REGIMEN ADHERENCE AND SELF-MANAGEMENT IN PERSONS WITH IMPAIRED GLUCOSE TOLERANCE AND TYPE 2 DIABETES

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Abstract: With the rising trend of obesity within the United States, the prevalence of Type 2 Diabetes (T2D) is increasing as well. The best way to stop the growing numbers of T2D is to prevent it completely. However, for those who already have T2D or Impaired Glucose Tolerance (IGT) healthy management of the disease is crucial for lowering life threatening complications and lowering mortality. There is strong evidence supported by decades of research that a lifestyle intervention (increased physical activity and healthy eating habits) is the best way to prevent T2D and to manage the disease. This type of management structure leaves out the humanity of the disease and doesn't account for the psychosocial factors at play. Depression, social support, self-care, coping mechanisms, and education on nutrition are a few of the psychosocial factors that are heavily evaluated in this study. The purpose of the present study is to calculate the magnitude of effect of a lifestyle intervention with a social support group on selfmanagement and regimen adherence, HbA1c, body weight, and body fat percentage. This study included a 12-week lifestyle intervention with the intervention group partaking in a weekly support group. All participants were given weekly educational materials covering a biopsychosocial spectrum. In addition to the biomarkers mentioned, 6 survey instruments were used to measure self-management and regimen adherence from baseline to end of study. Following the 12-weeks, the mean increase in minutes walked weekly was 197.5 min. Analysis on the survey data showed the intervention group lowered their diabetes related distress, increased self-care habits, and decreased utilization of food as a coping mechanism. The control group data showed a higher level of diabetes related distress and a lower level of self-control from baseline to end of study. Both groups showed a decrease in self-efficacy and self-control from baseline to end of study. These findings are meaningful and add to the small amount of research already done on biopsychosocial lifestyle interventions for persons with T2D and IGT. Larger scale studies will need to be done in the future to increase the validity of statistical findings.

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CHAPTER I

INTRODUCTION

The obesity epidemic in the United States is leaving a trail of chronic and acute illness in its wake, including rapidly growing rates of Type 2 Diabetes (T2D) and Impaired Glucose Tolerance (IGT), also known as prediabetes. According to research from the National Health and Nutrition Examination Survey (NHANES), over two-thirds of the United States population is overweight with one-third of that population considered obese (Flegal, Carroll, Kit, & Ogden, 2012). The obesity rate in the United States closely mirrors the prevalence of IGT and diabetes (Centers for Disease Control and Prevention, 2017). This figure should not come as a surprise when the risk factors for developing T2D include obesity, hypertension, and physical inactivity (DeFronzo, et al., 2015). According to the 2017 Centers for Disease Control and Prevention (CDC) National Diabetes Statistics Report, over 30% of the population has IGT, and nearly 10% of the population has diabetes, while less than 1% of the population has Type 1 Diabetes. The large prevalence of T2D and IGT has a major impact on our nation's economy. The medical costs to cover the direct and indirect care of diabetes surpassed \$300 billion in 2017 (2017). This highlights the need for an increase in Biopsychosocial lifestyle interventions that focus on the whole patient to assist in mitigating the high economic impact and medical costs associated with this condition.

Along with rising rates of T2D is the rising death toll associated with this chronic illness. Diabetes is directly linked to three of the top ten causes of death in the United States.

The CDC named diabetes as the seventh most common cause of death in the United States (Centers for Disease Control and Prevention, 2017). Meanwhile, heart disease continues to remain the most common cause of death, and among its primary risk factors is diabetes (2017). The ninth most common cause of death is nephrotic syndrome, which is a serious complication of uncontrolled T2D (2017). Again, these data highlight the need for more updated, whole-patient based interventions in order to reduce to death toll caused by diabetes in the United States.

Studies show that the best method to combat the steadily climbing rates of T2D in the U.S. is prevention. However, in a culture known for convenience food and increasingly sedentary lifestyles, the rates continue to increase. As a result of skyrocketing numbers of T2D and IGT cases (and associated deaths), numerous treatment options have been established; to care for those who have been diagnosed. Three significant models of treatment include biomedical, psychosocial, and biopsychosocial (BPS) methods. Countless studies have been conducted to show the effectiveness of treating the biological symptoms of T2D and IGT. Implementing lifestyle changes like physical activity and an improved diet for T2D sufferers, have been shown to lower blood glucose and glycated hemoglobin (HbA1c) levels in IGT and T2D persons (Dempsey, et al., 2016; Diabetes Prevention Program Research Group, 2002; Donnelly, et al., 2009; Dunstan, et al., 2012; Laaksonen, et al., 2005; Pan, et al., 1996; Williamson, Vinicor, & Bowman, 2004; Sigal, Kenny, Wasserman, Castaneda-Sceppa, & White, 2006; DeFronzo, et al., 2015). While addressing the biological symptoms alone has demonstrated clinical effectiveness, this approach does not address the treatment of patients from a psychosocial aspect (i.e. mental and bodily health). Alternatively, studies that include a psychosocial aspect focus on the other determinants of health such as increasing quality of life, developing social support networks, decreasing stress levels, and learning healthy coping methods (Chyun, et al., 2006; Peyrot, McMurry Jr., & Kruger, 1999; DeFronzo, et al., 2015). However, these two models do not take into account their own limitations; mainly, they focus on one aspect of T2D treatment and not complete patient care. This is where the BPS model stands out. The BPS model seamlessly

incorporates biomedical and psychosocial aspects without sacrificing one aspect for another. By exploring the biomedical, psychosocial and biopsychosocial models of T2D and IGT treatment, readers will be able to see exactly how BPS methods provide a more complete and holistic treatment of the disease than biomedical or psychosocial models alone.

Specific Aims

Inadequate self-management and regimen adherence are primary reasons persons with IGT and T2D struggle in the maintenance of their diagnosis. The current literature primarily assess the effectiveness of diverse types of physical activity, such as walking versus resistance training or leisure-time physical activity versus moderate-vigorous exercise, on glucose levels. There is also significant literature addressing the non-biomedical side of IGT and T2D treatment and prevention. Despite a multitude of evidence for success in both treatment options, the blending of the two is still incredibly rare. Therefore, the overall goal of the study is to examine the positive effect of social support in conjunction with lifestyle intervention in terms of increasing regimen adherence and self-management, lowering biomarkers (HbA1c and fasting glucose levels), and moderately decreasing bodyweight and body fat. The outcomes of this study could possibly provide a positive correlation between lowering biomarkers and participation in a biopsychosocial intervention for the management of T2D and IGT. We hypothesized that 1) the participants attending the weekly support groups would have increased self-management and regimen adherence skills built, 2) significantly lower HbA1c and fasting blood glucose levels, and 3) would have lost more weight and body fat compared to the group who does not participate in the weekly support group meetings by the end of the study.

Specific Aim #1: To quantify the magnitude of benefit, if any, of a social support group to regimen adherence and self-management of a lifestyle intervention.

The biggest challenge in the prevention and management of T2D is a person's ability to maintain consistency in their routine (regimen adherence) and to self-manage their diabetes care.

Participants learned skills such as healthy coping, maintaining motivation, stress management, mindful eating, and overcoming stigma in order to make them more self-sufficient and consistent in the daily management of IGT and T2D.

Specific Aim #2: To quantify the magnitude of benefit, if any, of a social support group to HbA1c levels of a lifestyle intervention.

Lifestyle interventions have been proven successful at lowering biomarkers in persons with IGT and T2D. In order to examine the effect a social support group has in decreasing these biomarkers further, one group did not participate in the weekly support group. This way, we could assess the effectiveness of the support group in conjunction with a lifestyle intervention against a lifestyle intervention group who only received the support group material via Canvas. **Specific Aim #3: To quantify the magnitude of benefit, if any, of a social support group to body weight and body fat of a lifestyle intervention.**

Many people with IGT or T2D have the misconception that weight loss needs to be 20% or more of their starting weight. Yet, research has shown that a moderate weight loss goal of 5-7% of initial body weight, along with 150 minutes of physical activity a week, and a low-fat diet can be effective in lowering fasting blood glucose and HbA1c levels. With the addition of a support group, we expected weight and body fat loss to be higher in the group which attends a weekly support group session.

CHAPTER II

REVIEW OF LITERATURE

BIOMEDICAL MODEL Overview

The biomedical model typically views T2D as the physical manifestation of poor lifestyle choices. As a result, sedentary lifestyle, poor diet, weight gain, insulin resistance, and genetics are the major biological factors addressed in the treatment and management of T2D and IGT. Treatment methods under this model include lifestyle intervention, antidiabetic medication, and managing the physical side effects of this disease. Once a person has been diagnosed with T2D or has IGT, there are some serious medical concerns and physical diabetic symptoms that must be managed. Some of the most serious physical symptoms of T2D include diabetic retinopathy, nephrotic syndrome, and diabetic ulcers leading to amputation (DeFronzo, et al., 2015). As a result, managing the physiological symptoms of T2D and IGT is vital.

Why It Works

Lifestyle Intervention

The goal of lifestyle interventions is to increase physical activity (PA) and decrease caloric intake, resulting in moderate weight loss of about 5-7% of beginning weight (Williamson, Vinicor, & Bowman, 2004).

Many lifestyle interventions assess the effectiveness of diverse types of PA on glucose levels, such as walking versus resistance training or leisure-time physical activity (LTPA) versus moderate-vigorous exercise (Dempsey, et al., 2016; Dunstan, et al., 2012; Laaksonen, et al., 2005; Sigal, Kenny, Wasserman, Castaneda-Scheppa, & White, 2006).

Lifestyle interventions are common in T2D prevention studies. In these types of studies, the control group is given generic information concerning exercise and diet, while the intervention group is given specific dietary recommendations (decrease fat intake; increase fiber intake) and physical activity recommendations (Diabetes Prevention Program Research Group, 2002; Laaksonen, et al., 2005; Pan, et al., 1996). Studies by the Diabetes Prevention Program Research Group, Laaksonen, et al. and Pan, et al., focused on preventing T2D in persons with IGT using these methods. Participants in lifestyle intervention group (Diabetes Prevention Program Research Group, 2002; Laaksonen, et al., 2005; Pan, et al., 2005; Pan, et al., 1996). These results prove that modest weight loss, careful dietary intake, and moderate physical activity can significantly reduce the incidence of T2D in persons with IGT. In addition, the results further showcase the necessity for tailored interventions in creating actual lifestyle changes.

Furthermore, in two trials conducted by Dempsey, et al., and Dunstan, et al., the researchers specifically tested the effectiveness of physical activity and its effect on lowering postprandial glucose levels. These studies are especially applicable for patients who are unable or unwilling to incorporate PA outside their working hours (2016; 2012). They found that periods of light-moderate walking or simple resistance activities for 2-3 minutes, every 20-30 minutes, effectively lowers blood glucose in IGT and T2D persons (2016; 2012). They also found that the intensity of walking as compared to simple resistance exercises had no significant difference on glucose levels; in fact, both types of PA were equally effective (2016; 2012). Neither study tracked participants beyond a three-month period, so application of their findings is limited. However, both studies are important pilot programs promoting the benefits of breaking up

sedentary behavior with short bouts of PA. Moreover, this form of lifestyle intervention is less invasive on schedules and routines for someone with a sedentary, office-type job.

However, there are patients who are more willing to incorporate PA in their daily lifestyle. An important aspect when looking at lifestyle interventions for IGT and T2D patients is the type, intensity, duration, and frequency of the physical activity they perform. The current recommendation for PA in adults is 150 minutes a week or 30 minutes a day (Laaksonen, et al., 2005). The American College of Sports Medicine (ACSM) suggests that 150 minutes a week of PA is needed to maintain weight and prevent weight gain, but upwards of ≥250 minutes of moderate-vigorous PA a week is needed for significant weight loss (Donnelly, et al., 2009). This is even more important when considering persons with IGT and T2D. Outside of the exercise duration, the type of PA can greatly impact their ability to lower HbA1c and glucose levels. For example, walking for 2.5 hours a week resulted in a 63-69% decrease in the incidence of T2D compared to those who walked less than one hour a week (Laaksonen, et al., 2005). In comparison, those who engaged in moderate-vigorous LTPA only had a 44% decrease in T2D incidence (2005). Clearly, walking as a form of physical activity for at least 2.5 hours a week is significantly more effective at preventing T2D as compared to non-walking LTPA.

Antidiabetic Medication

Lifestyle intervention is the most encouraged approach to reverse IGT and to safely manage or reverse T2D, but oral antidiabetic medication is complementary in many management plans. The types of medication include insulin, insulin/glucagon secretion promoters, hepatic glucose production inhibitors (metformin), and carbohydrate absorption suppressors (DeFronzo, et al., 2015). These oral medications each cause side effects, with some effects being significantly more severe than others. For instance, hypoglycemia is a side effect of nearly all antidiabetic medications and is associated with myocardial infarctions, weight gain, strokes, and irregular heartbeat (2015). The effectiveness of antidiabetic medications have been studied compared to lifestyle interventions in lowering glucose and HbA1c levels. The landmark study done by the Diabetes Prevention Program Research Group evaluated the effectiveness of metformin plus standard lifestyle recommendations, intensive lifestyle intervention, and standard lifestyle recommendations with placebo. (Diabetes Prevention Program Research Group, 2002). The intensive lifestyle intervention was 28% more successful at preventing the onset of T2D compared to the metformin group and 58% more successful than the placebo group (2002). This research shows that antidiabetic medications are effective in reducing the incidence of T2D when taken properly and in conjunction with a lifestyle intervention. This research points to the fact that a more tailored lifestyle intervention is most effective at preventing T2D, and metformin alone is not enough to make significant differences.

Responsibilities of Patients and Providers

When applying the biomedical model, there are specific commitments that must be made by both the patient and provider. The biomedical model puts a substantial responsibility on the patient, seemingly without patient input. Responsibilities of the patient include consistently taking their antidiabetic medication on time, monitoring their glucose levels, and actively participating in daily lifestyle changes. A patient's ability to make the correct lifestyle changes vary greatly from person to person. For example, finding time to participate in daily physical activity or even the ease of finding nutritious foods can dictate the success of a biomedical-style treatment. The provider must understand their patients' time constraints and physical limitations, along with the availability (or lack thereof) of nutritious food where the patient lives.

Yet, from the provider's standpoint, the biomedical model is simplistic. Post-diagnosis of T2D, the provider determines such factors as medications, physical activity recommendations and nutrition suggestions (DeFronzo, et al., 2015). In the case of diabetic retinopathy, ulcers, and nephrotic syndrome, the provider will refer the patient to the appropriate specialist to ensure the

best possible care is given for each physical symptom. The recommendations from provider to patient are generally one-sided and not presented for negotiation. Unfortunately, the biomedical treatment model tends to be a blanket prescription in which the patient has no say in (Engel, 1980).

Limitations

Regrettably, the biomedical model focuses solely on the biological processes and the serious and sometimes life-threatening symptoms. In this model, there is no exploration as to why a patient struggles with weight or poor eating habits. Symptoms are treated, but the root cause of these symptoms are left unexplored. Mental health, environmental, psychological, and social factors do not play a role in the treatment. Moreover, the patient holds generally no power in their own management and treatment options. A T2D or IGT diagnosis can be life changing and will force the patient to make many lifestyle adjustments that are not accounted for in the biomedical model. Fortunately, the psychosocial model incorporates mental health, psychological, social, and environmental factors in the care of patients with T2D and IGT.

PSYCHOSOCIAL MODEL Overview

The success of provider-recommended lifestyle interventions are contingent upon a patient's ability to change behavior. Setting realistic goals, creating a supportive social network, and developing coping strategies are three major factors in the psychosocial model. An additional factor in the psychosocial approach is the patient's perceived quality of life (QOL) including psychological factors and biological complications of diabetes.

Why It Works

Goal Setting

Goal setting is incredibly important for anyone with a chronic illness. However, effective goal setting involves setting realistic goals for improvement, unfortunately many T2D patients don't understand what a realistic goal might look like, especially when it comes to weight loss. Trendy diets and fad workouts might leave an overweight diabetic feeling lost and frustrated, especially if they have had failed weight loss attempts in the past. Moreover, many people with T2D have the misconception that weight loss needs to be 20% or more of their starting weight (Donnelly, et al., 2009). Yet, research has shown that a moderate weight loss goal of 5-7% of initial body weight, along with 150 minutes of physical activity a week and a low-fat diet, is sufficient to lower blood glucose and HbA1c levels (Diabetes Prevention Program Research Group, 2002; Laaksonen, et al., 2005; Pan, et al., 1996; Sigal, Kenny, Wasserman, Castanedda-Sceppa, & White, 2006; Williamson, Vinicor, & Bowarn, 2004).

Goal setting is largely influenced by locus of control; as a result, how a patient perceives control can be a major factor in the outcome of how they follow and manage their treatment goals (Brown & Wimpenny, P., 2011). In addition, self-efficacy plays a major role in a patient's ability to maintain goal setting. As a patient builds self-efficacy with the successful achievement of smaller, short-term goals, they can begin working towards larger, more long-term goals with increased efficacy. Internal locus of control puts the patient in charge of change and the outcome of their diagnosis. These patients tend to have high problem-solving abilities and are more equipped to use problem-oriented coping strategies (2011). Patients with an external locus of control feel less responsible for the outcomes of the diagnosis. When a patient can set realistic goals, they have taken ownership of and they feel more in control of their diagnosis, which is a benefit of the psychosocial model.

Social Support Network

Support can be categorized into four groups: instrumental, appraisal, informational, and emotional (Brown & Wimpenny, P., 2011). Instrumental support can be a key factor in lifestyle changes. For example, parents may feel they cannot get the physical activity they need without a babysitter. Changing behavioral patterns in someone who would otherwise be unable to leave their home or participate in PA can be as easy as hiring a babysitter or having family who can offer a ride to the gym. Likewise, appraisal support is just as important as instrumental support for those with T2D or IGT. Changing the food selection at home can be extraordinarily difficult, especially when living with others. In those cases, their food selection must also change in order to assist in T2D management. Therefore, supportive at-home family or friend groups choosing healthier food options provides positive reinforcement and helps prevent relapse into negative food choices (2011). Next, emotional support helps those with T2D and IGT feel accepted by those around them, especially if they are comfortable talking about their feelings, struggles, and insecurities. Emotional support is crucial in those struggling to lose weight or internalizing societal body-image (2011). Lastly, informational support primarily comes from external sources such as advertising campaigns in magazines, television, or radio (2011). Informal support sources must come from quality foundations for them to constitute as additive support. Higher levels of these types of support are equated to lower levels of anxiety and depression (Chyun, et al., 2006). Perceived increased support for diabetics is also linked to higher QOL (2006). Additionally, social support can encourage and promote behavioral change that will directly affect regimen adherence and self-management practices (Peyrot, McMurry Jr., & Kruger, 1999).

Social support, or perception of increased social support, has been linked to increases in glycemic control (Strom & Egede, 2012). Many studies have also shown that family and non-

physician support increases positive diabetes management behaviors such as meal prepping, glucose monitoring, exercise, and preventative care such as checking feet and making regular optometry appointments (Strom & Egede, 2012; Gao, et al., 2013; Shao, Shin, Wan, Yu, & Liang, 2017). Many diabetics with severe complications who visit their physician or healthcare provider on a more regular basis, consider their physician as their primary source of support in terms of their diabetes (Gao, et al., 2013). Diabetics without severe complications tend to feel they receive zero, or minimal support from their healthcare providers. There is a transition however, to a more digital approach (Telehealth) to support the diabetic community. Many of these virtual based support groups are still novel, and in the time of a global pandemic, could become a single source of diabetic support.

Coping Strategies

A patient's ability to effectively cope plays a large role in their ability to manage stress and regimen adherence. The American Association of Diabetes Educators (AADE) has placed a high priority on helping patients develop healthy coping mechanisms as part of their selfmanagement plans and diabetes education (Fisher, Thorpe, DeVellis, & DeVellis, 2007). The AADE suggests that emotion-focused and problem-oriented coping both have appropriate applications when dealing with T2D or IGT diagnosis (2007). Emotion-focused coping is a technique used to reduce negative emotions to external or internal stressors. This technique is incredibly beneficial for stress reduction and can be as simple as meditating or being mindful. For instance, a pilot study examined mindfulness-based stress reduction (MBSR) and its effect on glycemic control, and they found a positive correlation between the MBSR and glycemic control (Rosenzweig, et al., 2007). Furthermore, the study resulted in a reduction of both HbA1c levels and mean arterial pressure (2007). Additionally, psychological grief, depression, and anxiety in the participants was reduced by 35%, 43%, and 37%, respectively (2007). Although the study was small, this type of emotion-focused coping research has positive implications for MBSR techniques and glycemic control for those with T2D and IGT. Similarly, problem-oriented coping can directly affect regimen adherence through self-managed behavioral changes (Fisher, Thorpe, DeVellis, & DeVellis, 2007). This approach focuses primary on changing the situation at hand, rather than managing emotions. Taking personal charge of diabetes management and changing behaviors can successfully treat T2D and IGT; it will also facilitate effective changes in glucose levels and overall health (2007). Those who engage in both emotion-focused and problem-oriented coping can calmly and effectively handle their diagnosis and self-manage with success (Peyrot, McMurry Jr., & Kruger, 1999). These two coping strategies can also assist in combating stigma.

Coping with weight stigma is particularly important for those who are clinically obese or overweight. T2D and IGT patients face negative stereotypes such as being lazy, stupid, lacking self-control, or having no motivation, which can negatively affect emotional well-being. Stigma can come from a variety of sources such as family, friends, co-workers, doctors, and strangers. Doctors have been reported as the highest source of stigma, along with family members (Puhl & Brownell, 2006). The amount of stigma internalized is directly linked to the coping response the patients use (2006). Furthermore, the more weight stigma they face, the more coping mechanisms patients need to use in order to manage the situation. For example, the most frequently used coping strategies are responding with a negative comment back, positive self-talk, coping with faith, eating, and seeking social support (2006).

Unfortunately, stigma can also lead to an internalization of negative stereotypes and to self-blame, especially in women. Their self-blame can stem from the western view of beauty and the "ideal" body type of being thin and toned (Brown & Wimpenny, P., 2011). This type of self-blame can cause individuals to isolate themselves if negative feelings are not addressed early on. Self-isolation will also prevent a patients' support network from working effectively and can impact their relationships with partners at home (2011). For example, a mixture of self-blame and spousal embarrassment of their partner's weight can cause intimacy difficulties (Brown &

Wimpenny, P., 2011; Puhl & Brownell, 2006). Having coping mechanisms in place can help patients deal with stigma, self-blame and self-isolation.

Responsibilities of Patients and Providers

The psychosocial model adds more responsibility to the provider than the biomedical model, but it still expects the patient to self-manage their treatment plan. However, patients in the psychosocial model can negotiate a treatment plan that works best for them and form a more positive patient-provider relationship than in the biomedical model (Glasgow, Peeples, & Skovlund, 2008). Providers have to assess the mental wellbeing of the patient and prescribe the appropriate care plan. This could include a referral to a clinical psychologist, psychiatrist, and suggestions of support groups that can increase the patient's social support network. And, with the psychosocial model, providers should ask additional questions to better assess the patient's available social network, knowledge of coping strategies, and help them set goals for the management of their T2D or IGT. Furthermore, the provider must be a reliable source for information if the patient needs additional education about their diagnosis (Brown & Wimpenny, P., 2011).

During these patient-provider discussions, the patient must be empowered to ask questions and have the opportunity to explore treatment options with their provider (Glasgow, Peeples, & Skovlund, 2008). Furthermore, honesty by patients regarding to symptoms, regimen adherence, and behavioral patterns is key in helping the provider prescribe the best treatment option for each patient. Although the patient is still expected to adhere to the agreed-upon treatment plan, there can be and should be alterations to the treatment as time goes on based upon patient preference, available resources regarding the psychosocial model, and newly available treatments.

Limitations

A solely psychosocial approach to IGT and T2D ignores the biological problems directly associated with the disease. For example, roughly 10% of patients diagnosed with T2D have a genetic mutation that is unavoidable and will result in them developing the condition (DeFronzo, et al., 2015). Patients with the underlying genetic factor need antidiabetic medication to biologically regulate insulin and glucose levels as this genetic factor cannot be managed through psychosocial methods of goal setting, support networks, or coping mechanisms alone (2015). Furthermore, psychosocial approaches do not emphasize physical activity and nutritional benefits of a biomedical model lifestyle intervention.

BIOPSYCHOSOCIAL MODEL Overview

Engel (1977) recognized the relationship between biological processes and the link with behavioral and psychosocial data (Engel, 1977). His critique of the biomedical model was the failure of health care providers to see the patient as a human being and not a laboratory animal (Engel, 1980). Engel states that, "Nothing exists in isolation." (1980, p. 537). He believed that a symbiotic relationship exists between the biomedical and psychosocial process that affect disease from a behavioral and human experience standpoint. In fact, he believed our biological and psychological systems influence each other in a large, dynamic system (1980). Engel proposed to broaden the approach to disease treatment and develop a system that allows the biomedical and psychosocial models to work in harmony. As a result, the Biopsychosocial (BPS) approach looks at the patient's complete environment in order to treat not only the symptoms, but also treat the causes. Furthermore, Engel suggests that the BPS model does not add a significant amount of work for the provider. Engel envisioned that the BPS model would work as a framework for physicians and health care providers, while empowering both the physical illnesses or symptoms they may have. And, with the support of the American Diabetes Association (ADA) and CDC,

the BPS model is making its way into IGT and T2D treatment (Kalra, Singh Balhara, & Das, 2013).

Why it Works

Biological Responses to Psychosocial Factors

Biological responses can occur when psychosocial factors are changed or effected (Peyrot, McMurry Jr., & Kruger, 1999). Meaning, as psychosocial factors (QOL, perceived social support, successful goal setting, healthy coping etc..) improve and regimen adherence increases, positive biological responses begin to occur. Peyrot, McMurry Jr. and Kruger (1999) suggest that the behavioral and psychophysiologic models are the two pathways in which psychosocial changes effect glycemic control (1999). Therefore, if glycemic control is influenced via psychosocial factors, then the behavioral or psychophyiologic pathways must also be impacted. Consequently, the behavioral model looks at regimen adherence to include avoiding foods that increase glucose levels, maintaining the recommended PA levels, and taking medication at the proper time of day and in the proper dosage (1999). The psychophysiologic model looks at neurohormonal processes, suggesting that glycemic control is influenced by psychosocial stress. Although there is some debate as to whether stress and glycemic control are linked, there is enough evidence to support the claim that they are directly connected (1999). Stress responses in those with T2D is crucial because stress plays a key role in insulin production (1999). Stress can also negatively affect and possibly compromise behavioral routines and regimen adherence (1999). Likewise, coping strategies and social support directly affect stress levels, both positively and negatively.

The interconnectivity of the biological responses and psychosocial factors can be relatively complex and, in some cases, unexplainable. Blood glucose changes from moment to moment, and it can be difficult to confirm the specific method that controls it if multiple factors are involved. Chronic and transient control measures can also be taken into account when looking at the relationship between psychosocial and biological pathways in BPS methods (Peyrot, McMurry Jr., & Kruger, 1999). Chronic measures are seen as long-term and likely unchangeable (1999). These would include variables such as education level, socioeconomic status (SES), marital status, age, coping style, and the duration of diagnosis (1999). Transient measures are more short-term variables that are likely to change over time. These variables would include emotions, blood glucose, HbA1c levels, self-control, and stress. Therefore, chronic variables can suggest how transient variables will influence glycemic control (1999). For instance, education level, SES, and marital status can be indicators of support and available resources to manage T2D. When chronic measures indicate the patient is currently married and has a higher SES, the likelihood that transient measures will be controlled increase significantly (1999). All these factors indicate a great need for more complete, holistic care of patients with T2D and IGT.

Complete Medical Care

The BPS model can provide more complete and effective medical care for T2D than biomedical or psychosocial methods alone. This perspective has been voiced by many national and international diabetes associations. For example, The Diabetes Attitudes, Wishes, and Needs Program (DAWN) found that people with diabetes across 13 different countries suffer from major psychosocial issues. Unfortunately, these psychosocial issues are not adequately being addressed in their care plans (Glasgow, Peeples, & Skovlund, 2008). It is apparent that existing healthcare systems, across the globe do not adequately address psychosocial needs on the same level as the biological issues brought on by IGT and T2D. Additionally, the International Diabetes Federation (IDF) states there should be standards of care for the psychological aspects of diabetes in order to assess cognitive functioning and psychological status through the duration of the patient's care (International Diabetes Federation Guideline Development Group, 2014). Furthermore, their full position supports early screening and diagnosis alongside the care of

severe physical symptoms. In order to encourage this "whole person" style of care, the AADE funded a project that emphasized web-based data collection that patients can use at home (Glasgow, Peeples, & Skovlund, 2008). This system not only collects data, but also serves as an educational and web-based community system for diabetics. This type of initiative opens up pathways for more efficient and direct communication from the medical community to their patients and confirms the importance of each patient's mind *and* body. Fortunately, the AADE project is not the only one of its kind.

The Robert Wood Johnson Foundation (RWJF) created *The Diabetes Initiative* that ran in 14 cities across the United States until 2009 (Diabetes Initiave National Program Office, 2009). The initiative served a wide range of populations, including primary care organizations, cliniccommunity partnerships, rural, urban, Native American communities, and communities suffering from considerable health disparities. Although the program has since ended, many of the communities involved in this initiative still carry out the programs created and designed during the period of funding (2009). This initiative taught these communities how to pay attention to stressors, depression, healthy coping mechanisms, the significance of self-management, and the important of community health workers (2009)

The Diabetes Initiative website is still active today, and it provides much of the same resources for health care providers, medical institutions, and patients. After the program ended in 2009, the website added a "lessons learned" section, and each of the 14 original participating organizations uploaded their full program models onto *The Diabetes Initiative* webpage along with their own lessons learned. These full program models include everything from community specific goals, patient education, tips for success, and forms used during the initiative. This information is still accessible and available for use by health organizations. The webpage even has a section for communities wanting to build their own programs and has resources available to begin a diabetes initiative within a health care organization. *The Diabetes Initiative* program showed that a community-based, BPS approach has a high rate of success. Of the 14

organizations that participated in this initiative, 63% found the assessment tools useful in creating new services and program components (2009). Additionally, over 50% of all participating organizations found the following strategies taught by the initiative to be successful: enhancing clinical care, collaborative goal setting, teaching skills for self-management of blood glucose, health eating, problem solving, healthy coping, and physical activity, enhancing linkage among program components, addressing depression, individual assessments, organizational capacity for program delivery, and communications planning (2009).

Although the ADA does not have its own initiative, it has a joint position with the European Association for the Study of Diabetes (EASD). They advocate for a 'patient-centered approach' to diabetes (Kalra, Singh Balhara, & Das, 2013). Additionally, they believe there needs to be a BPS approach to T2D in order to control and manage the disease (2013). Their position also includes a cost breakdown of treatment plans, education for patients, and a list of health care providers. This empowers patients to take control of their treatment plans and places a focus on mental health in those with T2D.

Responsibilities of Patients and Providers

Both providers and patients have equal responsibility in the BPS model. The most important responsibility of the provider is to ensure the treatment plan fits the patient in all aspects of their life. Understanding the patient's biological, psychological, and social limitations and strengths will assist the provider in creating the most complete care and treatment plan. Therefore, if a patient is able to control their glucose and insulin with lifestyle changes and psychotherapy, then antidiabetic medication could be reduced or eventually be taken off the treatment plan.

Patients are also expected to express their opinions and concerns in the BPS model (Kalra, Singh Balhara, & Das, 2013). Voicing their opinions about treatment options and what is most realistic in their situation then allows their provider to prescribe the most effective treatment plan. This allows for a more open patient-provider relationship, which can enhance the support felt by patients (Brown & Wimpenny, P., Developing a holistic approach to obesity managment, 2011). Furthermore, patient honesty about regimen adherence and behavioral struggles can also aid the provider in adjusting treatment plans as necessary.

Limitations

The limitations of the BPS model come in the form of time, money, and education. Longer consultation times are required in order for health care professional to address all aspects of a patient's physical and mental wellbeing; this means fewer patients are seen in a day. If fewer patients are seen, it may result in fewer billable appointments. Moreover, medical centers need to be equipped and prepared to deal with all aspects of T2D care and management. Ideally, this would include in-house registered dieticians, certified exercise physiologists, Certified Diabetes Educators, clinical psychologists/psychiatrists, lifestyle coaches, and childcare centers. However, most health care organizations would not be able to support such a large staff, especially those in smaller towns or areas with lower SES. This creates a disparity in available care to many regions across the United States when many patients cannot afford to travel long distances for care.

Importantly, a more holistic approach to formal education needs to be a priority for all health care professionals. This is due to the fact that many health care providers do not receive formal training in psychosocial care of patients as it is not a requirement for medical school or most general practice health care professionals (Brown & Wimpenny, P., 2011). However, one major positive to medical school education is the Doctor of Osteopathic Medicine (DO) as compared to Doctor of Medicine (MD). Physicians trained in DO are given training and formal education on holistic care and are highly encouraged to think outside the biomedical model traditionally used by MDs in the United States. The American Osteopathic Association reports a steady rise in DOs and osteopathic medical students, which is up from 30,000 new DOs in 1990 to over 100,000 new DOs in 2017 (American Osteopathic Association, 2017). This means that

more patients are being seen by DOs and are being treated by a physician who has been classically trained in BPS practices.

Conclusion

The literature shows that biomedical and psychosocial methods, when used alone, may be less effective treatments of T2D and IGT patients. However, because BPS combines both the physical and psychosocial aspects of patient care, the patient health benefits. Therefore, it is evident that BPS methods provide a more comprehensive system of care and offer a well-rounded approach to the treatment of T2D and IGT. The BPS model humanizes the treatment and management of IGT and T2D by empowering the patient and provider, leading to better patient-provider relationships and mutualistic health care (Glasgow, Peeples, & Skovlund, 2008; Brown & Wimpenny, 2011).

The biomedical and psychosocial models both focus on key parts of T2D and IGT treatment. However, both models are linear and do not undertake aspects of methods outside their own. Significantly, the BPS model does not take away from the importance of biomedical issues associated with T2D, but rather complements the extreme difficulties T2D and IGT patients experience with psychosocial aspects of their care (Engel, 1980). Therefore, incorporating BPS treatment methods are critically important.

Large nationally recognized diabetes organizations have called for health care reform in terms of treatment and management of T2D and IGT, with prevention being at the forefront of the fight. With a steady increase of physicians trained in BPS best-practices and more diabetes prevention initiatives being funded and supported in the United States, the future is bright for the BPS model and for T2D and IGT patients. Research indicates that over the next 50 years, T2D will increase by 165% in the United States alone (Williamson, Vinicor, & Bowman, 2004). However, as emerging holistic healthcare plans like BPS continue to gain wider acceptance in T2D and IGT treatment, there remains hope for better treatment options for all.

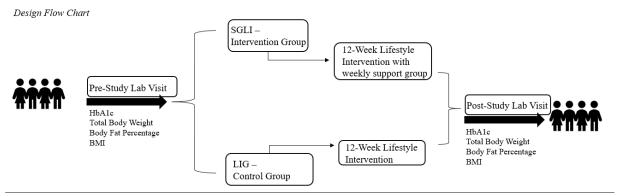
CHAPTER III

METHODOLOGY

Study Design

This was a repeated measures design with two groups, one control and one intervention group. Upon completion of the Qualtrics web screener for eligibility, each participant was randomly placed in either group 1 or 2. Group 1 was the intervention group where participants completed the 12-week lifestyle intervention with the added weekly support group. Group 2 was the control group where the participants completed a 12-week lifestyle intervention without the weekly support group. Participant data was collected at two time points, pre-study testing (before the start of the intervention) and post-study testing (after the completion of the 12-week intervention). At each testing visit, blood was drawn via finger-prick with lancet for measurement of HbA1c along with height, body weight and body fat percentage. Following the initial laboratory visit, each participant went through a 12-week lifestyle intervention. Each week discussed a different educational topic related to diabetes from healthy coping strategies to nutrition. Weekly topics detailed in Appendix I.

Figure 1



Note. Design flow chart. The schema demonstrates the protocol.

Participants

Four volunteers aged 21-65 years old participated in the study who have been diagnosed as having IGT (pre-diabetes) or T2D. IGT status will be determined by an HbA1c of 5.6 to 7.0 mmol/L. T2D status will be determined by an HbA1c of greater than 7.0 mmol/L. All participants were required to be either staff or faculty of Oklahoma State University (OSU). Exclusion criteria included: 1) diagnosis of Type 1 Diabetes, 2) currently pregnant or breastfeeding or plans to become pregnant in the next 12 months, 3) history of bariatric surgery or plans to receive surgery in the next 12 months, 4) history or current eating disorder, 5) currently on medication that would significantly impact weight gain or loss, 6) history or current substance abuse, 7) history or current psychotic, bipolar, or extreme depressive disorder, and 8) current major medical condition (e.g. cancer, thyroid disorder, on dialysis, or epilepsy). Additionally, participants were excluded if they were currently enrolled in or intended to be enrolled in a weight loss program during with the intervention timeline.

Recruitment

Mass e-mails were sent to 500 employees (staff and faculty) of OSU advertising the intervention and method of contact for willing participants. Flyers were distributed around the Stillwater Campus of Oklahoma State University in high traffic and departmental areas, including

the recreation center. Lastly, the Department of Wellness advertised the flyer on their official Facebook account to assist with recruitment numbers. Interested candidates were screened online via the Qualtrics system. Once a participant had passed the online screening, they obtained written physician's permission to participate in the intervention.

Baseline Visit

Interested persons who satisfied the inclusion criteria and produced their physician's permission were scheduled for a baseline visit. This visit began with attaining informed consent and the completion of the COVID-19 questionnaire to ensure all participants understood the nature, risk, and benefits of the study. During the baseline visit, candidates were interviewed using motivational strategies to assess their interest and readiness to participate in the trial. Additionally, each participant was given weekly goal sheets, activity and food logs, and a weekly reflection journal.

Assessment of Survey Instruments

All survey data were collected via Qualtrics at two time points throughout the study. The pre-survey results were collected within 1-week of beginning the intervention and the post-survey results were collected within the last week or up to 1-week following the intervention. Participants completed the following questionnaires in order to assess their baseline and post-treatment self-management and regimen adherence abilities: International Physical Activity Questionnaire (IPAQ), Diabetes Self-Management Questionnaire (DSMQ), Problem Areas in Diabetes (PAID), Emotional Eating Scale (EES), Brief Self-Control Scale (BSCS), and the General Self-Efficacy Scale (GSE). Adverse Childhood Experiences (ACEs) score was also determined.

The IPAQ (Appendix B), measures time and days spent walking and moderate and vigorous physical activity level. This questionnaire was used to determine if the lifestyle intervention increased physical activity and decreased sedentary behavior. Participants noted

time in minutes for physical activity and number of days within a week that type of activity was performed.

The DSMQ (Appendix C) is an instrument used in assessing self-care activities associated with glycemic control (Schmitt, et al., 2013). This instrument has 16-items that can further be broken down in four subcomponents: Glucose Management (GM) has 5 items, Dietary Control (DC) has 4 items, Physical Activity (PA) has 3 items, and Health-Care Use (HCU) has 4 items. The answers were based on a four-point Likert scale ranging from "Applies to me very much" to "Does not apply to me". Although the original creator of the instrument ranged the scores from 0 to 3, for this study, the ranges are from 1 to 4 with "Does not apply to me" equating to a score of 1 and "Applies to me very much" equating to a score of 4. The lowest score for this instrument is 16 with the highest score possible being a 64. A higher score indicates a higher level of self-reported self-care/self-management. This instrument could shed light on whether the person has increased self-management in their diabetes care by the end of the study.

The PAID (Appendix D) scale differs from the DSMQ in that the focus is on problem areas of diabetes (diabetes-related distress) and not self-care. This scale provides insight into psychosocial problems effecting the person by assisting in measuring items such as coping style, depression, social support and health beliefs (Polonsky, et al., 1995). This is a 20-item instrument on a 5-point Likert scale ranging from "Not a problem" to "Serious Problem". The original creators ranged the scores from 0 to 4, this study will use the range 1 to 5 with "Not a problem" equating to a score of 1 and "Serious Problem" equating to a score of 5. The lowest score for this instrument is 20 and the highest score is 100. The higher the value of the score, the more diabetes-related distress the participant is likely suffering from. By using this instrument, changes in psychosocial factors can be assessed.

The EES (Appendix E) was developed in order to assess negative emotions in conjunction with eating habits and overeating/binge eating (Arnow, Kenardy, & Agras, 1995). Overeating and poor eating habits can be correlated with poor coping mechanisms. This

instrument assisted in measuring whether eating was possibly still used as a coping mechanism when a person was experiencing negative emotions. This is a 25-item instrument that can further be broken down into three subcomponents: Anger/Frustration (AF) has 11 items, Anxiety (ANX) has 9 items, and Depression (DEP) has 5 items. Each item contains a single emotion and there are five total answers range from "No Desire to Eat" to "Overwhelming Urge to Eat". "No Desire to Eat" equates to a score of 1 and "Overwhelming Urge to Eat" equates to a score of 5. The lowest score for this instrument is 25 and the highest score is 125. A higher score value will indicate that negative emotions are correlated with ones urge to eat and possibly indicate negative emotions lend to binge eating and poor coping mechanisms. This instrument will assist in assessing whether health coping mechanisms were learned in place of eating when experiencing negative emotions.

The BSCS also aids in measuring healthy coping mechanisms by gauging self-control and impulses (Tangney, Baumeister, & Boone, 2004). This is a 13-item instrument with a 5-point Likert scale ranging from "Not at all like me" to "Very much like me". "Not at all like me" equates to a score of 1 and "Very much like me" equates to a score of 5. For the purposes of this study, a modified version and 10-item instrument was used (Appendix F). Modification included removing the items "I am lazy", "I have trouble concentrating", and "I have trouble resisting temptation". The reasoning behind removing those items are the key points were addressed in the IPAQ, EES, and GSE instruments. The 5-point Likert scale and the scores associated with each answer remain unchanged. The lowest score for the modified instrument is 10 and the highest score is 50. The higher the value of the score indicates a higher level of self-control and a lower lowlihood of giving into impulses.

The GSE (Appendix G) is intended to gain a general sense of a person's self-efficacy or self-esteem and can produce meaningful relationships with other psychological constructs (Schwarzer & Jerusalem, 1979; Luczczynska, Scholz & Schwarzer, 2005). This is a 10-item instrument with a 4-point Likert scale ranging from "Not true at all" to "Exactly true". "Not true

at all" equates to a score of 1 and "Exactly true" equates to a score of 4. The lowest score of the instrument is 10 and the highest score is 40. A higher score could indicate the person has a higher sense of self-esteem/self-efficacy. Measuring the participants self-efficacy is critical to measure their confidence in their ability to maintain regimen adherence and self-management following the end of the study (Shao, Liang, Wan, & Yu, 2017).

Assessment of Physiological Factors

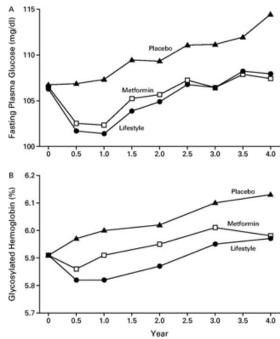
During the baseline and post-treatment appointment, each candidate's height and weight were measured with a medical scale to compute their body mass index (BMI) to compare initial versus post-treatment bodyweight. Participants' body composition was analyzed using the SECA mBCA body composition analyzer via bioelectrical impedance analysis. Blood assays for HbA1c levels were also be taken to ensure the participant fell within the IGT or T2D limits during the baseline visit. Additionally, blood assays were taken during the post-treatment visit for comparison. All blood analyses for HbA1c and fasting blood glucose took place at the Laboratory for Applied Nutrition and Exercise Science (LANES) at OSU.

Treatment Condition: Intervention Group and Control

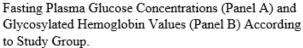
Participants were randomized to either the Lifestyle Intervention Group (LIG), or the Support Group plus Lifestyle Intervention (SGLI). The control group was the LIG and will not be attending the weekly support group meetings. Instead, they received the support group discussion material via Canvas each week.

Lifestyle Intervention

Both groups were on an active treatment arm as they each participated in the 12-week program for physical activity and nutritional advice (lifestyle intervention). All material was uploaded to Canvas in the form of PowerPoints in addition to videos recorded by the researcher and collaborator (Appendix I). Over the course of the study, both groups maintained a weekly physical activity and food log. The food log was maintained at a minimum of 2 days per week, including one-week day and one day over the weekend. The reasoning behind a daily food log was to compel the participants to write down everything they eat, and hopefully invoke more mindful food decisions. Additionally, if the participants are meeting or exceeding the physical activity values, but are not making any progress, their food diaries could provide clues if their caloric intake still outweighs their expenditure. The physical activity prescription was a minimum of 150 minutes of moderate walking per week, or 30 minutes of physical activity at least 5 days a week. Walking for 150 minutes per week has been shown to effectively decrease the risk of T2D by 63-69% and help maintain glycemic control. Additionally, 150 minutes per week of moderate walking is more effective at reducing T2D than Metformin alone (Figure 2) (Diabetes Prevention Program Research Group, 2002).







Note. Figure taken from *Reduction in the incidence* of Type 2 Diabetes with lifestyle intervention or metformin

Diabetes Initiative National Program Office. (2002).

Social Group Construct

The SGLI participated in a weekly support group session hosted virtually via the Department of Kinesiology, Applied Health and Recreation's Premium Zoom account, hosted by the researcher and co-hosted by a doctoral student in nutritional sciences and a Registered Dietician. Each session was roughly an hour in length and had a specific topic for discussion each week. The SGLI had their binders available during the weekly support group sessions and shared the information they had written in their journal with the rest of the group. The weekly support group should have enticed a sense of community, belonging, accountability, and encouraged them to attend as many sessions as possible over the 12 weeks. Participants in the SGLI were encouraged to share personal anecdotes surrounding that week's topic. The LIG filled out their thoughts and reflect on the support group material in their weekly reflection journal, but their material was not shared with the rest of the participants in the group. Participants in the SGLI were required to attend at least 6 of the 12 group sessions for their data to be used in the trial. Specifically, the participants must have attend at least 2 of the meetings per month over the 12 weeks.

Post-Treatment Visit

Upon the conclusion of the 12-week intervention, each participant who had successfully completed the study was brought back to the LANES lab over a 2-week period for their final testing. Each participant had their blood assay, body composition, height and weight redone for their post-treatment values. Additionally, patients had to retake the regimen adherence and selfmanagement questionnaires. Participants were encouraged to keep their binders and continue to work on their self-management and regimen adherence through the skills learned from the intervention.

Statistical Analysis

Baseline differences were compared with end of study results for both biometric data and survey responses. Means, confidence intervals, and effect sizes were determined for between groups and within groups across time.

CHAPTER IV

FINDINGS

Participant Characteristics

Of the 7 participants who began this study, 4 completed the 12-week intervention (Appendix J). Within the total number of participants who completed the study, 2 were female and 2 were male; mean age, 43.5 ± 12.5 years; mean starting BMI 42.3 kg/m² ±11.8; mean starting HbA1c 6.7 mmol/L ±2.2; mean starting body weight 121.8 kg ±21.2; mean starting body fat percentage $45.2\% \pm 19.4\%$; three participants were White and one was Southeast Asian.

Biometric Data Analysis

Baseline differences for HbA1c, BMI, body weight, and body fat percentages were plotted and graphed in Microsoft Excel (Figure 3). Effect size (ES) using Cohen's d were also plotted and graphed in Microsoft Excel (Figure 4) for each biometric data point. Effect size values are as follows: <0.2 = trivial ES, 0.2-0.49 = small ES, 0.5-0.79 = medium ES, 0.8-0.99 =large ES, and >1.0 = very large ES (Cohen, 1977). Each biometric data point was analyzed for the mean (M) pre and post-tests, M difference, standard deviation (SD) pre and post-tests, Confidence Interval (CI) pre and post-tests, and ES. All CI's are reported as 95%.

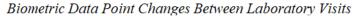
Baseline differences in body weight *M* between pre and post-tests for each participant are seen in Figure 3a. Between groups pre-test (M = 121.8 kg, SD = 15.1, CI = 107.0 kg-136.6 kg)

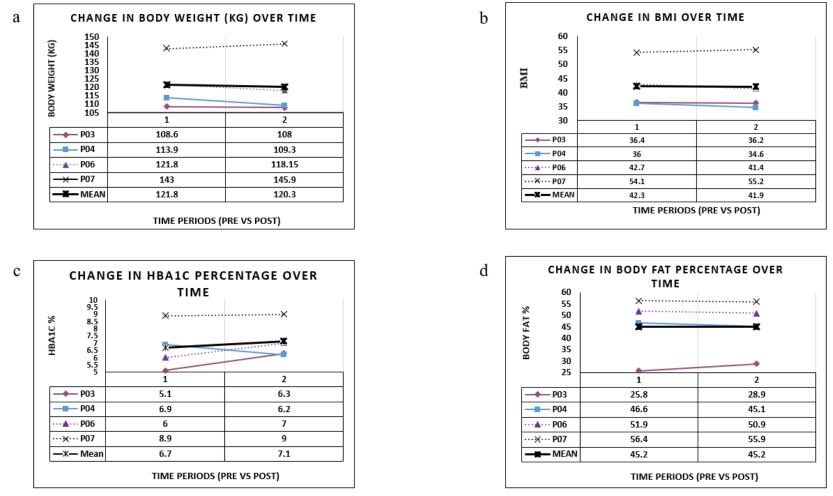
and post-test (M = 120.3 kg, SD = 17.6, CI = 103.1 kg-137.6 kg). The difference in the M between pre and post-tests was -1.5 kg and the ES was -0.105 (trivial). Within the intervention group pre-test (M = 111.3 kg, SD = 3.7, CI = 106.1 kg-116.4 kg) and post-test (M = 108.7 kg, SD = 0.9, CI = 107.4 kg-109.9 kg). The difference in the M between pre and post-tests was -2.6 kg and the ES was -1.981 (very large). Within the control group pre-test (M = 132.4 kg, SD = 15.0, CI = 111.6 kg – 153.2 kg) and post-test (M = 132.0 kg, SD = 19.6, CI = 104.8 kg-159.2 kg). The difference in the M between pre and the ES was -0.031 (trivial).

Baseline differences in BMI between pre and post-tests for each participant can be seen in Figure 3b. Between groups pre-test ($M = 42.3 \text{ kg/m}^2$, SD = 8.4, $CI = 34 \text{ kg/m}^2$ -51 kg/m²) and post-test ($M = 41.9 \text{ kg/m}^2$, SD = 9.4, $CI = 33 \text{ kg/m}^2$ -51 kg/m²). The difference in the M between pre and post-tests was -0.4 kg/m² and the ES was -0.059 (trivial). Within the intervention group pre-test ($M = 36.2 \text{ kg/m}^2$, SD = 0.3, $CI = 36 \text{ kg/m}^2$ - 36 kg/m^2) and post-test ($M = 35.4 \text{ kg/m}^2$, SD =1.1, $CI = 34 \text{ kg/m}^2$ - 37 kg/m^2). The difference in the M between pre and post-tests was -0.8 kg/m² and the ES was -0.9 (large). Within the control group pre-test ($M = 48.4 \text{ kg/m}^2$, SD = 8.1, $CI = 37 \text{ kg/m}^2$ - 60 kg/m^2) and post-test ($M = 48.3 \text{ kg/m}^2$, SD = 9.8, $CI = 35 \text{ kg/m}^2$ - 62 kg/m^2). The difference in the M between pre and post-tests was -0.016 (trivial).

Baseline differences in HbA1C between pre and post-tests for each participant can be seen in Figure 3c. Between groups pre-test (M = 6.7 mmol/L, SD = 1.6, CI = 5.1 mmol/L - 8.3 mmol/L) and post-test (M = 7.1 mmol/L, SD = 1.3, CI = 5.9 mmol/L - 8.4 mmol/L) The difference in the M between pre and post-tests was 0.4 mmol/L and the ES was 0.27 (small). Within the intervention group pre-test (M = 6.0 mmol/L, SD = 1.3, CI = 4.2 mmol/L - 7.8 mmol/L) and post-test (M = 6.3 mmol/L, SD = 0.1, CI = 6.2 mmol/L - 6.2 mmol/L). The difference in the M between pre and post-tests was 0.3 mmol/L and the ES was 0.277 (small). Within the control group pre-test (M = 7.5 mmol/L, SD = 2.1, CI = 4.6 mmol/L - 10.3 mmol/L) and post-test (M = 8.0 mmol/L, SD = 1.4, CI = 6.0 mmol/L - 10.00 mmol/L). The difference in the M between pre and post-tests was 0.6 mmol/L and the ES was 0.312 (small).

Figure 3





Note. Biometric data points between pre and post laboratory visits. **a** Depicts body weight (kg) changes between pre and post laboratory visits for each participant. **b** Depicts BMI changes between pre and post laboratory visits for each participant. **c** Depicts HbA1C changes between pre and post laboratory visits for each participant. **d** Depicts body fat percentage changes between pre and post laboratory visits for each participant. **d** Depicts body fat percentage changes between pre and post laboratory visits for each participant. **d** Depicts body fat percentage changes between pre and post laboratory visits for each participant. **d** Depicts body fat percentage changes between pre and post laboratory visits for each participant. Time between point 1 and 2 equates to 13 weeks. Dashed lines indiate those participants were in the control group while solid lines indiate participants in the intervention group.

Baseline differences in body fat percentage between pre and post-tests for each participant can be seen in Figure 3d. Between groups pre-test (M = 45.2%, SD = 13.5, CI = 31.9% - 58.4%) and post-test (M = 45.2%, SD = 11.7, CI = 33.7% - 56.7%). The difference in the *M* between pre and post-tests was 0% and the *ES* was 0.002 (trivial). Within the intervention group pre-test (M = 36.2%, SD = 14.7, CI = 15.8% - 56.6%) and post-test (M = 37%, SD = 11.5, CI = 21.1% - 52.9%) The difference in the *M* between pre and post-test was 0.8% and the *ES* was 0.087 (trivial). Within the control group pre-test (M = 54.2%, SD = 3.2, CI = 49.7% - 58.6%) and post-test (M = 53.4%, SD = 3.5, CI = 48.5% - 58.3%). The difference in the *M* between pre and post-test was -0.8% and the *ES* was -0.392 (small).

Survey Analysis

Survey data was exported into the statistical software IBM SPSS Statistics 26 for analysis. Compute variable function was used in order to find the *M* question scores per survey per participant. Individual mean question scores were calculated and graphed for both baseline values and end of study values (Figure 5).

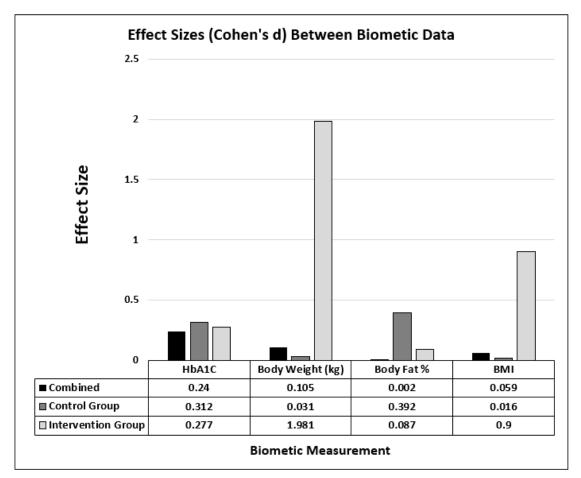
BSCS: M difference between groups from baseline to end of study was -0.2. Within the intervention group the *M* difference was -0.1 and within the control group the *M* difference was -0.4.

EES: M difference between groups from baseline to end of study was -0.6. Within the intervention group the *M* difference was -0.9 and within the control group the *M* difference was -0.3.

<u>DSMQ</u>: *M* difference between groups from baseline to end of study was 0.8. Within the intervention group the *M* difference was 0.3 and within the control group the *M* difference was 1.1.

Figure 4

Effect Sizes Between Biometric Data Points



Note. Cohen's d used for effect size (ES). Effect size values: <0.2 = Trivial ES, 0.2-0.49 = Small ES, 0.5-0.79 = Medium ES, 0.8-0.99 = Large ES, and 1.0+ = Very Large ES.

<u>*PAID:*</u> *M* difference between groups from baseline to end of study was -0.1. Within the intervention group the *M* difference was -0.2 and within the control group the *M* difference was 0.1.

<u>GSE:</u> M difference between groups from baseline to end of study was -0.1. Within the

intervention group the M difference was -0.1 and within the control group the M difference was

-0.1.

Further analysis was done into both the DSMQ and the EES based on the subcomponents of each scale.

<u>EES AF:</u> M difference between groups from baseline to end of study was -0.3. Within the intervention group the M difference was -0.8 and within the control group the M difference was 0. <u>EES ANX:</u> M difference between groups from the baseline to end of study was -0.8. Within the intervention group the M difference was -1.2 and within the control group the M difference was -0.2.

<u>EES DEP:</u> M difference between groups from baseline to end of study was -0.7. Within the intervention group the M difference was -1.2 and within the control group the M difference was -0.3.

<u>DSMQ GM</u>: M difference between groups from baseline to end of study was 1.2. Within the intervention group the M difference was 1.1 and within the control group the M difference was 1.2.

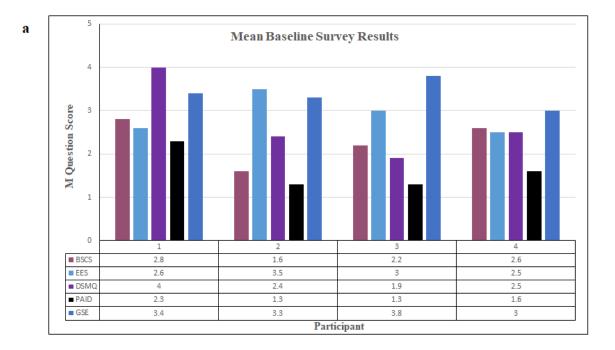
<u>DSMQ DC:</u> M difference between groups from baseline to end of study was 0.6. Within the intervention group the M difference was 0.3 and within the control group the M difference was 0.5.

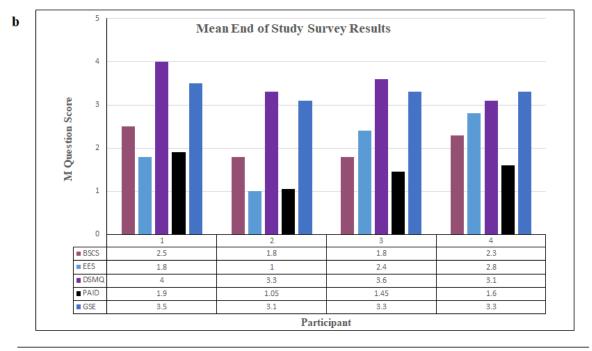
<u>DSMQ PA:</u> M difference between groups from baseline to end of study was 0.9. Within the intervention group the M difference was 0.4 and within the control group the M difference was 2.0.

<u>DSMQ HCU:</u> M difference between groups from baseline to end of study was 0.6. Within the intervention group the M difference was 0.4 and within the control group the M difference was 1.1.

Figure 5

Mean Question Scores from Surveys - Baseline vs End of Study



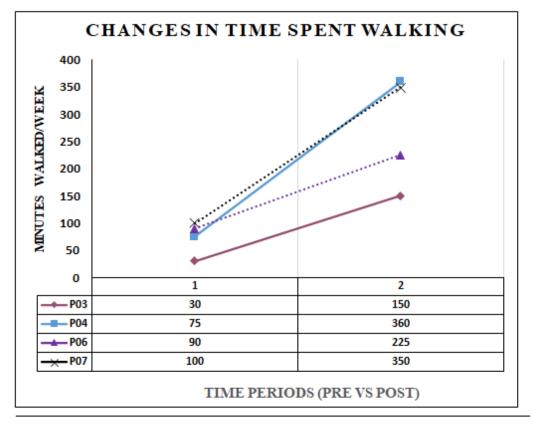


Note. Mean question scores for the BSCS, EES, DSMQ, PAID and GSE surveys. **a** Depicts mean baseline question scores. **b** Depicts mean end of study question scores. Columns 1 - 4 each represent a participant and their mean question scores per survey.

Although the IPAQ took information regarding vigorous and moderate physical activity, the researcher focused the data analysis on the walking statistics as that was the prescribed method of physical activity. Participants self-reported the amount of days and the average time walked each day per week. Minutes walked per week for each participant were compared between baseline and end of study surveys and can be seen in Figure 6. Between groups baseline (M = 73.8 min., SD = 30.9, CI = 43 min. - 104 min.) and end of study (M = 271.3 min., SD = 101.5, CI = 172 min. - 371 min.) The *M* difference between baseline and end of study was 197.5 min. and the *ES* was 3.04 (very large). Within the intervention group baseline (M = 52.5 min, SD = 31.8, CI = 8 min. - 97 min.) and end of study (M = 225 min, SD = 148.5, CI = 49 min. - 461 min.). The *M* difference between baseline and the *ES* was 2.7 (very large). Within the control group baseline (M = 95 min., SD = 7.1, CI = 85 min. - 105 min.) and end of study (M = 287.5 min, SD = 88.4, CI = 165 min. - 410 min.). The *M* difference between baseline and end of study (M = 287.5 min, SD = 88.4, CI = 165 min. - 410 min.).

ACE scores (Appendix H) were also determined for each participant at baseline. All participants had an ACE score of 0, minus one outlier who had an ACE score of 1.

Figure 6



Minutes Walked per Week Between Pre and Post Study Results

Note. Dashed lines indicate participants in the control group while solid lines indicate participants in the intervention group.

CHAPTER V

DISCUSSION

The purpose of the present study was to quantify the magnitude of benefit, if any, of a social support group to regimen adherence and self-management, HbA1c levels, body weight and body fat percentage of a lifestyle intervention. Biometric data markers were assessed in a laboratory setting with psychosocial factors assessed through survey instruments at the pre- and post-study study phases.

Interpretation of Results

Concerning the biometric data, there were a few key points. Both intervention and control groups had a negative M between pre and post-tests for body weight, -2.6kg and -0.4kg, respectively with a -2.2kg difference between the group means. This indicates that the intervention group collectively lost more weight throughout the course of the study. There is much research that supports lifestyle interventions decrease body weight, which this study also supports. Similar results could be seen regarding BMI between the groups. The intervention group's M difference in BMI was -0.8 kg/m² while the control group had a M difference of -0.1 kg/m². Again, the data shows that the intervention group. The opposite effect took place regarding body fat

percentage. The difference in M between pre and post-tests for the intervention and control group were 0.8% and -0.8%, respectively. This data shows that the control group's body composition changed more in terms of body fat percentage. This phenomenon could be due to both participants in the control group having less body fat post-study compared to the intervention group, where only one participant had less body fat compared to their baseline visit. The only biomarker that increased (did not improve) over the course of the 12-weeks for either group was HbA1c. The data shows that the intervention and control groups M difference between baseline and end of study was 0.3 mmol/L and 0.6 mmol/L, respectively. The researcher had been verbally told by both members of the control group at the post-study laboratory visit that their physicians had recently (within the last month) changed their diabetic medication in some way. One of the participants from the control group had each biomarker improve except her HbA1c, further indicating that the change in her Metformin likely had a large part to play in the lack of improvement. Furthermore, one of the participants from the intervention group demonstrated improvement in all his biomarkers, including HbA1c. The increase in the M difference from the intervention group is due to the 1.2 mmol/L increase by the other participant in that group. Due to the small number of participants within the study, it is difficult to draw conclusions regarding the biometric data. Only one participant had improvement on one biomarker while only one participant had improvement on all four. This shows how varied the results were from each participant and why any type of conclusions could not be made given the small participant pool.

Findings within the survey data showed an increase in physical activity, specifically time spent walking, from every participant. Between both groups, the mean difference from baseline to the end of study was 197.5 minutes. All but one participant reported increasing walking time per week to exceed the 150-minutes per week recommendation by the researcher and by health organizations such as the American College of Sports Medicine and the World Health Organization. The control group reported walking more than the intervention group per week,

192.5 min. and 186.7 min, respectively. This provides evidence that being consulted regarding physical activity prior to completing a lifestyle intervention may increase overall physical activity levels in those with T2D (Kirk, Mutrie, MacIntyre, & Fisher, 2003) This survey data also coincides with the DSMQ PA subcomponent answers. The control group shows a mean difference in this subcomponent by 2.0 where the intervention group's M difference was 0.4. These findings indicate the control group increased their physical activity self-care habits more than the intervention group. While these results are surprising, many factors may have influenced these results. For instance, the intervention group began the study shortly after the beginning of the COVID-19 pandemic. This may have resulted in reduced physical activity levels due to a fear of going outside. Furthermore, during this period many gyms and fitness centers were closed or had very limited hours. In addition, the intervention group completed the study during the fall and winter of 2020. Lower temperatures could have also been a factor for physical activity motivation as freezing temperatures cause physical hazards while being physically active outdoors. Not only did all participants increase their weekly walking times, they each indicated an improvement in dietary habits.

The DSMQ DC subcomponent data showed a mean increase in dietary control in the intervention and control group by 0.3 and 0.5, respectively. This data is also reflected in the EES survey. Mean differences for both groups improved in the EES by both groups ending the study with lower scores. All participants reported their highest question scores in the EES DEP subcomponent and their lowest question scores in the EES AF subcomponent. This indicates that the participants had a greater overwhelming urge to eat when they are sad/depressed, compared to being angry/frustrated. These data point out the need for emotion-focused eating habit education, specifically dealing with sad and depressive based emotions.

Between both diabetes specific scales (DSMQ & PAID), the intervention group showed improvement. The overall mean difference in this group was between the DSMQ and PAID was 0.3 and -0.2, respectively. This data indicates the intervention group increased their diabetes

specific self-care and had lower diabetes related distress post study compared to the control group. However, the control group did demonstrate a 1.1 mean difference in question scores for DSMQ, and a 0.1 mean increase in the question scores for PAID. The DSMQ mean question score was 0.7 higher in comparison to the intervention group, which is representative of greater improvement in self-care habits, yet this group also indicated their diabetes-related distress has gone up from baseline. This could be due to the control group feeling overwhelmed by the amount of information they absorbed over the previous 12 weeks.

Limitations

First, the generalizability of the findings is greatly limited due to the small participant pool. In addition, there was no sex variance between the groups. The control group was comprised of two females where the intervention group was exclusively male. Next, causality inferences could not be made due to the small participant pool and the homogeneity of the groups in regard to race and sex. As previously stated, three participants were White, and one was Southeast Asian. Third, all survey findings are from self-reported instruments and this study might suffer from self-report bias. In addition, the time each study took place was likely a limitation. The intervention group completed the 12-week intervention during the Fall/Winter of 2020 and the control group completed the intervention in the Spring/Summer of 2021. The variance in weather conditions during the different times of year could have impacted the participant's motivation or willingness to go outside and be physically active. Next, the researcher exclusively recruited participants who were considered faculty or staff from a college campus. This limited the possible participants and could have been a factor in the low recruitment numbers. Lastly, the global pandemic of COVID-19 was occurring during both recruitment periods for the study. The CDC stated that persons with T2D were at a higher risk of enduring complications related to COVID-19 and were strongly encouraged to practice social distancing and limit unnecessary contact.

It should be noted that the researcher was not able to analyze fasting blood glucose levels of any of the participants. This was due to a lack of validity with the glucometer selected. Participants came to the laboratory fasted in order to obtain an accurate reading, but the glucometer was reading roughly 20 mg/dL higher than was accurate. This also caused an increase in anxiety and temporary panic-like state for some of the participants at seeing such a high fasting blood glucose reading. Participants were able to confirm the inaccuracy of the glucometer as some had a continuous glucose monitor and others were able to pull up their fasting glucose readings from earlier that morning.

Recommendations for Future Studies

Many of these limitations could be addressed in future studies. Increasing the participant pool for a similar study in the future could prove easier now that COVID-19 vaccines are available, and the number of cases is decreasing worldwide. In addition, opening up the participant pool to those within the local community and even the student population on campus would allow the researcher to reach more possible participants. Both of these element would also likely prevent the homogeneity seen in this study. Another recommendation would be to test fasting blood glucose levels. Ensuring the researcher has a pre-tested, validated, and reliable glucometer or other instrument prior to working with subjects is suggested. This additional biometric data point could add further insight into the participant's lifestyle. Fasting blood glucose could also be added as a part of the logs submitted by participants. As this is a biomarker that can change multiple times a day (unlike HbA1c), this could be a valuable tool to validate the progress a participant is making on a monthly basis. Additionally, those with T2D need to learn how to manage this level on a day to day basis, so including this marker as part of the study could assist in that manner, especially if one of the weekly educational topics was dedicated to managing blood glucose on a daily basis.

Conclusion

In conclusion, although this study lacked the number of subjects to perform the analysis needed to make correlations, the study still shed light on the importance of having psychosocial factors included. The survey insights are equally as important as the biometric data in terms of understanding the best methods of treatment, and where a particular person sits in terms of psychosocial factors, which are overlooked in purely biomedical studies.

The overall increase in walking per week by each participant shows that this study was successful in creating healthy habits and increasing self-management and regimen adherence. In addition, the M EES scores between and within groups showed an improvement in no longer using food as a coping mechanism. A study like this on a much larger scale would continue to add to the research that exists on the benefits of biopsychosocial interventions for those with T2D and IGT (Peyrot, McMurry Jr., & Kruger, 1999; Diabetes Initiative National Program Office, 2009; Kalra, Singh Balhara, & Das, 2013).

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APPENDICES

APPENDIX A

IRB Approval



Oklahoma State University Institutional Review Board

08/18/2020

Beth Weichold

Jason Defreitas

Christina Sciarrillo

Expedited

Date: Application Number: Proposal Title:

IRB-20-353 Regimen Adherence and Self-Management in Persons with Impaired Glucose Tolerance and Type 2 Diabetes

Principal Investigator: Co-Investigator(s): Faculty Adviser: Project Coordinator: Research Assistant(s):

Processed as: Expedited Category:

Status Recommended by Reviewer(s): Approved 08/18/2020 Approval Date:

The IRB application referenced above has been approved. It is the judgment of the reviewers that the rights and welfare of individuals who may be asked to participate in this study will be respected, and that the research will be conducted in a manner consistent with the IRB requirements as outlined in section 45 CFR 46

This study meets criteria in the Revised Common Rule, as well as, one or more of the circumstances for which <u>continuing review is not required</u>. As Principal Investigator of this research, you will be required to submit a status report to the IRB triennially.

The final versions of any recruitment, consent, and assent documents bearing the IRB approval stamp are available for download from IRBManager. These are the versions that must be used during the study.

- As Principal Investigator, it is your responsibility to do the following:
 1. Conduct this study exactly as it has been approved. Any modifications to the research protocol
 must be approved by the IRB. Protocol modifications requiring approval may include changes to the title, PI, adviser, other research personnel, funding status or sponsor, subject population composition or size, recruitment, inclusion/exclusion criteria, research site, research procedures and consent/assent process or forms. Submit a status report to the IRB when requested
 - 2
 - 3. Promptly report to the IRB any harm experienced by a participant that is both unanticipated and related per IRB policy. Maintain accurate and complete study records for evaluation by the OSU IRB and, if applicable,
 - 4.
 - inspection by regulatory agencies and/or the study sponsor.
 Notify the IRB office when your research project is complete or when you are no longer affiliated with Oklahoma State University.

If you have questions about the IRB procedures or need any assistance from the Board, please contact the IRB Office at 405-744-3377 or irb@okstate.edu.

Sincerely,

Oklahoma State University IRB

APPENDIX B

IPAQ – INTERNATIONAL PHYSICAL ACTIVITY QUESTIONNAIRE

 The first question is about the time you spent sitting during the last 7 days. Include time spent at work, at home, while doing course work and during leisure time. This may include time spent sitting at a desk, visiting friends, reading, or sitting or lying down to watch television.

During the last 7 days, how much time did you spend sitting during a day?

____ hours ____ minutes

2 Think about the time you spent walking in the last 7 days. This includes at work and at home, walking to travel from place to place, and any other walking that you might do solely for recreation, sport, exercise, or leisure.

During the last 7 days, on how many days did you walk for at least 10 minutes at a time?

Days	\Rightarrow	How much time did you usually spend walking on one of those days?			
or □ No day		hours minutes			

During the last 7 days, on how many days did you do moderate physical activities like gardening, cleaning, bicycling at a regular pace, swimming or other fitness activities.

Think *only* about those physical activities that you did for at least 10 minutes at a time. Do not include walking.

Days	\Rightarrow	How much time did you usually spend doing moderate physical activities on one of those days?				
or □ No day		hours minutes				

4. During the last 7 days, on how many days did you do vigorous physical activities like heavy lifting, heavier garden or construction work, chopping woods, aerobics, jogging/running or fast bicycling?

Think only about those physical activities that you did for at least 10 minutes at a time.

Days	\Rightarrow	How much time did you usually spend doing vigorous physical activities on one of those days?		
□ No day		hours minutes		

APPENDIX C

DSMQ – DIABETES SELF-MANAGEMENT QUESTIONNAIRE

dia	following statements describe self-care activities related to your betes. Thinking about your self-care over the last 8 weeks, please cify the extent to which each statement applies to you.	Applies to me very much	Applies to me to a consider-able degree	Applies to me to some degree	Does not apply to me
1.	I check my blood sugar levels with care and attention. □ Blood sugar measurement is not required as a part of my treatment.	□3	□2	□1	0
2.	The food I choose to eat makes it easy to achieve optimal blood sugar levels.	□3	□2	□1	□0
3.	I keep all doctors' appointments recommended for my diabetes treatment.	□3	□2	□1	□0
4.	I take my diabetes medication (e.g. insulin, tablets) as prescribed. □ Diabetes medication / insulin is not required as a part of my treatment.	□3	□2	□1	□0
5.	Occasionally I eat lots of sweets or other foods rich in carbohydrates.	□3	□2	□1	□0
6.	I record my blood sugar levels regularly (or analyse the value chart with my blood glucose meter). Blood sugar measurement is not required as a part of my treatment.	□3	□2	□1	0
7.	I tend to avoid diabetes-related doctors' appointments.	□3	□2	□1	□0
8.	I do regular physical activity to achieve optimal blood sugar levels.	□3	□2	□1	□0
9.	I strictly follow the dietary recommendations given by my doctor or diabetes specialist.	□3	□2	□1	□0
10.	I do not check my blood sugar levels frequently enough as would be required for achieving good blood glucose control.	□3	□2	□1	0
11.	I avoid physical activity, although it would improve my diabetes.	□3	□2	1	□0
12.	l tend to forget to take or skip my diabetes medication (e.g. insulin, tablets). Diabetes medication / insulin is not required as a part of my treatment.	□3	□2	□1	□0
13.	Sometimes I have real 'food binges' (not triggered by hypoglycaemia).	□3	□2	□1	□0
14.	Regarding my diabetes care, I should see my medical practitioner(s) more often.	□3	□2	□1	□0
15.	I tend to skip planned physical activity.	□3	□2	□1	□0
16.	My diabetes self-care is poor.	□3	□2	□1	□0

APPENDIX D

PAID – PROBLEM AREAS IN DIABETES QUESTIONNAIRE

Instructions: Which of the following diabetes issues are currently a problem for you? Circle the number that gives the best answer for you. Please provide an answer for each question.

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

APPENDIX E

EES – EMOTIONAL EATING SCALE

Emotional Eating Scale

We all respond to different emotions in different ways. Some types of feelings lead people to experience an urge to eat. Please indicate the extent to which the following feelings lead you to feel an urge to eat by checking the appropriate box.

	No Desire to Eat	A Smali Desire to Eat	A Moderate Desire to Eat	A Strong Urge to Eat	An Overwhelming Urge to Eat
Resentful					
Discouraged					
Shaky					
Worn Out					
Inadequate					
Excited					
Rebellious					
Blue					
Jittery					
Sad					
Uneasy					
Irritated					
Jealous					
Worried					
Frustrated					
Lonely					
Furious					
On edge					
Confused					
Nervous					
Angry					
Guilty					
Bored					
Helpless					
Upset					

APPENDIX F

BSCS (M) – BRIEF SELF- CONTROL SCALE (MODIFIED)

Brief Self-Control Scale (Modified)

I have a hard time breaking bad habits. I get distracted easily. I say inappropriate things. I refuse things that are bad for me, even if they are fun. I'm good at resisting temptation. People would say that I have very strong self-discipline. Pleasure and fun sometimes keep me from getting work done. I do things that feel good in the moment but regret later on. Sometimes I can't stop myself from doing something, even if I know it is wrong. I often act without thinking through all the alternatives.

Rate each item on a scale of 1-5

- 1 = Not at all like me
- 2 = A little like me
- 3 = Somewhat like me
- 4 = Mostly like me
- 5 = Very much like me

APPENDIX G

GSE – GENERAL SELF-EFFICACY SCALE

Scale Name: General Self-Efficacy

Developers: Schwarzer, R., & Jerusalem, M.

Rating Scale:

1 = Not at all true 2 = Hardly true 3 = Moderately true 4 = Exactly true

Items:

- 1. I can always manage to solve difficult problems if I try hard enough.
- 2. If someone opposes me, I can find the means and ways to get what I want.
- 3. It is easy for me to stick to my aims and accomplish my goals.
- 4. I am confident that I could deal efficiently with unexpected events.
- 5. Thanks to my resourcefulness, I know how to handle unforeseen situations.
- 6. I can solve most problems if I invest the necessary effort.
- 7. I can remain calm when facing difficulties because I can rely on my coping abilities.
- 8. When I am confronted with a problem, I can usually find several solutions.
- 9. If I am in trouble, I can usually think of a solution.
- 10. I can usually handle whatever comes my way.

Scoring:

• Add up all responses to a sum score. The range is from 10 to 40 points.

APPENDIX H

ACEs – ADVERSE CHILDHOOD EXPERIENCES

Prior to your 18th birthday:

- Did a parent or other adult in the household often or very often... Swear at you, insult you, put you down, or humiliate you? or Act in a way that made you afraid that you might be physically hurt? No _____If Yes, enter 1____
- Did a parent or other adult in the household often or very often... Push, grab, slap, or throw something at you? or Ever hit you so hard that you had marks or were injured? No _____If Yes, enter 1_____
- Did an adult or person at least 5 years older than you ever... Touch or fondle you or have you touch their body in a sexual way? or Attempt or actually have oral, anal, or vaginal intercourse with you? No If Yes, enter 1____
- 4. Did you often or very often feel that ... No one in your family loved you or thought you were important or special? or Your family didn't look out for each other, feel close to each other, or support each other? No If Yes, enter 1____
- 5. Did you often or very often feel that ... You didn't have enough to eat, had to wear dirty clothes, and had no one to protect you? or Your parents were too drunk or high to take care of you or take you to the doctor if you needed it?
 - No___If Yes, enter 1___
- Were your parents ever separated or divorced? No___lf Yes, enter 1___
- 7. Was your mother or stepmother:

Often or very often pushed, grabbed, slapped, or had something thrown at her? or Sometimes, often, or very often kicked, bitten, hit with a fist, or hit with something hard? or Ever repeatedly hit over at least a few minutes or threatened with a gun or knife?

- No___If Yes, enter 1___
- Did you live with anyone who was a problem drinker or alcoholic, or who used street drugs?

No___If Yes, enter 1_

9. Was a household member depressed or mentally ill, or did a household member attempt suicide?

No___If Yes, enter 1___

10. Did a household member go to prison?

No___If Yes, enter 1___

Now add up your "Yes" answers: _ This is your ACE Score

APPENDIX I

WEEKLY INTERVENTION TOPICS

Week 1: (Psychological + Social)

Introduction to Goal Setting What is your goal over the next 12 weeks? Do you have any existing goals connected to your diabetes? Setting small goals – one small change every week makes a large impact.

Week 2: (Biological + Psychological)

Nutrition for Diabetes - Overview Was it a meal or a snack? What was your emotional state prior to and after eating? On a scale of 1-10, how hungry were you before you ate? On a scale of 1-10, how full were you when you finished eating?

Week 3: (Biological + Psychological)

Physical Activity: Why is this so important? What to expect when you start being more physically active. Health Benefits Working Out vs. Working In Starting Slow Importance of an "accountability-buddy"

Week 4: (Biological + Psychological)

Self-Care in Diabetes: 7 Key Points Healthy Eating Being Active Monitoring Taking Medication Problem Solving Reducing Risks Healthy Coping

Week 5: (Psychological + Social)

Healthy Coping: Strategies in Stress Management What does stress look like? How do you feel when you are stressed? What do you do when you are stressed? Support from family, friends, colleagues? Emotion vs Problem focused coping strategies.

APPENDIX I – CONTINUED

Week 6: (Biological + Psychological)

The Importance of Regimen Adherence and Self-Management Medication Physical Activity Nutrition Low-Carb – Pros and Cons Artificial Sweeteners Supplements Hypoglycemia

Week 7: (Biological + Psychological)

Grocery shopping and reading nutrition labels

What types of foods to avoid in the grocery store and what to look for. Nutrition labels 101 Fad Diets Eating out with T2D

Week 8: (Psychological + Social)

Maintaining Motivation

What is your motivation to stay healthy while having diabetes? Who helps you stay accountable? How to maintain motivation.

Week 9: (Biological + Psychological + Social)

OSU Employee Wellness Programs and events for faculty and staff. Resources available through the Department of Wellness at Oklahoma State. How to get the most out of the Colvin Recreation Center and Seretean Wellness Center.

Week 10: (Biological + Psychological)

Eating: Emotions and cravings Good replacements for sugary snacks How to not eat through emotions/stress Having snacks readily available that will not cause guilt

Week 11: (Social)

Having a Support System Health Care practitioners and your physician Co-Workers and Employers Family/Friends Diabetic Support Groups

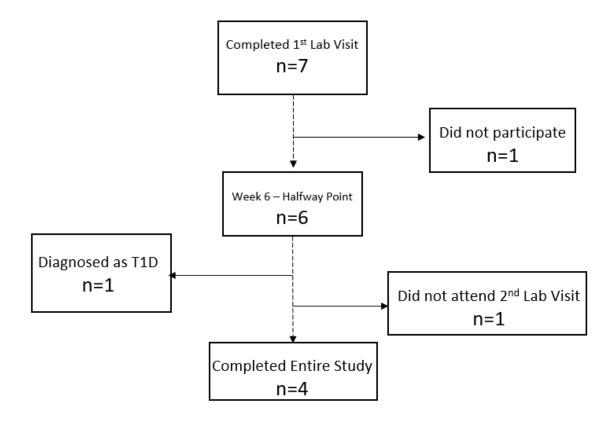
Week 12: (Psychological + Social)

Open Question/Feedback Week

Participants will have the opportunity to ask questions and give feedback or ask researchers to readdress topics from previous weeks.

APPENDIX J

PARTICIPANT ATTRITION



VITA

Beth Ann Weichold

Candidate for the Degree of Health and Human Performance

Master of Science

Thesis: REGIMEN ADHERENCE AND SELF-MANAGEMENT IN PERSONS WITH IMPAIRED GLUCOSE TOLERANCE AND TYPE 2 DIABETES

Major Field: Applied Exercise Science

Biographical:

Education:

Completed the requirements for the Master of Science in Health and Human Performance – Applied Exercise Science at Oklahoma State University, Stillwater, Oklahoma in July 2021.

Completed the requirements for the Bachelor of Science in Political Science at University of Central Missouri, Warrensburg, Missouri in May 2013.

Experience: IRB Coordinator – OSU Career Services Coordinator – OSU Administrative Research Specialist – OSU Human Resources Officer – US Army

March 2021-Present October 2019 – February 2021 April 2017 – October 2019 May 2013 – September 2016

Professional Memberships: American College of Sports Medicine (ACSM) – Student Public Responsibility in Medicine and Research (PRIM&R) – Professional