

ASSESSING THE EFFICACY OF A CULTURALLY INFORMED ADHERENCE
INTERVENTION FOR RURAL AFRICAN AMERICANS WITH TYPE 2 DIABETES

by

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African Americans (AAs) experience higher rates of type 2 diabetes mellitus (T2DM), and difficulty adhering to T2DM treatment plans. The current study aims were to create a culturally informed intervention for AAs with T2DM and determine its efficacy for increasing treatment adherence, diabetes knowledge, self-efficacy, problem-focused coping, and mindfulness, and reducing emotional distress and HbA1c levels.

A focus group with AAs with T2DM was conducted to understand barriers to treatment adherence. Information provided was incorporated into the development of a culturally informed T2DM adherence intervention for AAs. AAs with T2DM experiencing adherence difficulty ($N = 20$) recruited from a Family Medicine Clinic were randomly assigned to the intervention group (IG, $n = 12$) and an education comparison group (ECG, $n = 8$). Measures of adherence, knowledge, self-efficacy, and psychological factors were administered pre- (T1), immediately post- (T2), and 3-months post-intervention (T3). HbA1c levels were abstracted from participants' medical records at T1 and T3.

The sample was 50% female, 70% with some college, 50% single, 75% unemployed, with an average age of 50.8 years and T2DM diagnosis length of 6.9 years. No significant group differences were observed on T2 or T3 measures. A significant time effect on healthy dietary

behavior adherence reflected increases from T1-T2-T3 [Wilks' Lambda = 0.47, $F(2, 10) = 5.52$, $p = .02$]. Within groups, the IG exhibited a significant increase in physical activity adherence [$t(11) = -2.34$, $p = .04$] and mindfulness [$t(11) = -2.53$, $p = .03$] and approached a significant decrease in depressive symptoms [$t(4) = 2.31$, $p = .07$] from T1-T2; and a significant increase in healthy dietary behavior adherence [$t(7) = 2.76$, $p = .03$] and significant reduction in HbA1c [$t(8) = 2.55$, $p = .03$] from T1-T3. The ECG demonstrated a significant increase from T1-T3 on diabetes-specific self-efficacy [$t(4) = 2.83$, $p = .05$].

While no between-group differences were observed, findings indicate this intervention's components hold promise for changing adherence behaviors for rural AAs with T2DM. Future research with a larger sample is warranted to better elucidate treatment effects and adding a long-term follow-up component would allow assessment of longitudinal effects.

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I dedicate this work to the memory of my father, William Garboski, who always believed in my potential.

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Chapter I: Introduction

Prevalence of Type 2 Diabetes Mellitus

Type 2 diabetes mellitus (T2DM) is a major public health concern as it is one of the fastest growing chronic illnesses in the United States with multiple associated co-morbidities. According to the latest Centers for Disease Control and Prevention report (2011) on current T2DM trends, diabetes prevalence over the past 18 years has more than tripled (493,000 new cases in 1980 vs. 1.9 million in 2010). Currently, 18.8 million people are diagnosed with diabetes, of which 90-95% cases are T2DM. According to the CDC (2011), men and women have similar prevalence rates for diabetes (11.8% of men vs. 10.8% of women over 20 years of age). In the state of North Carolina (NC), the prevalence rate of T2DM is 9% (643,000) and approximately 1.2 million NC residents have some form of hyperglycemia (North Carolina Prevention and Control, 2009). The rate of T2DM is even higher in the eastern region of NC, with prevalence closer to 13%. Underlining the urgency of the current diabetes epidemic locally as well as nationally, the U.S. Department of Health and Human Services (2008) has demonstrated that T2DM doubles one's risk of premature death and is currently the seventh leading cause of death in the United States.

Economic Burden of T2DM

In terms of healthcare utilization, patients with T2DM account for 20% of hospital admissions in the United States (approximately 6.4 million) (Kim & Boye, 2009). This is high utilization of intensive medical treatment considering that patients with diabetes only make up approximately 8% of the U.S. population (CDC, 2011). Associated annual costs of diabetes are estimated at \$171 billion in hospital charges and \$90 billion in direct patient costs (Kim & Boye, 2009). Much of the medical costs are due to complications associated with T2DM such as

cardiovascular disease, end stage renal disease (ESRD), limb amputation, neuropathy, and retinopathy (Pelletier et al., 2008). Specifically in NC, over \$524 million dollars in Medicare expenditures were allocated towards the costs of T2DM hospitalizations and treatment.

Additionally, the American Diabetes Association estimated the total cost of diabetes in NC to be \$5.2 billion, including both medical costs as well as lost productivity, making the economic burden of this disease quite substantial (North Carolina Prevention and Control, 2009).

Racial Disparities in T2DM Prevalence

Compared to Caucasians, the risk of diagnosed diabetes is 18% higher in Asian Americans, 66% higher in Hispanics, and 77% higher in African Americans (AAs). The starkest racial comparison is between Caucasians and AAs, with AAs have significantly higher prevalence rates of diabetes (18.7%) than Caucasians (10.2%) (CDC, 2011). This disparity has been demonstrated to vary across body mass index (BMI) classifications, with the greatest disparity existing in the overweight category (33% prevalence rate for Caucasians compared to 60% for AAs) (Zhang, Wang, & Huang, 2009). Explanatory factors for why such a profound racial disparity exists between Caucasians and AAs include differential access to health care services, AAs having poorer insurance coverage and lower socioeconomic status (SES)/education, as well as higher rates of obesity (Buescher, Whitmire, & Pullen-Smith, 2010). This disparate trend is exemplified in NC, as diabetes rates are greater than 10% in many counties (CDC, 2008) (compared to the national average of 7.8%) (Egede, Strom, Durkalski, & Mauldin, 2010) and NC AAs are 2.6 times as likely as Caucasians to die from diabetes-related complications (Buescher et al., 2010).

A study conducted by LaVeist, Thorpe, Galarrga, Bower, and Gary-Webb (2009) specifically examined the mediating role of SES in explaining racial disparities in diabetes

prevalence. Results showed that among Caucasians and AAs that were equivalent in SES factors (income, resources) and living in an integrated community with similar access to care, the racial disparity diminished, suggesting that social context and environment plays a large factor in this disparity.

Pathophysiology of T2DM

Contrasted with Type 1 Diabetes (the inability to *produce* insulin), T2DM is characterized by the inability to properly *respond* to insulin. Insulin is an important endocrine hormone that binds to cells and allows the influx of glucose, which is crucial to cell functioning. It can be affected by lifestyle factors, such as poor diet, obesity, and low physical activity as well as advancing age and a family history of disease (CDC, 2008). T2DM is a progressive disease that generally begins as insulin resistance (IR- the inability of insulin to have a normal effect on cells, leading to an inability to absorb glucose effectively) and slowly develops into full T2DM, where IR and decreased insulin production are present (Casey, 2011).

β -cell dysfunction. The specific mechanisms of T2DM begin with β -cell dysfunction. These cells are responsible for production of insulin within the pancreas, and problems begin to occur when they become dysregulated (Mahler & Adler, 1999). This generally occurs in several stages, as described by Weir and Bonner-Weir (2004). The first stage is compensation, by which the pancreas attempts to maintain normal glucose levels (normoglycemia) and β -cell mass increases in order to maintain high levels of insulin production. The second stage is stable adaptation. This is when β -cells can no longer compensate for the high amounts of blood sugar being introduced into the blood stream and insulin secretion begins to diminish (also known as impaired glucose tolerance). This high-maintained level of blood sugar is called glucotoxicity. Stage 3 is unstable early decompensation and is characterized by a decrease in β -cells due to

glucotoxicity and increased insulin resistance. Without early intervention, the disease can then progress to stage 4- stable decompensation, which is considered full onset T2DM. This is characterized by significant β -cell mass reduction (~50%) as well as a marked inability to effectively secrete insulin. Initial onset of β -cell dysfunction can be due to various factors. One primary contributor noted in the literature is high adipose tissue concentration and associated free fatty acids (FFA), which antagonize insulin secretion and promote insulin resistance as well as inhibit glucose uptake in the muscles (Unger, 2010). This can lead to greater fatty acid accumulation in the skeletal muscles and liver, which can lead to lipotoxicity and increased inflammation and free radical production, which may attack β -cells (Casey, 2011).

Alpha cells and glucagon. Glycemic regulation is also influenced by alpha cells in the pancreas that produce a hormone called glucagon, which assists in the regulation of glucose output by the liver (Dunning & Gerich, 2007). Normally, the body's self-regulatory mechanisms suppress glucagon levels when glucose and, subsequently, insulin levels rise. However, it has been observed that in individuals with T2DM, there is a dysregulation of this feedback loop (most likely due to a lowered insulin response), leading to a higher concentration of glucagon when liver glucose is secreted.

Incretin hormones. Incretin hormones are secreted by the intestines, and one in particular has been under study due to its effect on the development of T2DM- glucagon-like peptide (GLP-1). GLP-1 has been associated with optimizing β -cell functioning by assisting in reducing hepatic insulin production (and therefore lower insulin demand), aiding in satiety cues to the central nervous system, and promote β -cell proliferation and insulin synthesis (Casey, 2011). Those with T2DM have decreased GLP-1 synthesis, which subsequently leads to a diminished effect on insulin regulation and β -cell functioning (Unger, 2010).

Acute diabetes complications. As a result of these various dysregulatory actions, chronic hyperglycemia can lead to several acute complications. These complications can include polyuria (dilute urine which can cause dehydration) as well as polydipsia (a compensatory chronic thirst as a result of dehydration). Other acute symptoms may include hyperosmolar hyperglycemic non-ketotic syndrome (HHNS- characterized by disorientation, hypotension, low skin turgor), skin infection, and blurred vision (Casey, 2011).

Measurement of hyperglycemia. Hyperglycemia is generally measured in one of two ways. One measure of short-term glycemic levels is through fasting blood glucose, where short-term plasma glucose levels are assessed. Normal blood glucose levels fall below 100 mg/dL and diabetes-associated hyperglycemia is indicated if levels are above 126 mg/dL (Casey, 2011). A more long-term measure of glycemic levels is through hemoglobin A1C (HbA1C) assay. Specifically, this marker indicates how much exposure red blood cells have had to glucose over the course of 3 months. Generally, if this measure is over 7%, hyperglycemia associated with diabetes is indicated and treatment is geared towards lowering HbA1C levels to under 7%, as that is associated with risk reduction for various health conditions (Nathan et al., 2008; Suh, Choi, Plauschinat, Kwon, & Baron, 2010).

Medical Co-Morbidities of T2DM

Dyslipidemia. Due to the high concentrations of fatty tissue in those with T2DM as well as a dysregulation of lipoproteins as a result of IR and pro-inflammatory mechanisms, there is usually high concurrence of dyslipidemia in these patients (Nelson et al., 2011). The prevalence of dyslipidemia ranges anywhere between 12-50% of T2DM patients, depending on age, race, and gender (Crawford et al., 2010). This places T2DM patients at a much higher risk of developing atherosclerosis and subsequent heart disease. Specifically, lipoprotein-associated

phospholipase A₂ (Lp-PLA₂) seems to play a large role in this dysfunction (Chan & Watts, 2010). This must be medically treated in conjunction with lifestyle changes in order to lower the risk of complications that may result from this comorbid condition.

Hypertension. Hypertension affects approximately 25% of individuals with T2DM (Crawford et al., 2010). Due to the vasoconstriction that occurs as a result of insulin resistance as well as obesity, hypertension is a common comorbidity with T2DM and can place a person at great risk of developing cardiovascular complications (Nelson et al., 2011).

Obesity. Obesity has been identified as a strong risk factor and common co-morbidity of T2DM (Kramer et al., 2010). The United States obesity prevalence trends have closely paralleled that of the current T2DM trends. Over the past 20 years, obesity has increased by 58% in those with T2DM to a total of two-thirds of individuals who have the disease. Additionally, those with co-morbid T2DM and obesity are also at higher risk of development of cardiovascular disease, especially among women (Kramer et al., 2010). Weight distribution also seems to play a factor. Android weight distribution (excess weight in the abdomen) has been especially linked to T2DM and dyslipidemia, as opposed to gynoid weight distribution (i.e. “pear shaped”), which is not associated with T2DM. This seems to be due to a high concentration of visceral fat cells and adipocytokines in abdominal fat, which can cause higher production of free fatty acids and contribute to insulin resistance (Whitmore, 2010). Weight loss has been found to contribute to better glucose control, with even a discrete weight loss of 5-10% showing marked improvements in blood sugar regulation as well as cholesterol and blood pressure (Bantle et al., 2008).

Cardiovascular disease. As previously mentioned, cardiovascular disease (CVD) is closely associated with T2DM. Part of this is due to the fact that those with T2DM fit the metabolic syndrome profile (excess abdominal adiposity, dyslipidemia, and insulin resistance),

which places them at an increased risk of developing CVD (Chan & Watts, 2010). Specifically, insulin resistance contributes to vasoconstriction, thrombosis, and inflammation, all of which can influence the course, severity, and progression of various CVD processes, such as heart failure, myocardial infarction, and stroke (Chahwala & Arora, 2009). Glucose regulation again plays a large role in the risk of this disease, as one study by Stratton and colleagues (2000) found that every 1% decrease in HbA1c was associated with a 14% risk reduction for myocardial infarction. The United Kingdom Prospective Diabetes Study Group (1998), a landmark study demonstrating the value of controlling glucose levels in patients with T2DM, noted a 25% risk reduction of developing microvascular complications associated with T2DM for every 1% decrease in HbA1c.

Nephropathy. Chronic kidney disease is a highly prevalent comorbidity of T2DM (up to 81%) (Chang & Watts, 2010). Risk of developing end-stage renal disease (ESRD) increases 12 fold if the person has T2DM (Afghahi et al., 2011) and diabetes is the most common diagnosis among individuals needing dialysis in the U.S., making up 44% of patients starting dialysis (McMurray, Johnson, Davis, & McDougall, 2002). Contributing factors include hypertension, dyslipidemia, obesity, proteinuria, and membrane damage to the kidneys (Afghahi et al., 2011; Casey, 2011). Interestingly, this disease process seems to adversely affect men more than women, perhaps due to the role of sex hormones in renal disease (with testosterone exacerbating disease progression and estrogen actually acting as a protective factor) (Maric, 2009).

Retinopathy. As damage to blood vessels is not localized to any particular system in T2DM, it is not surprising that it also damages the blood vessels within the retina, which contributes to eventual blindness (Casey, 2011). Retinopathy affects approximately 15% of T2DM patients and diabetes is the leading cause of non-congenital blindness in the U.S. (Costi,

Dilla, Reviriego, Castell, & Goday, 2010; The Eye Diseases Prevalence Research Group, 2004). It is also linked to all-cause mortality in T2DM patients (Anan et al., 2010) and can be exacerbated by conditions such as obstructive sleep apnea (West et al., 2010). If detected early, it can be effectively treated to prevent blindness.

Neuropathy. Neuropathy is characterized by peripheral nerve damage as a result of chronic hyperglycemia, lipotoxicity, and pro-inflammatory responses within the body as a result of insulin resistance. The hands and feet are generally the most affected areas (due to being the most distal) and usually involves sensations of pain, numbness or tingling (Casey, 2011) which can progress to complete numbness and loss of temperature and touch sensation. As a result foot ulceration is common and diabetes is the leading cause of non-traumatic amputations in the U.S. (Rajamani et al., 2009). This complication occurs in approximately 23% of individuals with T2DM (Kärvestedt et al., 2011). Neuropathy complications also seem to occur faster in men than women, partially due to testosterone deficiency, which inhibits protective neurosteroids (Kamenov, Parapunove, & Georgieva, 2010).

Psychological Co-Morbidities of T2DM

Depression. Studies have found that patients with T2DM have a higher prevalence of depression than the general population (27% vs. 7%) and differentially affects women more than men (28% vs.18%) (Lee et al., 2008). Some studies have shown rates of clinical depression among patients with T2DM to even be as high as 42% (Bot, Pouwer, Ormel, Slaets, & de Jonge, 2010). There seems to be a bidirectional effect between depression and T2DM, as depression can affect the behaviors associated with T2DM treatment regimen adherence (e.g. eating a healthy diet, engaging in regular physical activity, taking medication consistently) and, conversely, patient concerns and stress stemming from T2DM health complications can influence the

development and severity of depression (Naranjo, Fisher, Arean, Hessler, & Mullan, 2011; Whiting, Scammell, Gray, Schepers, & Bifulco, 2006). A longitudinal study following over 10,000 participants in the Nurses Health Study conducted by Pan and colleagues (2010) found that the presence of depression was associated with an increased risk of developing T2DM and those with T2DM had a significantly higher risk of developing depression than their non-diabetic counterparts. This association is partially explained by body mass index (BMI), lifestyle factors (e.g. physical activity and diet) and co-morbid conditions. The authors suggest the relationship between T2DM and depression is complex, bidirectional, and is influenced by various factors. Another study by Gonzalez, Delehanty, Safren, Meigs, & Grant (2008) found an inverse correlation between level of depression and diabetes-specific self-care in patients with T2DM, indicating that depression can negatively influence behaviors such as medical adherence, healthy dietary intake, exercise, and glucose monitoring. In all, depression and T2DM seem inextricably linked to some extent, leading many researchers to believe that T2DM is a “depressogenic” disease (Pan et al., 2010).

Emotional distress. Diabetes-related distress (DRD) has been found to be an independent construct from depressive symptoms in patients with T2DM (Gonzalez et al., 2008). This can be defined as emotional distress that arises from the management of T2DM and associated health concerns and symptoms (Fisher et al., 2009). While considered a separate phenomenon from depression, DRD has been identified as a mediator between depression and poor glycemic control (van Bastelaar et al., 2010). Another study by Hamer and colleagues (2010) found that DRD was an independent risk factor for death, partially due to its influence on glycemic control as well as engaging in salutatory health behaviors and T2DM self-management. Physiologically, the increased activation of the hypothalamic-pituitary-adrenal (HPA) axis as a

result of stress stimulates production of excessive cortisol, a glucocorticoid hormone released in response to stress. If chronically elevated, this can induce insulin resistance and T2DM (Chiodini et al., 2007). One 10-year prospective study conducted by Eriksson and colleagues (2008) found that men that exhibited high levels of distress, anxiety, and depression were two times as likely to develop pre-diabetes and three times as likely to develop T2DM.

Coping reactions. There is extensive literature on the study of how individuals appraise and cope with stress. One of the most accepted ways to dichotomize coping responses is by classifying them as problem-focused responses (attempting to directly change a stressor) or emotion-focused responses (managing emotional reactions caused by a stressor) (Lazarus & Folkman, 1984). While emotion-focused coping can bring short-term alleviation, it usually is not adaptive in the long-term, as it rarely tackles that which is causing stress. Coping styles in chronic illness populations has also been under investigation and this concept remains true. Though the chronically ill cannot dissolve the presence of illness, research has found that those willing to adapt to required changes in lifestyle (via engagement in problem-focused coping) generally are able to manage their disease better (de Ridder & Schreurs, 2001). Studies on coping responses in T2DM patients have found that the problem/emotion-focused coping dichotomy is consistent with patient experience (Decoster & Cummings, 2004). Additionally, problem-focused coping in T2DM has shown to be associated with better emotional health and better glycemic control (Shah, Gupchup, Borrego, Raisch, & Knapp, 2012).

Medical Treatment of T2DM

Chronic T2DM that is not well controlled through medication and a healthy diet and exercise regimen can lead to a multitude of diabetic complications, as previously discussed. Medical treatment for T2DM can be rather complicated due to the complex interplay of

comorbid conditions, but there are standard accepted classes of pharmaceutical drugs and treatment algorithms (as set forth by the American Diabetes Association and the European Association for the Study of Diabetes) for use of these medications in combination with behavioral change. Generally, metformin is considered a first line treatment for T2DM in combination with lifestyle changes (such as dietary changes and implementation of a regular exercise regimen and daily glucose self-monitoring) (Lavernia, 2009). Metformin's mechanism of action involves sensitizing insulin receptors in order to reduce resistance (Casey, 2011). If T2DM symptoms are resistant to this treatment (HbA1C levels >7%), basal insulin or sulfonylurea (which simulates insulin secretion) is usually added to the treatment in order to bring down glucose levels (Unger, 2010). Other classes of medication can also be used instead of or in conjunction with these standard protocols including glitazones (which trigger fatty acid uptake and improve insulin sensitivity), alpha-glucosidase inhibitors (which slow glucose absorption in the intestinal track, but are rarely utilized due to gastrointestinal side effects), and incretin therapies (which stimulate GLP-1 receptors) (Casey, 2011; Lavernia, 2009; Unger, 2010).

Adherence to T2DM Treatment Regimens

A primary struggle for those with T2DM is medical treatment adherence, which generally involves daily monitoring of blood sugar levels, 1-2 oral medications, dietary restrictions and recommendations, and at least 30 minutes of physical activity per day. Often times, this is in addition to other medications for concurrent medical issues, including hypertension, hyperlipidemia, neuropathy, and kidney dysfunction (as discussed above). Specific dietary recommendations for patients with T2DM vary depending on various personal factors including weight and other medical co-morbidities; however, general recommendations usually include the

following: lowering red meat intake and saturated fats to below 10% of daily caloric intake; increasing white meat intake; eating a wide range of carbohydrates (e.g. fruits, vegetables, legumes, whole grains); eating fiber-rich foods (which generally have a low glycemic value); and moderate intake of sugars ($\leq 50\text{g/day}$) (Mann, 2006). Some research has been supportive of the DASH (Dietary Approaches to Stop Hypertension) diet for those with T2DM, which supports high fruit and vegetable intake, high low-fat dairy intake, and low fat and sodium intake. One study by Liese, Nichols, Sun, D'Agostino, and Haffner (2009) found that those who adhered to the DASH diet exhibited higher insulin sensitivity and lower weight over a 5-year period, suggesting this diet may be a helpful way of structuring dietary recommendations. However, the research also found that this effect only seemed to apply to Caucasian participants and did not have a significant effect on African American or Hispanic participants, but this may have been due to a small sample of minorities. Recent data highlight the potential value of the Mediterranean diet on primary prevention of cardiovascular disease, including in diabetic individuals (Estruch et al., 2013).

Recommendations regarding self-monitoring blood glucose (SMBG) have been mixed for T2DM, especially for those that are non-insulin dependent (Kempf, Neukirchen, Martin, & Kolb, 2008; Latter et al., 2011). This is due to the lack of consistent treatment algorithms from randomized controlled trials that examine the use of SMBG as well as how patients should appropriately respond when they exhibit elevated readings (Kempf et al., 2008). However, approximately 63% of patients with diabetes do monitor their blood glucose at least once daily, suggesting that this is a practice to which many doctors are ascribing. The guidelines put forth by the International Diabetes Center Global Consensus Conference on Glucose Monitoring Panel in 2005 are suggested to be the most highly utilized among practitioners (Hirsch et al., 2008). These

guidelines suggest the following protocols for glucose monitoring: for those on insulin regimens, glucose monitoring (which consists of a blood sample via a finger prick which is then analyzed by a home glucose monitor) should occur three times a day; for those who are pharmacologically managed on oral medication and are not insulin dependent, but are above target on their HbA_{1c} levels (>7%), monitoring should occur twice per day; for those that are pharmacologically managed on oral medication (non-insulin dependent) and are on target with their HbA_{1c} levels (<7%), glucose monitoring should occur once per day with pre/post-prandial (before and after a meal) readings at least once per week; for those who are managed on lifestyle changes alone, monitoring should occur once weekly and include pre/post-prandial readings (Hirsch et al., 2008).

As few as 36% of people with T2DM fully adhere to prescribed treatment plans (Strayer & Caple, 2010). This non-adherence contributes to the deleterious health effects described above, which lead to more health complications, increased hospitalizations, and greater risk of death (Doggrell, 2010).

Factors Attributing to Adherence/Non-Adherence

A constellation of factors contribute to non-adherence, among which are medical regimen complexity, inability to pay for medication, co-existing psychological conditions (e.g., depression), cultural factors (e.g., fatalistic attitude about T2DM), low social support, and lack of perceived control over T2DM management (Strayer & Caple, 2010). In a meta-analysis conducted by Odegard and Capoccia (2007), the main barriers to adherence fell into three categories: patient factors (e.g. diabetes knowledge, self-efficacy regarding disease treatment, health beliefs and depression); medication factors (e.g. cost, adverse effects, regimen complexity, and frequency of dosing); and provider factors (e.g. knowledge of medications, demonstration

skills, inadequate educational support and inadequate follow-up). Given the heterogeneity in barriers, the researchers underlined the importance of matching one's intervention to the specific barriers identified by the patient, as there is no uniform set of barriers.

Cost. High patient cost has been identified as one predictor of non-adherence. Cost of medication for T2DM can be significant, especially when patients have limited health insurance coverage. Research has linked cost to non-adherent behaviors. A study conducted by Hunt, Rozenfeld, and Shenolikar (2009) found a positive relationship between HbA1c levels and cost-sharing for T2DM medication- as patient cost went up, so did HbA1c levels. Another study by Gibson and colleagues (2010) found that for every \$10 increase in patient cost for T2DM medication, adherence rates fell by 5.4% and this was associated with a greater number of hospitalizations, diabetic complications and sick days from work.

Regimen complexity and tolerability. Due to the complex nature of treatment protocols for patients with T2DM as well as the high number of common co-morbid conditions, daily medication regimens can become very complicated and sometimes confusing. The average patient with T2DM takes an average of at least five different medications per day (Bailey & Kodack, 2011). Polypharmacy can lead to a higher potential risk of adverse interaction effects and the experience of medication side effects, which can discourage patients from taking their medication and evoke a sense of distrust in the medical profession (Hauber, Mohamen, Johnson, & Falvey, 2009). Pollack, Purayidathil, Bolge and Williams (2010) examined tolerability problems in T2DM patients and found that medication tolerance was significantly associated with likelihood of non-adherence. For every episode of intolerability or adverse side effect, the likelihood of non-adherence increased by 28%.

Depression. As previously discussed, depression is a common comorbidity seen in T2DM patients and can influence rates of adherence. Individuals with depressive symptomology generally feel more fatigued, less motivated to stabilize their health and have lower self-efficacy regarding their ability to manage their condition (Bot et al., 2010). The relationship between adherence and depression is likely bi-directional, as adherence can affect severity and duration of depression (as individuals tend to feel worse and experience lower health-related quality of life due to non-adherence) and depression can influence rates of adherence (Sacco et al., 2007).

Social support. The presence of a close support system is considered a contributing force for T2DM treatment adherence. Those who are able to identify having a social support system that is readily available usually have much higher success rates in managing their disease. Of particular influence are intimate partner relationships. Research has found that as marital satisfaction increases, so does diabetes adherence to medication as well as lifestyle recommendations (e.g. healthy diet, physical activity) (Beverly & Wray, 2010; Trief, Orendorff, & Himes, 2001). This has important implications for designing diabetes interventions, as social support and feelings of belongingness seem to play a significant role in adherence behavior.

Health beliefs. Another point to consider is that T2DM patients place differential importance on the various aspects of their treatment. In one study by Broadbent, Donkin, and Stroh (2011), patients reported much higher adherence to their medications than their dietary and exercise prescriptions set forth by their physicians. They behaviorally attributed this finding to the immediate reward of taking medication, the minimal amount of effort it takes to receive this reward and the high amount of personal control the patients felt as a result of taking their medication.

Patient-provider communication. The dynamic relationship between patient and health care provider can play an important role in adherence. Successful patient-provider relationships that center on trust, education, empathy, and encouragement predict better treatment adherence (Piette, Schillinger, Potter, & Heisler 2003). Provider perceptions of patients based on race and SES has been found to influence communication style, treatment decision-making, and level of trust the patient has in his or her provider (Lutfey & Ketcham, 2005). Providers who hold stereotypical attitudes towards their patients (either intentionally or unintentionally so) typically lack the above mentioned characteristics of successful patient-provider relationship, which can lead to non-adherence. A study conducted by Heisler, Bouknight, Hayward, Smith and Kerr (2002) found that effective communication between provider and patient and the presence of a participatory decision-making style predicted successful adherence in T2DM patients, underlining how important this relationship can potentially be in disease management.

Racial Disparities in T2DM Adherence and Related Factors

AAs are more likely to have poorly controlled T2DM due to non-adherence, which in turn increases their risk for health complications (Egede et al., 2010). Identified factors associated with this include poor diabetes knowledge, low self-management skills, negative and/or fatalistic attitudes about T2DM, deleterious lifestyle behaviors, low patient-provider communication, and a general distrust of medical professionals (Egede et al., 2010).

One study by Chlebowy, Hood, and LaJoie (2008) conducted focus groups with AA T2DM patients regarding barriers to effective T2DM self-care. The results indicated that the main personal barriers to adherence included fear and avoidance of glucose monitoring, low self-regulation of dietary habits, and a perceived lack of control over the disease process. The

researchers recommended that future intervention research concentrate on assisting AAs with these identified personal barriers to adherence and facilitate a greater sense of personal control. Another study conducted by Hill-Briggs and colleagues (2005) identified low medication supply (due to financial concerns) and forgetting to take medication to be the most common reasons for non-adherence in a sample of AAs with T2DM. Additionally, younger AAs were identified to be more non-adherent and have poorer glucose control than their older counterparts. SES and sex were not significantly associated with level of adherence. The authors underlined the importance of diabetes education and skills training in order to assist AAs overcome these adherence barriers.

Research has also examined the role of health literacy and how this may play a factor in treatment adherence for AAs. One study conducted by Osborne, Cavanaugh, Wallston, White and Rothman (2009) examined the role of health literacy in adequate glucose control in AAs with T2DM. Specifically, the researchers looked at numeracy (the ability to use numbers in everyday life) and how low numeracy (both general and diabetes-specific) may affect glycemic control. Findings showed that while being AA did predict low glycemic control, when numeracy was taken into consideration, race as a predictor was reduced to non-significance. This implies that a potential significant contributor to the racial disparity seen in AAs may be health literacy and, specifically, numeracy, which has implications for culturally informed interventions for treatment adherence.

Social context is another important issue to consider when conceptualizing the adherence disparity observed in AAs. A qualitative study conducted by Samuel-Hodge and colleagues (2000) examined the role of environment and context in the day-to-day management of T2DM in AA women. A series of focus groups were conducted to better understand what psychosocial

variables (e.g. perceived self-efficacy, social environment, coping, quality of life) influenced lifestyle behaviors associated with T2DM self-care (e.g. medication management, physical activity, dietary patterns). Emerging themes from these focus groups included spirituality/religiosity, diabetes impact (e.g. fear of suffering, diet-related deprivation, mental tiredness), multi-caregiver role, stress, coping and social support. Implications from these findings include the fact that patient complaints of tiredness to their physicians may connote more than physical fatigue, and can include psychological tiredness that stems from disease-related fear and worry and should be probed to a greater extent. Additionally, the burden of having a multi-caregiver role that is imposed onto many AA women may also have a significant influence on self-care behavior as these women have a tendency to put their families' needs ahead of their own. As a result, the authors recommend that interventions focus on helping these individuals strike a balance between family responsibilities and taking care of themselves and also collectively involving the family in T2DM self-care behaviors.

In another study that was specifically geared towards adjustment to T2DM in AA men (Liburd, Namageyo-Funa, & Jack, 2007), the concept of masculinity was explored and how it potentially influenced T2DM self-care behaviors. Focus groups with AA men with T2DM were conducted and emerging themes were explored. Results showed that having a T2DM diagnosis seems to have a significant effect on men's appraisal of their self-efficacy and masculinity. Additionally, men cited that they were more likely to put up self-imposed boundaries to social support if they perceived family or friends to be "policing" them versus trying to gently assist. Lastly, AA men were more likely to continue normal dietary patterns post-diagnosis, even if the diet was contraindicated to appropriate disease management. Participants cited their reasoning to be that meal planning and concern with dietary intake is traditionally a woman's role and, by

assuming this role, masculinity is threatened. The authors concluded that addressing these culturally influenced gender roles and discussing disease management in context of these potential barriers may be important in future interventions that include AA men.

Current Interventions for T2DM Non-Adherence

According to the results disseminated by the Diabetes Prevention Program Research Group (2002), lifestyle interventions were found to be more effective in controlling the progression to T2DM than metformin pharmacotherapy in those with pre-diabetes. This finding was crucial in understanding how an emphasis on changing lifestyle behaviors can truly affect disease onset, course and progression. However, within the realm of lifestyle interventions, there is great heterogeneity in types and administration of interventions, which exhibit varying levels of effectiveness.

Education-based interventions. Education-based interventions have been considered the standard intervention for facilitating T2DM treatment adherence. There are various curricula available, provided by the CDC as well as local and state entities. The standard content topics for these education curricula as set forth by the American Association of Diabetes Educators (Funnell et al., 2010) include: describing the diabetes process; incorporating nutritional and physical activity in one's life; safe medication management; how to identify and treat acute and chronic complications; promoting the development of personal strategies to cope with the disease process and create lasting behavior change.

Education interventions have evolved over the past 30 years since first being introduced in both out- and in-patient medical settings. Education-based interventions have been found to increase diabetes knowledge (especially when given in a one-on-one setting); however, this increase in knowledge has not been found to translate to higher patient adherence or sustained

glycemic control (Brown, 1999). This may be due to the lack of incorporating a behavioral skills focus, which concentrates on the more applied barriers to adherence. In one study conducted by Campbell, Redman, Moffitt, and Sanson-Fisher (1996), the researchers constructed a comparative intervention study consisting of a minimal instruction intervention (2 one-hour sessions covering extremely basic T2DM self-care), a group education intervention (3 day seminar format), an individual education intervention (2 one-hours sessions within two weeks of enrollment) as well as an individual behaviorally focused intervention (1-hour session every three months for 12 months utilizing cognitive-behavioral strategies such as goal-setting, self-monitoring, and problem-solving). Both education interventions covered a greater depth and breadth of T2DM self-care and education regarding T2DM long-term complications than the minimal intervention. Results showed that those in the behavior-focused treatment showed longer-term reductions in blood pressure, cholesterol risk ratio, and were more likely to seek routine medical care than those in the minimal instruction or education groups. The researchers' interpretation of these results included that diabetes knowledge does not necessarily translate to better health outcomes and the dose response may need to be greater in behavioral interventions in order to see any changes in glycemic control (as no significant changes were observed in this study). In support of these findings, a more recent meta-analysis conducted by Ellis and colleagues (2004) found that education-only interventions that were most successful in influencing glycemic control incorporated some sort variant of behavioral strategies (e.g. self-monitoring, goal setting or problem-solving), suggesting this is an important factor when designing a diabetes adherence intervention. Another meta-analysis conducted by Norris, Lau, Smith, Schmid, and Engelgau (2002) found that the most successful education interventions were longer in duration (a decrease for every 1% HbAc1 was associated with an additional 23 hours of

intervention contact). This suggests that the dose-response for effective long-term glycemic control via education interventions may not be realistic or feasible in a managed care setting, considering the amount of needed contact to make clinically significant reductions in HbA1c levels.

So as supported by the literature base, while diabetes education has been recognized as an important factor for disease self-management, it has been noted that it is not sufficient in helping sustain ongoing disease management behaviors, as effects on glycemic control tend to diminish within six months of the education course (Funnell et al., 2010). As research on T2DM interventions have evolved, diabetes education is utilized more as a possible education comparison group for randomized clinical trial studies (Brown, 1999).

Behavioral interventions. As discussed above, traditional education interventions have not been adequate in promoting long-term adherence (Doggrell, 2010). In order to address non-adherence effectively, interventions need to assist in removing barriers to effective self-care, focus on emotional, cultural, and lifestyle factors that influence disease management, and discuss how relational factors (patient-provider relationship, personal relationships, etc.) may also play a part in one's ability to effectively adhere (Egede et al., 2010). Behavioral interventions have been demonstrated to be effective in a variety of settings, and are trending towards being more theoretically informed (as discussed below).

Theoretical bases of behavioral interventions. Recent trends in behavioral interventions have called for the development and use of interventions that are theoretically informed (Mitchie, Rothman, & Shearan, 2007). By creating, implementing and testing the efficacy of theoretically-informed interventions, researchers can better understand the effective components of interventions.

Biopsychosocial model. The biopsychosocial model of health recognizes that social, cultural, and psychological factors *in addition to* physiological factors affect a person's overall health and trajectory of illness (Engel, 1980). A 10-year outcomes study put forth by the Diabetes Prevention Program found that changing such lifestyle factors was twice as effective in the prevention of T2DM onset in comparison to medication in at risk adults, providing evidence that behavioral interventions are integral to overall health outcomes, with T2DM being especially relevant (Diabetes Prevention Program Research Group, 2009).

Social-cognitive theory. Recent interventions for patients with T2DM are focusing on problem-solving and coping skills development, which have successfully increased adherence (De Greef, Deforche, Tudor-Locke, & Bourdeaudhuij, 2010; Hill-Briggs et al., 2006; Peek et al., 2010). The social cognitive theory (SCT) of behavior change has influenced these types of interventions, as it posits that developing problem-solving and coping skills enhances self-confidence and feelings of efficacy, which make it easier to complete health-related behaviors (Bandura, 1998). By focusing on the application of disease knowledge and learning effective problem solving skills, patients are able to effectively work through some of the perceived barriers in their lives. Focus on increasing self-efficacy and outcome expectancies (the costs and benefits of one's actions) are primary tenants of SCT. However, research has supported that the focus on improving self-efficacy seems to play a large role in predicting behavior change (Baban & Crucian, 2007). SCT has been effectively used to change many health behaviors, including nutrition, physical activity as well as disease management and adherence in T2DM (De Greef, et al., 2010; Luszczynska & Tryburcy, 2008; Plonikoff et al., 2010; Senecal, Nouwen, & White 2000).

Small-change model. This emerging theory is focused on participant-selected goals in making discrete changes in diet and physical activity versus large changes in a short period of time that may be less amenable to long-term maintenance. It has been used very successfully for weight-management populations (who characteristically have a difficult time with adhering to multi-faceted regimens involving dietary and physical activity change) and has shown to promote initial weight loss in both middle aged healthy men and women (Lutes et al., 2008), and in patients with multiple co-morbidities (Damschroder, Lutes, Goodrich, Lowery & Gillon, 2010), and exhibit continued weight loss across long-term follow-up with minimal contact (Lutes et al., 2012). This is relevant to the current population as weight loss is associated with improvement in glycemic control for patients with diabetes (DPP Research Group, 2009). This theoretical approach has been developed to help individuals overcome the various barriers (emotional, cultural, and environmental) that may impede T2DM self-care and adherence behaviors. However, to date no intervention has been done using this theoretical approach in patients specifically with T2DM and warrants further consideration.

Mindfulness-based stress reduction. Mindfulness is considered a state of active awareness of one's life and purpose in the present moment. It focuses on fostering acceptance and thoughtful responses, which in turn can help facilitate more adaptive responses to stressful situations, resulting in reduction of negative effects of stress and greater health and well-being (Baer, 2003). A theory of mindfulness mechanisms of action proposes that responding, rather than reacting instinctively, to situations enables people to better understand their decisions and regulate their feelings and behaviors, which increases perceived control and decreases stress (Rosenzweig et al, 2007).

Types of behavioral interventions. Behavioral interventions for T2DM lifestyle changes and treatment adherence vary in terms of duration, venue, and delivery method. Use of SCT components for informing interventions seems to be a recurring theme among many of the more recent studies and will be of primary focus for this review.

Group intervention. Group interventions for T2DM have widely varied in scope and orientation. Many have focused on altering lifestyle factors such as physical activity and dietary intake in order to facilitate weight reduction. One study by De Greef and colleagues (2010) examined the effectiveness of a group-based pedometer intervention for increasing physical activity in those with T2DM. The intervention was informed by initial use of motivational interviewing (to strengthen commitment to change), cognitive-behavioral theory (CBT) as well as SCT. Central components of the intervention included self-monitoring, social support and immediate feedback (via the pedometer). No guidance was given regarding glycemic control or dietary recommendations. Five 90-minute sessions were conducted over the course of 12 weeks and focused on various CBT and SCT content including decreasing self-defeating thoughts, increasing time management skills, problem solving and action planning, as well as goal-setting. Results showed that the intervention groups significantly increased their daily steps and continued to show increased steps over a 12-month duration following the intervention; however, sedentary behavior did not stay improved over this period of time. These results indicate that this type of intervention has implications for lasting effects; however some type of long-term follow up may be indicated (such as phone call booster sessions).

A study by Senecal and colleagues (2000) examined the applicability of SCT themes for dietary self-care in participants with T2DM. The authors found that self-efficacy and self-regulation were associated with greater dietary adherence. In relation to this, a meta-analysis by

Spahn and colleagues (2010) examined the efficacy of theory-based behavioral interventions used in 87 studies that aimed to change dietary behaviors. CBT and SCT components including goal-setting, problem-solving and appropriate utilization of social support were all deemed effective strategies when trying to change food behavior, aiding support to the idea that these are important components to consider when designing an intervention.

Group interventions focused specifically on overall treatment adherence with glycemic control as a main outcome measure have been less abundant. In a meta-analysis conducted by Baker, Simpson, Lloyd, Baughman, and Singh (2011), group-based interventions were found to be the most commonly utilized intervention for prevention of T2DM. Group interventions were at times followed-up by intermittent individual counseling for long-term care in order to determine the effectiveness of these check-ins on maintaining glycemic control and high treatment adherence. The majority of the behavioral interventions included goal-setting, self-monitoring activities (e.g. food records, exercise logs, blood sugar records), and problem solving. Overall, the effectiveness of the 21 intervention studies assessed indicated moderate overall effectiveness in achieving stable glycemic control and treatment adherence, with no treatment efficacy differences between group and individual treatment protocols.

In another meta-analysis conducted by Vermeire, Van Royen, Hearnshaw, and Lindenmeyer (2005), interventions aimed at treatment adherence were minimal and have shown mixed results in reference to efficacy. The authors even went so far to say that due to the heterogeneity of results and outcome measures, there are currently no consistently effective interventions for treatment adherence in T2DM.

However, some recent literature does indicate that the research is beginning to shift. In a large scale clinical intervention study (Delahanty & Nathan, 2008), a group adherence

intervention (Look AHEAD) was developed that paralleled the lifestyle intervention used in the DPP (2009), with the major difference being that they included participants who were already diagnosed with T2DM. The intervention aimed to decrease CVD risk factors as well as measure indicators of treatment adherence including HbA1c, weight control/loss and physical activity. Behavioral strategies implemented included problem-solving, goal-setting, behavioral contracts, and self-monitoring. Preliminary results have shown that in comparison to an education and support control group, those in the intervention group showed significantly lower HbA1c levels, blood pressure, and cholesterol, making this study evidentiary that group-based lifestyle interventions can positively influence T2DM self-management. However, the trial was stopped in 2012 due to the lifestyle intervention not decreasing the likelihood of cardiovascular events (a main study aim) (Després & Poirier, 2013).

Telephone. Phone-based interventions for T2DM are becoming more common, especially for those in rural areas or those with transportation concerns. They have also been used as long-term follow-up after initial face-to-face interventions. One study conducted by Nesari, Zakerimoghadam, Rajab, Bassampour, and Faghihzadeh (2010) used a phone follow-up intervention after a three day T2DM workshop to elucidate the effect on long-term adherence (3-months). Phone calls were nurse-facilitated twice a week for one month and once a week for two months. During these 20-minute phone calls, health behaviors were assessed (using problem-solving as needed) and education was reinforced. After the three-month period, those in the phone intervention group have significantly lower HbA1C levels and reported greater levels of behavioral adherence than those who did not receive phone follow-up. In another study by Sacco Malone, Morrison, Friedman, and Wells (2009), a phone-based intervention was used to facilitate physical activity as well as medical adherence in T2DM patients. Weekly 20-minute

phone calls were placed by trained research assistants for 24 weeks, and focused on the importance of self-monitoring, education, and problem-solving for overcoming adherence barriers. Results showed that those in the intervention group increased their exercise frequency, improved diet and discreetly lower HbA1C levels. The authors identified goal-setting, increased self-efficacy and reinforcement as the primary mediators of behavioral change observed.

Web-based. Web-based behavioral interventions are a fairly novel approach in the realm of T2DM treatment. While not much literature on this topic exists in terms of medical treatment adherence for those with T2DM, the results so far look fairly promising for enhancing physical activity. A study conducted by Liebreich, Plotnikoff, Courneya, and Boule (2009) focused on examining the effectiveness of an internet-based behavioral intervention to increase physical activity among T2DM patients. Participants used an online self-monitoring system for keeping track of physical activity and they were encouraged to log onto the website at least once per week. Contents of the website included an interactive message board, diabetes education, as well as fitness tips. Participants also received weekly e-mail counseling for 12 weeks. Results showed that those in the intervention group exhibited significant improvements in physical activity as well as their capacity for altering their current lifestyle behaviors in comparison to a usual care control group. Future web-based interventions should build on this promising research and perhaps shift to more of an adherence-focus in order to better understand how it may affect long-term adherence behaviors.

Mindfulness-based interventions. Traditional mindfulness-based stress reduction (MSBR) interventions last eight weeks and focus on developing mindfulness skills to decrease stress and enhance coping (Baer, 2003). Research on MBSR has shown clinically significant reductions in physiological and psychological symptoms across a wide range of medical diagnoses and in high

stress populations. Specifically, it has been shown to significantly increase relaxation ability, effectiveness of coping with both short and long-term stressful situations, energy and enthusiasm for life, and self-esteem (Bishop, 2002). When used in various medical populations, MBSR demonstrates medium effect sizes corresponding to decreased stress and physical symptoms associated with disease states (Carmody & Baer, 2009). In the one study of MBSR's effect on glycemic control in T2DM patients, Rozenweig and colleagues (2007) examined MBSR's effect on HbA1c levels, blood pressure, and psychological factors such as depression and anxiety. Results showed that those in the MBSR intervention had significantly reduced HbA1c levels as well as reduced psychological distress. While these initial results are promising, MBSR effectiveness is still a relatively new area of research that requires further testing to fully understand how it can be implemented effectively and its effectiveness with T2DM populations.

Adherence interventions for African Americans. Adherence interventions targeted for rural, low income AAs are scarce. Most interventions have been found to be more effective for Caucasians, perhaps due to minimal consideration to cultural and social factors and appropriate communication and delivery methods for this population (Bogner & de Vries, 2010). These factors have been identified as current barriers as to why effective interventions for this population have been difficult to develop.

Despite these discouraging findings, one intervention mechanism that seems to work well with AAs is problem solving. Several studies have demonstrated the effectiveness of using problem solving skills in group-based interventions with African American. Research has shown that problem-solving skills seem especially under-developed in low-income, urban AA populations, which is correlated to poor glycemic control, warranting the use of this intervention technique (Hill-Briggs, 2003; Hill-Briggs et al., 2006). In a study conducted by Hill-Briggs and

colleagues (2011), a condensed (1 session) and intensive (8 session) intervention group was conducted to determine the effectiveness of a problem-solving based intervention for low income AAs. Content of the intervention concentrated on identifying barriers to self-management behaviors and how to apply problem-solving techniques. Results showed that the intensive intervention group participants showed the greatest reduction in HbA1C levels, as compared to the condensed intervention participants. Additionally, those in the intensive group exhibited improvements in blood pressure as well as lipid functioning. The results of this study indicate that while intervention strategies may need to differ for AAs, problem-solving techniques for behavioral change are effective.

Main Critiques of Current Adherence Interventions for T2DM

While a multitude of interventions exist to promote health and adherence among individuals with T2DM, there are still areas for growth. In a meta-analysis of adherence interventions conducted by Vermeire and colleagues (2005), some of the main weaknesses in the current literature include poor intervention descriptions and identification of mechanisms of action, which makes understanding the effective components difficult. Additionally, while many studies say they are measuring adherence, the operational definition of adherence is never explicitly discussed, so adherence is only vaguely defined by the constellation of outcome measures. Additionally, the outcome measure is generally one-dimensional (only actual measure cited is glycemic control), which does not always reflect level of adherence (especially in those with complicated disease presentations). The authors also highlighted the fact that most research reported statistically significant changes in health markers such as HbA1c; however, these changes are not necessarily clinically significant. The authors challenge future research to more specifically define their measures of adherence and to base clinical interventions in a theoretical

framework (due to the current heterogeneity in intervention approaches) so determinants of adherence can be better elucidated.

In summary, many specific behavioral interventions for lifestyle change (mainly focusing on physical activity and weight reduction) have been implemented and found to be effective. However, less research has examined the role of theoretically informed behavioral interventions that are aimed at total treatment adherence with physical health endpoints (specifically HbA1c levels). Additionally, there is a greater gap in the research when specifically examining the efficacy of behavioral interventions for AAs, who are most at risk for treatment non-adherence. Considering this paucity of research on culturally tailored and theoretically informed T2DM treatment adherence interventions, the current research proposal aims to help fill this gap.

Current Research Study Aims

The *first aim* of this dissertation research was to conduct a focus group to better understand what barriers to sustaining treatment adherence exist for AAs with T2DM in eastern NC. The *second aim* was to incorporate focus group feedback into the development of a culturally informed T2DM adherence intervention for AAs. The *third aim* was to conduct a pilot study with AAs with T2DM to determine if the intervention is effective in increasing treatment adherence and self-efficacy regarding the ability to control and adequately treat T2DM, and decreasing emotional distress and HbA1c levels compared to an education comparison group (ECG - diabetes education only).

Hypotheses

The PI hypothesized that the intervention group (IG) participants would exhibit: a) greater rates of adherence (in terms of medication usage and behavioral adherence to dietary/physical activity/glucose monitoring/feet checking, and reflected in lower HbA1c levels);

b) greater knowledge and self-efficacy regarding treating T2DM; c) lower stress and depressive symptoms; d) greater problem-focused coping and lower emotion-focused coping; and e) greater mindfulness compared to those in an education comparison group (ECG) at the end of treatment (T2) as well as three months post-treatment (T3).

Chapter II: Methods

Current Research Overview

Phase 1 of this study consisted of conducting a focus group in order to obtain information about perceived barriers to treatment adherence (study aim 1) and organize an intervention that was informed by this feedback as well as theory and research (study aim 2). Phase 2 consisted of the intervention phase where an intervention was piloted in a randomized controlled trial to test the efficacy of the intervention (study aim 3).

Phase 1: Focus Group

Recruitment. IRB approval from East Carolina University's (ECU) Social and Behavioral Sciences IRB was granted before any research took place (Appendix A). Approval for this research was also granted from the Family Medicine department executive board. The ECU Family Medicine Clinic (FMC) treats a high volume of patients with T2DM (~2500/year) from a large surrounding rural area. Adherence to T2DM medical treatment has been identified as a major problem, with few resources available to address this. After receiving appropriate approvals, eligible focus group participants (those who identified as African American (AA), were between the ages of 18-68, were diagnosed with T2DM, were cognitively able to provide informed consent, and had self-reported difficulties with treatment adherence in the past or currently) were recruited from weight management and diabetes education classes held at the ECU FMC. Interested patients were asked to provide their name and phone number and then were briefly screened via phone to determine eligibility and appropriateness for the focus group (in order to confirm diagnosis, difficulty with treatment adherence in the past or present).

Participants. A total of nine focus group participants were recruited from the weight management and diabetes education classes in the FMC at ECU. Participants were compensated

with \$10 Wal-Mart gift cards directly after participating in the one-hour focus group. All participants were AA with T2DM and self-identified as having adherence difficulty either in the past or present. Based on questionnaire data, the focus group was comprised of five women and four men, with an average age of 52 ($SD = 9.35$). Eight participants had at least graduated high school and four had completed at least two years of college. The average length of diagnosis was 7.3 years ($SD = 10.39$).

Procedure. Participants participated in a 1-hour session to discuss issues related to the treatment of T2DM. Topics of discussion included challenges to adherence, current knowledge of diabetes care, effective information delivery techniques, and attitudes about control over their condition. Prior to beginning the focus group, all participants completed a short questionnaire that asked demographic information and also asked them to endorse areas of problematic adherence (diet, medication, weight management, cost of treatment, and exercise). Based on a frequency analysis of questionnaire data, all participants endorsed that adhering to a healthy diet was a major challenge in their diabetes treatment regimen. Seven participants endorsed weight management and exercise as adherence challenges. Three participants endorsed cost of treatment as being a challenge and two participants endorsed taking medication consistently as being a challenge.

During the focus group, participants were asked a variety of questions about their experience with diabetes management, what was challenging and how they thought the experience of diabetes was perhaps different from those of other races (see Appendix B). The focus group session was audio recorded, transcribed, and then examined for themes regarding identified adherence barriers. Due to there being only one focus group and the homogeneity of responses to each question, a formal coding process was not necessary. Resoundingly (and

consistent with questionnaire responses), participants endorsed diet as one of the most significant challenges to treatment adherence. Specifically, they identified cost of healthy food and lack of information about how to portion and prepare foods as prohibiting healthy eating. Regarding their experiences as AAs with diabetes, participants mentioned feeling distrust regarding medication mechanisms working the same way for AAs as other races. They also noted that they felt others in the AA community (those without T2DM) were less supportive than social systems of other races. Participants endorsed feeling isolated and unsupported in efforts to stay adherent to their regimens. They noted while family/friends were generally willing to point out when participants weren't adhering to their treatment, they were not willing to assist in supporting adherence (e.g. preparing healthy foods). They noted this added to their overall stress level. They endorsed having T2DM-specific support groups and education regarding treatment management would be helpful in contributing to better adherence behaviors. When asked about effective delivery of information, they cited having group-based interactions would be very helpful when discussing how to increase T2DM treatment adherence. Specifically, learning how to adhere to dietary recommendations while on a limited budget, how to control stress resulting from blood glucose fluctuations, and having a venue to discuss with others who have similar difficulties were suggestions presented during the focus group.

Based on the focus group feedback, the PI developed a culturally informed group intervention that focused on symptom alleviation as well as skill and resource-building based on the SCT and small change models of health behavior change (Bandura, 2004; Lutes et al., 2008), with an additional focus on mindfulness meditation for emotional stress reduction.

Phase 2: Intervention Pilot

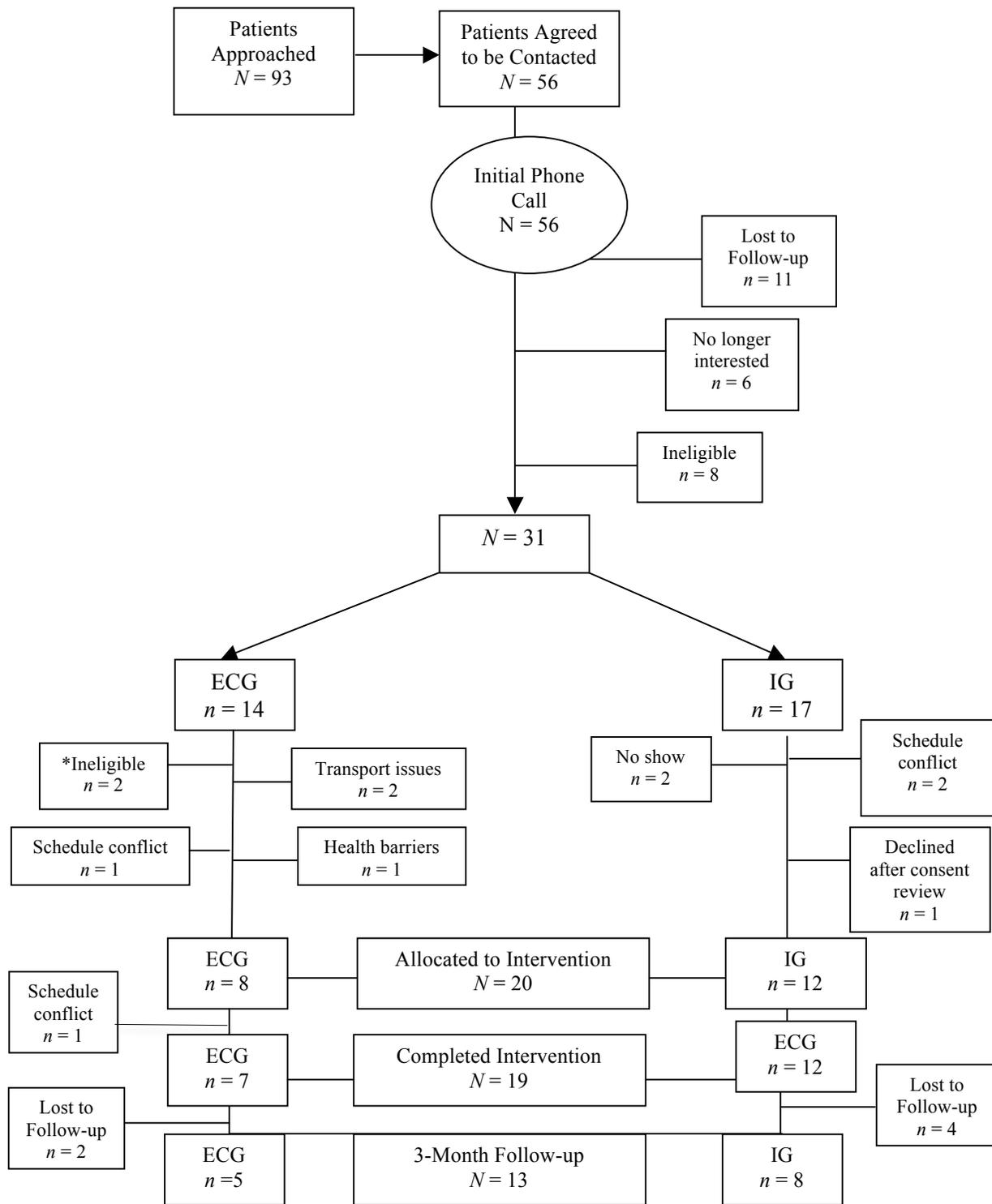
Recruitment. Eligibility criteria for the intervention phase included patients who attended the ECU FMC, identified as AA, were between the ages of 18-68, were diagnosed with T2DM, had current self-reported difficulties with treatment adherence, and reported recent HbA1c levels of at least 8%. Recruitment for the intervention phase consisted of a two-pronged approach. One approach consisted of recruiting patients during regularly scheduled medical appointments at the ECU FMC. Medical staff identified potential participants based on race, diagnosis, and most recent HbA1c level and alerted study personnel of when those patients were scheduled for that day. Patients were then initially gauged for interest in the study by medical staff, and if interested, were approached by study personnel. Interested patients were briefly informed about the study and were asked to provide contact information if they were interested in enrolling. The second approach consisted of recruiting patients who attended either the diabetes management or weight management groups that were held in the FMC. The PI approached these groups approximately once per month for three months and announced the overview of the study. A sheet soliciting names and phone numbers was passed around the groups for those who were interested in receiving more information. The PI then logged all interested participants' information into a database. Within a week of them giving contact information, the PI contacted potential participants and gave more general information about the groups, including frequency, length, and duration (which were the same across both the IG and ECG), with a vague description of content being focused on helping with diabetes treatment adherence. Basic eligibility criteria were also reviewed in order to confirm potential qualification for inclusion. Interested patients were asked to provide times available for attending groups in order to help the PI create group times that were conducive for patient schedules. Patients still interested were then randomized to groups via a free randomized subject selection website for

social science research (<http://www.randomizer.org/>). This was done to allow for unbiased randomization of participants into the intervention or education comparison condition. When approximately 12 individuals had been recruited and randomized into a condition, an IG and ECG were initiated. Recruitment efforts resulted in the formation of three IG's and three ECG's ranging from two to six patients per group. A full summary of the recruitment and enrollment process can be found in Figure 1, in concordance with Consolidated Standards of Reporting Trials (CONSORT) guidelines, which is considered the gold standard for providing complete information on methodology and results in randomized controlled trials (Shultz, Altman, & Moher, 2010).

Participants. Based on a power analysis (using G*Power 3.1; with a beta of .20 an alpha of .05, and the strength to detect a medium-size effect) approximately 128 participants would be needed (Faul, Erdfelder, Buchner, & Lang, 2009). Ultimately, the PI was able to recruit a total of 20 participants. Inclusion criteria for participants included: self-identified as AA, HbA1c \geq 8.0%, ages 18-68, and cognitively able to give informed consent. All participants were given a total of \$25 in Wal-Mart gift cards (\$10 after session 1 and \$15 after session 4). IG participants received intervention materials (workbook, logbook), while ECG participants were given an educational workbook based on the North Carolina Diabetes Education Curriculum.

Participants ranged from 35 to 66 years of age, with a mean age of 50.8 ($SD = 9.41$). The sample was comprised of 50% women and 50% men. Participants reported being diagnosed with T2DM an average of 6.9 years ($SD = 6.12$). Seventy-five percent of participants reported they were currently not employed, 20% reported working full time and 5% part-time. Ninety-five percent of participants had graduated high school, while 70% had received at least some college-

Figure 1. CONSORT Summary of Recruitment and Retention



Legend: IG = Intervention group; ECG = Education Comparison Group; * Patients were initially eligible but then had a recent HbA1c level <8.0

level education. A full table of demographic information for the IG and ECG can be found in Table 1.

Procedure. Pre-intervention (T1) measures were obtained at the start of the first group session, immediate post-intervention (T2) measures were obtained directly after the fourth session, and three-month post-intervention (T3) measures were collected via phone approximately 3-4 months after the end of the intervention. After completing informed consent and HIPPA consents, most recent HbA1c levels were abstracted from medical charts after session one. HbA1c levels were then again abstracted approximately 3-5 months later (when they were next seen for a medical appointment at the FMC). Retention strategies were employed in order to reduce attrition, and included a follow-up confirmation phone call after initial enrollment, weekly reminder calls for the IG and ECG groups, as well as compensation for time through two gift cards distributions during the intervention phase (\$10 after session 1 and \$15 after session 4). Participants were then contacted via phone three months later to complete an abbreviated questionnaire packet (consisting of the SDSCAQ, MMAS, PDSMS, PSS, and CES-D). Thirty-one potential participants (17 IG, 14 ECG) were initially randomized and enrolled in the study and then 20 participants were actually consented (12 IG, 8 ECG). Nineteen (12 IG, 7 ECG) finished the groups and immediate post-intervention measures (total attrition rate = .5%; IG = 0%; ECG = 1.25%), while a total of 13 participants (8 IG, 5 ECG) completed the measures three months post-intervention (total attrition rate = 35%; IG = 33%; ECG = 38%). Study personnel were able to abstract a total of 16 post-intervention HbAc1 levels (9 IG and 7 ECG). We were unable to abstract four participants' HbA1c levels due to the participants not attending their scheduled medical appointments.

Table 1

Participant Demographic Information

Demographic Variable	Intervention Group (n = 12)	Education Comparison Group (n = 8)	Total Sample (N = 20)	p-value
Age: In years, mean(<i>SD</i>)	45.6(6.5)	58.5(7.7)	50.75(9.4)	.001*
Sex: Women, <i>n</i> (%)	7(58)	3(38)	10(50)	.65
Education: <High school, <i>n</i> (%)	0	1(12.5)	1(5)	.29
High school	4(33)	1(12.5)	5(25)	
Some college, no degree	4(33)	4(50)	8(40)	
Two-year degree	4(33)	1(12.5)	5(25)	
Four-year degree	0	1(12.5)	1(5)	
Marital Status: Single, <i>n</i> (%)	6(50)	4(50)	10(50)	.95
Married	5(42)	3(37.5)	8(40)	
In a relationship	1(8)	1(12.5)	2(10)	
Annual Income: In \$, mean(<i>SD</i>)	15,589(10,708)	24,685(13,954)	19,569(12,679)	.16
Work Status: Unemployed, <i>n</i> (%)	9(75)	6(75)	15(75)	.71
Employed full time	3(25)	1(12.5)	4 (20)	
Employed part time	0	1(12.5)	1(5)	
Length of Type 2 Diabetes				
Diagnosis: In years, mean(<i>SD</i>)	6.5(7)	7.3(5)	6.9(6.1)	.44

Note. * Statistically significant ($p < .05$)

Each group intervention period lasted 4 weeks in order to provide enough time for treatment effects. Three waves of groups were conducted. Below is an outline of the general topics for each group (for both the IG and the ACG groups). The PI, a PhD candidate in clinical psychology, who had extensive experience running groups focused on health and behavior change, facilitated all groups.

Intervention Group:

- Week 1: Introduction of facilitator, establish group rules of conduct, introduction of group members, brief overview of diabetes pathophysiology, discussion of main barriers to adherence, introduction to problem-solving and making small changes, MBSR breathing exercise, orientation to logbooks.
- Week 2: Discussion of logbooks and monitoring challenges, discussion of dietary/physical activity recommendations for those with diabetes, and barriers to these behaviors, brainstorming ideas for self-directed goals related to diabetes management, MBSR mindful eating, goal-setting for upcoming week.
- Week 3: Discussion of logbooks and previous goals, discussion of medication and blood glucose monitoring, basic introduction of cognitive-behavioral principles and how thoughts, feelings and behaviors are linked, incorporation of this into problem-solving strategies, discussion of how to address negative thinking patterns, MBSR body scan, goal-setting for upcoming week.
- Week 4: Discussion of logbooks and previous goals, discussion of social support, discussion and reflection on session content and previous group meetings, MBSR breathing refresher, long-term goal setting.

[Note: Much of qualitative feedback that was given during the intervention group sessions was interwoven into the context of how the information was presented and how the PI prepared for each topic. For example, the cost of healthy food was often presented as a barrier for eating a balanced diet (a strong theme that came up during the focus group), therefore, the PI made sure to dedicate adequate time for this during group so that participants could each work through this barrier and help each other problem solve solutions (utilizing a high amount of group discussion that helped to develop camaraderie amongst members- another desirable characteristic for a group per the focus group feedback).]

Education Comparison Group:

(All topics and materials were drawn from the North Carolina Diabetes Education Curriculum)

- Week 1: Introduction of facilitator, establish group rules of conduct, introduction of group members, didactic presentation of what diabetes is and how it affects the body, overview of topics for subsequent three weeks.
- Week 2: Didactic presentation and short discussion of nutrition and importance of physical activity.
- Week 3: Didactic presentation and short discussion of medication management and monitoring.
- Week 4: Didactic presentation and short discussion on acute management and chronic complications of diabetes.

Measures. All measures were given to participants directly prior to session 1 and again directly after session 4. Selected measures were again administered via phone three months post-intervention. All chosen scales have been shown to have adequate reliability and validity, and be appropriate for use with low literacy. The type and length of questionnaires were consistent with

research the PI has helped conduct before and is considered acceptable for behavioral intervention research.

Adherence. Self-reported adherence was assessed via three different measures in order to fully encompass treatment adherence.

Summary of Diabetes Self-Care Activities Questionnaire (SDSCA). The SDSCA (Toobert, Hampson, & Glasgow, 2000) is a 25-item self-report questionnaire that assesses the frequency of various self-care behaviors associated with successful T2DM management including a healthy diet, exercise, foot care, glucose testing, and smoking. Each question asks how many days (from 0-7) in the past week respondents have completed each activity mentioned. Psychometric research on this measure has shown it to exhibit sound validity (based on correlations with other concordant measures, with validity coefficients ranging between 0.20 - 0.58) and reliability (inter-item correlation = .47 and test-retest = .40) for patients with T2DM. Higher scores indicate greater engagement in regular self-care behavior, which is predictive of stable treatment adherence (Toobert et al., 2000). Cronbach's alpha was not calculated for this total measure, as the authors noted that participants may endorse high adherence in one area, but not another, making a reliability coefficient a poor indicator of internal consistency. This measure was given at T1, T2, and T3.

Morisky Medication Adherence Scale (MMAS). The four-item MMAS (Krapek et al., 2004) was developed to predict medication-taking behaviors among diabetes patients. The questions are dichotomous yes or no questions asking about medication taking patterns including situations when the person does not take it (when feeling better or worse, etc.). Score thresholds are 0-2 "no" answers and 3-4 "no" answers. "No" answers to 0-2 questions indicates low medication adherence, while "no" answers to 3-4 questions indicates high medication adherence.

High medication adherence, as classified by this measure, has been associated with lower HbA1c levels (Krapek et al., 2004). Psychometric literature on this measure reported an item-to-total correlations average at .50 and Cronbach's alpha was determined to be .61. Concurrent validity has been assessed with blood pressure ($R^2 = .33$) and sensitivity and specificity levels at .81 and .44, respectively (Krapek et al., 2004). For the current study, Cronbach's alpha was calculated as .67. This measure was given at T1, T2, and T3.

HbA1c level. In addition to these self-report measures, a chart review for each participant was conducted to obtain pre- and post-intervention HbA1c levels. This was done in order to assess glucose control as a measure of adherence. The FMC generally takes HbA1c level readings through a finger stick sample obtained during routine medical appointments every 3-6 months. Pre-intervention HbA1c was classified as the last reading taken prior to the start of the intervention. Post-intervention HbA1c was classified as the most recent reading taken after the end of the intervention (which generally fell within 3-5 months post- intervention).

Diabetes knowledge. General knowledge of T2DM was assessed using the 24-item Diabetes Knowledge Questionnaire (DKQ) (Garcia, Villagomez, Brown, Kouzekanani, & Hanis, 2001). This questionnaire asks respondents to respond "yes", "no" or "maybe" to true and false statements regarding basic diabetes knowledge concerning disease etiology, interpretation of blood sugar levels, appropriate self-care, and medication management. Scoring is completed by assigning one point to every correct item and a mean score of 14 was determined for individuals with T2DM. Psychometric analyses determined Cronbach's alpha to be .78 and the average difficulty level of questions was .57 (Garica et al., 2001). For our study, Cronbach's alpha was .82. Construct validity was determined through a diabetes education intervention, which revealed

significantly higher DKQ scores post-intervention indicating validity of the instrument. This measure was given at T1 and T2.

Self-efficacy. The ability to take control of one's treatment management and belief in oneself was assessed using two measures of diabetes self-efficacy.

Diabetes Fatalism Scale (DFS). The 12-item DFS (Egede & Ellis, 2009) has been validated for use with T2DM patients. It consists of statements that gauge one's feelings of helplessness and lack of control toward disease management. A 6-point likert-type response scale is used (from *strongly disagree* to *strongly agree*) for each statement regarding perceptions of living with diabetes. Higher scores represent greater fatalism. Psychometric analyses determined Cronbach's alpha to be .81 and the measure was significantly correlated to self-management understanding ($r = -.35$), T2DM control problems ($r = .22$), self-care behavior ($r = -.30$), and HbA1c levels ($r = .20$), indicative of acceptable concordant validity (Egede & Ellis, 2009). For this study, Cronbach's alpha was .72. This measure was given at T1 and T2.

Perceived Diabetes Self-Management Scale (PDSMS). The 8-item PDSMS (Wallston, Rothman, & Cherrington, 2007) assesses respondents' levels of confidence and self-efficacy in managing diabetes and has been validated for use in both those with Type 1 diabetes and T2DM. Response choices are on a 5-point likert-type scale (from *strongly disagree* to *strongly agree*). Scores can range between 8-40, with higher scores representing greater confidence in one's ability to manage T2DM treatment. Based on psychometric research, Cronbach's alpha was 0.83, indicative of adequate internal reliability. The PDSMS was significantly positively correlated with good dietary behaviors ($r = .36$) and regular physical activity ($r = .22$) (higher scores were associated with higher frequency of these behaviors). Scores were also significantly negatively correlated with HbA1c levels ($r = -.30$; higher scores were associated with greater glycemic

control) (Wallston et al., 2007). For this study, Cronbach's alpha was .82. The PDSMS was given at T1, T2, and T3.

Psychological factors. Emotional distress was assessed by measuring depressive symptomology as well as the perceived stress level of participants.

Perceived Stress Scale (PSS). The 10-item PSS (Cohen, Kamarck, & Mermelstein, 1983) was used to assess the current general stress level of respondents. Items inquire about level of stress, perceived control over current situations and level of irritation and difficulty over the past month. Responses are scaled from 0-4 (*not at all* to *very much*) with total scores ranging from 0-40. Scoring consists of adding up response scores (with reverse-scoring for items 4,5,7, and 8). Higher scores are indicative of more stress. Cronbach's alpha has been determined to be adequate (.89) and item-to-total correlations ranged between .58 - .72. Convergent validity was deemed adequate via correlations with other measures of anxiety and stress (e.g. the STAI, $r = .73$) and divergent validity was also found to be adequate via measures of control (e.g. the Multidimensional Health Locus of Control, $r = -.16$) (Roberti, Harrington, & Storch, 2006). Cronbach's alpha for this study was calculated to be .76. The PSS was given at T1, T2, and T3.

Center for Epidemiological Studies Depression Scale (CES-D). The ten-item CES-D (Kohout, Berkman, Evans, & Cornoni-Huntley, 1993) is a screener of depressive symptomology and has been useful in general as well as chronic illness populations. Responses are on a 4-point scale ranging from 0-3 and require a respondent to note how often they have felt a certain way (sad, tired, depressed, etc.) during the past week (from *not at all* to *all the time*). Scoring is completed by adding the total number of points (which can range from 0-30) (with reverse scoring on items 5 and 8) and a score of 10 or greater is considered the cutoff for presence of significant depressive symptomology. Cronbach's alpha for this measure has been consistently

reported above .80 (Kohout et al., 1993) with sensitivity and specificity values being adequate (.88 and .81, respectively) and good discriminatory validity (AUC = .92). Consistently, Cronbach's alpha for the CES-D for the current study was .86. This measure was given at T1, T2, and T3.

Coping. Level of general coping was assessed through the 28-item Brief COPE (Carver, 1997). This measure assesses how a person generally responds to stressful situations. Response options are scaled from 1-4 (ranging from *not at all* to *a lot*). The measure has 14 subscales, each indicating a different coping reaction. All subscales have exhibited a Cronbach's alpha reliability coefficient between .5 and .9. Validity has been determined to be adequate based on a factor analysis comparison to the full version COPE, which revealed a similar factor structure. In the original COPE, eight of the subscales found in the brief COPE were categorized into either problem-focused coping (active coping, planning, instrumental support) or emotional-focused coping (religion, emotional support, acceptance, positive reframing, denial) (Carver, 1997; Carver, Scheier, & Weintraub, 1989). For this study, the humor subscale (which was not included in the original COPE) was added under the emotion-focused factor. For data reduction purposes, the PI used these parameters to categorize the subscales and then summed them for a problem-focused coping total and an emotion-focused coping total. For this study, Cronbach's alpha for problem-focused coping was .67 and emotion-focused coping was .74. This measure was administered at T1 and T2.

Mindfulness. The degree to which participants exhibit qualities of mindfulness was assessed through the Five Facet Mindfulness Questionnaire (FFMQ) (Baer, Smith, Hopkins, Krietemeyer, & Toney 2006). This measure consists of 39 items and inquires about frequency of intention and awareness to one's present situation. Measure items are scaled on a 0-4 point

response scale (from *not at all* to *very much*) and assess five subscales of mindfulness qualities (awareness, non-judging, non-reactivity, observing, and describing). Cronbach's alpha values for this measure range from .75 - .91 and inter-item correlations range from .32 - .56. Construct validity has been deemed adequate via strong correlations with the Psychological Well-Being Scale (with r values ranging from .34 - .52, depending on the subscale). For the current study, an abbreviated version of this measure was used that excluded the "describing" subscale, as the items are more focused on the ability to label and describe emotions, which may have been a barrier for lower-educated participants. Additionally, six of the items on the "observing" subscale were not applicable to the focus of the mindfulness exercises that were used in sessions (e.g., "When I'm walking, I deliberately notice the sensations of my body moving"), therefore, other items from the original full set of the FFMQ (e.g., "I noticed changes in my body, such as whether my breathing slowed down or sped up") were used instead. For data reduction purposes, only the total mindfulness score was analyzed. Cronbach's alpha was .88. This measure was given at T1, T2, and T3.

Group Experience. A brief qualitative measure was administered at T2 to assess participants' experience as group members. Six items on a 1-7 point scale (from *do not agree* to *definitely agree*) asked about their feelings regarding the utility of the information learned, level of accountability, motivation, positivity, sense of belonging, and universality (regarding diabetes adherence issues) they may have experienced a result of group membership. Higher total scores for this measure are meant to indicate greater benefit reported from being part of a group. Cronbach's alpha for this measure was .92.

Data Analysis Plan

Group differences in demographics and pre-intervention adherence, self-efficacy, diabetes knowledge, psychological distress (stress and depressive symptoms), coping, and mindfulness variables were assessed using Chi-square tests and independent samples t-tests. Repeated measures ANOVAs were used to test for group differences across the three time points for adherence behaviors, diabetes self-efficacy, and psychological distress. A series of one-way between-groups analyses of covariance (ANCOVAs) were conducted to examine the efficacy of the intervention (compared to the ECG) on adherence behaviors, self-efficacy, diabetes knowledge, and mindfulness, and lower depressive symptoms, stress, and HbA1c levels for T2 (controlling for T1) as well for T3 (controlling for T1). Paired samples t-tests were used to examine within group differences across time (T1-T2 and T1-T3) on these same variables. Given the length of the T1 and T2 questionnaires (which generally took participant 20-30 minutes to fill out in person), the T3 measures (administered via phone) were abbreviated to the most salient outcome measures of interest in order to cut down on the amount of time participants needed to spend on the phone. Fisher's Exact Tests were used to compare the IG and the ECG from T1 to T2 and from T1 to T3 on medication adherence. A one-way ANOVA was conducted to test for group differences in subjective group experiences and perceived benefit of participating in a group intervention.

Chapter III: Results

Data Screening

All data were entered and analyzed using SPSS 20. After verified entry, collected data were examined and cleaned. Unfortunately, due to a copying error, the first ten participants (6 IG and 4 ECG) were not administered the CES-D; therefore T1 and T2 data points for this measure were not obtained. Other missing cases were also identified, but were deemed to be missing at random. Total scores for those scales with missing data were computed by multiplying the scale items mean by the number of items on the scale. Total scale scores were calculated for the PSS, CES-D, DFS, DKS, PDSMS, MMAS, and FFMQ while mean item scores were calculated for the SDSCAQ. Nine brief COPE subscales were grouped into a “problem-focused coping” variable (active coping, planning, instrumental support) and an “emotion-focused coping” variable (religion, emotional support, acceptance, positive reframing, humor, self-blame, and denial) (Carver et al., 1989). Each participant’s MMAS total score was dichotomized as “high medication adherer” (total score of 3-4) or a “low medication adherer” (total score of 0-2) (Krapek et al., 2004). Assumptions of normality, linearity, homogeneity of variance, and homogeneity of intercorrelations were examined for violations. Violations were found for normality on the PSS and CES-D total scores due to significant positive skewness; therefore, square root transformations were applied and adequately corrected for this. Untransformed variable means are reported for interpretation purposes. Several outliers in the data were also identified (1 data point for T1 CESD-prior to transformation, 1 for T1 DKS, 1 for T1 Emotion-Focused Coping, 1 for T1 and T2 FFMQ, 2 for T2 PSS-prior to transformation, 1 for T3 PSS-prior to transformation, 2 for T2 DFS, and 4 for T2 SDSCAQ: Diet) but were not taken out due to them still being in a valid range for the measures and ultimately did not greatly influence

mean total scores on these measures (as verified in the 5% Trimmed Mean given by SPSS).

Additionally, a post-hoc analysis that took out outliers demonstrated that omitting outliers did not make a substantive difference in the results.

Descriptive Statistics

Descriptive statistics were calculated for all dependent variables. T1 SDSCAQ means for the total group substantiate that this is a sample with adherence difficulty. On average, participants endorsed completing appropriate adherence behaviors four or less days per week in two out of four categories at T1 (diet = 3.88, physical activity = 2.25, blood glucose monitoring = 4.85, feet checking = 4.98). Smoking was infrequently endorsed on the SDSCAQ and cessation was not targeted in the intervention; therefore it was excluded from subsequent analyses. For HbA1c levels, the total sample exhibited an average of 10.11 ($SD = 1.75$), which is well above 8.0%, the benchmark for medically uncontrolled. Regarding diabetes knowledge, the total sample scored an average of 66% correct ($SD = 4.19$), which is about 8% higher than the population sample on which the DKQ was normed (59%; Garcia et al., 2001). On PDSMS scores, the total sample scored an average of 25.5 ($SD = 5.14$), compared to a mean total of 29.03 in the normative sample of people with T2DM (Wallston et al., 2007), indicating lower confidence expressed by the current sample's ability to manage their diabetes regimen. For diabetes fatalism, the mean for the current sample was 32.75 ($SD = 8.45$) compared to 36.7 for the normative sample group (Egede & Ellis, 2009), suggesting the current overall sample was experiencing less fatalistic thinking. Regarding depressive symptomology, the aggregate sample yielded a mean CES-D total score of 10.1 ($SD = 6.38$). The cut-off score for significant depressive symptoms on the CES-D is 10 (Kohout et al., 1993), suggesting the current sample was experiencing significant difficulty with depressive symptoms. For the PSS, the current

sample exhibited a mean total of 13.3 ($SD = 7.15$), which is slightly above the normative population in the same age category (45-54; $M = 12.6$) and slightly below average for race ($M = 14.7$ for AAs) (Cohen & Williamson, 1988). For mindfulness, total average scores could not be compared to the normed group due to the edits made to the measure for this study. However, on subscale score totals, the current sample had similar average scores on Awareness compared to the normed community sample ($M = 25.1, SD = 6.41$; $M = 24.6, SD = 6.57$, respectively) as well as similar scores on Non-Judgment of Inner Experience ($M = 24.1, SD = 7.2$; $M = 23.9, SD = 7.33$, respectively) (Baer et al., 2008). The current sample also exhibited lower Non-Reacting subscale scores compared to a community sample norm ($M = 9.9, SD = 6.62$; $M = 19.53, SD = 4.48$, respectively), suggesting the current sample reported lower frequency of being able to let go of thoughts without getting wrapped up in them.

Group differences in demographics and pre-intervention adherence, diabetes knowledge, self-efficacy, and psychological variables were assessed using Chi-square tests and independent t-tests. For all pre, immediate post, and 3-month post-intervention means, and standard deviations for the IG and ECG, see Table 2. Results showed significant baseline differences on several variables. The IG exhibited significantly higher scores than the ECG on the CES-D [$t(7) = 2.46, p = .04$] and DFS [$t(18) = 2.59, p = .02$]. The IG was also significantly younger than the ECG [$t(18) = -4.05, p = .001$]. Despite utilizing a simple randomization procedure, differences in baseline variables occurred due to chance. In addition to the planned primary repeated measures ANOVA analyses, ANCOVA analyses were used to test for post-intervention group differences on these variables, controlling for pre-intervention levels.

Table 2

Pre, Immediate Post, and 3-month Post-Condition Descriptive Statistics

Variable	Pre-Condition		Immediate Post-Condition		3-months Post-Condition	
	IG	ECG	IG	ECG	IG	ECG
Adherence						
SDSCAQ:	4.02(1.22)	3.66(1.27)	4.29(1.3)	4.54(1.35)	5.06(0.99)	4.62(0.42)
Diet						
PA	2.21(1.91)	2.31(2.21)	3.50(1.85)	3.28(0.99)	2.81(1.58)	2.80(1.82)
BG	4.58(2.65)	5.25(2)	5.30(2.58)	6.0(1.55)	5.06(2.86)	5.11(2.66)
Feet	4.79(2.63)	5.25(2.15)	4.58(2.43)	5.79(2.02)	5.51(2.22)	5.43(2.43)
Smoke*	6.0(5.66)	2.0	3.0(2.83)	2.0	6.0(5.66)	3.0
MMAS**	92.0%	88.0%	83.0%	75.0%	100%	80.0%
HbA1c	9.53(1.64)	9.95(1.47)			8.57(1.15)	9.08(1.28)
Knowledge						
DKQ	15.3(3.14)	16.9(5.52)	16.6(4.52)	17.9(3.0 2)	-	-
Self-Efficacy						
DFS	36.3(5.74)	27.5(9.46)	33.7(9.25)	27.7(9.11)	-	-
PDSMS	23.9(5.38)	27.9(3.94)	26.0(6.35)	27.3(6.50)	26.8(5.4)	29.2(3.96)
Psychological						
CES-D	13.3(6.38)	5.25(1.5)	10.5(5.2)	5.33(2.52)	8.25(9.53)	3.60(3.78)
PSS	15.8(7.51)	9.63(4.93)	16.2(9.83)	8.0(6.03)	14.6(9.9)	5.62(4.4)
COPE: PF	17.1(2.23)	15.9(4.85)	16.5(4.34)	17.4(4.69)	-	-
COPE: EF	27.9(4.46)	29.6(7.01)	28.1(4.78)	30.9(5.73)	-	-
FFMQ	66.3(16.25)	80.4(14.5)	72.6(15.42)	81.1(15)	-	-

Note. Mean, SD's are in parentheses. IG = Intervention Group; ECG = Education Comparison Group; SDSCAQ = Summary of Diabetes Self-Care Activities Questionnaire; PA = Physical Activity; BG = Blood Glucose Testing; MMAS = Morisky Medication Adherence Scale; DKQ = Diabetes Knowledge Questionnaire; DFS = Diabetes Fatalism Scale; PDSMS = Perceived Diabetes Self-Management Scale; CES-D = Center for Epidemiologic Studies Depression Scale; PSS = Perceived Stress Scale; PF = Problem-focused coping; EF = Emotion-focused coping; FFMQ = Five Factor Mindfulness Questionnaire; * Average # of cigarettes smoked in a day for those who endorsed as smokers (2 participants in IG and 1 participant in ECG); ** % high adherers (score of 3-4)

Repeated Measures Analyses

A series of repeated measures analyses of variance were conducted, where the between subjects factor was group (IG or ECG) and the within-subjects factor was time (pre-, immediate post-, and 3-months post-intervention). These analyses were conducted to assess the influence of the intervention and education comparison programs on participants' scores on adherence (SDSCAQ: diet, physical activity, blood glucose monitoring, and feet checking), self-efficacy (PDSMS), and psychological measures (CES-D, PSS) across three time points in order to assess for any main effects for group or time, as well as any interaction effects (see Table 3 for full time effects). Eta squared (η^2) was also calculated to determine effect size ($SS_{\text{effect}}/SS_{\text{total}}$), which calculates how much of the total variance was accounted for by group, time, and interaction (where 1% of variance is considered a small effect, 6% a medium effect, and 14% a large effect) (Cohen, 1988).

Regarding adherence behaviors, there was a significant, large main effect for time observed for the dietary adherence measure (SDSCAQ: diet), with both groups exhibiting increases across the three time points. However, no other significant main effects for time, main effects for group or time by group interaction effects were observed for any adherence variables (see Table 3). A large effect for time was observed for the physical activity measure (both the IG and ECG increased in physical activity from T1 to T2 and then decreased from T2 to T3). A medium effect for time was noted for blood glucose (BG) testing (both the IG and ECG increased in BG testing from T1 to T2 and then decreased from T2 to T3).

Table 3

Repeated Measures ANOVA Time Effects for Pre- to Immediate-Post to 3-month Post-Intervention

Variable	Wilks' Lambda	df	F-value	p-value	η^2
Adherence					
SDSCAQ: Diet	.48	2, 10	5.52	.02*	.38
PA	.69	2, 10	2.26	.16	.16
BG	.77	2, 10	1.53	.26	.10
Feet	.94	2, 10	0.34	.72	.01
Self-Efficacy					
PDSMS	.69	2, 10	2.26	.16	.18
Psychological					
CES-D	.45	2, 3	1.81	.31	.45
PSS	.55	2, 9	3.73	.07**	.16

Note. SDSCAQ = Summary of Diabetes Self-Care Activities Questionnaire; PA = Physical Activity; BG = Blood Glucose Testing; PDSMS = Perceived Diabetes Self-Management Scale; CES-D = Center for Epidemiologic Studies Depression Scale; PSS = Perceived Stress Scale; * Statistically significant ($p < 0.05$); ** Marginally significant ($p < 0.10$). No significant main effects were observed for group and no significant interaction effects for group by time were observed.

For the self-efficacy measure (PDSMS), there were no significant main effects for time or group and there were no interactions observed for group by time. The IG increased steadily over time and the ECG initially exhibited decreased scores at T2 but then exhibited increased scores at T3. For psychological variables, there was a marginally significant, but large main effect for time on PSS scores, with scores decreasing for both the IG and the ECG by the T3 assessment (although the IG initially exhibited a slightly increased score at T2). There were no significant main effects for group and no significant interactions for group by time observed for the psychological variables; however, a small-to-medium time effect was observed for the CES-D scores. The IG decreased from T1 to T2 while ECG increased; however, both exhibited decreases in CES-D scores T2 to T3.

Immediate Post-Intervention Analyses

A series of one-way between-groups analyses of covariance (ANCOVAs) were conducted to examine the effect of the intervention on adherence behaviors, self-efficacy problem-focused coping and mindfulness as well as lower psychological symptomology in comparison to education comparison treatment. This analysis was chosen in order to control for several noted baseline differences between groups. The independent variable was the administration of the intervention and the dependent variables included immediate post-intervention adherence (SDSCAQ), self-efficacy (DFS and PDSMS), diabetes knowledge (DKS), and psychological measures (CES-D, PSS, Brief COPE, FFMQ). Participants' scores on the same measures pre-intervention served as covariates (see Table 4 for full statistics). Fisher Exact Tests were used to assess post-intervention differences between groups on scores for categorical variables (MMAS). In addition, paired samples t-tests were conducted to detect any significant within group differences in the dependent variables pre- to post-condition (see Table 5).

Regarding adherence behaviors, there were no significant between group differences pre- to immediate post-intervention for any sub-scales (diet, physical activity, blood glucose testing, and feet checking behaviors) on the SDSCAQ. Post-intervention the IG had greater scores on physical activity adherence, while the ECG exhibited greater scores on dietary adherence, BG testing, and feet checking. Paired t-tests revealed that the IG exhibited a significant increase in self-reported physical activity adherence from pre- to post-intervention. The ECG also increased in physical activity scores, but this difference did not reach statistical significance. Effect sizes for each group pre- to immediate-post were calculated using Glass's Delta, (0.2 = small effect; 0.5 = medium effect; 0.8 = large effect) (Cohen, 1988), which revealed a medium-sized effect for

Table 4

Pre- to Immediate-Post ANCOVAs

Variable	Post Intervention Est. Marginal Means		<i>df</i>	<i>F</i> -value	<i>p</i> -value	Partial η^2
	IG	ECG				
Adherence						
SDSCAQ: Diet	4.21	4.67	1, 16	1.87	.19	.10
PA	3.54	3.23	1, 16	0.23	.64	.01
BG	5.59	5.49	1, 16	0.02	.89	.001
Feet	4.89	5.27	1, 16	0.38	.55	.02
Diabetes Knowledge						
DKQ	17.03	17.1	1, 16	0.001	.98	<.001
Self-Efficacy						
DFS	31.9	30.7	1, 16	0.07	.80	.004
PDSMS	27.1	25.3	1, 15	0.39	.54	.03
Psychological						
CES-D	2.68	3.2	1, 5	1.09	.34	.15
PSS	3.64	2.9	1, 15	1.23	.28	.08
COPE: PF	16.4	17.6	1, 16	0.47	.50	.03
COPE: EF	28.9	29.5	1, 16	0.14	.71	.01
FFMQ	77.6	72.6	1, 16	1.45	.25	.08

Note. IG = Intervention Group; ECG = Education Comparison Group; SDSCAQ = Summary of Diabetes Self-Care Activities Questionnaire; PA = Physical Activity; BG = Blood Glucose Testing; DKQ = Diabetes Knowledge Questionnaire; DFS = Diabetes Fatalism Scale; PDSMS = Perceived Diabetes Self-Management Scale; CES-D = Center for Epidemiologic Studies Depression Scale; PSS = Perceived Stress Scale; PF = Problem-focused coping; EF = Emotion-focused coping; FFMQ = Five Factor Mindfulness Questionnaire

Table 5

Pre- to Immediate-Post Paired t-tests

Variable	t-value		p-value		Glass's Delta	
	IG	ECG	IG	ECG	IG	ECG
Adherence						
SDSCAQ: Diet	-1.22	-1.67	.25	.15	0.22	0.57
PA	-2.34	-1.52	.04*	.18	0.68	0.36
BG	-1.41	-1.18	.19	.28	0.27	0.20
Feet	0.52	0.00	.61	1.0	-0.08	0
Diabetes Knowledge						
DKQ	-1.11	-0.37	.29	.73	0.40	0.18
Self-Efficacy						
DFS	1.1	-0.28	.31	.79	-0.46	0.02
PDSMS	-1.58	0.38	.14	.72	0.40	0.24
Psychological						
CES-D	2.31	-0.32	.07**	.78	-0.44	0.17
PSS	0.08	0.82	.94	.45	0.06	-0.32
COPE: PF	0.54	-0.53	.60	.62	-0.26	0.15
COPE: EF	-0.71	0.00	.50	1.0	0.04	0
FFMQ	-2.53	0.47	.03*	.66	0.38	0.05

Note. IG = Intervention Group; ECG = Education Comparison Group; SDSCAQ = Summary of Diabetes Self-Care Activities Questionnaire; PA = Physical Activity; BG = Blood Glucose Testing; DKQ = Diabetes Knowledge Questionnaire; DFS = Diabetes Fatalism Scale; PDSMS = Perceived Diabetes Self-Management Scale; CES-D = Center for Epidemiologic Studies Depression Scale; PSS = Perceived Stress Scale; PF = Problem-focused coping; EF = Emotion-focused coping; FFMQ = Five Factor Mindfulness Questionnaire; * Statistically significant ($p < 0.05$); ** Marginally significant ($p < 0.10$)

the ECG regarding diet improvement (compared to a small effect in the IG), and a medium-to-large sized effect for the IG (compared to a small-to-medium sized effect for the ECG) on physical activity.

A Fisher's Exact Test was used to assess any differences in medication adherence rates between IG and ECG participants on the MMAS. Participant scores were dichotomized into "low medication adherers" (scores of 0-2) and "high medication adherers" (scores of 3-4). The analysis revealed that the IG and ECG did not significantly differ in medication adherence behaviors immediately post-intervention ($p = .54$). The IG group had a total of 11 high adherers

(92%) at baseline and 10 high adherers (83%) immediately post-intervention. The ECG had a total of seven high adherers (88%) at baseline and six high adherers (75%) immediately post-intervention. Therefore, each group actually had one participant who reported high adherence pre-intervention but then reported low adherence post-intervention.

There were no significant differences between groups for diabetes knowledge, with the ECG exhibiting greater scores at T2. No within group differences were observed; however, a small-to-medium sized effect was detected for the IG, demonstrating an increase in knowledge pre to post-intervention. [Note: Post-hoc, difference scores between T1 and T2 were computed for DKS scores. An ANOVA was used to test for differences between groups in terms of degree of change from pre- to post-intervention; however, no significant between-group differences were detected for the DKS variable.]

On self-efficacy measures, there were no significant group differences for PDSMS scores or DFS scores. Paired t-tests did not indicate any statistically significant changes from pre- to post-intervention; however, the IG did increase their PDSMS scores, with a small-to-medium size effect observed. The IG also exhibited decreased DFS scores, with a small-to-medium-size effect observed. The ECG remained stable on both measures from pre- to post-intervention. [Note: Post-hoc, difference scores between T1 and T2 were computed for PDSMS and DFS scores. An ANOVA was used to test for differences between groups in terms of degree of change from pre- to post-intervention; however, no significant between-group differences were detected for the PDSMS or DFS variables.]

On psychological measures, no differences were observed between groups on post-intervention CES-D scores; however the IG approached a significant decrease in depression scores, for which a medium size effect was observed. Comparatively, the ECG remained

relatively stable on CES-D scores from baseline. No differences were observed between groups on post-intervention PSS scores or COPE scores (for problem or emotion-focused coping), nor were any significant within group differences or substantive effect sizes observed. For mindfulness, no significant differences were observed between groups on the FFMQ. Within groups, the IG demonstrated a significant increase in mindfulness with a small-to-medium effect size observed.

Three-month Post-Intervention Analyses

A series of one-way between-groups analyses of covariance (ANCOVAs) were also conducted to examine the longer-term effects of the intervention compared to the education comparison treatment, by measuring adherence, self-efficacy and psychological variables, three months post-intervention. The independent variable was the administration of the intervention and the dependent variables included three-month post-intervention measures of adherence (SDSCAQ, HbA1c), self-efficacy (PDSMS), and psychological measures (CES-D, PSS; see Table 6). Participants' scores on the same measures pre-intervention served as covariates. Fisher's Exact Tests were used to assess post-intervention differences on scores for categorical variables (MMAS). In addition, paired samples t-tests were conducted to examine within group differences in the dependent variables pre- to 3-months post-condition (see Table 7).

Regarding adherence behaviors, there were no significant differences between groups for any sub-scales (diet, physical activity, blood glucose testing, and feet checking behaviors) on the SDSCAQ 3-months post-intervention. Within groups, paired t-tests revealed that the IG exhibited a statistically significant increase in diet adherence scores from pre- to 3-months post-intervention. While not statistically significant, the ECG also increased in dietary adherence. A large effect size for dietary adherence was observed for the IG and ECG. For HbA1c levels, there

Table 6

Pre- to 3-month Post ANCOVAs

Variable	Post Intervention Est. Marginal Means		<i>df</i>	<i>F</i> -value	<i>p</i> -value	Partial η^2
	IG	ECG				
Adherence						
SDSCAQ: Diet	4.91	4.84	1, 10	0.03	.87	.003
PA	2.79	2.84	1, 10	0.03	.96	<.001
BG	5.17	4.92	1, 10	0.04	.84	.004
Feet	5.48	5.43	1, 10	0.001	.97	<.001
HbA1c	8.6	9.02	1, 12	0.42	.53	.03
Self-Efficacy						
PDSMS	27.44	28.1	1, 10	0.06	.81	.006
Psychological						
CES-D	1.73	3.31	1, 2	1.22	.35	.29
PSS	3.34	2.71	1, 10	1.47	.25	.13

Note. IG = Intervention Group; ECG = Education Comparison Group; SDSCAQ = Summary of Diabetes Self-Care Activities Questionnaire; PA = Physical Activity; BG = Blood Glucose Testing; PDSMS = Perceived Diabetes Self-Management Scale; CES-D = Center for Epidemiologic Studies Depression Scale; PSS = Perceived Stress Scale

Table 7

Paired t-tests for Pre- to 3-month Post-Intervention

Variable	t-value		p-value		Glass's Delta	
	IG	ECG	IG	ECG	IG	ECG
Adherence						
SDSCAQ: Diet	-2.76	-2.10	.03*	.11	0.85	0.75
PA	-0.70	-0.63	.51	.56	0.31	0.22
BG	-0.37	0	.73	1.0	0.18	-0.07
Feet	0.52	-0.17	.96	.88	0.27	0.07
HbA1c	2.55	0.97	.03*	.38	-0.59	-0.59
Self-Efficacy						
PDSMS	-1.52	-2.83	.17	.05*	0.53	0.22
Psychological						
CES-D	1.98	1.0	.14	.5	-0.80	-1.10
PSS	1.65	1.80	.14	.15	-0.15	-0.91

Note. IG = Intervention Group; ECG = Education Comparison Group; SDSCAQ = Summary of Diabetes Self-Care Activities Questionnaire; PA = Physical Activity; BG = Blood Glucose Testing; PDSMS = Perceived Diabetes Self-Management Scale; CES-D = Center for Epidemiologic Studies Depression Scale; PSS = Perceived Stress Scale; * Statistically significant ($p < 0.05$)

were no significant differences in 3-months post-intervention values between groups. Paired t-tests revealed that both the ECG and IG groups exhibited decreased HbA1c scores from pre- to 3-months post-intervention; however, only the IG exhibited a significant decrease. A medium size effect was observed for both the IG and the ECG. [Note: Post-hoc, difference scores between T1 and T3 were computed for HbA1c levels. An ANOVA was used to test for differences between groups in terms of degree of change from pre- to post-intervention; however, no significant between-group differences were detected for HbA1c.]

For the MMAS, a Fisher's Exact Test revealed that the IG and ECG did not significantly differ in medication adherence behaviors 3-months post-intervention ($p = .39$). Eighty percent of those in the ECG (compared to 88% at baseline) reported high medication adherence in comparison to 100% of those in the IG (compared to 92% at baseline).

Regarding self-efficacy, there was no significant between-group difference on PDSMS scores 3-months post-intervention. Paired t-tests revealed that the ECG increased significantly in PDSMS scores, with a small effect size. Additionally, the IG increased in PDSMS scores, with a medium size effect observed. [Note: Post-hoc, difference scores between T1 and T3 were computed for PDSMS scores. An ANOVA was used to test for differences between groups in terms of degree of change from pre- to post-intervention; however, no significant between-group differences were detected for the PDSMS variable.]

On psychological measures, no differences were observed between groups on 3-month post-intervention CES-D or PSS scores 3-months post-intervention. While both groups exhibited differences in CES-D and PSS scores compared to baseline, no statistically significant differences within groups were observed for either the IG or ECG. However, a large effect was observed on CES-D scores for both the IG and ECG and a large effect was also noted for the ECG on the PSS (compared to a negligible effect size for the IG).

Subjective Group Experience

A brief qualitative measure of group experience immediate post-intervention was also analyzed using a one-way ANOVA. Results showed that the IG and ECG did not significantly differ on scores of perceived group benefit [$M = 35.83, SD = 7.58; M = 35.85, SD = 4.85$, respectively; $F(1, 17) < 0.001, p = .994$, partial eta squared $< .001$], which indicated that both groups endorsed similar levels of belongingness, universality, utility of information, motivation, accountability, and positivity in regards to belonging to a group for diabetes adherence

Chapter IV: Discussion

The present study aimed to create a culturally informed T2DM adherence intervention for African Americans and conduct a pilot efficacy study. There were several hypotheses regarding the outcomes of this current study. Hypotheses were that, post-intervention, the intervention group (IG) participants would exhibit: a) greater rates of adherence (in terms of medication usage and behavioral adherence to dietary/physical activity/glucose monitoring/feet checking, and reflected in lower HbA1c levels); b) greater knowledge and self-efficacy regarding treating T2DM; c) lower stress and depressive symptoms; d) greater problem-focused coping and lower emotion-focused coping; and e) greater mindfulness compared to those in an education comparison group (ECG) at both T2 and T3.

Adherence Measures

SDSCAQ. Findings from this pilot study indicated that adherence behaviors (healthy diet, physical activity, blood glucose monitoring, feet-checking, and medication-taking) did not significantly differ between the IG and ECG groups post-intervention (controlling for pre-intervention levels). Both groups increased in adherence behaviors pre to immediately post-intervention on healthy diet, physical activity, and blood glucose monitoring and then slightly decreased in reported adherence of physical activity and blood glucose checking by the 3-month assessment time point. While the ECG remained stable from T2 to T3, the IG continued to increase their frequency of healthy dietary behaviors by the T3 assessment. The IG also exhibited an increase in feet checking behaviors from T2 to T3, while the ECG decreased slightly. When examining significant within-group changes, those in the IG demonstrated a significant increase in physical activity from pre- to immediate post-intervention. These results partially confirmed the hypothesis that those in the IG would report better adherence rates, as

their physical activity and dietary adherence behaviors improved significantly post-intervention; however, diet was the only significant change from T1 to T3. These results could be seen as expected, given the lack of any regular follow-up after the last group session. In general, behavioral research has shown that behavior change patterns tend to improve from baseline to immediately post-intervention, but then slowly plateau or wane longitudinally (Griffin et al., 2011). This pattern was observed for both groups for physical activity adherence and blood glucose checking patterns. Prior research has attributed this to a lack of consistent follow-up, absence of external accountability, and less positive reinforcement for salutatory behavior change that had been previously provided by the interventionist/group (Eakin, Reeves, Winkler, Lawler, & Owen, 2010; Wong, Wong, & Chan, 2005). Research within the continual care model (while specifically in weight management, but which requires similar behavioral engagement in healthy eating and physical activity) has noted that the struggle to maintain healthy behaviors is on-going and without follow-up, salutatory behaviors show similar patterns of waning seen in the current study at long-term follow-up (Middleton, Paditar, & Perri, 2012). Therefore, maintaining healthy behaviors requires continuous contact with health providers in order to reinforce behavioral strategies, give positive feedback, foster motivation and help problem-solve continual barriers that may arise.

HbA1c. Analyses indicated that both the IG and ECG participants exhibited decreases in HbA1c levels from T1 to T3, with no significant difference between groups post-intervention (controlling for pre-intervention levels). While both the IG and ECG approached clinically significant reductions (which is considered 1%; Stratton et al., 2000) in HbA1c levels (-0.95% and -0.87%, respectively), the IG demonstrated a statistically significant reduction in HbA1c. These findings map on to the significant increases in dietary behaviors (T1-T3) observed for the

IG. The results did not confirm the hypothesis that those in the IG would demonstrate significantly lower levels compared to those in the ECG; however, the fact that the IG demonstrated a significant decrease is encouraging. Notably, the results exhibited a medium-to-large effect on HbA1c for both interventions. More impressively, the results from this study are in concordance with effects from other T2DM intervention studies, which generally demonstrate an approximate decrease in HbA1c of .76% (Ismail, Winkley, & Rabe-Hesketh, 2004). From a clinical significance standpoint, the IG approached a 1% reduction, which the literature indicates can reduce the risk of developing microvascular complications associated with T2DM by 25% (United Kingdom Prospective Diabetes Study Group, 1998) and the risk of experiencing a myocardial infarction by 14% (Stratton et al., 2000).

Diabetes Knowledge

Regarding diabetes knowledge, both the IG and ECG increased their knowledge base about diabetes pre- to immediately post-intervention and a medium size effect was detected for the IG. This does not support the hypothesis that IG participants would exhibit significantly higher diabetes knowledge scores compared to the ECG. This finding indicates that both education-based and behavior-based interventions can have a positive influence on disease-specific knowledge, especially when there is common curriculum coverage. The IG exhibited a medium-sized effect (compared to a small effect in the ECG), which is consistent with current meta-analyses of diabetes intervention effectiveness. Previous research suggests that utilizing interventions that contain education and cognitive-behavioral components in a face-to-face setting produce the most beneficial outcomes in terms of disease management knowledge and application (Ellis et al., 2004).

Self-Efficacy

Findings revealed no statistically significant differences between the IG and ECG on measures of self-efficacy (PDSMS, DFS) regarding diabetes management post-intervention (controlling for pre-intervention levels). Notably, the ECG exhibited a statistically significant increase in PDSMS scores from T1 to T3. Additionally, while not statistically significant, the IG exhibited a steady increase from baseline to 3-months post-intervention and a within-group medium-size effect was observed. DFS scores decreased for the IG and, while not statistically significant, a medium-size effect was observed from T1 to T2. Conversely, the ECG's DFS scores remained stable. These findings suggest that both groups experienced improved diabetes management self-efficacy and the IG reported an increased sense of disease control, which partially supports the hypothesis that the IG would report global higher self-efficacy than the ECG.

Current results regarding self-efficacy are partially supported by the literature, which has broadly shown that educationally-based and behavior-based interventions can both facilitate better self-efficacy regarding health management (Brown, 1999; Haltiwanger, 2012). However, research has also shown that behavior-based interventions informed by SCA models generally show more improvement in self-efficacy than education-based interventions due to the active identification of personal barriers and learning ways in which to overcome them in the various contexts of life (Bandura, 2004; Biddle, Hagger, Chatzisarantis, & Lippke, 2007; Senecal et al., 2000). It is possible that, given both interventions were administered in a small-group context, conversation in the ECG allowed more sharing of personal experience and issues experiences than would have been possible in a large-group format. Though not encouraged by the facilitator, group members in the ECG were very forthcoming with both their own problems as well as suggestions for possible solutions for other group members. This led to some participant-driven

diabetes adherence problem-solving during the question and answer portion of the ECG sessions, which may have resulted in increased self-efficacy regarding adherence and disease management. This finding could also be explained by the Hawthorne effect, whereby behavior change occurs as an artifact of being in a study and is not necessarily due to the actual intervention of focus (Adair, 1984).

Given the relatively new development of the DFS, there are few studies that have utilized it as an outcome measure. One study examining the association of fatalism to diabetes adherence and glycemic control found that DFS scores were significantly, negatively correlated to diabetes self-management (Walker et al., 2012); however, current results did not indicate similar significant associations (a secondary analysis examining correlations among dependent variables was conducted to detect significant correlations). Pre-intervention, the IG sample exhibited similar rates of fatalism to that of the normed population (total average score $M = 36.3$; ECG participants exhibited much lower average scores; $M = 27.5$), indicating that the current sample is comparable to other samples tested with this measure (Egede & Ellis, 2009). Additionally, the current study is the only one known to use the DFS in the context of an adherence intervention, which makes it a novel contribution to the literature.

Psychological Factors

Depression. Regarding depression symptoms, decreases were observed for both the IG and ECG in CES-D scores T1 to T3, with no between-group differences observed. Within-group analyses revealed that the IG exhibited a marginally significant decrease in CES-D scores from T1 to T2, with a small-to-medium effect size. In terms of clinical relevance, the mean total CES-D score for the IG was above the cutoff of 10 at baseline ($M = 14$, indicating the likely presence of depression) and decreased over time to below the cutoff ($M = 8$) at three months post-

intervention. This indicates a clinically significant reduction of depressive symptoms. This result is in concordance with previous research examining the effect of behavioral adherence interventions for T2DM, which have demonstrated that problem-solving, education, and group support can positively influence mood symptoms associated with T2DM (Bogner, Morales, de Vries, & Cappola, 2012; Sabourin, Vallis, & Currie, 2011; van Son et al. 2013).

Perceived stress. In reference to perceived stress, no between-group differences were observed on PSS total scores, yet marginally significant decreases were observed for both the IG and ECG over time. Notably, the ECG actually exhibited a decrease in PSS total scores with a large effect observed (compared to a small effect size in the IG). This result is not consistent with some previous research, which has shown that behavioral interventions for diabetes adherence have contributed to decreases in perceived stress (Karlsen, Idsoe, Dirdal, Hanestad, & Bru, 2004). However, one study conducted by Surwitt and colleagues (2002) found no significant differences in perceived stress levels for a sample of T2DM participants, while still observing a significant decrease in HbA1c after a five session behavioral stress management treatment. For the current sample, it may be the case that the IG participants (given that they were exhibiting higher global distress at baseline) were more likely to engage in negative cognitive appraisals of their current stressors, biasing them to higher perceived stress levels. This concept is discussed in greater detail directly below.

Coping. On coping strategy variables, the IG and ECG did not significantly differ on problem-focused or emotion-focused coping utilization post-intervention (controlling for pre-intervention levels). In terms of directionality, however, only the ECG increased in problem-focused coping (with a medium effect size observed). This finding does not support the hypothesis that the IG would exhibit increases in problem-focused coping and decreases in

emotion-focused. This could possibly be related to the high depressive symptomology observed in the IG. Lazarus and Folkman's transactional model of stress and coping suggests that health concerns, including depression, can influence cognitive appraisal of situations and subsequently influence what coping strategies are utilized (Lazarus & Folkman, 1984). A study conducted by Shah and colleagues (2011) found that in a T2DM sample, cognitive appraisal mediated the relationship among emotional distress and type of coping strategies utilized (with negative appraisal being associated with less adaptive strategies) and higher depression scores were associated with more emotion-focused coping. In the current study, while depression scores did improve over the course of treatment, it may be the case that cognitive appraisal and coping strategies were potentially part of a more pervasive pattern of interpreting and evaluating experiences and stressors; a four week period (pre- to immediate post-intervention) may not have been long enough to observe significant changes in these patterns.

Mindfulness. Both IG and ECG participants increased in mindfulness across their respective interventions and no between-group differences were observed between the IG and ECG on this variable. However, within-groups, the IG significantly increased on total mindfulness scores pre-intervention to immediately post-intervention. Currently, the literature base on the use of mindfulness-based interventions specifically for T2DM is nascent, and outcome measures have focused more on mood variables (depression, anxiety) rather than the development of mindfulness qualities. Therefore, current results present a novel contribution to the literature on the use of brief mindfulness-based strategies for T2DM. This study demonstrated that incorporating mindfulness strategies into the intervention program produced greater mindfulness, which potentially mediated the reduction of mood and distress symptoms. In terms of whether the current intervention was long enough to produce such effects, the

literature focusing on brief mindfulness-based interventions demonstrates that as few as 3 sessions can result in a significant effect on mood and mindfulness outcome variables (Zeidan, Johnson, Gordon, & Goolkasian, 2010). Therefore, the results obtained in this study (over four sessions) could be deemed adequate in facilitating mindfulness characteristics.

Findings Compared with Other AA T2DM Interventions

A primary aim of this research was to create a culturally informed intervention that would be effective for a rural, African American (AA) population. Few studies have examined the effectiveness of T2DM adherence interventions with this specific sub-population, despite it being a largely affected group. In comparison to other focus group studies of AA's with T2DM, the present study's participants reported many of the same issues noted by other AA's, including: need for adequate social outlets to discuss diabetes management (Tang, Brown, Funnell, & Anderson, 2008); feeling a loss of perceived control over their diabetes management; experiencing difficulty finding social supports that would assist with facilitating adherence behaviors (Wenzel, Utz, Steeves, Hinton, & Jones, 2005); and identifying dietary behaviors as a large factor in non-adherence and uncontrolled diabetes symptoms (Hill-Briggs, 2003). The intervention piloted in this study provided an opportunity for rural AA men and women to discuss common barriers experienced in diabetes management and glucose control, such as cost and preparation of healthy food, difficulty in incorporating physical activity, and associated social isolation that can accompany diabetes management. They were given opportunities to problem-solve ways in which they could address these issues in a realistic and relevant way.

Compared to other culturally informed intervention studies for AA's with T2DM, results from the IG show comparable effects on HbA1c reduction (pre-post difference scores ranging from -0.60 – 1.1% within 3-6 months of treatment) (Bogner & de Vries, 2010; Hill-Briggs et al.,

2010; Melkus et al., 2004; Melkus et al., 2010). Regarding adherence behaviors, compared to one study that used the same behavioral adherence measure (SDSCAQ) (Hill-Briggs et al., 2010), the current study demonstrated a commensurate effect size for overall adherence. For mood variables, IG participants exhibited steadily lowered depression scores three months post-intervention, which aligns similarly to other interventions tailored to AA's (Bogner & de Vries, 2010; Hill-Briggs et al., 2010; Melkus et al., 2004; Melkus et al., 2010).

Applying Findings to Theoretical Constructs

Social cognitive theory. As previously reviewed, SCT posits that perceived self-efficacy, level of knowledge, outcome expectancies, goal setting, and perceived facilitators/ barriers to goals are the core components of behavior change (Bandura, 2004). Centrally, perceived self-efficacy has a pervasive effect on the other outlined components, as low self-efficacy can influence outcome expectations, goal-setting, and perceived barriers to change. Current results demonstrated that diabetes self-efficacy was positively influenced by both the intervention as well as the education comparison treatment. However, diabetes fatalism scores (feeling out of control of diabetes management, which detracts from self-efficacy) declined post-intervention for the IG only, with a medium effect observed. Together, these findings suggest that the intervention may have had a greater influence on disease-related self-efficacy. Additionally, a medium-sized effect in diabetes knowledge for the IG was observed, as well as a significant increase in diabetes self-management behavior for diet. It is postulated under SCT that having the IG create goals and problem-solve barriers to adherence at each session was helpful in facilitating these behaviors. And although the ECG also showed similar trends, effect sizes were larger for the IG, suggesting greater effects for the culturally informed behavioral intervention.

Small change model. The small change model is an approach that is informed by theoretical constructs found in SCT, and focuses on individuals making small, self-directed goals (via self-monitoring and problem-solving barriers to change) that are relative to baseline behavior patterns (Lutes & Steinbaugh, 2010). The idea is that by accomplishing small goals, individuals can increase self-efficacy and create more sustainable changes over time, which then leads to salutatory health improvements. In the current study, the IG exhibited a significant increase in diabetes self-management behavior for diet, suggesting that a focus on making small, self-selected dietary changes had a positive influence.

Mindfulness constructs. A theory of mindfulness mechanisms of action proposes that responding, rather than reacting instinctively, to situations enables people to better understand their decisions and regulate their feelings and behaviors, which increases perceived control and decreases stress (Rosenzweig et al., 2007). As previously discussed, the current study found that the intervention may have had a greater influence on disease-related self-efficacy, given the increased self-management scores and decreased fatalism scores. In terms of mindfulness activation, the IG significantly increased in total mindfulness scores (encompassing the qualities of being non-judgmental, aware, non-reacting, and observing) pre- to immediate post-intervention, suggesting that the intervention did positively influence mindfulness development.

Limitations

Due to the small sample size, this pilot study was not sufficiently powered to detect statistically significant between-group differences, making it difficult to discern the actual effect of the intervention versus the education comparison condition (effect size calculations were used to help address this and calculate the magnitude of the differences between pre and post-intervention means). Additionally, a larger sample size would have allowed for statistics

involving regression models and path analyses, which could have better delineated the predictors of successful adherence outcomes in comparison to the control condition, as well as the intervention components that may be most effective.

Despite a randomization procedure, baseline differences were observed between the IG and ECG participants on CESD and DFS scores. The IG participants were also significantly younger than those in the ECG. This was likely a result of a small sample size, as the smaller the sample size, the more likely one will potentially observe non-equivalent group differences (Hsu, 2003). Additionally, the missing CES-D data for the first ten participants could have influenced this inequivalence for the CES-D variable. While these baseline scores were controlled for in the statistical analyses, the IG participants' significantly higher CES-D scores (five out of six IG participants at baseline had scores above 10, indicating likelihood of clinically significant depression, compared to zero of the four in the ECG) could have potentially been a harbinger for a constellation of issues that may have affected their outcome data. Psychological distress has been associated with poorer social support, more limited resources (independent of income), negative personality factors that could interfere with coping skills, and possibly unmanaged clinical symptoms of depression and/or anxiety that were not being treated effectively (Li et al., 2009; Naranjo et al., 2011; Whiting et al., 2006). These factors could have affected adherence behaviors in this study; therefore, the effect of the intervention could have been minimized as a result.

Selection bias was another limitation observed for this study. Recruitment was restricted to those actively seeking care and were motivated enough to self-select into the study. Given that the participants possessed enough insight to understand that their health was not ideal and that they could possibly make salutatory changes may have influenced the outcomes beneficially. A

random sample of a non-adherent AA population may have yielded different results that were more representative of the population as a whole, especially given that the current sample was more highly educated with a high unemployment percentage, which is aberrant compared to the norm at the ECU FMC. These qualities may have also influenced outcomes, given that these participants may have been better able to comprehend and apply materials and most did not have employment as a source of barriers to implementing health behaviors or attending groups.

Another limitation is that the MMAS and the problem-focused coping variable had alpha reliability coefficients below the optimal benchmark of .70 (.67 for both). Future research should consider using more internally consistent measures in order to ensure appropriate assessment.

An additional biomarker such as weight or BMI would have been a prudent addition to the current set of data collected. Given that BMI and HbA1c are closely correlated, it may be that some participants had made improvements in weight, due to the salutatory health behavior changes they made as a result of the intervention, but it had not yet been reflected in their HbA1c. Given that dysregulatory mechanisms of diabetes can be influenced by a number of factors outside of adherence behaviors (sickness, infection, stress, medication changes, etc.), having an alternative biomarker would have helped to strengthen results as well as perhaps provided an additional dimension of intervention effectiveness.

In some of the literature, culturally-tailored groups for AAs were matched with same-race facilitators (Melkus et al., 2004; Samuel-Hodge et al., 2000; Utz, Steeves, Wenzel, Jones, & Muphy, 2006). This was not the case in the current study, as the facilitator was Caucasian. While this did not appear to present as an overt barrier to treatment in the current study, it was difficult to truly assess what sort of effect it may have had. Being asked to discuss AA cultural norms and expectations and how those factors affected T2DM management could have been uncomfortable

or disconcerting to some participants, but remained unvoiced and undetected by the facilitator. Participants were given a chance to provide feedback at the end of their respective interventions regarding what they felt would help improve the group, and none mentioned having a same-race facilitator. Studies on therapeutic outcomes examining the role of race on the patient provider relationship have not shown differential effects when compared to therapeutic dyads that are matched for race. Rapport, cultural sensitivity, and interpersonal style seem to weigh more heavily in determining outcomes (Larrison & Schoppelrey, 2011; Sterling, Gottheil, Weinstein, & Serota, 1998).

Also of consideration is the possible effect of the same person facilitating both the IG and ECG. While conscious effort was made to make the group settings distinguished from one another (e.g., IG participants sat in a roundtable format with collaborative discussion throughout sessions while the ECG participants sat in a class format with only ten minutes reserved for discussion), it is possible that an unintentional spill-over effect of the intervention sessions may have influenced the tone, process, and facilitator perspectives given during the ECG sessions. Future research could control for this possible effect by having separate facilitators for the IG and ECG treatment arms.

Lastly, the majority of the outcome variables were self-report measures. It is possible that adherence behaviors may not have been accurately reported due to social desirability concerns or inaccurate recollection of adherence behaviors over the previous month, especially in terms of medication and behavioral adherence. The MMAS may be better utilized as a screening tool to detect problematic adherence (Krapek et al., 2004), rather than a measure to specify the degree of difficulty individuals are experiencing. HbA1c was used as a biomarker of adherence to help control for this. However, the time period in which post-intervention HbA1c was abstracted was

generally long after the intervention ended, allowing for confounding variables to potentially influence values (e.g., entrance into other lifestyle programs, impact of medical co-morbidities or acute illness, medication changes, etc.); therefore it is difficult to directly attribute decreases in HbA1c as a result of the intervention. In future research, it would be helpful to add more objective, real-time measures (e.g., logbooks that are collected at the end of each intervention session, blood glucose levels immediately post-treatment), which would perhaps help improve accuracy of reporting of adherence behaviors and what changes can be attributed to the intervention.

Implications/Future Directions

This pilot study suggests positive results from the culturally informed intervention that was delivered; however, this intervention needs to be replicated on a larger scale in order to achieve appropriate power (200 participants for a beta of 0.20) to detect statistically significant differences between intervention and active comparison groups. This could be done in a number of ways. The most obvious is prolonging the length of enrollment, which would help to increase the number of people that could be enrolled in the research and possibly building this line of research into the current clinical services that are offered in the FMC. Second, broadening the number of recruitment sites would also help in bolstering numbers. Recruiting from not only a family medicine venue, but also endocrinology clinics, internal medicine clinics, and nephrology clinics could all reap additional potential participants that would possess qualifying HbA1c levels. Third, holding groups in a venue where sessions could be held in the evenings (sessions in the current study could only be held up until the clinic closed at 5pm) could also facilitate the attendance of those who work during the day.

Additionally, it could be beneficial to broaden recruitment to the community at large. This would require a significant amount of resources to implement, but could potentially help to generalize findings for future studies. Additionally, holding groups in a community-based setting (rather than a medical center) could make the intervention more widely accessible to those in need of adherence assistance, rather than to that of just medical patients seeking services in a university medical center.

Linked to the idea of a longer and broader recruitment phase is also the possibility of collecting additional longitudinal data. Due to time limitations, the PI could only measure up to three months post-intervention. It would be prudent for future research to examine the longer-lasting influence of any immediate effects observed. Collecting longitudinal data is becoming much more commonplace in behavioral intervention research, as it is a reality that health-promotion and adherence behaviors are ever-changing based on circumstance. In order to fully test the concept of facilitating skills for consistent self-management, it would be very important to test how well the intervention helps participants learn adaptive strategies that can change with their needs, depending on their current life demands.

Shifting focus to the intervention itself, adding a self-management component for facilitating long-term adherence behaviors would make an interesting and potentially significant contribution to the current intervention. While the last session of the intervention included a topic on how to use the skills learned in the future, this alone is not likely adequate in perpetuating adherence behaviors long-term. Many technology-based interventions are trending in recent literature (via use of internet, smartphone application programs, short messaging service, tablets, etc.), which help to create a self-management loop (Bandura, 2004), where the participant receives abbreviated education and prompts for daily self-monitoring. The participant

is also given opportunities to initiate self-guided behavior change and is then given feedback by the program to keep this process perpetuated (Bandura, 2004; Sevick et al., 2012; Vervloet et al., 2011). These interventions have shown promise for creating consistent adherence behaviors for T2DM populations, so adding a technology-based self-management program for a longitudinal study could also be a viable avenue for future research.

Post-intervention, participants were asked to provide suggestions about how to make future groups more applicable or helpful. The majority of participants did not offer suggestions; however, several did suggest the possibility of increasing the number of sessions in order to cover topics in greater depth. Future research could focus on creating comparison groups of various length (ranging from four to eight) to better conceptualize the dose-response curve for this intervention.

During one group session, a participant brought a family member in hopes that they could also benefit from the group process and better understand the changes the participant was trying to implement. This event has implications for future research: encouraging participants to bring a family member or friend to the social support session. Given the great need of T2DM patients to feel understood by their social support in terms of disease management (Carter-Edwards, Skelly, Cagle, & Appel, 2004), this act could facilitate better understanding for social supports about the experience of T2DM and provide a context for participants to utilize communication skills in session.

Given the context in which this intervention was based (a family medical center burgeoning in integrated care initiatives) another potential avenue for future research would be to utilize dismantled components of the intervention for a primary care-based medical setting and evaluate its efficacy as an integrated care intervention. Patient-centered medical home models of

treatment delivery are rapidly trending (Dickinson & Miller, 2010). Additionally, some research has already shown beneficial effects of brief problem-solving interventions on glucose control for T2DM patients in primary care (Bogner et al., 2012). Components of the current intervention could be adapted into a shared medical appointment model, where patients are seen in a group setting for education by various health providers and given a brief one-on-one assessment by their physician. This would help to target behavioral goals and address barriers to adherence for a large patient population in need of adherence assistance. This type of intervention may help shift focus from a tertiary disease treatment model to a primary/secondary disease prevention model, which could facilitate enhancement of adherence behaviors before HbA1c levels become chronically uncontrolled and patients experience long-lasting deleterious co-morbidities.

Summary

In conclusion, participants in the culturally informed intervention did not demonstrate significantly different outcomes compared to those in a diabetes education group. It should be noted that the overall benefit observed in both groups is a testament to the power of being in a group-based intervention and how the weekly contact seemed to have similar salutatory effects on health behavior and mood for both IG and ECG participants. Having an outlet to discuss relevant T2DM management issues and ways in which to address problems in a social context seemed to be of benefit despite varied content and group process. However, those who completed the intervention did exhibit significant increases in dietary adherence and mindfulness, clinically and statistically significant reductions in HbA1c levels, and clinically significant decreases in depression scores. Future research with larger samples is needed to better elucidate treatment effects for this intervention. Additionally, given the population of interest,

community-based approaches may provide wider accessibility. Also, adding a long-term follow-up component would provide an opportunity to test longitudinal effects.

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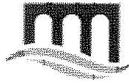
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Notification of Initial Approval: Expedited

From: Social/Behavioral IRB
 To: [Taylor Rush](#)
 CC: [Christyn Dolbier](#)
 Date: 1/12/2012
 Re: [UMCIRB 11-001133](#)
 Diabetes Adherence Study

I am pleased to inform you that your Expedited Application was approved. Approval of the study and any consent form(s) is for the period of 1/11/2012 to 1/9/2013. The research study is eligible for review under expedited category #5, 6, & 7. The Chairperson (or designee) deemed this study no more than minimal risk.

Changes to this approved research may not be initiated without UMCIRB review except when necessary to eliminate an apparent immediate hazard to the participant. All unanticipated problems involving risks to participants and others must be promptly reported to the UMCIRB. The investigator must submit a continuing review/closure application to the UMCIRB prior to the date of study expiration. The Investigator must adhere to all reporting requirements for this study.

The approval includes the following items:

Name	Description
Advertisement flier for Family Medicine Staff History	Recruitment Documents/Scripts
Chart Abstraction Data Collection Sheet History	Surveys and Questionnaires
Family Medicine Executive Council Minutes History	Additional Items
Focus Group Consent History	Consent Forms
Focus Group Questions History	Interview/Focus Group Scripts/Questions
HIPPA consent History	HIPAA Authorization
Letter of Support from Family Medicine Department Chair History	Additional Items
Phase 1 Demographic Questionnaire History	Surveys and Questionnaires
Rush Dissertation Proposal (Approved 6/2011) History	Study Protocol or Grant Application

The Chairperson (or designee) does not have a potential for conflict of interest on this study.

IRB00000705 East Carolina U IRB #1 (Biomedical) IORG0000418
 IRB00003791 East Carolina U IRB #2 (Behavioral/SS) IORG0000418 IRB00004973
 East Carolina U IRB #4 (Behavioral/SS Summer) IORG0000418

APPENDIX B: FOCUS GROUP QUESTIONS OUTLINE

- What was your experience adjusting to life with diabetes?
 - When you first found out, what was your reaction?
 - How did your doctor explain diabetes to you and how it can affect your health?
 - How did you initially feel about the treatment and recommendations that your doctor provided?
 - How difficult was it to adhere to your treatment in the beginning?
 - How did your family and friends react when (or if) you told them you had been diagnosed with diabetes?
 - Do you feel like your experience as an African American with diabetes is different from that of a person of another racial background? How so?

- Tell me about what you know about how diabetes affects your body.
 - What are some of the short-term effects of not adhering to treatment?
 - What are some of the long-term effects?
 - What are some of the best ways people have described diabetes to you?

- What has been the most difficult aspect of your diabetes treatment?
 - What challenges have you encountered in adhering to your recommended treatment?
 - Has there been a time when you have felt extremely sick as a result of not adhering to your treatment? Did that experience change your treatment adherence?
 - How in control do you feel in managing your diabetes?
 - What would be helpful (or has been helpful) in maintaining good treatment adherence?

- Do you feel talking about adherence challenges in a group setting would be helpful for you?
 - What types of topics would you want to talk about in a group setting?
 - Would you be interested in learning about relaxation strategies?
 - How would you feel about learning how to make small changes to your physical activity and diet to help improve your blood sugar levels?
What are some ways that you like to learn new information (handouts, discussion, activities, presentations, etc.)?

