BLOOD SUGAR BLUES: DIABETES, DEPRESSION, AND ADHERENCE

by

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ABSTRACT

Type 2 diabetes is a prevalent and chronic condition in the United States. In addition to medications, the primary point of treatment is through lifestyle modifications in the form of diet and exercise. Initiating lifestyle changes can be difficult and complicated. In fact, many of those with diabetes struggle to adhere to treatment recommendations. Research has highlighted a multitude of barriers that influence successful diabetes management such as access to health care, lack of knowledge about the disease, and competing lifestyle demands. There is evidence to support the negative relationship between perceived barriers and behavioral change. Also, mental health conditions such as depression have been found to impact both perceptions of barriers and adherence to diabetes treatment recommendations. However, limited research to date has explored the relationship between perceived barriers, depression, and diabetes self-care in low-income populations. Examining the impact of perceived barriers and depression on diabetes self-care activities may provide an opportunity to create better-targeted inventions. This study evaluated the predictive value of perceived barriers and depression on diabetes self-care adherence in 84 low-income adults ($M_{age} = 54.2$). A series of linear multiple regressions were conducted to explore these relationships. Results suggested perceptions of barriers to specific diabetes self-care domains (i.e., exercise, diet, blood glucose test, and medication) did not significantly predict self-care adherence in the corresponding areas. Depression had significant negative relationships with diabetes self-
care activities, specifically diet, blood glucose testing, and medication adherence. However, depression did not significantly predict exercise adherence. Results suggest that treatment of depressive symptoms may allow for better T2DM management through improved adherence.
# TABLE OF CONTENTS

**CHAPTER**

I. INTRODUCTION ................................................................................................. 1
   - Type 2 Diabetes .......................................................................................... 2
   - Who is Affected? ....................................................................................... 3
   - Treatment .................................................................................................. 4
   - Adherence .................................................................................................. 9
   - Barriers ..................................................................................................... 14
   - Theoretical Framework ........................................................................... 22
     - Health Belief Model ............................................................................. 25

II. METHOD ........................................................................................................... 30
   - Participants ............................................................................................. 30
   - Measures .................................................................................................. 30
     - Perceived Barriers .................................................................................. 30
     - Diabetes Self-Care ................................................................................. 31
     - Depression ............................................................................................ 33
     - Cognition ............................................................................................... 33
   - Procedure .................................................................................................. 34
     - Research Design and Statistical Analyses ........................................... 35

III. RESULTS ....................................................................................................... 36

IV. DISCUSSION .................................................................................................. 41
# LIST OF TABLES

<table>
<thead>
<tr>
<th>TABLE</th>
<th>Description</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Correlation Matrix</td>
<td>36</td>
</tr>
<tr>
<td>2.</td>
<td>Summary of Multiple Regression Analyses&lt;br&gt;For Depression and Barriers to Diet Predicting&lt;br&gt;SDSCA Self-Reported Dietary Adherence</td>
<td>39</td>
</tr>
<tr>
<td>3.</td>
<td>Summary of Multiple Regression Analyses&lt;br&gt;For Depression and Barriers to Exercise Predicting&lt;br&gt;SDSCA Self-Reported Exercise Adherence</td>
<td>39</td>
</tr>
<tr>
<td>4.</td>
<td>Summary of Multiple Regression Analyses&lt;br&gt;For Depression and Barriers to Blood Glucose Testing Predicting&lt;br&gt;SDSCA Self-Reported Blood Glucose Adherence</td>
<td>40</td>
</tr>
<tr>
<td>5.</td>
<td>Summary of Multiple Regression Analyses&lt;br&gt;For Depression and Barriers to Medication Predicting&lt;br&gt;SDSCA Self-Reported Medication Adherence</td>
<td>40</td>
</tr>
</tbody>
</table>
CHAPTER I
INTRODUCTION

Diabetes mellitus is a chronic condition that requires a high degree of self-management and behavioral changes. These changes involve monitoring blood sugar, diet, exercising, taking medication, and attending doctor’s appointments (e.g., endocrinology, ophthalmology, podiatry). Adhering to the recommendations of health care providers is often challenging for those experiencing diabetes mellitus. In fact, estimated rates of non-adherence range from 50% to 80% (Chatterjee, 2006). Non-adherence can result in medical complications such as neuropathy (nerve pain), diabetic retinopathy (disease resulting in damage to the retina of the eye), and nephropathy (kidney damage or disease) (“American Diabetes Association [ADA],” 2018). The resulting complications can lead to increased medical costs to both society and the patient and impacts quality of life.

While type 2 diabetes mellitus is unique in the sense that blood glucose levels can be controlled through lifestyle changes, the challenges patients face in making these changes often go unaddressed. Medical care that focuses only on medical and mental health comorbidities can lead to limited and inefficient care. Over the past decade, research has exposed a number of factors in the biological, psychological, and social realms, which influence adherence to diabetes recommendations. In other words, in addition to biological and psychological factors, individual and environmental factors can also play a role in self-care behaviors such as poor diet, medication non-adherence, and
physical inactivity. These factors create a complicated picture when examining adherence to diabetes self-care recommendations. While many barriers have been exposed, there is little known about how cognitions or a person’s perception of these barriers influence adherence to diabetes self-management.

Depression is common among those diagnosed with type 2 diabetes and can significantly impact adherence to diabetes recommendations. Additionally, depression has been found to relate to perceived barriers to diabetes self-care (Renn & Feliciano, 2015). Therefore, it is essential to assess the individual’s perception of barriers and the presence of depression to create a successful treatment plan.

The purpose of this paper is multifaceted: 1) review literature on type 2 diabetes, depression, adherence, and barriers to adherence, 2) discuss current diabetes interventions, 3) discuss the importance of addressing barriers, and 4) evaluate a study that explored the predictive value of depression and perceived barriers on adherence to diabetes self-care activities through an in-home diabetes management program. The health belief model is useful for understanding behaviors and was used as a theoretical framework for understanding barriers to diabetes management.

**Type 2 Diabetes**

Type 2 diabetes mellitus (T2DM) is a chronic condition characterized by the body’s inability to use insulin properly, resulting in higher than normal blood glucose levels (ADA, 2018). T2DM was previously differentiated from type 1 diabetes mellitus (T1DM) based on when it was diagnosed (i.e., in adulthood). However, T2DM may be diagnosed at any age. It was estimated that 30.3 million American’s had diabetes in 2015; 1.25 million had T1DM (“Statistics about Diabetes,” n.d.). In 2015, the Centers for
Disease Control and Prevention (CDC) suggested 90% to 95% of all cases of diabetes are attributed to T2DM. Those diagnosed with T2DM may experience symptoms such as frequent urination, excessive thirst, changes in vision, tingling or numbness in extremities, dry skin, and slow healing of wounds ("Diabetes Symptoms," n.d.). These symptoms can give rise to a myriad of serious health conditions. If left untreated, T2DM can result in heart disease, blindness, kidney failure, neuropathy, and amputations ("Type 2 diabetes," 2018). Additionally, those with diabetes are at an increased risk for mental health comorbidities such as depression and anxiety (Semenkovich, Brown, Svrakic, & Lustman, 2015).

There are many costs associated with diabetes and its accompanying health complications. The ADA reported the total cost of diabetes in 2012 was $245 billion with inpatient hospital care comprising 43% of the medical expenditures ("The Cost of Diabetes," n.d.). Diabetes confers both a physical and economic burden which impact individuals and society. Estimated medical expenditures for those diagnosed with diabetes is about $13,700 per year with $7,900 specifically related to diabetes ("The Cost of Diabetes," n.d.). Therefore, diabetes ensues a significant financial burden toward individuals and society.

**Who is Affected?**

There are several risk factors associated with the development of T2DM including obesity, age, physical inactivity, diets high in fat and sugar, race and ethnicity, menopause, and family history (ADA, 2018; Brand et al., 2013). Some specific risk factors are preventable while others are more difficult to address. For example, diabetes has a higher prevalence among minority individuals and those from lower socioeconomic
backgrounds (ADA, 2018). The risks for minority individuals and those from lower socioeconomic statuses are unlikely to change as upward social mobility is often hampered in those from low SES backgrounds (Narayan, Williams, Gregg, Cowie, & Teton Data Systems (Firm), 2011). Impoverished environments abound in low-income environments (e.g., lack of exercise facilities and parks in urban areas, food deserts) and low perceived self-efficacy in disease prevention contribute to barriers amongst those from lower socioeconomic statuses (Figaro, Elasy, BeLue, Speroff, & Dittus, 2009).

However, understanding and acknowledging one’s risk may be helpful in adopting preventative behaviors and navigating affordable health options. Addressing risk factors can create a space for intervention and reduce the likelihood of disease development.

**Treatment**

Many of the risk factors for T2DM noted previously can be controlled by adopting healthy lifestyle changes such as decreasing weight through physical activity and following a healthy nutrition plan. The ADA recommends that treatment includes “a patient-centered communication style that incorporates patient preferences, assesses literacy and numeracy, and addresses cultural barriers” (ADA, 2018). Commonly used interventions to improve diabetes knowledge include health education, didactic teaching, and direct instruction from a diabetes expert. However, research suggests standard diabetes education programs may be of limited value, particularly to those from disadvantaged populations who are more susceptible to diabetes and likely to experience more barriers (Pottie, Hadi, Chen, Welch & Hawthorne, 2013; Norris, Engelgau, Narayan, 2001). A systematic review on the effectiveness of diabetes self-management
training programs found self-management training was effective in improving knowledge of diabetes, blood glucose control, weight loss, blood pressure, cholesterol, and distress (Vas et al., 2017). Short educational and didactic interventions appear to be effective. However the effectiveness of interventions on sustained glycemic control remains in question, and long-term support for patients is likely needed for successful disease management.

While diabetes can be managed by changing lifestyle factors, it continues to be a pervasive condition. The ADA suggests T2DM is a global crisis on par with obesity. In 2015, an estimated 30.3 million people America had diabetes with 1.5 million Americans diagnosed with diabetes every year (“Statistics about Diabetes,” n.d.). Despite available interventions, there appear to be significant barriers affecting diabetes management.

**Diet.** The ADA created standards of care that contain a multitude of recommendations, some of which include nutrition, exercise, foot care, eye care, smoking cessation, and pharmacological interventions. When creating a treatment plan for diabetes, diet is of primary importance. In fact, it is widely understood that healthful eating is the foundation for treatment because it promotes healthy glucose levels and lessens the complications of the disease (Polikandrioti & Dokoutsidou, 2009). With that in mind, the ADA recommends individuals with T2DM follow a healthful eating plan which includes foods low in saturated and trans fat, low in salt and carbohydrates, lean protein, non-starchy vegetables, whole grains, healthy fats, and fruit (ADA, 2018).

Dietary interventions are often used in managing T2DM. A randomized controlled study used five hundred and ninety-three participants recently diagnosed with T2DM to compare the effects of no intervention (usual care), dietary intervention, and
dietary and physical activity on blood pressure and glucose concentration (Andrews et al., 2011). Participants in the dietary group received regular guidance from a dietitian regarding portion size, fat content, energy density, and glycemic index of foods. The dietary intervention sought to have participants lose 5-10% of their body weight and maintain this loss for the duration of the study. Participants in the diet and physical activity group received the same dietary intervention as the dietary group in addition to performing a brisk walk for at least 30 minutes at least five days per week. After six months and at the conclusion of the study (12 months) glycemic control was worse for the usual care group but improved in the diet and diet and physical activity groups. Analyses in this study indicated no additional benefits of physical activity in conjunction with dietary inventions suggesting that intensive dietary intervention alone can improve glycemic control (Andrews et al., 2011). Diet modification may be a useful and practical way to control T2DM in some cases. However, it is helpful to note that while physical activity was not found to have additional benefits over dietary interventions in this study, exercise has other health benefits that are relevant to diabetes management.

**Exercise.** Exercise is often recommended in conjunction with healthy eating. Specifically, it is recommended that adults with T2DM perform a minimum of 150 minutes of moderate-intensity aerobic physical activity each week. These activities are to be spread over at least three days throughout out the week with no more than two consecutive days of inactivity (ADA, 2018). In addition to guidelines for aerobic exercise, the ADA also has instructions for resistance exercise. Resistance exercise (e.g., free weights, weight machines) should be completed at least twice weekly (ADA, 2018).
It has been well established that regular exercise has benefits such as preventing T2DM (primary prevention) and improving blood glucose control in addition to improving blood pressure, reducing cardiovascular events, delaying mortality, and improving mood and quality of life (Colberg et al., 2010). Regular exercise can result in weight loss, which is of particular importance to those who are overweight and at risk for developing diabetes. In fact, Aune, Leitzmann, Tonstad, and Vatten (2015) conducted a meta-analysis to explore the relationship between physical activity and risk for T2DM. The meta-analysis was unique in that considered multiple types of physical activity including total physical activity (i.e., high vs. low), resistance exercise, low, moderate, and vigorous activity, occupational activity, cardiorespiratory fitness, and walking. The review indicated that each type of physical activity was associated with a statistically significant reduced risk of type 2 diabetes; 25-40% relative risk reduction. Another series of studies indicated that participants who were at high risk for developing diabetes and were unable to reduce their weight over a 5-6 year period were eventually diagnosed with diabetes, although a 5-7% weight loss can prevent the development of diabetes (Curtis & Wilson, 2005). While many studies have explored the impact of exercise on preventing or reducing the risk of T2DM, it is also important to consider the effect of exercise on those already diagnosed (secondary prevention efforts). Sigal et al., (2007) studied the effects of aerobic and resistance exercise on glycemic control. The study included 251 adults aged 39 to 70 diagnosed with T2DM. They discovered aerobic or resistance training alone created improvements in glycemic control. However, when both aerobic and resistance training were completed together, improvements in glycemic control were
more significant (Sigal et al., 2007). These results suggest exercise is a practical approach for preventing T2DM, as well as benefiting those already diagnosed.

**Blood glucose monitoring.** In addition to a healthy diet and regular exercise, maintaining glycemic control is imperative to effective diabetes management. Individuals can monitor their blood glucose in two ways: at home using a blood glucose monitor or at a medical appointment through laboratory blood work. The blood glucose monitor allows those with diabetes to monitor their blood glucose levels by pricking their finger to produce a droplet of blood. The blood is absorbed on a disposable test strip inserted into the machine. The machine then reports a number in units of mg/dl to indicate how much glucose is concentrated in the blood. The frequency at which blood sugar should be checked varies from person to person. Blood sugars may need to be tested postprandial (i.e., following a meal) to determine if the correct amount of insulin was prescribed. Additionally, people may check blood sugars after fasting or randomly to look for drastic changes in blood sugar levels (“Checking Your Blood Glucose,” 2018). The Hemoglobin A1C (HbA1c) is a blood test typically conducted in a medical clinic that measures average blood glucose level over a 3-month period (“A1C and eAG,” 2014). The ADA considers both of these tests as part of its standards of care and recommends patients with T2DM check their blood glucose levels at least twice per day (ADA, 2018), although primary care providers may use different standards (e.g., random blood glucose testing or more frequent testing). Self-monitoring blood glucose allows those with diabetes to understand the effect of diet, exercise, medications, and stress on blood sugar levels, providing opportunities to intervene.
**Medication.** When dietary and exercise modifications are not enough to adjust blood glucose levels, medications may be required. A significant proportion of patients diagnosed with T2DM are prescribed drugs to manage insulin resistance or remove excess glucose. The ADA states in high-risk patients (i.e., obese, severe/progressive hyperglycemia, rising HbA1C despite lifestyle changes) medications may be recommended (ADA, 2018). Common medications include: Metformin, which improves body tissue sensitivity to insulin; sulfonylureas, which are a class of drugs that help the body secrete more insulin; meglitinides, which stimulate the pancreas to secrete more insulin; thiazolidinediones, which are similar to Metformin in making the body’s tissue more sensitive to insulin; DPP-4 inhibitors, which help reduce blood sugar levels; GLP-1, which slows digestion to lower blood sugar levels; and SGLT2 inhibitors, which prevent the kidneys from reabsorbing sugar into the blood. Lastly, some patients require insulin therapy, which is administered by injections (“What Are My Options,” 2015). Insulin was once considered a last resort but is now prescribed earlier in some individuals (ADA, 2018). For many persons with T2DM, medication is an essential tool in gaining glycemic control, although adequate diabetes control through diet, weight loss and exercise can lead to a reduction in the need for medication.

**Adherence**

Adherence can be defined as the extent to which a patient accurately abides by medical advice (Au & Feemster, 2017). A diagnosis of T2DM can be challenging as individuals need to change their health behaviors by monitoring blood glucose levels, remembering to take medication, integrating exercise into their lives, and keeping track of appointments with specialists (e.g., podiatrists, dietitians, ophthalmologists). Managing
various treatment recommendations is demanding and requires organization, time, and motivation (Whittemore, 2000). These recommendations must be followed daily to be optimally effective (Cox & Gonder-Frederick, 1992). Patients who have good self-care behaviors should be able to accomplish glycemic control. On the other hand, those who are unable to manage self-care behaviors often struggle to maintain glycemic control, leading to the development of additional health problems. The diverse nature of diabetes self-care recommendations may be the cause of poor adherence among those with T2DM.

In fact, non-adherence rates for chronic illness and lifestyle changes are approximately 50%, with those diagnosed with diabetes experiencing significant difficulties with adherence (Haynes, Taylor, & Sackett, 1979; Kurtz, 1990). The following paragraphs will highlight adherence challenges and consequences to common diabetes recommendations and treatments.

**Dietary adherence.** Patients who adhere to dietary recommendations can expect more significant reductions in HbA1c compared to patients who do not adhere (Delahanty & Halford, 1993). However, adopting a permanent nutritional regimen can be challenging. Researchers suggest following a healthy diet is the most challenging aspect of T2DM management (Nagelkerk, Reick, & Meengs, 2006; Sullivan & Joseph, 1998). In the National Health and Nutrition Examination Survey of 998 community-dwelling adults, the proportion of adults who followed the ADA dietary recommendations for protein, saturated fat, unsaturated fat, and fiber consumption were 64, 48, 28, and 18.3% respectively (Resnick, Foster, Bardsley, & Ratner, 2006). Aside from protein, all other dietary recommendations were followed by less than 50% of those participating in the study. Given the effectiveness of dietary modifications on glycemic
control, high levels of non-adherence demonstrate the need to consider barriers to adherence to maximize the effectiveness of interventions and increase the quality of life among those with T2DM.

**Exercise adherence.** Integrating exercise into one’s daily routine also appears to be a difficult task. A study evaluating resistance and aerobic exercise among adults with diabetes estimated that only 51.5% of adults in the general U.S. population meet the ADA recommended guidelines for aerobic exercise. Even more alarming, is among those with diabetes, only 41.1% met ADA guidelines for aerobic activity (Mu, Cohen, & Mukamal, 2014). Regarding resistance exercise, 12.4% of those with diabetes met ADA guidelines (Mu, Cohen, & Mukamal, 2014). Exercise rates among people diagnosed with diabetes are especially troubling provided the benefits of regular physical activity on both diabetes and mood symptoms.

**Blood glucose monitoring adherence.** Up to 67% of patients with diabetes fail to consistently assess their blood glucose levels (Harris, Cowie, & Howie, 1993). The authors found deficits in blood glucose monitoring related to race, educational status, diabetes education, and the number of physician visits. Insurance and income appeared to affect noninsulin dependent diabetes mellitus but not for insulin-dependent diabetes or those with noninsulin-dependent diabetes who were not treated with insulin (Harris, Cowie, & Howie, 1993). Awareness, of blood glucose values, is imperative for acknowledging and preventing symptoms of hyperglycemia and hypoglycemia. Another study revealed 24% of those treated with insulin, 65% of those taking oral medications, and 80% of those treated exclusively with diet and exercise never monitored their blood glucose or did so less than once per month (Harris, 2001). Adherence rates are
problematic as glycemic control is crucial to effective diabetes management and self-monitoring through blood glucose testing is an essential component in a diabetic care regimen.

**Medication adherence.** As with the other diabetes self-care recommendations, adherence to medication recommendations is relatively low. A review of adherence to oral hypoglycemic agents in those diagnosed with T2DM revealed a wide range of adherence between 36-93% (Cramer, 2004). Regular medication usage, in addition to lifestyle changes, is a critical step in preventing symptoms related to changing blood glucose levels. This wide range has been connected to varying methodological designs. A recent meta-analysis found only 67.9% of participants diagnosed with T2DM prescribed oral antihyperglycemic agents were considered to be adherent across twelve studies (Iglay et al., 2015). Poor medication adherence is related to poor glycemic control and has significant deterrents to those experiencing T2DM and society at large. For example, results from the National Health and Wellness Survey, which included 1,198 participants with T2DM, suggested every one unit drop in self-reported medication adherence was related to increases in HbA1c (0.21%), physician visits (4.6%), emergency room visits (20.4%), and hospital visits (20.9%) (DiBonaventura, Wintfeld, & Huang, 2014). These services have associated financial costs to both individuals experiencing T2DM and society. Polonsky and Henry (2016) identified six factors which contribute to poor medication adherence: perceived treatment efficacy, hypoglycemia, treatment complexity and convenience, cost of treatment, medication beliefs, and physician trust. All of these factors are deemed to be amenable to change to increase medication adherence. Perceived
treatment efficacy and medication beliefs are particularly relevant to the present study and will be explored broadly in the following paragraphs.

**Psychological co-morbidities.** Those diagnosed with diabetes have a higher likelihood of developing depression or its associated symptoms (Ali, Stone, Peters, Davies, & Khunti, 2006). In one recent study, rates of depression in primary care patients with pre and type 2 diabetes who were receiving services in federally qualified health centers was over 67% (Renn, Obetz, & Feliciano, 2018). This rate is much higher than previously reported rates of 17.8-39% in a systematic review of depression and diabetes (Roy & Lloyd, 2012), highlighting the need for depression screening in these settings.

Adhering to diabetes recommendations can be further complicated by comorbid psychological conditions such as depression. In a study exploring diabetes self-care, adherence, and health care costs, Ciechanowski, Katon, and Russo (2000) found severity of depressive symptoms were related to poor diabetes self-care, functional impairment, and higher health care costs. Furthermore, a meta-analysis found that depression was significantly associated with non-adherence to self-care recommendations in those with T1DM and T2DM. Specific analyses looking at the effect of depression by self-care type revealed that the most substantial impact was found for missed medical appointments (Gonzalez et al., 2008). It is common for those experiencing depression to have decreased energy and to withdraw from social engagements these factors may account for the lack of adherence to medical appointments. While many researchers have explored the links between mental health disorders and T2DM self-care behaviors, others have sought to examine how mental health disorders impact perceptions of T2DM. Paschalides et al. (2004) studied 184 participants with T2DM and found depression was related to higher
perceived symptom load, poorer anticipated consequences, and perceived lack of control of T2DM. These factors were concluded to influence physical and mental functioning but did not appear to affect metabolic control.

While depression is commonly seen in those with T2DM, T2DM often co-occurs with other psychological disorders such as anxiety disorders. Multiple psychological co-morbidities in conjunction with T2DM can create complicated barriers to adherence of T2DM recommendations. Ducat, Philipson, and Anderson (2014) suggest anxiety disorders influence T2DM management in three ways: (1) symptoms of anxiety can overlap with symptoms of hypoglycemia, which blurs the lines between psychological and medical intervention; (2) anxiety related to needles may exacerbate anxiety symptoms upon T2DM diagnosis contributing to severe anxiety or panic disorder; (3) fear of hypoglycemia may cause patients to maintain blood glucose levels above suggested target levels. Psychological co-morbidities can make adherence more challenging for those with diabetes and should be considered when addressing diabetes management concerns.

**Barriers**

To improve patient adherence, researchers sought to explore why non-adherence to diabetes recommendations occur. This issue can be viewed from two perspectives: the patient and the provider. The following paragraphs will detail specific barriers from both the patient and provider side, explicitly considering psychological and social influences, along with provider, medical system, and treatment considerations.

**Provider perspectives on patient barriers.** Patients can experience many barriers, which impede their ability to manage their diabetes effectively. A study
exploring the views of healthcare professionals on the causes of dietary nonadherence identified five barriers including: complications with lifestyle/competing demands, denial/perception that diabetes is not serious, poor understanding of the diet/disease relationship, lack of self-efficacy, and misinformation from unreliable sources (Williamson, Hunt, Pope, and Tolman, 2000). The majority of participants (73%), who were registered dietitians in direct contact with diabetic patients, endorsed time constraints as the primary cause of complications with lifestyle/competing demands followed by lifestyle choices (including eating out), finances, portion control, and unwillingness to make permanent changes. Denial/perception that diabetes is not serious was primarily attributed to being asymptomatic (39%) in addition to lack of education/understanding, denial of diabetes, ineffective communication by the medical doctor, and previous experiences with others diagnosed with diabetes. Dietitians indicated a lack of education (59%) led diabetes clients to experience poor understanding of the diet/disease relationship. Misinformation, complicated instructions, denial, and feeling overwhelmed also influenced a poor understanding of a healthy diet. Lack of self-efficacy was related to poor self-esteem (39%), feeling out of control, lack of education, lack of support/feedback, and psychological issues. Lastly, misinformation from unreliable sources consisted of information gathered from family/peers/others with diabetes (79%), media, health food stores, and other health professionals (Williamson, Hunt, Pope, and Tolman, 2000). While the Williamson et al. study focused on barriers to dietary compliance, many of the causes of barriers can be extrapolated to other diabetes management areas. For example, exercise, blood glucose testing, and access to treatment. The majority of existing literature focuses on providers perceptions of patient barriers to
adherence. The lack of research focused on patient perspectives highlights a gap in the current literature base.

**Barrier 1: Complications with lifestyle/competing demands.** McEwen et al. (2011) explored how competing demands for time influenced diabetes management behavior in 5,478 adults with diabetes. They assessed four types of competing demands: those without caregiving or employment responsibilities, those with caregiving demands only, those with employment responsibilities only, and those with both caregiving and employment responsibilities. The findings suggested men and women with employment responsibilities had poor diabetes self-care behaviors (e.g., physical activity, foot self-care, self-monitoring blood glucose) and poor processes of care (e.g., eye exams, foot exams, assessments of glycemic control, immunizations) lending evidence to competing demands as a significant barrier to diabetes management.

Lack of financial resources also constitutes a complicated lifestyle demand. In fact, the cost of diabetes management is a substantial barrier for some patients. Adults diagnosed with diabetes who are uninsured or underinsured experience poorer health care compared to those with insurance (Nelson, Chapko, Reiber, & Boyko, 2005). Many factors contribute to poor diabetes management among the uninsured specifically, costs related to healthy foods and limited access to those foods (i.e., food deserts), limited access to primary care providers (e.g., due to availability of those providers or to lack of reliable transportation to appointments), and high costs of medications and blood glucose testing supplies (Davidoff, 2005; Glazier, Bajcar, Kennie, & Willson, 2006; Nam et al, 2011; Robbins, Thatcher, Webb, & Valdmanis, 2008).
Barriers 2 and 4: Denial/perception that diabetes is not serious and lack of self-efficacy. The literature examining the perception of risk is quite limited. However, one study explored diabetes knowledge, perceptions, and behavior among those with and without diabetes in addition to those at risk, in the context of assessing the effects of the National Diabetes Education Program (Piccinino, Griffey, Gallivan, Lotenberg & Tuncer, 2015). Surveys were used to measure perceptions of risk amongst a U.S. adult population, which included those at risk for diabetes and those with prediabetes. Participants were asked whether they felt as though they were at risk, why they felt at risk, and how they could reduce their risk. The results indicated knowledge of diabetes remained high over a 5-year period, but perceived risk remained low excluding those with prediabetes. Only 26% to 27% of people at risk for diabetes felt they were at risk for developing diabetes. The rates of perceived risks are problematic as many theories consider perceptions a core part of behavioral modification. However, Hivert, Warner, Sharader, Grant, and Meigs (2009) discovered high perceived risk was not associated with attempts to make healthy lifestyle choices. These findings suggest there are more contributors to lifestyle change than risk, for example, the complexity of self-care activities such as diet and exercise should be considered. The previous studies lend evidence to support perceptions as a barrier to initiation and adherence to diabetes self-care activities.

Self-efficacy is an essential part of diabetes management. As research supports, if one does not believe in their ability to perform a diabetes management task, it may be more difficult for them to follow through with the task. Specifically, Aljasem, Peyrot, Wissow, and Rubin (2001) found higher self-efficacy predicted more engagement with
self-care activities such as frequent blood glucose testing, less missed medications, less binge eating, and closer adherence to the diet.

**Comorbidities.** Given the bidirectional relationship between diabetes and depression (Renn, Feliciano, & Segal, 2011) and its high prevalence, identifying depression through screening has been emphasized as a part of diabetes care and treatment (ADA, 2015). Despite these recommendations, a national survey consisting of 33,653 physician-patient encounters in primary care settings suggested depression screening rates were low (4.2%) and whether or not an individual was screened varied by race, age, and pain status (Akincigil & Matthews, 2017). Furthermore, providers may not be comfortable implementing counseling to manage depressive symptoms (Peyrot, Rubin, & Siminerio, 2006).

In addition to psychological comorbidities, many people with diabetes commonly experience medical comorbidities such as obesity, dyslipidemia, hypertension, chronic kidney disease, and cardiovascular disease. One study exploring barriers to self-care of those with comorbid chronic diseases found participants reported barriers including augmentation of one condition by symptoms of another, problems with medications (adverse effects), and feeling overwhelmed by prevailing conditions (Bayliss, Steiner, Fernald, Crane, & Main 2003). Comorbidities can become a significant barrier to patients and should be addressed by healthcare professionals.

**Barrier 3 and 5: Poor understanding of the diet/disease relationship and misinformation.** Health information can be obtained from a variety of sources. Information is often sought from health care providers, family, friends, newspapers and magazines, and more recently, the Internet. With all these sources in mind, the accuracy
and quality of health information vary substantially. Furthermore, one study by Mann and colleagues demonstrated low-income minorities with diabetes had knowledge and beliefs about diabetes that were inconsistent with current diabetes knowledge and recommendations. A large proportion of the participants had misunderstandings about what is considered a high or low blood glucose level, treatment, symptoms, and disease monitoring (Mann, Ponieman, Leventhal, & Halm, 2009). A qualitative study on Swedish patients with T2DM found common themes of misconceptions. For example, participants appeared to see T1DM as the “real” diabetes. A high number of participants reported they had no feeling of symptoms during high or low blood glucose values, which led them to believe they were not ill. Not experiencing symptoms during high and low blood glucose levels also caused participants to see values on the glucose monitor as not related to symptoms associated with T2DM. Many participants were aware of some diabetes complications; however, some participants did not recognize their current experience with complications. Lastly, there were common misconceptions related to diet and medication (Holmström & Rosenqvist, 2005). Lack of knowledge about diabetes and misconceptions are barriers that can result in poor management. They are problematic as they affect how one views and engages with diabetes self-care activities. On the other hand, those with knowledge do not necessarily engage in proper self-care behavior. Many people have knowledge of their risks yet continue to engage in poor self-care behavior (Avis, McKinlay, & Smith, 1990). Thus, suggesting that knowledge is an important but insufficient factor when explaining difficulties with diabetes self-care activities. Other factors such as the complexity of self-care activities must be considered.
**Provider factors.** An abundance of information on diabetes self-care focuses on the patient; however, providers play a significant role in diabetes management. Therefore, it is vital to explore barriers providers experience when treating those with diabetes.

**Systematic barriers.** As a result of systematic constraints, providers often have to be goal-oriented to maximize their 15 to 20-minute interaction with the patient. These time constraints make it difficult to provide comprehensive diabetes care.

The ADA Standards of Medical Care in Diabetes calls for a holistic approach to diabetes care which includes education and counseling. Peyrot, Rubin, Lauritzen, Snoek, Matthews, and Skovlund (2004) examined patient and provider perspectives on psychosocial barriers and found providers recognized psychological problems but felt they did not have the resources to mitigate these problems. In fact, only 10% of patients included in that study received psychological treatment. These findings are concerning given the impact of comorbidities on diabetes self-care activities. Providers may lack resources (e.g., adequate time to assess/screen for mental health conditions) or may lack appropriate skills and knowledge to manage mental health conditions, which commonly occur in conjunction with diabetes.

Providing comprehensive diabetes care is further complicated by insurance. Exploring reimbursement as a barrier, Pozniak, Olinger, and Shier (2010) reported physicians perceived reimbursement for diabetes services as low, which limited the amount of time spent with patients. Thus, providers experience financial barriers when insurance reimbursement limits their capacity to provide proper diabetes education to patients.
**Communication.** Diabetes management requires not only lifestyle changes but also improved patient-provider relationships (Kruse et al., 2013). Inadequate communication between providers and patients has been associated with poorer glucose control (Daly et al., 2009). Young, Azam, Meurer, Hill and Cui (2016) advocate for a patient-centered approach to care which has the potential to enable and empower patients to effectively navigate the health care system and make health care decisions. Inadequate rapport with health care professionals may limit patient requests for information and inquiries leading to a weaker understanding of diabetes and its management.

**Knowledge/adherence.** The majority of patients with diabetes seek care from their primary care providers. However, the quality of diabetes care by primary care providers may be insufficient. In fact, the CDC suggest less than 5% of patients with diabetes receive care in alignment with the ADA (CDC, “Basics about Diabetes,” 2015). One study found adherence rates to diabetes guidelines among primary care physicians in rural areas to be low; 15% for foot exams, 20% for HbA1C, 23% for eye exam referrals, 33% for urine protein screens, 44% for lipid profiles, 78% for home glucose monitoring, and 78% for blood pressure measurements (Kirkman, Williams, Caffrey, & Marrero, 2002). These numbers are of concern to those with diabetes who rely on primary care providers for care. Overall, there is a lack of literature examining provider acceptance of or adherence to ADA standards in the United States.

To sum, there appears to be a significant gap between diabetes management recommendations and adherence. The barriers patients and providers experience in managing diabetes self-care are well-documented. However, there is limited research
exploring how diabetes patients perceive barriers and whether or not perceptions influence participation in diabetes self-care activities.

**Theoretical Framework**

Those who engage in diabetes self-care are less likely to require additional intervention; therefore, it is important to explore the challenges faced by those who have difficulties with self-care activities to improve our interventions. Individual barriers can result from social factors such as socioeconomic status, cultural beliefs, perception of disease, and accessibility to health services. Additionally, it is crucial to consider barriers related to cognitive factors such as knowledge of disease/risks, self-efficacy, control, and beliefs. Cognitive factors can be used to explore why people with similar backgrounds (e.g., socioeconomic status, education, diagnoses) vary in engagement with health behaviors. Social cognitive models, which examine how cognitive factors influence social behaviors, emerged to understand variations between individuals’ involvement in specific behaviors. Several models have been proposed, and many are used to predict health behaviors.

The transtheoretical model, theory of planned behavior, and health belief model are commonly cited, social cognitive models. However, each of these theories has its strengths as well as its limitations. The transtheoretical model posits that behavioral health change occurs as one moves through five stages of change (Prochaska & DiClemente, 1984). The first stage, *precontemplation*, is when a person has not decided to change or is unaware change is needed. Following precontemplation, is stage two, *contemplation*. At this stage, one is intending to change and weighing the pros and cons before fully committing to change. The third stage is *preparation*, people are preparing to
take action and may start informing others of their plan to change. Action, stage four, is when people have made the change to their behavior. The final stage maintenance is when one has changed their behavior and maintained this behavior change for over six months. Relapse is also a part of the stage change process. It occurs when a person has stopped a particular unhealthy behavior over a period and then resumes that behavior in the maintenance stage. Relapse often results in one returning to an earlier stage in the model. However, all progress is not lost in the event of a relapse. The transtheoretical model has been applied to many different health behaviors. However, it has been criticized as human behavior is too variable to be constrained by discrete stages (Bandura, 1997). Additionally, some suggest the six-month period was arbitrarily decided and that it operates under the assumption that people are thinking about behavioral change half a year in advance (Kraft, 1999). In their review consisting of 87 articles, Littell and Girvin (2004) discovered many findings in which stages did not seem to be independent of each other and that moving through stages consecutively was rarely documented. Overall, the utility of the transtheoretical model was found to have limited practical use due to concerns with validity (Littell & Girvin, 2004). As a result of the lack of clarity between stages and the limited practical utility, the transtheoretical model may not be the best fit for understanding the complex nature of diabetes self-care activities.

The theory of planned behavior (TPB), an extension of the theory of reasoned action, a theory that states increased intentions lead to increased likelihood of performing a behavior, suggests three factors influence one’s intention to perform a given behavior: behavioral, normative, and control (Ajzen, 1985). Behavioral beliefs consist of one’s positive or negative beliefs toward the behavior. Social pressures can lead to normative
beliefs about behavior, which are centered around the expectations of others. Lastly, control beliefs are beliefs one has about what would facilitate or impede the behavior. Aggregated from these three factors are attitudes toward the behavior, subjective norm, and perceived behavioral control. All these factors contribute to one’s intention to implement behavioral change. Meta-analyses have suggested the theory of planned behavior can explain 19-36% of the variance in health behaviors (Rich, Brandes, Mullan, & Hagger, 2015). However, Sniehotta (2009) explains the research using TPB over the past thirty years has not resulted in any changes to the theory regarding modifications, extensions, or abandonment; suggesting the theory is useful or, the research on this theory is not stringent. Sniehotta (2009) points out many correlational studies on the TPB but states randomized experiments are relatively rare. In her experimental study, Sniehotta (2009) found support for building intention to perform a behavior but found behavior change outcomes were inconsistent with the TPB. Lastly, TPB has been critiqued for the exclusion of emotional influences on behavior. However, the necessity of an emotional component is primarily debated among scholars. Mixed results and inconsistent measures of the TPB make it difficult to ascertain its utility in behavioral changes and interventions.

Of importance to the present study, the transtheoretical model and theory of planned behavior do not clearly account for the perceived barriers one may be experiencing when attempting to engage in specific health behaviors. However, other models may offer more explanatory power. For example, the next section will describe the health belief model as well as explore its strengths and limitations.
Health Belief Model

The health belief model (HBM) (Hochbaum, Rosenstock, & Kegels, 1952) is a theoretical framework created to understand and predict health behaviors. This model weighs perceived threats and benefits to pursuing health-related behavior by operating under three assumptions: (1) the individual feels an adverse health outcome can be avoided (2) the individual expects by taking action he or she will prevent a negative health condition (3) the individual believes in his or her ability to follow through with the recommended health behavior. Additionally, the HBM uses four constructs: (1) perceived susceptibility (2) perceived severity (3) perceived benefits (4) perceived barriers to determine one’s “readiness to act.” The model was later expanded to include “cues to action” and self-efficacy. The starting point is perceived susceptibility or one’s estimation of the probability of acquiring a condition. Perceived susceptibility is followed by perceived severity, which is one’s opinion of the seriousness of a disease and its consequences. Both perceived susceptibility and perceived severity can be influenced by outside factors such as age, race, ethnicity, and SES. Cues to action, for example experiencing symptoms related to diabetes, can affect one’s perceived severity. Lastly, perceived benefits are one’s judgment that the advised action will lessen the risk. Perceived barriers are one’s opinion of the physical and psychological expenses of the recommended action. Benefits and barriers contribute to one’s likelihood of changing his or her behavior.

Strengths/limitations. Two reviews have examined the utility of the health belief model. Janz and Becker (1984) reviewed 46 studies using the HBM from 1974 to 1984. Considering different dimensions of the HBM, Janz, and Becker created a significance
ratio by dividing the number of studies with significant findings by the number of studies within a given dimension. The results revealed percentages of how often each of the four constructs was significant. Across all relevant studies, susceptibility was significant 81% of the time, severity 65%, benefits 78%, and barriers 89%. In addition to considering all the studies together, the researchers looked at prospective and retrospective studies. In the prospective studies the significance ratios were found to be even higher: susceptibility 82%, severity 65%, benefits 81%, and barriers 100%. The results indicated barriers were the most reliable predictor of behavior. Additional analyses found barriers to be a significant predictor of preventive behavior and sick role behaviors. Overall, this review provided evidence in support of HBM predictions. However, the vote count method has been criticized as it only accounts for how often HBM constructs were significantly related to behaviors rather than effect sizes. Another limitation of the vote count method is that it only accounts for published papers, which may be a biased index.

The second review of the HBM was conducted by Harrison, Mullen, and Green (1992). The meta-analysis of 234 studies revealed only 6.8% of the studies measured all four HBM constructs. This review highlights a chasm amongst HBM researchers. Some researchers believe the HBM constructs must be considered together rather than measured independently, while others feel the constructs can operate individually and advocate for operationalization and standardization of these constructs (Weinstein, 1988). Harrison et al. (1992) performed analyses by converting HBM constructs and their relationship with behavior measures into meaningful effect sizes. By creating weighted averages, researchers found the four HBM constructs to have statistically significant effect sizes: 0.15, 0.08, 0.13, and 0.21 (susceptibility, severity, benefits, and barriers
respectively). While these effect sizes were found to be significant, they are relatively small (Cohen, 1988). The effect sizes, however, were larger for benefits and barriers in prospective studies as well as for severity in retrospective studies. Harrison et al. (1992) reported the effect sizes showed heterogeneity and that differences in measurement and construct conceptualization may have impacted the results. It has been suggested that the researchers should have combined all the constructs rather than consider them independently to see a potentially large effect. Overall, there is some evidence to support the utilization of HBM constructs; however, standard operationalization, reliability, and validity are important considerations in future research.

Initially proposed to explore preventative health behaviors, the health belief model has been extended to a wide range of health activities. However, there appears to be limited research using the health belief model as a framework for exploring diabetes self-care activities. The broad search terms “health belief model” and “type 2 diabetes” were inputted into CINAHL Plus, PubMed, and PsycINFO to determine existing literature on this topic. The results of the search were narrow and limited to only a few studies explicitly measuring adherence. These studies are reviewed in the following paragraphs.

To understand predictors of adherence to diabetes self-care behavior among women with T2DM, Karimy, Araban, Zareban, Taher, and Abedi (2016) provided 210 Iranian women with a 33-item health belief model questionnaire. The responses to this questionnaire were used to predict adherence to diabetes self-care activities using the revised Summary of Diabetes Self-Care Activities. The researchers discovered 59.9% of the variance in self-care behaviors could be explained by the HBM constructs with the
inclusion of self-efficacy and exclusion of severity. Each construct was a significant predictor of self-care behaviors with self-efficacy as the most influential predictor. This study provides supporting evidence for the HBM with a particular emphasis on self-efficacy as a predictor of adherence to diabetes self-care activities. However, the authors did not provide a rationale for excluding severity, a core part of the HBM. Additionally, many other HBM studies do not measure self-efficacy, which was later added to the HBM.

Dehghani-Tafti et al. (2015) also studied the predictive utility of the health belief model on diabetes self-care activities. This study included individuals who were insulin dependent. Contrary to previous research, they included a separate measure for each HBM construct. Perceived self-efficacy and social support were also measured. The Toobert and Glasgow’s Scale of Diabetes Self-Care Activities (SDSCA) was used to measure self-care activities. The researchers concluded constructs within the health belief model predicted 33.5% of the variance in self-care behaviors. Self-efficacy, perceived susceptibility, and barriers were the most significant predictors of self-care activities.

Lastly, Koch (2002) conducted a study to explore differences in health beliefs between 31 African-American women with T2DM who exercise compared to those who do not exercise. A 32-item health belief model diabetes scale was revised to assess health beliefs and adherence to exercise. Women who exercised regularly reported fewer perceived barriers and greater perceived benefits to exercise compared to women who did not exercise regularly. Barriers and benefits to exercise were significantly different between the exercise and no exercise groups suggesting health beliefs are connected to exercise adherence.
To sum, many studies have provided support for the health belief model; however, a significant portion of studies choose HBM constructs at random without giving a rationale rather than utilizing the whole model. Regarding diabetes self-care adherence, there is a limited amount of research. Additionally, few studies were conducted in the United States. The lack of research in the United States is of concern as the United States has a high prevalence of diabetes cases in comparison to other counties. Lastly, many of the studies contained a mix of men and women, socioeconomic classes, and insurance statuses which made results unclear and difficult to generalize.

The purpose of the present study is to determine if perceived participant barriers and depression can predict adherence to diabetes self-care in an in-home diabetes management program among lower socioeconomic adults living in the United States. It is hypothesized that higher levels of perceived barriers (as measured by the Diabetes Self-care Education Programme Situations Checklist), and higher levels of depression (as measured by the The World Health Organization’s 5-item Well-Being Index), will predict lower levels of adherence to diabetes self-care activities.
CHAPTER II

METHOD

Participants

Participants were recruited from Peak Vista Community Health Center (PVCHC), a federally qualified health center located in Colorado Springs, Colorado as part of a more extensive randomized controlled study on diabetes management. The majority of PVCHC patients are those from lower socioeconomic statuses who tend to be uninsured or underinsured. In 2015, 68% of PVCHC patients used Medicaid, 15% used no insurance, 10% used Medicare, and 2% used child health plan (CHP). Overall, 71% of patient income levels were at or below 200% of the federal poverty level (“Peak Vista Community Health Centers,” 2015). Of the patients seen at PVCHC, 44% identified as Caucasian, with 27% identifying as Hispanic, 8% identifying as African American, and 21% identifying as other (“Peak Vista Community Health Centers,” 2015). As part of the larger study participants were recruited from diabetes health education classes offered at PVCHC or through provider referral.

Measures

Perceived Barriers

The Diabetes Self-care Education Programme Situations Checklist (Glasgow, 1994) is a 31-item questionnaire used to assess perceived barriers participants experienced with diabetes self-care activities. The questions ask about potential situations that may make it more difficult for the participant to follow through with diabetes self-
care recommendations. Specifically, the question asks, “how often does each of the following happen to you?” Participants indicated their answers using Likert scale response options with 1 (very rarely or never), 2 (once per month), 3 (twice per month), 4 (once per week), 5 (twice per week), 6 (more than twice weekly), 7 (daily), and 0 (does not apply to me). The measure is divided into six subscales including barriers to diet, exercise, glucose test, medication, general barriers, and overall all score. The questions that correspond to a particular subscale are added to produce a score in that domain. Barriers overall scale is the average score for all 31 items. The present study will use subscale scores in the diet, exercise, blood glucose testing, and medication domains for analyses.

**Diabetes Self-Care**

The Summary of Diabetes Self-Care Activities (SDSCA; Toobert, Hampson, & Glasgow, 2000) is a questionnaire which uses a 7-point Likert scale, 0 (zero days) to 7 (every day), to assess patient’s self-report of how often they performed specific diabetes self-care recommendations during the past seven days. Higher scores are related to higher adherence to diabetes self-care activities. The first part of the measure includes 11 items concerning perceived adherence in the areas of diet (four items), exercise (two items), blood sugar testing (two items), foot care (two items), and smoking (one item, yes or no response). The second part of the scale explores whether or not the patient was advised to do commonly recommended diabetes activities by his or her healthcare team. The patient uses a check mark to indicate if they have previously received the advice (four items consisting of multiple sub-questions). The final ten items explore diet, medication, foot care (Likert), and smoking (yes or no and checklist) more specifically. A mean score is
computed for each scale (general diet, specific diet, exercise, blood-glucose testing, foot care, and medications). The SDSCA has been found to be reliable and valid leading to its extensive use in research and practice (Toobert, Hampson, & Glasgow, 2000). Internal consistency of the scales, computed by average inter-item correlations, was deemed acceptable ($M = .47$), excluding specific diet. Additional studies examining inter-item correlations ranged from .20 to .76 (Weinger, Butler, Welch, & La Greca, 2005). Moderate test-retest correlations over 3-4 months, analyzing multiple studies, ranged between .40 and .78. Furthermore, correlations with other diet and exercise measures upheld the validity of the SDSCA subscales ($M_r = .23$) (Toobert, Hampson, & Glasgow, 2000). Toobert and Glasgow (1994) used factor analyses to assess the SDSCA. The results suggested the three-factor structure (diet, exercise, and blood glucose testing) accounted for 70-80% of the variance; with diet items loading onto the diet factor, exercise items loading onto the exercise factor, and blood glucose items loading onto the blood glucose testing factor. Only SDSCA variables related to Glasgow barrier subscales were retained for analyses. Therefore, SDSCA footcare items and the smoking item were not included in the analyses.

It was hypothesized that those who score high on The Diabetes Self-Care Education Programme Situations Checklist subscale barriers (i.e., diet, exercise, glucose, and medication) will score lower in corresponding SDSCA subscale measures. For example, those who endorse barriers to diet on The Diabetes Self-care Education Programme Situations Checklist are predicted to have a lower score on SDSCA diet scales.
Depression

The World Health Organization’s 5-item Well-Being Index (WHO-5; WHO, 1990) is a screen for depression created to be used in a variety of clinical settings. The five items correspond to mood, interest in activities, and energy. Items are scored based on how often the participant feels he or she has experienced the indicated item 0 (all of the time), 1 (more than half of the time), 2 (less than half of the time), 3 (at no time), with the exception of item one “I feel downhearted and sad” which is reverse scored. A score less than or equal to 9 is considered clinically significant. Scores can range from 0 to 15 with lower scores representing higher depressive symptomology. The WHO-5 appears to have sound psychometric properties and is a sensitive and specific screening tool for depression (Topp, Winther, Østergaard, Søndergaard, & Bech, 2015).

Cognition

The Saint Louis University Mental Status Examination (SLUMS; Tariq, Tumosa, Chibnall, Perry, & Morley, 2006) is an 11-item brief cognitive screening tool. The maximum score is 30 and scores lower than 26 are indicative of cognitive impairment. The tool assesses multiple domains of cognition including, executive function, visuospatial, attention, language, and memory. The SLUMS has demonstrated improved psychometric properties compared to the Mini-Mental State Examination (MMSE) in veteran and civilian samples (Feliciano, Horning, Klebe, Anderson, Cornwell & Davis, 2013). Additionally, the SLUMS showed high specificity and sensitivity across high and low educational groups (76% and 95% in high educated sample and 81% and 92% in low educated sample) (Tariq Tumosa, Chibnall, Perry & Morley, 2006). The SLUMS was collected as part of the demographics for the purposes of this study.
**Procedure**

Participants were enrolled as part of a greater on-going study exploring the effectiveness of an in-home diabetes management program compared to treatment as usual. A research assistant contacted interested participants by phone to schedule an intake appointment. At the intake appointment, participants heard about the study in more detail and questions and concerns were addressed. During the intake appointment, the research assistant provided informed consent, and eligible participants provided HIPPA authorization. HIPPA authorization grants permission for the researcher to access the participant’s PVCHC medical record in order to collect demographic and other relevant medical information in addition to recording study-related outcomes. Participants were asked to provide permission to record sessions to ensure treatment fidelity and monitor the progress of therapy. As part of the parent study, a number of measures are given at intake and at individual treatment sessions (described elsewhere; see Steers, Renn, & Feliciano, 2014). Of particular interest to this study are the measures given at the first active treatment session, which includes diabetes self-care activities (SDSCA; Toobert, Hampson, & Glasgow, 2000), mood (WHO-5; WHO, 1990 and ORS; Miller, Duncan, Brown, Sparks, & Claud, 2003), barriers (Diabetes Self-care Education Programme Situations Checklist; Glasgow, 1994), sleep (GRSS; Glidewell, 2006), and cognition (SLUMS; Tariq, Tumosa, Chibnall, Perry, & Morley, 2006). The primary purpose of this study focused on barriers as identified in the literature (and tied to the theoretical frame utilized herein), thus not all measures available in the parent study were utilized in the analyses. Lastly, eligible participants were randomly assigned to the in-home diabetes
management group or the treatment as usual group. The present study focused on those who were assigned to the in-home diabetes group (or entered the in-home diabetes group after completing the treatment as usual condition) as barriers were not assessed until the participant entered the active treatment condition. Only participants who completed the barriers measure were selected for the present study. The study was approved by the University of Colorado, Colorado Springs Institutional Review Board.

All behavioral health clinicians (BHC) were graduate level psychology students under the supervision of a licensed clinical psychologist. All BHC’s attended at minimum biweekly meetings with the principal investigator (a licensed clinical psychologist) to obtain caseload supervision. Regular meetings with the PI helps to ensure study and measure protocols are administered accurately and consistently. Additionally, BHC’s used checklists which listed all measures to be administered at each session for standardization.

At the first in-home session, the BHC administered the Diabetes Self-care Education Programme Situations Checklist and SDSCA along with the other measures in the battery to gather baseline data. The SDSCA was administered at the beginning of each of the subsequent five weekly, one hour sessions, and the two follow up sessions.

**Research Design and Statistical Analyses**

The current study utilized an archival analysis of cross-sectional archival data collected as part of the parent study. Using IBM SPSS Statistics, version 25, bivariate linear regressions were used to evaluate the predictive value of perceived barriers (Diabetes Self-care Education Programme Situations Checklist) and depression (WHO-5) on the diabetes self-care activities (SDSCA).
CHAPTER III

RESULTS

Data from eighty-five participants enrolled in the active treatment condition were used for analyses \( (n = 85) \). The majority of participants identified racially as White (62.4%), followed by Hispanic (24.7%), African American (9.4%), and multiracial (3.5%). Women comprised 72.9% of the sample. Ages ranged from 24 to 89 and the average age of participants was 53.5 \( (SD = 11.5) \), the average education level was 13 years \( (M = 12.9, SD = 2.5) \), and average SLUMS score was 24.1 \( (SD = 4.0) \). Simple correlations were examined among all variable included in the study. The results of these Pearson correlations are shown in Table 1.

Table 1: Correlation Matrix

<table>
<thead>
<tr>
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<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. General Diet</td>
<td>1</td>
<td></td>
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<td></td>
<td></td>
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<td></td>
<td></td>
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<tr>
<td>2. Exercise</td>
<td>.131</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Blood Glucose Testing</td>
<td>.417**</td>
<td>.128</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>4. Medication</td>
<td>.327**</td>
<td>.050</td>
<td>.311**</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Barriers Diet</td>
<td>-.160</td>
<td>-.086</td>
<td>-.270*</td>
<td>-.059</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. Barriers Exercise</td>
<td>-.201</td>
<td>-.073</td>
<td>-.104</td>
<td>-.090</td>
<td>.556**</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. Barriers Glucose Testing</td>
<td>-.160</td>
<td>-.008</td>
<td>-.161</td>
<td>-.079</td>
<td>.568**</td>
<td>.519**</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8. Barriers Medication</td>
<td>-.083</td>
<td>-.130</td>
<td>-.082</td>
<td>-.211</td>
<td>.551**</td>
<td>.434**</td>
<td>.620**</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>9. Depression</td>
<td>-.373**</td>
<td>-.203*</td>
<td>-.247*</td>
<td>-.315**</td>
<td>.321**</td>
<td>.324**</td>
<td>.287**</td>
<td>.154</td>
<td>1</td>
</tr>
</tbody>
</table>

Note: **. Correlation is significant at the 0.01 level (2-tailed).
* . Correlation is significant at the 0.05 level (2-tailed).

General diet was significantly positively correlated with blood glucose testing \( (r(95) = .42, p < 0.01) \) and medication \( (r(79) = .38, p < 0.01) \) and significantly negatively
correlated with depression ($r(97) = -.37, p < 0.01$). General diet was not significantly correlated with exercise, barriers diet, barriers exercise, barriers glucose testing, or barriers medication. Exercise was significantly negatively correlated with depression ($r(97) = -.20, p < 0.05$). However, exercise was not significantly correlated with any other variables. Blood glucose testing was significantly positively correlated with medication ($r(79) = .31, p < 0.01$) and significantly negatively correlated with barriers diet ($r(80) = -.27, p < 0.05$) and depression ($r(94) = -.25, p < 0.05$). Blood glucose testing was not significantly correlated with exercise, barriers exercise, barriers glucose testing or barriers medication. Medication was significantly negatively correlated with depression ($r(78) = -.32, p < 0.01$). Medication was not significantly related to exercise, barriers diet, barriers exercise, barrier glucose testing, or barriers medication. Barriers diet was significantly positively correlated with barriers exercise ($r(83) = .56, p < 0.01$), barriers glucose testing ($r(82) = .57, p < 0.01$), and barriers medication ($r(80) = .55, p < 0.01$). Barriers diet was significantly negatively correlated with depression ($r(83) = .32, p < 0.01$). Barriers diet was significantly related to general diet, exercise, or medication. Barriers exercise was significantly positively correlated with barrier glucose testing ($r(82) = .52, p < 0.01$), barriers medication ($r(80) = .43, p < 0.01$), and depression ($r(83) = .32, p < 0.01$). However, barriers exercise was not significantly related to general diet, exercise, blood glucose testing, or medication. Barriers glucose testing was significantly positively correlated with barriers medication ($r(80) = .62, p < 0.01$) and depression ($r(82) = .29, p < 0.01$). Barriers glucose testing was not significantly correlated with general diet, exercise, blood glucose testing or medication. Depression was significantly correlated with all variables expect barriers medication.
Four standard linear multiple regression analyses were conducted to investigate the extent to which the independent variables of depression and perceptions of specific barriers (barriers to diet, barriers to exercise, barriers glucose test, and barriers medication) explained the variance in the dependent variables, i.e., corresponding diabetes self-care outcome variables (general diet, exercise, blood glucose testing, and medication). The results of the regressions are shown in Tables 2-5. Statistical assumptions for linear multiple regression were met. Prior to computing analyses, variable distributions histograms were visually inspected, and it was determined that each was normally distributed with no extreme outliers and no violation of homoscedasticity. Skewness values ranged from -1.99 to .80 for all variables, which are all within the recommended -2.00 to +2.00 range. A check for multicollinearity revealed tolerance values ranged from .89 to .96, which exceed the recommended threshold of .40. Lastly, X and Y scores were determined to be linearly related.

Each of the four multiple regressions included depression and one of the four barriers subscales (independent variables) to predict the corresponding SDSCA subscale (dependent variable). The first regression used depression and barriers to diet to predict general diet adherence. As can been seen in Table 2, depression scores and barriers to diet significantly explained 19.8% of the variance in general diet ($R^2 = .20$, adj. $R^2 = .18$, $F(2,84) = 10.1, p < .001$). Depression had significant negative beta weight, indicating that higher depressive symptoms corresponded to lower general diet adherence, after controlling for barriers to diet ($b = -.30, \beta = -.44, p < .001$).
Table 2: Summary of Multiple Regression Analyses for Depression and Barriers to Diet Predicting SDSCA Self-Reported Dietary Adherence \((n = 84)\)

<table>
<thead>
<tr>
<th>Variable</th>
<th>General Diet</th>
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<tbody>
<tr>
<td></td>
<td>(b)</td>
<td>SE ((B))</td>
<td>(\beta)</td>
</tr>
<tr>
<td>Depression</td>
<td>-0.30</td>
<td>0.07</td>
<td>-0.44***</td>
</tr>
<tr>
<td>Barriers Diet</td>
<td>-0.01</td>
<td>0.03</td>
<td>-0.02</td>
</tr>
</tbody>
</table>

\(R^2\) 0.20  
Adj. \(R^2\) 0.18  
\(F\) 10.11***

*Note:* \(*p < .05. \ **p < .01. \ ***p < .001.*

Depression and barriers to exercise did not significantly predict exercise adherence in the second regression \((F(2,84) = 1.38, p = .18, \text{ns})\), see Table 3. Both depression and barriers to exercise had non-significant negative beta weights which did not contribute to the variance in exercise adherence.

Table 3: Summary of Multiple Regression Analyses for Depression and Barriers to Exercise Predicting SDSCA Self-Reported Exercise Adherence \((n = 84)\)

<table>
<thead>
<tr>
<th>Variable</th>
<th>Exercise</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(b)</td>
<td>SE ((B))</td>
<td>(\beta)</td>
</tr>
<tr>
<td>Depression</td>
<td>-0.12</td>
<td>0.08</td>
<td>-0.17</td>
</tr>
<tr>
<td>Barriers Exercise</td>
<td>-0.00</td>
<td>0.03</td>
<td>-0.02</td>
</tr>
</tbody>
</table>

\(R^2\) 0.03  
Adj. \(R^2\) 0.01  
\(F\) 1.38

*Note:* \(*p < .05. \ **p < .01. \ ***p < .001.*

Barriers to blood glucose testing and depression significantly accounted for 12.7% of the variance in blood glucose testing \((R^2 = .13, \text{adj. } R^2 = .11, F(2,81) = 5.76, p < .005)\). Depression had a significant negative beta weight, demonstrating that high depressive symptoms were related to less blood glucose testing when controlling for barriers to blood glucose testing \((b = -.26, \beta = -.33, p < .005)\), see Table 4.
Table 4: Summary of Multiple Regression Analyses for Depression and Barriers to Blood Glucose Testing Predicting SDSCA Self-Reported Blood Glucose Adherence (n = 81)

<table>
<thead>
<tr>
<th>Variable</th>
<th>Blood Glucose Testing</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>b</td>
<td>SE (B)</td>
<td>β</td>
</tr>
<tr>
<td>Depression</td>
<td>-0.26</td>
<td>0.09</td>
<td>-0.33**</td>
</tr>
<tr>
<td>Barriers Blood Glucose Testing</td>
<td>-0.03</td>
<td>0.04</td>
<td>-0.08</td>
</tr>
</tbody>
</table>

R^2    0.13  
Adj. R^2 0.11  
F 5.76**  

Note: *p < .05. **p < .01. ***p < .001.

Lastly, depression scores and perceived barriers to medication significantly explained 24.9% of the variance in medication adherence (R^2 = .25, adj. R^2 = .23, F(2,67) = 10.8, p < .001), see Table 5. Depression had a significant negative beta weight signifying that higher levels of depression corresponded to lower levels of medication adherence (b = -.27, β = -.46, p = < .001).

Table 5: Summary of Multiple Regression Analyses for Depression and Barriers to Medication Predicting SDSCA Self-Reported Medication Adherence (n = 67)

<table>
<thead>
<tr>
<th>Variable</th>
<th>Medication</th>
<th></th>
<th></th>
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<tbody>
<tr>
<td></td>
<td>b</td>
<td>SE (B)</td>
<td>β</td>
</tr>
<tr>
<td>Depression</td>
<td>-0.27</td>
<td>0.07</td>
<td>-0.46***</td>
</tr>
<tr>
<td>Barriers Medication</td>
<td>-0.04</td>
<td>0.03</td>
<td>-0.12</td>
</tr>
</tbody>
</table>

R^2    0.25  
Adj. R^2 0.23  
F 10.80***  

Note: *p < .05. **p < .01. ***p < .001.
CHAPTER IV
DISSCUSSION

This study assessed perception of diabetes-specific barriers among men and women from lower socioeconomic backgrounds in Southern Colorado. Previous studies exploring barriers and T2DM focused on specific populations (e.g., women, African-Americans, Iranians) which limited generalizability to the population as a whole. This study contributed to the literature by exploring the impact of depression and perception of barriers on diabetes self-care. The focus on patients enrolled in a Federally Qualified Health Center expanded the generalizability of findings to lower SES groups and targeted those patients who are at a higher risk of developing and having complications of T2DM. However, findings may not be predictive of higher SES groups living in the United States. More research is necessary to understand the complexity of the barriers to diabetes management, given the prevalence of uncontrolled diabetes.

The results from this study suggest that depression significantly impacted self-reported adherence to self-care activities in the dietary, blood glucose testing, and medication domains. These findings are in line with current literature that indicates depression is associated with reduced adherence to self-care activities (Sumlin et al., 2014). Depression was not significantly related to exercise, contrary to predictions. Post hoc power analyses suggested statistical power for the multiple regression using depression and barriers to exercise to predict self-reported exercise was low at 27%. Given the troubling exercise adherence rates among those T2DM, it is possible that the
relationship between depression and exercise is difficult to capture (Mu, Cohen, & Mukamal, 2014). The literature suggests individuals with T2DM are not exercising at recommended rates in general; therefore the impact of depression on exercise may be marginal since the baseline is low. A systematic review of the effects of exercise training on psychological well-being among those with T2DM suggested mixed results and advocated for increased randomized control trials (Van der Heijden, van Dooren, Pop & Pouwer, 2013). Another possibility for the lack of significance is the manner in which the SDSCA measures exercise may not adequately capture the level of physical activity. Two questions are used to capture exercise over the past week (1) Did you participate in at least 30 minutes of physical activity? (2) Did you participate in a specific exercise session (such as swimming, walking, biking) other than what you do around the house or as part of your work? (Toobert & Glasgow, 1994). Overall, the SDSCA lacks specificity in its operationalization of exercise. Considering social determinants of health among those from disadvantaged populations, continuous physical activity and exercise sessions may be less clinically relevant as these types of exercise may not be attainable. It may be beneficial to explore other aspects of physical activity in this population rather than exercise. For example, taking housework, manual labor or reduction of sedentary behavior into consideration.

Contrary to hypothesized results, perceived barriers were not found to be significantly related to any self-care activities. It is possible that the method of analysis may be a factor. Standard multiple regression were used for analyses. A limitation to multiple regression is that only unique variance is attributed to each predictor. Therefore, shared variance is not considered. Perceived barriers appeared to have accounted for only
a small proportion of the variance in self-care activities which may be because perceived barriers share a large portion of the variance with depression. Therefore, the shared variance between depression and barriers may not have been captured in this study.

The Diabetes Self-care Education Programme Situations Checklist (Glasgow, 1994) was initially designed from patient perspectives. However, it is possible that the barriers included in the measure were less applicable to patients in this population. For example, people involved in this sample were likely to be retired or disabled. Many of the items on the measure ask about “not being at home when its time to (e.g., exercise, test blood glucose, etc.)” which would not be a barrier among this population because of retired or disabled status. Additionally, the majority of the people who participated in this study did not have access to reliable transportation which is why they selected to do the in-home program. Therefore, they may be homebound or spend the majority of their time at home, which would make items less relevant. There are also items that relate to a lack of diabetes education. For example, “I am unsure about the amount of one or more food items I consume.” Participants had to have participated in a diabetes education class or be referred by their provider to be involved in the study. Since participants recently engaged in diabetes education, they may not have felt items corresponding to lack of knowledge applied to them. Lastly, the measure was based on patient perceptions over 20+ years ago when the measure was created. It is possible that the perceived barriers presented in the measure are not the perceived barriers that the patients are experiencing today. Overall, the nature of the sample and idiosyncrasies of the items on the Diabetes Self-care Education Programme Situations Checklist may have contributed to the findings (i.e., the observed barriers lacking significance as a predictor of adherence).
Implications

Given the impact of depression on T2DM, early detection of depression may provide an opportunity for treatment. Treatment of depressive symptoms could allow for better T2DM management through improved adherence. As discussed earlier, those who adhere to diabetes self-care recommendations have better clinical outcomes and reduced risk for medical complications. An alternative hypothesis may be that cognitive perceptions of barriers may not be a contributing factor to T2DM management. Instead, behavioral aspects of depression (e.g., hypersomnia, loss of energy) may be essential predictions of engagement with diabetes self-care activities.

Limitations

While this study contributes to the literature, it is not without limitations. First, this study is cross-sectional in design, therefore, it is unclear how the predicted relationships may change over time. For example, if depressive symptoms improve, do perceptions of barriers also shift?

Next, this study relied on participants’ self-reported treatment adherence. Self-reported adherence may not be in line with objective measurements indicative of adherence (e.g., HbA1C, blood sugar levels). Additionally, participants may genuinely perceive themselves as doing well when objectively they are not or vice versa (i.e., biased perceptions).

Another possible limitation could relate to self-selection bias. Participants were recruited from diabetes health education classes. Thus, it is possible that these participants may have been amongst those patients who were motivated to improve T2DM management. Participants who attend health education classes may perceive fewer
barriers overall and therefore may not be representative of the patient population as a whole. Future research should attempt to reach those patients diagnosed with diabetes who have not attended a diabetes health education class or prefer to receive face-to-face diabetes care instructions from their providers.

Finally, barriers data was obtained from participants in the active treatment condition only. It is possible that the differential dropout rate between those randomized to active treatment and those randomized to treatment as usual at the intake session of the parent study may have influenced the results. Participants with greater barriers may be less likely to follow up, especially in the treatment as usual condition.

**Future Directions**

Future research may consider studying depression severity and duration on diabetes treatment adherence. Additionally, including a physical indicator of adherence (e.g., biomarkers) may be useful to explore the relationship between depression, barriers, self-reported self-care adherence and objective adherence. It seems possible that those experiencing depression may view themselves as having worse T2DM management even when objectively they are adhering well. Also, future studies should explore behavioral strategies for depression reduction such as behavioral activation. Behavioral activation is known to have positive effects on both depression and diabetes.

Clinical screening measures account for symptoms of depression but do not address the source of depressive symptoms (Fisher, Gonzalez, & Polonsky, 2014). Fisher et al., 2014 coined the term “diabetes distress” which considers the specific challenges an individual experiences related to diabetes management, emotional distress, and support. Additional studies have discovered that diabetes distress is significantly related to
diabetes self-care activities rather than depression (Fisher et al., 2009). If one experiences diabetes distress, then he or she may not feel empowered to engage with change. One of the primary tenants of the health belief model is that one must believe negative consequences of the disease can be avoided. For examples, patients with diabetes may routinely test their blood glucose levels and see no reduction in blood glucose levels despite interventions. This example highlights the concept that patients may feel powerless and that they do not have control. (Egdege & Bonadonna, 2003). Fatalism had been related to poor diabetes management and decreased quality of life (Egede & Bonadonna, 2003). Diabetes distress and fatalism may be barriers in and of themselves which aid in avoidance of change. Future studies may desire to consider the possibility that fatalism and diabetes distress may be contributing sources of diabetes depressive symptoms.

The current study adds to the existing literature on the relationship between depression and T2DM management. Depression continues to be a significant predictor of poor disease management. The evidence here suggests perceived barriers are not related to self-care activities in the absence of depression. Future research needs to replicate these findings and should explore other factors that may impact self-care, as early interventions can improve the prognosis and quality of life of the person experiencing T2DM.
REFERENCES


APPENDIX

University of Colorado Colorado Springs
Institutional Review Board (IRB)

REQUEST FOR CONTINUING REVIEW (RENEWAL) FORM

PLEASE NOTE: IRB Training is required for all PI's, Faculty Advisors and Personnel involved with human subject research and must be completed PRIOR TO CONTINUING REVIEW. If you do not provide the Completion Report Number (located at the bottom of the Completion Report) and the date of your most recent training, YOUR PROTOCOL WILL BE RETURNED TO YOU WITHOUT IRB REVIEW. Go to www.ctsforum.org and follow the instructions to complete the training.

A. PROTOCOL STATUS INFORMATION
   1. Are you still collecting data on new or previously recruited subjects? ☑ Yes ☐ No
   2. Are you still analyzing data? ☑ Yes ☐ No
      (If you answered "Yes" to either question 1 or 2, complete the form and submit for continuing review. If you answered "No" send an email to IRB@uccs.edu with your protocol title and IRB number with a request to close your protocol.)
   3. Has the protocol expired? ☑ Yes ☐ No
      (If you answered "Yes" to question 3, Note: Federal regulations and the UCCS IRB Standard Operating Procedures prohibit the use of human subjects beyond the IRB approval expiration date, therefore, if a renewal request is not reviewed by the IRB and approved by the expiration date, all research activity on the protocol must cease until such time the approval is received.)

B. ORIGINAL PROTOCOL INFORMATION
   Title of Protocol: Extending Current Models of Diabetes Management
   IRB # 66-249
   Expiration Date: 6/19/2017
   Original Investigator (if different from above) ☑
   Original Category of Review ☑ Expedited ☐ Full ☐ Exempt

C. PRINCIPAL INVESTIGATOR
   Name: Leilani Pelikiano, Ph.D.
   IRB Training Completion Number: 18873200 Most recent IRB Training Date: 5/30/2015
   Check one: ☑ Faculty/Staff ☐ Current UCCS Student*  
   Department, Center, or Institute: Psychology
   Mailing Address: 1400 Austin Bluffs Parkway, Colorado Springs, CO 80918
   Phone: 719-355-4174
   UCCS E-mail address: felicia@uccs.edu

D. CO-PI (IF APPLICABLE)

Version 7.15.2015
Name:
IRB Training Completion Number: ______ Most recent IRB Training Date: ______
Check one: □ Faculty/Staff □ Current UCCS Student* □ Non-UCCS Personnel (Note: Non-UCCS personnel must be approved).
If checked, explain the role of the non-UCCS personnel: ______
Department, Center, or Institute: ______
Mailing Address: ______
Phone: ______
UCCS E-mail address: ______

E. FACULTY ADVISOR (* REQUIRED FOR STUDENTS)
Name: ______
IRB Training Completion Number: ______ Most recent IRB Training Date: ______
Department, Center, or Institute: ______
Phone: ______
UCCS E-mail address: ______

F. Please provide the following information for all current additional personnel involved in the project:

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<thead>
<tr>
<th>Name(s)</th>
<th>Check box if a student</th>
<th>CITI Completion #</th>
<th>CITI Training date</th>
<th>Personnel role in the project, i.e. doing interviews, data analysis, etc.</th>
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<td>1/1/13</td>
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<tr>
<td>Katie Johnson</td>
<td>□</td>
<td>4403826 14075660</td>
<td>9/17/14</td>
<td>graduate research assistant</td>
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<tr>
<td>Lauren Schneider</td>
<td>□</td>
<td>503248 17132390</td>
<td>9/2/15 9/4/15</td>
<td>graduate research assistant</td>
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<tr>
<td>Allison Wilden</td>
<td>□</td>
<td>20775683</td>
<td>9/7/2016</td>
<td>new graduate research assistant to start pending IRB approval</td>
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<tr>
<td>Adrienne Bohlen</td>
<td>□</td>
<td>17749082</td>
<td>11/5/15</td>
<td>new undergraduate research assistant to start pending IRB approval</td>
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<tr>
<td>Brady Smith</td>
<td>□</td>
<td>23103432</td>
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<tr>
<td>Claudia Margiotta</td>
<td>2464436</td>
<td>9/1/14</td>
<td>Claudia is a volunteer</td>
</tr>
</tbody>
</table>

*Note: Non-UCCS personnel are subject to approval

Version 7.15.2016
G. Is any work for the protocol being performed at/with the Lane Center clinics?
   ☒ Yes  ☐ No

   If yes, please describe: *Intake interviews for our participants (who are Peak Vista patients) are sometimes conducted at the Peak Vista Community Health Center, Lane Center Clinic.*

H. THE UNIVERSITY OF COLORADO AND FEDERAL REGULATIONS REQUIRE REVIEW AT LEAST ANNUALLY OF ALL PROTOCOLS THAT ARE CURRENTLY ACTIVE.

1. Is your study actively recruiting subjects?   ☒ Yes  ☐ No
   a. If not active, what is the status of the protocol and the data resulting from the protocol? You are reminded that informed consent forms are privileged institutional records and must be protected for confidentiality of information on individual subjects.  _____
   b. If active, is the protocol proceeding as originally approved with no substantial modifications?   ☒ Yes  ☐ No
      If no, describe/list all changes to protocol since the original approval:  _____

2. Is there new risk or benefit that should be disclosed to the subjects?
   ☐ Yes  ☒ No
   If yes, please provide an explanation:  _____

3. Provide a breakdown of the number of subjects enrolled in the study:
   a. The number approved (by the IRB) to enroll for the study: *We were approved to continue to recruit participants until we have enough participants to detect meaningful differences. Using G*Power 3.0.10, n = 88 participants in each group is required to detect group differences given an alpha of .05 and a medium effect size. Therefore we need at least 88 people to complete our protocol (intake plus all 3 treatment sessions) in each treatment arm (a minimum of 68 at home participants and 88 treatment as usual/waitlist participants for a total of at least 176 participants minimum).*
   b. The number of total subjects accrued: 278 of which only 83 (at home) and 27 (treatment as usual) in each group have completed all required sessions.
c. The number of subjects accrued within the last year: N/A

d. A description of any adverse events or unanticipated problems involving risks to subjects or others, withdrawal of the subjects from the research, or complaints about the research: N/A

e. A summary of any recent literature, findings or other relevant information about risks associated with the research: N/A

f. Attach a copy of the current informed consent document: Attached

I. HAS THERE BEEN A CHANGE IN FUNDING STATUS SINCE THE MOST RECENT APPROVAL?

☐ Yes, Awarded ☐ Yes, Submitted ☐ Yes, Not Awarded ☐ Yes, No Longer Funded
☐ No

If Awarded or Submitted, provide the following information:

- [ ] Speedtype ____ or OSP Proposal Number ____
- [ ] Name of Sponsor ____ and Funded Proposal Title ____

(For assistance, contact the Office of Sponsored Programs at X3321)

J. CERTIFICATIONS/ASSURANCES:

INVESTIGATOR’S CONTINUING RESPONSIBILITY TO IRB:

Once the renewal request has been approved it is the Principal Investigator’s (PI) responsibility to:

- Ensure additional personnel take the CITI training and understand their responsibility when working with human participants.
- Report all changes in research activity related to the study by submitting a Report of Change to the IRB.
- Provide the IRB all study and consent form amendments and revisions. The IRB must approve these changes prior to their implementation. All changes to advertisements recruiting study participants must also receive prior approval by the IRB.
- Promptly report any injury, adverse event, or detrimental incident experienced by a research participant that is or may be related to the research procedures.
- Continue to renew the study with the IRB prior to expiration. All studies must have a continuing review at least annually. Some studies will have the continuing review more frequently as determined in the initial review and approval. Retro-active approval for lapsed studies is not allowed. If the study approval lapses, you need to complete a new IRB Application.
- Notify the IRB (irb@uccs.edu) when the study is complete.

Failure to comply with these federally mandated responsibilities may result in suspension or termination of the study.

INVESTIGATOR ACKNOWLEDGMENT:

- I have read the definitions of Misconduct in Research
- I have read the Training requirements for IRB review
- I have read the Investigator’s Continuing Responsibilities to the IRB
• I understand the definitions of Scientific Misconduct and Conflicts of Interest and my continuing responsibilities to the IRB.
• I will conduct my study in compliance with the UCCS IRB Standard Operating Procedures.
• By submitting this Request for Continuing Review, I attest to my agreement to continue to conduct this research study in such a manner that acts of misconduct in research and conflicts of interest will not be committed and I will comply with the continuing responsibilities to the UCCS IRB.
• If the protocol should expire prior to receiving the approval, I certify that all research activity on the protocol will cease until such time that the approval is received.

* FACULTY ADVISOR ACKNOWLEDGMENT:
By submitting this Request for Continuing Review to irb@uccs.edu, I acknowledge that the information contained in the study is accurate to the best of my knowledge. I verify that I am the faculty advisor for the Principal Investigator for this study and that I shall be responsible for the oversight of the conduct of the research and adherence to all applicable University policies and procedures.

By submitting this form, as Principal Investigator, I hereby certify that to the best of my knowledge, the information furnished above is true and complete, and that I have read and understand the Investigator Acknowledgement section. I understand that if found to be otherwise, it is sufficient cause for refusal or dismissal. I authorize representatives of the University of Colorado Colorado Springs to make any and all appropriate inquiries regarding the information listed in this supplement. I hereby release you or others from any liability or damage that may result from furnishing the information requested.

SUBMISSION PROCEDURES:
• Attach all consent/assent documents and a copy of the methods and human subjects sections of your grant proposal (if applicable).
• UCCS Graduate and Undergraduate students must have their faculty advisor submit the application via the faculty advisor's email address to irb@uccs.edu.

Submit Requests for Continuing Review as a PDF to irb@uccs.edu.