A LIFESTYLE INTERVENTION FOR WOMEN WITH COMORBID TYPE 2 DIABETES AND DISORDERED EATING

by

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ABSTRACT

ALYSSA MARIE VELA. A lifestyle intervention for women with comorbid type 2 diabetes and disordered eating. (Under the direction of DR. FARY CACHELIN)

Rates of type 2 (T2) diabetes continue to rise in the United States and around the world, with growth to epidemic proportions largely attributed to health behaviors such as poor diet, overeating, and lack of physical activity. T2 diabetes management is demanding, requiring daily effort with responsibilities pertaining to eating behaviors, physical activity, and blood glucose monitoring. Eating is often the most challenging aspect of diabetes management, and when disordered, has been associated with increased risk for diabetes-related complications. Thus, high rates of T2 diabetes and barriers to treatment indicate the need for further development of low-cost accessible treatment modalities for T2 diabetes and related health problems, including disordered eating. The current project sought to assess the efficacy and acceptability of an eating-focused CBT guided-self help (CBTgsh) lifestyle intervention for women with T2 diabetes who engage in disordered eating and wish to improve their eating behaviors, health and well-being. Ten women completed the 12-week intervention that sought to support them in establishing a regular pattern of eating, food monitoring, adjusting thought patterns about eating and health, and increasing physical activity. Results indicated that the intervention was effective in reducing disordered eating behaviors, HbA1c, and diabetes distress, and was acceptable to participants in the current sample. Additionally, participants spoke highly of the program, even stating that it was life changing, and reported that they would recommend the intervention to others. Feedback and the lived experiences of participants were used to make recommendations for the further development and dissemination of the intervention.

DEDICATION

This dissertation is dedicated first to my husband, Joe. Your constant love, support, and expertise in editing have been vital to the success of this project and my educational journey. I am so grateful to have you as my partner in life. I would also like to dedicate this dissertation to my family, to my parents and my sisters, Julia and Natalie. Your love and encouragement to achieve higher education have helped me through the most challenging points of this process. Finally, to the wonderful friends I've gained through my time in the Health Psychology program and while living in Charlotte, you've provided shoulders to lean and have always met me with a compassionate ear. I'm incredibly appreciative of the relationships I have formed along the way.

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TABLE OF CONTENTS

LIST OF FIGURES

LIST OF TABLES

LIST OF ABBREVIATIONS

T2	type 2 (diabetes)
QOL	quality of life
DQOL	diabetes-specific quality of life
HRQOL	health-related quality of life
DSE	diabetes self-efficacy
BMI	body mass index
BED	binge eating disorder
CBT	cognitive behavioral therapy
GSH	guided self-help

Chapter 1: Introduction and Review of the Literature

Between 1980 and 2011, the number of Americans diagnosed with type 2 (T2) diabetes more than tripled to rates of over 20 million, representing a growth of 175 percent (CDC, 2013). Indicative of the severe implications of the disease, diabetes was the seventh leading cause of death amongst adults in 2013. With continued growth in prevalence over the past several decades, the CDC categorizes diabetes as a national epidemic and continues to work towards reduction in incidence, as well as prevention of the many complications associated with T2 diabetes (CDC, 2014).

Of the three forms of diabetes, T2 is most common, accounting for over 90 percent of diagnoses in the United States (CDC, 2014). T2 diabetes is a chronic metabolic disease characterized by high levels of blood glucose, often referred to as high blood sugar, that is caused by a lack of insulin in the body or the inability to effectively use insulin (NIH, 2014). T2 diabetes typically develops gradually and can be identified early with routine medical care, to allow an opportunity for prevention of diabetes-related complications. Those who develop T2 diabetes increase their risk for other serious medical problems such as cardiovascular diseases, circulatory issues, and diabetes-specific complications such as retinopathy and neuropathy (NIH, 2014).

The continual increase in rates of Americans diagnosed with T2 diabetes is related to the numerous risk factors and health behaviors associated with the development of the disease, namely overweight and obesity, poor dietary habits, overeating, and sedentary lifestyles (CDC, 2013). Members of some ethnic and racial groups, such as Latinos and African Americans are disproportionately likely to be diagnosed with T2 diabetes during their lifetime (CDC, 2014). According to the US Census Bureau, ethnic and racial minorities

are also more likely to live in poverty and experience greater barriers to access services such as health care (Macartney, Bishaw, & Fontenot, 2013). The combination of high rates of T2 diabetes and barriers to treatment indicate the need for further development of low-cost accessible treatment modalities for T2 diabetes and related health problems, such as disordered eating.

The current project aims to assess the feasibility and acceptability of a lifestyle intervention for women with T2 diabetes who engage in disordered eating and wish to improve their eating behaviors, health and well-being. The intervention has been developed to support women who may experience barriers to more intensive forms of treatment, through the minimization of costs and remote support by phone. Based on a previously conducted study designed to assess the lived experiences of individuals with T2 diabetes who engage in disordered eating, the current intervention is expected to be a feasible method to reduce disordered eating behaviors (Vela, Palmer, Cachelin, Gil-Rivas, & Coffman, 2016).

The unpublished study by Vela and colleagues (2016) employed a phenomenological approach to interview six individuals diagnosed with T2 diabetes within the past two years. Participants described regular and severe episodes of disordered eating characterized by the consumption of large amounts of food (binge eating), as well as the consumption of large amounts of high-fat and high-sugar foods. When describing these episodes, participants also described a sense of loss of control over eating, and distress associated with feelings of guilt and shame related to the behavior and their diagnosis of T2 diabetes. Overall, participants reported difficulty managing diabetes, particularly the incredibly important aspect of eating. The results of the study demonstrate that for some individuals with T2 diabetes, engagement

in disordered eating behavior appears to have important implications for diabetes management.

Diabetes Management

Unlike many chronic diseases, T2 diabetes can be managed entirely through engagement in disease-appropriate health behaviors, such as diet, physical activity, and blood-glucose monitoring. The effects of management behaviors on T2 diabetes are influenced by demographic factors such as age, physical condition, and lifestyle (NIH, 2014). For some individuals, T2 diabetes can be managed entirely through health behaviors, while others rely on medications. Diabetes management is challenging and time consuming, particularly for recently diagnosed individuals who are still adjusting to the diagnosis and the need to engage in appropriate management behaviors (Kuznetsov et al., 2013). Many recently diagnosed individuals receive little information and/or support in diabetes management, often increasing the difficulty in adjusting to the diagnosis and management (Kuznetsov et al., 2013). Good management of diabetes is critical in the prevention of diabetes-related complications and may prevent or reduce the need for reliance on medication.

Good diabetes management involves the active self-engagement in activities to care for one's diabetes and overall health, in consideration of both short and long term prevention of diabetes-related complications (ADA, 2016). Good diabetes management typically includes: regular visits with a primary care physician or other medical provider (typically every three to six months), demonstration of active responsibility for one's own health management, progress toward or maintenance of goal levels of blood glucose, blood pressure and cholesterol, engagement in physical activity, appropriate diet, managing and monitoring

blood glucose on a regular basis, stress and distress management, weight loss or maintenance, and medication adherence when appropriate (ADA, 2016). Typical dietary recommendations for individuals with T2 diabetes cover portion control, balancing carbohydrate intake, and time-specific meal planning for those who require medication and/or insulin. There is, though, also some variation in the dietary recommendations made to individuals with T2 diabetes, often varying by individual needs and the amount of support an individual has from health care providers (ADA, 2016).

T2 diabetes management: Eating.

Eating behavior is one of the most pivotal aspects of T2 diabetes management. The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK; 2014) provides guidelines for individuals with diabetes concerning what to eat, how much to eat, and when to eat with the goals of feeling well, maintaining target range of blood glucose, losing weight if appropriate, and preventing diabetes-related complications. NIDDK (2014) recommends regularly scheduled meals and snacks, planned in accordance with guidance from one's health care team, and eating a certain number of items from each food group to correspond with one's size and physical activity. For example, they recommend eight servings of starches per day for a large woman or small man, with at least one starch consumed at each meal.

NIDDK (2014) also provides resources on appropriate portion sizes and food choices for individuals with diabetes, while repeatedly encouraging readers to develop a specific food plan with their medical team. Though useful, these recommendations may be overwhelming for newly diagnosed individuals, and many may not have access to a medical team to provide support and information in developing an individuated plan. Making sense of dietary

recommendations is only one of many challenges individuals diagnosed with T2 diabetes face in learning to manage the disease through eating and other behaviors.

Behavioral recommendations are some of the most common recommendations for diabetes management for all diabetics regardless of time since diagnosis, indicating the potential value of behavioral interventions across time post-diagnosis (Mellin et al., 2004). However, disordered eating behaviors may already be in place and become increasingly problematic with a diabetes diagnosis, or may develop as a result of the strong focus on food and restriction often associated with diabetes management (Mellin et al., 2004). Despite the advantages of behavior change in diabetes management, particularly adjusting and maintaining diabetes appropriate eating behaviors, doing so is challenging for many, as self-management requires both a high level of understanding and motivation to change (Sullivan & Joseph, 1998).

Prevention of diabetes related complications requires excellent diabetes self-management, something newly diagnosed individuals may intend to do yet struggle with because of lack of experience making such lifestyle changes. Recently diagnosed T2 diabetics may not experience many symptoms or complications of T2 diabetes and therefore may not fully understand their risk for complications, or the treatments they have been prescribed. Good self-management of T2 diabetes is necessary to allow early detection of diabetes-related complications which is advantageous in preventing further health problems (Thoolen, de Ridder, Bensing, Gorter, & Rutten, 2008). Despite the understanding that eating behavior is one of the most crucial aspects of T2 diabetes management, and that disordered eating can exacerbate risk for diabetes related complications, little is known about the mechanisms by which disordered eating influences diabetes management.

A metasynthesis of research on diabetes self-management for individuals with T2 diabetes concluded that diabetes management is influenced by a complex interaction of factors including gender and gender roles, interpersonal relations, social context, age, and availability of care (Gomersall et al., 2011). While diabetes management is multifaceted, medication is considered by many a primary mechanism for managing T2 diabetes. Most Americans with T2 diabetes are prescribed some form of medication; more than half of individuals are prescribed oral medication such as the drug Metformin (CDC, 2014). The purpose of Metformin is to improve insulin sensitivity and decrease the liver's production of glucose. For individuals diagnosed with T2 diabetes who are prescribed more than behavior change strategies, many are prescribed oral medication in addition to dietary changes and physical activity. However, medication compliance is still often not sufficient to manage T2 diabetes and prevent related complications; additional management behaviors are necessary (Peel et al., 2005). Fortunately, risk for disease progression of T2 diabetes and diabetes-related complications can be reduced by individuals' diabetes management behaviors, which can greatly impact improvement or worsening of symptoms (Gomersall, Madill, & Summers, 2011). The preventable nature of diabetes-related complications further supports the need to understand how individuals with T2 diabetes are managing their diabetes, and the ways in which they struggle with behaviors such as diet.

Individuals with T2 diabetes are typically encouraged by medical professionals to engage in health behaviors that intend to control blood glucose levels and reduce risk for diabetes-related complications, such as investment in a healthier lifestyle post-diagnosis, eating according to physician recommendations and engaging in sufficient physical activity (Kenardy et al., 2001). Behavioral interventions such as maintaining a healthy diet

appropriate for a T2 diabetic can be effective in preventing recently diagnosed patients from requiring insulin or oral medications (Peel et al., 2005). Some of the most common behavioral interventions recommended by physicians include diet change, dietary restriction, and weight loss (Mellin, Nuemark-Sztainer, Patterson, & Sockalosky, 2004). As newly diagnosed T2 diabetics adjust to their diagnosis and learn to monitor and respond to blood glucose levels, behavioral interventions are often encouraged to prevent disease progression, the need for more serious medications, and other diabetes related complications. However, disordered eating behaviors can add to difficulty adjusting to the diagnosis and managing the disease.

Disordered Eating

Consistent with the research that supports that eating is the most important aspect of diabetes management for many individuals with T2 diabetes, the development of disordered eating behaviors including binge eating, emotional eating, external eating, and restriction likely has negative implications for diabetes management and overall health and wellbeing. External eating occurs when individuals overeat as a response to external food cues such as the sight, smell or taste of food (van Strien et al., 1986). Quite differently, restrained eating is indicative of reduced intake of food, similar to engaging in a diet (Strice, Ozer, & Kees, 1997). Restrained eating is also characterized by avoidance of particular foods or categories of foods, typically in an effort to control body weight (van Strien et al., 1986). When engaging in restrained eating, individuals tend to eat less than desired (Stice et al., 1997). Engagement in restrained eating behaviors has been associated with greater overall disordered eating and has been linked to poor coping skills (Stice, 2002). *These three forms of disordered eating behaviors--emotional, external, and restrained eating--are examples of*

the ways in which individuals with T2 diabetes may struggle with eating, thereby further increasing their risk for additional disordered eating and diabetes-related complications.

With the broad nature of the categorization of disordered eating, researchers have sought to identify common types of disordered eating in addition to binge eating, such as emotional eating, external eating and restriction of eating. A neuroimaging study by Chechlacz et al. (2009) found that the areas of the brain associated with emotional processing and motivation were activated when individuals with T2 diabetes were presented visually with food stimuli, more so if the foods were high in fat. Such research is indicative of the strong associations with food many develop, which can be especially problematic for individuals with T2 diabetes who are expected to engage in dietary change. Emotional eating tends to occur specifically in response to negative emotional stimuli and has been associated with great difficulty in engagement with dietary change following a T2 diabetes diagnosis (Robbins & Fray, 1980; Van de Laar et al., 2005).

For individuals with T2 diabetes, disordered eating alone can exacerbate risk for diabetes-related complications (i.e. retinopathy, neuropathy, and cardiovascular disease; Kenardy et al., 2001). Research has also indicated that those who suffer from both disordered eating and T2 diabetes are at greater risk for a number of serious physical complications associated with T2 diabetes (ADA, 2014). Disordered eating includes a range of abnormal eating behaviors, including binge eating, and is characterized by erratic and chaotic eating patterns. During episodes of disordered eating, hunger and satiety signals are often ignored (NEDC, 2016). Other characteristics of disordered eating include preoccupation with food that results in distress, compulsive or emotionally-driven eating, and “yo-yo” dieting (Anderson, 2015). It is important to note that disordered eating is distinguished from the

eating disorders described by the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V), as it is not a diagnosis but a descriptive label (APA, 2013). Individuals who engage in disordered eating may or may not meet clinical criteria for an eating disorder diagnosis such as binge eating disorder (BED) or bulimia nervosa (Anderson, 2015; APA, 2013).

Among individuals with T2 diabetes, disordered eating appears to be quite common, though rates remain uncertain. A large study of individuals with T2 diabetes indicated rates of clinically significant eating disorders between six and eight percent, with lifetime prevalence rates falling between 10 and 14 percent (Herpertz et al., 1998). However, disordered eating is thought to occur more often in patients with T2 diabetes than in the general population for several reasons, including: diabetes-related stress, possibility of controlling weight with diabetes medication, major weight changes, and attempts to maintain diabetic-specific diets that are low in carbohydrates and sugars (Peveler, 2000). Many of these factors are related to other T2 diabetes management behaviors, such as dietary regulation, physical activity, and blood glucose monitoring, which may influence risk for disordered eating. As criteria for eating disorders included in the study were stricter than the definition of disordered eating, there is reason to believe that rates of disordered eating are even higher than clinical eating disorders among T2 diabetic individuals. Additionally, T2 diabetics were more likely to meet criteria for BED than other eating disorders, indicating potentially high rates of binge eating as an unhealthy behavior among T2 diabetics (Herpertz et al., 1998).

More literature has explored the relationship between T2 diabetes and BED than disordered eating, with a particular focus on the role of overweight and obesity in moderating

the relationship (Celik et al., 2014; Meneghini, Spadola, & Florez, 2006; Raevuori et al., 2015). Research has supported that rates of BED are higher among T2 diabetic populations than the general population for both men and women, in part due to distorted eating attitudes that may occur as the result of dietary restriction and result in loss of control (LOC) over eating (Celik et al., 2014). Binge eating also appears to be a risk factor for diabetes, independent of comorbidities such as overweight and obesity, and BED has been associated with higher blood glucose levels (Kenardy et al., 2001; Meneghini et al. 2006). Other research has indicated that abnormal glucose metabolism contributes to the onset and continuance of BED symptoms (Raevuori et al., 2015). *The strict criteria of BED may result in overlooking problematic, yet subclinical, disordered eating behaviors that have a significant major impact on numerous health and quality of life outcomes for high-risk groups such as T2 diabetics.*

Dietary Balance of Diabetes

Research has indicated that individuals with T2 diabetes appear to have a limited understanding of what dietary balance entails. Specifically, one study found that participants lacked knowledge of the effects of carbohydrates on blood glucose levels, focusing instead on reducing sugar consumption (Breen et al., 2016). External variables such as the influence of important others, opportunities to eat foods inconsistent with a balanced diet, and financial constraints all appeared to influence the beliefs and understanding patients reported regarding carbohydrate consumption (Breen et al., 2016). This tendency for individuals with T2 diabetes to lack the necessary knowledge about food and eating behaviors sufficient to successfully manage their disease exacerbates risk for disordered eating and serious diabetes-related complications.

These results speak to the potential importance of increasing knowledge and improving dietary behaviors following a T2 diabetes diagnosis. Additionally, for those who engage in disordered eating that interferes with the ability to manage T2 diabetes, the ongoing challenges of the management process may have negative physiological and psychological implications including higher body mass index (BMI), higher blood glucose, distress, and lower quality of life. The potential implications of disordered eating for diabetes management are numerous, and include increase in BMI, poor glycemic control, diabetes distress, and lower quality of life (QOL).

Implications: Interference of Disordered Eating in Diabetes Management

The American Diabetes Association (ADA, 2016) reports that evidence consistently supports the value of obesity management in the treatment of T2 diabetes. For example, some research has indicated that weight loss is associated with improved glycemic control and may reduce the need for medication to manage T2 diabetes. BMI is an indicator of body fat that is typically used as a screening tool for overweight or obesity in both research and clinical work (CDC, 2016). Research has indicated an important relationship between BMI and disordered eating among women. Thus, while weight loss is often a health goal for individuals with T2 diabetes, those who engage in disordered eating are potentially at risk for weight gain and increased BMI, further exacerbating risk for serious complications (ADA, 2016; Goncalves, Silva, & Gomes, 2015). Further, the potential health complications associated with a BMI in the overweight (range)and obese (range) range further necessitate the importance of good glycemic control among individuals with T2 diabetes.

Glycemic control

The two primary methods of blood glucose monitoring and glycemic control for individuals with T2 diabetes include patient self-monitoring of blood-glucose (SMBG) and a test of HbA1c (ADA, 2016). HbA1c, also referred to as simply A1c, is a reflection of an individual's blood glucose level over the past three months. Both SMBG and HBA1c may indicate the extent to which an individual is or is not improving their eating and other management behaviors and are used to monitoring blood glucose in an effort to make sense of the effects of treatment and diabetes management behaviors. The goals of many interventions is to meet and/or maintain a goal HbA1c level that is appropriate for the individual patient (ADA, 2016).

Importantly, disordered eating has been associated with higher HbA1c and impaired metabolic control among women with type 1 diabetes (Rydall et al., 1997). Thus, disordered eating is likely to have negative implications for glycemic control, as is likely related to other physiological and psychological outcomes associated with T2 diabetes. For example, research has linked higher levels of HbA1c with depression and poor diabetic control among women with T2 diabetes, even after controlling for serious diabetes-related complications (Lee et al., 2009). Difficulty meeting physician suggested goals for SMBG and HbA1c may also further exacerbate patient's distress related to the disease and management process.

Diabetes distress

Diabetes distress is the disease-specific distress associated with the burden of T2 diabetes and associated management. This form of distress has been connected with feeling isolated in understanding the challenges of diabetes management, feelings of inadequacy related to one's diabetes management, a general feeling of being overwhelmed by diabetes

self-management, as well as worries about the quality of health care one receives (Carper et al., 2013). Diabetes distress has been associated with a number of negative health outcomes, such as poor adherence to appropriate diabetes management behaviors, poor glycemic control, and raised levels of lipids (Carper et al., 2013). Diabetes distress is also associated with poor diabetes management, particularly an inability to control eating behaviors, indicating a cyclical relationship among negative health outcomes (Karlsen, Oftedal, & Bru, 2011).

Importantly, research has indicated that both individual coping styles and perceived support from healthcare professionals play a role in patient's reported levels of diabetes distress (Karlsen et al., 2011). One study found that individuals with T2 diabetes tend to use problem-focused coping rather than emotion-focused coping when managing distress associated with diabetes, while more than 60 percent of the sample also reported self-blame when experiencing diabetes-related distress. Coping style and social support also appear to have a greater impact on diabetes distress than do clinical indicators such as duration of the disease, BMI and HbA1c (Karlsen et al., 2011). High levels of distress are also likely to negatively impact quality of life.

Diabetes-related quality of life

Quality of life (QOL) is a widely used outcome variable across many fields of research, with health-related quality of life commonly employed to assess the impact of severe and chronic medical problems on the multiple domains of QOL (Cerrelli et al., 2005). Individuals with T2 diabetes tend to report lower health-related QOL (HRQOL) than members of the general population and disordered eating among T2 diabetics is associated with even lower HRQOL scores. However, cognitive-behavioral treatments have been found

to be effective in improving HRQOL outcome measurements (Cerrelli et al., 2005). In addition to the assessment of HRQOL, recent studies have considered diabetes-specific QOL, a measure similar to HRQOL but focused on aspects of health and experiences specific to those with T2 diabetes.

Numerous factors impact self-reported DQOL, one of which is social support. Social support plays an important role in the diabetes management behaviors and positively perceived social support behavior has been associated with better DQOL, while negative social support behaviors have been associated with lower DQOL (Tang, Brown, Funnell, & Anderson, 2008). One study by Tang and colleagues (2008) considered the impact of social support on various aspects of DQOL among African Americans, a group at especially high risk for T2 diabetes. Overall, the study found that patient satisfaction with social support was associated with better DQOL and better blood glucose monitoring, an important diabetes management behavior. Positively perceived social support also predicted other important diabetes management behaviors, including: following a healthy diet, appropriate spacing of carbohydrates consumed throughout the day, and physical activity. Negatively perceived social support behavior predicted poor diabetes medication adherence (Tang et al., 2008). The results of the Tang et al. (2008) study further support the importance of social support for good diabetes management and QOL among individuals with T2 diabetes. To date, several lifestyle interventions have been developed in an effort to help individuals with T2 diabetes improve QOL, as well as to reduce diabetes distress, improve HbA1c, improve eating and diabetes management behaviors, and other health-related outcomes such as weight loss. Such interventions have in common the goal of creating a change in lifestyle rather than

a temporary solution to the many challenges associated with symptoms and complications of T2 diabetes.

Opportunity for Intervention: Breaking the Disordered Eating Cycle

Numerous government task forces have been developed in recent decades to recommend effective interventions for T2 diabetes. In 2014, the Community Prevention Services Task Force reported that programs focused on a combination of dietary change and physical activity were effective interventions to prevent further complications for individuals recently diagnosed with T2 diabetes (CDC, 2014).

Based on the existing empirical literature focused on the importance of eating for diabetes management, it is expected that intervening to reduce disordered eating behaviors may reduce the interference of eating problems on diabetes management. It's also expected that such interference will have positive implications for associated physiological and psychological outcomes including BMI, glycemic control, distress and QOL. *Thus, the current study seeks to determine the efficacy and acceptability of a low-cost, accessible lifestyle intervention focused on improving eating behaviors in an effort to break the cycle of disordered eating and in this way improve diabetes management.*

Project model

Based on the empirical literature discussed in this chapter, an intervention aimed at reducing disordered eating behaviors is likely to have a positive impact on diabetes management, and associated factors including distress, self-efficacy, and QOL. Reduction of disordered eating behaviors may also have a positive impact on overall health, specifically BMI and blood glucose (A1c), important indicators of well managed diabetes (NIH, 2014). The following conceptual model was developed to describe the possible connections between

diabetes management, disordered eating, and associated variables, as well as the opportunity for intervention (see figure 1).

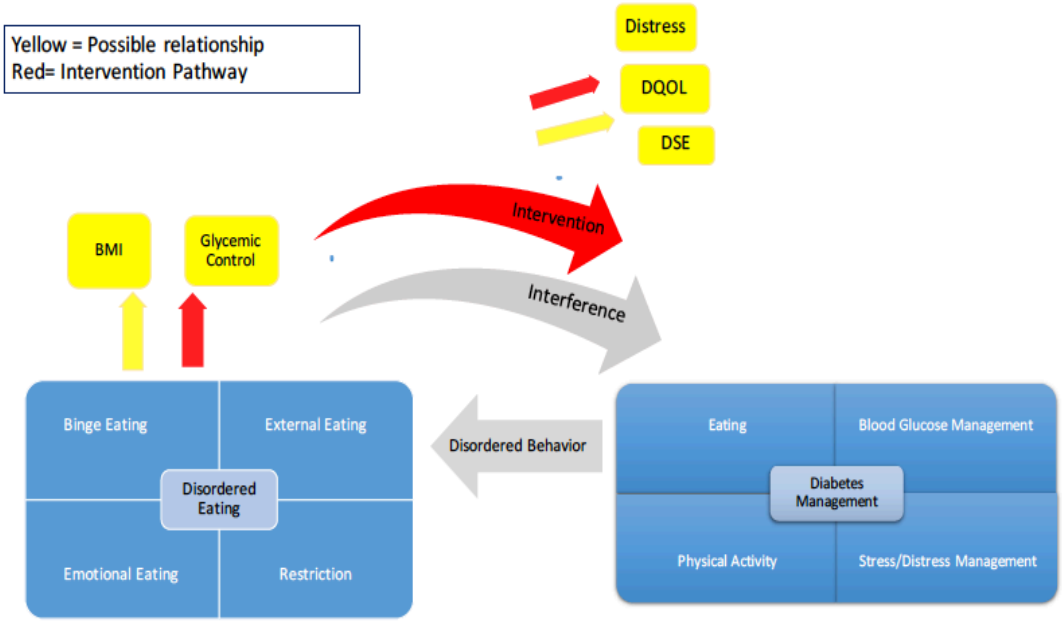

Figure 1. Project Model

As depicted by the model, the proposed intervention is expected to impact diabetes management by reducing the interference of disordered eating on diabetes management behaviors. The development of disordered eating behaviors, including binge eating, external eating, emotional eating, and restriction may lead to increased BMI and/or poor glycemic control, two common issues associated with poorly managed T2 diabetes. The interference of disordered eating on diabetes management may result in diabetes distress, lower diabetes self-efficacy, and lower QOL. In turn, distress, low self-efficacy, and low QOL are likely to make the difficult process of managing T2 diabetes well even more difficult. Thus, an intervention aimed at reducing disordered eating is likely to impact the other aspects of the diabetes management experience described by the model in Figure 1. While no intervention has been developed specifically to target disordered eating among individuals with T2

diabetes, there have been several types of interventions employed to support diabetes management and disordered eating distinctly.

Diabetes self-management interventions

Patients with T2 diabetes are responsible for the daily responsibilities associated with managing a complex chronic disease. Previous research and the American Diabetes Association (ADA, 2016) *Standards for Medical Care in Diabetes* indicate the importance of patient education in diabetes self-management to ensure good management and to reduce the probability of diabetes-related complications. Numerous studies have sought to understand the efficacy of interventions focused on diabetes self-management and diabetes self-management education (DSME).

Diabetes self-management education (DSME) is a resource to help patients actively engage in the management of their own disease (Fan & Sidani, 2009). A meta-analysis of 50 randomized-controlled trials (RCTs) that assessed outcomes associated with patient engagement in DSME indicated a larger effect for behavioral interventions than educational and psychological interventions for both self-management behaviors and metabolic outcomes, such as BMI. Overall, this study indicates the value of DSME, particularly when the nature of the intervention is behavioral (Fan & Sidani, 2009). A systematic review by Sherafali et al. (2015) found that diabetes self-management programs that include education and/or support have demonstrated important implications for reduction in HbA1C, as well for other indicators of overall health such as blood pressure. In consideration of overall health, QOL is of great importance.

A meta-analysis of 20 studies that included QOL outcomes indicated that participation in diabetes self-management training programs was associated with improved

QOL (Cochran & Conn, 2008). These results are important as individuals who suffer from chronic diseases such as T2 diabetes seek not only to decrease risk for complications and mortality but also to improve QOL. Further, the potential for improved QOL may be a more salient and motivating factor for some individuals to adhere to and maintain good diabetes management (Cochran & Conn, 2008). Research also has indicated the value of a collaborative care model in the provision of diabetes self-management programs. A study by Sturt, Whitlock, and Hearnshaw (2006) demonstrated a reduction in HbA1c following a three-month diabetes self-management intervention facilitated by a collaborative team. The study also found that patients reported an increase in participant's self-efficacy, a result that may have important implications for future diabetes self-management outcomes.

Another important aspect of good diabetes self-management is the ability to engage in problem solving. A systematic review of studies that employed problem-solving interventions for diabetes self-management demonstrated reduced HbA1c and improved self-management behaviors (Fitzpatrick, Shumann, & Hill-Briggs, 2013). These results demonstrate the potential importance of including problem-solving as a component of a diabetes self-management intervention that is focused on eating (problems) as a different aspect of self-management.

Finally, it's important to consider the populations for which the interventions reviewed to date have been effective. A systematic review of 15 studies focused on DSME for underserved populations, including ethnic minority, low income, and aged populations (Eakin, Glasgow, & Mason, 2002). Results of the review indicate that there is a clear need for different methods of delivery of DSME for underserved populations of individuals with diabetes. Specifically, in the delivery of DSME for minority populations barriers to treatment

such as financial and transportation limitation must be considered. Multi-level and interdisciplinary engagement in DSME also may be especially important for underserved populations in order to increase their ability to engage in diabetes self-management (Eakin et al., 2002).

Despite the value of diabetes self-management in addressing patient's level of diabetes-related knowledge, self-efficacy, problem solving, and QOL, among other factors, this research has not to date examined comorbid disordered eating. As outlined previously, disordered eating often has a profoundly negative impact on individual's ability to engage in good self-management of T2 diabetes. Disordered eating is also negatively associated with other outcomes addressed by existing diabetes self-management and DSME interventions such as physical activity, suggesting that individuals with T2 diabetes may especially benefit from an intervention to reduce symptoms of disordered eating.

Cognitive behavioral interventions

Cognitive behavioral therapy (CBT) has been demonstrated to be a highly effective treatment for disordered eating behaviors, including the often unhelpful cognitions associated with the behavior. The overall purpose of the treatment is to redevelop rigid patterns of thinking, replace unhealthy eating behaviors with regular healthy patterns of eating, and to help prevent relapse of symptoms (Grilo, 2006). In one study, CBT was found to be more effective in the reduction of binge eating symptoms and BMI than a comparison behavioral weight loss treatment, both of which occurred over the course of 16 weekly treatment sessions. CBT was also associated with quicker improvement in binge eating symptoms than was the comparison weight loss treatment (Munsch et al., 2007). CBT has demonstrated long-term benefits for patients with BED. A study by Devlin et al. (2007) found that CBT

was associated with decreased binge frequency and improvement in the amount of time with absence from binge eating, and that those improvements were maintained two years post-treatment. Such results indicate the potentially long-term impacts of brief CBT-based treatment for binge eating symptoms (Devlin et al., 2007).

Unfortunately, CBT can be expensive and inaccessible to some populations. A guided self-help version of the CBT protocol for binge eating, CBTgsh, was developed to address such barriers to treatment by providing participants with an opportunity to follow a self-help manual while also receiving guidance from a "supporter" who aids the participant in employing the manual (Shea et al., 2016; Streigel-Moore et al., 2010). Research has indicated that CBTgsh programs have been effective in the reduction of binge eating symptoms for women of various racial and ethnic groups (Grilo & Masheb, 2005; Shea et al., 2016; Striegel-Moore et al., 2010; Wilson, 2012). However, to date, the low cost, high access method of CBTgsh has not been employed for women with comorbid disordered eating behaviors and a chronic medical problem such as T2 diabetes. Additionally, while CBTgsh has been employed extensively with women who engage in binge eating, the method of intervention has not been specifically employed with disordered eating symptoms that are subthreshold for an eating disorder. For individuals with T2 diabetes, even subthreshold disordered eating symptoms are associated with severe and problematic health outcomes (Kenardy et al., 2001).

Though the intervention employed by the current study was originally developed as a self-help program for binge eating disorder, the intervention has been adapted to include a broader scope and to incorporate lifestyle aspects including dietary choices and physical activity. CBT has demonstrated treatment efficacy and symptom reduction across eating

disorder diagnoses, including eating disorder not otherwise specified, and has also demonstrated positive effects for psychopathology associated with eating disorders, such as anxiety (Knott, Woodward, Hoefkens, & Limbert, 2015). Thus, it's expected that the CBT principles, such as food monitoring, applied to reduce binge eating will also be useful in reducing other forms of disordered eating. It is also important to note that in respect to the model (see Appendix A) the intervention does not seek to intervene directly with aspects of diabetes management that might necessitate additions or modifications to the current intervention protocol.

Other Methods of Intervention

In consideration of interventions for disordered eating behaviors among individuals with T2 diabetes, concurrent attention to barriers to treatment is necessary. An Australian study employed 27 phone sessions over the course of 18 months as an intervention with the goals of weight reduction and improved HbA1c for individuals with T2 diabetes (Goode, Winkler, Reeves, & Eakin, 2015). Participation in the phone-based intervention was compared to usual care practices consisting of regular medical visits, and consisted of a focus on increasing physical activity, reduction of food consumption, and behavioral therapy for weight loss. The phone sessions were supported through a work/activity book that was provided to participants, along with a scale and pedometer. The purpose of the phone sessions was to check on progress, problem solve, identify barriers to success, and maintain a plan for the goals of the intervention (Goode et al., 2015). Results indicated that those with baseline diagnoses of anxiety or depression participated in fewer of the intervention phone sessions. Overall, the study found that a phone-based intervention was more effective than care as usual in weight reduction for a T2 diabetic population, but effects were not found for

HbA1c improvement (Goode et al., 2015). The authors also noted that in general, more calls were associated with better outcomes, with the average number of phone sessions completed being 17. The results of this study are important in indicating that a phone-based intervention is an effective option in supporting overweight and obese individuals with T2 diabetes in weight loss. Such results also speak to the potential further use of phone-based interventions to support T2 diabetics in reaching other clinical outcome goals in a manner that is associated with less barriers to participation than in-person interventions (Goode et al., 2015).

A recent meta-analysis found support for the efficacy of multi-component interventions that include dietary change and physical activity, including both aerobic and resistance training exercise (Aguiar et al., 2014). The authors found that multi-component lifestyle interventions were modestly effective in the prevention of T2 diabetes, as in general such interventions were associated with weight loss, improvements in fasting glucose, as well as improved diet and physical activity outcomes (Aguiar et al., 2014). Overall, this research is important as it supports the use of multi-component lifestyle interventions that are consistent with the broad goals for both at-risk individuals and recently diagnosed T2 diabetes.

Researchers also have begun to explore internet-based dietary interventions for T2 diabetes, a method that may be particularly salient for those with limited access to healthcare due to geography, disability, and more. A 2015 study by Ramadas et al. employed a website developed to include lesson plans and guidelines with a user-centered approach to improving dietary behaviors for individuals with T2 diabetes. Participants accessed the website for six months, and provided positive feedback for the website. Dietary knowledge, attitude and behavior was correlated with satisfaction with the content of the website, as well as

acceptability and usability of the website (Ramadas et al., 2015). These results indicate that interventions conducted remotely can be effective in improving important health behaviors that compose diabetes management for individuals with T2 diabetes. Additionally, this study indicates that participants may be open to internet-based interventions, as they overcome some of the common barriers to treatment such as transportation and cost (Ramadas et al., 2015).

Summary

Overall, the current empirical literature reflects that a CBT-based lifestyle intervention for individuals with T2 diabetes may feasibly reduce disordered eating behaviors. CBT-based interventions have been effective in reducing binge eating and improving health outcomes in various populations of women. However, to date no studies have specifically addressed disordered eating behaviors as a component of lifestyle interventions for individuals with T2 diabetes. As previously discussed, rates of disordered eating are expected to be higher among individuals with T2 diabetes than the general population, and some research has supported that first improving symptoms of disordered eating is necessary to improve overall diabetes management, with the long-term goal of preventing complications from T2 diabetes.

Despite the clear value of CBT-based lifestyle interventions for T2 diabetes, there remains a need to determine the feasibility of such an intervention to address disordered eating among individuals with T2 diabetes. Such an intervention should also be cost-effective and highly accessible in order to reduce barriers and improve treatment outcomes. To date, phone-based interventions and CBTgsh interventions have proven effective in reducing some barriers to support treatment outcomes. The goal of reducing disordered eating is likely to

have a positive impact on other important variables that are indicative of the impact of T2 diabetes on one's health, including BMI, glycemic control, DQOL, and diabetes distress, all of which may have a positive impact on overall diabetes management. The purpose of the current study is to test the feasibility and acceptability of a lifestyle intervention consistent with these goals and the current state of the empirical literature.

Current Study

Current research has indicated a continued need for services and interventions to better manage T2 diabetes in an effort to reduce the burden of disease management costs for individuals and their families, as well as to reduce the financial burden on the health care system in the United States (CDC, 2014). Additionally, research indicates that eating is arguably the most important and challenging aspect of diabetes management for many patients. Intervening to reduce disordered eating behaviors may thus have important implications for overall diabetes management, as well as for the previously discussed associated variables including distress, QOL, and important health outcomes such as BMI and blood glucose. The purpose of the current study was to determine the efficacy and acceptability of a CBT-based lifestyle intervention focused on the reduction of disordered eating behaviors for women with T2 diabetes who seek to improve their eating behaviors and disease management.

To control for gender differences in disordered eating, health care utilization, and treatment compliance the current study sample included only women (Courtenay, McCreary, & Merighi, 2002; Hazel-Fernandez et al., 2015; Schneider, O'Leary, & Jenkins, 1995). An all women sample is consistent with the lack of research in the area of disordered eating interventions for individuals with T2 diabetes. Additionally, previous adaptations of the

CBTgsh protocol, as mentioned in chapter one, have been conducted with women samples (Grilo & Masheb, 2005; Shea et al., 2016; Streigel-Moore, 2010), further justifying the gender-specific focus of the current study.

The current study sought to evaluate the preliminary efficacy and acceptability of a 12-week lifestyle intervention employing the CBTgsh model for women with T2 diabetes who endorsed disordered eating and a desire to improve their eating behaviors.

Study Aims

Aim 1.

To test the preliminary efficacy of an eating-focused CBTgsh lifestyle intervention developed to aid participants in making health behavior changes including reduction of binge eating, increase in fruit and vegetable consumption, and increase in physical activity over 12 weeks.

Aim 1: Hypothesis 1.

Based on previous employment of the CBTgsh protocol with diverse populations of women, it was expected that the intervention would be associated with significant reductions in disordered eating behaviors as measured by the EDE-Q and the DEBQ.

Aim 1: Hypothesis 2.

As eating is the most important and impactful factor of diabetes management, it is expected that the intervention will be effective in improving diabetes management as measured by significant improvement in glycemic control, diabetes quality of life (DQOL), diabetes self-efficacy, and significant reduction of diabetes distress, and BMI.

Analysis Aim 1.

Efficacy was assessed by comparing pre to post-intervention participant self-report data. Pre- to post- changes were specifically assessed by paired t-tests across variables that measured disordered eating, glycemic control, diabetes distress, DQOL, diabetes self-efficacy, and BMI.

Aim 2.

To test the acceptability of an eating-focused CBTgsh lifestyle intervention developed to aid participants in making health behavior changes including, reduction of binge eating, increase in fruit and vegetable consumption, and increase in physical activity over 12 weeks.

Hypothesis Aim 2.

Based on previous employment of the CBTgsh protocol with diverse populations of women, it's expected that the manual content and structure of the intervention will be acceptable to a sample of women with T2 diabetes.

Analysis Aim 2.

Acceptability was assessed using the client satisfaction questionnaire (CSQ-8) and qualitative feedback about the intervention, including participant's likes, dislikes, and suggestions for change.

Chapter 2: Methods

CBTgsh interventions and lifestyle interventions have been found to be independently effective in improving both diabetes management outcomes and reducing disordered eating behaviors among women. To date, no published study has developed a CBTgsh lifestyle intervention protocol to specifically target disordered eating and lifestyle factors associated with diabetes management for women with T2 diabetes. The current study sought to pilot test the CBTgsh lifestyle intervention for women with T2 diabetes, a population for which similar disordered eating-focused interventions have not been studied. More specifically, the current study sought to determine the acceptability and preliminary efficacy of the intervention for the specific target population, without the inclusion of diabetes-specific modifications to the intervention. The literature review and rationale provided in chapter one highlight the need and value of such research for women with T2 diabetes who engage in disordered eating behaviors. An overview of the methods for the current study is provided below.

Procedure

Recruitment.

Participants were recruited via flyers and email at a large southeastern university and from community health care organizations in an urban southeastern setting. Flyers and emails described a research study seeking women over the age of 18 with a diagnosis of T2 diabetes who endorse disordered eating behaviors and want help to improve their eating. Interested individuals completed a pre-screen by phone to determine inclusion and exclusion criteria, as well as to provide a brief explanation of the study to ensure interest in participation. Following oral consent for participation, the phone-screening process included select

questions from the Eating Disorder Examination Questionnaire (EDE-Q; Fairburn & Beglin, 2008), presented orally by the screener, to assess for symptoms of disordered eating that meet criteria for inclusion in the study. Inclusion criteria included T2 diabetes diagnosis, female gender, at least 18 years of age, current disordered eating behavior, and a desire to improve one's eating behaviors. Exclusion criteria included current participation in another intervention, currently pregnant, a brain injury or impairment that would affect their recall or ability to complete assessments, a serious medical condition that would require immediate hospitalization, or undergoing current treatment for an eating disorder. As the current study included no major dietary changes, consent from a medical professional was not required to participate.

Orientation and Survey.

Eligible participants were invited to participate in an in-person orientation session at which time they were introduced to the intervention and asked to complete a series of questionnaires. All questionnaires were completed on the computer using the internet-based survey system, Qualtrics. The questionnaires assessed demographic information, disordered eating, DQOL, diabetes distress, diabetes self-efficacy, BMI, diabetes history, and glycemic control. Participants were compensated with a $25 gift card for their time and participation.

Following the completion of the questionnaires the research assistant, also known as the participant's "supporter," described the intervention to the participant, walked them through the intervention manual, discussed reasons for change and motivation for participation, and addressed any concerns or potential barriers to participation. During the orientation session participants were provided with a copy of the manual, an example spreadsheet for daily food and physical activity monitoring as well as an electronic version,

and a scale to be used for the weekly weighing component of the program. The purpose of the orientation sessions was two-fold. First, to provide participants a clear explanation of what to expect from the intervention and ensure their interest and commitment to participating. Second, to establish rapport between the participant and the research assistant who worked with the individual participant to guide and support them throughout the 12 weeks of the intervention.

Intervention.

The current intervention consisted of eight sessions of support by an individual research assistant/supporter to guide participants through the 12-week lifestyle intervention. In an effort to reduce barriers to participation the in-person orientation session was the only face-to face contact and all support sessions were completed by phone. All phone-based support sessions were provided by the research assistant who conducted the orientation to the program (supporter). Participants followed the steps outlined in the self-help manual developed by The Women's Health Project research team at the University of North Carolina at Charlotte. The self-help manual, "A Lifestyle Guide: Managing Eating and Physical Activity" incorporates information from Christopher Fairburn's (1993) book "Overcoming Binge Eating," in conjunction with physical activity and fruit and vegetable consumption recommendations consistent with the current research literature. The manual included information about the importance of daily physical activity, as well as suggestions to help participants monitor and improve their level of physical activity (ODPHP, 2016). Fruit and vegetable consumption, consistent with national guidelines, will also be encouraged throughout the manual by providing participants with useful information about the value of

fruit and vegetable consumption, as well as strategies to increase consumption (ODPHP, 2016).

The purpose of the intervention was to facilitate completion of the eight steps of the CBTgsh program with the guidance and support of the participant's supporter. The intervention focused on food monitoring, establishing a regular pattern of eating, development and use of strategies to prevent disordered eating behaviors, and relapse prevention. To complement the eating behavior components, discussion of strategies to increase physical activity and fruit and vegetable consumption through monitoring and other strategies occurred throughout the intervention. For a more in-depth breakdown of the eight sessions of the intervention refer to Appendix A.

The supporter was in contact with their assigned participant for pre-scheduled support sessions weekly for four weeks and biweekly for eight weeks, for a total of eight sessions over the course of the 12-week intervention. Support sessions conducted by phone were approximately 20 to 25 minutes in duration. During each support session the supporter followed a semi-structured script to ensure that all necessary components of the session were completed, as well as to maintain consistency between supporters. Four supporters provided all the support sessions for the current study, with 7 participants assigned to one supporter. The purpose of each session was to check in with the participant about the goals of the step on which they were working, to identify and discuss any challenges or barriers to completing that step, to follow-up on progress with food and physical activity monitoring that occurred throughout the intervention, to check in on the participant's weekly weighing with the scale provided, and to help the participant determine if they were ready to move on to the next step in the manual or if they needed to spend additional time focused on the step in progress. The

supporter's role was to guide the participant through the program while also providing encouragement and positive feedback to celebrate the participant's successes.

Follow-up.

Following the completion of the 12-week intervention and the termination of support, participants were asked to complete follow-up versions of the questionnaires immediately after completing their eighth and final phone session. The follow-up questionnaires and interviews allowed for participants to demonstrate changes in variables of interest over the course of the intervention, as well as to complete a participant feedback questionnaire. Questionnaire completion was conducted remotely via computer using the software system, Qualtrics, with the supporter typically remaining on the phone to answer any questions during the time of completion. Participants were then compensated $75 in the form of a gift card for their time and participation in the questionnaires. Gift cards were sent to participants via mail.

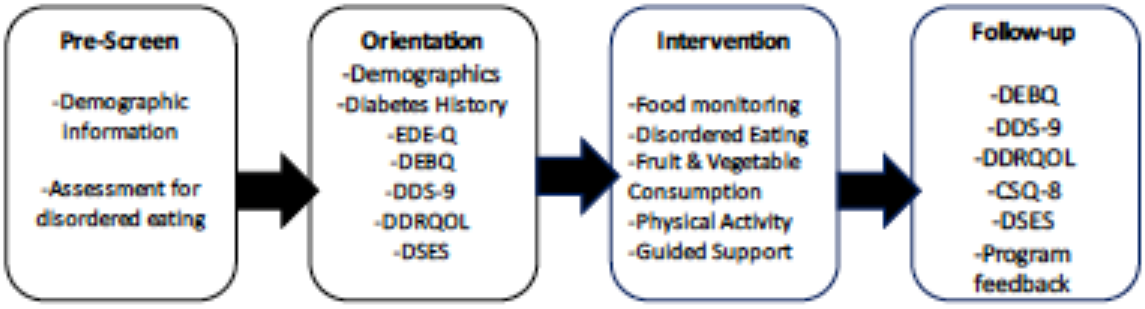

Figure 2: Study overview

Measures

Screener Variables.

Demographic characteristics.

Age, date of birth, country of origin, ethnicity, height, and weight, sex, level of education, and annual income were collected via self-report.

Diabetes history.

Information regarding diagnostic history, current diabetes treatment, most recent HbA1c, three days of blood glucose self-monitoring, family history of diabetes, and the role of others in their diabetes management were collected via self-report (see Appendix B).

Focal Variables.

Eating Disorder Examination Questionnaire (EDE-Q).

The purpose of the EDE-Q was to screen for eating disorders among community samples. The 41-item self-report questionnaire is an adaptation of the Eating Disorder Examination (EDE; Fariburn & Cooper, 1993) and includes four subscales in addition to the global score: restraint, eating concern, shape concern, and weight concern. A higher overall score on the EDE-Q is indicative of greater eating pathology. The scale was used to determine the degree to which participants report problematic eating behaviors, particularly binge eating.

Dutch Eating Behaviors Questionnaire (DEBQ).

The purpose of the 33 question DEBQ was to assess general eating behaviors across three subscales: restrained eating, emotional eating, and external eating. For example, a question from the emotional eating subscale is: “Do you have the desire to eat when you are irritated?” (van Strien, Frijters, Bergers, & Defares, 1986). Higher overall score on the DEBQ is indicative of greater disordered eating, while higher scores on each of the three subscales are indicative of greater subscale-specific eating pathology. Research has indicated that the subscales demonstrate high internal consistency, as well as appropriate validity (van Strien et al., 1986).

Client Satisfaction Questionnaire, 8th edition (CSQ-8).

The purpose of the eight question CSQ was to assess general participant satisfaction with their experience and engagement in a given program. Instructions clarify that responses are requested to help improve the program. Participants are asked to respond to questions such as "If a friend were in need of similar help, would you recommend our program to him or her?" Responses fall on a four-point scale that varies for each question, for example from "no definitely not" (4) to "yes, definitively" (1). Research has indicated that the scale demonstrates appropriate reliability, construct validity, criterion validity, and internal consistency (Larsen, Atrkinsoon, Hargreaves, & Nguyen, 1979). This measure was only administered at follow-up.

Participant Feedback.

Following the completion of the CSQ-8 participants were prompted to complete five open-ended questions to further assess the feasibility and acceptability of the program. Questions addressed what participants liked and disliked about the program, changes they would recommend, why they would or would not recommend the program to others, and an opportunity to express anything else that might be useful to the research team. This measure was only administered at follow-up (see Appendix C).

Secondary Variables.

Diabetes Distress Scale (DDS).

The purpose of the DDS is to assess emotional distress specifically related to the diagnosis and management of diabetes. The scale includes 17 questions that compose four subscales: emotional burden (EB), physician distress (PD), regimen distress (RD), and interpersonal distress (ID). An example question from the emotional burden subscale is:

"Indicate the degree to which [each] item may be bothering you in your life: feeling that my diabetes is taking up too much of my mental and physical energy every day" (Polonsky et al., 2005). Both the total score of diabetes distress and the subscale scores can be interpreted. A higher overall score is indicative of greater distress, and higher subscale scores are indicative of greater pathology. The DDS has been empirically validated and is a reliable measure of diabetes-distress for individuals with T2 diabetes (Polonsky et al., 2005).

Diabetes Quality of Life (DQOL).

The purpose of the DQOL is to assess diabetes-specific quality of life. The scale assesses global diabetes quality of life, as well as four subscales: satisfaction, impact, diabetes-related worry, and social/vocational worry. An example question from the satisfaction subscale is: "how satisfied are you with the amount of time it takes to manage your diabetes?" (Jacobson, Barofsky, Cleary, & Rand, 1987). Higher overall score, as well as score on the satisfaction subscale are indicative of better DQOL, while higher scores on the subscales diabetes-related worry, impact, and social/vocational worry are indicative of lower DQOL. Though the scale was developed initially for insulin-dependent populations, the measure also has demonstrated reliability and validity for other groups of individuals with diabetes who use other forms of medication and management strategies (Jacobson et al., 1987; Jacobson, de Groot, & Samson, 1994).

Diabetes Self-Efficacy Scale.

The purpose of the Diabetes Self-Efficacy Scale is to measure self-efficacy among individuals diagnosed with T2 diabetes. Self-efficacy is defined as an individual's belief in their own ability to effectively complete the actions necessary to handle a given situation. The scale is composed of eight questions that prompt participants to determine if they feel

totally confident (10) to not at all confident (1) on questions such as, “How confident do you feel that you can control your diabetes so that it does not interfere with the things you want to do?” Research has indicated that the scale has demonstrated appropriate content and construct validity, internal consistency, and stability (Bijl & Shortridge-Baggett, 1999).

Body mass index (BMI).

BMI is a measure indicating underweight, normal weight, overweight or obese. It was calculated using self-reported height and weight by dividing weight in pounds by height in inches squared and multiplying by 703. According to the center for disease control (CDC) BMI is for most adults, a reliable indirect indicator of body fatness and is used to screen for possible weight related health issues (CDC, 2014). The CDC has categorized BMI into four categories of weight status: underweight- BMI less than 18.5, normal weight- BMI between 18.5 and 24.9, over weight- BMI between 24.9 and 29.9, and obese- BMI of 30.0 and above (CDC, 2014).

Glycemic control.

To assess for participant’s average ability to control their blood glucose levels they were asked to report their most recent HbA1c (A1c) and the date it was collected. To add to our understanding of glycemic control, participants were also asked to provide their self-monitored blood glucose readings for the three days prior to completion of the study questionnaires. Blood glucose readings were averaged across the three days to create a measure of average blood glucose.

Design

The current study employed a pre-post design with one group. The purpose of the study was to determine the preliminary efficacy and acceptability of a lifestyle intervention

developed to address disordered eating and related health behaviors for women with T2 diabetes. In an effort to assess the effectiveness of the current intervention to promote change, participant's reports of disordered eating behavior, binge eating, DQOL, diabetes distress, diabetes self-efficacy, BMI, and glycemic control were compared from pre to post-intervention. Acceptability was assessed by participant feedback provided on open-ended questions at follow-up and by scores on the CSQ.

Research assistants underwent extensive training before working with participants of the current study as supporters. Training included several months of listening to previously recorded support sessions, reading and learning the manual, and audio-recorded practice sessions of the orientation and each of the 8 sessions with feedback from trainers. All phone sessions for the current study were recorded and throughout data collection, audio recordings of support sessions were selected and listened to by the trainers, supervisors, and other supporters. This regular review process was in an effort to establish fidelity.

Plan of Analysis

The current study employed both quantitative and qualitative methods to meet each of the two aims.

Analysis Aim 1.

The primary goal of the analyses conducted to address aim 1 was to determine the efficacy of the intervention to reduce symptoms of disordered eating. The secondary goal was to determine the efficacy of the intervention to improve DQOL, diabetes self-efficacy, glycemic control, and reduce BMI and symptoms of diabetes distress. All quantitative analyses were conducted in SPSS version 23 (IBM, 2013). Descriptive statistics were used to determine the demographic characteristics of participants who completed the program, as

well as the one participant who engaged but did not complete the intervention. Pre-post paired *t*-tests were conducted for each variable of interest. No corrections for type 1 error were indicated, as all tests were hypothesis driven and the nature of the study was a preliminary pilot. Missing data was minimal and will be discussed in the following chapter.

Analysis Aim 2.

The primary goal of the analyses conducted to assess aim 2 was to determine the acceptability of the intervention. Aim 2 was assessed quantitatively by participant's mean score on the CSQ-8 and qualitatively by participant feedback that was provided in response to open-ended questions from the post-intervention questionnaires. Responses were analyzed qualitatively to determine themes using constant-comparative analysis with the intention of focusing on participant's lived experiences and patterns among those experiences (Hewitt-Taylor, 2001). Analyses were conducted by a two-person coding team, with agreed upon themes being included in the final results. Disagreements regarding themes were resolved through discussion until consensus about that specific code was reached. Themes were developed within the context of the five open-ended questions completed by participants. The goal of this process was to identify patterns that are consistent with the lived experiences of participants, and the codes developed are outlined in the following chapter to summarize the experiences of participants while completing the program. The data also were employed towards consideration of important implications for the feasibility of future iterations of the program for women with T2 diabetes

Validity of the results is supported by triangulation, or convergence amongst sources of information, in this case participants' reports of subjective experience. Triangulation is a validity procedure in which overlapping areas within codes and themes are systematically

eliminated to ensure the researcher's lens is maintained (Creswell & Miller, 2000). The coding team's self-disclosure of stance, demographics, and disclosed interaction with the participants further served to support the validity of this plan for analysis (Mattis, 2015).

Missing Data

As a pilot study with a small sample size we were able to minimize missing data. One participant reported that she does not monitor her blood glucose and is not currently connected with a primary care physician or other medical professional to allow her regular A1c measures, thus her data was missing from the section on glycemic control. There was no other missing data in the current study.

Summary

The current study employed a mixed method approach with the goal of examining the preliminary efficacy and acceptability of a 12-week disordered eating-focused lifestyle intervention for women with T2 diabetes. The use of both quantitative and qualitative analysis allowed for a rich understanding of the outcomes related to participation in the study, as well as the perspective of participant's experiences during program completion.

Chapter 3: Results

Data collection for the current study occurred over the course of eight months from October 2016 to May 2017. Fifteen women who endorsed having been diagnosed with T2 diabetes were screened and invited to participate in the current study. All pre-screened participants were eligible, which may be attributed to the subclinical disordered eating threshold for inclusion, as well as to recruitment strategies. Eleven of the 15 eligible (73%) completed the orientation and engaged in one or more of the weekly phone sessions that comprise the intervention. Just over 90 percent of participants (*N*=10) completed the 12-week intervention and follow-up questionnaires. The single participant who dropped out was also an outlier, and excluded from all analyses, thus the remainder of the discussion section will refer to those participants who have completed the study. Discussion of attrition (*n*= 1) and details regarding this participant who dropped out will occur later in this chapter.

Participant Demographics

Participants were an average age of 49.45 (*SD*=7.48). Only one participant was categorized as overweight, with the remaining 9 participants (90.0 %) categorized as obese. 90 (*n=9)* percent of participants were recruited via campus email and flyers at a large southeastern university. One participant was recruited from a local primary care clinic affiliated with the university research lab from which this study was conducted.

It should be noted that while most participants were recruited on a university campus, only four reported they were students, two part-time and one full-time. Over half of the participants worked full or part-time jobs (*n*=6), three reported they are disabled (27%) and receive disability support, and one reported she is retired. Additional participant characteristics are presented in Table 1.

Table 1.

Participant Characteristics

		***M*/%**	**(*SD*/*n*)**
Age		49.45	(7.28)
BMI		34.15	4.55
Race	Black	70	(7)
	White	30	(3)
Ethnicity	Latino	0	(0)
Student Status	Part-time	10	(1)
	Full-time	20	(2)
Employment Status	Full- or part-time	50	(5)
	Retired	10	(1)
	Disabled/On disability	30	(3)
Marital Status	Married/Living as Married	50	(5)
	Separate/Divorced	20	(2)
	Single/Never Married	20	(2)
	Widowed	10	(1)
Number of children		1.36	(1.26)
Education	Some college	80	(8)
	4-year Degree	20	(2)
Household Income	Less than $25,000/year	50	(5)
	More than $25,000/year	50	(5)
Months Insured Past 5 years		48.40	(19.09)
Months since diagnosis		92.70	66.69

Diabetes History

All participants reported a diagnosis of T2 diabetes by a medical doctor. At the time of completion of their participation in the current study, participants had been diagnosed with T2 diabetes for an average of 92.70 months (*SD*= 66.69), or just over seven years. Interestingly, two participants enrolled in the current study within two months of being diagnosed. All participants reported at least one family member who has also been diagnosed with T2 diabetes, including parents, siblings, aunts, and uncles. Only one participant also described a history of gestational diabetes during her single pregnancy.

All participants reported the use of some medication to help manage diabetes. Metformin, a commonly prescribed medication to treat high blood glucose levels (US National Library of Medicine, 2017), was reported by 50 percent of participants (*n*=5), two of whom reported concurrent medications, Jenuiva, an oral medication prescribed to help lower blood glucose levels, and insulin (US National Library of Medicine, 2017a). Four participants reported the use of insulin (40%), two of whom specifically reported the use of the insulin pens Lantus and Levemir. Other medications reported included Glyburide, Invokana, and Glyxambi, oral medications used to treat T2 diabetes often in combination with insulin (US National Library of Medicine, 2017b).

When asked to describe any education received regarding T2 diabetes diagnosis and management, three participants reported diabetes and/or nutrition classes, while two reported receiving information from their doctor. Additionally, there were individual reports of participating in a diabetes wellness program, meeting with a nutritionist following initial diagnosis, and obtaining information from health care professionals while receiving dialysis. At baseline, half of participants reported currently engaging in physical activity, with several

reporting walking (*n*=4) and one stating "I usually try to ride my stationary bike each morning but sometimes if I'm running late I will skip it."

In regards to blood glucose management, 80 percent (*n*=8) of participants reported they do check their blood glucose, four of whom reported they check once per day in the morning, and three of whom reported checking twice per day - once in the morning and once in the afternoon or evening. Participants were also asked to report their target blood sugar range. Nine participants gave specific ranges, with one participant providing two different ranges for morning and evening. The remaining two participants reported "no idea" and "idk [I don't know]." Reported target blood glucose ranged from 70 to 180.

Most participants were able to report their most recent A1c (*n*=9), which ranged from 5.9 to 10.1, with levels between 5.7 and 6.4 typically indicating prediabetes, and 6.5 and above indicative of diabetes (NIDDK, 2017). Additionally, 60 percent (*n*=6) of participants were able to report their blood glucose levels for the past three days, with one additional participant providing a guess "around the 120's." Recent blood glucose levels reported ranged from 90 to 272. The Joslin Diabetes Center (2017) suggests that for individuals with diabetes blood glucose should fall between 70 and 180, with higher ranges appropriate within two hours following the consumption of a meal and with lower numbers as the goal for before breakfast (after fasting) and before the consumption of a meal.

Baseline Data

Prior to engaging in the 12-week CBTgsh lifestyle intervention participants reported moderate to moderately high levels of disordered eating behaviors, including binge eating. These baseline data (see Table 2) are consistent with the level of pathology described among the general T2 diabetes population in chapter one, and while perhaps not of great concern for

the general population, such level of disordered eating described could be detrimental to the health of an individual with T2 diabetes. Participants also described low to moderate levels of diabetes distress, diabetes-specific QOL, and diabetes self-efficacy, important variables associated with diabetes management. These baseline results are in the context of a small sample size with important individual variation among the 10 participants who went on to complete the program.

Aim 1: Efficacy of Intervention

Participants reported great benefits and change from their participation in the 12-week CBTgsh lifestyle intervention, with one participant stating "you changed my life." Results indicate that the current sample did in fact demonstrate benefit and improvement from pre-intervention to follow-up. Specifically, paired samples *t*-tests revealed significant reductions in disordered eating behaviors, diabetes distress, some facets of diabetes quality of life, and A1c. Additionally, participants of the current study did show a general decrease in BMI at follow-up (n=33.37, SD=5.33), however paired t-tests indicated that this difference was not significant (see Table 2).

Aim 1, hypothesis 1: Disordered eating.

Across two measures, paired *t*-tests revealed a significant reduction in disordered eating behaviors and general disordered eating pathology. Following the 12-week CBTgsh lifestyle intervention, participant's average EDE-Q score was significantly reduced, indicating a reduction in disordered eating behaviors, specifically binge eating ($t(9)=7.85$, $p<0.00$). Each of the four EDE-Q subscales also demonstrated statistically significant changes from pre to post-intervention, including restraint, eating, shape, and weight. This pattern indicates more specifically that participants reduced restrained eating behaviors,

general disordered eating, focus on their weight, and focus on their shape to a statistically significant degree over the course of the 12-week intervention (see Table 2). On the DEBQ, another measure of disordered eating, results indicated statistically significant change from pre- to post-intervention ($t(9)=3.09$, $p<0.01$). The external eating subscale indicated a statistically significant reduction in reports of behaviors consistent with external eating, or eating in response to external stimuli ($t(9)=7.91$, $p<0.00$). The two remaining DEBQ subscales, emotional eating and restrained eating, did not demonstrate statistically significant pre- to post-intervention changes (see Table 2).

Aim 1, hypothesis 2: Diabetes.

Following completion of the CBTgsh lifestyle intervention, paired *t*-tests revealed a significant decrease in A1c ($t(8)=3.40$, $p<.00$). The average A1c decreased more than one full point, from 8.28 to 7.24 with 88.89% of participants demonstrating a decrease or stability in their self-reported A1c. Participants were also asked to report their blood glucose levels over the past three days. These levels were averaged to create a three day blood glucose average in an effort to gain information about participants' blood glucose changes in addition to A1c. Average blood glucose over the past three days demonstrated a slight increase from an average of 126.25 to 129.25 from pre- to post-treatment; however this change was not significant ($t(7)=-0.30$, $p<0.36$).

Results indicate overall diabetes distress was significantly reduced by completing the CBTgsh lifestyle intervention ($t(9)=2.25$, $p<.03$). Of the DDS subscales, distress related to one's diabetes regiment was the only to demonstrate a statically significant reduction from pre- to post-intervention ($t(9)=0.59$, $p=0.00$). In regards to quality of life, participants reported higher diabetes quality of life (DQOL) at follow-up, though this difference was not

significant ($t(9)= -3.21$, $p<0.06$). Across the DQOL subscales, all four also demonstrated an increase in quality of life; however only the social and impact subscales were statistically significant. In regards to diabetes self-efficacy, results indicate that on the DSE, participants reported consistent levels of diabetes self-efficacy from pre to post-intervention with no statically significant change (see table 2).

Table 2.

Pre- to Post-Intervention Scores on Outcome Variables

		Baseline		Post-Treatment				
		M	**(SD)**	**M**	**(SD)**	***t***	***p***	***d***
EDE-Q	Total score	3.86	1.37	1.12	1.29	7.85	0.00	2.00
	Restraint	4.60	1.33	2.80	1.34	5.58	0.00	1.35
	Eating concerns	3.08	1.27	2.80	1.74	4.15	0.00	0.18
	Shape concerns	3.72	1.28	3.22	0.37	8.23	0.00	0.50
	Weight concerns	3.60	1.56	3.36	1.69	7.14	0.00	0.16
DEBQ	Total score	2.97	0.73	3.65	0.81	3.09	0.01	-0.88
	Restrained eating	2.81	0.72	2.87	0.82	0.26	0.40	-0.11
	Emotional eating	3.62	1.14	4.17	0.94	-1.65	0.07	-1.37
	External eating	2.47	0.49	3.90	0.77	-7.91	0.00	-1.22
DDS	Total score	2.15	0.93	1.75	1.03	2.25	0.03	0.41
	Emotional burden	2.16	0.83	1.74	1.02	1.61	0.07	0.45
	Physician distress	1.47	1.26	1.65	0.97	-1.02	0.15	-0.16
	Regimen distress	2.84	1.07	1.86	1.01	0.59	0.00	0.94
	Interpersonal distress	1.87	1.07	1.70	1.27	0.59	0.28	0.15
DQOL	Total score	3.46	0.29	3.78	0.29	-3.21	0.01	-1.41
	Satisfaction	2.42	0.57	2.56	0.68	-0.85	0.21	-0.22
	Impact	3.72	0.48	4.12	0.09	-2.64	0.02	-1.16
	Diabetes-related worry	3.80	0.51	4.00	0.39	-0.91	0.16	-0.44
	Social/vocational worry	3.90	0.91	4.40	0.53	-2.85	0.02	-0.67
DSE		6.81	1.02	6.80	1.14	0.02	0.49	0.01
BMI		34.15	4.55	33.37	5.33	1.00	0.16	0.16
HbA1c		8.28	1.63	7.24	1.23	3.40	0.01	0.72
Avg. blood glucose		126.25	23.72	129.25	19.78	-0.30	0.36	-0.14
CSQ-8		-	-	23.00	1.05	-	-	-

Note. EDE-Q= Eating Disorder Examination Questionnaire; DEBQ= Dutch Eating Behavior Questionnaire; DDS= Diabetes Distress Scale; DQOL= Diabetes Quality of Life; DSE= Diabetes Self-Efficacy Scale; CSQ-8= Client Satisfaction Questionnaire

Aim 2: Acceptability

In an effort to determine the acceptability of the current intervention for women with T2 diabetes and comorbid disordered eating, participants completed a brief measure of client satisfaction, CSQ-8. All 10 participants who completed the intervention completed the CSQ-8 and reported a mean score of 23.00 (*SD*=1.05) on a 32-point scale, indicative of moderately high general satisfaction with the intervention. Further client satisfaction feedback was elicited through five open-ended questions from which qualitative data were derived.

A two-person coding team was employed to analyze the following qualitative data, comprised of the PI for the current study who is a 26-year-old Latina female, and a 31-year-old White female, both graduate students in Health Psychology. Themes were identified independently, and overlapping themes that emerged were identified and are presented below. Disagreement and variation in theme identification was discussed until consensus for code development was reached. A total of nine themes emerged within the categories corresponding with the open-ended questions, with one question not eliciting sufficient responses to allow for coding (see Table 3).

Table 3.

Qualitative Themes

Program Likes		
	1	Connection and accountability
	2	Clear and useful information
Program Dislikes		
		Insufficient data to develop a theme
Future Modifications		
	1	Easier way of monitoring desired
	2	Addition of group support/meetings
Recommendations		
	1	Positive recommendation of the program
	2	Clear, useful, and thought provoking
Other		
	1	Positive change in perspective

Participant feedback: Likes and dislikes.

Overall, participants reported predominantly positive feedback regarding the program, with eight positive statements related to their experience, and only two statements regarding dislikes. In regards to the aspects of the program participants did like, three themes emerged, the first being connection and accountability. Participants described that they liked the weekly calls from their supporters and the consistent support provided by their individual supporter over the course of the 12-week intervention. For example, one participant stated, "It's great to be able to gain the rapport with the person you have assigned to you!"

A second theme that emerged from the aspects of the program participants reported they liked was that the clear and useful information provided throughout the program (i.e. the manual and the supporter) helps with participant success. For example, "I think the program helps put facts in front of participants. It's useful and realistic." The third theme, self-help through a personalized and flexible intervention spoke to participant's feedback that the structure of the program was supportive and worked for them throughout the 12 weeks. For example, "The personalization is important in allowing you to gain the understanding of the program from the beginning and gives you the determination to want to continue to strive to be your best from start to finish!"

In regards to participant's dislikes, there was insufficient data to identify any themes, with several participants stating that they had no dislikes. The only data indicated that one participant disliked "tracking food," or completing the daily monitoring, and another stated "the journaling might be a challenge if a person isn't used to doing it." Though there was insufficient data to develop a code, the tedious and often inconvenient nature of monitoring may be considered in future iterations of this program. Additionally, despite the lack of

dislikes reported, participants of the current study were able to provide useful feedback and suggestions for modifications and development of future programs.

Participant feedback: Future modifications.

Participants were clear regarding two themes for future program modifications, first that an easier way of monitoring food, physical activity, weight, etc. should be included. For example, one participant stated "an app," while another stated [having discussed the idea of using an app with her supporter during the program] "as for your app, if you could include a way of tracking sugar levels, I think that would be awesome." A different participant suggested another example of a more convenient way to monitor, stating "Possibly a small journal to carry the information and make it portable and easy to store." The second theme that emerged regarding future modifications was the addition of group meetings and support to add to the current protocol. Participants reported suggestions such as, "group setting may be better" and "group meeting at the gym or other social events, would be a bonus."

Participant feedback: Recommendation of the program

When asked why or why not participants would recommend the program to others, the first theme, a consensus, was that they would recommend the program. One participant stated, "I do recommend this program because it will cause the individual to think more about their health." While another participant stated, "I would recommend it to others to get real current information about others like us. There is less judgment in the material and it confirms for women that we are not alone in our pursuit of better health." A second theme that emerged is that participants would recommend the program because the material is clear, useful, and thought provoking. For example, "I would recommend the program because it's a step by step guide that allows you to see your difficulties and gives you self guidance of how

to work through them over time." Similar to their responses regarding recommendation of the program to others, participants of the current study provided overwhelmingly positive other feedback. The third theme was that the clear structure of the program allowed for major lifestyle changes to seem easier, for example, "I would because I have completely changed how I eat. Lifestyle changes are difficult and yet this felt natural." Overall, participants appeared enthusiastic in their desire to share their success and positive perspective on the intervention.

Participant feedback: Other.

The final question when completing the follow-up questionnaires for the current study was "what else would you like the research team to know?" There were five responses to this question, and the overall theme was that participants were able to identify an overall positive change in their self-esteem and/or self-confidence. One participant stated "I'm glad I participated because I feel so much better about myself," and another, "it helped me want to manage my diabetes instead of just letting it go." One participant summarized her experience and change as, "I'm down to 181 pounds and my sugar is running between 130-156. That is half what it was. You have changed my life! Participating in your study was one of the smartest decisions I've made." Thus, participants were consistent in their reports that they had a positive and impactful experience through their participation in the program, that the material provided through the manual was clear and helpful, that they enjoyed and appreciated the support provided throughout by the research assistant they were assigned to work with, and that their participant was useful in improving their overall health and lifestyle behaviors.

Drop out and barriers to completion

Only one individual did not complete the study. This participant was a White, 35-year-old woman with a BMI of 54.66 at baseline who demonstrated a great deal of disordered eating behaviors. She had been diagnosed with T2 diabetes approximately three years prior to enrollment and entered the program highly motivated to improve her health through better eating behaviors, weight loss, and better diabetes management. This participant was compliant to the intervention, completing the weekly monitoring forms and sending them to her supporter, reading and completing one step per week, and demonstrating a high level of engagement until she dropped out in week five of the program. She described her reasons for dropout in an email addressed to her supporter through the project's email account and was unresponsive to follow-up emails and calls.

She wrote: "I had an appointment with my primary physician today. We talked about weight-loss along with my diabetes meds, management and my thyroid numbers being out of whack consistently. She has recommended a diet plan and I am scheduled to see her in a month. I let her look at the book and we spoke about the pros & cons of this study. She and I thought it would be best to concentrate on her plan for now to get my numbers in order and my new routines with her in place. While skimming the guide, she said it seemed like beneficial info, but agreed I needed to focus on my new meds and a paleo type diet since I appear to be having some sort of ongoing inflammatory response. I appreciate the opportunity to be included in your study, but I cannot continue. I apologize for this. I am truly sorry. I need my primary to assist me at this point. Thanks so much and good luck with your continued research." The need for physician support for the current program among participants with T2 diabetes will be further discussed in the discussion chapter.

Summary

Overall, participants appeared to benefit from their participation in the 12-week CBTgsh lifestyle intervention. Ten participants completed the intervention and paired *t*-tests revealed statistically significant improvements in disordered eating behaviors, glycemic control, diabetes distress, and some facets of diabetes-specific quality of life. In a series of open-ended questions, participants spoke highly of the program and their personal lived experience, even stating that the program was "life changing." The results indicate that the current protocol is both effective and acceptable for women with T2 diabetes who engage in disordered eating behaviors. Implications of these results will be discussed in the following chapter.

Chapter 4: Discussion

Type 2 diabetes continues to impact the United States and the world in epidemic proportions (CDC, 2014). For those diagnosed with T2 diabetes, diet/eating is the most critical aspect of diabetes management, yet research suggests also the most challenging for patients (NIDDK, 2014; Sullivan & Joseph, 1998). Additionally, problematic and disordered eating behaviors for individuals with T2 diabetes have been repeatedly demonstrated to be significantly related to serious diabetes-related complications such as neuropathy and retinopathy (ADA, 2014; Gomersall et al., 2001; Kenardy et al., 2001). Thus, the literature speaks to the potential value of focusing treatment on disordered eating behaviors in an effort to improve diabetes management and important diabetes outcomes such as glycemic control.

Additionally, it is important to note the complex and burdensome nature of diabetes management, even for those with good medical care. Individuals with T2 diabetes never have time off from managing the disease (Carolan, Holman, & Ferrari, 2014). Every meal, every snack, every day individuals are responsible for making decisions that impact their diabetes and overall health. Thus diabetes management can drastically impact quality of life both emotionally and psychologically as it may place burdens on time, energy, resources, (Carolan et al., 2014).

Behavioral lifestyle change, rather than a diet or a treatment, may allow for some reduction in the experience of burden related to diabetes management. Though difficult, changes in one's lifestyle behaviors, specifically diet and physical activity, may be more generally supportive of treatment goals and outcomes such as improvement in glycemic control (Cradock et al., 2017). To date, no studies have assessed for the feasibility of a lifestyle intervention to specifically target disordered eating and health behaviors necessary

for good diabetes management. The current study therefore aimed to examine the efficacy and acceptability of a 12-week eating-focused CBTgsh lifestyle intervention for women with comorbid T2 diabetes and disordered eating.

The sample for the current pilot study was small ($N = 10$), though attrition was low with only one participant dropping out. The sample was somewhat racially diverse, with almost equal numbers of African American and White participants, and well-educated with all participants having completed some college. Importantly, many participants could be considered low-income with three of the 10 reporting that they are disabled and receive disability, further reflecting the diversity in functioning that is the result of a chronic condition and other comorbid conditions. Further, there was variation among participants in time since diabetes diagnosis, ranging from within the past couple of months to several years prior, and all participants were overweight or obese. In consideration of the translation of the current study it is important to note that the majority of the current sample was recruited through fliers and emails on a university campus, rather than in medical settings. The diversity in the current sample may nonetheless serve as a useful foundation for making sense of the efficacy and acceptability of the CBTgsh lifestyle intervention.

Overall, the present findings suggest that the current CBTgsh intervention was both effective and acceptable for women with T2 diabetes who engaged in disordered eating behaviors. The findings meet the aims of assessing both the preliminary efficacy and acceptability of the intervention through the use of both quantitative and qualitative data and analyses. The data highlight that the intervention was effective in improving both disordered eating and diabetes management outcomes, and that participants were overall pleased with, and would recommend the current intervention to others. Additionally, the rich feedback

regarding the impactful nature of the intervention for the current study's participants is indicative of the value of such an intervention to directly address disordered eating, as well as to have important implications for diabetes management outcomes. A discussion of the implications of the results and directions for further research of the current lifestyle intervention protocol is presented below.

Implications of sample characteristics

Despite variation in opinion regarding the rates of disordered eating and eating disorders among individuals with T2 diabetes (Herpertz, 1998; Peveler, 2000), as well as the subclinical disordered eating inclusion criteria for the current study, participants reported moderate to high levels of disordered eating at baseline as well as interest in improving their eating behaviors. For the current sample there was understanding of the important role of eating in diabetes management, and motivation to improve eating behaviors despite great variation in time since diagnosis from within a couple of months to several years prior. Participant's understanding and motivation may speak to patient's desire to better understand and engage in effective strategies and lifestyle behaviors for diabetes management, that may also positively impact diabetes distress and quality of life.

Related to their interest in the intervention, participants of the current study reported minimal engagement in diabetes management education and strategies, particularly in regards to nutrition and appropriate dietary choices for individuals with T2 diabetes. Minimal exposure to such information and resources was true for both recently diagnosed participants, as well as for those who reported that they had been diagnosed several years ago. Participants did report general satisfaction with their medical providers and primary care physicians, and only moderate distress related to interactions with one's physician. However, the complex

nature and daily burden of diabetes management indicate the need for additional accessible and low-cost resources and support.

Similarly, in regards to blood glucose monitoring, the majority of participants reported that they do in fact monitor their blood glucose levels but without much specific direction from medical providers. It was telling that one participant was unable to report any blood glucose numbers, stating that she does not monitor and that she is not currently connected with a medical provider for A1c testing. In contrast, all other participants were able to report their most recent A1c at both pre- and post-intervention assessment; this may speak to participants' general level of access and connection with their medical providers responsible for supporting their diabetes treatment. Research has indicated the social concordance between patient and provider is linked to patient outcomes, and that continuity of care between a specific provider and their patient may serve a protective role in regards to outcomes (Kurek, Teevan, Zlateva, & Anderson, 2016). Thus participants in the current study appear to understand the value of blood glucose monitoring and engaging with their medical provider, while also seeking additional education and strategies to engage in the complex process of diabetes management.

Aim 1: Efficacy outcomes and implications

Aim 1 of the current study was to assess the efficacy of the proposed intervention to support health behavior change. Results indicated the current intervention was an effective method to reduce disordered eating behaviors, blood glucose levels (A1c), and diabetes distress. Consistent with the hypothesized model (refer to Figure 1), intervening with a primary focus on disordered eating, not only impacted specific behaviors associated with disordered eating, such as binge eating and emotional eating, but also impacted diabetes-

specific outcomes. The proposed model outlined in chapter one, predicted that there may be an impactful relationship driven through the eating-focused intervention on glycemic control, BMI, diabetes distress, and diabetes-specific QOL. Thus, the intervention did appear to ifluence each of these factors to varying degrees and demonstrated preliminary efficacy to both reduce disordered eating and improve diabetes management outcomes. It is also important to note that while BMI decreased slightly from pre- to post-intervention, the lack of statistical significance in this change is consistent with other studies with disordered and binge eating intervention protocols. Disordered eating and binge-eating targeted interventions tend to be effective in behavior change but less effective in the short term on weight loss, particularly in contrast to behavioral weight loss interventions (Grilo et al., 2013; Peat et al., 2017).

Aim 1, hypothesis 1: Disordered eating.

Research has indicated a number of impactful variables in eating and dietary choice for individuals with T2 diabetes. Eating patterns in particular appear to be influenced by an individual's knowledge of diabetes management, social and familial support, and self-efficacy (Savoca & Miller, 2001). With the current sample demonstrating moderate levels of diabetes self-efficacy and describing generally good social support, their eating behaviors were effectively impacted by the current intervention. Across two measures and several eating-specific factors, participants of the current study demonstrated a significant decrease in disordered eating.

As we continue to learn more about disordered eating, and clinically-relevant binge eating disorder, in a variety of specific populations, it becomes more evident that rates of disordered eating may be higher among individuals with T2 diabetes than initially believed,

even more so for women and ethnic minorities who demonstrate higher rates of disordered eating than the general population (Herpertz et al., 1998). Not only was general disordered eating reduced by participation in the current intervention, but external eating behaviors, and focus on one's shape and weight was also significantly reduced from pre- to post-intervention. External eating behaviors, eating in response to food cues, such as the sight or smell of really delicious food at a party or buffet, is a common experience yet can be detrimental for individuals with T2 diabetes who are especially influenced by external eating cues (van Strien et al., 1986; Tak et al., 2015). External eating behavior, among other disordered eating behaviors also appears to be exacerbated by the rate of daily hassles experienced (O'Conner, Jones, Conner, McMillan, & Ferguson, 2008). For those with T2 diabetes, the hassles associated with diabetes management may further compound the impact of daily hassles that they already experience, in turn impacting their disordered eating behaviors.

One study found that it was tendency to overeat, to engage in behaviors such as external eating, rather than restriction that predicted weight gain and overeating four years after a dietary intervention (van Strien et al., 2007). These findings highlight the impact that individual perspective on food and eating can have on the implications of both short- and long-term interventions. It may also speak to the value of employing an intervention, as did the current study, from a cognitive behavioral perspective that seeks to tackle some of the specific thinking and behaviors related to food and eating. Interestingly, between the two disordered eating scales employed in the current study, change in restrained eating from pre- to post-intervention was significant on the EDE-Q, while not on the DEBQ. These results might be due to the cognitive-behavioral nature of the intervention and the goals of reducing

black and white and rigid thinking patterns related to food and eating (Hilbert & Tuschen-Caffier, 2004). For example, participants were encouraged by the manual to not engage in avoidance or restriction of specific foods in an effort to not label them as "bad," in order to avoid experiencing negative thoughts and emotions if and when such foods were consumed.

The significant decrease in focus on one's weight and shape also demonstrates the multifaceted reduction in overall disordered eating behaviors and related thoughts through participation in the CBTgsh intervention. Such a change is essential, as overvaluation of one's weight and shape has been linked to binge eating, and probable binge eating disorder (BED), as well as to greater difficulty in emotion regulation (Harrison, Mitchison, Rieger, Rodgers, & Mond, 2016). Thus, the current intervention may have reduced some of the risk for more severe disordered eating pathology associated with overvaluation of weight and shape. Such results are especially important for future considerations with populations who report high levels of overvaluation.

Overall, the results discussed thus far are unique, as the current lifestyle intervention was eating focused rather than diabetes self-management focused. This demonstrates that eating-focused interventions can impact a variety of disordered eating behaviors and lead to positive outcomes for women with T2 diabetes. These results are also important as disordered eating alone has been shown to predict severe diabetes-related complications and to exacerbate risk for other serious health problems. Effective interventions to reduce disordered eating in this high-risk population are needed (Kenardy, 2001).

Aim 1, hypothesis 2: Diabetes.

Despite the current lifestyle intervention not directly targeting or discussing diabetes management, results indicate that the intervention was effective in supporting improvements

in some of the most common indicators of diabetes management. A1c has been recommended by an international task force as an effective indicator of diabetes and glycemic control for those already diagnosed with diabetes (NIDDKa, 2014). The test for A1c has continuously improved over the years and is generally an accurate gauge of blood glucose over the past three months. Thus, a patient's A1c is the gold standard measure for medical providers to make treatment recommendations and adjustments, typically for medication (NIDDKa, 2014). A provider's goal for patients with T2 diabetes is typically to lower the A1c over the course of time, which is measured up to four times per year, as target blood glucose is associated with less risk for serious diabetes-related complications and greater life expectancy (NIDDKa, 2014).

Impressively, participants in the current study demonstrated a statistically and clinically significant change in average blood glucose across the 12-week participation period. More than 90% of the participants reported stability or reduction in A1c, with the average decrease of more than one whole point. The implications of these results in the context of diabetes management goals are significant. With rising rates of T2 diabetes around the world, prevention of complications is a goal both in the United States and worldwide. In 2004, the Global Partnership for Effective Diabetes Management, a multinational and multidisciplinary group, was formed to support diabetes management efforts in light of data that demonstrated more than half of patients with diabetes are not meeting target blood glucose ranges (Del Prato et al., 2005). In fact, one of the first concerns for this international group was to begin to address ineffective and conservative dietary and physical activity interventions through the use of multidisciplinary patient education and self-care (Del Prato et al., 2005).

In contrast to the notable results regarding A1c, average blood glucose increased only slightly from pre- to post-intervention and this change was not significant, reflecting consistency in daily average blood glucose levels. The NIDDK (2014) has stated that before a meal blood glucose should be between 80 and 130 mg/dL, and less than 180 mg/dL two hours after the start of the meal. Thus, there is much more range in daily blood glucose monitoring than in A1c levels. Participants in the current study reported overall average blood glucose levels in the normal range both pre- and post-intervention. However, there was also a great deal of variability and a lack of clarity regarding the specific time points at which blood glucose measures were taken, which may have impacted the results.

Interestingly, and perhaps related to the non-significant change in average blood glucose levels from pre- to post-intervention, there was also no significant difference in diabetes self-efficacy following participation in the lifestyle intervention. Diabetes self-efficacy, as measured by the DSE, spoke to participant's confidence in their ability to maintain a regular pattern of eating, follow a diet, exercise regularly, manage and monitor daily blood glucose levels, and prevent diabetes from interfering with daily life (Lorig et al., 2009). As the CBTgsh intervention targeted patterns of eating, dietary choices, and physical activity it was expected that participants would demonstrate increased diabetes self-efficacy. However, these results may be explained by the lack of focus and information on monitoring blood glucose and other diabetes management behaviors within the context of the manual. These results are also important because research has demonstrated that self-efficacy is associated with good diabetes self-management behaviors among diverse racial and ethnic groups, and future interventions should specifically seek to support an increase in diabetes self-efficacy (Sarkur, Fisher, & Schillinger, 2006).

Despite the inverse relationship typically identified in patients between self-efficacy and diabetes distress (Wang et al., 2016), the results of the current study indicate that the intervention was a feasible method to reduce overall diabetes distress for women with T2 diabetes who engage in disordered eating. Additionally, distress related to one's regiment also significantly reduced. These results are interesting as regiment refers to all aspects of diabetes management including eating, physical activity, and blood glucose monitoring. Thus change in eating and physical activity alone was sufficient to allow for average diabetes distress related to diabetes management to decrease significantly. Results related to diabetes distress are important as ADA reports that doctors and researchers are at the early stages of making sense of diabetes distress and its impact on health and diabetes outcomes (Gebel, 2013). Recent research found that an increase in personal sense of empowerment, as well as general improvement in self-management behaviors has been associated with reduced diabetes distress (Wang et al., 2016).

Unlike both diabetes self-efficacy and diabetes distress, overall DQOL did increase from pre- to post-intervention, yet the change was not significant. Similar to the concerns addressed with diabetes self-efficacy, this may speak to the program's lack of focus specifically on diabetes management and language, as only the eating and physical activity components of diabetes management were targeted in the current study. While QOL is an important issue and most individuals with T2 diabetes may indicate a desire for greater QOL, to change and improve one's QOL can be difficult and take a great deal of time. Additionally, diabetes complications significantly impact QOL, and many participants reported other health concerns (Hayes et al., 2016). For example, one participant is legally blind as a result of diabetes retinopathy while also receiving dialysis three times weekly for

kidney failure. Thus, while 12 weeks might seem long for participants to commit to an intervention, it yet may not be sufficient time to demonstrate significant change in DQOL.

However, it should be noted that there was a significant improvement in two of the DQOL subscales, specific to social interactions surrounding diabetes and the overall impact of diabetes on one's life. Such results demonstrate that the current intervention was effective in improving some aspects of DQOL and that participants may have been able to apply the cognitive behavioral and lifestyle changes to their social interactions with others, thus impacting how they feel physically and emotionally. Further, research indicates that there is still much to be learned about the complex and nuanced individual portrayal of quality of life, in particular for those with T2 diabetes who have a daily responsibility to manage a chronic condition that is often accompanied by other health complications (Rubin, 2000).

To summarize, aim one of the current study was met by demonstrating that the 12-week eating-focused CBTgsh intervention was an effective treatment for disordered eating and related aspects of diabetes management among a diverse sample of women with T2 diabetes. Specifically, results indicated that the intervention was successful in supporting the reduction of disordered eating behaviors, A1c, and diabetes distress. Equally as important, the lack of significance in change from pre- to post-intervention in overall DQOL, diabetes self-efficacy, and average blood glucose speak to the need for additional tailoring of the intervention and further research. While efficacy is incredibly important, participant buy-in and acceptance of the intervention is equally as important and was assessed to meet aim two of the current study.

Aim 2: Acceptability outcomes and implications

The second aim of the current study was to explore the acceptability of the intervention designed to support lifestyle changes for women with T2 diabetes and comorbid disordered eating. Acceptability was determined using one questionnaire that provided quantitative data, and a series of open-ended questions that provided. Results of the CSQ-8 indicated moderately high satisfaction with the current intervention. Questions on the CSQ-8 were general questions of satisfaction with the material and experience throughout the intervention, and did not speak to the specific goals or nature of the intervention. Thus, perhaps more telling are the results from the codes developed from the qualitative data.

The open-ended questions demonstrated significant support for and liking of the current intervention protocol, indicating that the CBTgsh lifestyle intervention was acceptable for a pilot sample of women with T2 diabetes who engaged in disordered eating at baseline and had been diagnosed for varying periods of time. Overall, participants provided rich feedback regarding their likes of the program than their dislikes. Of the seven themes that emerged, perhaps the most important was that overall participants would positively recommend the program: “I would recommend it because it’s such a positive experience.” This feedback demonstrates that the program was generally acceptable to the current sample and that they could see the intervention as translatable at least to other women similar to themselves.

With respect to endorsement of the program, participants described the information presented in the manual as clear, thought-provoking, and non-judgmental. These factors appear to have been key in their success and positive regard towards the program: “I would recommend it to others to get real current information about others like us. There is less

judgment in the material and it confirms for women that we are not alone in our pursuit of better health." Such results are consistent with the empirical literature stating that both intrinsic and extrinsic motivators and barriers should be considered in the development and assessment of an intervention. For example, intrinsic factors such as health beliefs, attitudes and self-efficacy either can be supportive of behavior change or serve as barriers to successful behavior change. Likewise, extrinsic factors such as access to care and familial support also can serve to support health behavior change in a diabetes intervention, or to create barriers to success (Rodriguez, 2013).

Similar to their positive recommendation of the program, one of the themes identified from the category of participants' likes was that clear and useful information helps with success. Despite the difficult nature of making lifestyle changes, particularly over a time limited 12-week period, participants described that they found the plan and structure of the program to help those changes feel easier. Other studies have similarly reported the value of structure as a key component to successful lifestyle change for patients with T2 diabetes (West, Coulon, Monroe, & Wilson, 2016; Whittemore, Chase, Mandle, & Roy, 2002).

When asked what else you would like the research team to know, the overall theme that emerged was that participants reported an overall increase in self-esteem and self-confidence. The responses to the question for feedback seemed full of pride, that participants wanted the research team to know that they had been positively impacted by their participation in the intervention. For example, one participant stated, "It helped me want to manage my diabetes instead of just letting it go." This statement speaks to the participants' increased confidence in their ability to manage T2 diabetes, but also that they made sense of the program as an effort to support their diabetes management, despite the fact that diabetes

management was not directly addressed in the current manual or by their assigned supporter. As previously mentioned, self-confidence and self-efficacy appear to be key intrinsic factors related to the success of lifestyle changes related to T2 diabetes interventions (Rodriguez, 2013).

The two other themes identified in response to participants' likes were that they found the program to offer connection and accountability in the form of the weekly calls and support sessions. This theme is important because the primarily phone-based intervention was developed specifically to reduce participant burden, yet the one in-person orientation session was added to an all phone protocol to serve as a foundation for rapport between the participant and their assigned supporter. Other studies specifically have sought to assess the efficacy of phone-based interventions for individuals with T2 diabetes or disordered eating with a common goal of reducing burden and increasing access for participants (Cachelin et al., 2014; Goode et al., 2015;). This emergent theme surrounding support and successful program completion is also consistent with other feasibility research employing a CBTgsh model (Cachelin et al., 2014).

In regards to future adaptations to the intervention, a theme suggesting the addition of group meetings or group support emerged. To date, there have been no published studies of CBTgsh protocol with group-based support for disordered eating. However, group-based interventions have been effective in improving T2 diabetes outcomes, for example in primary care settings (Hellgren, Jansson, Wedel, & Lindblad, 2016). Group-based interventions allow for patients to learn from one another and to gain support and normalization from their peers. Interventions that use a group format instead of individual support can also reduce the burden placed on those providing the intervention (Hellgren et al., 2016). An in-person group-based

intervention or component would be in contrast to the barrier-reduction efforts of a primarily phone-based intervention as previously described as a positive aspect of the current program. However, a phone or video chat group component would well meet the feedback noted in the theme, while still supportive of the efforts of the research team to reduce barriers and develop an accessible intervention.

It is important to note that there was insufficient feedback to elicit a theme for dislikes about the program. The lack of data may speak to participants' genuine like for the program, or their discomfort providing negative and/or critical feedback. The two responses that were provided alluded to some dislike for the daily food and physical activity monitoring that is the foundation of the program and included in step one. The responses were vague, but may speak to the challenging and time consuming nature of engaging in food and activity monitoring on a daily basis, another burden for individuals who already have a great deal of daily tasks required for diabetes management. The responses may also speak to the difficult nature of monitoring on the computer using the electronic spreadsheet that was provided to participants in addition to the monitoring outline in the manual, or monitoring on paper. Such feedback is also consistent with the section on changes to be made to the program. One of the themes from that question was that participants suggested that the research team develop an easier way of monitoring, such as the development of a cellphone app. Potential app development will be discussed later in this chapter.

In summation, participants of the current study found the intervention to be successful and an overall positive experience, even describing their experience as life changing. Seven themes emerged from participants' qualitative feedback, including liking the structure, support, and positive nature of the material and the support from the assigned research

assistant. Though participants reported that they would recommend the intervention to others, their feedback also pointed out the need for an easier method of self-monitoring and an additional social support or group component to the intervention. Participant feedback is an important consideration in the future directions for the current intervention protocol.

Attrition

In regards to attrition, participants were invested in the program despite busy lives and ongoing demands both for diabetes management and otherwise. The only attrition was related to lack of support from a participant's primary care physician (see direct quote in chapter 3) and speaks to the need for physical involvement and support to allow for feasibility of the current intervention in future research. Suggestions for collaboration with other medical professionals will be discussed later in this chapter.

Strengths and limitations

The current study was not without limitations. First, and perhaps most apparent is the small sample size associated with the nature of the pilot study. While the results and rich participants' feedback provide meaningful indication of the potential value of the current intervention, the application to other populations is potentially limited. While not a limitation, it is important to consider that the current sample was primarily recruited from a university, thus translation of results to community-based treatment-seeking populations, may be limited. Second, the purpose of the manual was not to address specific questions and concerns related to diabetes management and at times left participants to seek additional information on their own. Participants were unable to rely on the manual or their assigned supporter for diabetes management-specific questions, for example related to blood glucose monitoring and glycemic control. Future iterations of the manual and intervention may seek

to include additional diabetes-specific language to assure participants that the eating and lifestyle-focused material is consistent with ADA guidelines for a healthy diabetic lifestyle.

Strengths of the current study include a very low rate of attrition. Only one participant who engaged in the intervention did not complete, and her drop out was attributed to lack of support from her primary care physician, an issue that speaks to the need for greater provider buy-in for such interventions. Participants of the current study were also highly engaged and provided feedback to their assigned supporter throughout the intervention. Participant engagement spoke to the supportive and effective nature of the intervention, and feedback at follow-up further reinforced the positive engagement with the study. Finally, research assistants and supporters were highly trained and measures were sound and validated with this population.

In sum, the empirical literature focused on disordered eating among T2 diabetes populations remains largely underdeveloped and there is a lack of understanding of the complex issue that is disordered eating in a population that is impacted by eating behaviors and dietary choices. Thus, it is vital to continue to gain an understanding of the basic underlying issues while moving forward with intervention and treatment for a population especially vulnerable to diabetes-related complications. Despite some limitations and the general nature of pilot-study research, the current study contributes significantly to the extant literature and had a number of methodological strengths. Overall, there is need for further development of such evidence-based interventions in an effort to better populations with T2 diabetes who suffer from disordered eating behaviors.

Future Directions

The current eating-focused CBTgsh intervention has demonstrated both efficacy and acceptability for women with T2 diabetes to reduce disordered eating behaviors and improve diabetes management outcomes. Thus, future directions should include the incorporation of participant feedback and expand upon the results and success of this pilot study. Based on participant feedback and experiences, next steps should include: 1. Adaption of the manual to include additional diabetes-specific information and language consistent with ADA guidelines; 2. Involvement of a medical doctor and other medical professionals to support the further development and implementation of the intervention; 3. Follow up of the current pilot-study of the intervention with a larger and more diverse sample; 4. Development of a technology component to improve ease of self-monitoring; and 5. More careful and specific measurement of important factors within the intervention such as compliance with monitoring, understanding of the manual, physical activity completion, and fruit and vegetable consumption. Incorporation of the five stated areas for future development may allow for a more refined, accessible, and well-utilized intervention for individuals with T2 diabetes and comorbid disordered eating.

The first suggestion for future adaption of the manual is to include additional diabetes-specific information and language consistent with ADA guidelines (ADA, 2016). Though the current eating and physical activity recommendations are consistent with the general literature and CDC recommendations, and do not contradict ADA guidelines, the language does not specifically refer to “diabetes” or “diabetic-diet.” Adding such specific language may help to reduce confusion for participants, allow for the manual to more clearly address the needs and management goals of individuals with T2 diabetes, and meet the

established standards of medical care for diabetes that are regularly updated by the ADA. For example, the 2017 ADA standards provide guidelines for the assessment and consideration of diabetes distress, an issue that the manual addresses in other ways but that could be more specifically addressed using the terminology "diabetes distress" (ADA, 2016). By adapting the manual to be consistent with ADA guidelines, it may feel more relevant to participants and allow for greater support from medical professionals.

Thus, an additional future direction is to allow for the involvement of a medical doctor and/or other medical professionals such as a registered dietitian (RD) to endorse and provide feedback on the manual and dissemination of the intervention. As was noted in the results and discussion sections, the only incidence of attrition was related to the lack of support for the program from the participant's primary care physician (PCP). Research has indicated that while individuals who engage in disordered eating and/or meet criteria for an eating disorder tend to seek care from their PCP first, many physicians lack sufficient training in such a specialty are and may be unprepared to identify and/or treat the disordered eating (King, 1989; Whitehouse, Cooper, Vize, Hill, & Vogel, 1992). For those with comorbid T2 diabetes, identification and treatment may be even more challenging for PCPs. Provider buy-in may also allow for greater recruitment for future studies within medical settings such as primary care offices.

Future studies should seek to follow up the current pilot study with a larger and more diverse sample. As has been already noted, only one participant in the current sample was recruited from a primary care clinic. All other participants were recruited from a large southeastern university campus. While there was some diversity within the sample in regards to race and ethnicity, age, and length of time since diagnosis, additional sampling of a more

diverse population would be useful in an effort to support the translation of this intervention to the wide range of individuals who may benefit.

A diverse range of individuals and populations with T2 diabetes may suffer from disordered eating and may benefit from the current intervention. For example, research has indicated that ethnic minority populations are more likely to be diagnosed with both T2 diabetes and disordered eating (Alegría et al., 2007; CDC, 2014; Kessler et al., 2013;). Longer-term, this area of research and specific intervention would likely benefit from further cultural adaptation in order to best serve ethnic minority populations, as well as men who suffer from comorbid T2 diabetes and disordered eating, groups that are currently underrepresented in the empirical literature. As additional phases of research develop the current intervention, there may be great benefit from learning more about the specific aspects of the intervention itself and the role they play in impacting disordered eating and diabetes management.

Accordingly, the development of a new technological component of the program, such as a smartphone app, may serve to allow for additional data collection during the course of the intervention and future manual refinement. Development of a technological component to compliment the intervention would also meet participants' recommendation for an easier and more accessible method of self-monitoring. Over the past several years, researchers have begun to explore the use of app-based technology in the support or facilitation of behavior interventions. One study found a calorie-monitoring app to be useful in a diabetic sample seeking to improve diabetes management, while another app based study was effective in supporting weight loss in patients at risk for T2 diabetes (Goh et al., 2015; Fukuoka, Gay, Joiner, & Vittinghoff, 2015). While there is much additional research to be done, there is

reason to believe that a technological component such as an app, that could be utilized to easily monitor food, physical activity, and blood glucose, would be a useful addition to the current intervention for both the participants and the support team. Finally, the development of a phone app or inclusion of phone or computer-based group chat software, such as Google Hangout, could be employed to support participant's desire to engage in group support with peers. Facilitating such group support virtually would allow for reduction in barriers to treatment in a way that is consistent with the current intervention.

The final recommendation for the future of this area of research is to develop additional careful and specific measurement of the important factors that make up the intervention. For example, the current study only collected data pre- and post-treatment, while a great deal is happening for participants throughout their 12-week participation. Future research should thus develop a systematic way of monitoring and evaluating participant's use of and compliance with self-monitoring food and physical activity, participant's overall understanding of the manual that may reflect their ability to apply CBT from a self-help perspective, the rate at which participants are engaging in physical activity, and changes in fruit and vegetable consumption throughout the intervention. Monitoring these aspects of the intervention will allow for further adaption of the manual to highlight the aspects that are most effective and to improve the aspects of the manual and support that are less effective. The development of new technology, such as an app, may be employed to help obtain additional insight into participant engagement and the efficacy of the various aspects of the intervention. As the need for prevention of diabetes-related complications and improved diabetes management continues to grow, the five areas of future direction

discussed touch on a variety of ideas and room for such growth in an area of research that is at the early stages of development.

Conclusions

The current study investigated the preliminary efficacy and acceptability of an eating-focused CBTgsh intervention to reduce disordered eating behaviors and improve diabetes-management outcomes among a sample of women with T2 diabetes and comorbid disordered eating. Results indicated that the intervention was successful in reducing disordered eating behaviors, including binge eating and external eating, from pre- to post-intervention. In regards to diabetes management, both A1c and diabetes distress were also significantly reduced from pre- to post-intervention. Although the intervention did not directly address diabetes management behavior change, the results are reflective of the indirect yet important implications of the current intervention for diabetes management and related outcomes. Thus, the current intervention may serve as an accessible and low-cost option to improve disordered eating and diabetes management for women, lowering risk and preventing serious diabetes-related complications. Future studies should therefore add diabetes-specific language to the intervention manual and support, test the intervention with a larger and more diverse sample(s), and incorporate the support of medical doctors and other medical professionals who work with patients diagnosed with T2 diabetes. In addition, further research in understanding the complex nature of disordered eating among individuals with T2 diabetes who engage in disordered eating is needed in an effort to encourage both prevention of disordered eating and early intervention for disordered eating behaviors and diabetes-related complications.

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APPENDIX A: CBTgsh Lifestyle Intervention Session Outlines

Orientation:

- Research assistant (RA)/Supporter will provide an overview of the program.
- Discussion of participant's motivation for change.
- Discussion of potential advantages and disadvantages of the program.
- Tips for success
- Introduction to monitoring

Step 1: Starting Well

- Establishing self-monitoring of food and beverage consumption, and physical activity
    - Importance of self-monitoring
    - Benefits of daily physical activity
- Weekly weighing, explanation of importance
- Description of monitoring record and how to use it

Step 2: Establishing a regular pattern of eating and physical activity

- Planning regular meals and snacks daily, without skipping meals
    - Adjusting timing based on schedule and circumstances
- Planning for physical activity engagement
- How to get back on track when things go wrong
- Advice regarding self-induced vomiting, and the misuse of laxatives and diuretics
- Setting realistic goals for the program

Step 3: Healthy dietary guidelines, increasing physical activity, overcoming challenges

- Benefits of fruit and vegetable consumption, suggestions for increasing consumption
- Healthy dietary guidelines and suggestions
- Ideas and suggestions for increasing physical activity
- Re-evaluating goals and overcoming challenges

Step 4: Alternative to binge eating, challenging dichotomous thinking

- Create a list of alternative activities to binge eating
    - Carry the list for use in difficult times
    - Use the list as appropriate
    - Review effectiveness of the different activities, make improvements
- Challenge dichotomous thinking about eating and physical activity
    - Learn about unhelpful thoughts

APPENDIX A (CONTINUED)

Step 5: Dieting vs. healthy eating, challenging unrealistic expectations

- Learning healthy eating
    - Eating at regular intervals
    - Normal quantities of food
    - Avoiding restriction
    - Practicing eating enjoyable foods to reduce anxiety
- Tackling forms of avoidance
- Challenging unrealistic expectations for the program
    - Setting realistic goals

Step 6: Problem solving

- Problem solving during difficult times
    - Six-steps of efficient problem solving
    - Reviewing problem strategies after their use
- Importance of social support for maintaining behavior change

Step 7: Body image concerns and reviewing progress

- Addressing body image concerns through monitoring
    - Understanding cultural and social pressures for eating and body image
- Reviewing progress in the program
    - Determine if and how the program is helping
    - Discuss barriers to change
    - Discuss any changes in weight
    - Determine what else needs to be addressed during the program

Step 8: Progress, maintenance, and relapse prevention

- Acknowledging progress in reducing disordered eating, improving fruit and vegetable consumption, increasing physical activity
- Discussion of maintaining changes, “lifestyle” intervention
- Relapse prevention and how to manage setbacks
- Completion of the program and termination with the RA supporter

APPENDIX B: Diabetes History Questionnaire

Date of diabetes diagnosis:

Who else in your family has Type 2 diabetes? (List all)

Does anyone in your household have Type 2 diabetes? (List all)

What medication(s) do you take to manage diabetes? (List all)

Who helps with your diabetes? (select all that apply)

No one	*Healthcare provider*
Family	*Support group*
Friends	*Others*

Have you received any education about diabetes?

No *Yes- Please describe*

Do you exercise regularly?

No *Yes- Please describe type and amount*

Do you check your blood sugar?

No *Yes*

If you answered yes to the previous question:

What meter do you use?

How often do you test?

What times of day do you test?

What is your target blood sugar range?

When was your last Hemoglobin A1c (HbA1c)?

Date:

What was the result (number)?

Report number:

Please list your blood glucose (blood sugar) levels for the past 3 days.

Yesterday _____

2 days ago _____

3 days ago _____

Do you have any history of gestational diabetes?

No *Yes-describe*

APPENDIX C: Participant Feedback Questions

1. What did you like about the program?

2. What did you dislike about the program?

3. What changes would be important for future participants in the program?

4. You responded earlier about recommending the program to others. Why would you recommend or not recommend the program to others?

5. What else would you like the research team to know?