity, such as parking the car further from the entrance to a building, exercising while watching TV, or replacing TV watching with walking. Control participants were given a short educational booklet on diabetes management, but were not instructed to make any behavioral changes. All participants received compensation for completing assessments at baseline (\$225) and 6 and 12- months (\$100 each); intervention participants were also compensated (\$10) for travel to and attendance at individual sessions.

Measures

Sedentary Time. Sedentary time was measured by with the Global Physical Activity Questionnaire (GPAQ; Armstrong & Bull, 2006). The GPAQ was interviewer-administered and assesses the time spent in a typical week performing moderate-vigorous physical activity during work and leisure-time, walking or biking for transportation, and sedentary time. Sedentary time was assessed using one item asking participants how much time they usually spend sitting or reclining on a typical day, including all sedentary activity (includes sitting at work) with the exception of time spent sleeping. The reliability and validity of the GPAQ sedentary time item and the item from which it was derived in the short-form International Physical Activity Questionnaire (IPAQ) have been tested in over 12 countries. It has shown generally acceptable test-retest reliability 3-10 days after initial administration (.18-.95, with the large majority > .60) and zero to moderate correlation with pedometer steps (ρ 's = .00 - -.37, with the majority > .20) and

with accelerometer-derived sedentary time (Spearman's ρ 's = -.02 - .61) with the large majority > .20 and U.S. samples with ρ 's = .45 and .49 (Bull, Maslin, & Armstrong, 2009; Booth et al., 2003; Rosenberg, Bull, Marshall, Sallis, & Bauman, 2008; Healy et al., 2011). In the 71 participants in the present study that had both complete sitting time and pedometer data, the correlation between the two measures was low but comparable to that found in some studies ($\rho = -.23, p = .051$).

Moderate-vigorous physical activity and active transport. Moderate–vigorous physical activity (MVPA) during work and leisure-time, and walking and biking for transport, were measured using the GPAQ, described above. Participants were asked on how many days per week and for how much time in a typical week they spend engaging in MVPA at work and during leisure time, including only activities performed for at least 10 minutes continuously. Participants were also asked on how many days and for how much time they spend walking or biking for transport, only including times they spend traveling for at least 10 minutes continuously (Armstrong & Bull, 2006). MVPA was included as a covariate and was analyzed as average daily minutes of physical activity (includes walking and biking for transport). The GPAQ physical activity scales and the scales from which they were derived in the short-form IPAQ have shown generally acceptable test-retest reliability 3-10 days after initial administration (ρ 's = .25-.81, with the majority > .6) and zero to moderate correlation with accelerometer-derived physical activity (ρ 's = -.12 - .57, with the majority > .25) and with pedometer data (ρ 's = 0 - -.37, with the majority > .20; Armstrong & Bull, 2006; Bull, Maslin, & Armstrong, 2009; Booth et al., 2003) in over 12 countries. In the 73 participants in the present study that

had both complete sitting time and pedometer data, the correlation between the two measures was low but comparable to that found in some studies ($\rho = .29, p = .014$).

Pedometer Steps. Participants were given the Omron activity monitor and asked to monitor and self-report their daily number of steps for 7 days before their assessment. Participants' daily average number of steps was calculated by summing the number of steps recorded each day and dividing by the number of days with recorded steps. Pedometer data was used in the analysis of specific aim 1 only because too few participants had complete pedometer data at the 6-month and 12-month follow-up assessments.

Depressive symptoms. Depression was assessed with the Beck Depression Inventory II (BDI-II; Beck, Steer, & Brown, 1996), a 21-item self-report measure of depressive symptom severity, with ratings of each item on a severity scale of 0-3. The BDI-II has been validated in multiple populations including primary care medical patients (Arnau, Meagher, & Norris, 2001), and has shown adequate internal consistency and test-retest reliability (Sprinkle et al., 2002). The BDI-II showed adequate internal consistency in the baseline sample of the current study (Cronbach's alpha = .86). Depressive symptom severity was modeled as a continuous variable.

Cardiometabolic risk variables. Body weight (kg) was measured using a Tanita Body Composition Analyzer (TBF-300A). Waist circumference (cm) was determined by measuring tape during the baseline examination. Three blood pressure measurements were taken at two-minute intervals from the participant's right arm using an automatic sphygmomanometer (the OMRON HEM-907 XL) with the patient seated, following at least 5 minutes of quiet rest. The average of the three measures was used for the present

study. Blood samples were collected by a phlebotomist after a 12-hour fasting period to analyze levels of HbA1c, triglycerides, and HDL-cholesterol. A composite cardiometabolic risk score was calculated by summing the values for systolic and diastolic blood pressure, waist circumference, HbA1c, triglycerides, and HDL-cholesterol (subtracted because it is protective) for each participant. The total cardiometabolic risk score for each participant was then standardized by subtracting the mean from each participant's value and dividing by the standard deviation.

Medical History Questionnaire. The medical history questionnaire was used to obtain participants' diabetes duration, and their use of antidepressant medication, anti-diabetic medication, anti-hypertensive medication and hyperlipidemia medication.

Sociodemographic variables. Age, gender, ethnicity, household income, and years of education completed were obtained by self-report questionnaire at the screening/baseline examination in order to characterize the sample. Because of the restricted range in household income (89% < \$50,000) and ethnicity (84% Hispanic), and in order to limit the number of covariates due to the small randomized sample size, only age and gender were used as covariates.

Statistical Analyses

Preliminary analyses. Preliminary analyses were performed using SPSS Version 22.0. Variables were evaluated for the extent of missing data, outliers, and univariate normality within the entire baseline sample (i.e., includes non-randomized and randomized participants), as well as the randomized sample only. Participants leaving the sedentary time item blank, reporting < 1 hour, or > 18 hours were considered to have missing sedentary time values. This approach is consistent with a previous study using

the same sedentary time variable (Yates et al., 2012), with the modification that participants reporting < 1 hour, rather than 0, were excluded. Twenty-two participants in the baseline sample were missing values on the sedentary time variable, and an additional 14 participants who reported sedentary times < 1 hour or > 18 hours were considered to have missing values, resulting in 262 participants with completed sedentary time values. Within the randomized sample (N = 111), 9 participants at baseline, 4 at 6 months, and 6 at 12 months were considered to have missing sedentary time values. Participants with less than 4 days of recorded steps were considered to have missing pedometer data. Although only 74 out of 298 baseline participants had pedometer data, it was used in the analysis of specific aim 1 in order to strengthen the measure of sedentary behavior by including information from both pedometer data and self-reported sitting time. All variables were evaluated as continuous variables with the exception of inherently categorical variables, which were dummy coded. Means and standard deviations for continuous variables and percentages for categorical variables were evaluated in order to characterize the sample. Zero-order correlations between self-reported sedentary time from the GPAQ and sociodemographic variables at baseline were analyzed. Within the randomized sample, independent samples t-tests and chi-square tests of independence were used to test for differences between the control group and intervention group on study variables at baseline to ensure that randomization was successful.

Specific Aim 1. Primary analyses were performed using Mplus version 7.0 (Muthén & Muthén, 2007). Structural regression was used to examine the associations between a latent variable representing sedentary behavior, which pulls the shared variance between self-reported daily sedentary time and average daily pedometer steps,

and each cardiometabolic risk factor and depression, adjusting initially for age, gender, and medication use (i.e. anti-hyperglycemics with HbA1c, antidepressants with depressive symptoms, and anti-hypertensives, anti-hyperlipidemics, and anti-hyperglycemics with the composite metabolic risk score), and then further adjusting for total minutes of self-reported physical activity (i.e., moderate-vigorous activity plus walking/biking as active transport). Significant associations were determined at $p \leq .05$.

Specific Aim 2. Latent growth modeling (LGM) was used within the randomized study sample to evaluate the effect of the intervention as compared with standard care on the trajectory of self-reported sedentary time as reported on the GPAQ across the three assessment time points (baseline, 6-months and 12-months post-baseline), within a structural equation model (SEM). LGM estimates the within-individual variability of between-subject patterns of change over time. Basic growth models allow for the estimation of fixed latent variable effects (i.e. mean intercept and mean slope across the entire sample) and random effects (i.e. variance of individual intercepts and slopes around the group means; Curran, Obeidat, & Losardo, 2010).

Based on the observed sedentary time means at each assessment time-point, change was estimated to occur linearly over the 12-month study period, so the loadings for the latent variable representing slope were specified at 0, 6, and 12 months. The slope of sedentary time in the best-fitting model was regressed on randomization group to examine whether study condition (intervention or standard care control) significantly predicted the change in sedentary time, controlling for age and gender. Analyses were intent-to-treat.

Chapter 3

Results

Preliminary Analyses

Baseline Sample (includes non-randomized and randomized participants).

The baseline sample consisted of 298 participants aged 35-69 years ($M = 55.20$, $SD = 7.57$). The sample was primarily female (62.5%), Hispanic (83.5%), had a yearly household income less than \$20,000 (65%), and reported taking anti-hyperglycemic medication (74.2%). Descriptive information for all sociodemographic and medication variables is presented in Table 1. Participants reported sitting (sedentary time) for an average of 275.74 ($SD = 176.25$) minutes/day. Pedometer data indicated that participants took an average of 4289.42 ($SD = 2721.89$) steps per day. Baseline means and standard deviations for all psychological, behavioral, and cardiometabolic risk variables across the entire sample and separated by male and female gender are presented in Table 2. Zero-order Pearson r correlations indicated that self-reported sedentary time was not significantly associated with age ($r = .03$, $p = .664$), yearly household income ($r = .07$, $p = .298$), or years of school completed ($r = .08$, $p = .220$). One-way ANOVAs indicated that it was also not significantly associated with gender ($F [1, 258] = .05$, $p = .818$) or race/ethnicity ($F [2, 257] = 1.47$, $p = .232$).

Randomized Sample. 111 participants aged 35 – 69 years ($M = 54.86$, $SD = 7.34$) were randomized at baseline, with 54 participants allocated to standard care (the control group), and 57 participants allocated to the multi-component lifestyle intervention group. The consort diagram is shown in Figure 1. Comparable to the entire baseline sample, the randomized sample was primarily female (70.3%), Hispanic (84.7%), had a

yearly household income less than \$20,000 (84.7%), and the majority reported taking anti-hyperglycemic medications (83.8%). Participants in each randomization group did not differ significantly on any sociodemographic or other study variables at baseline, with the exception of race/ethnicity, with Caucasian participants being overrepresented in the control group compared with the intervention group (9.3% vs. 0%, chi-square [2] = 6.32, $p = .042$). Descriptive statistics for sociodemographic and medication variables are presented in Table 1. At baseline, participants reported sitting for an average of 255.94 (SD = 157.27) minutes/day. The observed sedentary time means at each time point are shown in Table 3.

Primary Analyses

Specific Aim 1. Results indicated that a latent factor representing time spent in sedentary behavior was significantly, positively associated with waist circumference, controlling for age and gender ($b = 4.47$, 95% CI [.08, 8.87], $p = .046$), but was no longer significantly associated after further controlling for MVPA ($b = 4.13$, 95% CI [-.13, 8.50], $p = .057$). The sedentary behavior factor was standardized within analyses, so the regression coefficient (b), can be interpreted as the unit change in the outcome variable per 1 standard deviation (SD) increase in the sedentary behavior factor. In the case of waist circumference, for every standard deviation increase in the sedentary time factor, there was a 4.47 cm increase in waist circumference, controlling for age and gender. Sedentary behavior was not significantly associated with BMI while controlling for age and gender ($b = 1.38$, 95% CI [-.13, 2.89], $p = .072$), or while further controlling for MVPA ($b = 1.34$, 95% CI [-.08, 2.76], $p = .065$). Sedentary behavior was also not significantly associated with HbA1c, controlling for age, gender, and use of anti-

hyperglycemic medications ($b = .04$, 95% CI $[-.30, .37]$, $p = .841$), or while further controlling for MVPA ($b = .03$, 95% CI $[-.32, .38]$, $p = .876$). Although sedentary behavior was not significantly associated with a composite cardiometabolic risk score while controlling for age, gender, and the use of antihypertensive, anti-hyperglycemic, and anti-hyperlipidemic medications ($b = .35$, 95% CI $[-.01, .71]$, $p = .054$), the association became significant in the hypothesized direction when further controlling for MVPA ($b = .34$, 95% CI $[.002, .62]$, $p = .049$), with increased sedentary time associated with higher cardiometabolic risk scores. In contrast to hypotheses, sedentary behavior was not significantly associated with depressive symptom severity, controlling for age and gender ($b = .65$, 95% CI $[-1.21, 2.51]$, $p = .494$), or while further controlling for MVPA ($b = .45$, 95% CI $[-1.90, 2.79]$, $p = .707$). MVPA was not significantly associated with any outcomes when included in the models with sedentary behavior. Of note is that the p values presented do not correct for the testing of multiple comparisons. When correcting for multiple comparisons, none of the associations remain significant. The results of all regression models are reported in Table 4.

Specific Aim 2. Results indicated that across the entire randomized sample, the latent growth model of self-reported daily sedentary time fit a linear change in the data over the 12-month period, with the residual variances held equal across baseline and 6-months only ($Chi-square [2] = 0.705$, $p = .703$, CFI = 1.000, RMSEA $< .001$ [90% CI $<.001, 0.142]$, SRMR = .034]. The slope of sedentary time was not significantly associated with the intercept of sedentary time ($b = -344.35$, 95% CI $[-953.72, 265.03]$, $p = .268$), indicating that change in sedentary time was not associated with participants' reported baseline minutes per day of sedentary time. The mean slope of sedentary time

was not significant ($b = -2.94$, 95% CI $[-6.07, .19]$, $p = .066$), but this included both control and intervention participants, so it was not expected to be significant. The variance in the slope of sedentary time was significant ($b = 116.09$, 95% CI $[19.96, 212.23]$, $p = .018$).

Structural regression analyses in which the sedentary time slope was simultaneously regressed on randomization group, age (standardized), and gender indicated that randomization group (0 = standard care control, 1 = intervention) was a significant predictor of the change in sedentary time, controlling for age and gender ($b = -6.54$, 95% CI $[-11.61, -1.47]$, $p = .012$). As hypothesized, the mean change in minutes/day of self-reported sedentary time per month was not significant in control group participants ($b = 1.39$, 95% CI $[-2.59, 5.38]$, $p = .492$). Also as hypothesized, there was a significant decrease in sedentary time in intervention group participants ($b = -5.15$, 95% CI $[-9.13, -1.16]$, $p = .011$). According to the model, intervention participants reduced their self-reported time spent in sedentary behavior by 5.15 minutes per month on average, or a total of 61.80 minutes from baseline to the 12-month assessment. After controlling for randomization group, age, and gender, the variance in the slope of sedentary time was no longer significant ($b = 66.92$, 95% CI $[-5.78, 139.62]$, $p = .071$). All structural regression results are summarized in Table 5. The sedentary time means at each time point that are implied by the structural regression model are shown in Figure 2.

Chapter 4

Discussion

The present study examined whether a latent variable of sedentary behavior representing the shared variance between self-reported time spent in sedentary behavior and daily average pedometer steps was associated with selected cardiometabolic risk factors and depressive symptoms in an overweight/obese sample of T2DM patients of primarily ethnic minority and low socioeconomic status. The study also determined whether the Community Approach to Lifestyle Modification for Diabetes (CALM-D) intervention resulted in significantly reduced self-reported time spent in sedentary behavior in overweight/obese individuals with T2DM with significant depressive symptoms who were randomized to receive either the multi-component CALM-D intervention or standard care.

The major findings of the study were that greater time spent in sedentary behavior, represented by a latent factor, was significantly associated with greater waist circumference, but only before controlling for MVPA, and with greater composite cardiometabolic risk, but only after controlling for MVPA. However, results were not significant after correcting *p*-values for testing multiple comparisons. Sedentary behavior time was not significantly associated with BMI, HbA1c or depressive symptom severity. Additionally, the CALM-D lifestyle intervention was successful at reducing self-reported sedentary time compared with the standard care condition. The study findings, implications, and future directions are discussed below.

Self-reported Sedentary Time in the Study Sample

Participants who completed the baseline examination reported sitting for an average of 4.6 hours/day outside of hours spent sleeping. This was significantly less than the accelerometer-derived sedentary time reported in several population-based studies (Matthews et al. 2008; Healy et al., 2008; Qi et al., 2015). Considering our sample consisted of overweight/obese individuals with T2DM, we would expect sedentary time to be greater than in the general population, so it is highly likely that our study participants underreported the amount of time they typically spend in sedentary behavior. It is not uncommon for individuals to underreport sedentary time and over-report physical activity time on self-report questionnaires compared with accelerometer-derived data, with studies showing only low-moderate correlations between the two measures. There may be an even greater discrepancy between self-report and criterion measures when assessing total sitting time using a single item, as was used in the present study, compared with composite and domain-specific measures of sedentary behavior time. It may be more difficult to recall overall sitting time across all domains than to recall the time spent in specific behaviors such as watching TV, computer use, sitting at work, and sitting during transport, which could result in misreporting and greater measurement error (Healy et al. 2011).

Participant characteristics may contribute to greater underreporting of sedentary time on self-report questionnaires, although to my knowledge, there are no studies examining participant predictors of underreporting sedentary behavior. Population-based studies have found that individuals underreport their caloric intake using dietary recall, and that although underreporting of caloric intake occurs across BMI categories,

overweight and obese individuals underreport to a greater degree than normal weight individuals (Archer, Hand, & Blair, 2013). There are few studies of sedentary behavior in clinical samples with diabetes. It is possible that our sample of overweight/obese diabetes patients underreported their sedentary time more than the general population due to their clinical or other participant characteristics. In addition, the Global Physical Activity Questionnaire (GPAQ), from which the sedentary time item was measured, was developed for population-based surveillance of physical activity across countries, and not developed for individuals with clinical conditions such as diabetes that are associated with physical activity and sedentary behavior patterns (Armstrong & Bull, 2006).

The present study used additional information from pedometer data to create a measurement model of sedentary behavior that was more reliable. A pedometer-based intervention study of 92 patients with T2DM patients in Belgium found that participants reported taking approximately 5,000 steps/day at baseline (DeGreef et al., 2011). Our participants reported taking an average of 4,289 steps. Although there are also limitations to using pedometers, including it likely improved the reliability of sedentary time measurement in this study.

Sedentary Behavior Latent Factor Associations with Cardiometabolic Risk

Variables and Depressive Symptoms

Sedentary behavior was significantly associated with waist circumference in the direction hypothesized when controlling for age and gender, which is consistent with previous studies that have found positive associations between time spent in sedentary behavior and measures of adiposity, including weight, waist circumference, BMI, and presence of obesity (see literature review above). However, in our study, sedentary

behavior was not associated with BMI and was only marginally significantly associated with waist circumference after controlling for MVPA. The associations in the present study were all nonsignificant after applying a Bonferroni correction for multiple tests, but it is possible that with an even stronger measure of sedentary time the associations would have been more robust. Additionally, the associations may have been weak because only overweight/obese individuals were included in the present study; therefore, ranges of BMI were restricted compared with studies conducted in general populations. To my knowledge, no other studies have examined these associations in samples restricted to overweight/obese adults.

Sedentary behavior may be associated with waist circumference as a result of decreased energy expenditure, increased energy consumption, and continued impaired carbohydrate metabolism (Thorp, Owen, Neuhaus, & Dunstan, 2011, Tremblay et al., 2010), but these possibilities were not tested in the present analyses. The data were cross sectional; thus, we cannot only assume that sedentary behavior resulted in greater waist circumference in our sample, because it is also plausible that heavier participants were less likely to engage in physical activity because of difficulties associated with their weight.

The association between sedentary behavior and the cardiometabolic risk composite score was not quite significant when controlling for age and gender; however, it was significant ($p = .049$), when controlling for MVPA, with increased sedentary time associated with greater cardiometabolic risk. This result is consistent with a number of studies that have shown that increased time spent in sedentary behavior is associated with worse cardiometabolic risk profiles, including greater triglycerides, glucose levels,

adiposity, blood pressure, presence of the metabolic syndrome, and overall metabolic risk, as well as lower HDL-cholesterol (Owen, Healy, Matthews, & Dunstan, 2010). Future studies should examine these associations longitudinally in individuals with type 2 diabetes.

Sedentary behavior was not significantly associated with HbA1c or scores on the Beck Depression Inventory – II, while adjusting for age, gender, and medication use. The non-significant associations could be because of the limitations of the sedentary time measure used, the restricted ranges of outcomes within a T2DM sample in which a majority of participants were on antidiabetic medications, or the associations truly not existing in the study sample.

Further work examining sedentary behavior in T2DM patients is needed with close attention paid to the measurement of sedentary time, particularly because so few studies in this area have been conducted in T2DM samples.

CALM-D Intervention Effects on Sedentary Time

The multi-component lifestyle intervention resulted in significantly reduced self-reported sedentary time compared with standard care. Participants in the control condition did not report significant changes in their sedentary time over the course of the 12-month study. These results are encouraging, considering that reducing sedentary time specifically was not a goal of the intervention. Furthermore, the participants included in the trial endorsed clinical levels of depressive symptoms, and patients with comorbid diabetes and depression tend to have worse diabetes self-care outcomes than patients without depression (Egede, Ellis, & Grubaugh, 2009; Gonzalez et al., 2007; Lin et al.,

2004), emphasizing the importance of decreasing health risk behaviors such as inactivity in these individuals.

Sedentary time was self-reported in this study, but the results point to the possibility that a multi-component, psychoeducational and cognitive-behaviorally based lifestyle intervention can be successful at reducing sedentary time in T2DM patients with depressive symptoms. Interventions that focus more specifically on reducing sedentary behavior, perhaps by increasing time spent in both light-intensity activity and moderate-vigorous activity, should be examined in order to confirm the success of these interventions. In addition, studies should be designed to be able to examine whether the change in sedentary behavior as a result of lifestyle interventions mediates the change in cardiometabolic risk and in psychosocial outcomes such as depressive symptoms. The CALM-D lifestyle intervention was successful in reducing weight, HbA1c, and depressive symptoms (Moncrieft et al., in press) compared with standard care, so it is possible that the changes in sedentary behavior partially contributed to these improvements. Studies should also employ more objective measures of sedentary time (e.g. stricter use of pedometer or accelerometer use) and/or multi-item measures of sedentary behavior that lower the likelihood of underreporting sedentary time in studies where it is not practical to use objective measures.

Strengths and Limitations

A limitation of the present study was the measure of sedentary time, which was self-reported and consisted of a single item. There was likely underreporting and a high degree of measurement error in the sedentary time data, which may have reduced the power to detect significant associations. However, it is likely that a similar amount of

bias was present in the sedentary time data at the baseline, 6 month, and 12 month assessment times, suggesting that the change in sedentary time over the course of the intervention may not be biased due to underreporting. Additionally, a strength of the present study was that it increased the reliability of sedentary time measurement in the cross-sectional analyses by including pedometer data from a subset of participants. A second limitation of the study is that it used a small, convenience sample consisting of primarily Hispanics/Latinos of low socioeconomic status in Miami, FL, so we may have had lower power because of the small sample size, and results may not be generalizable to other populations of interest. However, the use of randomization in the intervention portion of the study increases the internal validity of the results. The exclusion of an extended follow-up period precluded us from examining the maintenance of sedentary time reductions beyond the 12-month intervention period.

An additional strength of the study was that a large number of objective measures of cardiometabolic risk were collected, allowing for the examination of associations between self-reported health behaviors, pedometer measured steps, and objective measures of risk. In addition, there were a sufficient number of assessment points during the intervention to model change in sedentary time using latent growth modeling, a more powerful method of modeling change over time than other tests. The intervention was feasible and of relatively low demand for a low-income, community-based sample that may be at high risk for greater levels of inactivity (Rhodes, Mark, & Temmel, 2012).

Conclusions

This study showed preliminary evidence for a weak, but positive association between time spent in sedentary behavior, waist circumference, and overall cardiometabolic risk in a sample of overweight/obese T2DM patients of primarily low

income and ethnic minority status. Furthermore, it showed that a multi-component lifestyle intervention could reduce self-reported sedentary time in patients with comorbid diabetes and significant depressive symptoms. This is one of very few studies to examine sedentary behavior in adults with diabetes, although there is increasing evidence from population-based studies that individuals who spend more time engaging in sedentary behavior are at higher cardiometabolic risk.

The use of a single-item measure of sedentary time was a limitation of the study, but it was strengthened with the addition of pedometer data. It may not be feasible or practical for investigators to include more objective measures of sedentary time such as accelerometers in multi-component intervention studies examining a number of behavioral, physiological, immunological, and/or medical variables. The extant literature provides an important rationale for paying closer attention to sedentary behavior and light-intensity activity in addition to MVPA in both healthy and diseased populations. Investigators with interest in sedentary behavior may wish to utilize interviewer-administered self-report measures of sedentary behavior that include questions about sedentary time within multiple domains and with effective probing of participants. Future intervention studies within T2DM patient samples should focus on the measurement of sedentary behavior and on study design in order to increase understanding of the effects of reducing inactivity on cardiometabolic risk and psychosocial outcomes in these populations.

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Figure 1

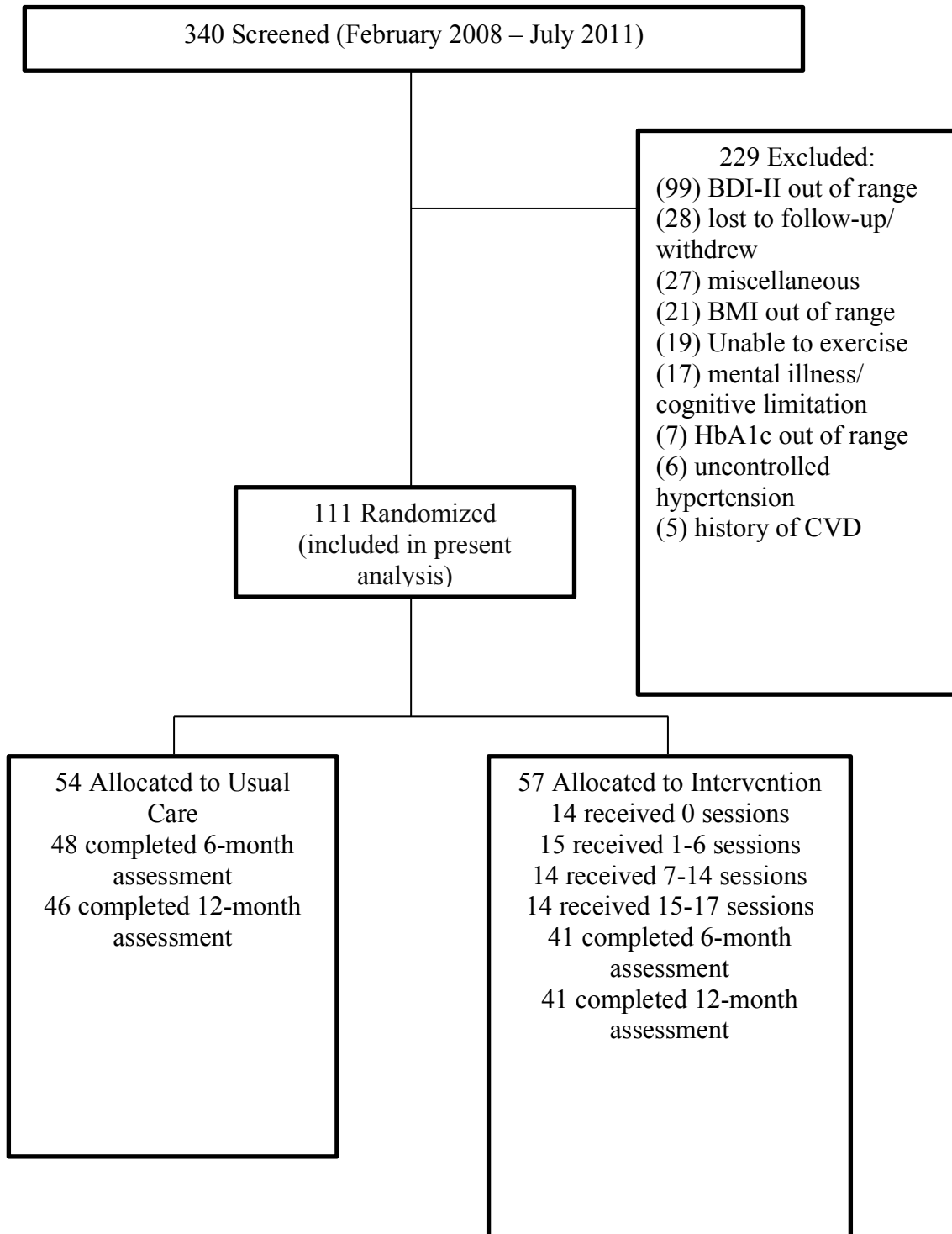
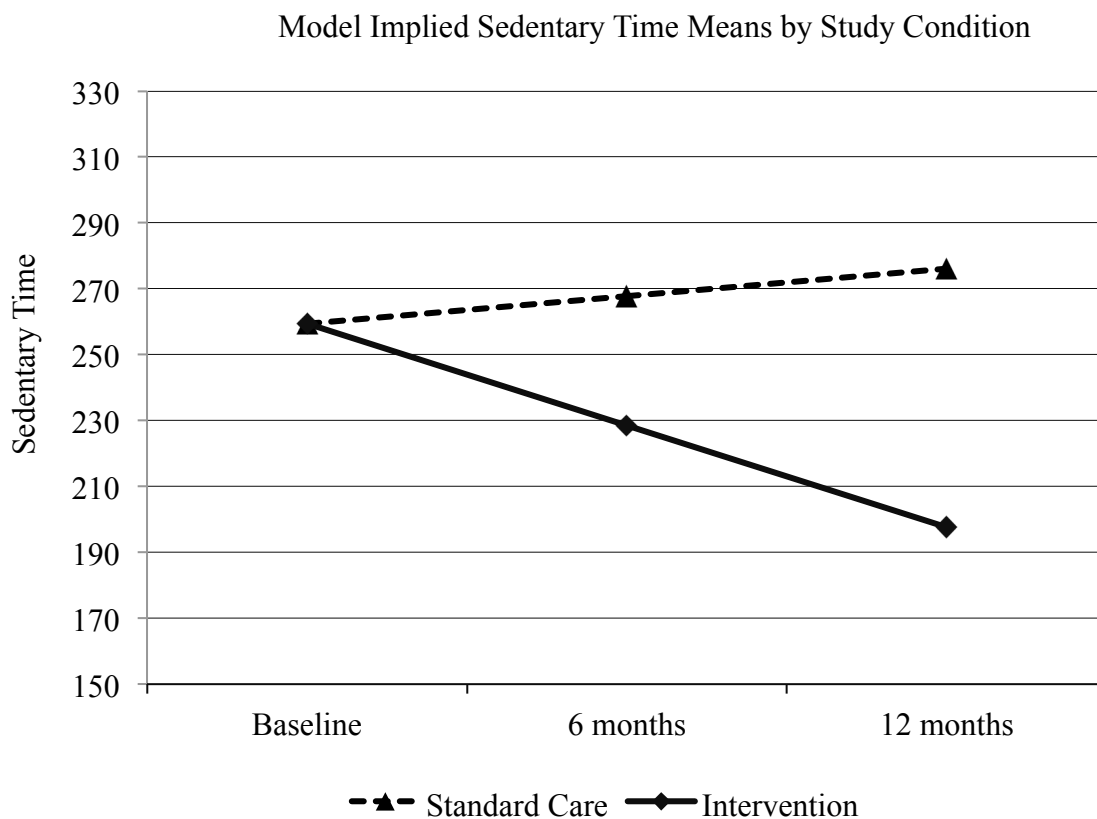


Figure 2



Note. Figure 2 displays intervention and standard care participants' mean sedentary time based on all available data at each point as implied by the structural regression model, controlling for age and gender. Means were calculated as follows: Control-Baseline = intercept (259.38 for all groups); 6-month = intercept + b (control)*6; 12-month = intercept + b (control)*12; Intervention- Baseline = intercept; 6-month = intercept + b (intervention)*6; 12-month = intercept + b (intervention)*12. B is the unstandardized change in minutes/day of sedentary time.

Table 1

Baseline Sample (Total and Randomized Only) Characteristics: Sociodemographic and Medication Variables

Variable	Mean (SD), Range or Frequency (%)			
	Total Baseline Sample (N=298)	Randomized Baseline Sample		
		Total (N=111)	Control (N=54)	Intervention (N=57)
Age (years)	55.20 (7.57), 35 - 69	54.86 (7.34), 35-69	54.70 (6.31), 39-67	55.02 (8.25), 35-69
Female Gender	178 (62.7%)	78 (70.3%)	41 (75.9%)	37 (64.9%)
Race/Ethnicity				
Black	36 (12.7%)	12 (10.8%)	7 (13%)	5 (8.8%)
Caucasian	11 (3.9%)	5 (4.5%)*	5 (9.3%)	0 (0%)
Hispanic	237 (83.5%)	94 (84.7%)	42 (77.8%)	52 (91.2%)
Yearly Household Income				
≤ \$20,000	178 (65%)	70 (66.6%)	36 (69.2%)	34 (64.1%)
\$20,001 - \$40,000	61 (22.3%)	20 (19.1%)	11 (21.1%)	9 (17%)
≥ \$40,001	10 (3.6%)	3 (2.9%)	0 (0%)	3 (5.7%)
Selected “No Answer”	25 (9.1%)	12 (11.4%)	5 (9.6%)	7 (13.2%)
Years of School Completed	12.34 (3.41), 2 - 20	12.46 (3.36), 4-20	12.28 (3.57), 4-20	12.64 (3.16), 6-20
Anti-depressant Use	28 (9.4%)	18 (16.2%)	10 (18.5%)	8 (14.0%)
Anti-hyperglycemic Use	221 (74.2%)	93 (83.8%)	44 (81.5%)	49 (86.0%)
Anti-hypertensive Use	131 (44.0%)	62 (55.9%)	30 (55.6%)	32 (56.1%)
Anti-hyperlipidemic Use	87 (29.2%)	47 (42.3%)	22 (40.7%)	25 (43.9%)

*Significant difference in means between Control and Intervention Conditions ($p < .05$).

Table 2

Baseline Sample Descriptives for Psychological, Behavioral, and Cardiometabolic Risk Variables (N=298)

Variable	Range	Total Mean (SD)	Women Mean (SD)	Men Mean (SD)
Depressive Symptom Severity (BDI-II)	0 – 49	16.29 (9.14)	17.16 (8.68)	14.91 (9.87)
GPAQ Sedentary Time (minutes/day) ^a	60 - 968	275.74 (176.25)	274.52 (181.11)	279.70 (170.32)
Pedometer Steps (daily average), N=74	711-17,447	4289.42 (2721.89)	4322.49 (2943.23)	4262.45 (2517.05)
GPAQ MVPA (minutes/day)	0 – 752	52.70 (112.95)*	41.23 (87.83)	69.97 (144.01)
Body Mass Index	24 – 60	32.50 (4.54)	32.261 (4.63)	32.24 (4.36)
Waist Circumference (cm)	81 – 200	107.30 (13.58)*	104.20 (12.07)	112.71 (14.34)
Triglycerides (mg/dl)	19 – 749	171.36 (91.30)	164.86 (85.69)	184.14 (99.64)
HDL-cholesterol (mg/dl)	17 – 106	42.92 (10.38)*	45.27 (9.96)	38.63 (9.56)
Hemoglobin A1c (%)	5.2 – 11.9	7.82 (1.34)	7.78 (1.27)	7.92 (1.45)
Systolic Blood Pressure (mmHg)	79 – 189	130.25 (18.67)	130.52 (11.43)	129.77 (15.40)
Diastolic Blood Pressure (mmHg)	49 – 114	79.04 (10.74)	78.78 (11.43)	79.53 (9.20)
Cardiometabolic Risk composite (standardized) ^b	-2.69 –4.38	0 (1)*	-.24 (.08)	.41 (.11)

Abbreviations. BDI = Beck Depression Inventory. GPAQ = Global Physical Activity Questionnaire. MVPA = Moderate-Vigorous Physical Activity (includes active transport).

^a Participants with values < 60 minutes and > 1080 minutes (18 hours) were considered missing.

^bThe cardiometabolic risk scores is the standardized sum of values for waist circumference, triglycerides, HbA1c, systolic and diastolic blood pressure, and the inverse of HDL-cholesterol.

* Significant difference in means between men and women ($p < .05$).

Table 3

Randomized Sample Descriptives for Sedentary Time by Study Condition at Baseline and Follow-ups

Variable	Mean (SD), Range		
	Baseline (N=111)	6-months (N=90)	12-months (N=87)
	Sedentary Time (minutes/day)^a		
Standard Care	235.10 (141.57), 60-540	251.74 (178.72), 60-840	250.47 (179.27), 60-720
Intervention	277.20 (170.63), 60-720	251.71 (158.16), 60-900	200.53 (110.08), 60-600

^a Participants with values < 60 minutes and > 1080 minutes (18 hours) were considered missing.

Table 4

Sedentary Behavior Factor Associations with Cardiometabolic Risk Variables

Outcome Variable	Model 1 ^a			Model 2 ^b		
	b (SE)	95% CI	<i>p</i>	b (SE)	95% CI	<i>p</i>
BMI	1.38 (.77)	[-.13, 2.89]	.072	1.34 (.74)	[-.08, 2.76]	.065
WC	4.47 (2.24)	[.08, 8.87]	.046*	4.18 (2.20)	[-.13, 8.50]	.057
HbA1c	.04 (.17)	[-.30, .37]	.841	.03 (.18)	[-.32, .38]	.876
CM Risk Composite ^c	.35 (.18)	[-.01, .71]	.054	.34 (.17)	[.002, .62]	.049*
BDI-II	.65 (.95)	[-1.21, 2.51]	.494	.45 (1.20)	[-1.90, 2.79]	.707

Abbreviations. b = the unit change in the outcome variable (original metric) per 1 SD increase in the sedentary behavior factor. BMI = body mass index. WC = waist circumference. HbA1c = glycated hemoglobin. CM = cardiometabolic. BDI = Beck Depression Inventory.

^a Model 1: Adjusts for age, gender, and medication use where appropriate.

^b Model 2: Adjusts for age, gender, medication use where appropriate, and total physical activity (min/day).

^cThe cardiometabolic risk composite is standardized, so b = the SD unit change in CM risk per 1 SD increase in the sedentary behavior factor.

* $p < .05$

Table 5

Association between Study Condition and Sedentary Time

Predictor	b (SE)	95% CI	<i>p</i>
Randomization Group (0 = Control, 1 = Intervention)	-6.54 (2.59)	[-11.61, -1.47]	.012*
<i>Mean Slope (Change) in Sedentary Time by Study Condition</i>			
Group	Mean Δ in sedentary time minutes/month (SE)	95% CI	<i>p</i>
Control Participants	1.39 (2.03)	[-2.59, 5.38]	.492
Intervention Participants	-5.15 (2.04)	[-9.13, -1.16]	.011*

Note. b = unstandardized regression coefficient. Analyses control for age and gender.