Predicting Treatment Success: Assessing Theoretically-Driven Constructs that Impact the Management of Type 2 Diabetes Mellitus Among African American Women in a Novel Peer-Delivered Small Changes Treatment Approach

by

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Rural African American women have greater prevalence of Type 2 Diabetes Mellitus (T2DM) and poorer treatment outcomes compared to Caucasians. Some research suggests that self-efficacy, subjective norms, and locus of control (LOC) impact this population differently and may be linked to behavioral treatment outcomes. However, these relationships have not been directly examined. EMPOWER, a culturally-tailored T2DM intervention that utilizes community health workers (CHWs) to provide patient-centered care using a Small Changes Model (SCM), was developed as an innovative treatment approach for African American women. This study was designed to explore the best predictors of treatment success within the EMPOWER program and to determine whether self-efficacy, subjective norms, and LOC impact outcomes.

Assessments utilized program results of two hundred middle aged (age=53.45±10.24) obese (BMI=37.67±8.02) African American women with poorly-controlled diabetes (HbA1c=9.09±1.83) enrolled in EMPOWER. Half (*n*=102) were randomly assigned to a phone-based EMPOWER group while half (*n*=98) were assigned to a mail-based didactic comparative group. Weight, HbA1c, medication adherence, self-care behaviors, self-efficacy, and depression

were measured at 0, 6, and 12-months. At 12-month follow-up, subjective norms and LOC were measured. Repeated measures ANOVAs indicated that both groups had a reduction in weight $F(1.82, 197)=4.15$, $p=0.020$, $\eta^2=0.021$ but no changes in HbA1c. Independent samples t-tests revealed a significant difference in God LOC between the EMPOWER group ($M=19.16$, $SD=8.20$) and the Mail group ($M=22.42$, $SD=7.48$; $t(143)=-2.49$, $p=0.014$) and between participants who used insulin ($M=21.86$, $SD=7.55$) and those who do not ($M=18.88$, $SD=8.21$; $t(139)=-2.18$, $p=0.031$). Theoretically-based moderated-mediation models assessed self-efficacy and subjective norms as mediators and God and Internal LOC as moderators of outcomes. While no mediation interactions were found, models revealed that subjective norms significantly impacted self-care behavior change ($\beta=1.48$, $p=0.037$). God LOC served as a moderator that enhanced this relationship ($\beta=0.078$, $p=0.013$). Results suggest that subjective norms may play a more important role in diabetes management behavior change among African American women than previously understood. Further, God LOC was shown to be an important and complex treatment factor that likely relates to both internal and external LOC. These findings have important implications for future health behavior change programs for African American women.

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Chapter I: Introduction and Review of Literature

Diabetes Mellitus is a pervasive health problem in the US (Centers for Disease Control and Prevention; CDC, 2005). Currently 11% of US adults are diagnosed with diabetes (CDC, 2005) and another 35% have pre-diabetes (CDC, 2011). In 2007 researchers estimated that the cost of diabetes in the US alone, including medical expenditures and loss of productivity, was $174 billion. Twenty-seven billion of these dollars were spent on the direct treatment of diabetes, and half of this was spent on hospital inpatient care (American Diabetes Association, 2008). While Type 1 Diabetes Mellitus and diabetes secondary to medical conditions account for approximately 5-10% of diabetes cases, at least 90% of people living with diabetes have Type 2 Diabetes Mellitus (T2DM). T2DM is closely linked to obesogenic lifestyles and is more prevalent in populations with higher rates of overweight and physical inactivity (CDC, 2011).

T2DM is a metabolic disorder characterized by hyperglycemia, or high blood glucose levels, and an inability to produce or use insulin effectively (Rhodes, 2005). Insulin is a vital hormone generated by the pancreas that metabolizes protein, fat, and carbohydrates by facilitating the uptake of blood glucose into tissue, where it is stored as glycogen. If this process does not occur, then the over-abundance of glucose in the bloodstream can lead to toxic effects and the lack of glucose in the cells can lead to cellular dysfunction (Gilbert & Liu, 2012; Hardy, Czech, & Corvera, 2012; Rhodes, 2005). T2DM is ultimately caused by a disturbance in insulin production in beta cells, cellular deficiency in the use of the insulin that is made, and/or increased hepatic production of glucose (Inzucchi, 2005). T2DM is diagnosed if a patient has the following: 1) HbA1c >/= 6.5%, 2) 8-hour fasting plasma glucose >/=126 mg/dL, 3) 2 hour plasma glucose >/=200 mg/dL, 4) episodes of hyper- or hypo-glycemia, 5) confirmation of elevated blood sugar levels via a second round of testing, and 6) a patient history that suggests

that symptoms are not better explained by Type 1 diabetes mellitus or gestational diabetes (American Diabetes Association, 2012).

While patients can assess their blood glucose at any given time using a hand-held monitor, physicians typically monitor glucose levels by measuring a patient's glycated hemoglobin levels, also known as HbA1c. This measure requires a drop of blood and indicates one's typical glucose concentration over approximately three months (Al-Ansary et al., 2011). Because of this, researchers often utilize HbA1c results instead of glucose readings to develop a more comprehensive picture of a patient's T2DM management.

T2DM Symptoms

Extended periods of elevated HbA1c resulting from T2DM are typically, but not always, associated with a variety of symptoms. These include excessive urination, fatigue, vision troubles, slow healing of wounds, and excessive thirst (Lin & Sun, 2010). Weight loss, genital itching (Nielsen, Gannik, Siersma, & Olivarius, 2011), shortness of breath, nausea, and constipation (Sudore et al., 2012) are also commonly reported. One large-scale follow-up study of 13,171 older patients with T2DM found that as many as 42% of patients had acute pain, 40% had chronic pain, 24% had neuropathy, 25% had fatigue, and 24% had significant sleep disturbance (Sudore et al., 2012). Overall, 47% of participants reported three or more T2DM symptoms and 22% reported two symptoms. However, health care providers should be aware that many people with T2DM are asymptomatic and others report that symptoms present very gradually over a long period of time. This may partially explain why patients live with T2DM for an average of 7 years before they are diagnosed (Harris, Klein, Welborn, & Knuiman, 1992). Unfortunately, it may be challenging to convince T2DM patients with limited symptomology of

the importance of lifestyle management when they are not "feeling" the results of diabetes mismanagement.

T2DM Causes

Insulin resistance in people with T2DM often results because excessive visceral adiposity leads to lipid build-up in the organs, which causes the release of adipokines that impair insulin sensitivity. Lipid build-up also likely creates an overabundance of inflammatory cytokines that promote insulin resistance by reducing the effectiveness of insulin-producing beta-cells in the pancreas (Hardy, Czech, & Corvera, 2012). This is more likely to occur if an individual has a genetic precursor to T2DM. Research shows that genetic coding impacts fat metabolism, inflammation, and cellular function, all which can contribute to T2DM (Gilbert & Liu, 2012; Hardy, Czech, & Corvera, 2012; Rhodes, 2005).

Obesity appears to be the strongest contributor to T2DM development, particularly among females (Relative Risk (RR) = 12.41; CI: 9.03-17.06; Guh et al., 2009). In fact, one prospective cohort study assessing over 100,000 nurses showed that weight status is the single largest risk factor that predicts T2DM (Colditz et al., 1995). This study illustrated that the RR for developing T2DM was 9.06 times greater for obese female nurses compared to normal-weight female nurses (95% CI: 7.60–10.8). Likewise, in the Health Professionals Follow-Up Study, for every kilogram gained by male participants, T2DM risk increased by 7.3% (Koh-Banerjee et al., 2004). This likely explains why 90% of those with T2DM are also overweight (Mitchell, Catenacci, Wyatt, & Hill, 2011).

Research has been able to identify specific links between obesogenic lifestyles and T2DM development. Some researchers argue that the relationship between T2DM and obesity is primarily mediated by an energy-dense diet (Wang et al., 2008). One large-scale 12-year follow-

up study found that when assessing 27,000 individuals, high protein and low fiber intake significantly predicted the development of T2DM ($p = 0.01$) beyond other variables (Wang et al., 2008). Specifically, processed meats and eggs were highly correlated with T2DM (Ericson et al., 2012). Physical inactivity, a common concern among both obese and diabetic populations, also independently predicted T2DM. Worldwide, it is estimated that physical inactivity causes 7% of the disease burden of T2DM (Lee et al., 2012). Taken together, it is evident that obesogenic lifestyles play a key role in the development of T2DM and weight management is thus a primary focus in diabetes interventions. The relationship between weight and T2DM is made more complex by the fact that medications designed to treat T2DM can also contribute significantly to weight gain. One open-label prospective study showed that participants gain as much as 7.60 kg in a 6-month time frame when taking metformin and insulin to treat T2DM (Jacob, Salinas, Adams-Huet, & Raskin, 2007).

T2DM Physiological Co-morbidities

Considering the link between T2DM and obesity, it is not surprising that T2DM is associated with significant co-morbidities, including heart disease, stroke, hypertension, periodontal disease, kidney disease, and hypertension (CDC, 2011). In a study that assessed patients with T2DM who filed with a commercial insurance company and were covered between 12-24 months, chronic heart disease, vascular disease, renal failure, retinopathy, and neuropathy were prevalent in at least 10% of T2DM cases (Pelletier et al., 2008). Alarmingly, 7.2% of T2DM patients experienced a heart attack, 14% were diagnosed with heart failure, and 11% had renal disease throughout the course of the study (Pelletier et al., 2008).

Large-scale assessments of T2DM populations have found that 28.5% of T2DM patients over 40 years of age have diabetic retinopathy and 70% have nervous system damage (CDC,

2011). T2DM has also led to more than 60% of non-traumatic amputations and 44% of kidney failure cases (CDC, 2011). Further, the Center for Disease Prevention and Health Promotion found that, based on the death certificates of patients with T2DM, 68% of diabetes-related deaths were due to heart disease and 16% were due to stroke. These co-morbidities are often to blame for the 8-year decrease in life expectancy of diabetic adults over 50 years old (Franco, Steyerberg, Hu, Mackenbach, & Nusselder, 2007).

T2DM and Depression

T2DM co-morbidities are not only biomedical in nature. Psychological co-morbidities are also common (Nefs, Pouwer, Denollet, & Pop, 2012). An assessment of over 13,000 adults reveals that approximately 24% of patients with T2DM are depressed (Sudore et al., 2012). A review of ten controlled studies with a total of over 50,000 people found that the prevalence of depression was significantly higher in T2DM patients compared to non-diabetic samples (17.6 vs. 9.8%, overall risk = 1.6), although this meta-analysis did not control for factors such as socio-economic status (Ali, Stone, Peters, Davies, & Khunti, 2006).

Research further shows that, compared with non-diabetic controls, people with T2DM have a 24% increased risk of developing depression (Nouwen et al., 2010). These statistics are alarming, especially considering that depression is related to worse glycemic control (Lustman et al., 2000). These data have implications for African American women in particular, who are significantly less likely to receive care for depression, despite the fact that some research has found an increased rate of depression in this population (Carrington, 2006).

Other studies suggest that depression may also play a role in the development of T2DM. A meta-analysis of nine studies illustrated that depressed adults have a 37% increased chance of developing T2DM (Knol et al., 2006). While this meta-analysis was criticized for using studies

that included "self-reported depression" (de Jonge & Rosmalen, 2006), another meta-analysis that used only validated measures of depression found depression was still associated with a 20% increase of T2DM diagnoses (Cosgrove, Sargeant, & Griffin, 2008). Considering the important role that depression plays in T2DM, T2DM interventions should consider depression rates for participants before and after treatment.

Taken together, it is evident that T2DM is a complex disease state that affects a large number of US citizens. T2DM's associated symptoms, complications, and co-morbidities in combination with a complex and expensive treatment regimen likely create significant barriers for those trying to manage this chronic illness state. Unfortunately, this disease burden is unequally born by minority patients with T2DM (CDC, 2005). It is important for interventionists to understand these disparities in order to provide more appropriate treatment for all patients in their care.

Diabetes Disparities among African American Women

The rates and trends for diabetes are significantly worse for minorities in the US. Alarmingly, three times as many African Americans currently suffer from T2DM than Caucasians (CDC, 2005). While some of this disparity is accounted for by age differences, national survey data illustrate that even after correcting for age, 7.1% of Caucasians are diabetic compared to 12.6% of African Americans (CDC, 2011). Research further shows that end stage renal disease (Lanting, Joung, Mackenbach, Lamberts, & Bootsma, 2005) and diabetes-related complications (such as foot amputations or retinopathy) occur more frequently among African Americans (Johnson & Lavernia, 2011; Lanting et al., 2005).

Obesity, the primary predictor of T2DM, is a significant contributor to the disproportionately high rate of T2DM in African Americans (Colditz, Willett, Rotnitzky, &

Manson, 1995). Currently, 76.1% of African American adults are overweight, compared to only 64.2% of Caucasian adults (Ogden et al., 2006). These trends are particularly high for African American women. Research shows that African American women are twice as likely to develop T2DM compared to Caucasian counterparts, and obesogenic lifestyle accounts for almost half of this risk (Brancati, Kao, Folsom, Watson, & Szklo, 2000). Currently 50% of African American women (compared to 37% of African American men) are considered obese (Mitchell, Catenacci, Wyatt, & Hill, 2011). This trend is on the rise: The obesity gap between Caucasian and African American women has grown by 5% in the past several decades (Johnston & Lee, 2011).

Several population differences likely contribute to the increased rate of obesity and T2DM among African American women. One long-term follow-up study illustrated that higher rates of hypertension are found in African American women compared to Caucasian women, which was in turn linked to differential rates of diabetes development (Brancati et al., 2000). A review of the literature also suggests that a lower resting metabolic rate (RMR) in African American women compared to Caucasian women may account for weight differences (Forman, Miller, Szymanski, & Fernhall, 1998; Gannon, DiPietro, & Poehlman, 2000) although this trend is not seen across men (Sharp et al., 2002) or among children or other racial groups (Luke, Dugas, & Kramer, 2007).

Other researchers argue that socioeconomic differences account for at least a portion of the weight gap between African Americans and Caucasians (Robert & Reither, 2004). It is estimated that individual diabetic patients with T2DM spend $11,744 per year on health costs (American Diabetes Association, 2008). This financial burden may have a disproportionate impact on African American patients who suffer from significantly higher rates of poverty than their Caucasian peers (Thorpe et al., 2008) and are more than twice as likely to be uninsured

compared to Caucasians (Gary, Narayan, Gregg, Beckles, & Saaddine, 2003). The astronomical cost of T2DM management in combination with the disproportionately disadvantaged financial status of African American patients may be an important reason why African Americans suffer from T2DM and disease-related complications at higher rates than other ethnic groups.

However, the key contributor to weight disparities among African American women may be health behaviors. Research shows that African American women are more sedentary than Caucasian women (Schoenborn, Adams, Barnes, Vickerie, & Schiller, 2004), eat fewer fruits and vegetables (Dubowitz et al., 2008; Kumanyika, 2002), and consume more calories (Johnston & Lee, 2011). It is important to continue to investigate the weighted contributions of these factors to inform intervention, especially considering that researchers predict that if this trajectory continues, 100% of black women will be overweight or obese in less than three decades (Wang, Beydoun, Liang, Caballero, & Kumanyika, 2008). This alarming projection has profound implications for future T2DM morbidity and mortality. Considering the significant T2DM-related disparities among African American women, effective evidence-based treatment programs that promote improved glycemic control and address treatment barriers within a relevant and culturally-sensitive format are critically needed.

T2DM Treatment

Medical Treatment for T2DM. The primary goal of pharmacological T2DM treatment is to improve the body's ability to process glucose, resulting in the reduction and stabilization of blood glycogen levels. Research shows that reducing HbA1c by only 1% can reduce the risk of eye, kidney, and nerve diseases by 40% (CDC, 2011) and can improve life expectancy, quality of life, cost of care, and cardiovascular complications (Valentine, Palmer, Nicklasson, Cobden, & Roze, 2006). Because of this, 58% of diabetic patients take oral medications, 12% take injectable

insulin, and 14% take both oral medication and injectable insulin (only 16% take no medications; CDC, 2011). The main classes of oral medications for T2DM include drugs to stimulate insulin secretion, reduce hepatic glucose production, delay digestion and absorption of carbohydrates in the intestine, and improve the action of insulin (Krentz & Bailey, 2005). Currently, the most popular oral medication for diabetes is Metformin. Metformin has been shown to reduce the risk T2DM by 31% in pre-diabetic populations (CDC, 2011) and to significantly reduce HbA1c levels in adults already diagnosed with T2DM (Gonzalez-Ortiz et al., 2012). Further, Metformin is linked to a reduction in the risk of myocardial infarction and other cardiovascular factors in T2DM patients (Krentz & Bailey, 2005).

If oral anti-diabetics prove insufficient, then T2DM patients are often prescribed injectable insulin. Insulin is designed to be given 1-3 times a day in order to keep insulin levels as close to normal as possible and has been proven to be effective in the management of diabetes (Schramm, 2012). However, the impact of insulin dosages are different depending on timing, injection technique, diet, physical activity, and even stress, so hypoglycemia and hyperglycemia are still common in patients who use injectable insulin. Further, the complexity, discomfort, and expense of this treatment often prevent patients from using injectable insulin correctly (Abrahamson & Peters, 2012; Freemantle et al., 2006).

Medication Non-Adherence. While laboratory-based research shows the effectiveness of medical T2DM interventions, the literature shows that adherence has proven to be a major challenge in practice. In fact, less than one-half of patients with T2DM achieve glycemic targets as recommended by practice guidelines (Abrahamson & Peters, 2012). Adherence rates for patients prescribed oral medications in particular were found to be as low as 36% (Cramer, 2004). Following this trend, studies that assess injectable insulin adherence show that fewer than

two-thirds of insulin-using patients even fill their insulin prescriptions regularly (Cramer, 2004). Of note, three-fourths of physicians in an international survey reported that on average their patients do not take insulin and typically skip an average of 10 injections per month (although patients' self-reported adherence is higher; Peyrot, Barnett, Meneghini, & Schomm-Draeger, 2012).

While cost has been cited as a primary challenge to adherence, rates remain low even in studies where treatment is free (Bailey et al., 2012). Other cited barriers to T2DM medication adherence include medical side effects, lack of coordinated care, psychological co-morbidities, literacy/education (Bailey et al., 2012), complexity of treatment regimen, and stigma (Odegard & Capoccia, 2007). Notably, African Americans (Bhattacharya, 2012) and depressed patients with T2DM have a higher rate of non-adherence (Bogner, Morales, de Vries, & Cappola, 2012). One study of low-income patients found that depressed women in particular were most commonly non-adherent ($p = 0.05$; Lerman et al., 2009) and some (but not all) studies suggest that improving depression rates may improve adherence (Markowitz, Gonzalez, Wilkinson, & Safren, 2011).

Diabetes Education. Some interventionists argue that participants do not engage in proper self-management behaviors due to lack of knowledge regarding T2DM and self-management needs. Because T2DM and its self-care regimen is particularly complex, one key intervention for patients recently diagnosed with T2DM is diabetes education. The American Diabetes Association (1991) encourages all people with diabetes to engage in education programs. The American Dietetic Association has developed educational resources for use within primary care settings (American Dietetic Association, 2010). Topics include healthy snacking, managing medications, monitoring blood glucose, and engaging in physical activity.

For many patients, particularly those who do not attend physician appointments regularly, these educational materials may be the majority of the self-management assistance they receive.

While results are mixed, some research shows that education in both individual or group formats can improve knowledge, weight status, health-related quality of life, attitudes and HbA1c immediately following education classes (Rickheim, Weaver, Flader, & Kendall, 2002). Other studies reported that self-monitoring improved following self-management education classes (Gumbs, 2012), and a short-term (5-session) program helped patients to gain less weight and achieve better physical functioning than standard care participants.

Limitations of Diabetes Education. Despite initial success, the studies discussed above and other education-based intervention studies did not assess long-term changes in participants (Noel et al., 1998). It may be that health benefits resulting from education programs are not sustained. One longer-term study showed that improvements in HbA1c, physical activity, diet, and medication intensification were equivalent to baseline rates after six months post-treatment (Sperl-Hillen et al., 2012). In a study assessing culturally tailored education in minority groups, education predicted better HbA1c outcomes at 3 and 6 months, but this relationship was not significant at 12 months post-intervention compared to usual care. Further, this treatment had no impact on lipid levels, blood pressure, quality of life, attitude, empowerment, or self-efficacy at any point during the intervention (Hawthorne, Robles, Cannings-John, & Edwards, 2008). The short-lived gain from education programs may be explained by the short-term social support or peer encouragement provided via class. It may be that health behaviors return to baseline along with social support after classes are completed and participants no longer meet with their peers.

Education also seems to have differing results between demographic groups. An Australian sample of T2DM patients showed that older people and minorities were significantly

less likely to attend diabetes education classes (32% and 70%, respectively; Bruce, Davis, Cull, & Davis, 2003). Likewise, in the US, only 70% of Hispanic patients (Noel et al., 1998) and 46% of African American women have attended diabetes education classes (Gumbs, 2012). Differential benefit of diabetes education between non-minority and minority patients enrolled in diabetes education classes has also been found (Kurian & Borders, 2006). Diabetes management education did not improve the pursuit of any preventive secondary services in Hispanic populations and only led to foot exams but not HbA1c or eye exams in African Americans. In contrast, Caucasians benefitted from education in all preventive areas (Kurian & Borders, 2006).

Lifestyle and Weight-Management Treatment. While helpful, it appears that medications and education alone tend to fall short in the treatment of diabetes, particularly for minority patients. Regarding medical treatment, it is first important to state that drugs are intended to mitigate the progression of a disease state and reduce symptoms but do little to prevent or reverse disease. Second, non-adherence prevents most patients from reaping the benefits of medication. Third, medications do not address the poor health behaviors and weight status that typically underlie T2DM. Fourth, African American women are less likely to adhere to medications and thus benefit from treatment. Regarding education, there appears to be limited long-term gain and clear differential benefit by ethnic groups. Lifestyle interventions could potentially address each of these concerns and are thus the first-line of defense against T2DM. Lifestyle interventions typically focus on weight loss, diet, exercise, and medical adherence.

Research shows that lifestyle interventions can be highly effective in preventing the development of T2DM. In fact, reviews find that lifestyle interventions can prevent or delay T2DM by 50% (Laws, St George, Rychetnik, & Bauman, 2012). The Diabetes Prevention Program (DPP), one of the largest T2DM intervention studies to date, found that lifestyle

intervention reduced the risk of future development of diabetes by 58% compared to Metformin, which reduced the risk by 31% in a sample of over 3,000 non-diabetic individuals with an elevated fasting glucose (Knowler et al., 2002). In this study, half of participants reached their goal weight loss of 7% and self-report indicated that 74% reached a goal of 150 minutes or more of physical activity per week. The average dietary reduction was 450 kcal in the lifestyle intervention group (Knowler et al., 2002). Importantly, the DPP found that a weight loss of as little as 5-7% of body weight led to a 58-71% risk reduction for T2DM, depending on age (CDC, 2011).

The Finnish Diabetes Study likewise found that weight loss, reduced fat intake, increased fiber intake, and more physical activity led to a 43% reduction in relative risk across time. Importantly, three years after the end of treatment participants without T2DM were still 36% less likely to develop T2DM than controls (Lindstrom et al., 2006). In the China Da Qing Diabetes Prevention Study, lifestyle intervention was associated with a 51% reduction in T2DM rates across a 6-year intervention and 43% reduction over the course of two decades after the intervention (Li et al., 2008). Finally, in the National Nurses Health Study, a weight loss of at least 5.0 kg reduced T2DM risk by over half (Colditz et al., 1995). These studies show the value that lifestyle interventions can have on the key factors underlying T2DM development.

Lifestyle interventions do not just have preventive value. Japanese patients diagnosed with T2DM who underwent a 16-week lifestyle intervention with Metformin experienced almost 4 kg weight loss and a 2.5% drop in HbA1c (Sumitani et al., 2012). Another New Zealand intervention study focused on T2DM patients with poor glycemic control, despite following an optimized medication plan. This study found that, compared to controls, the lifestyle intervention resulted in significantly greater weight loss ($p = 0.032$) and HbA1c reduction ($p = 0.007$; Coppell

et al., 2010). The results of this study have been replicated in similar interventions (Thomas & Elliott, 2009). A review of 11 randomized controlled trials show that following a low glycemic diet significantly reduces incidences of hyper- and hypoglycemic events, which in turn reduces complications of T2DM (Thomas & Elliott, 2009).

In over 5,000 T2DM patients, the largest and longest clinical trial examining the impact of intensive lifestyle intervention to date, the Look AHEAD Trial showed that weight reduction following intensive lifestyle intervention was significantly associated with a reduction in insulin usage (Wadden et al., 2011). Notably, half of participants maintained significant 5% weight loss at 8 years posttest and reported greater weight control behaviors compared to a comparison supportive diabetes education group (Look AHEAD Research Group, 2014). Yet another review paper also found that lifestyle interventions for T2DM patients achieved 50% reduction of glucose intolerance overall (Ferchak & Meneghini, 2004). One reason for these positive trends may be that lifestyle interventions can significantly improve medication adherence. One study targeting rural hypertensive patients found that medication adherence was significantly higher in patients receiving brief patient counseling (Ramanath, Balaji, Nagakishore, Kumar, & Bhanuprakash, 2012). Taken together, it is evident that lifestyle interventions can have a significant impact on diabetes management behaviors.

Challenges in Lifestyle Interventions for T2DM. While promising, there are a significant number of studies that show that T2DM patients are also frequently non-adherent to lifestyle interventions. In fact, one study found that, when unadjusted for risk factors, adherence scores for behavioral interventions in a primary care setting hover around 50% (Klotsche et al., 2011). Adherence rates were even worse in older samples. Further, adherence rates were low in programs where a large number of behaviors were targeted or in programs where participants

had a large number of unachieved goals (Klotsche et al., 2011). Some researchers have found that the primary predictor of program drop-out was perceived rule complexity in a cognitively demanding weight loss program (such as Weight Watchers) versus a less demanding program (such as one using a cook-book; Mata, Todd, & Lippke, 2010). These data suggest that, perhaps in this target population, interventions should focus on simple, small goals versus large/complex goals.

With the exception of highly intensive programs (Look Ahead Research Group, 2014), 70-80% of participants regain their lost weight after lifestyle intervention programs have been completed (Westenhoefer, 2001). Within one year post-treatment, two-thirds of weight lost is typically regained and weight typically reaches baseline at 5 years post-intervention. Potential contributors to this trend include obesogenic environments and lack of positive reinforcement (Perri & Corsica, 2002). Addressing long-term social support in future interventions may help patients overcome some of these obstacles.

Other contributors to poor treatment outcomes may include disappointment, frustration, or even shame for failing to achieve personal weight loss goals. Researchers have found that participants typically have unrealistically high expectations for weight loss. One study assessing a four-month lifestyle intervention found that women thought that a 17 kg weight loss was "disappointing." These women instead expected to achieve a 32% body weight reduction within a four-month time period (Foster, Wadden, Vogt, & Brewer, 1997). This highly unlikely expectation of initial weight loss during treatment in combination with the challenges inherent in maintaining weight loss after treatment inevitably sets participants up for failure. Researchers have attempted to change this pattern and improve outcomes by promoting more modest weight loss and expectations (Ames et al., 2005; Foster, Phelan, Wadden, Gill, Ermold, Didie, 2004) and

utilizing continuous care models of treatment (Perri, Sears, & Clark, 1993), but evidence to support these approaches is limited. Future research should consider how to promote more attainable goals while still promoting weight loss.

Other predictors of non-adherence and drop-out to lifestyle interventions include non-modifiable risk factors, such as being African American (Wilbur, Michaels, Miller, Chandler, & McDevitt, 2003), being a woman, being younger, having a higher weight status, having been previously enrolled in weight management programs (Bautista-Castano, Molina-Cabrillana, Montoya-Alonso, & Serra-Majem, 2004), and low SES (Shay, 2008). Conversely, modifiable predictors of adherence include self-efficacy, social support, perceived benefit, provider support, knowledge, and lower stress levels (Shay, 2008). Therefore, future interventions should target these factors as well as direct management behaviors in order to improve adherence and, in turn, treatment outcomes.

While medication, education, and lifestyle interventions have all been shown to improve outcomes to different degrees, none of these treatment options have been able to fully reduce the T2DM burden, particularly in African American populations. Taken together, these studies suggests that future interventions should help participants target a smaller number of manageable behavioral goals and consider long-term social support, which will in turn likely increase their goal completion. It is likely that completing one or two smaller goals is better than attempting and failing to complete many large, complex goals. Further, the literature suggests participants may be more likely to achieve goals by engaging stronger social support.

Treatment Considerations for African American Women

While the treatment challenges discussed above are important to consider for all patients seeking medication, education, or lifestyle intervention treatment, it is important to discuss

treatment factors particularly impacting minority patients across treatment settings considering racial disparities evident in T2DM treatments across modality and intervention type. African American women are less likely to participate in or receive benefit from education programs (Gumbs, 2012), are less likely to adhere to prescribed medication regimens (Bhattacharya, 2012), and typically lose less weight than other subgroups in lifestyle interventions (Fitzgibbon et al., 2012). Because of this, some have begun to suggest that interventions targeted in this population should be to prevent weight gain instead of encourage active weight loss (Bennett et al., 2012). Regardless, by better understanding the factors that impact outcomes for African American women in particular, treatments may be developed that are catered more directly to a population that bears the greatest T2DM burden.

Traditional programs that promote standardized, "one size fits all" goals and treatment protocols may not allow for catering to unique differences among African American women. For example, in the standardized DPP, all race and gender groups responded similarly to the standardized lifestyle intervention protocol with the exception of African American women, who had approximately half the weight loss success of other genders and ethnicities. Even compared to African American men, who experienced a 7.1% weight decrease, African American women only lost 4.5% (West, Elaine, Prewitt, Bursac, & Felix, 2008). Data from the National Weight Control Registry (NWCR) shows similar results. The NWCR is a database developed to identify the keys to successful weight management in order to inform intervention. The NWCR documents the weight management behaviors of US adults who have lost a minimum of 30 pounds and maintained this loss for over 12 months. A 2005 study found that, of the 4,000 people who were registered at the time, 95% of registry members were Caucasian and 82% of participants were college educated (Wing & Phelan, 2005). These data suggests that African

American women of low SES are largely unrepresented in the research that most informs current treatment practices.

Treatment Expectations and Perspectives among African American Women

It is important to consider that treatment expectations may differ between ethnic groups and ultimately impact outcomes. One important study found that before engaging in an exercise program, African American women reported higher self-efficacy than Caucasian women, only to experience significantly less adherence and a substantial drop in self-efficacy by the end of the 24-week intervention (Wilbur et al., 2003). This trend may be partially explained by perceived interference in daily life and perceived severity of disease, which was higher in African Americans undergoing lifestyle treatment, even after controlling for demographic and disease-related factors (Hausmann, Ren, & Sevick, 2010).

Another potential contributor to poor treatment outcomes among African American women is orientation toward weight loss. While research shows that 68% of African American women and 72% of Caucasian women want to lose weight (Mack et al., 2004), how these groups of women want to lose weight varies greatly. For example, African American women are more likely to desire individual counseling and culturally tailored treatment, including culturally relevant food counseling, compared to Caucasian women (Blixen, Singh, Xu, Thacker, & Mascha, 2006). This is important considering the role that some traditionally relevant foods in south-eastern African American culture may play. These traditional foods are often served in African American households as a form of social currency, and cooking often plays an important role in family and community functions (Kumanyika, 2002). To try to restrict these foods (as traditional diets often do) would be to restrict a cultural practice among many African American women.

Research also suggests that African American women have concerns of becoming "too thin" or "sickly" (Barnes et al., 2007). This is understandable considering that research shows that African American women are more satisfied with their body size than Caucasian women and disagree with the "thin ideal," preferring instead a significantly higher weight status (Thomas, Moseley, Stallings, Nichols-English, & Wagner, 2008). Perspiration and appearance while exercising have also been identified as common barriers among African American women who do not exercise regularly (Thomas et al., 2008). This may partially contribute to high rates of attrition in African American women in physical activity interventions (Banks-Wallace & Conn, 2002).

Thus, from the perspective of the African American woman, it may be that lifestyle interventions over-utilize group delivery, over-emphasize body image, and encourage diets and physical activity that do not fit within one's cultural norms. This "disconnect" may contribute to treatment disparities. Future interventions should consider whether a more flexible program that allows for different perspectives and more client-selected goals would lead to better treatment outcomes.

Mistrust for Caucasian Primary Providers Among African American Patients

Barriers to T2DM management among African American women also include feelings of discomfort when working with Caucasian healthcare providers. Research shows that obese African American men and women have identified a consistent mistrust of Caucasian providers and often feel undervalued and not respected in medical settings (Kennedy et al., 2007). Interviews with 40 African American and Latino adults found that participants typically did not feel that they received adequate information from their provider, did not expect much help from their providers, and did not feel comfortable asking their provider questions (Heisler et al.,

2009). Another study similarly found that African American women perceive that their physicians are much less attentive to them compared to the attention that Caucasian women report (Basanez, Blanco, Collazo, Berger, & Crano, 2012). It has been shown that this disparity is not just perceived by patients. Research in oncology clinics demonstrate that that physicians engage in more relationship building with white versus non-white patients. Further, more emotional support was given to Caucasian, higher-educated, and younger patients (Siminoff, Graham, & Gordon, 2006).

The Role of African American Peers in Treatment

Feeling minimal encouragement from providers may be particularly detrimental considering that some African American women also report receiving minimal encouragement to manage their health conditions within the home. Alarmingly, in a study that identified an 80% attrition rate for poor African American women, one-third of the women who dropped out noted that their family and/or friends disapproved of them spending time pursuing physical activity (Felton, Boyd, Bartoces, & Tavakoli, 2002; Wallace, Williams, Dilworth-Anderson, & Goodwin, 2003). Conversely, pressure to engage in healthy behaviors from peers predicted positive health behaviors in African American men (Hammond, Matthews, & Corbie-Smith, 2010).

Considering the evidence that positive peer pressure may be beneficial for treatment outcomes, community peers, or Community Health Workers (CHWs) may improve treatment outcomes for African American participants. CHWs are typically non- or para-professionals with an intimate knowledge of a community and a shared cultural/ethnic background with the residents whom they serve. CHWs are trained to coach women through lifestyle changes. While a 2009 review of CHW-led interventions shows mixed outcomes (Viswanathan et al., 2009), there is a growing body of literature that shows promise for such interventions. Among Hispanic

patients with T2DM, CHW interventions have shown improvement in HbA1c, education self-efficacy, (Brown et al., 2012), health status, emergency department utilization, diet, activity, medical adherence, and weight status (Babamoto et al., 2009). Even 20-year projections from a home-based CHW program anticipated a significant drop in heart attacks, foot ulcers, and amputations and gained quality of life years among disadvantaged Hispanic T2DM patients (Brown et al., 2012). Further, interviews with 40 African American and Latino revealed that participants found CHWs offer education and support to fill the gaps that primary providers left in treatment (Heisler et al., 2009). Taken together, it is important to consider whether treatments that utilize a peer-delivery model might increase trust and better encourage African American women to engage in treatment.

Spirituality among South-Eastern African American Women

Variations in spiritual perspectives may also play a role in treatment outcomes for African American women. "Spirituality" refers to individuals' beliefs, search for meaning, and framework for understanding the world around them (Aukst-Margetic & Margetic, 2005). Spirituality and religiosity are found to be significantly greater among African American women than other races and genders (Lynch, Hernandez-Tejada, Strom, & Egede, 2012) and is often an important impetus to foster relationships among the family, church, and community (Polzer & Miles, 2005).

Spirituality is most strongly reported among African Americans in the southeast US who reside in the "Bible Belt" (Robinson & Wicks, 2012). African American women in these communities report attending church more often than men and other ethnic groups (Giger, Appel, Davidhizar, & Davis, 2008). Because faith shapes cognitions and plays a role in everyday decisions for many African American women, the link between health decisions and spiritual

orientation is not surprising (Robinson & Wicks, 2012). Focus group interviews with 70 southern African American women with T2DM found that spirituality was a primary factor in health decisions and coping strategies (Samuel-Hodge et al., 2000) and other research has found spirituality to be related to decreased depression in a diabetic sample (Lynch et al., 2012).

While it is evident in the literature that belief in God plays an important role in behavior change for African American women, there appears to be a complex relationship between health and faith. For example, in one study of African American women at high risk for breast cancer, women of high faith were more likely to engage in avoidance coping and were less likely to seek mammograms or follow health recommendations (Kinney, Emery, Dudley, & Croyle, 2002). However, in another study, spirituality predicted better treatment adherence in southern African American HIV patients (Konkle-Parker, Erlen, & Dubbert, 2008). In a third study, spirituality predicted better glycemic control in diabetic African American women, but the expected theoretical mechanisms of change (emotional distress and social support) were found to be unassociated with outcomes (Newlin, Melkus, Tappen, Chyun, & Koenig, 2008; Polzer & Miles, 2005). These mixed outcomes suggest that, while important, there is limited understanding of the mechanisms between spirituality and health. This literature may also suggest that there are other factors at play in the relationship between spirituality and health that have yet to be identified in the African American community. Future research needs to more directly identify not just "if" but "how" spirituality impacts health.

Considering the unique cultural differences between African American women and other genders/ethnicities, it is not surprising that mainstream treatment approaches developed primarily for a Caucasian population may be insufficient to affect positive and sustained treatment outcomes. Taken together, the research indicates that the identified key management

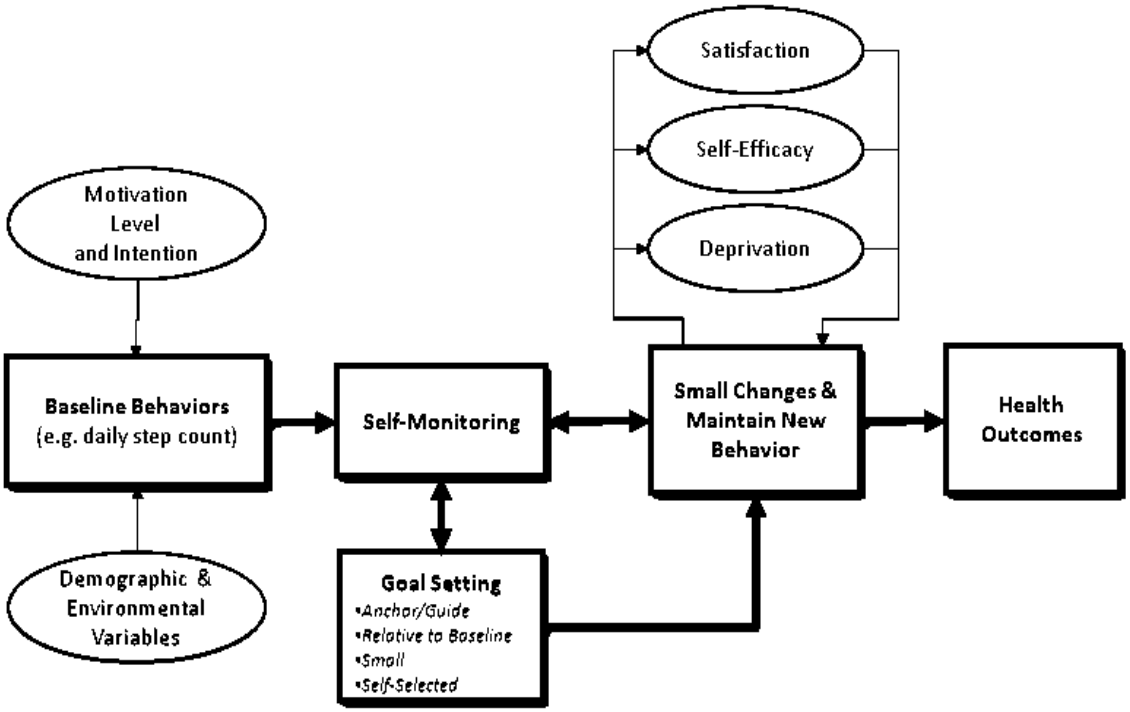
strategies in traditional lifestyle interventions may not lead to significant health outcomes in African American women without considering these key cultural factors. It is further evident that we know little about what weight management factors are significant for African American women who are successful at weight management. Some literature suggests differences in culture and perspectives, positive peer pressure, and spirituality may play a role in outcome differences. This has led researchers to call upon interventionists to tailor more flexible treatments that may better address cultural and ethnic differences so that we can better set African American women with T2DM up for successful T2DM management (Kumanyika, Morssink, & Agurs, 1992). Future research should consider novel approaches and different treatment factors when intervening with African American women.

A Novel Treatment for African American Women with T2DM

The Small Changes Model. African American women face many unique factors affecting T2DM management, including weight perspectives, mistrust of Caucasian providers, the need for increased peer encouragement, and the lack of spiritual perspectives in traditional interventions. There has been a call from researchers to utilize treatment approaches that are sensitive to these factors so that we may better set participants up for success (Kumanyika, Morssink, & Agurs, 1992; Scollan-Koliopoulos, Rapp, & Bleich, 2012). Alternative approaches such as the Small Changes Model (SCM; see Figure 1) may better fit this need because it allows for client directed treatment and lifestyle catering.

Figure 1.

The Small Changes Model.



Based on Social Cognitive Theory (SCT; Bandura,1986) and Decision Theories (Sbrocco, Nedegaard, Stone, & Lewis, 1999), SCM is unique because it is client-centered and encourages small changes within the context of one's lifestyle (Lutes & Steinbaugh, 2010). This means that foods, activities, community environments, religious duties, spiritual beliefs, care-taking obligations, and other culturally relevant factors for African American women can be incorporated into treatment. Unlike traditional lifestyle intervention programs, there are no standard recommendations or programmatic goals in SCM. All goals are purely client-driven. Goals are designed to be: 1) relative to baseline nutrition and physical activity patterns, 2) selected by participants instead of assigned by interventionists, 3) small and manageable in order to reduce the feelings of burden and failure in a participant, and 4) modified throughout the program based on the participant's needs (for examples of goals see Table 1). Problem-solving

theory (Perri, Nezu, McKelvey, Shermer, Renjillian, & Viegener, 2001) and supportive therapy are also used in SCM to assist the participants in problem-focused coping. The ultimate goal of SCM is to cater to one's lifestyle in order to reduce unique barriers and promote goal achievement. This will in turn increase self-efficacy, thus maximizing long-term achievement (see SCM model, Figure 1). While potentially beneficial at reducing unrealistic expectations for any participant, this philosophy may be particularly useful in a minority population that has traditionally been forced to fit a treatment model predominantly designed for non-minority participants with limited success.

Table 1.

Examples of Small Changes Goals.

Original Behavior	Goal	Plan
5000 steps/day	5500 steps/day	When needing to use the restroom at work, participant planned to use the restroom on the third floor and walked each hall on her way to the restroom and back
5 sodas/day	4 sodas/day	Participant replaced dinner-time soda with a cup of water
Check glucose 4 days/week	Check glucose 5 days/week	Participant put a note and testing supplies in her church bag to remind her to check her blood sugar on Sunday when her schedule is normally very busy
3 vegetables/day	4 vegetables/day	Participant added a frozen one-serving vegetable tray to each dinner.

Studies have shown SCM to have promising implications for weight management (Damschroder, Lutes, Goodrich, Gillon, & Lowery, 2010; Lutes et al., 2012; Lutes et al., 2008) regardless of treatment modality. When used for a weight loss program targeting nutrition and physical activity, 59 participants lost approximately 5% of their total body weight and managed to maintain all weight loss after three months of no study-related contact (Lutes et al., 2008). More recently a telephone based SCM treatment program for an inactive group of military

Veterans with multiple co-morbidities resulted in a 4% body weight decrease (Damschroder et al., 2010). Moreover, a recent study showed that with bi-weekly phone calls for 6 months after initial treatment, 25 women were successful at not just maintaining, but continuing weight loss across 9 months in order to reach a clinically significant weight loss (5%). Taken together, considering the effectiveness of SCM in weight management settings, particularly with low-income, high-co-morbidity participants (Damschroder et al., 2010), this treatment model may be promising among a sample of underserved T2DM patients. However, to date no study has specifically looked at the impact of a small changes treatment approach in either diabetic or African American patient populations.

Community Health Workers and the SCM. While the SCM has shown positive results, it has typically been delivered by master or doctoral level clinicians, within university settings, and has not involved matching interventionists with their participants for gender, ethnicity, or age. Considering the literature that suggests that African American women may benefit from having peer-led treatment, a CHW-delivered SCM treatment may enhance the therapeutic relationship between participant and interventionist and increase positive social pressure. This may in turn positively impact treatment outcomes. Further, having a peer to disseminate treatment might improve the patient's overall satisfaction rating of the treatment (Saha, Komaromy, Koepsell, & Bindman, 1999). Moreover, this may reduce attrition rates within an intervention.

However, research has not examined the combination of this treatment and delivery approach within a sample of African American women with T2DM. This is the primary goal of the EMPOWER study. The EMPOWER study is a novel, CHW-led, SCM–based intervention that is designed specifically for rural African American women with poorly-controlled T2DM.

This study will allow researchers to examine the effectiveness of a CHW-led SCM approach in this population while identifying theoretical factors that facilitate positive diabetes-focused behavior change. By using theoretical constructs we may not just identify differences in treatment outcomes, but explain why those difference occur. We can then be better equipped to provide lifestyle interventions that best meet the interests of African American women with T2DM.

Theoretical Constructs that May Impact Behavior Change in African American Women with T2DM

It is evident that more research should be done to determine if a CHW-led SCM approach may address barriers faced by African American women with T2DM. It is important to use research not just to determine if CHW-led SCM has a positive impact on behavioral outcomes but also to identify the mechanisms by which this change occurs. Assessing theory-based constructs within treatment allows researchers to identify the specific biological, structural, and psychological impact of treatment on behavior change (Rothman, 2004). It has been proposed that an integrative use of theory within intervention may address unique population characteristics and lead to improved treatment outcomes (Hagger, 2010). Below is a review of applicable behavior change theoretical constructs that may shed light onto treatment mechanisms relevant to African American patients undergoing CHW-led SCM treatment in particular.

Self-Efficacy. Self-efficacy is arguably the most important theoretical construct in the SCM (see Figure 1) and is believed to mediate the relationship between treatment and treatment outcomes. Originally identified in the SCT by Bandura (1986), self-efficacy is defined as an individual's confidence that he or she can achieve a particular behavior (Bandura, 1986; Glanz, Lewis, & Rimmer, 1997; Rogers et al., 2005). While self-efficacy has been related to positive

health behavior change in primarily Caucasian samples (Gallagher et al., 2012), this construct may play a different role in behavior change for African American women.

Research within African American populations suggests that high self-efficacy may not translate into behavior change. Studies that assessed healthful eating show that high self-efficacy to eat healthy foods did not translate into healthier diets among African Americans (Pawlak & Colby, 2009). Likewise, high self-efficacy before a physical activity intervention was not related to physical activity change (Wilbur et al., 2003). This may be because other factors are moderating this relationship, particularly among African American participants. Similar to the literature, preliminary assessments of 6-month data in the EMPOWER study indicated a lack of relationship between outcomes and self-efficacy (Lutes, Cummings, Littlewood, Dinatale, & Solar, 2014). Further, CHWs reported observation of differences between perceived self-efficacy and outcomes during treatment. For example, CHWs typically asked participants how confident they were on a scale of 0-10 about completing their particular goals during each session. CHWs reported during weekly supervision meetings that participants often rated their confidence at the highest level week after week, regardless of actual performance or failure to complete the goal during previous attempts. This spurred the investigators to consider factors beyond self-efficacy that may influence primary study outcomes. Because of this, Internal and God LOC and subjective norms were introduced at 12-month assessments to explore whether these factors may be more culturally suited to explain treatment outcomes. This is the primary goal of this project.

Internal and God Locus of Control (LOC). Developed by Rotter in 1966, the Locus of Control Theory defines internal LOC as the belief that life events (whether positive or negative) are determined by one's own actions, whereas an external LOC is the belief that life events occur due to the will of others or chance (Rotter, 1966). This model has been used to predict health

behaviors (i.e., those who have high internal locus of control will be more likely to engage in health behaviors because they believe that their behaviors will lead to positive outcomes). While Rotter created a two-dimensional, internal/external scale to measure control (Rotter 1966; Wallston, Wallston, Kaplan, & Maides, 1976), Wallston and colleagues (1978) were the first to develop a multi-dimensional health-related LOC measure (the Multidimensional Health Locus of Control Scale; MHLCS) to assess perceptions of control within health domains.

The MHLCS is a 24-item measure created to assess perceptions of internal control, God's control, the control of powerful others, the control of doctors, and the impact of chance within health behaviors (Wallston, et al., 1976; Wallston et al., 1999; Wallston, 2005). Research suggests that Internal LOC is particularly related to positive intentions and behavioral health outcomes (Berglund, Lystsy, & Westerling, 2014; Holt, Clark, & Kreuter, 2001; Milte, Luszcs, Ratcliffe, Masters, & Crotty, 2014) and is the target of most interventions that utilize LOC. The extent of influence of different external sources of LOC are much more dependent on the population in question. Research suggests that God LOC is particularly important among rural South-Eastern African Americans and impacts health behavior in both positive and negative ways (Debnam, Holt, Clark, Roth, Herman, Foushee, et al., 2012). Considering the importance of spirituality within African American culture, the God MHLCS may be a particularly important construct within this study and will thus be a primary factor of interest.

While it is evident that spirituality plays an important role in the health of African American patients, this relationship is complex (Masters, 2012) and spirituality has had differing impacts on health outcomes (Kinney et al., 2002; Konkle-Parker et al., 2008). The LOC may play a key role in explaining how spirituality can have both a positive and negative impact on health behavioral outcomes as previously identified in the literature. While many southern

African American women "turn to God" to cope with illness and glean comfort and guidance from their faith while having an internal LOC and actively managing their disease state, other women may "turn it over to God" and play a passive role, believing that God will manage their disease for them if they have faith (Polzer & Miles, 2005). This means that although women may report similar spiritual beliefs, their interpretation of those beliefs may lead to opposing behaviors. If spiritual women have an internal LOC they may believe that they are responsible for their health and thus be more likely to engage in self-management, but if they have an external God LOC, they may play a more passive role in health management.

Research using the God LOC subscale in a sample of patients with systemic sclerosis and arthritis has shown that a higher God LOC was associated with poorer adjustment, whereas a study with a healthy population found that God LOC was related to positive health behaviors (Wallston et al., 1999). This may occur because patients who experience significant symptoms and a high God LOC may feel that only God can heal such an illness, whereas those who are relatively healthy feel more independence. This may have interesting implications among spiritual African American women with T2DM. With this tool future researchers cannot only assess spirituality, but both internal and God LOC, when studying intervention factors that impact health outcomes.

Self-Efficacy and LOC. While self-efficacy and LOC were initially presented as independent constructs within different theories, Bandura (1977) and Wallston (1992; 2005) both propose that these factors may interact with each other. This means that a combination of these two constructs will better predict outcomes when considered together than either construct independently (Rosenstock et al., 1988). According to Wallston (1992), a high internal locus of control will only predict health behaviors if an individual has the skills and confidence (i.e., self-

efficacy) to complete the task. Likewise, women high in self-efficacy may still not be driven to complete health behaviors if they believe that it should be God, and not themselves, who is responsible for making changes occur. This may explain why self-efficacy alone has been shown to be a poor predictive factor in behavior change among African American women (Pawlak & Colby, 2009; Wilbur et al., 2003). For these reasons, other researchers have chosen to consider self-efficacy and God LOC together to better explain health behaviors such as physical activity in African American women (Robinson & Wicks, 2012).

Considering this, when assessing the CHW-led SCM approach for African American women with T2DM, researchers should assess the interplay of these constructs as they relate to behavioral outcomes. The interaction between LOC and self-efficacy may better explain the conditions within which high rates of self-efficacy do or do not predict change in African American women. However, neither of these constructs consider social implications, which may also may significantly contribute to treatment outcomes within this population.

Subjective Norms. According to the Theory of Planned Behavior (TPB), the intention to engage in health behaviors is partially shaped by subjective norms (Plotnikoff, Lubans, Trinh, & Craig, 2012). Subjective norms describe the perceived importance of a certain health behavior according to peers and the perceived peer pressure to engage in that health behavior. While they may seem similar, subjective norms differ from social support in that subjective norms refer to perceived pressure to perform a behavior, whereas social support refers to getting assistance in performing a behavior (Courneya et al., 2000). Subjective norms are based on the belief that important others would approve or disapprove of one's behavior (Kothe, Mullan, & Butow, 2012). While the predictive power of subjective norms has been debated within the model, it may be that instruments that measure subjective norms assume people in certain roles are most

influential (i.e. my spouse wants me to eat healthy) instead of recognizing that different groups and individuals may identify different influential people, such as friends or neighbors (Pasick, Barker, Otero-Sabogal, Burke, Joseph, & Guerra, 2009). In fact, research shows that ethnic groups may differ in who they find most influential (Stewart, Rakowski, & Pasick, 2009). This means that existing subjective norms questionnaires may not appropriately assess subjective norms for African American women. New questionnaires should be designed that better cater to minority populations, such as the one designed for this study in the EMPOWER project.

Considering the importance of community in African American culture (Wallace et al., 2003) and the role that social pressure has been shown to play in adherence rates (Felton et al., 2002), it stands to reason that subjective norms may also predict behavioral intentions related to diabetes treatment outcomes among African American women. This trend is reflected in a sample of African American men who illustrated that social peer pressure may be an important factor in health outcomes (Hammond et al., 2010). Unfortunately, the mistrust and disconnect experienced with Caucasian healthcare providers (Klassen, Smith, Shariff-Marco, & Juon, 2008) and the potential lack of encouragement from friends and family (Felton et al., 2002) suggests that one treatment barrier for African American women is poor subjective norm influences for health behaviors.

Like LOC and self-efficacy, it may be that subjective norms modify the impact of self-efficacy on outcomes. For example, women with T2DM may have particularly high self-efficacy, but without social pressure to complete the behavior, motivation to pursue the behavior may remain low. Hopefully, the use of CHWs will be able to establish higher rapport and more positive pressure than "outside" providers. Assuming that CHWs are more trusted than providers outside of the community, they may be able to build up more social clout to influence subjective

norms and, in turn, behavioral intentions, and ultimately, behaviors. When assessing CHW-led SCM treatments, researchers should assess whether utilizing a CHW of the same sex and ethnicity within the same community to deliver treatment will enhance positive pressure from subjective norms and mediate treatment outcomes.

Review of the literature suggests that adding subjective norms to self-efficacy or LOC measures may improve the prediction of treatment outcomes. In one study, intention to not engage in smoking was predicted through subjective norms and self-efficacy (de Vries, Dijkstra, & Kuhlman, 1988). Likewise, subjective norms have been assessed with self-efficacy and fatalism, arguably a type of external LOC, to better predict engagement in cancer screenings among Latinos (Fernandez, Savas, Wilson, Byrd, Atkinson, Torres-Vigil, et al., 2014). Some researchers have gone so far as to suggest a merging of theories. One group has suggested that LOC and self-determination be considered as additional factors within the TPB model to predict motivation for engaging in certain behaviors (Hagger & Armitage, 2004). This group utilized mediation modeling to find that LOC influences attitudes/intentions mediated by intrinsic motivation.

In summary, considering literature that presents an unclear picture of the role of self-efficacy in behavior change for African American women, it is important to assess the presented constructs together with self-efficacy in an attempt to better explain this relationship. Further, considering the importance of self-efficacy in the SCM-based EMPOWER program, the way in which self-efficacy interacts with outcomes is key to understanding the impact of this particular treatment approach. Finally, subjective norms and LOC are important to assess within themselves in this study considering the importance of community and spirituality among women in the African American community. By measuring these theory-based constructs in a

tailored program designed for African American women, researchers may be able to identify factors that would contribute to a more culturally appropriate treatment approach for this population.

Study Purpose and Hypotheses

Considering the significant health disparities for African American women in the southeast, it is evident that researchers should develop treatment approaches to better set these patients up for success. Traditional T2DM and weight management programs may not be as relevant for African American women, who differ from Caucasian peers in weight perspectives, relationship with providers, the importance and availability of peer encouragement, and spirituality. A CHW-led SCM approach may be more applicable within this population because it uses a client-driven, lifestyle-focused, supportive peer treatment perspective that can be catered to address these issues. The effectiveness of this approach is being assessed by the EMPOWER program, which compares a 12-month long, phone-based CHW-led SCM treatment (EMPOWER) with a more traditional, mail-based American Dietetic Association education-only intervention (Mail) for rural African American women with poorly controlled T2DM. Because this is a novel approach to diabetes management within this population, it is unknown how theoretical behavior change constructs interact within the EMPOWER intervention in this population. The primary purpose of this study is to determine what predicts treatment outcomes for African American women enrolled in EMPOWER and to explore new relationships between self-efficacy, subjective norms, and LOC and outcomes.

According to the SCM, the ability to create one's own goals and pursue small changes that fit one's lifestyle will increase goal achievement via improved self-efficacy. However, at 6-month assessment it was evident that self-efficacy was not predicting behavior change as expected. At

this time self-efficacy was not related to treatment changes and CHWs reported that participants were reporting high levels of confidence in engaging in healthful behaviors that often did not translate into behavior change. This is reflected in the literature, which demonstrates that self-efficacy may not predict behavior change the same way in African American women that it does in Caucasian peers. Considering that self-efficacy may interact with other factors, such as subjective norms (de Vries, et al., 1988; Fernandez, et al., 2014) and LOC variables, to predict outcomes (Bandura**,** 1977; Rosenstock et al., 1988; Wallston, 1992), it was proposed that self-efficacy and subjective norms be assessed together as mediators with Internal and God LOC serving as moderators in order to better understand this complex interaction. While self-efficacy is a key assessment point within the EMPOWER study and was assessed at all time points, subjective norms and LOC were included at 12 months in an attempt to better explain the relationship between treatment and potential outcomes in this population that was not evident upon 6-month assessment. By assessing these constructs at 12-month assessment, we can explore how these factors may impact treatment outcomes among African American women and better cater future treatment approaches. Based on the literature, important outcomes for T2DM lifestyle interventions that were collected in the EMPOWER study include HbA1c change, weight change, medication adherence, self-care behaviors, and depression. It was hypothesized that:

1) Participants in the EMPOWER group will have improved weight and HbA1c changes compared to baseline at the 12-month assessment.
2) Participants in the EMPOWER group will have greater weight and HbA1c changes compared to the Mail group at the 12-month assessment.

3) Participants in the EMPOWER group will report improvement in medication adherence, self-efficacy, and self-care and reduced depression at 12-months compared to baseline.
4) Participants in the EMPOWER group will report greater improvements in medication adherence, self-efficacy, and self-care and reduced depression compared to the Mail group at 12-months.
5) When subjective norms is considered a mediator and Internal and God LOC are considered moderators, self-efficacy will partially mediate the relationship between EMPOWER treatment and the following outcomes: weight change, HbA1c change, medication adherence, and self-care.
6) The EMPOWER group will report higher subjective norm scores compared to the Mail group at 12-months.
7) When self-efficacy is considered a mediator and Internal and God LOC are considered moderators, subjective norms will partially mediate the relationship between EMPOWER treatment and the following outcomes: weight change, HbA1c change, medication adherence, and self-care.
8) In the EMPOWER group, Internal LOC and God LOC as measured by MHLCS will moderate the relationship between treatment and the following outcomes: weight change, HbA1c change, medication adherence, and self-care.

If mediation/moderation models are not found to be significant, subjective norms, self-efficacy, God LOC, and Internal LOC will be assessed as moderators to determine if they have an impact on treatment outcomes individually outside of the proposed model. It is hoped that the results of this study will not only highlight important factors that influence behavior change among African American women, but will provide theoretically-based arguments as to how to

best design future treatment programs so that interventionists may better set African American participants up for success regarding diabetes management.

Chapter II: Method

Participants

This study was reviewed and approved for human subject protection by the University and Medical Center Institutional Review Board (see Appendix A). Inclusion criteria required that participants be African American women between 19 and 75 years old with T2DM and a recent HbA1c >/= 7.0. Exclusion criteria included women who were not ambulatory or who were undergoing dialysis or chemotherapy treatment. Because the primary goal of the EMPOWER study was to develop a program that may overcome common barriers and limitations to diabetes management in this unique population, participants were not excluded due to common co-morbidities or limitations unless they directly prevented them from participating in the program. These broad criteria allowed us to more directly assess the "real-world" application of this treatment to all participants, not only low-risk individuals with non-comorbid conditions.

Community Health Workers

Researchers identified and hired 6 CHWs from three rural eastern North Carolina counties to deliver the treatment based on referrals from community contacts and phone-based interviews. Each of the CHWs held leadership roles in their churches. CHWs included a pastor, Bible study leaders, and a Sunday school teacher. The CHWs delivered treatment within their own county. Each county's CHW pair included an "ambassador" and a "navigator." The ambassador delivered the SCM-based EMPOWER treatment to participants. The navigator was chiefly assigned to assist with resource identification and promotion among SCM-based EMPOWER participants and to provide the introduction information for the MAIL group at randomization. Both ambassadors and navigators received the same 40-hour training period across the course of 5 weeks. Training included didactic instruction about T2DM and diabetes

management, the SCM philosophy, motivational interviewing and other therapeutic techniques, problem-solving, and phone-based treatment. The CHWs illustrated mastery of these skills through extensive role-playing exercises that focused on rapport building, psychosocial support, communication strategies, and review challenging situations that may arise during treatment. After recruitment began, CHWs received bi-weekly supervision to promote these skills and address challenges.

Recruitment

Participants were recruited from three rural counties in eastern North Carolina using a variety of means, including church health fairs and presentations, health clinic lists from local physicians, and snowball sampling. Interested and potentially eligible participants were contacted by researchers and scheduled to attend an in-person assessment in a centralized location within the participant's county. At these assessments, participants gave their informed consent and completed a packet of questionnaires (described below). HbA1c and weight was measured during this assessment. Interested women who qualified for the study were then randomized to one of two interventions: 1) a phone-based, SCM intervention delivered by the ambassadors (EMPOWER), or 2) a mail-based, didactic intervention (Mail). The first session of each intervention was delivered in-person so that participants could receive their treatment materials and further establish rapport with their CHW before beginning the phone or mail-based intervention. All participants were given $25 gift certificates at baseline, 6-month, and 12-month assessments to thank them for their participation.

Treatment Groups

Both treatment groups were scheduled to receive 16 contacts over the course of 12 months. Participants were required to meet face-to-face with the study staff at baseline, 6-

month, and 12- month assessments in order to complete their assessments. It is important to note that this program was not designed to replace medical care but instead to complement it through tailored self-management and support of patient-doctor goals. Participants were therefore encouraged to continue to see their physician for any medical concerns.

EMPOWER Group. The EMPOWER group participants received treatment through 15-30 minute phone conversations with their ambassador. Because one common barrier to T2DM management is time and transportation, the EMPOWER group was designed so that participants could schedule each session at a time that best suited their busy lives and complete treatment from their own home. This phone-based treatment was also designed with the goal of reducing interventionist burden and travel costs as a potential sustainable model for future dissemination.

The sessions focused on a range of T2DM related topics, including physical activity, nutrition, and medication adherence, as well as psychosocial topics, such as social support, stress management, depression, coping with health-related frustrations, and cognitive restructuring (see Table 2). Keeping with the SCM philosophy, ambassadors did not instruct the participants but instead provided encouragement to identify behaviors that the participant desired to change, and facilitated the implementation of specific goal setting strategies in order to help promote behavior change. Participants who needed additional assistance were contacted by the navigators, who offered information and support regarding community-based resources. For example, navigators helped participants find a physician, a cheaper payment plan for medications, or a public transportation option to assist with travel if available.

Table 2.

EMPOWER Group Treatment Sessions

Session	Topic	Session	Topic
Session 1	Welcome to EMPOWER!	Session 9	Social Support: Working Your Network
Session 2	How Small Changes can Result in Losing Weight and Keeping it Off	Session 10	Mindfulness and Awareness
Session 3	The Main Ingredient: Monitoring Nutrition and Physical Activity	Session 11	Asking for Help and Communication
Session 4	Effective Small Changes: It's Not "Will-Power" It's "Skill-power"	Session 12	How Time Flies: Planning and Time Management
Session 5	Diabetes 101	Session 13	Whoops! Dealing with Slips
Session 6	What to Expect When You Are Expecting…To Lose!	Session 14	Coping with Stress
Session 7	Breaking the Chain: Avoiding Stinkin' Thinkin'	Session 15	Community and YOU
Session 8	Problem Solving 101	Session 16	Planning Ahead

Because research has illustrated that self-monitoring is key to behavior change, the EMPOWER program utilized tools to track both physical activity and nutrition. Physical activity was tracked by an Omron pedometer, which measures daily step counts. Nutrition was tracked using a modified self-monitoring system based upon Epstein's "Stoplight Guide," originally designed to address childhood obesity (Epstein, 2008). The Stoplight Guide was adapted for adults and has been shown to be successful with high-risk, medically complex veterans (Damschroder & Lutes, 2010). The stoplight guide avoids tedious calorie counting by taking a simple tally of three food categories. Green foods (e.g. raw vegetables) are foods that have high nutritional value and low glycemic index, yellow foods (e.g. turkey) have a significant amount of nutritional value but also more calories or sugar, and red foods (e.g. cake) typically have low nutritional value and high glycemic index.

Participant goals were established based on self-monitoring records. To create a "small changes goal," participants typically chose to make a quality, quantity, or frequency change. For example, if a participant was drinking three sodas a day, she may be asked whether she would be willing to consider modifying the quality (e.g., diet instead of regular), the quantity (e.g., 12 ounces instead of 20 ounces), or the frequency (e.g. two per day instead of three) of consumption. Additional goals were added only after the participant succeeded in her initial goal and felt at least 70% confident that she could continue the goal.

Mail Group. Participants in the Mail group received 16 mailings based on American Dietetic Association worksheets (American Dietetic Association, 2010) over the course of 12-months. Each mailing was approximately 4 pages and covers a diabetes-management topic written by the American Dietetic Association. Topics included nutrition, physical activity, medication, and snacks (see Table 3).

Table 3.

Mail Group Treatment Sessions

Session	Topic	Session	Topic
Session 1	Type 2 Diabetes	Session 9	Insulin
Session 2	Staying Healthy with Diabetes	Session 10	Low Blood Glucose
Session 3	Weight Loss	Session 11	Herbal Supplements
Session 4	Physical Activity	Session 12	Sick Days
Session 5	Snacks	Session 13	Travel
Session 6	Eating Out	Session 14	Blood Glucose Control
Session 7	Complications	Session 15	Glycemic Index
Session 8	Diabetes Medications	Session 16	Artificial Sweeteners

Assessments

At baseline, 6-month, and 12-month assessments, participants' HbA1c and weight was measured. Participants also completed a self-report questionnaire packet at each assessment that included the Morisky Modified Medication Adherence Scale (MMMAS), the Summary of

Diabetes Self-Care Activities Measure (SDSCA), Center for Epidemiologic Studies Depression Scale (CES-D), and the Stanford Self-Efficacy for Managing Chronic Disease 6-Item Scale (SSE). Following 6-month assessment review of treatment progress, the Subjective Norm measure (SNM) and the Multidimensional Health Locus Control Scale (MHLCS) were added to the 12-month assessment packet to determine their impact on treatment outcomes. Attrition rate was calculated at the end of 12-month assessments by number of participants who did not complete the program. Outcomes were also compared between participants using insulin and participants not using insulin. This is because insulin use is related to greater disease progression and typical weight gain trajectories among patients with T2DM (Jacob et al., 2007; Russell-Jones & Khan, 2007; UK Prospective Diabetes Study Group, 1998). Research indicates that insulin usage leads to significant long-term weight gain, even as it lowers HbA1c, and that more intensive pharmacological treatment is related to more significant weight gain across time (UK Prospective Diabetes Study Group, 1998). Because of this, one may expect that some treatment effects, particularly those related to weight loss, may be more evident in those who do not take insulin compared to those taking insulin.

Weight. Each participant's weight was measured using a standard bathroom scale to the nearest 0.1 pound at baseline and 12-month assessments. Participants were measured without shoes and measurements were taken by trained study staff.

HbA1c. In order to measure the average glucose readings over the course of approximately three months, a Siemens DCA Vantage Analyser ® machine was used to assess the HbA1c readings for each participant. This machine required a drop of blood from each participant and approximately 6 minutes to determine the participant's HbA1c percentage up to 14.0%. HbA1c readings were conducted at baseline, 6 month, and 12-month assessments.

The MMMAS. The MMMAS is an 8-item measure normed on a large sample (N = 1367) of primarily low-income (54.1%) African American (76.5%) patients with hypertension (Morisky, Ang, Krousel-Wood, & Ward, 2008). Each item allows for a dichotomous yes/no response with a 5-point Likert-scale item at the end. Questions focus on medication behaviors (i.e. "did you take your medicine yesterday?"). The measure has been found to be reliable (α = 0.83) and significantly related to disease control ($p < 0.05$) in past studies (Muntner, Joyce, Holt, He, Morisky, Webber, & Krousel-Wood, 2011). Assessment of baseline data in EMPOWER demonstrated good internal consistency (α=0.72). Scores below 6 on the MMMAS indicate low adherence, scores of 6 and 7 indicate medium adherence, and scores greater than 8 indicate high adherence (Muntner et al., 2011). A score of below 6 identified patients with poor blood pressure control with 93% accuracy (specificity = 53%).

Attrition. Attrition was measured by the number of participants per group who did not complete 12-month assessment due to being lost to follow-up or quitting the program.

The SDCSCA. The SDSCA consists of 11-items that assess how many days in the previous week a particular diabetes self-care behavior was completed. This measure is scored by averaging the number of days a behavior was completed within each sub-item. Sub-items include diet, exercise, blood-glucose testing, foot-care, and smoking status (Toobert, Hampson, & Glasgow, 2000). While reliability and validity for this modified measure have yet to be assessed in the literature, assessment of baseline data in EMPOWER demonstrated good internal consistency (α=0.76).

The CES-D. This 11-item shortened measure uses a 0-2 scale to assess symptom level and includes four subscales: Depressed affect, positive affect, somatic symptoms, and interpersonal concerns (see Appendix B). An overall cut-off score of 9 or greater suggests

presence of depression. Past studies demonstrate that these subscales were found to be reliable (0.86, 0.81, 0.79, and 0.81, respectively; Gellis, 2010; Takeshita et al., 2002). Assessment of baseline data in EMPOWER demonstrated good internal consistency (α=0.81).

The SSE. The SSE is a 6-item questionnaire that measures self-efficacy by rating one's confidence (on a scale of 1-10) that one can perform disease-related self-management behaviors. This measure includes items such as "How confident are you that you can keep the emotional distress caused by your disease from interfering with the things you want to do?" Past data show good convergent construct validity (Spearman rank correlation 0.578, $p < 0.001$) and high internal consistency (α = 0.930) within a German population (Freund, Gensichen, Goetz, Szecsenyi, & Mahler, 2011). In a Canadian sample of men and women with Parkinson's disease, the SSE's chronbach's alpha was 0.91 and the test-retest reliability was 0.72. Assessment of baseline data in EMPOWER demonstrated excellent internal consistency of the SSE measure (α=0.95).

The MHLCS. The MHLCS is a 24-item measure created to assess perceptions of internal control, the control of powerful others, the control of doctors, role of chance, and the control of God in regarding health behaviors and health outcomes (Wallston et al., 1976; Wallston et al., 1999; Wallston, 2005). Each section of the MHLCS (i.e. God LOC, Internal LOC) is scored separately. The author stresses that the validity of LOC depends on the subscale being used and the context in which it is being used (Wallston, 2005). Overall, these LOC subscales have been found to have a chronbach alpha score between 0.60-0.75 and a test-retest reliability between 0.60-0.70. While the author of these measures warns against generalizing validity scales to various populations considering the complex nature of the constructs, evidence of concurrent validity among arthritic patients correlated between $r = 0.38$ and $r = 0.65$. In a study conducted

in the southeast, the 6-item God LOC subscale had an alpha reliability as high as 0.90. Based on baseline data in the EMPOWER study, the MHLCS was found to have overall good internal consistency for most subscales: Internal LOC α=0.77, God LOC α=0.86, Powerful Others LOC α= 0.76, and Chance LOC α=0.84. Only Doctor LOC demonstrated poor internal consistency (α=0.37). Because one of the primary purposes of this study is to assess the impact of God LOC versus Internal LOC on treatment outcomes, God and Internal LOC will be the primary subscales utilized.

The SNM. The SNM is an 8-item measure assessing subjective norms related to diet and exercise behaviors (see Appendix C). Assessment of baseline data in EMPOWER demonstrated good internal consistency (α=0.87). The SNM was created for this study based on research by Kothe, Mullan, and Butow (2012) and guidance from Francis and colleague's manual on the construction of questionnaires based on TPB (Francis et al., 2004). This SNM was created with the goal of allowing participants to select their own "important others" instead of providing a potentially limited list of people who may be considered important. This decision was based on research which demonstrates that different ethnic groups may identify a wide array of influential people, such as friends or neighbors, that traditional subjective norms questionnaires normed on primarily Caucasian participants may not identify (Pasick et al., 2009; Stewart et al., 2009).

The SNM questionnaire was also designed to address both injunctive and descriptive norms. Injunctive norms refer to one's perception that important others believe she should engage in a behavior. An example question is: "Those close to me expect me to exercise regularly." Descriptive norms refer to one's perception that important others are engaging in a particular behavior themselves. An example question is "The people in my life whose opinions I value eat healthy." Each question is measured on a 5-point Likert scale that ranges from

"strongly disagree" to "strongly agree." The purpose of this measure is to assess participants' perceived pressure from important others to engage in diet and exercise behaviors.

Statistical Analyses

Data were analyzed using the Statistical Package for the Social Sciences (SPSS for Windows, Version 20 SPSS Inc., Chicago, IL), with statistical significance set at $p < .05$. Imputations based on multiple data points across time were calculated to substitute missing values in the data set. Descriptive statistics were used to assess the characteristics of each group, including age, weight, HbA1c, medication adherence, self-care, self-efficacy, depression, education, income, and marital status. Chi-square analyses were utilized to identify differences in attrition rates. Differences between groups at baseline were determined using independent samples t-tests. Repeated measures analyses of variance (ANOVA) were used to assess differences by time point and between groups in weight, HbA1c, medication adherence, self-care, self-efficacy, and depression. Independent samples t-tests and ANOVAs were used to assess outcome differences between those who used insulin and those who did not.

The moderated mediation model hypotheses were tested by the PROCESS macro within SPSS (Hayes, 2013). Coefficients were calculated to assess relationships between mediators, moderators, treatment, and outcomes. The zero-order correlations were calculated by computing the product of coefficients to determine the indirect effect of the constructs on the relationship between treatment and outcomes. This statistical approach was also used to determine if there was a moderating effect of LOC on the relationship between self-efficacy and outcomes. Repeated-measures ANOVAs that include covariate variables were also used to assess whether self-efficacy, subjective norms, and LOC had a moderation effect on the relationship between treatment group and outcomes.

Chapter III: Results

Of the 285 women who showed initial interest in the study, 263 women attended the assessment and 200 were enrolled. Across 12 months, 163 of the 200 women, (81%), completed the 12-month assessment and program. See Figure 2 for the Consolidated Standards of Reporting Trials (CONSORT) diagram (Schulz, Altman, & Moher, 2010) of participation throughout the EMPOWER study. Overall, participants were middle aged (M = 53.45, SD = 10.24), married (33.5%) and single (28.9%), moderately obese (BMI M = 37.67, SD = 8.02) African American women with poorly controlled diabetes (HbA1c M = 9.09, SD = 1.83) who had been diagnosed with diabetes for over a decade at baseline (M = 10.9 years, SD = 8.4; see Table 4). Data show that 60.3% of the study sample was also insulin-using at baseline. The majority of participants had an annual income below $30,0000 (78.7%). A substantial percentage of participants made below $10,000 (41.5%). Baseline questions designed to assess social support indicated that participants' primary care providers, children, family members with diabetes, and friends provided them with the greatest social support in managing their diabetes.

Participants were randomly assigned to one of two groups: 1) a phone-based, SCM intervention delivered by CHWs (EMPOWER), or 2) a mail-based, didactic intervention (Mail). Participants in the Mail group received standard 4-page educational handouts based on materials from the American Dietetic Association 16 times via mail. Materials focused heavily on information regarding medication and glucose management. Participants in the EMPOWER group received an average of 270 minutes of phone-time with CHW throughout the year and completed an average of 9.6 out of 16 sessions, receiving 60% of the possible treatment program. CHWs reported that phone disconnections, illness, acute life stressors, and address changes were common reasons why participants did not engage in all sessions. CHWs made up to three

attempts per scheduled session to contact each participant. If the participant could not be reached after three attempts, the CHWs waited until the next scheduled call to reach the participant.

While there were no significant differences between groups at baseline, weight differences were trending towards significance (EMPOWER M = 215.80 lbs, SD = 46.66; Mail M = 229.23 lbs, SD = 55.78; p = 0.067). There were no differences in completers and non-completers across outcomes, demographic measures, or psychological measures. There was a trend toward significance in level of depression and attrition rate (p=0.055). This suggests that women who were more depressed may be less likely to complete the study. However, attrition rates did not vary between groups. Assessment of differences between participants who used insulin and those who did not revealed that those who used insulin had significantly higher HbA1c (p<0.001), poorer self-efficacy (p=0.027), and higher endorsement of depressive symptoms (p = 0.017) compared to those who did not use insulin. For a more thorough examination of differences between groups and baseline factors, see Tables 4-6.

Notably, while the EMPOWER and Mail groups were meant to be independent from one another, informal fidelity checks throughout the study indicated that CHWs often provided additional support to the Mail group beyond the mailings, despite repeated encouragement to refrain from providing additional care to this comparison group. The dual roles of CHWs as friends, family, and community leaders of participants made it difficult to prevent extra supportive interactions from occurring within the Mail group. For example, one CHW reported that she handed out pedometers to Mail group members in her church who were interested in tracking their step counts and asked her for help. Another CHW had weekly dinners at a friend and Mail group participant's home and often talked about dietary changes with her. Considering this, there is likely some cross-contamination of treatment protocols between groups.

Figure 2.

Consort Guidelines.

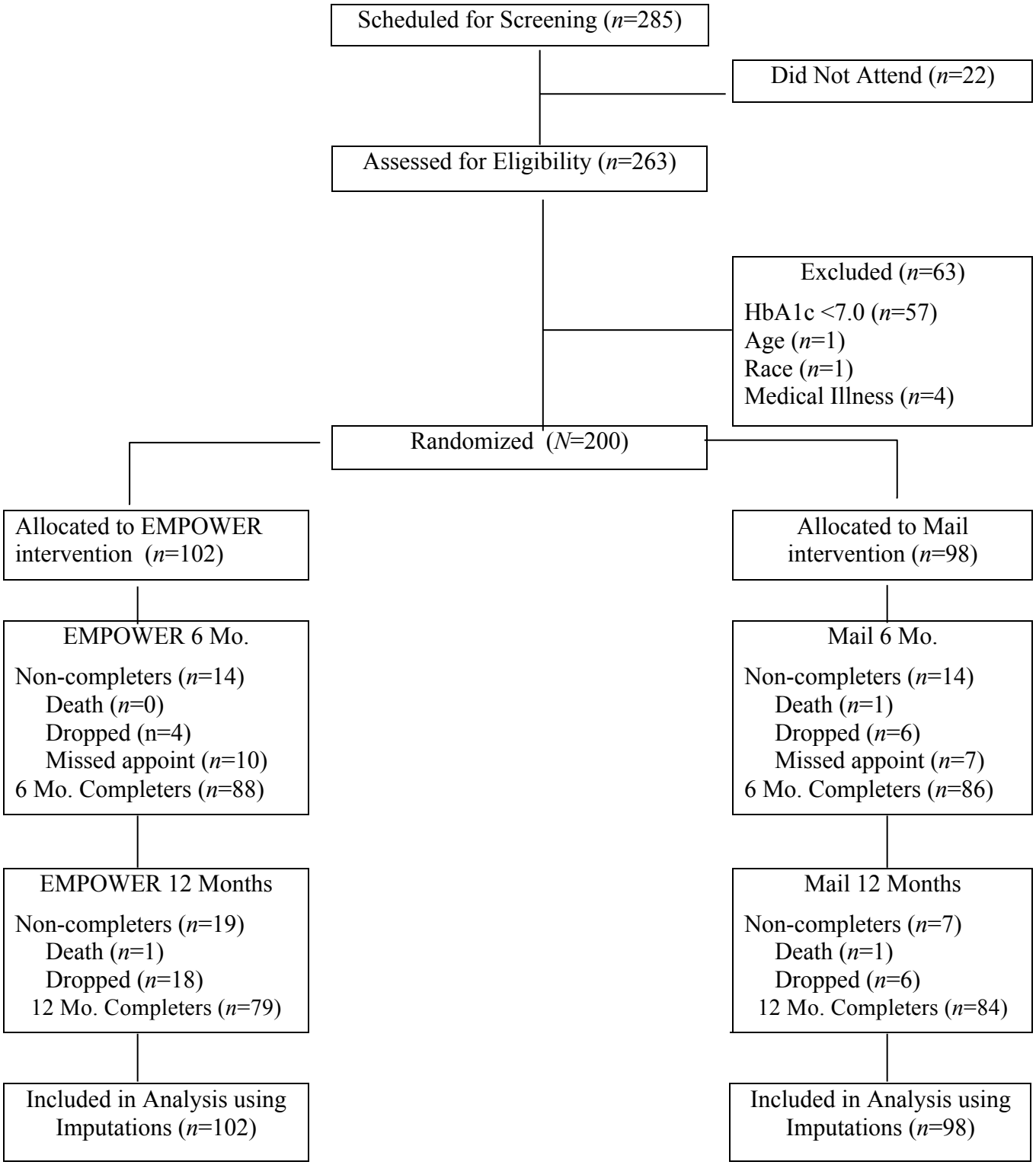


Table 4.

Baseline Characteristics and Differences Between Groups.

Demographic	EMPOWER *n* = 102 *M(SD)*	Mail *n* = 98 *M(SD)*	*p*
Age	52.70(10.62)	54.20(9.85)	0.31
Weight[1]	215.8(46.66)	229.23(55.78)	0.067
HbA1C	9.13(1.79)	9.05(1.88)	0.74
Med Non-Adherence[1]	5.28(2.19)	5.45(1.81)	0.57
Self-Care	33.86(13.67)	34.25(13.91)	0.85
Self-Efficacy	37.60(14.84)	39.22(16.00)	0.48
Depression	7.35(4.23)	7.44(4.29)	0.89
Insulin Use	46.2%	53.8%	0.41
Education (%)			
Grammar	12.2%	10.3%	
High School	35.7%	36.1%	
Some College	21.4%	22.7%	0.81
Bachelors	8.2%	11.3%	
Graduate	5.1%	3.1%	
Other	0.0%	0.5%	
Income (%)			
< $10,000	41.5%	41.5%	
$10-29,999	34.0%	40.5%	
$30-49,999	17.0%	11.7%	0.68
$50-74,999	5.3%	3.2%	
$75-99,999	2.1%	2.1%	
Over $100,000	0.0%	0.5%	
Marital Status			
Divorced	14.3	14.6	
Sig Other	3.1	5.2	
Married	33.7	33.3	0.91
Separated	7.1	4.2	
Single	29.6	28.1	
Widowed	12.2	14.6	

Note. *Indicates that the difference is significant at the $p < .05$ level.
[1]Corrected for violations of sphericity (Mauchly's Test of Sphericity < 0.05).

Table 5.

Baseline Characteristics between Completers and Non-Completers.

	Completers *n*=163	Non-Completers *n*=37	
Demographic	*M(SD)*	*M(SD)*	*p*
Age	53.66(10.10)	52.51(10.98)	0.55
Weight	221.93(49.59)	224.41/(60.60)	0.79
HbA1C	9.14(1.83)	8.87(1.84)	0.42
Med Non-Adherence	5.40(1.98)	5.19(2.17)	0.57
Self-Efficacy	38.75(15.51)	36.82(15.07)	0.52
Self-Care	34.70(13.83)	31.06(13.14)	0.18
Depression	7.12(4.13)	8.78(4.58)	0.055
Insulin Use	61.6%	54.3%	0.27
Education (%)			
Grammar	9.4%	20.0%	
High School	36.9%	31.4%	
Some College	38.7%	37.2%	0.51
Bachelors	10.0%	8.6%	
Graduate	4.3%	2.9%	
Other	0.6%	0.0%	
Income (%)			
< $10,000	41.9%	39.4%	
$10-29,999	35.4%	45.5%	
$30-49,999	7.7%	6.1%	0.13
$50-74,999	4.5%	3.0%	
$75-99,999	2.6%	0.0%	
Over $100,000	0.0%	0.5%	
Marital Status			
Divorced	12.6%	22.9%	
Sig Other	4.4%	2.9%	
Married	35.2%	25.7%	0.66
Separated	5.7%	5.7%	
Single	28.3%	31.4%	
Widowed	13.8%	11.4%	

Note. *Indicates that the difference is significant at the $p < .05$ level.

Table 6.

Baseline Characteristics between Insulin Users and Non-Insulin Users.

	Non-Insulin Using *n*=77	Insulin Using *n*=117	
Demographic	*M(SD)*	*M(SD)*	*p*
Age	53.63(10.15)	53.22(10.31)	0.79
Weight	221.97(51.69)	221.85(50.52)	0.99
HbA1C	8.56(1.68)	9.51(1.85)	<0.001*
Med Non-Adherence	5.58(2.17)	5.20(1.92)	0.22
Self-Efficacy	41.39(14.16)	36.27(15.93)	0.027*
Self-Care	32.87(14.07)	34.62(13.43	0.41
Depression	6.46(4.07)	8.02(4.23)	0.017*
Education (%)			
Grammar	10.4%	12.0%	
High School	32.5%	37.6%	
Some College	24.7%	20.5%	0.11
Bachelors	14.3%	6.8%	
Graduate	7.8%	1.7%	
Other	0.0%	0.9%	
Income (%)			
< $10,000	33.8%	46.9%	
$10-29,999	36.5%	37.2%	
$30-49,999	17.6%	12.4%	0.15
$50-74,999	8.1%	1.8%	
$75-99,999	2.7%	1.8%	
Over $100,000	1.4%	0.0%	
Marital Status			
Divorced	16.9%	12.9%	
Sig Other	2.6%	5.2%	
Married	39.0%	29.3%	0.20
Separated	1.3%	8.6%	
Single	28.6%	29.3%	
Widowed	11.7%	14.7%	

Note. *Indicates that the difference is significant at the $p < .05$ level.

Table 7.

Attrition Rate between Groups, 1-Sided Chi Square.

	Completed *n*(%)	Discontinued *n*(%)	*p*
EMPOWER	79(77.45%)	23(22.55%)	0.093
Mail	84(85.71%)	14(14.29%)	

Note. *Indicates that the difference is significant at the $p < .05$ level.

Weight, HbA1c, self-care, medication adherence, depression, and self-efficacy was measured at 0, 6, and 12 months. See Table 8 for descriptions of outcome variables at each time point.

Table 8.

Outcome Characteristics across Time-Intent to Treat.

	Baseline *M*(*SD*)	6-Month *M*(*SD*)	12-Month *M*(*SD*)	Change *M*(*SD*)
Weight				
EMPOWER	215.80(46.66)	214.99(46.38)	212.83(48.68)	-2.98(13.68)
Mail	229.23(55.78)	229.73(55.77)	228.38(56.63)	-0.85(10.06)
HbA1c				
EMPOWER	9.13(1.79)	8.87(1.92)	8.84(1.98)	-0.29(1.84)
Mail	9.05(1.88)	8.89(2.11)	9.10(2.24)	0.048(1.61)
Med Adherence				
EMPOWER	5.28(2.19)	5.66(2.05)	5.59(1.80)	0.31(1.69)
Mail	5.45(1.81)	5.64(1.67)	6.10(1.68)	0.65(1.75)
Self-Efficacy				
EMPOWER	37.49(14.99)	39.24(11.06)	40.99(12.96)	3.19(15.98)
Mail	39.14(16.07)	40.15(12.28)	40.29(13.17)	0.88(16.64)
Self-Care				
EMPOWER	34.10(13.64)	40.70(12.03)	40.27(12.23)	5.97(13.27)
Mail	33.85(13.48)	43.73(9.28)	42.08 (9.35)	7.47(13.76)
Depression				
EMPOWER	7.00(3.9)	6.59(3.29)	6.58(3.80)	-0.42(3.04)
Mail	7.34(4.33)	7.06(3.92)	6.76(3.58)	-0.58(3.25)

Weight Change

Participants weighed an average of 215.80 lbs (*SD* = 46.66), or 98.10 kg (*SD* = 21.20) in the EMPOWER group and 229.23 lbs (*SD* =55.78), or 104.20 kg (*SD* = 25.40) in the Mail group at baseline (see Table 4). Because participants were recruited based on HbA1c and not weight status, weights varied widely and ranged from 116.0 lbs to 421.0 lbs (52.62 kg to 190.96 kg). Baseline weight did not differ between those who were insulin using compared to those who did not use insulin. Repeated Measures ANOVAs revealed that there was a statistically significant effect of time on weight, $F(1.82, 197) = 4.15$, $p = .020$, $\eta^2 = 0.021$, indicating that participants' weight significantly decreased over time regardless of group. Effect size was small but significant. While weight differed by group assignment, $F(1, 197)=4.02$, $p = 0.046$, $\eta^2 = 0.020$, there was not a significant time by group effect: $F(1.82, 197) = 1.055$, $p = 0.34$ (see Table 9). This is likely due to the high variability and sub-significant differences of weight status between groups at baseline (p=0.067).

Table 9.

Repeated Measures Analysis of Variance for Weight.

	Effect	*df*	*F*	*p*	Eta squared
Weight[1]	Time	1.82	4.15	0.020*	0.021
	Group	1	4.02	0.046*	0.020
	Time x Group	1.82	1.055	0.34	0.005

Note. *Indicates that the difference is significant at the $p < .05$ level.
[1]Corrected for violations of sphericity (Mauchly's Test of Sphericity < 0.05).

Linear regressions revealed that no factors significantly predicted weight change for the EMPOWER group (see Table 10). Self-efficacy ($\beta = 0.44$, $p = 0.048$) and Doctor LOC ($\beta = 0.61$, $p = 0.039$) both predicted weight change in the Mail group. Correlational analysis demonstrated that weight change was not related to any other 12-month factors among overall participants (see Table 11). Weight change across the study was greater for participants who were not insulin-

using (*M* = -4.51 lbs, *SD* = 12.64; *M* = 2.1 kg, *SD* = 5.7) compared to those who manage their diabetes with insulin injections (*M* = 0.11 lbs, *SD* = 11.32; *M* = 0.1 kg, *SD* = 5.1; *t*(192) = -2.65, *p* = 0.009; see Table 12). Among non-insulin using participants, the EMPOWER group (*M* = -5.20 lbs, *SD* = 14.63; *M* = 2.36 kg, *SD* = 6.64) and the Mail group (*M* = -3.64 lbs, *SD* = 9.70; *M* = 1.65 kg, *SD* = 4.40) did not differ in weight change: *t*(75) = -0.53, *p* = 0.60. For those who were insulin-using, the EMPOWER group (*M* = -0.49 lbs, *SD* = 12.68; *M* = 0.22 kg, *SD* = 5.75) and the Mail group (*M* = 0.62 lbs, *SD* = 10.09; *M* = 0.28 kg, *SD* = 4.58) also did not differ in weight change: *t*(115) = -0.53, *p*=0.60.

Table 10.

Linear Regressions between Posttest Variables and Weight Change.

	B		*SE B*		*Beta*		*p*	
	EMPOWER	Mail	EMPOWER	Mail	EMPOWER	Mail	EMPOWER	Mail
HBA1c Change	0.17	-1.71	0.92	1.29	0.028	-0.31	0.85	0.20
Self-Efficacy	-0.13	0.37	0.16	0.18	-0.13	0.44	0.41	0.048*
Self-Care	0.076	-0.44	0.15	0.23	0.083	-0.46	0.61	0.073
Med Adherence	0.32	0.92	0.92	0.55	0.052	0.30	0.73	0.10
Internal LOC	0.45	0.46	0.31	1.30	0.22	0.079	0.15	0.73
Chance LOC	-0.13	0.26	0.39	0.42	-0.071	0.12	0.75	0.55
Doctor LOC	-0.68	0.85	0.69	0.39	-0.15	0.61	0.33	0.039*
Others LOC	-0.63	-0.85	0.65	0.94	-0.18	-0.17	0.34	0.37
God LOC	0.27	-0.58	0.27	0.59	0.19	-0.22	0.31	0.34
Subj Norms	-0.17	0.22	0.38	0.33	-0.068	0.17	0.65	0.52

Note. *Indicates that the relationship is significant at the $p < .05$ level.

Table 11.

Correlations between Factors.

	Weight Change	HbA1c Change	Subj Norms	Self-Care	Self-Efficacy	Med Adher	Depress	Internal LOC	Chance LOC	Doctor LOC	Others LOC
God LOC	r=0.086 p=0.30	r=0.032 p=0.70	r=0.011 p=0.91	r=0.22* p=0.009	r=-0.006 p=0.94	r=0.006 p=0.95	r=0.021 p=0.80	r=0.17* p=0.04	r=0.64* p<0.001	r=0.17* p=0.041	r=0.39* p<0.001
Others LOC	r=-0.050 p=0.54	r=0.12 p=0.14	r=-0.001 p=0.99	r=0.070 p=0.39	r=-0.086 p=0.29	r=-0.020 p=0.81	r=0.006 p=0.94	r=-0.019 p=0.82	r=-0.58* p<0.001	r=0.092 p=0.27	
Doctor LOC	r=-0.032 p=0.69	r= 0.012 p=0.88	r=0.085 p=0.36	r=0.12 p=0.14	r=0.13 p=0.11	r=0.087 p=0.29	r=-0.060 p=0.46	r=0.39* p<0.001	r=0.20* p=0.018		
Chance LOC	r=0.051 p=0.53	r=0.057 p=0.49	r=-0.027 p=0.77	r=0.11 p=0.19	r=-0.097 p=0.24	r=-0.14 p=0.088	r=0.020 p=0.81	r=0.16* p=0.049			
Internal LOC	r=0.15 p=0.058	r=0.081 p=0.32	r=0.068 p=0.46	r=0.007 p=0.93	r=0.08 p=0.32	r=-0.10 p=0.20	r=0.015 p=0.86				
Depress	r=0.081 p=0.31	r=-0.086 p=0.28	r=0.007 p=0.94	r=-0.11 p=0.17	r=-0.47* p<0.001	r= -0.22* p=0.004					
Med Adher	r=-0.011 p=0.88	r=-0.072 p=0.32	r=0.059 p=0.52	r=0.33* p<0.001	r=0.28* p<0.001						
Self-Efficacy	r=-0.089 p=0.21	r=-0.009 p=0.90	r=0.12 p=0.19	r=0.43* p<0.001							
Self-Care	r=-0.007 p=0.93	r=-0.067 p=0.35	r=0.18 p=0.050								
Subj Norm	r=0.040 p=0.66	r=0.17 p=0.056									
HbA1c Change	r=0.003 p=0.97										

Note. *Indicates that the correlation is significant at the $p < .05$ level.

Table 12.

Outcome Characteristics between Non-Insulin Using and Insulin Using Participants.

	Non-Insulin Using *n*=77			Insulin Using *n*=117		
	EMPOWER	Mail	Diff	EMPOWER	Mail	Diff
	M (SD)	*M (SD)*	*p*	*M (SD)*	*M (SD)*	*p*
Weight Change	-5.20 (14.63)	-3.64 (9.70)	0.60	-0.49 (12.68)	0.62 (10.09)	0.60
HbA1c Change	-0.71 (1.87)	0.75 (1.56)	0.056	-0.004 (1.85)	0.026 (1.66)	0.94
Depression	6.38 (3.88)	6.56 (3.04)	0.85	6.72 (3.71)	7.00 (3.81)	0.72
Subjective Norms	29.47 (6.87)	28.94 (8.07)	0.81	30.93 (4.10)	30.35 (6.79)	0.68
Medication Adherence	5.63 (1.66)	5.90 (1.73)	0.48	5.51 (1.89)	6.12 (1.64)	0.068
Self-Care	37.56 (13.37)	41.76 (11.36)	0.15	41.56 (12.10)	41.35 (8.78)	0.92
Self-Efficacy	41.65 (12.44)	40.68 (13.87)	0.10	40.54 (13.59)	39.79 (12.89)	0.76

Note. *Indicates that the difference is significant at the $p < .05$ level.

HbA1c Change

Baseline average HbA1c scores were $M = 9.13$ ($SD = 1.79$) for the EMPOWER group and $M = 9.05$ ($SD = 1.88$) for the Mail group (see Table 4), indicating that participants had poorly controlled diabetes (HbA1c>7). While HbA1c was significantly higher for those who used insulin at baseline ($p<0.001$), HbA1c change across the course of the study did not differ

between groups (p=0.14). Repeated Measures ANOVAs showed that there were no significant effects of time, group, or time-by-group interactions (see Table 13).

Table 13.

Repeated Measures Analysis of Variance for HbA1c.

	Effect	*df*	*F*	*p*	Eta squared
HbA1c	Time	2	1.55	0.21	0.008
	Group	1	0.072	0.79	0.00
	Time x Group	2	1.04	0.36	0.005

Note. *Indicates that the difference is significant at the $p < .05$ level.

While repeated measures ANOVAs revealed there were no significant differences in HbA1c between groups, the trajectory of change for each group varied. While both groups had a reduction in HbA1c until 6 months, after 6 months the mail group's HbA1c began to increase while the EMPOWER group's HbA1c continued to decrease. This trajectory suggests that long-term treatment may eventually lead to significant HbA1c change between groups (see Figure 3). HbA1c change was similar for those who were not insulin using (M = -0.37, SD = 1.78) and those who manage their diabetes with insulin injections (M = 0.014, SD = 1.74; t(191) = -1.48, p = 0.14, see Table 12). For those who were not insulin-using, EMPOWER (M = -0.71, SD = 1.87) and Mail (M = 0.075, SD = 1.56) groups did not have statistically significant differences in HbA1c, although data demonstrate a strong trend towards HbA1c improvement in the EMPOWER group t(74)= -1.94, p = 0.056. For those who were insulin-using, EMPOWER (M = -0.0004, SD = 1.85) and Mail groups (M = 0.026, SD = 1.66) did not differ in HbA1c change: t(115) = -0.081, p = 0.42.

Linear regressions revealed that greater HbA1c changes were predicted by lower depression scores (β = -0.29, p = 0.041) for the EMPOWER group (see Table 14). Greater HbA1c changes are predicted by greater subjective norms in the Mail group (β = 0.41, p =

0.031). Correlational analysis for all participants revealed no relationships between HbA1c change and other 12-month variables among participants (see Table 11).

Figure 3.

HbA1c Based on Repeated Measures ANOVA.

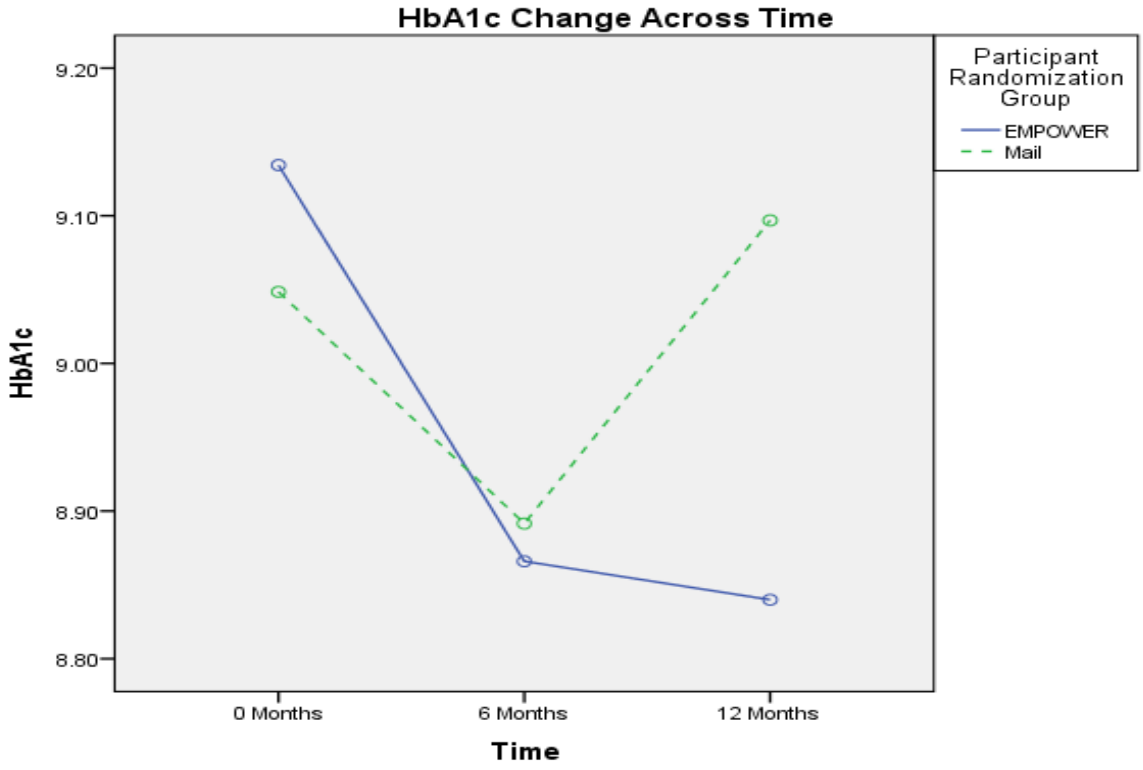


Table 14.

Linear Regressions between HbA1c Change and Posttest Variables.

	B		*SE B*		*Beta*		*p*	
	EMPOWER	Mail	EMPOWER	Mail	EMPOWER	Mail	EMPOWER	Mail
Weight Change	0.004	-0.021	0.020	0.035	0.023	-0.11	0.85	0.56
Self-Efficacy	-0.006	-0.005	0.024	0.035	-0.038	-0.034	0.80	0.88
Self-Care	-0.001	-0.017	0.022	0.046	-0.005	-0.10	0.97	0.71
Med Adher	-0.22	-0.38	0.13	0.21	-0.22	-0.36	0.10	0.087
Internal LOC	0.067	-0.043	0.046	0.078	0.21	-0.11	0.15	0.59
Chance LOC	-0.012	-0.012	0.057	0.076	-0.041	-0.048	0.83	0.87
Doctor LOC	0.008	-0.14	0.10	0.16	0.011	-0.15	0.94	0.42
Others LOC	0.14	0.099	0.095	0.11	0.25	0.21	0.15	0.38
God LOC	0.008	-0.021	0.040	0.060	0.034	-0.098	0.85	0.70
Subjective Norms	0.076	-0.005	0.055	0.053	0.18	0.41	0.18	0.031*

Note. *Indicates that the relationship is significant at the $p < .05$ level.

Behavioral Treatment Outcomes

Data indicates that the average baseline depression score was $M = 7.00$ ($SD = 3.9$) for the EMPOWER group and $M = 7.34$ ($SD = 4.33$) for the Mail group (see Table 4). These scores are below the cut-off score of 9 and indicate low rates of depression in this sample. However, participants who used insulin had significantly more depressive symptoms (p=0.017). Repeated measures ANOVAs indicated that scores did not significantly change over time or between groups (see Table 15). Correlational analysis between factors for all participants revealed that

low 12-month depression was related to higher self-efficacy (r = -0.47, p <0.001) and medication adherence (r = -0.22, p = 0.004) among participants (see Table 11).

Table 15.

Repeated Measures Analysis of Variance for Depression.

	Effect	*df*	*F*	*p*	Eta squared
Depression	Time	2	1.77	0.17	0.012
	Group	1	0.36	0.55	0.002
	Time x Group	2	0.13	0.87	0.001

*Indicates that the difference is significant at the $p < .05$ level.

Participants' self-care score at baseline was M = 34.10 (SD = 13.64) for the EMPOWER group and M = 33.85 (SD = 13.48) for the Mail group (see Table 4). This indicates that participants engaged in self-care activities an average of approximately 3.5 days per week at baseline. Repeated measures ANOVAs revealed there was a large, significant effect of time on self-care $F(1.84, 143) = 43.33$, p <0.001, η^2=0.23, suggesting that both treatment programs had a positive impact on self-care activities (see Table 16). Correlational analysis between factors for all participants revealed that high 12-month self-care was related to high God LOC (r = 0.22, p = 0.009), medication adherence (r = 0.33, p <0.001) and self-efficacy (r = 0.43, p <0.001) among participants (see Table 11).

Table 16.

Repeated Measures Analysis of Variance for Self-Care.

	Effect	*df*	*F*	*p*	Eta squared
Self-Care[1]	Time	1.84	43.33	<0.001*	0.23
	Group	1	0.91	0.34	0.006
	Time x Group	1.84	1.48	0.23	0.010

*Indicates that the difference is significant at the $p < .05$ level.
[1]Corrected for violations of sphericity (Mauchly's Test of Sphericity < 0.05).

Participant medication adherence scores were M = 5.28 (SD = 2.19) for the EMPOWER group and M = 5.45 (SD = 1.81) for the Mail group at baseline (see Table 4), indicating that

participants overall had low adherence to prescribed medications (cut-off below 6; Muntner et al., 2011). Repeated measures ANOVAs demonstrated that there was a small significant effect of time on medication adherence $F(2, 181) = 7.01$, $p = 0.001$, η^2=0.037 (see Table 17), demonstrating that medication adherence improved regardless of group assignment.

Table 17.

Repeated Measures Analysis of Variance for Medication Adherence.

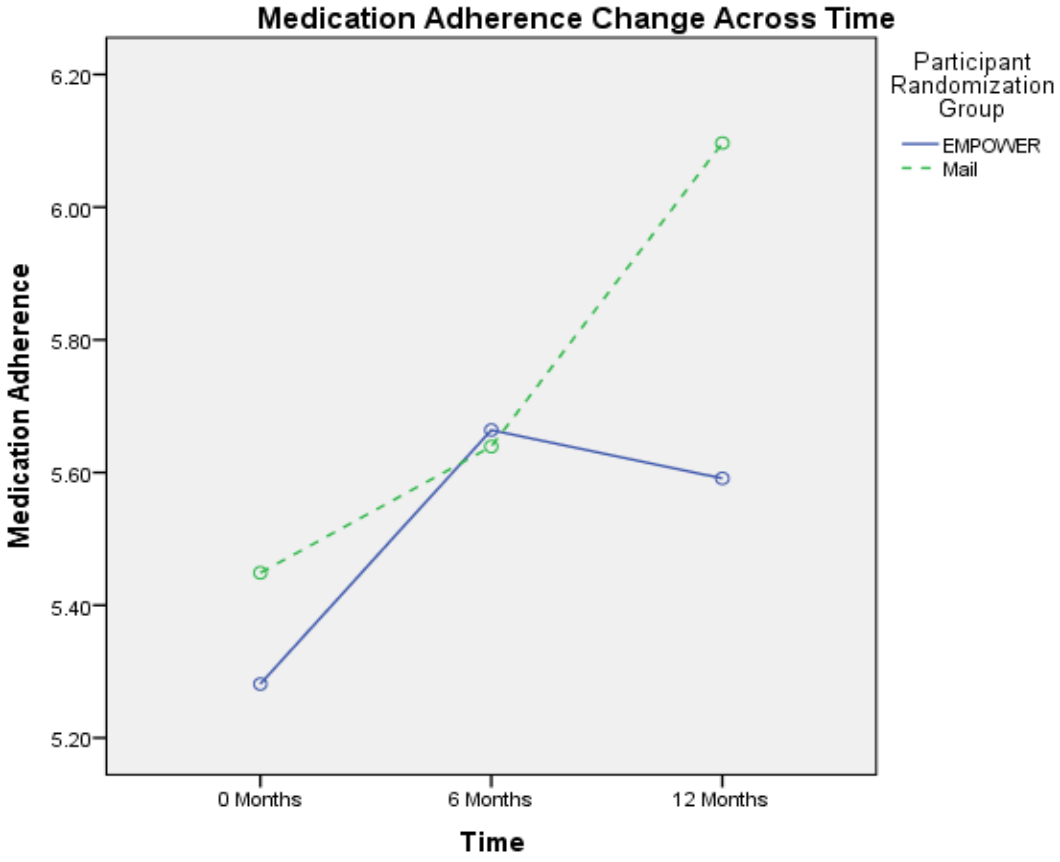
	Effect	*df*	*F*	*p*	Eta squared
Medication Adherence	Time	2	7.01	0.001*	0.037
	Group	1	0.84	0.36	0.005
	Time x Group	2	2.18	0.12	0.012

*Indicates that the difference is significant at the $p < .05$ level.
[1]Corrected for violations of sphericity (Mauchly's Test of Sphericity < 0.05).

Repeated measures ANOVAs further revealed that medication adherence followed unique trajectories between groups. While there were no significant differences between groups and medication adherence seemed to improve for both groups in the first 6 months, after 6 month assessment medication adherence worsened for the EMPOWER group but continued to improve within the Mail group (see Figure 4). Correlational analysis between factors for all participants revealed that higher 12-month medication adherence was related to lower depression ($r = -0.22$, $p = 0.004$) and higher self-care ($r = 0.33$, $p <0.001$) and self-efficacy ($r = 0.28$, $p <0.001$) among participants (see Table 11).

Figure 4.

Medication Adherence Based on Repeated Measures ANOVA.



Participants self-efficacy score was $M = 37.49$ ($SD = 14.99$) for the EMPOWER group and $M = 39.14$ ($SD = 16.07$) for the Mail group at baseline (see Table 4). Considering that scores range from 0-60, participants had an overall moderate-high level of self-efficacy. Assessment revealed that those who used insulin had less self-efficacy than those who did not use insulin (p=0.027). Repeated Measures ANOVAs indicated that there were no significant changes of self-efficacy based on time, group assignment, or time by group interaction (see Table 18). Correlational analyses between factors for all participants revealed that an increase in 12-month self-efficacy was related to a decrease in depression ($r = -0.47$, $p < 0.001$) and an increase in self-care ($r = 0.43$, $p < 0.001$) and medication adherence ($r = 0.28$, $p < 0.001$) among participants (see Table 11).

Table 18.

Repeated Measures Analysis of Variance for Self-Efficacy.

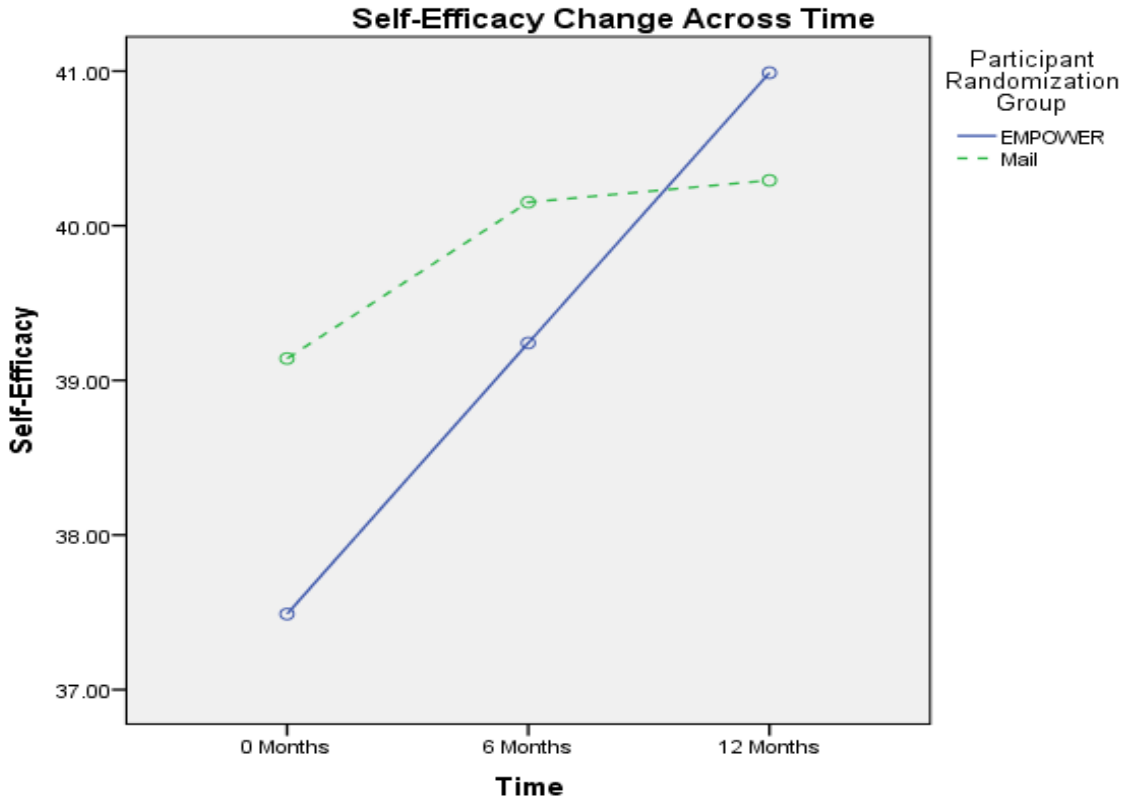
	Effect	*df*	*F*	*p*	Eta squared
Self-Efficacy[1]	Time	1.94	2.19	0.12	0.012
	Group	1	0.17	0.68	0.001
	Time x Group	1.94	0.58	0.56	0.003

*Indicates that the difference is significant at the $p < .05$ level.
[1]Corrected for violations of sphericity (Mauchly's Test of Sphericity < 0.05).

While there were no significant differences in self-efficacy scores between groups, trends indicate that self-efficacy was changing at a higher and more consistent rate across the course of the study for the EMPOWER group compared to the mail group (see Figure 5).

Figure 5.

Self-Efficacy Based on Repeated Measures ANOVA.



LOC

Independent samples t-tests revealed that there was a significant difference in God LOC between the EMPOWER group (M = 19.16, SD = 8.20) and the Mail group (M = 22.42, SD = 7.48), $t(143) = -2.49$, $p = 0.014$ (see Table 19). Considering randomization of participants at baseline, this suggests that the EMPOWER intervention may have implications for God LOC during the course of treatment, although this is inconclusive due to the lack of baseline data. No other moderating or mediating variable differed significantly between groups. Correlational analyses between factors for all participants revealed that God LOC was significantly positively correlated with all LOC measures and self-care ($r = 0.22$, $p = 0.009$). Chance LOC was positively correlated with all LOC measures except Others LOC, which had a significant negative relationship ($r = -0.58$, $p < 0.001$). Internal LOC was also related to Doctor LOC ($r = 0.39$, $p < 0.001$). See Table 11 for description of all correlational relationships.

Table 19.

Characteristics and Differences between Groups for One-Time Measures.

	EMPOWER $n = 76$	Mail $n = 78$			
	M(SD)	*M(SD)*	*t*	*df*	*p*
Internal LOC	27.75(5.78)	28.15(5.24)	-0.44	150	0.66
Chance LOC	15.15(6.89)	16.30(7.38)	-0.98	148	0.33
Doctor LOC	14.47(2.71)	14.84(2.23)	-0.91	149	0.37
Others LOC	6.88(3.56)	7.42(3.89)	-0.90	151	0.37
God LOC	19.16(8.20)	22.42(7.48)	-2.49	143	0.014*
Subject Norms	30.36(5.45)	29.90(7.15)	0.41	122	0.68

*Indicates that the difference is significant at the $p < .05$ level.

God LOC also differed between participants based on insulin dependence. Those who were insulin using were more likely to have higher God LOC (M = 21.86, SD = 7.55) compared to those who did not take insulin (M = 18.88, SD = 8.21; $t(139) = -2.18$, $p = 0.031$; see Table 20).

Table 20.

Characteristics between Non-Insulin Using and Insulin Using Participants.

	Non-Insulin Using n=77	Insulin Using n=117	
	M(SD)	*M(SD)*	*p*
God LOC	18.88(8.21)	21.86(7.55)	0.031*
Internal LOC	27.57(5.20)	28.03(5.71)	0.62
Subjective Norms	29.29(7.23)	30.68(5.40)	0.23
Self-Efficacy	41.22(13.01)	40.14(13.16)	0.57

*Indicates that the difference is significant at the $p < .05$ level.

Subjective Norms

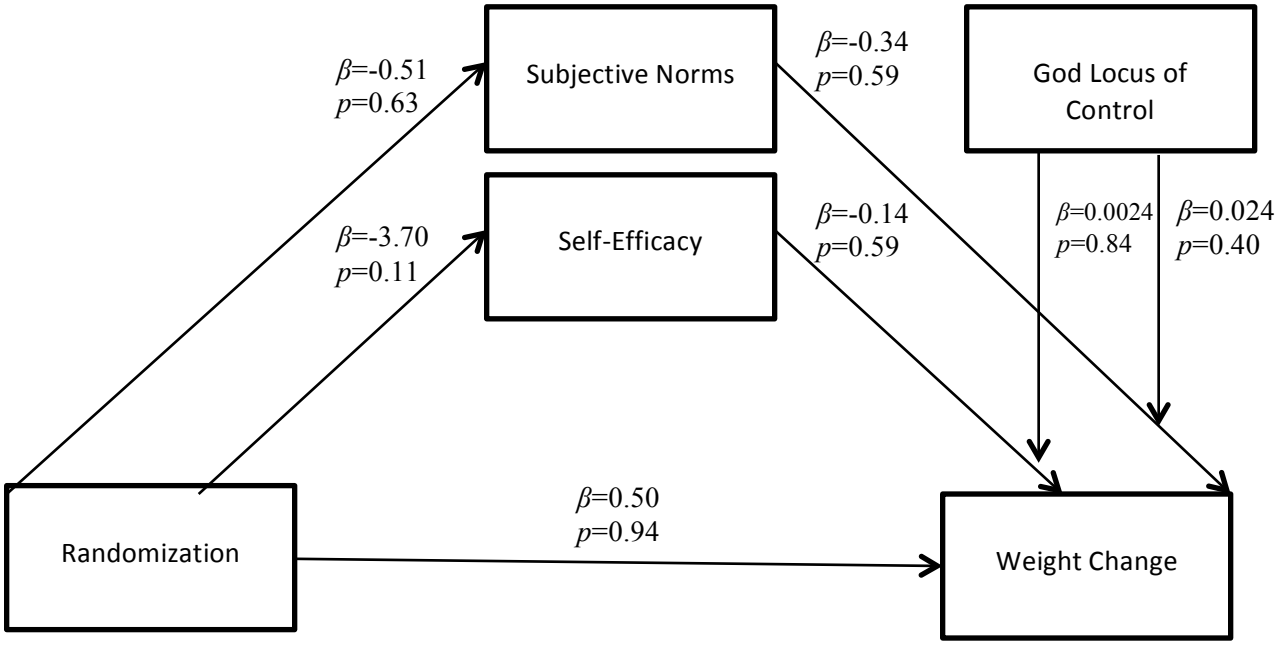
T-tests reveal that subjective norms did not differ between the EMPOWER group (M = 30.36, SD = 5.45) and the Mail group (M = 29.90, SD = 7.15) at 12-months: $t(122) = 0.41$, p = 0.68 (see Table 19). However, linear regressions revealed that subjective norms predicted improvement in HbA1c in the mail group ($\beta = 0.41$, $p = 0.031$; see Table 14).

Moderated-Mediated Relationships

To assess the hypotheses that subjective norms and self-efficacy serve as mediators and Internal and God LOC serve as moderators in the relationship between treatment and outcomes, multi-factorial models were created using HbA1c change, weight change, medication adherence change, and self-care change as outcomes. Figure 6 and 7 demonstrate no significant relationships that validate these proposed mediation and moderation relationships for weight change. No mediators or moderators significantly impacted the models.

Figure 6.

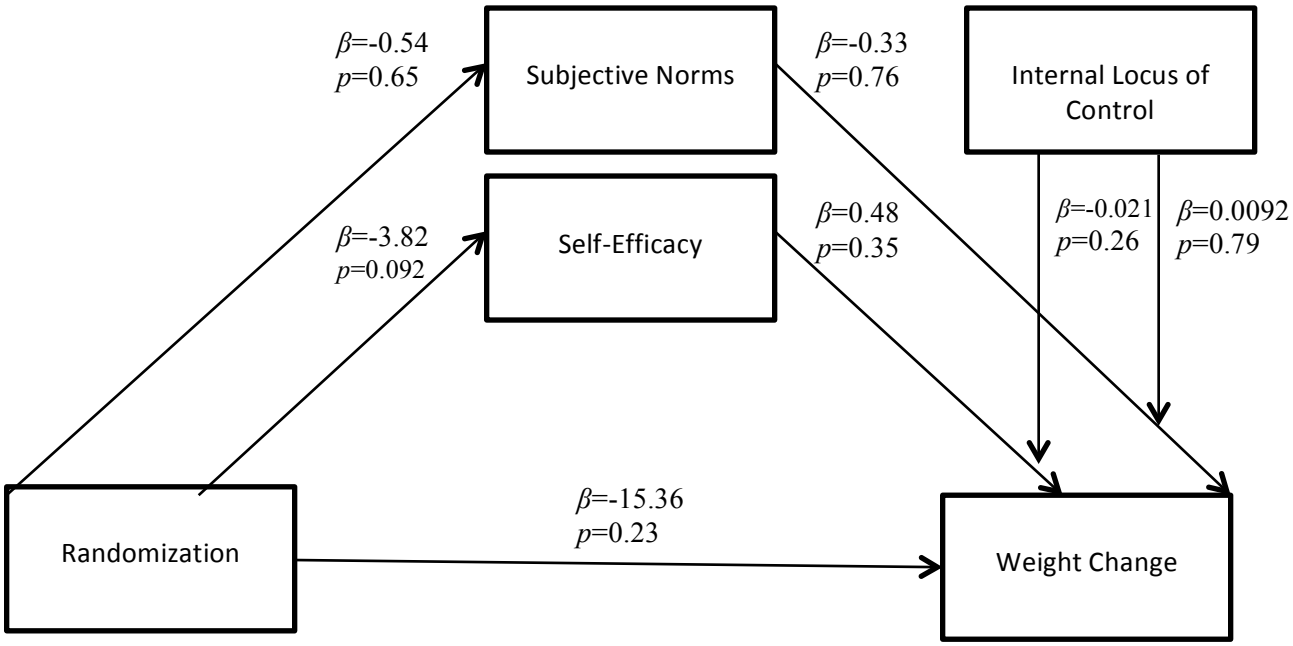
Moderated-Mediated Model of Weight Change with God LOC as Moderator.



Note. *Indicates that the relationship is significant at the $p < .05$ level.

Figure 7.

Moderated-Mediated Model of Weight Change with Internal LOC as Moderator.

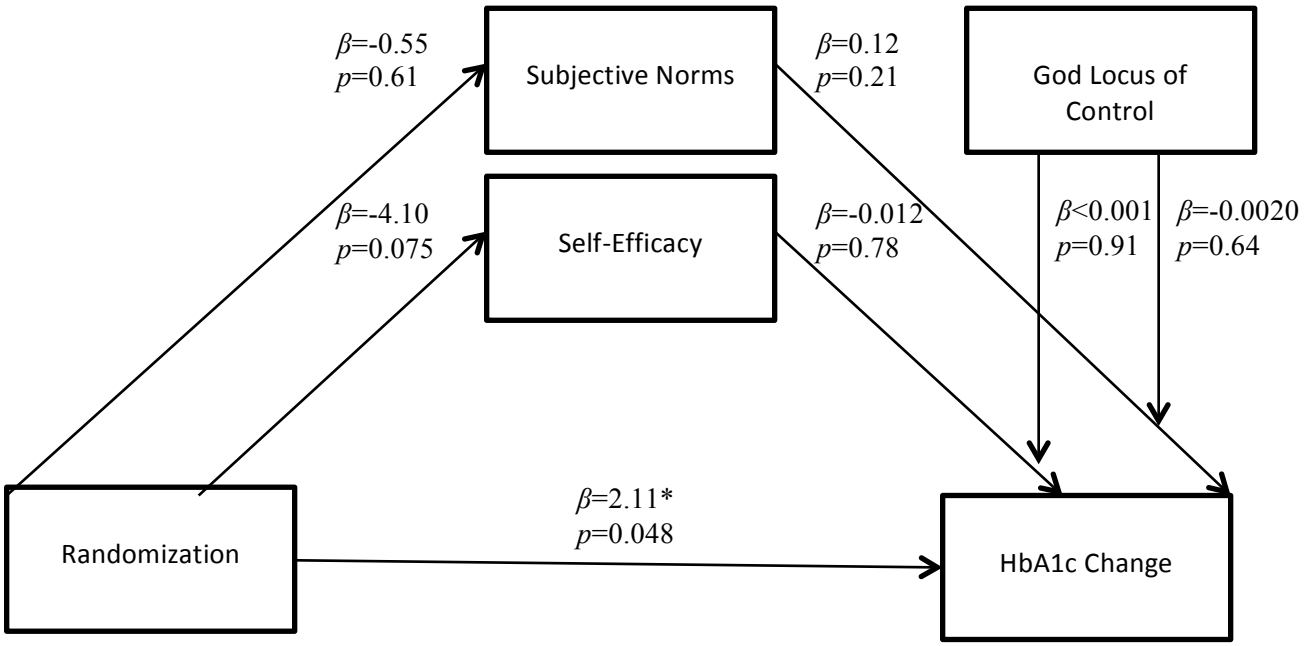


Note. *Indicates that the relationship is significant at the $p < .05$ level.

While models that utilize God and Internal LOC as moderators and subjective norms and self-efficacy as mediators demonstrated no significant moderation or mediation effects for HbA1c change, it is notable that when these factors are controlled for the relationships between intervention and HbA1c change is significant (God LOC model: $\beta = 2.11$, $p = 0.048$, Internal LOC model: $\beta = 5.26$, $p = 0.010$; see Figure 8 and 9). This suggests that these variables have an impact on treatment and outcomes, although not in the way predicted by this model.

Figure 8.

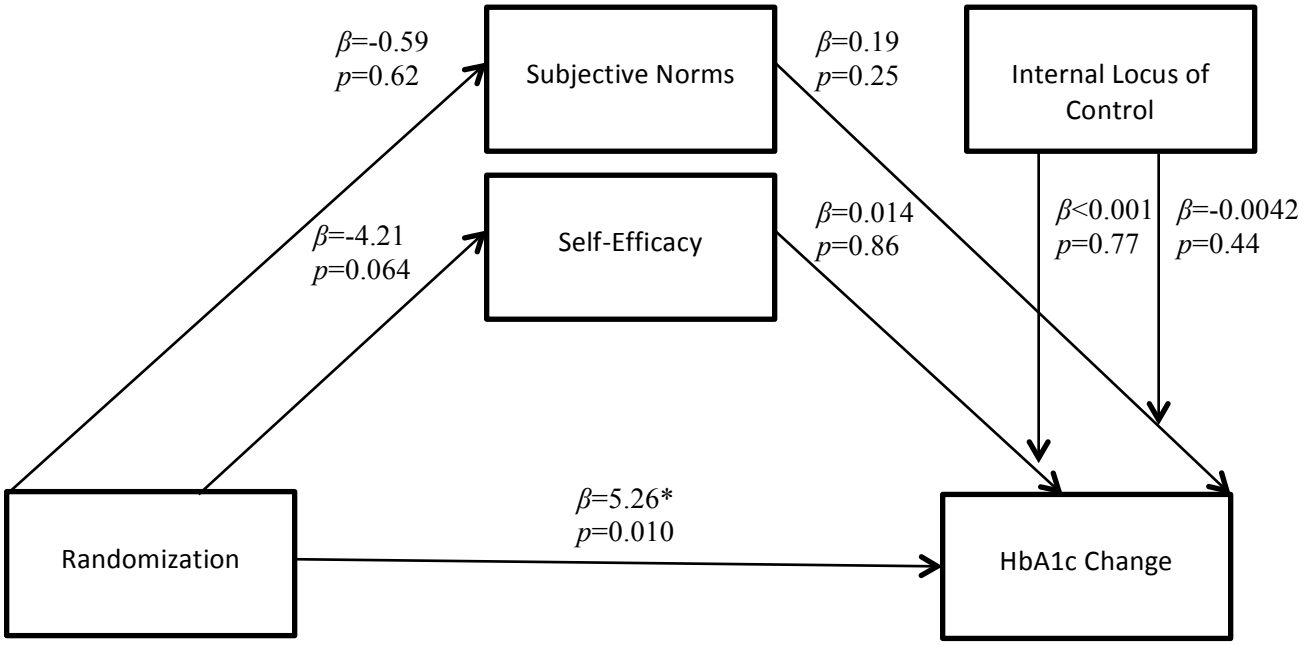
Moderated-Mediated Model of HbA1c Change with God LOC as Moderator.



Note. *Indicates that the relationship is significant at the $p < .05$ level.

Figure 9.

Moderated-Mediated Model of HbA1c Change with Internal LOC as Moderator.

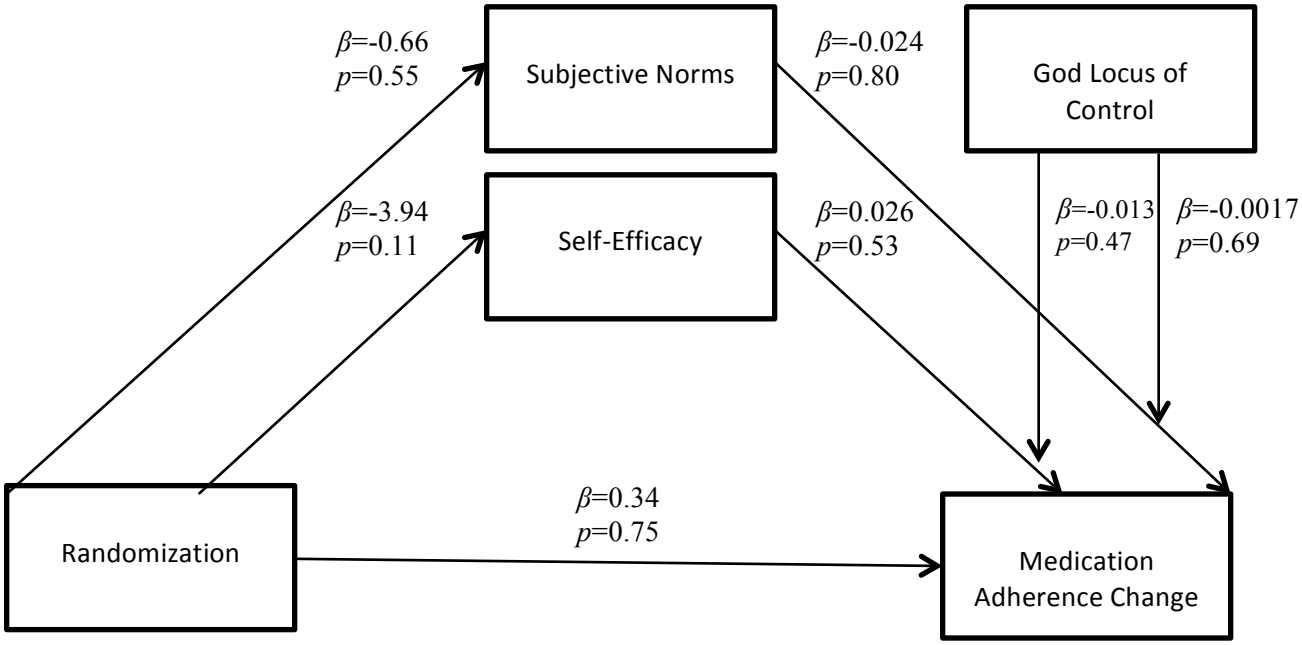


Note. *Indicates that the relationship is significant at the $p < .05$ level.

Because subjective norms is a construct related most closely to intention to engage in health behaviors, models that used behavioral outcomes of medication adherence change and self-care change were also assessed. Figure 10 and 11 demonstrate no significant relationships that validate these proposed mediation and moderation relationships for medication adherence change. No mediators or moderators significantly impacted the model.

Figure 10.

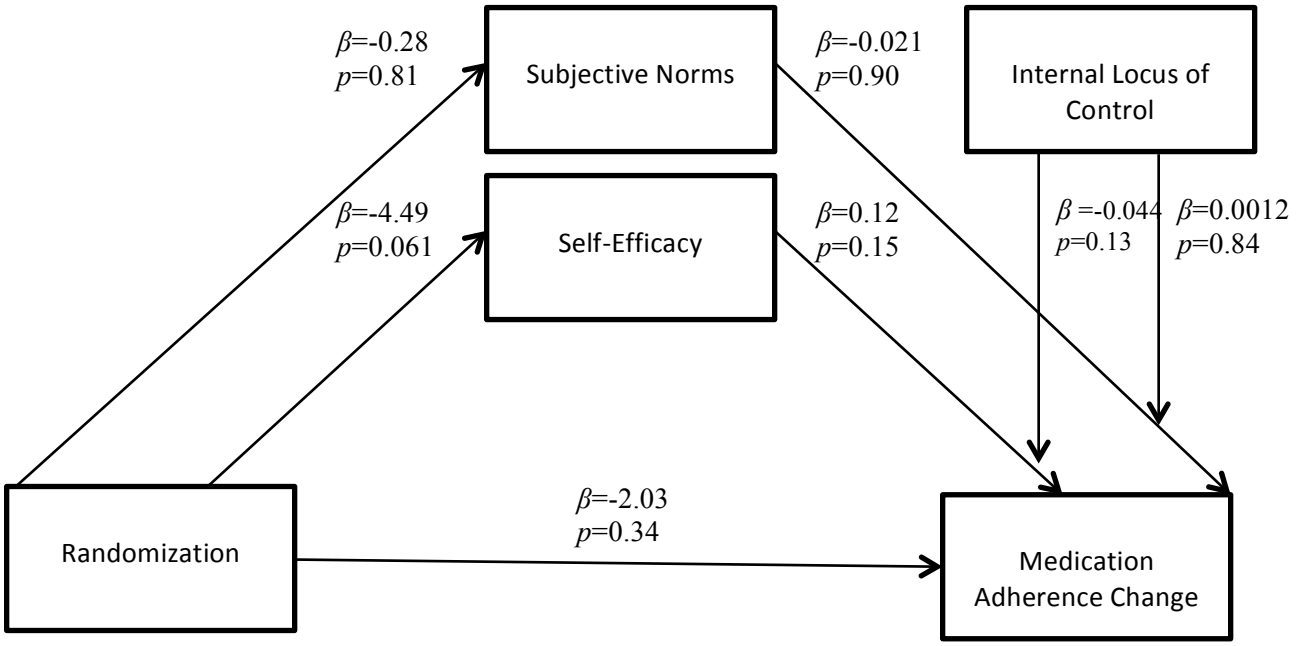
Moderated-Mediated Model of Medication Adherence Change with God LOC as Moderator.



Note. *Indicates that the relationship is significant at the $p < .05$ level.

Figure 11.

Moderated-Mediated Model of Medication Adherence Change with Internal LOC as Moderator.

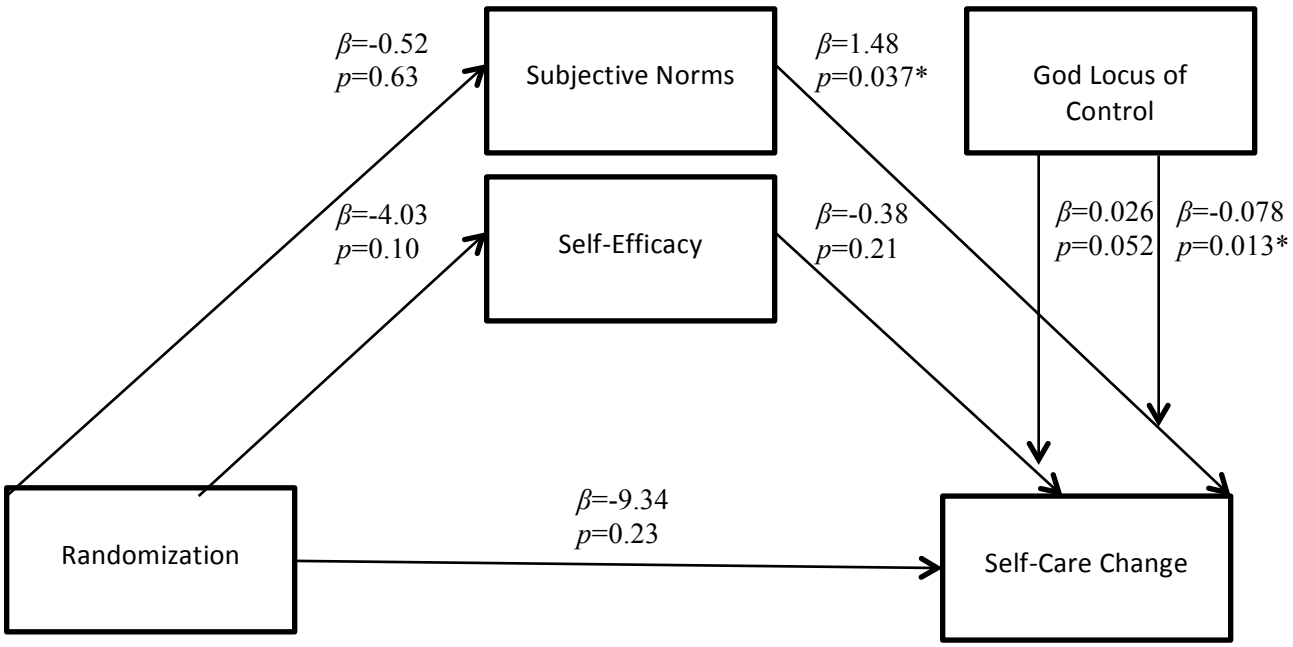


Note. *Indicates that the relationship is significant at the $p < .05$ level.

Figure 12 reveals that in models which use God LOC as a moderator and self-care change as the outcome, subjective norms significantly impacted self-care change (p=0.037). This relationship became even stronger when moderated by God LOC (p=0.013). Figure 13 illustrates that this relationship does not exist when Internal LOC is considered the primary moderator for self-care change in place of God LOC, demonstrating a unique interaction between subjective norms, God LOC, and self-care behaviors. This suggests that higher subjective norms with high God LOC interacts to strengthen self-care change in participants.

Figure 12.

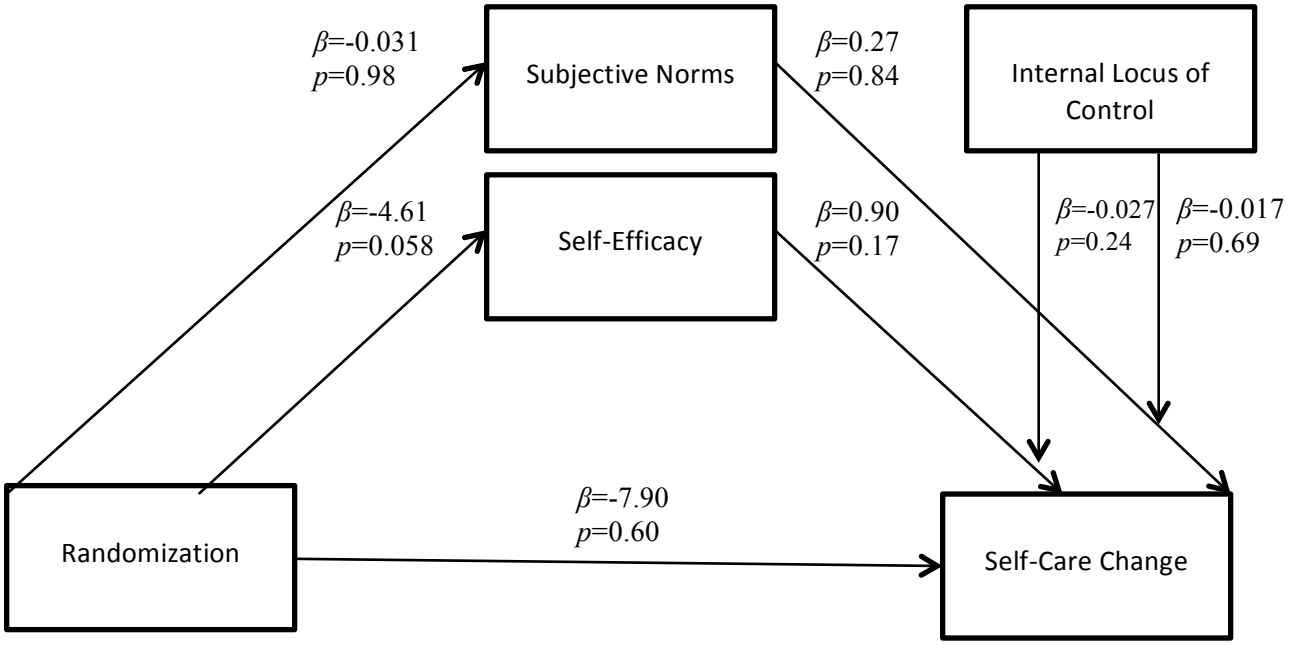
Moderated-Mediated Model of Self-Care Change with God LOC as Moderator.



Note. *Indicates that the relationship is significant at the $p < .05$ level.

Figure 13.

Moderated-Mediated Model of Self-Care Change with Internal LOC as Moderator.



Note. *Indicates that the relationship is significant at the $p < .05$ level.

While baseline differences in insulin dependence suggest there may be different mediation/moderation interactions based in insulin use, there were no differences in behavioral or medical outcome models when controlled for insulin use.

Alternative Moderation Models

In order to explore different ways in which theoretical factors may impact outcomes, analyses were completed to determine if these factors may moderate the relationship between randomization and outcomes independently. Results indicated that neither subjective norms, self-efficacy, God LOC, or Internal LOC moderated weight change, medication adherence, or self-care (see Table 21), although a time by subjective norms interaction was discovered for HbA1c $F(1, 120) = 4.04$, $p = 0.047$, $\eta^2 = 0.033$ (see Table 21). However, the relationships between subjective norms and each time point for HbA1c were overall variable and non-significant. Linear regressions revealed that the relationship between subjective norms and HbA1c was small

and negative at baseline (β=-0.017, p=0.51), small and negative at 6-months (β=-0.019, p=0.53), and small and positive at 12-months (β=0.037, p=0.29). Interestingly, despite significant differences in God LOC between groups, LOC variables had no impact on the relationship between treatment and outcomes.

Table 21.

Moderation Using Repeated Measures Analysis of Variance.

Outcome	Effect by Time	*df*	*F*	*p*	Eta squared
Weight Change	Self-Efficacy	1	1.47	0.23	0.007
	Subjective Norms	1	0.22	0.64	0.002
	Internal LOC	1	3.52	0.063	0.023
	God LOC	1	0.75	0.39	0.005
HbA1c	Self-Efficacy	1	0.004	0.95	0.00
	Subjective Norms	1	4.04	0.047*	0.033
	Internal LOC	1	0.88	0.35	0.006
	God LOC	1	0.016	0.90	0.00
Medication Adherence	Self-Efficacy	1	0.46	0.63	0.005
	Subjective Norms	1	2.32	0.10	0.023
	Internal LOC	1	0.51	0.60	0.005
	God LOC	1	1.71	0.18	0.017
Self-Care	Self-Efficacy	1	1.42	0.24	0.016
	Subjective Norms	1	0.36	0.70	0.004
	Internal LOC	1	1.86	0.16	0.021
	God LOC	1	0.59	0.56	0.007

*Indicates that the difference is significant at the $p < .05$ level.

Chapter IV: Discussion

Rural African American women have greater prevalence of T2DM (CDC, 2005), disease-related morbidity (Johnson & Lavernia, 2011; Lanting et al., 2005), and poorer treatment outcomes (Bhattacharya, 2012; Fitzgibbon et al., 2012; Gumbs, 2012) compared to other demographic groups. Differences in self-efficacy (Wilbur et al., 2003), subjective norms (Felton et al., 2002; Hammond et al., 2010; Stewart et al., 2009; Wallace et al., 2003), and LOC (Polzer & Miles, 2005) may partially contribute to differential treatment outcomes for this population. The EMPOWER program is a novel, culturally-tailored T2DM intervention that utilized community health workers (CHWs) to provide a SCM-based cognitive behavioral lifestyle intervention for rural African American women. The purpose of this study was to determine what factors predict treatment outcomes and whether certain theoretical constructs mediate and moderate treatment outcomes within this population, particularly assessing self-efficacy, subjective norms, and God and Internal LOC. The development of this project was largely based on the desire to identify alternative factors impacting health behaviors in addition to self-efficacy following initial assessment of 6-month EMPOWER data and feedback from CHWs, who observed a disconnect between perceived self-efficacy and treatment outcomes.

Hypotheses predicted that the EMPOWER group would have significant improvements in health behaviors, self-efficacy, depression, and weight and HbA1c change and that these improvements would be greater than those in the Mail group. Results indicated that both groups had significant improvements in weight change, medication adherence, and self-care over time, although these outcomes were not statistically different between groups. This suggests that both EMPOWER and Mail treatments have an important impact on treatment outcomes in this

population. This is particularly important considering the relatively low-burden, low-cost design of each of these interventions.

Weight Loss

The sustained weight loss demonstrated throughout the EMPOWER study in particular has important health implications for women with T2DM. Research shows that healthy young African American women gain approximately 10 kg in 20 years (Sheehan, DuBrava, DeChello, & Fang, 2003). Individuals who are diabetic and on medications such as sufonylureas have a 3 kg weight gain every 3-4 years (Lahiri, 2012). Individuals newly diagnosed with T2DM starting insulin and metformin may gain as much as 7.60 kg in 6 months (Jacob et al., 2007). Considering the typical weight gain for African American women in general and individuals managing T2DM in particular, sustained weight-loss through EMPOWER demonstrates that these weight gain trends may not only be stopped but reversed across a year through this intervention.

Further, participants' weight loss in the EMPOWER study is comparable with results from other large-scale, more intensive interventions for non-diabetic African American women. In a 24-month tailored in-person, phone- and internet-based weight management program targeting 365 primarily disadvantaged African American women with hypertension, participants lost 3.7 lbs (1.7 kg) over the course of 2 years (Bennett et al., 2012). It is notable that the EMPOWER one-year intervention utilizing a relatively inexpensive, low-burden modality (approximately 270 minutes of phone intervention from a CHW) resulted in comparable weight outcomes. As predicted by the SCM model, weight loss in this study was slow but sustained across the year (Lutes & Steinbaugh, 2010).

Importantly, weight loss was significant across groups despite high rates of insulin use in this sample. It is not surprising that weight loss nonetheless varied based on insulin use. While

EMPOWER participants had significant overall weight loss of 2.98 lbs (1.4 kg), EMPOWER participants who were not insulin-using lost 5.20 lbs (2.36 kg) compared to insulin-using participants, who lost only 0.49 lbs (0.2 kg). This is likely due to the fact that insulin use is related to greater disease progression and weight gain (Jacob et al., 2007; Russell-Jones & Khan, 2007; UK Prospective Diabetes Study Group, 1998). In fact, research indicates that greater intensity of pharmacology treatment leads to greater weight gain over time. Comparisons between patients undergoing intensive pharmacological T2DM therapy (defined as a fasting plasma glucose goal below 7 mmol/L) versus conventional pharmacological T2DM therapy (defined as a fasting plasma glucose goal below 15 mmol/L) over 10 years found that the HbA1c levels of those in intensive treatment was 0.9% less compared to conventional treatment participants, although the same participants gained 3.1 kg more over time. Those using insulin gained 4.0 kg more compared to participants receiving other medications (UK Prospective Diabetes Study Group, 1998). Considering the typical weight gain associated with insulin, the fact that EMPOWER participants on insulin were able to achieve and maintain weight loss again highlights the effectiveness of EMPOWER in encouraging diabetes management.

HbA1c Change

While there were no significant changes or differences in HbA1c, data assessing only participants who were not taking insulin revealed that HbA1c reduction was trending toward significance in the EMPOWER group (p=0.056), demonstrating that those who are non-insulin using may have better treatment outcomes across the course of treatment and may benefit from the EMPOWER intervention in particular. This finding also highlights the importance of early intervention for those who are diabetic and pre-diabetic. Further, while not significant, trends suggest that the EMPOWER group's HbA1c scores continued to decrease while the Mail group's

HbA1c began to increase after 6 months. If this trend continues it suggests that over time there may become a significant difference in HbA1c change between groups and that the EMPOWER group may manage HbA1c at a more consistent rate than the Mail group. However, considering the fact that medication adherence followed an opposite trajectory at 6 months, more support for medication management in particular may be important in the EMPOWER group to encourage HbA1c improvement beyond treatment. These results suggest that future EMPOWER studies may enhance focus on blood glucose and medication management in particular to better encourage positive HbA1c change and help participants to maintain changes across time.

Overall, considering the importance of weight and HbA1c change in diabetes management (Colditz et al., 1995; Coppel et al., 2010; Knowler et al., 2002; Laws et al., 2012; Lindstron et al., 2006; Sumitani et al., 2012; Thomas & Elliot, 2009), results from both the EMPOWER and Mail groups indicate promise regarding diabetes management promotion over an extended period of time. Contrary to hypothesis, results from the Mail group suggest that there is significant utility in disseminating educational materials to rural southeastern African American women, demonstrating positive benefit from a very inexpensive and low-burden intervention. This is somewhat discrepant from previous studies that suggest limited benefit from education programs (Gumbs 2012; Hawthorne et al., 2008). This finding may reflect that rural African American women from low-income communities in Eastern North Carolina may have particularly limited access to health information and that mailed materials may help to supplement health education within the community. Alternatively, it may reflect additional support that CHWs offered to Mail participants across the course of the study, despite treatment protocol.

It is interesting to note that within the Mail group only, higher self-efficacy predicted weight change ($p = 0.048$) and subjective norms predicted HbA1c change ($p = 0.031$). This predictive power was not found within the EMPOWER group. This may be because without the guidance and support of the EMPOWER treatment intervention, a primary influence on outcomes for participants in the Mail group was their confidence in their abilities and important others in their environment. These relationships may have been overshadowed in the EMPOWER group by other treatment factors and highlights the importance of self-confidence and peer perspective in lieu of traditional treatment in this African American community.

Self-Efficacy

In order to understand and replicate effective treatment programs, it is important to first understand what theoretical factors influence treatment outcomes. According to the SCM and SCT models, a key factor to consider within the EMPOWER study is self-efficacy. However, contrary to these behavior change theories, self-efficacy did not improve across time or differentially between groups. This finding is consistent with literature on African American women that suggests that self-efficacy is not as impacted by treatment or related to significant outcomes compared to Caucasian peers (Pawlak & Colby, 2009; Wilbur et al., 2003). This led to the hypothesis that self-efficacy may mediate the relationship between treatment and outcomes only when considered with other important constructs to this population such as subjective norms and LOC. In other words, self-efficacy would only be effective in this population if participants also believed that change was their responsibility and within their control (Wallston, 1992) and felt pressure from their community to engage in important behaviors (Fernandez et al., 2014). Contrary to hypotheses, data from moderated-mediation modeling revealed that self-efficacy did not mediate the relationship between treatment and outcomes when considered with

subjective norms as a mediator and LOC as a moderator. Self-efficacy was also not found to be a moderator of treatment outcomes and was only related to weight change in the Mail group (p = 0.048). This suggests that self-efficacy, whether considered independently or combined with other constructs, does not play a significant role in outcomes within the EMPOWER intervention for African American women with T2DM as predicted by the SCM. Future behavior change models specific to African American women should consider placing less emphasis on self-efficacy and consider instead other behavior change constructs that may have a more significant impact on weight and HbA1c change, such as subjective norms.

Subjective Norms

While moderated-mediation modeling using subjective norms as a mediator demonstrated no significant relationship between treatment and changes in weight, HbA1c, and medication adherence, subjective norms was shown to significantly impact changes in self-care outcomes (p=0.037). This relationship was stronger when God LOC was included as a moderator (p=0.013). This finding demonstrates that high subjective norms in combination with high God LOC contributed to better self-care outcomes in the EMPOWER study. The important role of subjective norms in EMPOWER stands in contrast with some literature that debates the predictive power of subjective norms compared to other parts of the TPB model (Pasick et al., 2009). The findings in EMPOWER may be partially due to the fact that a new subjective norms measure was created for this study that expands the options of "important others" in order to be more culturally sensitive to social influences among rural African American women. In other words, a more inclusive measure may be able to better assess true subjective norms and highlight relationships in treatment in this population.

While high perceived pressure from others seems to play a role in outcomes, assessment of the SNM shows that participants responded "neutral/somewhat agree" on average to questions asking if they were able to identify important people in their lives who pressure them to engage in healthful behaviors. This suggests that there is an opportunity to better engage important others to encourage healthy behavior change in future interventions. In an attempt to broaden the definition of "important others" in the SNM, sensitivity to assess the influences of particular people were lost. By modifying the SNM to include a variety of potential "important others," interventionists can identify who is most influential and encourage their engagement in participants' treatment to better promote participants' intention to engage in positive behavior changes. EMPOWER baseline assessment questions revealed that physicians, children, family members with diabetes, and friends were most supportive of participants' diabetes management behaviors. Considering the important social support role these individuals play, perhaps they should be targeted more directly in future measures of subjective norms to determine if they also provide perceived pressure to engage in positive health behaviors.

Considering the community-based, peer-focused intervention modality of EMPOWER, it was predicted that subjective norms scores would be higher in the EMPOWER treatment group because they gained a peer coach that would increase positive social peer pressure (Felton et al., 2002; Hammond et al., 2010; Wallace et al., 2003). Contrary to hypotheses, subjective norms did not differ between the EMPOWER and Mail group at 12 months. While this finding must be interpreted with caution because baseline subjective norms data was not collected, the lack of difference in SNM between groups at 12 months may suggest that the use of CHWs in the EMPOWER group were not sufficient to result in differential pressure from important others between groups at 12 months. It may be that treatment should not only be delivered by a peer but

focus on identifying and including important others who can be a greater positive influence to enhance intention to engage in behaviors. Future interventions may consider involving friends and family in treatment or establishing a support group to enhance positive pressure more directly. This suggestion must be weighed with the understanding that African American women tend to prefer 1:1 interventions for delivered treatment. It may thus be beneficial to have supplemental group meetings for participants in addition to individual sessions, which may enhance the positive influence of important others and provide additional social support. Taken together, it appears that for African American women, subjective norms should be a more central focus in the SCM than self-efficacy and should be a target for interventions in future studies.

LOC

In addition to self-efficacy and subjective norms, LOC subscales were analyzed at 12-month assessment. Results show that on average participants scored particularly high on the Doctor LOC subscale (15/18), the Internal LOC subscale (28/36), and God LOC subscale (19/36), although poor internal consistency within the Doctor LOC subscale suggests that results utilizing Doctor LOC should be interpreted with caution. Overall participants seemed to be relatively less oriented to Chance LOC (16/36) and Powerful Others LOC (7/17). These data suggest that participants strongly believe that their health is most determined by doctors, self, and God. Further, Doctor LOC predicted weight change in the EMPOWER group (p=0.039) and participants reported that their doctor is the most important source of diabetes-specific social support in baseline questionnaires. The important role that doctors play in diabetes management as endorsed by participants stands juxtaposed to the fact that African American women often face many challenges to meeting with their medical providers. These include such barriers as feeling disrespected by or uncomfortable around Caucasian providers (Basanez et al., 2012;

Heisler et al., 2009; Kennedy et al., 2007), receiving less time and attention from providers compared to Caucasian patients (Siminoff et al., 2006), and experiencing disproportionate financial burden that may prevent them from attending medical appointments (Gary et al., 2003; Thorpe et al., 2008). These results again highlight the importance of reducing barriers that prevent African American patients from engaging with providers. Practitioners should strive to provide ample time, effort, and quality of care to their patients, particularly considering how influential doctors are in diabetes management among the EMPOWER study sample.

In addition to Doctor LOC, participants strongly endorsed Internal and God LOC. Both Internal and God LOC may play a particularly important role among rural African American women and are thus the main focus in these analyses. Research shows that southeastern African American women are generally more religious than their peers (Lynch et al., 2012). This holds true for our sample of participants, especially considering that participants were primarily recruited from the church community. According to Wallston's model of LOC (1992), it was believed that this would heavily load onto God LOC instead of Internal LOC, essentially resulting in a greater external LOC. It was believed this would in turn moderate self-efficacy and subjective norms.

Surprisingly, participants did not consider different LOC perspectives to be exclusive from one another. Correlations indicate that higher self-reported God LOC was related to higher self-reported Internal LOC ($r = 0.17$, $p = 0.04$), Chance LOC ($r = 0.64$, $p < 0.001$), Doctor LOC ($r = 0.17$, $p = 0.041$), and Powerful Others LOC ($r = 0.39$, $p < 0.001$). This may be explained by the fact that participants understood health control to be complex and multidimensional and their faith in God to be influential despite attitudes of control. Notably, it was reported by interventionists that participants expressed frustration and confusion with the LOC questionnaire

during administration due to the mutually exclusive nature of internal and external LOC items. Specifically, participants felt like they were being forced to choose an LOC orientation that did not fully describe their LOC perspective or reflect their faith.

The number of participants who scored high on both Internal and God LOC demonstrates the complexity of a spiritual perspective that God is both an internal part of self as well as a separate, willful external being. Thus the question of internal versus God LOC as described by Wallston (1992) may not be sensible from this spiritual perspective. Alternatively, some researchers have recently made the distinction between "active spirituality" versus "passive spirituality" (Debnam et al., 2012) in an effort to understand these dynamics. Fiori and colleagues (2004) created a "God-mediated control model" in which participants who view God as a mediator through which they have personal control have more coping and pro-active response to health problems. Factors such as viewing God as "friend or guide," requesting strength or guidance from God, and communicating with God were associated with God-mediated self-control. Alternatively, participants who feel that God wields all power or asserts his will in a non-collaborative way may have a more external God LOC. These individuals are found to have a more negative perspective on stressful events, lack of resolution when challenges arise, and more anger (Fiori, Hays, & Meador, 2004). These "God-mediated" models may better describe participants perspectives within the EMPOWER study.

Considering these alternative models and EMPOWER results, it may be that LOC would be better measured by developing a God-mediation questionnaire in the EMPOWER program that considers "active" versus "passive" faith. For example, future LOC scales may consider questions such as "I believe God gives me the strength to change my own health when I choose to do so" (internal/spiritual LOC) versus "Only God determines when my health will improve

and when it will worsen" (external/spiritual LOC). This would allow spiritual people to maintain God-focused perspective while still endorsing an internal or external LOC. In comparison, current questions on the MHLCS include "God is in control of my health" versus "the main thing that affects my health is what I do myself." While these questions capture internal versus external LOC, it does not allow for God and faith to be present in someone with an internal LOC.

One of the most intriguing, yet unexpected, findings of this study was that the EMPOWER group had significantly lower God LOC compared to the Mail group ($p = 0.014$). Specifically, EMPOWER participants were far less likely to agree with the following statements compared to Mail participants: 1) Whatever happens to my health is God's will, 2) Whether or not my health improves is up to God, and 3) God is in control of my health. Considering randomization at baseline, this raises the question: Did treatment impact God LOC? Unfortunately, this cannot be determined because God LOC was only measured at one 12-month time point. However, differences in God LOC at 12 months could reflect the CHW's encouragement of active spirituality. CHWs reported they often encouraged EMPOWER group participants to utilize their faith in a non-passive, pro-active way. For example, one CHW was known to often tell her participants, "God gives you the tools, but you've got to do the work." While not a part of the written protocol, CHWs often discouraged a passive spiritual approach to health among participants.

God LOC may also have been different between groups at 12 months because higher God LOC occurred among participants who felt less control over their health status. Participants who were in the Mail group were aware that they were not getting the more intensive EMPOWER treatment and may have "handed it over to God" until they felt they could engage in a more action-oriented program. Similarly, God LOC was higher in insulin-using participants compared

to non-insulin using participants (p = 0.031). Considering that insulin use is related to weight gain (UK Prospective Diabetes Study Group, 1998), there is likely a discrepancy between participant efforts and weight outcomes among insulin-users which participants may explain by God's will. This finding is significant considering that the insulin-using group also had poorer weight outcomes than non-insulin using participants (EMPOWER non-insulin using: M = -4.51, SD = 12.64; EMPOWER insulin using: M = +0.11, SD = 11.32; p = 0.009).

The complex influence of God LOC was again observed when assessing moderation and mediation models. Hypotheses predicted that high Internal LOC and low God LOC (i.e. patients who believe change is within their own control and not determined by an outside force as predicted by Wallston, 1992) would significantly moderate the impact self-efficacy and subjective norms on treatment outcomes. It was believed that subjective norms (pressure by important others to be motivated to engage in change behaviors), and self-efficacy (the skills and confidence to achieve behavior change) could only be effective if patients felt that they had the power and responsibility to change their own behavior. However, data revealed that this relationship did not exist when examining changes in weight, HbA1c, and medication adherence. Further, God LOC played an opposite role than predicted regarding self-care change. While it was assumed that high God LOC would reflect more external LOC attitudes, the fact that high God LOC both correlated with high self-care behaviors (p=0.009) and moderated self-care behavioral outcomes demonstrates that God LOC is related to pro-active engagement in self-care. This again reflects the observation that God LOC may have both an internal and external LOC influence.

Depression

Despite overall low rates of depressive symptoms, depression nonetheless was related to important constructs throughout the study. Most notable was that women taking insulin were more likely to endorse depressive symptoms. Further, trends show that women with higher depressive symptoms were almost significantly more likely to drop out of treatment (p=0.055). Further, depression was related to poorer self-efficacy and medication adherence among all participants. While it did not directly impact outcomes, it is important to recognize the relationship between depressive symptoms and poor predictors of diabetes management. These relationships may have been even stronger without the potential floor effect that occurred due to low overall rates of depression. Future studies should consider adding additional support for patients who endorse depressive symptoms. By reducing depressive symptoms interventionists may be able to enhance behavioral outcomes, and in turn, biological outcomes.

Behavioral Outcomes

Baseline measures indicated that participants were only engaging in diabetes-related self-care behaviors half of the time and medication adherence was overall poor. This was a troubling yet unsurprising finding considering this sample was comprised of participants with poorly controlled diabetes. The fact that both EMPOWER and Mail group participants had significant improvements in both behaviors across treatment highlights the effectiveness of both interventions. Importantly, both self-care and medication adherence were related to each other, and both were correlated with self-efficacy throughout the study. While treatment helped participants make significant changes in these behaviors, 12-month outcomes reveal room for continued improvement in these areas. Future EMPOWER programs may consider adding a follow-up program to continue to encourage improvement in these areas. Considering the

complexity of pharmacological diabetes management and the benefit the Mail group received from the glucose management educational materials, future studies may also try to further increase medication adherence by increasing education regarding diabetes medications. Further, considering the importance of influential others within this population, including friends and family in treatment may give participants the needed support to engage more readily in self-care behaviors on a daily basis.

Strengths and Limitations

Strengths of this study include the community-focused treatment delivery method and the fact that there were few exclusion criteria in order to maximize real-world applicability. Another particular strength of this study is that it targeted a significantly under-represented group of participants: Rural African American women with poorly managed diabetes. Further, both the EMPOWER and Mail treatments demonstrated the value of low-cost, low-burden interventions over the course of a year beyond that of even more intensive treatments. The fact that this is the first study to date to explore the SCM approach within this population is also an important contribution to research on theoretically oriented treatments for T2DM management. Finally, the ability to add additional measures into the 12-month assessment session allowed researchers to respond to treatment observations and explore alternative explanations of behavior change during the study, adding to the understanding of theoretical constructs that impact treatment outcomes.

There are several limitations regarding the present study. First and most importantly, LOC variables and subjective norms were only measured at one post-test time point. This was because these variables were introduced to the treatment after initial assessment of 6 month data revealed that self-efficacy was not having anticipated effects and alternative explanations were

explored. Considering the potential for these factors to be influenced across time and between groups, additional assessments of LOC and subjective norms at 0- and 6- months would have given valuable information about these factors and the impact of treatment over time. Considering the difference between groups in the endorsement of God LOC, it may be that assessing God LOC across time points would reveal important and unforeseen effects of treatment across time. While having one-time measures obviously limited our ability to determine whether treatment had an impact on subjective norms and LOC across time, our primary concern was determining whether these factors had an impact on outcomes, which we were able to assess using 12-month data.

Another major limitation was the potential confounding role of the CHW's providing support/treatment to the mail-based control group. It was noted throughout the study that CHWs often interacted with and provided additional support for Mail group participants above and beyond the treatment protocol due to their supportive dual roles in the community as church leaders, community advocates, and friends/neighbors/relatives. This was an unforeseen confounding factor that was reported by interventionists throughout the study, despite regular reminders and rationales as to why a randomized design was necessary in the present project. The extra support and guidance offered to the Mail group may have diluted differences between groups throughout the study.

Another limitation to this study may be the patient burden of assessment measures. While measures were written at the 5th grade reading level and were anticipated to take little time to complete (approximately 20 minutes), many participants took significantly longer to complete questionnaires (over an hour) and found many of the questions to be confusing or unclear. While there were always research assistants and CHWs onsite to assist participants in completing these

questionnaires, these challenges may have impacted assessment outcomes to a certain degree. Future studies should consider using shorter, easy-to-read assessment packets to reduce participant burden and assure accurate responding.

Another unforeseen challenge of this study was the difficulty of assessing LOC dimensions using the MHCLS. Although the MHCLS is the primary LOC measure used throughout the health literature, it was evident that participants in EMPOWER did not view Internal and God LOC as independent variables. A measure that considered both active and passive spirituality may have better reflected LOC in this population. Another potentially confounding variable is that results may have been artificially inflated due to social desirability. Questions about personal responsibility and faith in God like those described in the MHLCS may be difficult for participants to answer honestly when there is social pressure to respond in a certain way, particularly if they are being assisted with questionnaires by CHWs. Results may reflect a need to further consider alternative ways to measure LOC that allow for the complexity and sensitivity of the spiritual domain.

Conclusions

Overall, considering the importance of weight and sustained HbA1c change in diabetes management (Colditz et al., 1995; Coppel et al., 2010; Knowler et al., 2002; Laws et al., 2012; Lindstron et al., 2006; Sumitani et al., 2012; Thomas & Elliot, 2009) this study's results indicate promise regarding low-cost, low-burden interventions that utilize both phone and mail modalities to promote diabetes management within this population over time, particularly for those who are non-insulin using. In fact, outcomes of this study were comparable and even exceeded those of other health management trials in African American populations (Bennett et al., 2012). It is important to note that there were little differences between the EMPOWER group and the Mail

group, suggesting that an even the lowest burden treatment approach, education via mail, may be effective in promoting diabetes management over the course of a year in rural African American populations. This highlights the great need that rural African American communities may have for access to diabetes management education and support. Notably, the treatment materials for the Mail group emphasized medication management and glucose monitoring more than materials in the EMPOWER group. This may highlight the need for more education related to medication management in particular.

Considering weight gain typically associated with pharmacological management of diabetes, it is notable that the EMPOWER study led to significant and sustained weight loss across time, despite the fact that the majority of participants were using insulin to manage their glucose. Further, the fact that approximately 9.6/16 sessions were actually completed by EMPOWER group participants suggests that minimal intervention using the EMPOWER approach may still result in positive outcomes. This has important implications for a population with high attrition rates in traditional behavioral health interventions.

The EMPOWER study outcomes are important to better understand factors that influence the course of treatment. Primary results of this study suggest that self-efficacy has a lower impact on treatment outcomes and subjective norms has a higher impact on treatment outcomes than predicted by SCM and SCT. While self-efficacy is considered a primary mediator in health behavior models (Bandura ,1986; Lutes & Steinbaugh, 2010), it did not seem to be enhanced by treatment or moderate overall treatment outcomes. However, subjective norms, which is not a construct included in the current SCM, impacted diabetes self-care behaviors.

The significance of subjective norms found in the EMPOWER study may be because the subjective norms is a more influential factor in an African Americans compared to Caucasian

peers regarding health management behaviors. This is also supported in the literature. A study that assessed TPB among Caucasian, African American, and Puerto-Rican American young women found a direct relationship between subjective norms and smoking behavior for African American women, but not Caucasian or Puerto Rican counter-parts (Shirar Hanson, 1995). In line with traditional health behavior modeling, attitude and perceived behavioral control were most important for Caucasian and Puerto-Rican participants but not African American participants. Similarly, a study of multi-vitamin supplement use among African American women showed that subjective norms had the greatest influence on behavioral intention among all study variables, which in turn predicted vitamin use (Pawlak, Connell, Brown, Meyer, & Yadrick, 2005). These data in combination with EMPOWER results suggest that subjective norms are particularly important for African American women and that current health behavior models should consider these to be a key influence on not only intention to engage in behaviors but medical treatment outcomes themselves.

The way in which subjective norms are quantified in future studies is also important to consider. Literature review suggests that the measurement limitations of subjective norms may be a reason it is sometimes found to be a poor predictor of intentions (Armitage & Conner, 2001; Pasick et al., 2009). Subjective norms may have been better measured in the EMPOWER study because the subjective norms questionnaire used was created specifically to include a wide variety of possible "important others" within the participant's community. This differs from more traditional, specific, non-culturally oriented subjective norms questionnaires that assume the identities of important others (i.e. "my husband thinks I should eat healthy"). It is important to expand the scope of influential people when assessing African American women in particular, whose "important others" may include extended family, neighbors, and community members

(Pasick et al., 2009). However, the broad "important others" label used in the SNM also prevented interventionists from being able to identify specific people who are influential to participants. Future studies should address which important others are most influential for participants within this community so they may be included in future interventions.

Importantly, data showed the relationship between high subjective norm scores and diabetes self-care behaviors was greatly improved when patients endorsed high God LOC. While this was unexpected considering that God LOC is associated with an external LOC based on Wallston's research with the MHLCS, this provides important evidence that spirituality is a complex factor that has both internal and external influences that plays a role in health behavior engagement. Additional evidence that supports the need for more sensitive and multidimensional God LOC is the fact that patients in the EMPOWER group and patients who are not insulin-using had significantly lower God LOC compared to participants without supportive intervention or those on medications that induce weight gain. This may be because participants who felt less in control of their care or behavioral outcomes may be more likely to "hand it over to God" and have a strong God LOC. This may be particularly salient for participants on insulin, who may be sicker and have limited control over weight changes (Russell-Jones & Khan, 2007). Future studies should use a questionnaire that better teases apart "active" versus "passive" God LOC may allow for better understanding of these findings and more guidance in how to set up an intervention that is sensitive to spiritual perspectives of control. This is particularly important considering the impact of God LOC on self-care behavioral outcomes.

While there were not significant differences between EMPOWER and Mail groups, this may be partially explained by the fact that CHWs interacted with Mail participants more than anticipated and provided support beyond the treatment protocol. CHWs initially enrolled Mail

participants, introduced them to the program, and gave them their initial materials. In addition, CHWs often play dual supportive roles in the community. These interactions may have led to peer-support bonds with the Mail group beyond treatment that allowed for Mail group participants to gain additional support from them throughout the year. Future studies that utilize CHWs should try to control for these interactions between CHWs and comparison groups as much as possible.

While this study has allowed for an initial exploration of factors that contribute to behavior change in the EMPOWER program, these factors should be assessed to a greater length in future studies. Next steps should include assessing subjective norms and LOC across time to better understand how they impact treatment outcomes. Further, alternative LOC measures that consider both active and passive God LOC should be used. When designing future interventions for African American women, interventionists should carefully monitor and provide referral or treatment options for participants endorsing high rates of depression considering that depression is related to treatment engagement and important predictors of poor treatment outcomes. In summary, it is evident throughout the literature that African American women have different responses to T2DM interventions compared to Caucasian counterparts. Future interventionists should strive to bridge this gap by altering or creating new behavior change models with relevant theoretical constructs that better serve this under-represented group.

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APPENDIX A. Institutional Review Board Approval

EAST CAROLINA UNIVERSITY
University & Medical Center Institutional Review Board Office
1L-09 Brody Medical Sciences Building• 600 Moye Boulevard • Greenville, NC 27834
Office 252-744-2914 • Fax 252-744-2284 • www.ecu.edu/irb

TO: Doyle Cummings, PharmD, Department of Family Medicine, ECU, Mailstop #728

FROM: UMCIRB

DATE: July 22, 2011

RE: Expedited Category Research Study

TITLE: "Empowering Rural African American Women and Communities to Improve Diabetes Outcomes"

UMCIRB #11-0418

This research study has undergone review and approval using expedited review on 6/29/11. This research study is eligible for review under an expedited category number 7 which includes research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.). The Chairperson (or designee) deemed this **Bristol-Meyers Squibb Foundation** sponsored study **no more than minimal risk** requiring a continuing review in **12 months**. 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 above referenced research study has been given approval for the period of **6/29/11** to **6/28/12**. The approval includes the following items:

- Internal Processing Form
- Grant application
- Informed consent (dated 4/19/11)
- COI disclosure form (dated 6/21/11)
- Demographic questionnaire
- Diabetes distress scale
- Weight, nutrition and physical activity questionnaire
- Life questionnaire
- Self assessment questionnaire

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

The UMCIRB applies 45 CFR 46, Subparts A-D, to all research reviewed by the UMCIRB regardless of the funding source. 21 CFR 50 and 21 CFR 56 are applied to all research studies under the Food and Drug Administration regulation. The UMCIRB follows applicable International Conference on Harmonisation Good Clinical Practice guidelines.

APPENDIX B: The CES-D

EMPOWER! PROJECT

CENTER FOR EPIDEMIOLOGIC STUDIES-DEPRESSION SCALE (1 of 2)

STUDY ID #:	**COUNTY:**	**DATE:**

For each of the following statements circle how often you felt or behaved this way during the PAST WEEK.

1. I did not feel like eating; my appetite was poor.

0 Hardly ever or never *1 Some of the time* *2 Much or most of the time*

2. I felt depressed.

0 Hardly ever or never *1 Some of the time* *2 Much or most of the time*

3. I felt that everything I did was an effort.

0 Hardly ever or never *1 Some of the time* *2 Much or most of the time*

4. My sleep was restless

0 Hardly ever or never *1 Some of the time* *2 Much or most of the time*

5. I was happy

0 Hardly ever or never *1 Some of the time* *2 Much or most of the time*

6. I felt lonely

0 Hardly ever or never *1 Some of the time* *2 Much or most of the time*

CENTER FOR EPIDEMIOLOGIC STUDIES-DEPRESSION SCALE (1 of 2)

7. People were unfriendly

0 Hardly ever or never *1 Some of the time* *2 Much or most of the time*

8. I enjoyed life

0 Hardly ever or never *1 Some of the time* *2 Much or most of the time*

9. I felt sad

0 Hardly ever or never *1 Some of the time* *2 Much or most of the time*

10. I felt like people disliked me

0 Hardly ever or never *1 Some of the time* *2 Much or most of the time*

11. I could not "get going"

0 Hardly ever or never *1 Some of the time* *2 Much or most of the time*

APPENDIX C: The SNM

SUBJECTIVE NORMS

1. Most people who are important to me think that I should eat healthy

1	2	3	4	5
Strongly Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Strongly Agree

2. Most people who are important to me think that I should exercise

1	2	3	4	5
Strongly Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Strongly Agree

3. Those close to me expect me to eat healthy most days

1	2	3	4	5
Strongly Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Strongly Agree

4. Those close to me expect me to exercise regularly

1	2	3	4	5
Strongly Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Strongly Agree

5. The people in my life whose opinions I value eat healthy

1	2	3	4	5
Strongly Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Strongly Agree

6. The people in my life whose opinions I value exercise regularly

1	2	3	4	5
Strongly Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Strongly Agree

7. Those who are closest to me eat healthy

1	2	3	4	5
Strongly Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Strongly Agree

8. Those who are closest to me exercise regularly

1	2	3	4	5
Strongly Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Strongly Agree