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**Biopsychosocial Outcomes of a Resilience and Diabetes Self-
Management Education Intervention in African American Adults
with Type 2 Diabetes**

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with Type 2 Diabetes**

by

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Dedication

First, and most importantly, I dedicate this work to Jesus Christ, who continually directs my path. “He does not grow weary, and His knowledge is beyond scrutiny...They that hope in the Lord will renew their strength, they will soar with eagle’s wings; they will run and not grow weary...” *Isaiah 40: 28-31*.

I must also dedicate this work to Dutch Schroeder who has been a one of a kind mentor! Thank you for all your help, advice, letters of recommendation, and years of friendship. I especially thank you for strengthening my presentation skills during my undergraduate days at Baylor-- you just never know when you’ll need to remain poised during a public lecture! But most of all, thank you for the many encouraging words and prayers throughout the years. You were a well needed supporter when times were difficult and served as a constant reminder of my Baylor roots!

Finally, I dedicate this work to Cha Cha Lee Chihuahua, my dog. You are the ‘person’ I neglected the most over the last five years, but you were my most supportive and comforting friend throughout this entire journey.

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Madonna Marie Mamerow, PhD
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Type 2 diabetes (T2DM) currently affects more than three million African American adults with double the number expected by 2025. The most effective and safest treatment for T2DM is lifestyle change therapy, including healthful eating, monitoring of blood glucose, and physical activity. However, current lifestyle change interventions are limited in their scope to alter the behaviors of individuals to more healthful ones. These limitations may be attributed, in part, to a lack of attention given to enhancing an individual's psychosocial process variables, such as resilience, coping skills, self-leadership, and empowerment. Incorporating resilience education into lifestyle change therapies is a novel approach that addresses the behavior modification limitations of

current interventions by aiming to enhance psychosocial process variables. Therefore, the purpose of this project was to conduct a six-month pilot study to determine the feasibility of our resilience and diabetes self-management intervention, *The Diabetes Coaching Program: Transforming Lives Through Resilience Education*, in a convenience sample of African American adults (n=16) with T2DM. The intervention included four weekly resilience and diabetes education classes and eight bi-weekly support group sessions. Survey data and blood samples were collected at baseline and at six months. Twelve participants completed the study (75% retention). Results indicated that higher perceived stress scores were associated with less resilience, fewer adaptive coping skills, lower self-leadership, lower diabetes empowerment and greater depressive symptoms. However, diabetes empowerment was the only psychosocial process variable to be significantly enhanced by the intervention at six months. Weight, BMI, HbA_{1c}, total cholesterol, LDL cholesterol, blood pressure, and IGF-1 levels were significantly decreased at six months, whereas, lymphocyte proliferation and physical activity were significantly increased. These data indicate that our intervention has the potential to improve diabetes self-management among African Americans with T2DM and increase positive health outcomes, though further studies are needed to confirm these findings. Additionally, several lessons were learned from conducting the pilot study that may be useful for improving the intervention for future studies, including: recruitment and retention strategies; cultural competency issues; the use of complementary and alternative medicine practices by African Americans with T2DM; and approaches for increasing participant self-assessment and goal-setting.

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List of Commonly Used Acronyms

Brief COPE:	Brief Coping Orientations to Problems Experienced Scale
CD-RISC:	Connor-Davidson Resilience Scale
CES-D:	Center for Epidemiologic Studies Depression Index
CRP:	C-reactive protein
CVD:	cardiovascular disease
DES:	Diabetes Empowerment Scale
FBG:	fasting blood glucose
HbA_{1c}:	hemoglobin A _{1c}
HDL:	high density lipoprotein
IGF-1:	insulin-like growth factor 1
LDL:	low density lipoprotein
PANAS:	Positive and Negative Affect Schedule
PBMC:	peripheral blood mononuclear cells
PSS:	Perceived Stress Scale
SES:	Socioeconomic Status
SLS:	Self-Leadership Scale
T2DM:	type 2 diabetes mellitus
TG:	triglyceride

Chapter 1

Review of Literature

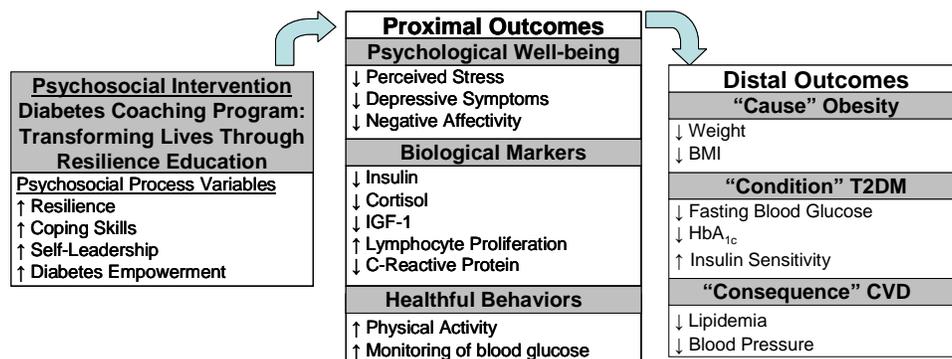
1.1 Overview

African Americans are at high risk for the development type 2 diabetes (T2DM), displaying a 1.8 times higher rate than non-Hispanic whites (13). Statistics show that T2DM is typically preceded by obesity and results in a 2 to 4 times higher rate of cardiovascular disease (CVD) (121). Currently, 70% of African Americans are overweight and 40% are obese, which is much higher than the general population at 61% overweight and 26% obese (13). Likewise, CVD is currently the leading cause of death among African Americans (3). More interestingly, these disorders are highly correlated with a cluster of metabolic abnormalities including abdominal obesity, insulin resistance, hyperglycemia, dyslipidemia, and hypertension (2), which have been collectively labeled as the metabolic syndrome. The most effective and safest treatment for the metabolic abnormalities associated with T2DM is lifestyle change therapy (109), including healthful eating, monitoring of blood glucose, and physical activity. These lifestyle changes are the foundation of proper diabetes self-management. However, the prevalence of T2DM continues to increase (164, 244). Therefore, Healthy People 2010 stresses the need for more effective interventions to be developed and implemented that address the behavior modification limitations of current interventions (5).

Research shows that 40% of individuals with T2DM report poor psychological well-being and 85.2% report diabetes-related emotional distress (181), which are highly correlated with poor self-directed diabetes care and quality of life (66, 82, 124, 151, 162,

185). Furthermore, African Americans report greater levels of perceived stress and depression than non-Hispanic whites (132). Therefore, helping African Americans to effectively cope with daily stressors and the adversities of living with a chronic illness such as T2DM may improve adherence to diabetes self-management regimens and overall health outcomes. As outlined in Figure 1.1, we propose resilience education as a supplement to standard diabetes self-management education in an effort to enhance the psychosocial process variables of resilience, coping skills, self-leadership, and diabetes empowerment to generate improvements in psychological well-being (i.e. perceived stress, depressive symptoms, and negative affectivity), biological markers (i.e., insulin, cortisol, IGF-1, lymphocyte proliferation, and CRP), and healthful behaviors (i.e., adherence to physical activity and monitoring blood glucose). With improvements in the above variables, we also anticipate a reduction in the metabolic risk factors associated with the disease progression of obesity (i.e., weight, BMI), T2DM (i.e., fasting blood glucose, HbA_{1c}, and insulin sensitivity), and CVD (i.e., lipidemia and blood pressure).

Figure 1.1. Conceptual Model of Intervention and Proposed Outcomes



1.2 Objectives

The *primary objective of this project* was to conduct a six-month pilot study to determine the feasibility of a resilience education and diabetes self-management intervention in African American adults with type 2 diabetes. Therefore, the study aimed to answer the following research questions:

- 1) What are the effects of the intervention at six months on the psychosocial process variables of resilience, coping skills, self-leadership, and diabetes empowerment?
- 2) What are the effects of the intervention on the psychological, biological, and behavioral factors potentially involved in the development and progression of T2DM at six months?
 - i) Psychological: perceived stress, depressive symptoms, negative affectivity
 - ii) Biological: insulin, cortisol, insulin-like growth factor-1 (IGF-1), peripheral blood mononuclear cell proliferation (PBMC), and C-reactive protein (CRP)
 - iii) Behavioral: physical activity, monitoring of blood glucose
- 3) What are the effects of the intervention on the metabolic risk factors associated with the disease progression of obesity, T2DM, and CVD at six months?
 - i) Obesity: weight, BMI
 - ii) T2DM: fasting blood glucose, glycosylated hemoglobin, insulin sensitivity
 - iii) CVD: blood pressure, dyslipidemia

The objectives of this research project are consistent with priority health promotion and disease prevention objectives of Healthy People 2010 and address a major public health concern for African American adults. Specifically, the study addresses

Focus Area 5 of Healthy People 2010, to reduce the burden of diabetes and improve the quality of life for those who have diabetes (244). To the investigator's knowledge, this is the first study ever conducted to evaluate the effectiveness of resilience education on improving adherence to self-management of type 2 diabetes in African American adults and addresses the behavior modification and empowerment limitations of current diabetes self-management programs implemented in ethnic minority populations as well as the psychological aspects of living with a chronic illness. This study also builds upon past research that has evaluated the impact of the stress response on hormonal alterations and immune function in relationship to chronic disease development and progression (141) by assessing the effects of the health education intervention on the endocrine and immune systems. Therefore, the conceptual framework of this study was designed with the expectation of generating a vast range of positive health outcomes to improve the overall quality of life for individuals experiencing the curriculum.

1.3 Background

Diabetes Self-Management Interventions

Over the last three decades, increased attention has been given to diabetes self-management programs in an effort to prevent, manage, and/or impede the progression of T2DM. Past intervention programs have utilized a variety of techniques and strategies to improve self-management, including: knowledge and skill development, dietary recommendations, physical activity, behavioral and cognitive strategies, pharmacological therapy, as well as various combinations of the above strategies (123). Meta-analyses support the effectiveness of diabetes self-management education in the short-term (<6 months) on knowledge, self-reported dietary habits, and glycemic control (104). However, studies that had follow-up periods longer than one year had mixed results, as well as methodological concerns related to internal (e.g., selection, attrition) and external validity (104). Likewise, the effectiveness of interventions on body weight, physical activity, blood pressure, and lipids are more variable (169). Because T2DM is a chronic condition, interventions that produce long-term adherence are essential. Meta-analyses suggest that both short- and long-term studies have focused too narrowly on knowledge and glycemic control at the exclusion of important psychosocial process variables that may offer insight into the mechanisms that affect diabetes self-management and other quality of life outcomes such as reducing CVD (100). To address these concerns, recent trends in diabetes self-management research have shifted from didactic presentations to more patient “empowerment” approaches in an effort to produce greater long-term adherence to positive behavior changes (20, 22, 93, 95). The patient empowerment approach aims to enable individuals to take more control of decision-making

responsibilities for their own health care. Therefore, diabetes self-management education has evolved to provide more individualized outpatient education and coaching within community settings that focus on helping individuals develop skills and self-awareness for goal setting, problem solving, stress management, coping, social support, and motivation (25).

Cultural Competence and Diabetes Self-Management Education

Although diabetes self-management education has demonstrated promise for producing positive lifestyle changes and improved blood glucose control, traditional self-management approaches have proven to be ineffective among ethnic minority groups due, in part, to culturally inappropriate education curriculums (45, 138, 257). For instance, traditional self-management approaches typically fail to incorporate important cultural issues such as a group's beliefs, values, customs, traditional foods, dietary patterns, language, literacy levels, socioeconomic status and availability of resources. Overlooking important cultural characteristics such as these has hindered the empowerment process for proper diabetes self-care among ethnic minority patients (46). Unfortunately, however, many ethnic minority groups have been inaccurately labeled as 'non-compliant' to diabetes self-management regimens and continue to be underrepresented in clinical trials. Increasing efforts have been made in recent years for the development of more culturally competent diabetes self-management programs, and an increase has been witnessed in the number of studies investigating culturally appropriate approaches for specific minority groups. Literature has identified several important cultural considerations for diabetes self-management interventions when

working with African American adults, including: low socioeconomic status (SES) and lack of resources (101); low literacy levels (256); a high prevalence of depression and chronic stress (96); a general mistrust of health care professionals (155, 190); the importance of the church setting (236, 242); and dietary behaviors (16).

U.S. Census data indicates that African Americans are overrepresented among the poor with nearly 25% falling at or below the poverty line (71). Likewise, approximately 19.7% lack health insurance and are burdened with limited access to medical and mental health care (71). Since access to health care is limited, many cannot afford the necessary blood glucose testing supplies or regular medical check-ups with a health care professional. In addition, many tend to rely on close friends, family members and their religious community rather than mental health professionals during times of emotional distress (6). Low SES is also typically correlated with lower education and literacy levels which have also been associated with poorly controlled diabetes (200). Lack of education and low literacy are known to affect one's ability to read and understand prescription drug labels as well as acquire disease-specific knowledge, thereby increasing the risk for hospitalization and poor health outcomes (4, 256). Low SES is also correlated with high levels of perceived stress among African Americans (241). Research indicates that stress typically precedes depression, and depression is also strongly correlated with African American ethnicity and low SES. Moreover, the cumulative effects of stress, depression, and low SES are reported to severely increase the risk for the development of T2DM and CVD among African Americans (67) and may play a significant role in self-care behaviors and health outcomes when implementing a diabetes self-management intervention.

A general mistrust of health care professionals is also witnessed among African Americans. Trust is a multidimensional construct that is described as the expectation that medical care providers will act in the patient's best interest, and is dependent upon the provider's technical expertise and interpersonal skills and the patients perceptions that their welfare is of great importance to the provider (110). Reduced trust can affect adherence to medical treatments as well as the length and quality of relationships between the patient and the health care provider (110). In a study by Halbert, et. al., 44.7% of African Americans report low levels of trust in health care professionals than do their white counterparts (110). Lack of trust among African Americans has been linked to prior dissatisfactory interactions with health care providers (110); communication barriers with health care providers (159); low SES (110); the historically high averages of institutionalization among African Americans with mental illness (137); and previous mistreatments in such tragic events as the Tuskegee syphilis study (116). However, African Americans report greater trust when the health care provider is of the same race (110). Yet, there are fewer minority health care professionals nationally than whites. Mistrust of health care professionals contributes to the relative isolation of African Americans and therefore lower acquisition of general health care information. As a result, many African Americans have not gained the full benefits of the aggressive public education campaigns on diabetes and mental health issues in recent years. Likewise, mistrust of health care professionals may partly explain why African Americans initially rely on close friends, family, and clergy when coping with medical and mental health care concerns.

One campaign that has been successful in distributing information to African Americans about diabetes is the African American Diabetes Initiative Program sponsored by the American Diabetes Association (220). Since the church is known to play an important role in the lives of African Americans, this program utilizes the church setting to increase awareness about the seriousness of diabetes, the risk factors involved, and to inform church members about the resources available. Therefore, churches may be a good setting for the implementation of diabetes self-management interventions with African Americans. Utilizing resources participants have available to them in their community (e.g., churches, high school tracks, nature trails, community pools, etc.) may also increase the long-term effectiveness of interventions as well as the cost effectiveness. Likewise, Tedeschi and Kilmer state that knowledge and use of community resources are important factors for enhancing empowerment and adaptation to adversity (235). These concepts are congruent with the chronic care model (36, 37, 183, 222) and current literature on patient empowerment (20, 92) in that they concentrate on the individual developing the skills and knowledge one needs to make healthy lifestyle choices rather than the need for expensive gym memberships, personal trainers, and nutritionists that would not be practical or feasible for someone of low socioeconomic status.

Finally, research indicates that southern African Americans with T2DM report the most difficulty with dietary self-management (16). Because meals are often associated with social events among African Americans, culturally competent self-management interventions should incorporate African American food traditions as well as attempt to involve family members and friends (15). The preferred diet of southern African

Americans usually includes southern cuisines and “soul foods” which are typically high in saturated fat, cholesterol, and salt. In order to retain cultural traditions, the ADA recommends creating simple meal plans for teaching African Americans how to modify southern cuisines and “soul foods” to lower saturated fat, cholesterol, and salt content (16). Simplifying meal plans is important since many African Americans tend to report dissatisfaction with using complicated exchange lists to plan meals (261). In a study by Ziemer, et. al., a meal plan system emphasizing healthy food choices was found to be equally as effective as using an exchange based meal plan in urban African Americans with T2DM (261). Ethnic food models have also shown promise as a successful mechanism for teaching portion control and carbohydrate counting (15). Taken together these recommendations may facilitate greater long-term improvements in dietary self-management among African Americans.

Potential Cost Savings

In 2007 the annual economic cost of diabetes in the United States was approximately \$174 billion (1). Complications from diabetes, such as cardiovascular disease, accounted for approximately \$58 billion of the direct medical costs. Indirect costs accrued another \$58 billion due to work days lost, disability, restricted activity, or death. Annual per capita health care costs for individuals with diabetes were \$11,744 per individual in 2007. In contrast, annual medical expenditures for individuals without diabetes was approximately 2.3 times lower than those with diabetes (1).

There is evidence suggesting that lifestyle interventions far dominate pharmaceutical treatment in regard to cost effectiveness and prevention of diabetes. For

example, the Diabetes Prevention Program (DPP), determined that lifestyle interventions delayed the development of T2DM in pre-diabetic individuals by 11 years whereas pharmaceutical therapy with metformin delayed development by only 3 years. This amounts to an approximate cost of \$1,100 per quality adjusted life-year (QALY) for the lifestyle intervention and \$31,300 per QALY for the pharmaceutical intervention (115). However, a limited amount of data exists regarding the economic cost-effectiveness of diabetes self-management interventions for those currently diagnosed with diabetes. This is due to insufficient accounting of costs in past studies as well as an inability to properly compare studies because of the diversity among diabetes self-management intervention approaches and outcomes (129, 168).

Many studies advocate that diabetes self-management is more cost-effective in the long-term than pharmacological therapies due to a reduction in adverse events, diabetes-related complications, and hospitalizations (68, 191). Yet, meta-analyses of published intervention research indicate that less than 10% of all individuals with diabetes are able to successfully adhere to diabetes self-management programs and resort to managing their diabetes primarily with pharmacological treatments that are less effective over time and have more side effects (168). Likewise, many health care providers may rely on drug therapies simply because they are more convenient to implement than trying to promote lifestyle changes among patients (155). In order for cost savings to be retained long-term for those with diabetes, further research is needed to determine cost-effectiveness as well as how to improve diabetes self-management interventions to promote long-term adherence, in particular for ethnic minorities.

Important Psychosocial Process Variables

In an effort to gain more information for improving diabetes self-management programs, researchers have begun to assess the differences between individuals who maintain proper glycemic control and those who do not. Several diabetes self-management interventions and diabetes prevention programs noted important psychological determinants that predicted positive health outcomes (124, 125, 201). For example, the Diabetes Prevention Program (DPP) noted that greater readiness for change and higher diet and exercise self-efficacy correlated with better results at one year and 3-year follow-up (70). Another study identified African American individuals with higher internal locus of control (i.e., those who believe their behavior is guided by personal decisions and efforts) to have better metabolic outcomes than those with high external locus of control (i.e., those who believe their behavior is guided by external circumstances) (113). Several studies have reported that social support groups in combination with diabetes education resulted in improved psychological well-being and better glucose control than diabetes education alone (66, 105, 213). In another study, African Americans with greater problem-solving coping skills had better glycemic control (116). A resilience and diabetes education intervention conducted by Bradshaw and colleagues found that intervention participants had higher levels of resiliency at six months, as indicated by knowing positive ways of coping with diabetes-related stress than control subjects (41). These theory-based interventions focused on the individual and identified potentially important psychosocial variables that may help to explain the mechanism by which individuals adhere to diabetes self-management regimens and maintain better glycemic control. Prior to a complete understanding of this mechanism

we must first determine whether psychosocial process variables can be improved in individuals with T2DM. Thus, the first objective of this study is to test whether our resilience and diabetes self-management intervention can enhance psychosocial process variables.

One psychosocial process variable of interest in this study is resilience, which is described as the process of being able to cope with change and stressful life situations in ways that maintain healthy levels of psychological and physiological functioning despite disruption or chaos (50). This is not to say that resilient individuals do not feel stressed, upset, disturbed, or unhappy about the occurrence of an adverse event, but rather, their reactions to stress do not interfere with their ability to continue functioning in their daily lives. The construct of resilience is part of the “positive psychology” movement and presents a paradigm shift in the literature away from problem-oriented and disease-oriented models toward understanding the strengths and virtues that aid individuals to grow and thrive in the face of change and adversity. Since living with a chronic illness such as diabetes can be very stressful and adjustments must be made to an individual’s lifestyle in order to properly manage T2DM, interventions that foster resilience may help to promote long-term adherence to diabetes self-management and improve overall health outcomes and quality of life.

A great deal of research has been conducted to determine the characteristics of resilient individuals. Several positive character strengths identified by the literature that correlate with resilience include, but are not limited to: optimism, hope, positive affect, happiness, faith, determination, wisdom, gratitude, forgiveness, hardiness, problem-solving skills, and responsibility (238). However, it is necessary for researchers to

distinguish the traits that are outcomes of resilience from those that produce resilience through moderating or mediating resistance to stress by enhancing adaptive behaviors. For instance, Kobasa's work in regard to hardiness, which has been operationalized as high life stress with a low rate of illness, found that one's sense of commitment, challenge, and control were the protective factors that mediated the positive adaptations and resistance to stress (135). Other possible protective factors that may mediate or moderate resistance to stress include, but are not limited to: self-esteem, self-efficacy, social support, a sense of empowerment, positive life events, self-leadership, and adaptive coping strategies (166, 204).

In evaluating the dynamic process of developing resilience, assessing an individual's coping skills becomes a very important psychosocial process variable to evaluate. Coping is defined by Lazarus and Folkman as "constantly changing cognitive and behavioral efforts to manage specific external and/or internal demands that are appraised as taxing or exceeding the resources of the person – p. 141 (140)." Research indicates that adaptive coping strategies strongly correlate with beneficial psychological and physiological health outcomes (140, 166, 227). Adaptive strategies include problem-focused coping and rational reappraisals (140). Problem-focused coping involves directing activities toward minimizing the impact of the stressor and leads to the belief that the stressor is controllable. Problem-focused coping may include other adaptive coping strategies such as seeking social support, planning, and active coping. Rational reappraisal is a concept drawn from the transactional model of stress and coping in an effort to minimize perceived threats (140). In this model, objective environmental events, or stressors, require an adaptive response from the individual. The adaptive response

elicited is dependent upon a series of primary and secondary appraisals. During the primary appraisal, the individual assesses the potential threat posed by the event; judging its significance as 1) positive, challenging, and controllable; 2) negative, threatening and stressful; or 3) irrelevant. Then a secondary appraisal occurs in which personal strengths or resources are assessed that may help resolve or manage the event. Rational reappraisals are well established in the literature as contributors to enhancing stress-tolerance (140). In evaluating coping strategies among African American T2DM patients, those with higher scores on problem-solving coping and social support are reported to have better glycemic control than those using maladaptive coping strategies (41, 66, 67, 82, 116, 185, 239).

Maladaptive coping strategies include emotion-focused coping strategies such as avoidance, denying, blaming, and wishful thinking (49) (27). For instance, denying and blaming are considered to be dysfunctional because it often leads to alienation by others and thereby reduces social support. Likewise, blaming oneself and being overly critical of the self can lead to reduced self-esteem. Wishful thinking is considered maladaptive because it usually results in not managing the stressful situation or irrational and unrealistic approaches for coping with the stressor. Maladaptive coping strategies have often been associated with higher levels of perceived stress, depression, negative affect, and lower quality of life in breast cancer patients (52). However, Lazarus makes the clear point that classifying the discrete actions of problem-focused or emotion-focused coping as either completely adaptive or completely maladaptive is problematic because all strategies have an adaptive potential for coping with stress (140). For instance, emotion-focused and avoidance coping may be considered adaptive coping methods in low-

control short-term situations. Likewise, in highly uncontrolled chronic diseases, such as cancer, short-term denial is often found to be an effective tool for readjustment to certain aspects of being diagnosed with the disease (157). However, in chronic diseases that are controllable, such as T2DM, using maladaptive coping strategies are most likely adverse for achieving optimal health and well-being. Therefore, one must consider the situational characteristics and variables involved in the presiding stressor.

Several scales have been developed to assess coping, a few of which include: the Ways of Coping (87), Multidimensional Coping Inventory (79), the Coping Strategies Inventory (237), and the COPE inventory (53). Each of these scales evaluates adaptive and maladaptive coping responses. In this study we utilize the Brief COPE scale which is a shortened version of the COPE inventory (51). The Brief COPE consists of 14 scales of two items each which measure active coping, planning, positive reframing, acceptance, humor, religion, emotional support, instrumental support, self-distraction, denial, venting, substance abuse, behavioral disengagement, and self-blame. We selected the Brief COPE as compared to other inventories to minimize the time demands required of subjects and because of its multiple measures for both problem-focused and emotion-focused coping strategies.

Many researchers have concluded that resilience is a process that can be taught to individuals and is not necessarily a trait that an individual is born with or without (253). This notion is reiterated by the fact that personality traits are believed to remain constant over time, whereas resilience is modifiable (8). Therefore, many clinicians have developed resilience education programs based upon the empirical research surrounding stress and coping. The aim of resilience education is typically threefold: 1) to help

individuals enhance their protective factors by improving their adaptive coping skills and positive character strengths and reducing maladaptive coping behaviors; 2) to reduce perceived threat and increase perceived coping resources; and 3) to help individuals identify and maximize the motivating force that empowers one to seek harmony and thus achieve growth and thriving (193).

Several reliable and valid instruments have been developed to assess the effectiveness of resilience education in adults, which include the Baruth Protective Factors Inventory (BPFI) (31), Brief Resilience Coping Scale (BRCS) (225), Connor-Davidson Resilience Scale (CD-RISC) (58), Dispositional Resilience Scale (DRS) (30), Resilience Scale (RS) (248), and Resilience Scale for Adults (RSA) (91). Each of these scales uses a self-rated Likert scale to evaluate resilience or resilient aspects by determining either personal protective factors and protective resources (31, 248), adaptive coping skills (225), dimensions of hardiness (30), or by distinguishing between high and low resilient individuals (58). For purposes of this research project, the CD-RISC was selected to evaluate resilience due to its more conclusive quantification of resilience. For instance the CD-RISC draws its content from a number of studies, including: evaluations of hardiness from the work of Kobasa (135); evaluations of patience and tolerance of negative affect from the work of Lyon (145); evaluations of optimism and faith from the works of Connor and Davidson (58); and from the work of Rutter, social support, goal-setting, self-efficacy, the strengthening effects of stress, the effects of past successes, realistic views of control and choice, humor, adaptability to change, and the use of action oriented approaches are assessed (204).

Interventions to improve resilience have been evaluated in children, older adults, trauma victims, patients with chronic illness, and college student populations, as well as in workplace settings (193, 227). In many studies resilience education was found to improve psychosocial traits, purpose in life, and workplace performance and has decreased perceived stress, depression, symptoms of illness, and sick-days lost (193). In fact, previous research has shown that a theory-based resilience education intervention, *Transforming Lives Through Resilience Education*, was effective in reducing stress, depressive symptoms, and symptoms of illness, and increasing effective coping strategies in college students (227, 229). Yet, few studies have examined the effects of resilience education in minority populations with chronic illnesses. Recently, a resilience education approach was used to improve health outcomes in individuals with T2DM who had previously received standard diabetes education (40). This study found that resilience education significantly promoted higher levels of resilience, as evidenced by improved coping skills, improved diabetes empowerment, having fun in life, healthful eating, and physical activity, and significantly reduced diabetes-related stress in the intervention group as compared to the control group at six months (41). However, the study was unable to significantly improve glycosylated hemoglobin scores and waist measurements at six months. This study also did not include African American subjects in the study population though other races were represented. Given these data and the fact that African Americans experience high levels of perceived stress, resilience education simultaneously administered with standard diabetes self-management education may help low SES African Americans with T2DM to enhance their level of resilience and improve their adherence to healthful behaviors.

A psychosocial process variable that has been correlated with problem-focused coping and resilient behaviors is the concept of self-leadership. Self-leadership in this study is based on the Internal Family Systems model, which identifies an individual as possessing an internal community or “family” of multiple subpersonalities (e.g., the achiever, the caretaker, the critic) that are directed by a core Self (210). An example of the internal family organization is perhaps best provided by Dolbier, et.al. which illustrates the internal family as being structured similarly to other organizations, such as a school or corporation, “functioning best when leadership is clearly designated, respected, fair, and capable – p. 469 (72).” However, many times certain subpersonalities are forced into more extreme roles than necessary, usually as a result of emotional pain or stress, which causes the parts of the internal system to struggle with one another.

Three subpersonalities highlighted by the IFS model are the “managers,” the “exiles,” and the “firefighters.” The manager subpersonality is important for helping individuals maintain control over their internal and external environments and is considered to be a strategic planner that helps to minimize the activation of exile subpersonalities. Exile subpersonalities are the vulnerable parts of the self system that typically hold the pains of past experiences and are sequestered away by the managers for the exile’s protection as well as for the protection of the self. Firefighter subpersonalities are considered to be the protectors and work to calm the exiles as quickly as possible by acting impulsively. Firefighter subpersonalities may also rely on a counter stimulus to override the emotions presented by the exiles, commonly through the use of alcohol, food, drugs, work, and sex. However, when the self is leading, the various subpersonalities operate together more harmoniously and the individual progressively

experiences feeling more centered and calm and thus has a greater sense of well-being. Therefore, the Self can be thought of as our core identity that is not attached to any specific agenda and provides a safe and nurturing environment within us.

Instruments that have been used to evaluate self-leadership include the Internal Family Systems Scale (IFSS) (211), the Core Wellness Scale (CWS) (10), and the Self-Leadership Scale (SLS) (228). Other measures include various scales to assess self-efficacy and self-esteem. The IFSS evaluates how extreme the various subpersonalities are and gives a valuable profile of the individual. The other two scales evaluate an individual's perception of a secure sense of self or the positive qualities that are present in an individual when the self is leading. In this study we use the SLS which is a 20-item scale that measures the frequency of experiencing such statements as "I feel a sense of inner peace" and "I treat myself with kindness." This measure was selected because it has been previously validated as a reliable measure when assessing self-leadership in relationship to stress, coping, resilience and health outcomes (72).

Research assessing the self in relation to stress management and health outcomes indicates several beneficial results for those with high self-leadership. For instance, a study by Dolbier et. al. (72) indicated that higher levels of self-leadership were significantly correlated with effective coping skills, greater optimism and hardiness, less interpersonal distrust, increased perceived wellness, less perceived stress, and fewer symptoms of illness in college students. Other studies also suggest that threats to the self or one's image of the self can be very stressful and can affect health outcomes. For instance, many African American men diagnosed with T2DM reported that having diabetes decreased their self-esteem (143). Similarly, women with diabetes reported that

struggling with multiple responsibilities created challenges in relationship to the self which affected their management of diabetes and overall quality of life (179). This is noteworthy because low self-esteem is reported to make coping with diabetes more difficult and is associated with poor glycemic control (124). However, improving physical activity, nutrition habits, and increasing social support have been found to foster improvements in self-esteem (70). Likewise, studies regarding self-efficacy in diabetes self-management have found that higher self-efficacy scores are associated with better dietary behaviors, increased physical activity, greater self-monitoring of blood glucose, and proper foot care (207) as well as greater health literacy levels (207). Furthermore, a study conducted with low-income African Americans with T2DM suggested that low self-efficacy may be an even greater barrier in achieving proper physical activity levels than environmental barriers (75). Therefore, improving one's self-leadership may help to minimize diabetes-related distress that may threaten the esteem of individual subpersonalities through creating more harmonious relationships within the IFS system.

Empowerment is a final psychosocial process variable that is evaluated in this study and is considered to be one of the driving forces that promotes resilience. Empowerment is defined as the process of enabling an individual or group to make informed decisions and transform those decisions into desired actions and outcomes (93). In the traditional medical model, health care providers are typically viewed as the sole decision-makers and the responsible party in the treatment and care of their patients. However, with the rise in chronic illnesses such as diabetes, more emphasis is being placed on promoting patient independence in an effort to maximize the patient's potential for achieving optimal health and well-being. This paradigm shift in the medical model

acknowledges that the patient is the one who lives with the consequences of treating the disease on a daily basis and must be given the right to be the primary decision-maker regarding medical treatment (103). To enhance empowerment, the health care provider's role is to supply the patient with the necessary information and guidance to make informed decisions regarding illness behaviors. In this regard, the patient acts as a fully participating member of the health care team by sharing responsibility in his or her treatment plan (84, 103).

Many diabetes educators agree that enabling patients to become more empowered begins with the patient acquiring information and therefore should be viewed as an outcome of the education process (93). Yet, traditional diabetes self-management education has overlooked the emotional, spiritual, social, and cognitive aspects of living with diabetes (25) which may affect an individual's level of empowerment. Therefore, diabetes educators have begun to incorporate information to help individuals develop skills and self-awareness in stress management, coping, social support, goal-setting, problem-solving, and motivation (25). Likewise, individuals with diabetes are also being educated about how to utilize the health care system and other community resources that may assist them with their diabetes management (93).

Motivational interviewing techniques are also used to increase empowerment by helping healthcare providers gather more information about the patient and their lifestyle so that diabetes self-care regimens can be tailored according to the individual's specific needs and circumstances (197). For instance, patients may be asked to discuss their typical day so that individualized recommendations can be made that consider the patient's lifestyle. Diabetes educators may also ask the individual to discuss his or her

health beliefs about diabetes so that the true nature of the disease can be discussed if there are any misconceptions presented. As well, patients can be advised about any changes or modifications needing to be made in their health care practices or lifestyle choices. Health care providers and educators may also talk to the patient about his or her expectations of present treatments or future outcomes and address any concerns about current self-care activities for achieving future goals. Finally, interviews may also encourage open and honest discussions about any lack of resources or other factors that may impede acquiring appropriate health care in order to help the participant become better-informed about available options. By using such motivational interviewing techniques diabetes educators and health care providers are able to further assist the individual in his or her decision-making and move toward greater empowerment.

Several instruments have been developed to evaluate the effectiveness of diabetes self-management education and may also be used to evaluate individual aspects involved in the process of diabetes empowerment, including: The Diabetes Knowledge Test (85); Diabetes Attitudes Scale (17); Problem Areas in Diabetes Survey (185); Appraisal of Diabetes Scale (48); Barriers in Diabetes Questionnaire (161); Personal Models of Diabetes Questionnaire (111); Diabetes Independence Survey (260); Multidimensional Diabetes Questionnaire (171); and Diabetes Self-Management Profile (171). However, only one survey instrument, the Diabetes Empowerment Scale (DES) (21), has been developed with the specific goal of evaluating diabetes empowerment. The DES was developed in the early 1990's by the Michigan Diabetes Research and Training Center (MDRTC) to assess the psychosocial self-efficacy of people with diabetes by measuring satisfaction, setting goals, solving problems, emotional coping, managing stress,

obtaining support, motivating oneself, and making decisions. The DES instrument includes 37 questions with three subscales, including: managing the psychosocial aspects of diabetes; dissatisfaction and readiness to change; and ability to set and achieve goals. The scale has also been modified to a short-form version, the DES-SF (18), which includes 28 questions with the same subscales and was used to evaluate empowerment in this study.

In the current decade, diabetes empowerment approaches for African American adults with T2DM have mainly focused on incorporating more culturally relevant strategies for educating individuals about diabetes self-management, which have been discussed in the previous sections. However, a few studies have presented some unique strategies specifically targeted at improving empowerment in African American adults with T2DM. For instance, the Pounds Off With Empowerment study (POWER) (149) placed attention on weight management approaches for African Americans with diabetes. The unique aspect of this study was that participants were provided with a “toolbox” which outlined problem-solving strategies regarding specific barriers associated with weight loss. This approach was identified by participants as the most important aspect of the study for self-monitoring and achieving weight loss goals. In the Managing Your Diabetes (MYD) program (107), investigators focused on empowering low-income African American diabetes patients that visited community health clinics. The MYD program conducted individualized counseling sessions that assisted patients in developing a nutrition plan that suited their lifestyle and budget as well as sensible ways to incorporate physical activity through structured exercise programs and walking. Physicians also discussed the meaning of screening results with the patient and

emphasized an equal partnership with the patient to problem-solve and set goals. Finally, in a study by Funnell, et. al. (95), a patient-directed program was implemented with urban African Americans in which participants attended six weekly sessions that simply allowed participants to ask questions to a panel of experts about proper diabetes self-management. At the conclusion of each session participants set a behavior change goal for the following week. Participants were then asked to conduct “self-management experiments” until the next week’s session. The subsequent sessions discussed each week’s self-management experiments and identified barriers experienced in behavior change goals and then the group engaged in problem-solving approaches. Study results showed that National Standards for Diabetes Self-Management Education Programs were sufficiently addressed using this approach and participants reported being able to make positive changes that were relevant and meaningful to their own experiences. Collectively these studies indicate that empowerment-based approaches enable diabetes patients to act responsibly in making important and often complex decisions regarding their own health care and thus promote resilience.

Psychological Well-Being

Psychological well-being is one outcome that may be enhanced through the improvement of psychosocial process variables. This is important because a massive international study conducted with approximately 5,500 adults with T2DM known as the Diabetes Attitudes, Wishes and Needs (DAWN) study aimed to determine why over half of individuals affected by T2DM do not achieve good health and quality of life even though effective medical treatments exist (181). The study found that more than 40% of

individuals with diabetes reported poor psychological well-being and 85.2% experienced diabetes-related emotional distress (202). These statistics are consistent with studies conducted in diabetes self-management which indicate that diabetes patients reporting lower levels of perceived stress, depression, and anxiety tend to have better glycemic control (66). Yet, one third of health care providers do not feel they can sufficiently address the psychological needs of diabetes patients (182, 221). The study urged that emotional barriers must be overcome in order for current therapies to become more effective and that psychological care is greatly needed for people with diabetes.

A high level of perceived stress is commonly mentioned in the literature as a contributing factor in the development and progression of disease and may be a strong predictor of poor adherence to diabetes self-management (201). Hans Selye was the first to recognize that stress could cause physiological changes to occur in the body, which he labeled as the General Adaptation Syndrome (215). In the General Adaptation Syndrome Selye delineated the various stages of physiological response to a stressor, including: the alarm reaction stage, the resistance stage, and the exhaustion stage. He speculated that during the exhaustion stage disease and damage transpire due to unsuccessful attempts to overcome the stressor during the alarm and resistance stages. This theory goes hand in hand with the more recent allostatic load theory of disease development, in which the body attempts to maintain allostasis, or a variable but stable state, when faced with stress (153). Allostasis is considered to be a normal physiological response that helps the organism to interact with its environment and protect itself during times of threat, and is often thought of as the “fight or flight” response. However, when the allostasis response is not functioning properly by remaining at either extreme of fight or flight for long

periods of time, allostatic load occurs and damage ensues. With these theories in place, Cohen has described stress as any environmental demand placed on an organism that surpasses the organism's adaptive ability, resulting in biological and psychological alterations that may be unfavorable and increase the chance for disease development (57). Thus, the link between stress and pathogenesis may be attributed to 1) direct affects on prolonged physiological changes, such as increased glucocorticoid and catecholamine secretion, increased blood glucose levels, and elevated blood pressure; or 2) indirect affects through poor behavior choices, such as physical inactivity, overeating, or alcohol and drug abuse (73). However, researchers are still unclear as to the mechanisms underlying the stress-disease model.

In an effort to better predict the contributing factors of stress to disease development and health outcomes, Elliot and Eisdorfer developed a taxonomy system for identifying different types of stressors (77). This taxonomy includes five categories: acute time-limited, brief naturalistic, stressful event sequences, chronic stressors, and distant stressors. Acute time-limited stressors are usually the types of stressors that can be easily elicited in a laboratory setting such as performing a mental arithmetic activity within a given time limit. Brief naturalistic stressors are real-life short-duration challenges individuals undergo such as taking an academic examination. Stressful event sequences include events that will have a series of related challenges following the event such as in the occurrence of a natural disaster, house fire, or loss of a spouse. Chronic stressors include those stressors that force one to restructure their identity and social roles because there is usually no clear end point to the stressful event, such as living with a permanent disability. Distant stressors are traumatic events that have happened in the past that still

impose emotional and cognitive consequences, such as child abuse, rape, and war combat. Each of these variables has given qualitative insight into the possible adaptive demands required of the individual during a stressful event. However, research has shown that the physiological responses to the different types of stressors are not entirely different from one another, but rather it is the duration and magnitude of the stressor that differentiate whether the physiological response is damaging (77). Thus, the greater the duration and the more intense the perceived threat, the more likely deleterious effects will occur to the body and result in disease onset and progression. Researchers have also differentiated stressors according to their predictability and controllability (33) and have found that the more predictable and controllable a threat is the less intense the stressor is perceived (79). However, as previously discussed, an individual's strengths, vulnerabilities, and cognitive appraisals play a large role in how one copes with stress, and thus how long a stressor lasts and the intensity to which it is experienced.

Various instruments exist to evaluate stress, which range from assessing stress-related symptoms, sources of stress, life stress events, and perceived stress to those that evaluate the duration and intensity of stressors. In this study we use the 10-item Perceived Stress Scale which measures the degree to which an individual finds life unpredictable, uncontrollable and overloading. We selected this scale since our goal is to help individuals improve coping skills and positive reappraisals of stressful situations. Likewise, this instrument has been previously tested with African American subjects undergoing a weight loss intervention and has been proven to be a reliable and valid instrument for this population (224).

Chronic stress may explain the differences witnessed in health status between ethnic minorities and non-Hispanic whites. For example, African Americans are documented to have a higher exposure to chronic stressors than non-Hispanic whites including lower socioeconomic status, racial bias, lack of health care, lower education, and higher levels of crime and violence (255). Elevated exposure to chronic stressors may explain why African Americans report higher levels of perceived stress, depression, and anxiety than non-Hispanic whites (132). Several studies also show that African Americans elicit stronger reactions to stressful life events, showing greater emotional distress than whites (158, 166, 241). Likewise, individuals diagnosed with diabetes typically report high levels of diabetes-related distress which manifests in physical and emotional tiredness, worry, and fear of diabetes-related complications (206). Therefore, African Americans with T2DM are at a particular disadvantage for experiencing increased levels of chronic emotional stress.

A psychological concomitant of chronic stress is depression, which is also associated with poor health outcomes in many studies. The DSM-IV classifies depression as a mood disorder that can range for mild clinical depression to major depressive disorder (14). Various degrees of symptoms exist across depressive disorders which include: affective symptoms such as depressed mood and feelings of worthlessness or guilt; behavioral symptoms such as social withdrawal and agitation; cognitive symptoms such as difficulty concentrating or making decisions; and somatic symptoms such as insomnia or hypersomnia (14). Many factors can contribute to depression including negative thinking patterns, biological factors, genetic factors, gender, situational and environmental factors, medications, and co-morbidities.

The National Institute of Mental Health reports that 20.9 million adults are affected with a mood disorder such as depression (131). African Americans are reported to shoulder a disproportionate burden for the development of depressive disorders as compared to whites (196). Furthermore, studies indicate that individuals with diabetes are twice as likely to report depression as those without diabetes (55, 247), and those of low SES have a 1.5 times higher prevalence rate for depression (196). Thus, low-income African Americans with T2DM are particularly at risk for the development of a depressive disorder (67, 99, 137) which is highly correlated with adverse diabetes outcomes (67, 99, 137, 247). However, African Americans are less likely to seek treatment for depression than non-Hispanic whites (64). A recent literature review revealed that African Americans do not seek treatment for depression due to a lack of recognition of its somatic symptoms; the stigma associated with depression; competing clinical demands of co-morbid illnesses; problems with the physician-patient relationship; and lack of comprehensive primary care services and/or health insurance (64).

In this study we evaluate depressive symptoms using the 20-item Center for Epidemiologic Studies Depression Index (CES-D) (189). The CES-D is comprised of six scales that evaluate major dimensions of depression including: depressed mood, feelings of guilt and worthlessness, feelings of helplessness and hopelessness, psychomotor retardation, loss of appetite, and sleep disturbance. We selected this scale not only because of its wide acceptance as a reliable and valid measure of depressive symptoms, but also because it has been used to evaluate depressive symptoms in samples of African American adults with T2DM (246).

The ability to regulate negative emotions may be protective against stress and depression (175). Therefore, decreasing the capacity and duration of negative affect may be beneficial for promoting resilience, decreasing stress and depression among African American T2DM patients. Negative affect refers to such traits of being distressed, upset, guilty, scared, hostile, irritable, ashamed, nervous, jittery, and afraid (175). Negative affect has been associated with maladaptive coping strategies, pessimism, and lack of positive reappraisals (175). In a laboratory experiment that stimulated arousal of negative affect in diabetes patients, proinflammatory cytokines were stimulated as well as an increase in insulin resistance (233). By contrast, positive affect has been documented as a protective factor against stress (175) and is associated with resilience, decreased autonomic arousal and positive reappraisal (88). Positive affect is described as the trait of being joyful, interested, and content (88) and is documented to build long-lasting personal resources for coping with stress (90). In fact, a greater level of positive affect was found to predict lower risk of mortality among diabetes patients (163) as well as better blood glucose control (119).

A number of mood scales exist to measure positive and negative affect. However, many of these scales have low reliability or poor convergent or discriminant validity. In this study we measured negative affect using the 20-item Positive and Negative Affect Schedule (PANAS) (249). This scale asks participants to determine the degree to which they experience various positive (i.e., joyful, interested, etc.) or negative (i.e., upset, scared, hostile, etc.) affects. The PANAS was selected due to its brevity, reliability, and validity. It has also been tested thoroughly with African American subjects (150, 167, 219, 223).

Biopsychosocial Interactions

Research studies typically focus within the margins of individual disciplines, viewing factors such as health behaviors, psychosocial process variables, psychological well-being, and race as affecting health outcomes independently. Yet, a large body of research indicates that these factors interact between themselves and with biological systems. Empirical research conducted in the field of psychoneuroimmunology over the past several decades has produced a wealth of evidence indicating direct associations between psychosocial factors and neuroendocrine and immune responses (172, 245), which in turn influence the course of disease progression or resistance. Therefore, examining these interactions at the biological level is necessary to further understand the impact of psychosocial factors on metabolic dysfunction and disease outcomes.

One biological marker of interest is insulin since it is the key regulator of glucose metabolism (231). During the fed state, insulin functions to increase glucose uptake by the liver and muscle tissue and store it in the form of glycogen. Insulin also targets the adipose tissue to take up blood lipids for conversion to triglyceride as well as store excess sugars in the form of fat. Insulin can also increase DNA replication and protein synthesis, decrease lipolysis, decrease gluconeogenesis, increase amino acid uptake, and relax the micro-arteriole walls to increase blood flow. However, T2DM patients typically show reduced production of insulin and/or insulin insensitivity which leads to a diminished ability of the tissues to utilize glucose resulting in “cell starvation” and elevated blood glucose levels (231).

The biosynthesis and secretion of insulin occurs in the islets of Langerhans β -cells in the pancreas (231). Within the β -cells, a precursor molecule known as proinsulin

undergoes an endoproteolytic cleavage to produce insulin, which is then stored in secretory vesicles until needed. The chief mechanism by which insulin is released from the secretory vesicles occurs when glucose levels rise and enter the β -cells through the glucose transporter, GLUT2 (231). As glucose undergoes glycolysis within the cell, ATP is produced causing potassium channels to close and depolarize the cell, which in turn causes calcium (Ca^{++}) channels to open and Ca^{++} to flow into the cell. Increased Ca^{++} levels activate phospholipase C which cleaves phosphatidyl inositol 4,5-bisphosphate to form 1,4,5-triphosphate (IP3) and diacylglycerol. IP3 binds membrane receptors on the endoplasmic reticulum (ER) and allows further release of Ca^{++} from the ER which further raises Ca^{++} levels within the β -cells and causes a release of insulin from the secretory vesicles (231). Other regulators involved in the release of insulin include: amino acids from protein consumption; acetylcholine released from the parasympathetic nervous system, and cholecystikinin (231). The release of insulin fluctuates every 3-6 minutes in the hours following ingestion of food resulting in blood levels that can vary from less than 100 pmol/L to greater than 800 pmol/L (231). This fluctuation in insulin levels allows time for glucose to be cleared from the blood and prevents insulin receptor down-regulation in target tissues.

Once insulin is released it binds cell surface receptors on the plasma membrane of target tissues (231). Upon insulin binding its receptors, intracellular insulin receptor substrate-1 (IRS-1) is phosphorylated and, in turn, activates PI-PLC, Grb2/Sos, and PI3K to further propagate cell signal transduction, in particular through the Ras/Raf/Map-Kinase pathway. Through this pathway, gene transcription occurs to promote growth, stimulate glycogen synthesis, and inhibit glycogenolysis. Insulin also activates the

translocation of the glucose transporter, GLUT4, to the plasma membrane for the uptake of glucose into target tissues, including adipose tissue, skeletal muscle and heart muscle (231).

Interestingly, during times of psychological and physiological stress the hypothalamic-pituitary-adrenal (HPA) axis signals a need for more glucose as fuel, and is thus involved in the inhibition of insulin secretion through the release of counterregulatory hormones such as catecholamines, glucagon, cortisol, and growth hormone (127). The inhibition of insulin is critical during the stress response for limiting glucose uptake by tissues that do not play a role in protecting an individual during times of stress, such as storing excess glucose as fat in adipose tissue. This allows glucose to be taken up by the tissues that need it the most, such as the brain and muscle tissue (127). For example, under stressful conditions catecholamines stimulate glucagon to release glucose from liver glycogen stores. Catecholamines also increase respiration and vasodilation which allow for greater blood flow and transport of nutrients to the brain, heart, and muscle tissue. In addition, catecholamines promote lipolysis in adipose tissue to provide an alternative fuel for target tissues. In the case of muscle tissue, during increased physical activity GLUT4 is translocated to the cell surface which acts as a compensatory mechanism to allow glucose to enter the muscle tissue (127). These counterregulatory responses may also explain the autonomic symptoms observed in diabetes patients during hypoglycemic conditions such as tremors, nervousness, palpitations, diaphoresis, anxiety, apprehension, and pallor (127).

Whereas catecholamines and glucagon provide more immediate and acute responses during stress, cortisol provides extended physiological stress responses when

the stressor is chronic or prolonged and may play a role in metabolic dysfunction (231). The release of cortisol begins with the production of cortisol releasing hormone (CRH) from the paraventricular nucleus of the hypothalamus, which in turn activates pro-opiomelanocortin (POMC) gene transcription in the anterior pituitary. The POMC protein produced is the precursor for the synthesis of adrenocorticotrophic hormone (ACTH) which is the major hormone released from the anterior pituitary to trigger cortisol secretion from the adrenal cortex (231). Once released, 90% of cortisol is bound to its binding globulin (CBG) to increase its half-life, which is between 70-120 minutes (231). However, only free cortisol exerts effects on target tissues, such as increasing respiration, vasodilation, blood pressure, and blood glucose levels and decreasing immune function (231). Cortisol is also diurnally active in humans, with peak concentrations (7-24 $\mu\text{g}/\mu\text{L}$ in humans) occurring in the early morning and steadily decreasing until early evening (231). Stress, exercise, obesity, infections, trauma, and disease can all influence plasma cortisol concentrations (231).

Studies indicate that cortisol alone has only a minimal effect on hepatic glucose release. However, when cortisol combines with catecholamines and glucagon it extends hepatic gluconeogenesis, and slows the oxidation of glucose by muscle and adipose tissue (231). Cortisol, along with growth hormone (GH), antagonizes insulin-mediated uptake and utilization of glucose, which occurs by decreasing insulin receptor affinity (118). Administration of dexamethasone, a cortisol analog, was also found to inhibit glucose transporter translocation to the plasma membrane for glucose uptake (127). Cortisol is also shown to increase lipolysis by activating hormone-sensitive lipase which is otherwise inhibited when insulin is present (231). Another important finding shows that

11 β -hydroxysteroid dehydrogenase (11 β -HSD1) type 1, the enzyme which converts inert circulating corticosterone to active cortisol in humans, is found in high levels in the liver, adipose tissue, and brain (178). Overexpression of 11 β -HSD1 in adipose tissue of mice resulted in full metabolic syndrome. Furthermore, glucose and lipid homeostasis improved with inhibition of this enzyme (178).

Elevated cortisol levels may play an integral role in the development of obesity (74). For instance, cortisol has been implicated in the anticipation of mealtimes due to its diurnal variation and remains elevated if food is restricted, which may play a role in the stress individuals feel when dieting (38). Secondly, elevated cortisol levels in response to a laboratory stressor increased high-fat and high-carbohydrate food consumption in women (81), which may contribute to weight gain if stressors are chronic. Likewise, the cumulative effects of elevated cortisol result in abdominal obesity possibly due to the decreased lipolytic activity found in abdominal adipose tissue compared to other adipose tissue regions (231).

Disorders involving high cortisol levels, such as Cushing's syndrome, exhibit characteristics of metabolic syndrome such as abdominal obesity, insulin resistance, dyslipidemia, and hypertension (74). Cushing's syndrome patients are also highly likely to develop T2DM and CVD (74). Recently, another condition known as subclinical hypercortisolism (SH) was defined as an impaired state among ACTH and cortisol homeostasis (54). Research shows that patients with SH have a high risk for developing T2DM. More importantly, those with diabetes can experience improvements with SH removal. In one study, prevalence of SH was higher in individuals with diabetes than in control subjects, and those with severe diabetes (defined by the coexistence of

hypertension, dyslipidemia, and insulin treatment) were significantly associated with SH (54). Another study showed that elevated plasma cortisol levels existed in glucose-intolerant men (192). These data suggest that alterations in the central regulation of the cortisol response may be important in the development of T2DM and metabolic syndrome.

Whereas cortisol is a catabolic hormone, insulin-like growth factor-1 (IGF-1) plays an anabolic role. IGF-1 is a member of a large family of insulin-related peptides that demonstrate rapid insulin-like metabolic actions, growth-promoting actions and can be potent cell survival factors (118). IGF-1 causes cell differentiation to occur in skeletal muscle cells, myoblasts, osteoblasts, adipocytes, and oligodendrocytes and can induce erythropoiesis and granulopoiesis (127). IGF-1 is produced by the liver and is regulated by the secretion of growth hormone from the anterior pituitary through the hypothalamic activation of growth hormone releasing hormone (GHRH) (127). IGF-1 levels are age and sex dependent, with normal levels peaking at puberty (580 ng/mL) and later decreasing in old age (213 ng/mL) (160). IGF-1 levels are also known to fluctuate with stress and nutritional status in humans (118) and may also be differentially regulated by dietary composition (165).

Unlike insulin which circulates in the blood in free form, in human serum 99% of IGF-1 molecules are found in 150 kDa complexes with their binding protein, IGFBP-3, which aids in the transport of IGF-1 to its cell surface receptors and extends IGF-1's half-life by protecting it from degradation (118). In contrast, another binding protein, IGFBP-1, negatively regulates IGF-1 transport to its receptors. This is important because during times of prolonged stress, starvation (calorie restriction), or severe illness, cortisol

production increases, which blunts IGF-1's anabolic effects on the cell by causing 1) a down-regulation of IGFBP-3 to transport IGF-1 to its cell surface receptors by increasing IGFBP-1 or 2) by depleting IGF-1 stores due to the continual need for its restorative actions, thus resulting in cachexia or damage to the body (118).

The primary variable found in controlling IGF-1 secretion is nutritional status. Levels of IGF-1 decrease in humans with caloric restriction and weight loss (156). However, IGF-1 levels do not acutely fluctuate from minute-to-minute as witnessed with insulin during carbohydrate intake. In fact, IGF-1 serum concentration only changes after multiple days of inadequate caloric intake (<800 kcal/day for three or more days) and/or protein in humans and thus is highly correlated with nitrogen balance. IGF-1 levels are shown to increase with high fat or high carbohydrate diets, but remain unchanged with high protein diets (165). Caloric restriction also attenuates the responsiveness of IGF-1 to growth hormone, most likely due to growth hormone receptors being down-regulated by 50% in the liver during starvation. Likewise, IGFBP-3 proteases are dramatically increased under caloric restriction, thereby decreasing transport of IGF-1 to cell surface receptors (65). In addition, IGFBP-1 is upregulated with calorie restriction, weight loss, and stress. IGFBP-1 also responds quickly to changes in metabolic status and appears to be regulated by insulin (142). When insulin levels decrease, IGFBP-1 levels increase thus limiting IGF-1 activity. Furthermore, when IGFBP-1 was injected into rats, blood glucose levels increased (142). These data suggest that IGF-1 may play an important role in T2DM.

A considerable amount of research indicates that the neuroendocrine and metabolic systems are vastly integrated with the immune system and that proper

functioning of these systems seems to be highly dependent upon one another. The underlying notion for the coordination of these systems is that each is fundamental for survival under environmental stressors; that is to withstand threats, starvation, and mount effective defenses to pathogens. As previously discussed, this coordination is considered to be advantageous by diverting glucose away from anabolic pathways, such as that witnessed in the cases of insulin, GH, and IGF-1 during times of stress to other tissues that are more critical to survival. However, this response is only effective under acute stressors (214). Conversely, none of these systems has evolved enough to compensate for the lifestyles and behaviors of modern humans in which there is a chronic state of metabolic overload due to over-consumption of nutrients and lack of physical activity. Thus, chronic metabolic overload with hyperglycemia can lead to aberrant immune responses (120).

In recent years it has been proposed that T2DM may, in part, be advanced by an acute phase reaction of the innate immune system, in which the adipose tissue creates a low grade inflammatory response by releasing large amounts of proinflammatory mediators, including: adipokines, cytokines, chemokines, adhesion molecules, and acute-phase proteins (184). This inflammatory response is most likely due to macrophage infiltration into the adipose tissue under obese conditions and may be involved in the clearance of necrotic adipocytes (56). Adipocyte death is most likely the main event enhanced by obesity that causes the infiltration of macrophages into the adipose tissue. Yet, macrophage infiltration may also occur to limit the further expansion of adipocyte cells in the obese condition. There is also evidence suggesting that obesity accompanied by chronically elevated blood glucose levels induces oxidative stress and increases

reactive oxygen species (ROS) at the cellular and molecular level which also promote low-grade inflammation (63). Interestingly, behavioral changes such as low-carbohydrate and low-fat diets and increased exercise have shown direct anti-inflammatory responses on the innate immune system and adipose tissue in T2DM patients through a marked reduction in IL-6, IL-18, TNF- α and an up-regulation in anti-inflammatory IL-10 and IL-1R antagonists (120). Exercise and improved diet also improve immuno-responsiveness to antigen attacks (245).

An inflammatory response also occurs in atherosclerosis due to mononuclear blood cell infiltration into the arterial intima in response to vessel wall damage (89). C-reactive protein (CRP) is an important acute phase protein that is synthesized by the liver to limit injury and aid in healing and prolongs the inflammatory response in vessel walls (177). High levels of CRP (>3.0 mg/L) are found in individuals with T2DM and CVD (139). Furthermore, CRP levels continue to increase as the severity of T2DM and CVD increase (139). Pharmacological interventions in which high-dose aspirin was administered to T2DM patients showed reduced systemic CRP levels accompanied by a 25% decrease in fasting blood glucose levels and an even more significant decline in triglyceride levels; thus further supporting the role of inflammation in T2DM (218). CRP also has a major action on the central nervous system by controlling behavior and psychological responses to stress (177). It is therefore reasonable to assert that low-grade inflammation via the action of CRP is an important pathogenic factor to investigate in T2DM and CVD.

Impairments in the acquired immune system have also been found with obesity, insulin resistance, hyperglycemia, and T2DM. For instance, insulin receptors are known

to emerge on human peripheral T lymphocytes after activation with a mitogen or antigen within 24 hours and plateaus at 72 hours (230). Once insulin binds these receptors, it can enhance lymphocyte function, differentiation, proliferation and maintain the activated state of the lymphocyte by enhancing the energy requirements and protein synthesis necessary for proper lymphocyte functioning. However, T lymphocytes have the capacity to distinguish chronic and acute changes in the ambient insulin levels and have the ability to change their insulin receptor generation capacity (230). Defects in insulin actions, such as those witnessed in T2DM, may lead to inappropriate immuno-responsiveness. Delayed responsiveness of T lymphocytes to antigens has been reported to be the greatest in diabetic patients with poor glycemic control and insulin resistance, which can be reversed to normal with proper glycemic control and improved insulin sensitivity (230). Additionally, a diminished early response in mobilization of peripheral blood mononuclear cells to sites of skin infection was found in diabetic subjects and an even greater delay was found in acidotic patients (180). These data may explain altered acquired immunity in individuals with T2DM, such as in response to an infection or wound healing.

Furthermore, studies in the field of psychoneuroimmunology indicate that chronic emotional distress, anxiety, and depression, are highly correlated with the suppression of T lymphocyte function and are also associated with obesity, T2DM, and CVD (245). Other psychosocial variables reported to correlate with immune suppression are low self-esteem, loneliness, hopelessness, and lack of social support (245). In addition, neuroendocrine responses to stress increase glucocorticoid and catecholamine secretion that are also known to suppress immune function. During times of sickness, behavior is

also altered by the immune system, including: reduced physical activity, decreased social interactions, depressed mood, increased fatigue, and decreased feeding (245). These alterations in behavior may serve as adaptive responses for conserving energy to fight infection.

When assessing the affects of different types of stressors on the immune system, a meta-analysis conducted by Segerstrom and Miller (214) indicated several interesting results. Acute time-limited stressors were found to increase the number of natural killer cells and cytotoxic T cells in peripheral blood with an increase in the CD8:CD4 T lymphocyte ratio, suggesting suppression of helper T lymphocytes. Likewise, salivary IgA levels, IL-6, and INF- γ were highly increased with acute stressors. Brief naturalistic stressors indicated a shift away from cellular immunity (Th1 type cytokines INF- γ) toward humoral immunity (Th2 type cytokine IL-6); thus T cell proliferative response was decreased. Stressful event sequences typically resulted in decreased natural killer cells with no other affects on the immune system. Finally, chronic stressors were found to have negative effects on every functional measure of the immune system. Given the direct and indirect consequences of stress on health outcomes, objective two of this study is to examine whether our resilience and diabetes-self management intervention can improve psychological well-being, biological markers, and healthful behaviors.

Metabolic Risk Factors

As mentioned previously, metabolic syndrome is associated with the development of T2DM and CVD. The National Cholesterol Education Program's Adult Treatment Panel III (NCEP ATP III) characterizes metabolic syndrome as having three or more of the following metabolic abnormalities: abdominal obesity, hyperglycemia, hypertension, insulin resistance, high triglyceride levels, and low HDL cholesterol concentrations (2). In African Americans only two of the five criteria need be present to increase the risk of developing T2DM or CVD (188). In fact, 68% of African Americans with T2DM have full metabolic syndrome (188).

Research suggests that becoming overweight or obese may be the initiator for developing metabolic syndrome. Consequently, nearly 80% of all individuals with T2DM are classified as overweight or obese (13). Losing weight is the best way to control T2DM and prevent further progression of the disease. In fact, as little as a 5-10% decrease in initial body weight significantly decreases the symptoms associated with metabolic syndrome (106). Body Mass Index (BMI) is typically used to assess weight status among a population and is highly correlated with disease risk. BMI values of 20-25 are associated with the lowest risk, whereas values of 40 or more are associated with the highest risk. The USDA categorizes a BMI of 25-29 as overweight and 30 or above as obese (152). Monitoring BMI over time may provide important clues as to the overall health behaviors of an individual.

The best way to assess blood glucose control is by measuring the amount of glycosylated hemoglobin in the blood, or HbA_{1c} (209). The HbA_{1c} test takes advantage of the lifecycle of red blood cells and measures the average daily blood glucose over a period of three to four months (i.e., the lifecycle of the RBC). HbA_{1c} scores are expressed

as a percentage, with 3% to 6% considered normal and 7% or below being the goal for a diabetic patient. Research has shown that for every percent decrease in HbA_{1c} a 21% reduction is witnessed in all-cause mortality and a 37% reduction is seen in microvascular complications (102, 209). In fact, Khaw and colleagues suggest that a decrease of 0.1% to 0.2% in glycated hemoglobin could dramatically affect the incidence of cardiovascular related complications (134). The average glycosylated hemoglobin level at diagnosis of diabetes is 10.9% to 15.5%. In uncontrolled diabetes, HbA_{1c} levels usually range from 8 to 11.9% (9). Thus, monitoring HbA_{1c} levels is a valuable tool for assessing the management of T2DM.

Hypertension and dyslipidemia are the final two risk factors associated with metabolic syndrome, leading to further progression of T2DM and increased risk of CVD. The American Heart Association (AHA) defines hypertension as a systolic blood pressure greater than 140 mmHg and a diastolic blood pressure greater than 90 mmHg. However, the American Diabetes Association (ADA) recommends that people with diabetes keep blood pressure at or below 130/80 mm/Hg. The AHA defines normal triglyceride levels as less than 150 mg/dL; high density lipoprotein levels as 50 mg/dL or greater for women and 40 mg/dL or greater for men; low density lipoprotein levels as less than 100 mg/dL; and total cholesterol less than 200 mg/dL. As many as two out of three adults with diabetes have hypertension (23) with African American men and women having the highest rates of hypertension compared to other races (188). African American men and women also experience high levels of LDL cholesterol, low levels of HDL cholesterol, and high TG levels, which can lead to atherosclerosis (59).

Hyperglycemia contributes to vascular dysfunction by increasing the viscosity of blood, thereby making it coagulate and stick to artery walls more easily. The combination of dyslipidemia and high viscosity of blood reduces blood flow to the heart, brain and kidneys, which increases blood pressure and induces myocardial ischemia and stroke. In fact, research shows that 20% of all patients with T2DM have a silent form of ischemia which can lead to heart attack and death (35). Therefore, the final objective of this study is to determine whether our intervention can impede the disease progression of obesity, T2DM, and CVD by reducing metabolic risk factors.

Chapter 2:

Current Status of Diabetes Self-Management Interventions for African American Adults with Type 2 Diabetes: An Integrative Review

2.1 Abstract

Diabetes self-management education has shown promise for promoting positive lifestyle changes that result in improved glycemic control and reduced diabetes-related complications. Since African Americans show a disproportionate burden for the development of type 2 diabetes, there is a growing need to evaluate various self-management education strategies that are successful within this population. A number of diabetes self-management interventions are now focusing on culturally competent strategies that address the psychosocial needs of African Americans living with diabetes. The purpose of this chapter is to summarize the recent literature regarding diabetes self-management interventions implemented in African American adults with type 2 diabetes, and to present an example of a self-management intervention designed to help African American adults cope with the adversities of living with type 2 diabetes through the use of resilience education.

2.2 Introduction

African Americans show a disproportionate burden for the development of type 2 diabetes (T2DM), displaying a 1.8 times higher rate than non-Hispanic whites (13). Statistics show that T2DM is typically preceded by obesity and results in a 2 to 4 times higher rate of cardiovascular disease (CVD) (121). Currently, 70% of African Americans are overweight and 40% are obese, which is much higher than the general population at

61% overweight and 26% obese (13). Likewise, CVD is currently the leading cause of death among African Americans (3). Furthermore, these disorders are each highly correlated with a cluster of metabolic abnormalities including abdominal obesity, insulin resistance, hyperglycemia, dyslipidemia, and hypertension, (2) which collectively affect 68% of African Americans with T2DM (188). Without proper management of diabetes and its associated metabolic disorders, additional long-term complications typically result that further diminish one's quality of life, such as retinopathy, neuropathy, atherosclerosis, lower leg amputations, and end-stage renal disease. Thus, T2DM and its numerous adverse health outcomes have placed a huge strain on the United States health care expenditure, with an approximate cost of \$174 billion reported in 2007 due to direct medical costs, work days lost, disability, and premature deaths (1). However, many of these complications are highly preventable through maintaining proper lifestyle and behavior changes including healthful eating, monitoring of blood glucose, and physical activity (109). These lifestyle changes are the foundation of proper diabetes self-management. Therefore, developing culturally competent and effective diabetes self-management education programs that produce long-term positive behavior changes have the potential to greatly impact health outcomes and overall quality of life for African Americans, as well as reduce health care costs.

Past intervention programs have utilized a variety of techniques and strategies to improve self-management, including: knowledge and skill development, dietary recommendations, physical activity, behavioral and cognitive strategies, pharmacological therapy, as well as various combinations of the above strategies (123). Meta-analyses support the effectiveness of diabetes self-management education in the short-term (<6

months) on knowledge, self-reported dietary habits, and glycemic control (104). However, studies that had follow-up periods longer than one year had mixed results, as well as methodological concerns related to internal (e.g., selection, attrition) and external validity (104). Likewise, the effectiveness of interventions on body weight, physical activity, blood pressure, and lipids are more variable (169). Because T2DM is a chronic condition, interventions that produce long-term adherence are essential.

Meta-analyses suggest that both short- and long-term studies have focused too narrowly on knowledge and glycemic control at the exclusion of important emotional, spiritual, social, and cognitive aspects of living with diabetes that may offer insight into the mechanisms that affect diabetes self-management and other quality of life outcomes such as reducing CVD (100). To address these concerns, recent trends in diabetes self-management research have shifted from didactic presentations to more patient “empowerment” approaches in an effort to produce greater long-term adherence to positive behavior changes (20, 22, 93, 95). The patient empowerment approach aims to enable individuals to take more control and decision-making responsibilities for their own health care. In order to increase empowerment and address the above psychosocial needs for ethnic minorities living with diabetes, researchers have acknowledged the need for more culturally appropriate strategies to be incorporated into diabetes self-management education programs. Culturally competent strategies involve the group’s beliefs, values, customs, traditional foods, dietary patterns, language, literacy levels, socioeconomic status and availability of resources. Therefore, diabetes self-management education has evolved to provide more culturally appropriate individualized outpatient education and coaching within community settings that focus on helping ethnic

minorities develop skills and self-awareness for goal setting, problem solving, stress management, coping, social support, and motivation (25).

One example of an intervention that was designed to improve diabetes self-management and address the psychosocial needs of African Americans living with T2DM is *The Diabetes Coaching Program: Transforming Lives Through Resilience Education* (DCP). The DCP was implemented at a predominantly African American church in East Austin and consisted of four weekly, two-hour formal instructional class sessions that incorporated a resilience education curriculum with standard diabetes self-management education and eight, one and half hour, bi-weekly support group sessions. The DCP lasted a total of six months. The aim of the DCP was to help African Americans to develop skills and self-awareness for goal setting, problem-solving coping, stress management, social support, and motivation. The resilience education portion of each class lasted approximately one hour and included the following topics: 1) Transforming stress into resilience; 2) Taking responsibility; 3) Focusing on empowering interpretations; and 4) Creating meaningful connections. A modified version of the International Diabetes Center Type 2 Diabetes BASICS course (194) was used to guide the diabetes knowledge and self-management curriculum portion of each class and lasted approximately one hour of each class session. Participants also received handouts of the information discussed during each class session as well as a journal to log their blood glucose readings, physical activity and eating behaviors, and to document their personal self-care goals. After the four class sessions, participants attended 5-months of bi-weekly support group meetings each lasting one and half hours. During the support group sessions, open discussions of group led topics were encouraged. Topics discussed

included reviews of the information presented during the class sessions, barriers faced in promoting self-care, healthy recipes, exercise tips, journal entries and personal goals. In addition, test results from each participant's glucometer were analyzed with WinGlucoFacts version 1.3 and individual recommendations were given to aid in glycemic control. Participants then completed 15-30 minutes of physical activity at a local high school track near the intervention site. Each participant established his or her own level of intensity. The duration of the physical activity was dependent upon each participant's own willingness, desire, and/or ability to perform the activity.

Recently, the DCP was evaluated for feasibility and acceptance in a pilot study conducted with 16 African American adults with T2DM. Preliminary results indicate that the DCP has potential for promoting a vast number of positive health outcomes for African American adults, including both psychological and physiological. At six months study participants showed significant improvements in diabetes empowerment as well as weight, physical activity, BMI, HbA_{1c}, total cholesterol, LDL cholesterol, blood pressure, lymphocyte proliferation and IGF-1 levels at six months. Currently, the DCP is being revised to enhance the cultural appropriateness of the program according to recommendations provided by study participants during a focus group discussion following the conclusion of the intervention.

2.3 Methods

Search

The Medline, PsycARTICLES, and PsycINFO databases were utilized in the literature search. For each database the following medical subject heading (MeSH) terms

were used: *African Americans, type 2 diabetes, self-management, intervention, diabetes education, lifestyle change therapy, self-care, patient education, disease management, stress management, and psycho-educational*. Each search was restricted to studies conducted in the U.S. with human subjects age 18 or older from January 2000-March 2008.

Selection

Results from each database were independently reviewed and any duplicate articles were excluded. Abstracts were reviewed to insure that a lifestyle change therapy/self-management intervention was implemented in individuals with type 2 diabetes. Intervention studies were excluded if African American adults were not included in the study population, the intervention was intended to screen for diabetes in at risk populations, or the intervention was a diabetes prevention program. Qualitative as well as quantitative study designs were included in the literature selection.

2.4 Results

Despite the disproportionate burden of diabetes among African Americans, culturally specific diabetes self-management education interventions continue to be limited for this population as well as the number of African Americans participating in clinical studies. The database searches identified 127 publications, of which 27 met the criteria for inclusion in the review. Table 2.1 summarizes the current publications (January 2000 to March 2008) of diabetes self-management interventions implemented in

African American adults with T2DM. These publications include 3 qualitative studies, 14 randomized controlled trials, 7 quasi-experimental studies, and 3 comparative studies.

Of the 27 studies listed in Table 2.1, fourteen studies reported recruiting fewer than 100 subjects, and of these, nine had fewer than 50 subjects. Typically, slow accrual of subjects as well as large attrition rates were reported and tended to affect the design and statistical evaluation of the intervention outcomes. For instance, many of the studies with smaller sample sizes were pilot studies that utilized either a quasi-experimental one-group study design or focus group discussions and interviews that assessed the efficacy and/or acceptance of the intervention. Study designs that allowed for smaller cohorts of 8-10 participants had lower attrition rates than many of the larger clinical trials. When experimental study designs were applied, attrition rates were higher among control group participants than experimental groups. Across all studies attrition rates averaged approximately 30-45%. In general, these data reflect a desire for more individualized care among this population and further emphasize the importance of the patient-provider relationship among African Americans. Recruitment and retention of subjects was similar for the DCP intervention, with a 25% attrition rate for the intervention group and 0% retention of the control group. Therefore, the DCP pilot study had to be evaluated as a quasi-experimental one-group study design. To increase retention within control groups we recommend maintaining frequent contact with control subjects as well giving the control subjects a more participatory role in the study. This could be accomplished by simply having control subjects wear a pedometer that is evaluated weekly or biweekly by an investigator. Methods such as this seem plausible considering that the patient-healthcare provider relationship is highly important to African Americans as well as the

interest in more individualized care. Thus, if the control group is not being actively engaged in the study in some form, these participants may quickly lose interest and withdraw from the study.

Subject characteristics were varied across the studies. Thirteen of the studies included mixed-races, whereas 14 studies utilized solely African American subjects. When only African American subjects were included many times a single gender was also selected. However, when studies included mixed genders, females were typically the predominant gender. Usually if African Americans were the predominant race in a study the other races were not identified. Yet, when mixed races were identified, non-Hispanic whites, Hispanics and/or Latinos were typically among those reported. In many studies, participants were also selected according to living in either urban or rural communities, or low-income and medically underserved areas with shortages of healthcare professionals. In other studies low-literacy populations were evaluated.

The studies were also conducted in a variety of settings, some of which compared the effectiveness of utilizing different settings. Eleven interventions were conducted within a community based setting (including community education centers, churches, and homes of patients); 10 were conducted at a local hospital or clinic (many of which were rural clinics for underserved populations, the indigent, and the homeless); and 5 were implemented at universities or diabetes education centers. Therefore, a trend was witnessed for conducting interventions within the community and homes of study participants. Results of the studies also suggested that interventions implemented in the community-setting were more effective than those implemented in hospitals and clinic settings. Several studies also trained lay persons to deliver the diabetes education

materials within the community setting. In the DCP study, we conducted the intervention at a local community church. In our experience, many participants stated feeling more comfortable attending class sessions within their community environment rather than traveling to an unfamiliar location. This seemed to facilitate more open and honest discussions among participants by providing a safe and supportive environment. In addition, conducting the study within the participants' community allowed the participants to stay in close proximity to their regular daily activities. For instance, after DCP meetings several participants immediately went to choir practice or to the men's worship group meetings. Likewise, this saved participants additional bus fares as well as extra trips for family members and kept trips to the study location within a relatively short distance from home. We also made one visit to the home of a wheel-chair bound participant that was unable to attend one of the DCP meetings and one visit to a local hospital for a participant whose husband was hospitalized. We found this strategy to be quite favorable with participants and also helped to build good rapport with the study group. In addition, participants from the DCP pilot study are now being trained as mentors to help instruct participants in future studies.

Culturally appropriate methods for delivery of diabetes-related information were also tested in the studies. Strategies evaluated for cultural competency included videotape vignettes, diabetes education literature incorporated into church bulletins, simplified instruction manuals with pictures for low literacy levels, and empowerment-based approaches such as "toolboxes" with coping strategies for various diabetes-related issues. In one intervention, an empowerment based approach was utilized in which participants simply asked questions to a panel of experts. Since African Americans typically report

difficulty with dietary behaviors, many studies evaluated different methods for teaching meal planning. Typically, meal planning instructions focused on portion control methods, reducing salt, sugar, and saturated fat in diets. In the DCP study we found plastic food models to be an effective method for teaching portion control compared to exchange-based meal plans which was also reported in the study by Ziemer et. al. (261). Likewise, the DCP incorporated instructions for reducing salt, cholesterol, and fat in the diet.

Alternative strategies were also tested in conjunction with diabetes education. Mindfulness-based strategies as well as acceptance and commitment therapies were implemented in two of the studies in an effort to improve emotional aspects associated with diabetes. These studies found increased positive behavior changes among participants as well as reduced anxiety, depression, and diabetes-related distress. Strategies such as these reflect the growing need for self-management interventions that emphasize improving psychological well-being among diabetes patients.

Most studies reported frequent contacts or follow-ups with participants. Methods for follow-up included phone-calls, home-site visits, post cards, mail-out reminders for appointments, and to a lesser extent e-mails. In addition, many studies conducted support group sessions as well as focus group discussions following the completion of interventions. In the DCP, we implemented biweekly support group sessions for five months following the education sessions to reinforce previously learned information and to answer questions about information that was not clear as well as to provide social support. During these sessions, many participants invited family members not only for support, but also because they wanted family members to learn more about diabetes as well as what to do during emergency situations, such as during hypoglycemic attacks.

Additionally, we contacted each participant by phone to remind them about upcoming meetings and to check-in on their self-management progress. Social support was rated as one of the most beneficial features of the DCP by participants.

The most common outcome variables assessed to test the effectiveness of current interventions were HbA1c, blood pressure, weight, BMI, and cholesterol levels. In the DCP we evaluated each of these variables as well cortisol, insulin-like growth factor-1, C-reactive protein, and lymphocyte proliferation. Many studies also assessed the effectiveness of interventions with self-report instruments, including: diabetes-related distress, problem-focused coping, diabetes knowledge, diabetes empowerment and dietary habits. In the DCP study we evaluated resilience, coping skills, self-leadership, diabetes empowerment, perceived stress, depression, and negative affect. However, many of the self-reported measures proved to be ineffective for this population. This was surprising considering it was apparent that study participants were using more self-leadership and affective coping strategies to direct their diabetes self-care which was evidenced by the significant improvements found in blood glucose control as well as other biological measures. Therefore, it may be necessary to conduct more studies to develop and/or adapt these instruments to produce more representative results. Thus, the necessity of conducting pilot work is essential not only for the development and implementation of diabetes self-management interventions, but also to determine the cultural appropriateness of instruments to evaluate outcome variables within this population.

2.5 Discussion

The studies summarized in Table 2.1 indicate that though recruitment and retention of African American subjects are still a challenge for many researchers, diabetes self-management continues to show positive beneficial health outcomes. Interestingly, conducting studies with smaller subject numbers may be advantageous for identifying the specific elements of interventions that produce long-term adherence to behavior changes and improved health outcomes by facilitating an opportunity for the collection of more qualitative data. This is especially important since diabetes self-management is a multidisciplinary activity and numerous self-management approaches are often implemented simultaneously. According to a recent review on reaching underserved populations (46), pilot studies and focus groups are an important strategy implemented by investigators to gain a greater understanding of the target population when developing, implementing, and evaluating self-management intervention programs. By conducting smaller studies, investigators are better able to determine which components of the intervention or protocols need revision as well as the selection of culturally appropriate instruments to evaluate intervention outcomes (46). Therefore, smaller pilot studies will continue to be very important for developing effective and culturally appropriate self-management education programs when working with African American adults. Moreover, smaller population sizes will also allow investigators and educators to develop more individualized care plans and actively engage the patient in the development process of his or her self-management regimen. Programs that encourage active participation of the patient are likely to increase patient self-efficacy and empowerment which are shown to increase self-management skills and improve health

outcomes (20). The recent studies also indicate a trend for effective interventions to be implemented within the community settings and homes of African American patients, which also suggest a desire for more individualized care among this population. However, the overall generalizability of these diabetes self-management methods across larger populations is limited due to the investigators' inability to accurately test hypotheses with small samples sizes for reliability and validity. Yet, investigators are beginning to evaluate more strategies for administering individualized care to larger sample sizes. For instance, training community health workers and peer-educators to work in conjunction with health care providers appear to be effective strategies implemented among the interventions reviewed for providing on-going support to larger populations of African Americans.

Self-management programs for African Americans, including the DCP, are also incorporating more strategies to improve stress management skills, goal-setting, social support, problem-solving skills, and coping strategies. Positive health outcomes were often noted among the recent studies with enhancement of at least one or more of these psychosocial variables; thus highlighting the importance of addressing the emotional, spiritual, social and cognitive aspects of living with a chronic disease such as diabetes in self-care programs. In addition, these psychosocial aspects seem to be important for enhancing diabetes empowerment and improving dietary self-management among African Americans. However, more research is needed to improve the cultural competence of these diabetes self-management strategies.

Outcome variables in most studies continue to be limited to HbA1c, FBG, weight, BMI, cholesterol, and blood pressure. However, due to the genetic predisposition of

African Americans to develop obesity, diabetes, and cardiovascular disease, more studies should evaluate the role diabetes self-management plays in impeding the disease process at the cellular and molecular levels in order to further understand the mechanisms underlying diabetes initiation and progression. For instance, in addition to the above outcome variables, we evaluated the impact of the DCP intervention on cortisol, insulin-like growth factor-1, lymphocyte proliferation, and C-reactive protein, all of which have been found to be dysregulated in diabetes or similar disorders associated with diabetes, such as obesity and CVD. By evaluating the impact of diabetes self-management on such variables, we can better determine whether these variables are contributing factors to disease onset or outcomes of uncontrolled blood glucose levels, insulin dysregulation, and/or overweight and obese conditions. Understanding the initiation and progression of diabetes from a molecular and cellular level could potentially identify risk factors that occur early in the disease process and thus allow for preventive strategies to be implemented sooner as well as the development of better pharmacological therapies. Thus, diabetes self-management may have even greater clinical implications in determining the onset and progression of diabetes among African Americans and across other races, though more funding needs to be allocated to the translational research of self-management interventions.

Nonetheless, diabetes continues to be a complex disease from both a psychosocial and biological perspective. Progress is being made for treating diabetes, yet diabetes self-management education programs continue to be the most influential treatment for altering the lifestyle factors and behaviors of individuals that may cause T2DM and are involved in the progression of the disease. Therefore, the development, implementation, and

testing of culturally competent diabetes self-management education interventions remain critical for addressing the growing prevalence of diabetes among African Americans. The self-care strategies and outcomes provided by the recent literature provide greater insight for further improving diabetes care in this population.

Table 2.1: Publications of diabetes self-management interventions in African American adults with type 2 diabetes: January 2000 through March 2008

Study and year	Purpose of study	Design	Subjects	Setting	Description of intervention	Major findings
Anderson <i>et.al.</i> (19) March/April 2000	Assess the cultural relevance of 12 videotape vignettes in diabetes education for urban AA	Focus groups and surveys to evaluate cultural appropriateness and usefulness of videos	74 AA diabetes patients and 20 Healthcare Professionals	Detroit, MI Michigan Diabetes Research and Training Center	12, 5-minute videotape vignettes viewed followed by 10 min. discussion b/t each video	Videotapes were successful means for educators to deliver diabetes education to AA; discussed desire to learn more about how to cope with diabetes & seek social support
Anderson-Loftin <i>et.al.</i> (22) July/Aug 2005	Evaluate the Soul Food Light education program on physiological outcomes and self-management behaviors	Longitudinal study using randomized pre-test posttest control group design	97 AA with T2DM; 49 controls; 48 experimental mean A1c= 7.5, BMI=35	Rural South Carolina diabetes education center	4 weekly culturally competent classes of low-fat diet strategies; 5 monthly focus groups; weekly telephone follow-ups	33% Attrition At 6 mo. experimental group had 1.8 kg weight ↓ with ↓ trends in A1c and lipids; control remained unchanged w/ 1.9 kg mean weight ↑
Anderson-Loftin <i>et.al.</i> (16) March/April 2002	Evaluate the feasibility of implementing dietary self-mgt. educ. prog. for AA w/ T2DM to improve physiological outcomes and cost of care	Longitudinal quasi-experimental	23 AA adults w/ diabetes at high risk for diabetes-related complications	Family practice office in rural North Carolina	Culturally competent diet education led by RD and NCM-CDE; 4, 1hr. biweekly low-fat diet classes, 30 min. discussions; 5, 1 hr. monthly discussion groups; 1 follow-up home visit and weekly phone calls	16 Completed; Significantly improved fat-related diet habits, A1C, FBG, frequency of acute care visits, trends in ↓ lipids and wt. significant ↓ in cost of care indicated by number of acute care visits and length of hospital stay

AA-African American; AI-American Indian; A1C-hemoglobin A1c; BMI- body mass index; BP-blood pressure; b/t-between; char.-characteristics; CDE-Certified Diabetes Educator; CHO-carbohydrate; CHW-community health worker; exper.-experiment; FBG-fasting blood glucose; HA-Hispanic American; LA-Latin American; LCSW-licensed clinical social worker; NCM-nurse care manager; NP-nurse practitioner; prog.-program; RN-registered nurse; RD-registered dietitian; SMBG- self-monitored blood glucose; T2DM-type 2 diabetes mellitus; TG- triglycerides; wk.-weekly; wt.-weight; w/- with; ↑-increase; ↓-decrease

Table 2.1: Publications of diabetes self-management interventions in African American adults with type 2 diabetes: January 2000 through March 2008

Study and year	Purpose of study	Design	Subjects	Setting	Description of intervention	Major findings
Banister <i>et al.</i> (28) May 2004	Assess the effectiveness of diabetes self-mgt. prog. at a community clinic for baseline data and cost effectiveness in diabetes patients	One group pre-test post-test 12 mo. study design	70 subjects w/ diabetes: 39 HA, 16 AA, 11 White, 4 Other; T2DM; mean A1C 9.7;	Austin, TX Community Clinic	4, 1-hr group monthly classes, one or more individual consults with a dietician, monthly support groups; lectures, discussions, demonstrations, video	Mean A1C ↓ from 9.7% to 8.2%; 61% experienced positive medication outcomes; reduced cost per patient served at the clinic
Batts <i>et al.</i> (32) May/June 2001	Assess priorities and needs of urban AA adults with T2DM	Interviews conducted by NCM or CHW during 3 of the intervention visits with subjects from "Project Sugar" (which was an experimental randomized study)	119 subjects: Urban AA; 75% female; mean age 59 y; mean BMI 33; mean BP 127/75; mean A1C 8.7	Johns Hopkins Outpatient Dept, Baltimore, MD	Group 1: usual care Group 2: NCM Group 3: CHW Group 4: joint care	Diabetes priorities most reported: 61% SMBG, 47% medication, 36% healthy eating, 77% of the intervention visits addressed non-diabetes related health issues and social issues
Bray <i>et al.</i> (44) Fall 2005	Explore the efficacy of combined NCM and interdisciplinary group educ. for rural AA w/ T2DM	Convenience sample w/ control group	160 diabetes patients 90% AA; 112 attended intervention w/ mean A1c=8.2, 57% female and 48 in control group w/ mean A1c=8.3, 52% female	2 primary care practices in rural counties in eastern North Carolina with healthcare professional shortage	4-session educ./ support group program led by nurse, physician, pharmacist, and nutritionist. Controls received usual care.	Intervention group A1c significantly ↓ at 12 mo. whereas control A1c scores significantly ↑.

AA-African American; AI-American Indian; A1C-hemoglobin A1c; BMI- body mass index; BP-blood pressure; b/t-between; char.-characteristics; CDE-Certified Diabetes Educator; CHO-carbohydrate; CHW-community health worker; exper.-experiment; FBG-fasting blood glucose; HA-Hispanic American; LA-Latin American; LCSW-licensed clinical social worker; NCM-nurse care manager; NP-nurse practitioner; prog.-program; RN-registered nurse; RD-registered dietician; SMBG- self-monitored blood glucose; T2DM-type 2 diabetes mellitus; TG- triglycerides; wk.-weekly; wt.-weight; w/- with; ↑-increase; ↓-decrease

Table 2.1: Publications of diabetes self-management interventions in African American adults with type 2 diabetes: January 2000 through March 2008

Study and year	Purpose of study	Design	Subjects	Setting	Description of intervention	Major findings
Bray <i>et al.</i> (43) Sept/Oct 2005	Assess the feasibility and cost effectiveness of implementing case mgt., group visits, and electronic diabetes registry in rural AA	Process measures assessed from the cardiovascular disease emergency mgt. system (CVDEMS) database	314 patients with T2DM, 72% AA, 54% female, mean age 61 yrs.	5 solo or small group primary care practices in rural North Carolina	4-session educ./ support group program led by nurse over a period of 12 months; diabetes registry and visit reminder system implemented	↑ % of patients w/ documented self-mgt. goal, lipid panel, and foot exams, achievement of self-mgt. goals, and encounters w/ a physician; improved billing and productivity
Bray <i>et al.</i> (42) Dec 2006	Evaluate baseline characteristics of Look AHEAD prog. in overweight and obese people w/ T2DM	16-center longitudinal randomized clinical controlled trial comparing intensive wt. loss intervention to standard diabetes education and support on time and incidence of cardiovascular events over 11.5 years (2001-2012)	5145 overweight and obese people w/ T2DM; 63.3% white; 15.6% AA; 13.2% HA; 5% AI; 1% Asian; mean age 59; 60% women	16 health centers throughout United States	Multidisciplinary team; First 6 mo. attend 1 individual and 3 group sessions/ mo. & encouraged to replace 2 meals and 1 snack a day w/ liquid shakes and meal bars; Months 7-12 attend 1 individual & 2 group sessions/ mo. & encouraged to replace 1 meal a day for rest of study; Years 2-4 one site visit/mo. & 2 nd contact by phone, mail, email. After yr 4, month visit.	BMI= 36 kg/m ² 83.6% of the men and 86.1% of women having a BMI > 30 kg/m ² ; 17.9% of men and 25.4% of women having a BMI > 40 kg/m ²

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Table 2.1: Publications of diabetes self-management interventions in African American adults with type 2 diabetes: January 2000 through March 2008

Study and year	Purpose of study	Design	Subjects	Setting	Description of intervention	Major findings
Funnell <i>et.al.</i> (95) Jan/Feb 2005	Describe the implementation of an empowerment based self-mgt. prog. for urban AA w/ diabetes	Randomized, waitlisted control design; cohorts of patients recruited at one time and assigned to an intervention or control group; 14 experiments and 28 group programs conducted over 4 years	239 AA participants with T2DM as well as family members were invited to attend the educ. sessions	Variety of community-based locations in Detroit, MI	6, 2-hr group-directed problem-based educ. sessions; No lectures were used, subjects asked to conduct weekly self-mgt. experiments and reflect on their behaviors, experiences and emotions	All participants showed small to modest positive behavior changes that were maintained at 1-yr follow-up; national standards of diabetes self-care were met
Gary <i>et.al.</i> (98) 2003	Determine whether multifaceted culturally sensitive primary care-based intervention by NCM and/or CHW could improve A1C, lipids, BP in urban AA w/ T2DM	Randomized control trial Piloted a 4-arm clinic and home-based intervention	186 urban AA w/ T2DM 76% female Mean age 59	Johns Hopkins University; Baltimore, MD clinic and home-based	Four groups: usual care NCM= 45 min clinic visit; CHW= 60 min home visit and/or telephone call joint care= both NCM/CHW	84% retention 25% in NCM group & 62% CHW had at least 3 visits; NCM or CHW had modest decline in A1C compared usual care; joint care had greatest decline in A1C, TG, BP compared to usual care

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Table 2.1: Publications of diabetes self-management interventions in African American adults with type 2 diabetes: January 2000 through March 2008

Study and year	Purpose of study	Design	Subjects	Setting	Description of intervention	Major findings
Gary <i>et.al.</i> (97) 2004	Determine effectiveness and cost-effectiveness of primary care and community-based interventions in urban AA w/ T2DM	2-yr randomized control trial Baseline and 24 mo. follow-up	542 urban AA w/ T2DM w/ multiple comorbidities; 74% female; mean age 58; 35% had yearly incomes >\$7500	Johns Hopkins University Managed Care Organization Baltimore, MD clinic and home-based	Minimal intervention- usual care + telephone calls, mailings Intensive care-usual care + individually tailored counseling w/ NCM visit at clinic once/ yr and CHW home visit 1-3 times/ year	85% SMBG; 35% at least 1 visit w/ nutritionist; 23% had 1 hospitalization; 69% w/ BMI≥30; 72% BP≥130/80 mmHg; mean A1c=7.9 assessed outcomes of physical and psychosocial variables for translational research- data pending
Greene <i>et.al.</i> (107) Apr/June 2006	Describe the Managing Your Diabetes (MYD) program and assess preliminary outcomes in low-income AA community	Pilot study; one-group pretest posttest	185 diabetes patients; 84% women; 95% AA; mean A1c=9.1%; 4.3% had foot exam, 2.3% had retinal exam	Community health clinic in Nashville, TN	Monthly educ. sessions w/ individualized counseling to create self-mgt. plans and nutrition plans, and receive screenings. Emphasis on empowerment and creating patient-provider partnership	At 1 yr mean A1c scores ↓, foot and retinal exams ↑, patients rate helpfulness and quality of sessions as excellent or very good

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Table 2.1: Publications of diabetes self-management interventions in African American adults with type 2 diabetes: January 2000 through March 2008

Study and year	Purpose of study	Design	Subjects	Setting	Description of intervention	Major findings
Gregg <i>et.al.</i> (108) 2007	Evaluate diabetes educ. in combination w/ acceptance and commitment therapy (ACT)	Experimental, randomized control trial	81 T2DM patients, 23.5% white, 9.9% AA, 28.4% HA, 1.2 % NA, 29.6% PI, 2.7% Arabic; 37.8% had hypertension; Mean BMI=32.6	English speaking T2DM patients attending low-income community health center in San Francisco, CA	Patients received 7 hr workshop of diabetes education alone or 4 hr educ. workshop plus mindfulness and ACT	100% retention ACT therapy group had better acceptance, understanding, self-care, and lower A1c scores at 3 mo.
Harris <i>et.al.</i> (112) Sept/Oct 2000	Evaluation of diabetes educ. prog. for low-income	One group, pretest and posttest design	85 recruited but only 25 completed; low income, low literacy AA w/ diabetes	Greensboro, NC urban clinic for homeless and indigent	RN and CDE led 4, 1.5 hr educ. sessions for low literacy level	71% attrition; 16 of 22 ↓ A1c; ≥50% positive change in behaviors; transportation problems reported; follow-up difficult
Hendricks and Hendricks (114) Nov/Dec 2000	Compared outcomes of mo. follow-up vs. every 3-mo. after diabetes educ. program	Experimental pretest posttest design w/ 2 experimental conditions	30 AA men w/ T2DM	Wheaton, MD Community-based self-mgt. skills training center	4 weekly 2 hr. sessions delivered by LCSW and NP-CDE; telephone follow-up mo. or at 3 mo. intervals for 6 mo.	25 completed follow-up No difference between those contacted monthly or every 3 mo.

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Table 2.1: Publications of diabetes self-management interventions in African American adults with type 2 diabetes: January 2000 through March 2008

Study and year	Purpose of study	Design	Subjects	Setting	Description of intervention	Major findings
Keyserling <i>et.al.</i> (133) Sept/Oct 2000	Describe the New Leaf Program, a culturally relevant, community-based diabetes self-mgt prog.	Randomized clinical trial w/ descriptive analyses of baseline data	200 AA women w/ T2DM diagnosed for 10.5 y; mean age 59 yrs, A1c= 11.1%; 75.5% high BP; overwt. and inactive	Subjects recruited from 7 primary care practices in North Carolina	4 individual counseling sessions, 2 group sessions, monthly telephone call, and 1 follow-up group session that focused on diet, exercise, self-care	Self-reported 1299 kcal/d at 47% CHO, 20% PRO, 34% Fat; 91% controlled glucose w/ diet
Mayer-Davis <i>et.al.</i> (149) May 2001	Determine optimal study design for evaluating wt. mgt. strategies in T2DM patients living in rural underserved communities: Pounds off w/ Empowerment (POWER)	Pilot study, randomized to one of two 8 wk interventions	33 patients w/ T2DM; 96% AA; 82% female; mean BMI 37.9%	Randomly selected participants from diabetes registry of federally funded healthcare center in rural South Carolina	Group 1: Lifestyle Intervention-low fat, low kcal diet, ↑ exercise Group 2: Lifestyle Intervention plus ongoing formal evaluations	28 completed study; Both interventions reported modest ↓ in wt. (2 kg) as well as improved blood glucose. No differences were found b/t groups
Nothwehr <i>et.al.</i> (170) Mar/April 2001	Compared effects of sequencing content in 2 diet and exercise programs	Pilot study, experimental randomized control design pretest posttest	23 AA women w/ T2DM for longer than 1 yr; mean age 49 yrs	Indianapolis, IN; Predominantly low-income AA urban neighborhoods	Group 1: 10 weekly 90-min nutrition sessions & 6 wks of physical activity training Group 2: reversed sequence	Similar attendance for each program; at 1 yr follow-up both groups had ↑ activity levels and vegetable intake and ↓ in kcal from fat

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Table 2.1: Publications of diabetes self-management interventions in African American adults with type 2 diabetes: January 2000 through March 2008

Study and year	Purpose of study	Design	Subjects	Setting	Description of intervention	Major findings
Rimmer <i>et.al.</i> (195) July/Aug 2002	Determine the feasibility and efficacy of a health promotion program to ↑adherence and improve health outcomes	Quasi-experimental, single group pretest posttest design	30 AA w/ T2DM; mean age 54.9 yrs.; BMI=42.3; 80% AA; 75% high BP; 48% high cholesterol; 24% heart problems; 41% depression	University-based setting; Subjects were recruited from several local hospitals and clinics in Chicago area	12-wk prog.; participants met 3 days/ wk for 3 hrs/ day; 1 hr exercise; 1 hr nutrition instruction; 1 hr health educ.	19 Completed; 72.5% compliance; significant improvements in total cholesterol, LDL-cholesterol, cardio fitness, strength, endurance, and nutrition knowledge
Rosenzweig <i>et.al.</i> (199) Sept/Oct 2007	Determine the efficacy of a mindfulness-based stress reduction prog. (MBSR) on glycemic control, wt., BP, and stress-related psychological symptoms	Prospective observational pilot study w/ outcome measures at baseline, 8 wk, and 1-mo. follow-up	14 patients w/ T2DM; 9 women; 5 men; 10 Caucasians and 4 AA; mean age=59; A1C=7.5; wt=236 lbs.; arterial pressure=100	Academic health center	8 weekly 150 min sessions plus a 7-hr weekend session using mindfulness techniques along with 2 practice CD's to take home for 20-30 min of meditation a day, 6 days/wk	At one-month A1C ↓ by .48%; mean arterial pressure ↓ by 6 mmHg; a ↓ in depression, anxiety, and general psychological distress
Rothman <i>et.al.</i> (200) March/Apr 2004	Determine the efficacy of a diabetes self-mgt. prog. that included low-literacy oriented approaches	6-mo. pretest posttest study w/ high literacy and low literacy T2DM patients	159 patients w/ T2DM and A1C scores≥8%; 85% AA; 56% female; 55% had literacy levels at the 6 th grade level or below; mean A1C=10.7%; BMI=34.3; mean age=60	University of North Carolina General Internal Medicine Practice which serves a large indigent population	Pharmacists led individualized diabetes educ. sessions with an initial 1 hr. educ. session that met ADA guidelines; easy-to-read picture-based materials supplemented the educ. sessions	111 completed follow-up data; Initial A1C scores were not different b/t literacy groups; Low and high literacy patients had same A1C improvements at 6 mo.

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Table 2.1: Publications of diabetes self-management interventions in African American adults with type 2 diabetes: January 2000 through March 2008

Study and year	Purpose of study	Design	Subjects	Setting	Description of intervention	Major findings
Samuel-Hodge <i>et.al.</i> (206) July 2006	Describe and present baseline characteristics of a culturally sensitive church-based diabetes self-mgt. prog. for AA with/ T2DM (A New DAWN)	Randomized controlled trial	201 AA w/ T2DM 8-20 participants recruited from each of 24 churches	24 churches in North Carolina	1, 60 min. individual counseling session w/ RD; 12 group sessions held at each church opened w/ prayer, focused on diet, exercise, SBGM, ended with 15 mins of chair exercises; sessions 1-7 led by RD; sessions 8-11 led by other healthcare professional; trained church members to lead efforts	118 churches contacted 30 agreed; 24 enrolled the minimum required participants; 64% women; mean age=59 yrs; A1C=7.8%; BMI=35; diagnosed mean 9 yrs; more had private health insurance, higher educ., higher income, less likely to use insulin, had lower A1C scores than in other studies
Skelly <i>et.al.</i> (226) April 2003	Test the effectiveness of an in-home, nurse-delivered, symptom-focused teaching and counseling intervention in rural older AA women with T2DM	Pilot study w/ 2 group randomized design	43 AA women with T2DM; mean age 61.9 yrs with many diabetes- related complications Completed study: 23 in intervention group; 18 in control group	Recruited from one health dept., two community-based practice; and one community health center providing care to 3 rural counties of a southeastern state	Experimental group: 6, 1 hr. biweekly home visits by a nurse; 4 visits included diabetes symptom-focused mgt. modules Comparison group: received 3, 1 hr. biweekly home visits and 1 telephone call	41 completed study; Intervention group significantly improved medication, diet, SMBG, self-care, perceptions in quality of life and ↓ distress from symptoms. Both groups improved A1C

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Study and year	Purpose of study	Design	Subjects	Setting	Description of intervention	Major findings
Tang <i>et.al.</i> (234) Jan/Feb 2005	Examine the feasibility and acceptability of an ongoing community-based diabetes self-mgt. intervention aimed at enhancing and sustaining health care behaviors in urban AA with T2DM	Longitudinal, prospective, pretest posttest study design	62 AA; 81% women; mean age 65 yrs; mean A1C=7.5; BMI=34.5	Community based setting in greater Detroit area	24 weekly 90 min. community-based diabetes self-mgt support/educ. groups guided by questions and concerns of participants and led by a nurse CDE; components included reflecting on relevant experiences, the role of emotion, problem-solving, answering self-care questions; and providing feedback	Significant improvements in BMI, total cholesterol, HDL cholesterol, LDL cholesterol and self-care behaviors No change in BP or A1C
Two Feathers <i>et.al.</i> (240) 2005	Determine the effects of a culturally tailored community-based diabetes lifestyle intervention on risk factors for diabetes complications in AA and Latinos (Detroit REACH study)	Non-randomized one group pretest posttest	151participants AA and Latino w/ T2DM; 40 dropped out prior to intervention start; 111 participants completed intervention; 81% female 64% AA 42% had less than HS educ.	3 healthcare systems in Detroit, MI	10 AA and Latino trained community residents delivered 5, 2-hr. group meetings every 4 wks, combined educ., behavioral & social learning strategies, stress mgt., goal-setting & social support in culturally relevant formats; based on social cognitive theory	74% retention; significant improvement in self-care knowledge, healthy eating, exercise, A1C

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Study and year	Purpose of study	Design	Subjects	Setting	Description of intervention	Major findings
West <i>et.al.</i> (252) May 2007	Examine the effectiveness of motivational interviewing in conjunction w/ a wt. loss intervention to improve glycemic control and wt. loss in overweight women w/ T2DM	Randomized, control, clinical trial assessments at baseline, 6, 12, 18 mo.	217 overweight women w/ T2DM; 38% AA	Recruited from Birmingham, AL area	18 mo. group-based behavioral obesity treatment with intervention group receiving 5 individualized motivational interviewing and attention control sessions	7% attrition Motivational interviewing helped women lose more wt. at 6 and 18 mo. which were mediated by enhanced behavioral changes; AA lost less wt. than white women; Greater reductions in A1C were found for the motivational group at 6 mo. but not at 18 mo.
Ziemer <i>et.al.</i> (261) June 2003	Compare a simple meal plan emphasizing healthy food choices to traditional exchange-based meal plans in urban AA w/ T2DM	Randomized 2 group study design assigned to either simple meal plan or exchange-based meal plan	648 T2DM patients; 90% AA; 65% women; mean age 52 yrs; mean wt.=94 kg; duration of diabetes 4.8 yrs; mean A1C=9.4%	Grady Health System Diabetes Clinic that serves predominantly urban AA adults	Dieticians implemented a Simple meal plan or Exchange meal plan at wks 1, 2, 4 and then again at 2, 4, and 6 mo. Nutrition counseling was 1 hr the first session and 30 mins each subsequent session.	66% attrition; Improvements in A1C, HDL cholesterol, and triglycerides were similar for both groups at 6 mo.; both groups had similar diet intake of CHO and fat; obese patients had similar wt loss in both groups

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Chapter 3

A Pilot Study to Determine the Feasibility of a Resilience and Diabetes Education Intervention in African American Adults with Type 2 Diabetes

3.1 Abstract

Purpose: This pilot study was conducted to test the feasibility of our resilience and diabetes education intervention, *The Diabetes Coaching Program: Transforming Lives Through Resilience Education*, in a population of African American adults with type 2 diabetes. *Methods:* Twenty-two participants were recruited to participate in the intervention. Using convenience sampling methodology, 16 participants elected to participate in the intervention and 6 participants chose to be in the waitlisted control group. Data were collected at baseline and at six months. Outcome variables included measurements of psychosocial processes (i.e., resilience, coping skills, self-leadership, and diabetes empowerment), psychological well-being (i.e., perceived stress, depressive symptoms, and negative affectivity), biological variables (i.e., cortisol, insulin-like growth factor-1, c-reactive protein, immune proliferation), healthful behaviors (i.e., physical activity, monitoring of blood glucose, and eating behaviors) and metabolic risk factors (i.e., weight, BMI, glycosylated hemoglobin, dyslipidemia, and hypertension). *Results:* Twelve participants completed the intervention (i.e., 75% retention) and no participants from the waitlisted control group returned for the six month data collection. The attendance rate for the four class sessions was 100%, which included make-up classes and attendance rate for the support group sessions was 56.6%. Statistical analyses conducted with the intervention group indicated that higher scores on perceived stress were associated with greater depressive symptoms, less self-leadership, less effective

coping strategies, less resilience, and lower diabetes empowerment. However, diabetes empowerment was the only psychosocial variable to be significantly enhanced by the intervention. Intervention group participants displayed significantly lower glycosylated hemoglobin scores, weight, and BMI and significantly enhanced proliferation of peripheral blood lymphocytes post-intervention. Female participants also displayed significantly decreased IGF-1 levels and blood pressure post-intervention, whereas, male participants showed significantly lower LDL levels and total cholesterol. *Conclusions:* These data suggest that our intervention may be beneficial for improving diabetes self-management and reducing metabolic risk factors associated with type 2 diabetes, but no clear effects were attributed to resilience in the short-term.

3.2 Introduction

Type 2 diabetes (T2DM) is one of the leading causes of morbidity and mortality among African American adults (3). An estimated three million African Americans have been diagnosed with T2DM amounting to nearly a two times higher prevalence rate than non-Hispanic whites (13). Alarming, the number of African Americans diagnosed with T2DM continues to escalate along with many other diabetes-related complications, including: retinopathy, neuropathy, end-stage renal disease, lower leg amputations, and cardiovascular disease (CVD) (13). Likewise, a condition known as metabolic syndrome currently affects approximately 68% of African Americans with T2DM, which is a cluster of metabolic abnormalities including abdominal obesity, hyperglycemia, dyslipidemia, and hypertension (188). It is becoming increasingly evident that these metabolic abnormalities initiate and promote the generalized vascular endothelial

dysfunction observed in diabetes. Furthermore, metabolic insults incurred from cytokine-mediated inflammation (89, 139, 177, 184, 243) (e.g., elevated C-reactive protein), activation of the sympathoadrenal system (62, 74, 80, 148, 192, 205) (e.g., increased cortisol levels), as well as neuroendocrine imbalances (83, 86, 128, 142) (e.g., increased insulin-like growth factor-1) may play roles in the microvascular and macrovascular damage associated with T2DM. Despite these negative consequences, as many as 82% of African Americans affected with T2DM do not comply with recommended treatment regimens (203).

Lifestyle change therapy is the foundation of diabetes self-management and is the safest, least expensive, and most effective form of treatment available to diabetes patients (254). Lifestyle changes include monitoring blood glucose, increasing physical activity, maintaining a healthful diet, and visiting a healthcare provider regularly. However, most diabetes patients find it overwhelming to maintain multiple lifestyle changes over the long-term due to the chronic nature of the disease (254). In addition to these challenges, African Americans are confronted with several barriers that may negatively influence diabetes self-management such as low income, less education, low literacy, lack of health insurance, and poor quality healthcare (162). Consequently, these barriers collectively contribute to high levels of perceived stress among African Americans with T2DM (166), which is also predictive of non-compliance to lifestyle change therapies, increased levels of depression, and poor quality of life (70).

Healthcare providers are in agreement that more attention needs to be given to improving the psychological well-being of individuals with T2DM, especially African Americans, in order to improve adherence to lifestyle changes and overall health

outcomes (181, 182, 221). Resilience education is a novel approach that aims to help individuals cope with change and stressful situations in ways that sustain healthy levels of psychological and physiological functioning despite being faced with a chronic illness such as T2DM. Improving psychosocial process variables such as resilience, coping strategies, self-leadership, patient empowerment, and social support may help low income African Americans cope with daily life stressors more effectively as well as diabetes-related stress.

Purpose of the Study

The overall goal of this study was to determine the feasibility of a resilience and diabetes education intervention in African American adults with T2DM. Therefore, we aimed to answer the following research questions: 1) What are the effects of the intervention at six months on the psychosocial process variables of resilience, coping skills, self-leadership, and diabetes empowerment? 2) What are the effects of the intervention on the psychological, biological, and behavioral factors potentially involved in the development and progression of T2DM at six months (i.e., psychological variables including: perceived stress, depressive symptoms, and negative affectivity; biological variables including: cortisol, insulin, insulin-like growth factor-1 (IGF-1), peripheral blood mononuclear cell (PBMC) proliferation, and C-reactive protein (CRP); and behavioral variables including: adherence to physical activity and monitoring blood glucose)? 3) What are the effects of the intervention on the metabolic risk factors associated with the disease progression of obesity (i.e., weight, BMI), T2DM (i.e., fasting

blood glucose, glycosylated hemoglobin), and CVD (i.e., blood pressure, dyslipidemia) at six months?

3.3 Methods

Design

The present study was a pilot study to test the efficacy of our resilience and diabetes education intervention, *The Diabetes Coaching Program: Transforming Lives Through Resilience Education (DCP)*, in a convenience sample of 22 African American adults with T2DM. All twenty-two participants were invited to attend the intervention. However, only 16 individuals (8 females; 8 males) attended the first education session and were designated as the intervention group. The six individuals that did not attend the first meeting (4 females; 2 males) were designated as the waitlisted control group.

Participant Selection and Procedure

After attaining approval by the Institutional Review Board of The University of Texas at Austin, participants were recruited on a voluntary basis from the East Austin community via announcements made at churches with predominantly African American congregations and through radio broadcasts. Individuals interested in participating in the study were asked to sign-up after church or contact the primary investigator of the study by phone. Prospective participants were given the date, time and location of the initial data collection, which included a survey instrument, anthropometric measures, blood pressure evaluation, and a blood draw. Study participants were contacted the day before the initial data collection and reminded to fast after 11:00 p.m. until the blood draw the

next morning at 7:00 a.m. (approximately an 8 hour fast) and to refrain from taking insulin during the fasting period. Informed consent was obtained from each participant upon arrival at the test site. To be eligible for the study, participants had to be age ≥ 40 and ≤ 70 ; diagnosed with T2DM; African American ethnicity; overweight with a BMI ≥ 24 ; under the care of a medical physician; and able to complete the assessment battery. Twenty-four individuals attended the initial data collection and received compensation of \$20 cash, refreshments after completing the blood draw, and a copy of their test results. Two individuals did not meet the inclusion criteria and were excluded from the study. The 22 remaining participants were invited to participate in the intervention. Using convenience sampling methodology, 16 participants elected to participate in the intervention and six participants chose to be in the waitlisted control group.

Participants electing to be in the waitlisted control group were informed that they would be contacted for a six month follow-up assessment and would be compensated another \$20 cash, receive a copy of their follow-up test results, and be given the opportunity to attend a one day resilience and diabetes education workshop. Intervention group participants attended the resilience and diabetes education classes and support group sessions held at a local church in East Austin, and were compensated with a Bayer Ascensia Contour Glucometer kit; a six month supply of test strips; a copy of their follow-up test results; and an additional \$80 cash, dispersed in \$20 increments throughout the intervention and at post-data collection. Therefore, the total possible monetary compensation from pre-data collection to post-data collection was \$40 cash for the waitlisted control group and \$100 cash for the intervention group. A synopsis of the incentives disbursement is presented in Table 3.1.

Characteristics of the Intervention

The intervention consisted of four weekly class sessions that integrated resilience and diabetes education and eight bi-weekly support group sessions. The intervention was titled, “The Diabetes Coaching Program: Transforming Lives Through Resilience Education.” The four resilience and diabetes education sessions were presented as two-hour formal instructional classes which met once a week for four weeks at a local church in East Austin. The resilience education portion of each class lasted approximately one hour and included the following topics: 1) Transforming stress into resilience; 2) Taking responsibility; 3) Focusing on empowering interpretations; and 4) Creating meaningful connections. A modified version of the International Diabetes Center Type 2 Diabetes BASICS course (194) was used to guide the diabetes knowledge and self-management curriculum portion of each class and lasted approximately one hour of each class session. Diabetes-related topics included: 1) An introduction to diabetes and blood glucose monitoring; 2) Diabetic food planning and physical activity; 3) Helpful tips for food planning and physical activity; and 4) Living well with diabetes. Participants received handouts of the information discussed during each class session as well as a journal to log their blood glucose readings, physical activity and eating behaviors, and to document their personal self-care goals. After the four class sessions, participants attended 5-months of bi-weekly support group meetings each lasting one and half hours. During the support group sessions, open discussions of group led topics were encouraged. Topics discussed included reviews of the information presented during the class sessions, barriers faced in promoting self-care, healthy recipes, exercise tips, journal entries and personal goals. In addition, test results from each participant’s glucometer were analyzed

with WinGlucoFacts version 1.3 and individual recommendations were given to aid in glycemic control. Participants then completed 15-30 minutes of physical activity at a local high school track near the intervention site. Each participant established his or her own level of intensity. For instance, some participants chose to walk and at times some individuals elected to jog. The duration of the physical activity was dependent upon each participant's own willingness, desire, and/or ability to perform the activity. The entire intervention lasted a total of six months. A summary of the intervention methodology is found in Table 3.1.

Measures

The testing battery was administered at baseline and at 6 months and included a survey instrument, anthropometric measures, blood pressure evaluation, and blood analyses. The following are descriptions of each measure.

Survey Instrument:

The survey instrument included measures of demographics, psychosocial process variables (i.e., resilience, coping skills, self-leadership, and diabetes empowerment), psychological well-being (i.e., perceived stress, depressive symptoms, and negative affect) and physical activity. Participants answered each item of the survey instrument in respect to the past few weeks or previous month.

The 25-item Connor-Davidson Resilience Scale (CD-RISC) was used to measure resilience during the past month. The CD-RISC was developed as a clinical measure to assess the positive effects of treatment for stress reactions, anxiety, and depression (58).

Participants were asked to reply to a five-point Likert scale ranging from 0 (*not true at all*) to 4 (*true nearly all the time*). Sample items included “I am able to handle unpleasant or painful feelings like sadness, fear and anger” and “Under pressure, I stay focused and think clearly”. The CD-RISC has a previous α reliability of 0.87 (58). The present study had an α reliability of 0.91 for the pre-test and 0.90 for the post-test.

Coping skills were assessed using the 28-item Brief Coping Orientations to Problems Experienced (Brief COPE) scale (51). The Brief COPE measures a broad range of cognitive and behavioral coping strategies that individuals typically use in stressful situations. Items from the Brief COPE were grouped as either problem-focused/approach coping strategies or emotion-focused/avoidant coping strategies, which are the most common categorizations for coping strategies listed among the literature. Problem-focused coping strategies were used to address stressful situations directly and included active coping, planning, positive reframing, acceptance, emotional support, instrumental support, and religion. The problem-focused coping alpha was 0.87 at pre-test and 0.78 at post-test. Emotion-focused coping strategies were used to minimize or manage the emotional aspects of stress, and included self-distraction, denial, venting, substance use, behavioral disengagement, self-blame, and humor. The emotion-focused coping alpha was 0.89 at pre-test and 0.73 at post-test.

Self-Leadership was determined using the 20-item Self-Leadership Scale (SLS) (211). Participants indicated how frequently they experienced such statements as “I feel a sense of inner peace” and “I treat myself with kindness” on a five-point Likert scale ranging from 1 (*never/almost never*) to 5 (*always/almost always*). The SLS has a previous

α reliability of 0.92 (11, 211). In this study, the α reliability was 0.71 at pre-test and 0.90 at post-test

The 28-item Diabetes Empowerment Scale-Short Form (DES-SF) was used to measure diabetes empowerment (18). On a five-point Likert scale ranging from 1 (*strongly disagree*) to 5 (*strongly agree*), participants responded to items such as, “I believe that I know the things about myself that either help or prevent me from reaching my diabetes goals.” The DES-SF has a previous overall α reliability of 0.85 (18). The three subscales of the DES-SF evaluated the respondent’s ability to manage the psychosocial aspects of diabetes (9 items; pre-test $\alpha = 0.52$; post-test $\alpha = 0.91$), dissatisfaction and readiness to change (9 items; pre-test $\alpha = 0.74$; post-test $\alpha = 0.82$), and ability to set and achieve goals (10 items; pre-test $\alpha = 0.87$; post-test $\alpha = 0.91$). For this study the overall DES α reliability was 0.89 at pre-test and 0.95 at post-test.

The 10-item perceived stress scale (PSS) measures the degree to which situations in one's life are perceived as stressful (57). Using a five-point Likert scale ranging from 0 (*never*) to 4 (*very often*), participants indicated the extent to which they experienced such feelings as “Felt that you were unable to control the important things in your life” and “Felt difficulties were piling up so high that you could not overcome them” during the past month. The PSS has a previous α reliability of 0.88 (57). For this study, the α reliability was 0.72 at pre-test and 0.83 at post-test.

Depressive symptoms were measured using the 20-item Center for Epidemiologic Studies Depression Index (CES-D) (189). Participants indicated on a four-point Likert scale ranging from 0 (*rarely or none of the time – less than 1 day*) to 3 (*all of the time – 5 to 7 days*), the extent to which they experienced various depressive symptoms during the

past few weeks such as “I felt that everything I did was an effort” and “I had crying spells”. The CES-D has a previous α reliability of 0.85 (189). For this study, the α reliability was 0.80 at pre-test and 0.85 at post-test.

Negative affect was measured with the 20-item Positive and Negative Affect Schedule (PANAS) (249). This version of the PANAS includes 10 items measuring positive affect and 10 items measuring negative affect. Positive affect items were included to reduce respondent bias. On a five-point Likert scale ranging from 1 (*not at all*) to 5 (*very much so*), participants indicated to what extent they generally felt various negative feelings and emotions such as “distressed” and “irritable”. The PANAS has a previous α reliability of 0.87 (249). For this study, the α reliability for negative affect variable was 0.91 at pre-test and 0.91 at post-test.

Physical activity was assessed using a modified version of the Blair Physical Activity Scale of the Institute for Aerobics Research (136). Participants were asked to report their physical activity levels during the past month ranging from 0 (sedentary) to 4 (moderate to active at least 5 times per week for at least 30 minutes).

Anthropometric Measures:

The weight and height of each participant was assessed using a calibrated balance-beam weight and stadiometer scale. Participants were measured without shoes to the nearest 0.5 pound and to the nearest 0.5 inch. BMI was calculated using the following equation: $BMI = (\text{weight in kg}) / (\text{height in m}^2)$.

Blood Pressure Evaluation:

Systolic and diastolic blood pressures were assessed using an Omicron HEM-712C Automatic Inflation Blood Pressure and Heart Rate Monitor (Omicron, Philadelphia, PA). Participants were instructed to sit quietly while blood pressure was measured in triplicate with a two minute waiting period between each assessment. The first blood pressure reading was discarded and the final two readings were averaged. The American Heart Association (AHA) defines hypertension as a systolic blood pressure greater than 140 mmHg and a diastolic blood pressure greater than 90 mmHg. Prehypertension is defined as 120 to 139 mm Hg and a diastolic blood pressure between 80 to 89 mm Hg. However, the American Diabetes Association (ADA) recommends that people with diabetes keep blood pressure at or below 130/80 mm/Hg.

Blood analyses:

Two tubes of blood were collected from each participant by a licensed phlebotomist from 7:00 am to 9:00 am using a 23 G needle placed in the antecubital vein of the non-dominant arm. One 9.5 mL volume of blood was collected into an EDTA coated tube (BD Co., Franklin Lakes, NJ) for lymphocyte proliferation assays, lipid analyses, and glycosylated hemoglobin assessments, and a second 9.0 mL volume was collected into a polymer gel coated tube (BD Co., Franklin Lakes, NJ) for serum protein assays. The samples were placed on ice and transported to the lab for centrifugation. Plasma, serum, and buffy coat layers were then separated into different tubes. Plasma and serum samples were immediately stored at -80°C. Peripheral blood mononuclear cells (PBMCs) were extracted from the buffy coat layer using Lymphocyte Separation

Medium (Cambrex, Baltimore, MD), counted using a Cell-Dyn 900 Hematology Analyzer (Sequoia-Turner Corp., Chicago, IL) and immediately prepared for proliferation assays.

To determine serum cortisol, insulin, and C-reactive protein (CRP) levels, a Human Cortisol ELIZA kit and a Human CRP ELIZA kit were used according to manufacturer instructions. All three kits were purchased from Alpha Diagnostics International in San Antonio, TX and utilized the same procedure. Briefly, standards and serum samples were plated in duplicate and an enzyme conjugate for either cortisol, insulin, or CRP was added. After a short incubation, the plates were washed and an HRP substrate was added. The reactions were stopped and optical densities were read on a microplate reader at 415 nm.

Insulin-like growth factor-1 (IGF-1) levels were measured with an IGF-1 TiterZyme Enzyme Immunometric Assay (EIA) Kit (Assay Designs, Inc., Ann Arbor, MI) per manufacturer instructions. First, IGF-1 was extracted from plasma with 100% ethanol and 2N HCl and the supernatant was decanted and neutralized. The plasma samples were diluted 1:70 with assay buffer prior to use. Standards and plasma samples were plated in duplicate. After a brief incubation, a secondary polyclonal antibody to IGF-1 was added. The plate was washed and an HRP substrate was added. The reaction was stopped and optical density was read on a microplate reader at 415 nm.

To test PBMC proliferative ability, preliminary experiments were first conducted to determine optimal time points and cells needed per well. Based on the preliminary experiments, 1×10^6 cells/well were plated in duplicate and stimulated with 0.01 $\mu\text{g}/\mu\text{L}$ plate-bound anti-CD3 or left unstimulated for 72 hours at 37°C in a media environment

containing RPMI 1640, 10% FBS, Penicillin/Streptomycin, L-Glutamine. Lymphocyte proliferation was measured using an MTT Cell Proliferation Assay (ATCC, Manassas, VA) according to manufacturer instructions. Briefly, MTT reagent was added to the cells and incubated for four hours at 37°C until a purple precipitate was visible. Cells were permeabilized with detergent and incubated for two hours at room temperature. Absorbance was read at 570 nm and values were corrected for background. Percentage proliferation was determined using the following equation: $[1 - (\text{the absorbance of unstimulated cells}) / (\text{the absorbance of CD3 stimulated cells})] * 100$.

Glycosylated hemoglobin levels (HbA_{1c}) were determined via an affinity chromatography method using a Micromat II HbA_{1c} CLIA Waived Test (Bio-rad, Hercules, CA) according to manufacturer instructions. First, the Micromat II was calibrated with a control cartridge to insure the accuracy of the ranges detected. Then, 10µL of EDTA-treated whole blood sample was loaded into a test cartridge consisting of several tubes containing different reagents that were each decanted at different time points into a central reservoir and a percentage score was obtained and recorded. HbA_{1c} scores are considered normal between 3% to 6% and 7% or less is acceptable for a diabetic patient.

Lipids and lipoproteins were analyzed using a Vitros DT60 analyzer (Ortho-Clinical Diagnostics, Raritan, NJ) according to manufacturer instructions with the use of calibrators verified by the College of American Pathologists. In short, plasma samples were fractionated and high density lipoprotein (HDL) cholesterol was separated from low density lipoprotein (LDL) cholesterol. These samples were loaded onto various slides that used a multilayered reagent system which oxidized the cholesterol to hydrogen peroxide.

The hydrogen peroxide was then oxidized to a colored dye and measured by reflectance spectrophotometry. The color measured was directly proportional to the concentration of cholesterol in the plasma sample. Triglyceride (TG) analysis was performed by a similar method, except TG was dissociated from the lipoprotein fraction in each plasma sample. Then, the glycerol portion of the TG was isolated and further reduced to a quantifiable colored dye and analyzed as described above. The AHA defines normal TG levels as less than 150 mg/dL; HDL levels as 50 mg/dL or greater for women and 40 mg/dL or greater for men; LDL levels as less than 100 mg/dL; and total cholesterol less than 200 mg/dL.

Statistical Analysis

All data at baseline and six months were entered into SPSS for Windows version 15.0. Descriptive statistics including means, standard deviations, numbers, frequencies, and percentages were calculated for all variables at baseline in both the waitlisted control group and the intervention group. Independent t-tests were used to determine baseline equivalence between groups. Because no control participants returned for the six month data collection, only the intervention group outcomes were determined post-intervention. Therefore, general trends were assessed for each measure in the intervention group at six months using paired t-tests to minimize loss of effect due to small sample size. In addition, the data were not skewed. Therefore, conducting other statistical tests such as non-parametric analyses would have caused statistical significance to be lost. Anthropometric, blood pressure, and biological data for the intervention group were also entered into GraphPad Prism 5.0 software (San Diego, CA) at baseline and six months and statistical differences were determined by paired t-tests and graphed +/- the standard

error of measurement. Cohen's d was used to calculate the effect size of each measure post-intervention. A large effect was considered $d \geq 0.8$. Bivariate Pearson's correlations were also calculated to determine relationships between psychosocial process variables and measures of perceived stress in the intervention group.

3.4 Results

Psychosocial, anthropometric, and biological data were obtained on 22 participants at baseline. However, no participants from the waitlisted control group ($n=6$) returned for the 6 month follow-up due to lack of interest or inability to contact participants because of disconnected phone numbers. Of the 16 participants in the intervention group, 4 participants were unable to complete the 6-month follow-up due to work-related conflicts, relocation, or lack of interest. In addition, one female participant in the intervention group was unable to attend the blood draw at the 6 month follow-up, but completed the survey measure, anthropometric measures, blood pressure assessment and allowed 10 μL of blood to be obtained for HbA_{1c} analysis. The retention rate for the intervention group was 75%. Of the 12 participants who completed the intervention, 100% attended all four resilience and diabetes education classes. This percentage includes those participants who received make-up class sessions, which were held on two occasions: once at the home of a wheelchair bound participant and once at a local hospital for a participant whose husband was hospitalized. In addition, 56.6% attended the support group sessions.

Baseline Participant Characteristics

Independent t-tests found no significant differences between the waitlisted control group and the intervention group at baseline for demographic variables, psychosocial variables, and physical activity, as reported in Tables 3.2 and 3.3. No significant differences were found between groups for biological variables except IGF-1 among females and are shown Table 3.4.

Psychosocial Process Outcomes at 6 months

Paired t-tests were conducted to determine the differences between means of psychosocial process variables at baseline and 6 months among intervention group participants and are presented in Table 3.5. Diabetes empowerment was the only variable to be significantly enhanced by the intervention ($p=0.001$). All three DES-SF subscales were also found to be significantly enhanced at 6 months which included: Managing Psychosocial Aspects of Diabetes ($p=0.000$); Readiness to Change ($p=0.003$); and Setting and Achieving Goals ($p=0.023$). Cohen's d confirmed a large effect for the DES-SF ($d=1.226$) and two of the DES-SF subscales; Managing Psychosocial Aspects of Diabetes ($d=1.412$) and Readiness to Change ($d=1.077$).

To explore whether there were differences among genders for each psychosocial process variable, paired t-tests were conducted for female participants only and male participants only at 6 months and are shown in Table 3.6. Again, the only psychosocial process variable to be significantly increased by the intervention within each gender was diabetes empowerment. However, females had less significant scores for the DES-SF ($p=0.073$) than males ($p=0.009$). In addition, females reported significant changes for

only one of the DES-SF subscales at 6 months, Managing Psychosocial Aspects of Diabetes ($p=0.032$), whereas males reported significant differences for all three subscales including: Managing Psychosocial Aspects of Diabetes ($p=0.008$); Readiness to Change ($p=0.020$); and Setting and Achieving Goals ($p=0.059$). Cohen's d calculated large effect sizes for the DES-SF in females ($d=0.924$) and males ($d=1.674$) at 6 months. Females also reported a large effect for the Managing Psychosocial Aspects of Diabetes subscale ($d=1.208$) and males reported large effects for Managing Psychosocial Aspects of Diabetes ($d=1.719$), Readiness to Change ($d=1.376$) and Setting and Achieving Goals ($d=0.993$).

Psychological Well-Being and Physical Activity Outcomes at 6 months

To determine the effectiveness of the intervention to improve psychological well-being among participants, perceived stress, depressive symptoms and negative affect were assessed at baseline and 6 months. Paired t-tests showed no significant differences for psychological well-being variables at 6 months among the intervention group participants or within separate genders, as presented in Tables 3.5 and 3.6. However, bivariate Pearson's correlations were performed on the intervention group and indicated that higher scores on perceived stress were associated with greater depressive symptoms, less self-leadership, less effective coping strategies, less resilience, and lower diabetes empowerment.

Significant differences were found for self-reported physical activity among all intervention group participants ($p=0.087$) and female participants alone ($p=0.025$) at 6 months, whereas males did not report significant changes in physical activity post-

intervention, as shown in Tables 3.5 and 3.6. Cohen's d also determined a large effect size for female participants on self-reported physical activity ($d=1.293$) post-intervention.

Biological Outcomes at 6 months

To determine whether the intervention could alter biological factors that may potentially contribute to the underlying metabolic syndrome experienced by many T2DM patients, paired t-tests were conducted on serum cortisol, plasma insulin-like growth factor-1 (IGF-1), peripheral blood mononuclear cell (PBMC) proliferation, and serum c-reactive protein (CRP) at 6 months. Unfortunately, t-tests were unable to be performed on serum insulin levels due to extremely skewed data. Serum cortisol levels showed no significant differences for females ($p=0.561$) or males ($p=0.225$) post-intervention (data not shown). However, female participants demonstrated a 11.9% decrease in plasma IGF-1 levels at 6 months, which was found to be significant ($p=0.030$) whereas, males showed no significant change ($p=0.650$), as presented in Figure 3.1. In addition, Cohen's d indicated a large effect for plasma IGF-1 levels at 6 months in females ($d=1.477$).

To determine the impact of the intervention on acquired immune function, PBMC proliferation was analyzed following stimulation with anti-CD3 at baseline and 6 months. In Figure 3.2, percent proliferation of PBMCs was significantly enhanced at 6 months for females ($p=0.095$) and males ($p=0.043$). Greater significance differences were found in proliferation when both females and males were grouped together ($p=0.005$). These differences resulted in a 60.1% increase in PBMC proliferation for females; a 61.5% increase for males; and a 61.9% increase for the intervention group as a whole. Cohen's d indicated a large effect for proliferation post-intervention in females ($d=2.071$), males

($d=1.864$), and for both females and males ($d=1.612$). In addition, serum CRP levels were assessed to determine the impact of the intervention of innate immune function. No significant differences were found in mean CRP levels for females ($p=0.425$) or males ($p=0.972$) post-intervention (data not shown). However, intervention participants had highly elevated mean CRP levels (≥ 3.0 mg/L) at baseline and post-intervention with mean levels reaching 7.1 mg/L \pm 8.7 and 7.0 mg/L \pm 6.4 , respectively, indicating an elevated risk for CVD.

Metabolic Risk Factor Outcomes at 6 months

Weight and BMI were measured as markers of obesity at baseline and 6 months and are shown in Figure 3.3. Paired t-tests determined a significant decrease in the mean body weight of males ($p=0.037$) at 6 months, which amounted to a 1.9% mean weight loss or 1.9 kilograms. Females showed a 2.1% mean weight loss or 1.8 kilograms, however this change was not found to be significant ($p=0.121$). Cohen's d determined a large effect for weight loss in males ($d=1.149$), but not females. Significant decreases in BMI were also found post-intervention for females ($p=0.093$) and males ($p=0.025$), and even greater significance differences were found when both females and males were grouped together ($p=0.006$). Cohen's d showed large effects on BMI for females ($d=0.847$), males ($d=1.293$), and when grouped together ($d=0.995$).

To determine whether the intervention could improve glycemic control, glycosylated hemoglobin (HbA_{1c}) scores were obtained at baseline and 6 months. The mean HbA_{1c} score for the intervention group at baseline was $6.9\% \pm 1.7$, which is classified as normal for diabetic patients. However, significant decreases were observed

for HbA_{1c} in females ($p=0.042$) and males ($p=0.056$) post-intervention as shown in Figure 3.4. The level of significance improved ($p=0.004$) when females and males were grouped together. These differences resulted in a 1.8% decrease in HbA_{1c} for females (pre-test=7.5%; post-test=5.7%); a 0.9% decrease for males (pre-test=6.4%; post-test=5.5%); and a 1.3% decrease for the intervention group as a whole (pre-test=6.9%; post-test=5.6%). Large effects were found for HbA_{1c} scores in females ($d=1.111$), males ($d=1.009$), and when grouped together ($d=1.042$). Furthermore, the mean HbA_{1c} score for the intervention group at 6 months decreased to $5.6\% \pm 0.81$, which is within the normal range for individuals without diabetes.

Dyslipidemia and hypertension were assessed as markers of CVD. At baseline, female participants showed within normal ranges for mean total cholesterol ($169.7 \text{ mg/dL} \pm 32.4$) and mean TG ($132.3 \text{ mg/dL} \pm 78.4$); slightly elevated mean LDL ($101.7 \text{ mg/dL} \pm 27.8$); and lower than normal mean HDL ($41.7 \text{ mg/dL} \pm 11.0$). At baseline, male participants demonstrated normal ranges for mean total cholesterol only ($186.3 \text{ mg/dL} \pm 29.6$); elevated levels for mean LDL ($113.3 \text{ mg/dL} \pm 40.3$) and mean TG ($178.2 \text{ mg/dL} \pm 113.4$); and slightly lower than normal levels for mean HDL ($37.2 \text{ mg/dL} \pm 7.5$). No significant changes were found for HDL and TG levels in either females ($p=0.296$ and $p=0.688$, respectively) or males at 6 months ($p=0.410$ and $p=0.755$, respectively) (data not shown). In Figure 3.5, results indicate significant changes at 6 months in males for LDL levels ($p=0.007$) and total cholesterol ($p=0.003$). This resulted in a 22.8% decrease in LDL levels and a 15.1% decrease in total cholesterol levels for males. When females and males were grouped together, the level of significance improved for LDL ($p=0.005$), but not for total cholesterol ($p=0.043$), which was still significant. Large effects were also

determined for LDL ($d=1.792$) and total cholesterol ($d=2.159$) in males. However, when females and males were grouped together only LDL showed a large effect size ($d=1.081$).

In regard to blood pressure, the intervention group did not display hypertension, but did display prehypertension, with a mean systolic blood pressure of $134.6 \text{ mmHg} \pm 16.7$ and a mean diastolic blood pressure of $82.0 \text{ mmHg} \pm 11.2$. In Figure 3.6, significant decreases are shown for systolic ($p=0.002$) and diastolic ($p=0.057$) blood pressure in females and in the intervention group as a whole ($p=0.018$ and $p=0.031$, respectively). This resulted in a 12.5% decrease in systolic blood pressure and an 11.4% decrease in diastolic blood pressure for females. Likewise, the intervention group as a whole showed a 7.5% reduction for systolic blood pressure and 7.3% reduction in diastolic blood pressure. Cohen's d confirmed large effect sizes for systolic ($d=2.350$) and diastolic ($d=1.004$) blood pressure in females. However, a large effect was only found for systolic blood pressure ($d=0.803$) when females and males were grouped together.

3.5 Discussion

This pilot study was conducted not only to test the feasibility of a resilience and diabetes education curriculum in a population of African Americans with T2DM, but also to gain insight as to how the curriculum could be improved to become more culturally relevant to the needs of African American adults. The conceptual framework of this study was designed to generate both positive psychological and physiological health outcomes by enhancing psychosocial process variables to increase adherence to diabetes self-management. Study findings indicated that the intervention successfully enhanced diabetes empowerment, self-reported physical activity, and PBMC proliferation and

significantly decreased glycosylated hemoglobin scores, body weight, BMI, blood pressure, LDL and total cholesterol as well as female IGF-1 levels at 6 months.

Though diabetes empowerment was the only psychosocial variable to show significant increases at six months, general trends demonstrated a shift toward improved scores on resilience, self-leadership, and perceived stress. However, the use of effective coping strategies remained unchanged at six months. These results may be due to the short-term length of the intervention and the fact that only one individual had previously received standard diabetes education. This is noteworthy in that many African Americans have limited access to quality medical care and general health information (3). Therefore, participants may have been more concerned with acquiring knowledge about diabetes rather than focusing on coping with diabetes-related stress. Alternatively, acquiring knowledge about diabetes and becoming more empowered to manage the disease may be the first step to alleviating stress among African Americans (12) as well as increasing resilience, problem-focused coping skills, and self-leadership. As individuals become more confident and comfortable with diabetes self-management, greater improvements may be witnessed in psychological well-being. More resilience education classes may also be needed before significant psychosocial changes are reported by participants. Likewise, resilience education may prove to be more effective in the long-term for maintaining the necessary lifestyle changes introduced by the diabetes education component of the curriculum. However, more long-term studies are needed to better determine the role resilience education plays in adherence to lifestyle changes necessary for proper diabetes self-management and in the psychological well-being of African Americans with T2DM.

In keeping consistent with the chronic care model (183) and current literature on patient empowerment (20), the intervention only utilized resources that participants had easy and open access to within the community (e.g., churches, neighborhood walking trails, high school tracks, local grocery stores, etc.). This concept provided participants with the skills and knowledge necessary to make healthy lifestyle choices upon completion of the study rather than the need for expensive gym memberships, personal trainers, and nutritionists that would not be practical for low income African Americans. This may explain why individuals reported significantly increased levels of physical activity at 6 months. Likewise, the church community served as an outlet for social support to the individuals participating in the intervention. By remaining culturally sensitive to the social environment of African Americans, the long-term compliance to lifestyle changes such as diet and exercise may be enhanced as well as the cost effectiveness.

Biological markers were also assessed in this study. Cortisol was one hormone of interest because it is regulated by the sympathoadrenal system in response to emotional stress and is also highly correlated with abdominal obesity (62). African Americans are also documented to report elevated levels of perceived stress (132, 255). In addition, disorders involving high cortisol levels, such as Cushing's syndrome and Subclinical Hypercortisolism, increase the risk for developing T2DM and CVD (54, 74, 192). More importantly, normal metabolic function is restored when cortisol imbalances are corrected (54, 74, 192). In this study no significant decreases were found in self-reported perceived stress, so it was not surprising that serum cortisol levels remained unchanged at 6 months. In addition, all study participants were within normal ranges for serum cortisol

levels. However, only total circulating serum cortisol levels were measured and not physiologically active cortisol. Future studies should examine the levels of active circulating cortisol as well as the levels of 11 β -hydroxysteroid dehydrogenase (11 β -HSD1) type 1 enzyme which converts inactive corticosterone to active cortisol in humans (178).

Insulin-like growth factor-1 (IGF-1) was another hormone examined in this study. IGF-1 is an insulin-related peptide that demonstrates rapid insulin-like metabolic actions, growth-promoting actions and can be a potent cell survival factor. IGF-1 levels are documented to decrease in humans with calorie restriction and weight loss (156). In addition, IGF-1 levels are elevated under acute physiological stress and can become depleted with chronic physiological stress due to the continual need for its restorative actions such as in ischemic heart disease (118). In this study, significant decreases were found in female subjects, but not male subjects at 6 months. This result was interesting because male study participants showed more significant reductions in weight than females, but did not demonstrate comparably significant decreases in IGF-1 levels, although males demonstrated decreasing trends. One explanation for this finding may be that females reported better glycemic control than males at 6 months. However, male participants had better glycemic control than females at baseline. Recent literature suggests that IGF-1 may protect against glucose intolerance and the onset of CVD (128). Therefore, IGF-1 may become up-regulated during states of insulin resistance and poor glycemic control and serve as a compensatory mechanism for glucose transport which may explain the decreases witnessed with better glycemic control in females. Future studies should also focus on assessing IGF-1 binding protein levels and the degree of

insulin resistance in study participants to give further insight into the mechanism of this finding. For instance, when IGF binding protein-1 (IGFBP-1) increases, it limits IGF-1's ability to bind its cell surface receptors. This is important because IGFBP-1 levels are elevated when insulin levels decrease (142). Thus, IGFBP-1 levels are low in cases of insulin resistance thereby allowing for increased IGF-1 levels, and may serve as an important predictor of further disease progression.

Because many patients with T2DM experience poor wound healing and delayed responses to infection, this study also evaluated the effects of the intervention on acquired immune function. Study results indicated significantly increased PBMC proliferation at 6 months in both females and males after undergoing anti-CD3 stimulation for 72 hours. Insulin receptors are known to emerge on human peripheral T lymphocytes after activation with a mitogen or antigen within 24 hours of stimulation and plateau at 72 hours (230). Once insulin binds these receptors, it can enhance lymphocyte function, differentiation, proliferation and maintain the activated state of the lymphocyte by enhancing the energy requirements and protein synthesis necessary for proper lymphocyte functioning. T lymphocytes also have the capacity to distinguish chronic and acute changes in the ambient insulin levels and have the ability to change their insulin receptor generation capacity (230). Therefore, in chronic states of insulin resistance T lymphocyte insulin receptors may become down-regulated, thereby decreasing lymphocyte proliferation. Study participants showed better glycemic control post-intervention and may have experienced decreased insulin resistance. However, to further confirm the relationship between increased PBMC proliferation and better glycemic control, further studies are needed to determine T lymphocyte insulin receptor generation

capacity and insulin levels post-intervention. Nonetheless, these results may indicate a beneficial effect for individuals with T2DM who display altered immuno-responsiveness to infection and may help to improve wound healing.

Additionally, it is suspected that T2DM may, in part, be advanced by an acute phase reaction of the innate immune system, in which the adipose tissue creates a low grade inflammatory response by releasing large amounts of cytokines. An inflammatory response also occurs in atherosclerosis due to mononuclear blood cell infiltration into the vessel wall endothelium which is prolonged by the acute phase protein, C-reactive protein (CRP) (184). High levels of CRP (>3.0 mg/L) are found in individuals with T2DM and CVD and continue to elevate as the severity of these conditions increase (89). In this study, CRP remained unchanged post-intervention, though was found to be highly elevated in both female and male subjects. Because CRP levels remained unchanged with improved glycemic control and decreased body weight in study participants, it may serve as an independent risk factor in the development of T2DM and CVD. However, study participants only demonstrated approximately a 2.0% weight loss. Several previous studies report significant decreases in CRP levels with weight losses between 5-10% (243). Therefore, with more dramatic weight loss a clear effect may be established.

Since African Americans experience higher rates of obesity, T2DM and CVD than the general population, it is necessary to develop therapies that concurrently ameliorate the multiple metabolic abnormalities associated with this disease progression. The findings from the present study show that the resilience and diabetes education intervention was effective in simultaneously improving almost all metabolic risk factors in African American adults except for HDL cholesterol and TG levels. However, lipid

and lipoprotein levels were not extremely out of range for the intervention group at baseline. Overall, these results have important economic implications for the healthcare costs of African Americans. In 2002, approximately \$93 billion of U.S. healthcare expenditures was attributed to complications resulting from overweight and obesity (232); \$132 billion was spent on diabetes (117); and \$150 billion was spent on CVD (198). Currently, healthcare costs for African Americans with diabetes are more than double those without diabetes (3). Therefore, eliminating or reducing multiple metabolic abnormalities through lifestyle change therapy could significantly improve the quality of life for African Americans while at the same time reducing healthcare expenditures.

The greatest limitation of this study was the inability to collect follow-up data from the control group participants. This limitation was due to small sample size, participant lack of interest, and the inability to contact control participants post-intervention due to disconnected phone numbers. Because this was a pilot study with limited funding, over-sampling of the intervention group was purposely performed to assure that an adequate number of participants completed the intervention. However, a larger sample size for the waitlisted control group would have been optimal and may have improved the attrition concerns. Secondly, after the initial data collection was performed, no further contact was made with the control participants to avoid influencing normal diabetes self-management practices. In hindsight, increasing investigator contact with the control group participants throughout the study may have increased retention rates by maintaining the interest of the control participants and would also serve as a means to update participant contact information periodically. Another method for possibly increasing retention rates in the control group may be to collect pedometer

information for physical activity assessments throughout the extent of the study, which would also strengthen the reliability and validity of self-reported physical activity.

A second limitation of the study is that the participant sample was, for the most part, within normal ranges for many of the metabolic risk factor variables at pre-test and therefore large improvements may not have been possible for these variables. For instance, at baseline the mean glycosylated hemoglobin score for the participant group was near 7%, which is an acceptable score for diabetes patients. Likewise, participants displayed near to within normal ranges for most lipid and lipoprotein values and were classified as prehypertensive rather than hypertensive. However, most participants were taking medication to manage these symptoms. Therefore, it was difficult to see changes at six months for some of these variables. Assessing the amounts and frequencies of medications prescribed to participants may provide additional information for determining the effects of the intervention.

In conclusion, the resilience and diabetes education intervention promoted considerable beneficial effects on multiple metabolic risk factors associated with the disease progression of obesity, T2DM, and CVD, as well as markers of neuroendocrine and immune function. These beneficial health outcomes are most likely attributed to better glycemic control and modest decreases in body weight. Therefore, resilience and diabetes education may reduce diabetes-related medical complications, healthcare costs, and improve quality of life among African American adults with T2DM. However, additional long-term studies are needed to determine the role resilience education plays in maintaining these positive health outcomes and improving the psychological well-being of African Americans with T2DM.

Future directions of the research include: 1) conducting focus group sessions with the current participants to refine and revise the curriculum; 2) developing a participant manual and facilitator manual for the resilience and diabetes education program that is culturally relevant for African American adults; 3) continuing monthly support group sessions with the current participants for one additional year with focus given to developing more effective coping strategies for dealing with stress; and 4) conducting a one-year follow-up study with the current participants to test the long-term effectiveness of the intervention.

Table 3.1 Summary of Methodology

Baseline	Intervention		Post-Intervention (6 months)
	Diabetes Coaching Program: Transforming Lives through Resilience Education		
<i>Measures (2 hours)</i>	<i>4 weekly education sessions (2 hours each)</i>	<i>8 bi-weekly support group sessions (1.5 hours each)</i>	<i>Measures (2 hours)</i>
<ul style="list-style-type: none"> • Survey Instrument • Anthropometric Measures • Blood Pressure • Blood Analysis 	Class 1) Transforming stress into resilience/ Introduction to type 2 diabetes Class 2) Taking responsibility/ Your diabetes food plan and physical activity Class 3) Focusing on empowering interpretations/ Helpful tips for food planning and physical activity Class 4) Creating meaningful connections / Living well with diabetes <ul style="list-style-type: none"> • Journaling • Blood glucose monitoring 	<ul style="list-style-type: none"> • Open discussion of group led topics • Review information from classes • Barriers faced in promoting self-care • Share recipes and exercise tips • Journal entries • Goal-setting • Blood glucose monitoring • Blood glucose analyses and recommendations • 15-30 minutes of walking 	<ul style="list-style-type: none"> • Survey Instrument • Anthropometric Measures • Blood Pressure • Blood Analysis
Compensation			
<ul style="list-style-type: none"> • \$20 cash, refreshments, biological test results 	<ul style="list-style-type: none"> • \$20 cash after attending all four class sessions • Glucometer kit • 6 month supply of test strips 	<ul style="list-style-type: none"> • \$20 cash after the fourth support group • \$20 cash after the eighth support group 	<ul style="list-style-type: none"> • \$20 cash, refreshments, biological test results • Waitlisted control participants also received the opportunity to attend a one day workshop on resilience and diabetes education

Table 3.1 is a summary of the methodology used to conduct the intervention.

Table 3.2: Baseline Participant Demographic Characteristics

Variable	Control Group (n=6)	Intervention Group (n=16)
Gender		
Female	66.7% (4)	50.0% (8)
Male	33.3% (2)	50.0% (8)
Age (years)	53.7 ± 8.64	53.9 ± 6.53
Education level		
High school or less	16.7% (1)	18.8% (3)
Some college or more	83.4% (5)	81.4% (13)
Gross household income		
\$39,000 or less	50.0% (3)	43.8% (7)
\$40,000 to \$59,999	16.7% (1)	37.5% (6)
\$60,000 or more	33.4% (2)	22.8% (3)

Table 3.2 reports baseline demographic characteristics of the waitlisted control group (n=6) and the intervention group (n=16). Independent t-tests determined no significant differences existed at baseline between groups for all demographic variables.

Table 3.3: Baseline Participant Psychosocial and Physical Activity Characteristics

Variable	Control Group (n=6)	Intervention Group (n=16)
Resilience	80.6 ± 11.71	82.82 ± 10.24
Self-Leadership	81.5 ± 9.81	83.17 ± 9.87
Problem Focused Coping	36.00 ± 9.51	39.03 ± 5.92
Emotion Focused Coping	33.17 ± 7.78	31.61 ± 8.27
Diabetes Empowerment	4.04 ± 0.60	3.84 ± 0.45
Negative Affect	19.50 ± 6.06	16.13 ± 5.37
Physical Activity	0.83 ± 0.98	1.44 ± 1.26

Table 3.3 reports baseline psychosocial and physical activity characteristics of the waitlisted control group (n=6) and the intervention group (n=16). Independent t-tests determined no significant differences existed at baseline between groups for psychosocial or physical activity variables.

Table 3.4: Baseline Participant Biological Characteristics

Variable	Control Group (n=6)	Range for Control Group	Intervention Group (n=16)	Range for Intervention Group
Cortisol (µg/dL)				
Females	12.65 ± 3.10	9.55 - 15.58	13.18 ± 3.14	8.12 - 18.77
Males	14.1 ± 4.18	11.14 - 17.06	16.72 ± 7.12	7.66 - 30.85
IGF-1 (ng/dL)				
Females	357.97 ± 60.94	305.41 - 443.55	273.24 ± 47.39	222.15 - 354.02
Males	289.91 ± 4.49	286.73 - 293.08	263.63 ± 43.33	219.81 - 326.52
PBMC Proliferation (%)	32.84 ± 17.01	18.77 - 53.42	5.08 ± 37.78	-70.72 - 69.00
CRP (mg/L)	13.27 ± 14.18	0.815 - 38.10	7.1 ± 8.68	0 - 31.97
Mean BMI	34.3 ± 4.46	29 - 41	34.1 ± 5.67	24 - 42
HbA1c (%)	7.6 ± 2.00	5.7 - 10.2	6.9 ± 1.51	4.6 - 11.1
HDL (mg/dL)				
Females	53.0 ± 26.61	30 - 90	42.38 ± 9.68	32 - 62
Males	32.0 ± 2.83	30 - 34	34.5 ± 8.14	24 - 48
LDL (mg/dL)	109.0 ± 27.94	61 - 147	101.31 ± 40.15	10 - 187
TG (mg/dL)	127.83 ± 85.00	71 - 296	142.19 ± 86.73	51 - 328
Total Cholesterol (mg/dL)	180.5 ± 37.23	117 - 224	173.69 ± 31.24	127 - 235
Systolic Blood Pressure (mmHg)	150.33 ± 33.28	123 - 214	134.06 ± 16.72	100 - 160
Diastolic Blood Pressure (mmHg)	95.67 ± 19.54	80 - 131	82.81 ± 9.85	66 - 100

Table 3.4 reports baseline biological characteristics of the waitlisted control group (n=6) and the intervention group (n=16). Independent t-tests determined no significant differences existed at baseline between groups for each biological variable except IGF-1 levels in females.

Table 3.5: Mean Differences for Psychosocial Process Variables, Psychological Well-being Variables, and Physical Activity for All Intervention Participants (n=12) Pre-and Post-Intervention

Measures	Both Female and Male Participants (n=12)					
	Baseline		6 months		P value	Cohen's <i>d</i> Effect Size
	Mean	SD	Mean	SD		
Psychosocial Process Variables						
Resilience (CD-RISC)	83.18	8.48	84.08	8.38	0.734	0.100
Coping Strategies (Brief COPE)						
Problem Focused Coping	38.63	4.62	39.08	3.20	0.795	0.077
Emotion Focused Coping	32.89	9.17	32.92	5.98	0.992	0.003
Self-Leadership (SLS)	83.22	7.76	84.33	9.37	0.574	0.167
Diabetes Empowerment (DES)	3.75	0.39	4.37	0.41	0.001*	1.226
Managing Psychosocial Aspects	3.63	0.36	4.42	0.40	0.000*	1.412
Readiness to Change	3.79	0.41	4.28	0.46	0.003*	1.077
Setting and achieving goals	3.83	0.54	4.41	0.42	0.023*	0.764
Psychological Well-being Variables						
Perceived Stress (PSS)	16.50	4.03	15.58	5.00	0.381	0.264
Depressive Symptoms (CES-D)	11.57	7.08	11.75	7.79	0.925	0.028
Negative Affectivity (PANAS)	16.75	5.29	17.50	6.61	0.652	0.134
Physical Activity Variable						
Physical Activity (BIAR)	1.42	1.17	2.08	1.17	0.087‡	0.542

Table 3.5 shows means, standard deviations, *p* values, and effect sizes of self-reported psychosocial process variables, psychological well-being variables and physical activity at baseline and 6 months for all intervention participants (n=12). A large effect was considered $d \geq 0.8$. * Significant difference of $p \leq 0.05$ post-intervention. ‡ Significant difference of $p \leq 0.1$ post-intervention.

Table 3.6: Psychosocial Process Variables, Psychological Well-being Variables and Physical Activity of Females (n=6) and Males (n=6) Pre-and Post-Intervention

Measures	Females (n=6)						Males (n=6)					
	Baseline		6 months		P value	Cohen's d Effect Size	Baseline		6 months		P value	Cohen's d Effect Size
Mean	SD	Mean	SD	Mean			SD	Mean	SD			
Psychosocial Process Variables												
Resilience (CD-RISC)	82.14	5.72	83.00	6.75	0.787	0.116	84.22	11.07	85.17	10.30	0.843	0.085
Coping Strategies (Brief COPE)												
Problem Focused Coping	38.67	4.41	39.17	3.87	0.855	0.079	38.59	5.25	39.00	2.76	0.875	0.068
Emotion Focused Coping	35.50	10.77	33.67	7.53	0.626	0.212	30.29	7.27	32.17	4.54	0.521	0.282
Self-Leadership (SLS)	82.17	4.40	83.17	6.11	0.804	0.107	84.28	10.52	85.50	12.36	0.363	0.408
Diabetes Empowerment (DES)	3.73	0.38	4.32	0.34	0.073 ‡	0.924	3.77	0.42	4.42	0.49	0.009 *	1.674
Managing Psychosocial Aspects	3.54	0.34	4.39	0.44	0.032 *	1.208	3.72	0.38	4.44	0.56	0.008 *	1.719
Readiness to Change	3.80	0.35	4.22	0.27	0.107	0.800	3.78	0.50	4.33	0.62	0.020 *	1.376
Setting and achieving goals	3.85	0.61	4.35	0.44	0.231	0.556	3.81	0.51	4.47	0.43	0.059 ‡	0.993
Psychological Well-being Variables												
Perceived Stress (PSS)	18.33	3.20	17.50	4.46	0.685	0.175	14.67	4.18	13.67	5.13	0.275	0.500
Depressive Symptoms (CES-D)	14.15	6.10	13.50	8.14	0.862	0.075	9.00	7.56	10.00	7.75	0.474	0.316
Negative Affectivity (PANAS)	16.67	4.13	18.50	7.00	0.487	0.307	16.83	6.68	16.50	6.69	0.889	0.060
Physical Activity Variable												
Physical Activity (BIAR)	1.67	0.82	2.33	0.82	0.025*	1.293	3.50	0.55	3.50	0.63	1.000	0.381

Table 3.6 shows means, standard deviations, *p* values, and effect sizes of self-reported psychosocial process variables, psychological well-being variables, and physical activity at baseline and 6 months for females only (n=6) and males only (n=6). A large effect was considered $d \geq 0.8$. * Significant difference of $p \leq 0.05$ post-intervention. ‡ Significant difference of $p \leq 0.1$ post-intervention.

Figure 3.1: Mean Plasma IGF-1 Levels Pre-and Post-Intervention

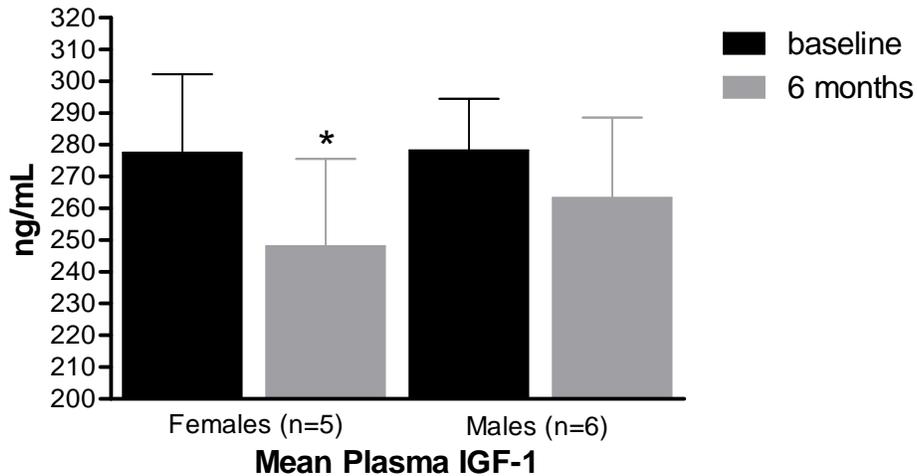


Figure 3.1 shows mean plasma IGF-1 levels at baseline and six months for females (n=5) and males (n=6) at baseline and 6 months. Plasma IGF-1 samples were diluted 1:70 and plated in duplicate on an IGF-1 TiterZyme EIA Kit (Assay Designs, Inc., Ann Arbor, MI) and read at 415 nm. IGF-1 levels were significantly lower in females post-intervention. Values are the mean \pm SEM. * Significant difference of $p \leq 0.05$ post-intervention.

Figure 3.2: Percentage PBMC Proliferation +/- anti-CD3 for 72 hours Pre-and Post-Intervention

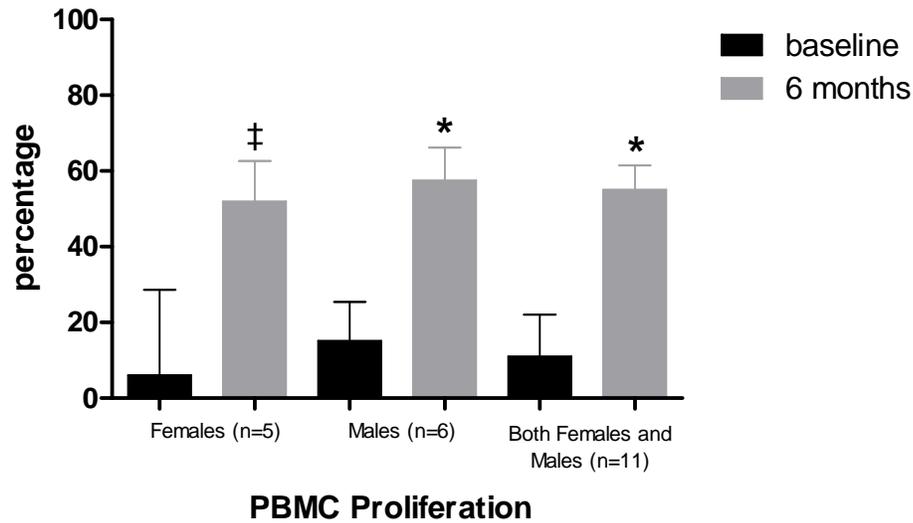


Figure 3.2 shows percent peripheral blood mononuclear cell (PBMC) proliferation \pm anti-CD3 stimulation at baseline and 6 months for females (n=6), males (n=6), and all intervention participants (n=11). PBMCs were isolated from whole blood samples and stimulated in duplicate for 72 hours \pm plate-bound anti-CD3. Proliferation was assessed using an MTT Cell Proliferation Assay (ATCC, Manassas, VA). Absorbance was read at 570 nm and values were corrected for background. Percentage proliferation was determined using the following equation: $[1 - (\text{the absorbance of unstimulated cells}) / (\text{the absorbance of CD3 stimulated cells})] * 100$. Percent PBMC proliferation was significantly increased in females and males post-intervention. Values are expressed as the mean percentage \pm SEM. * Significant difference of $p \leq 0.05$ post-intervention. ‡ Significant difference of $p \leq 0.1$ post-intervention.

Figure 3.3: Mean Weight and BMI Pre- and Post-Intervention

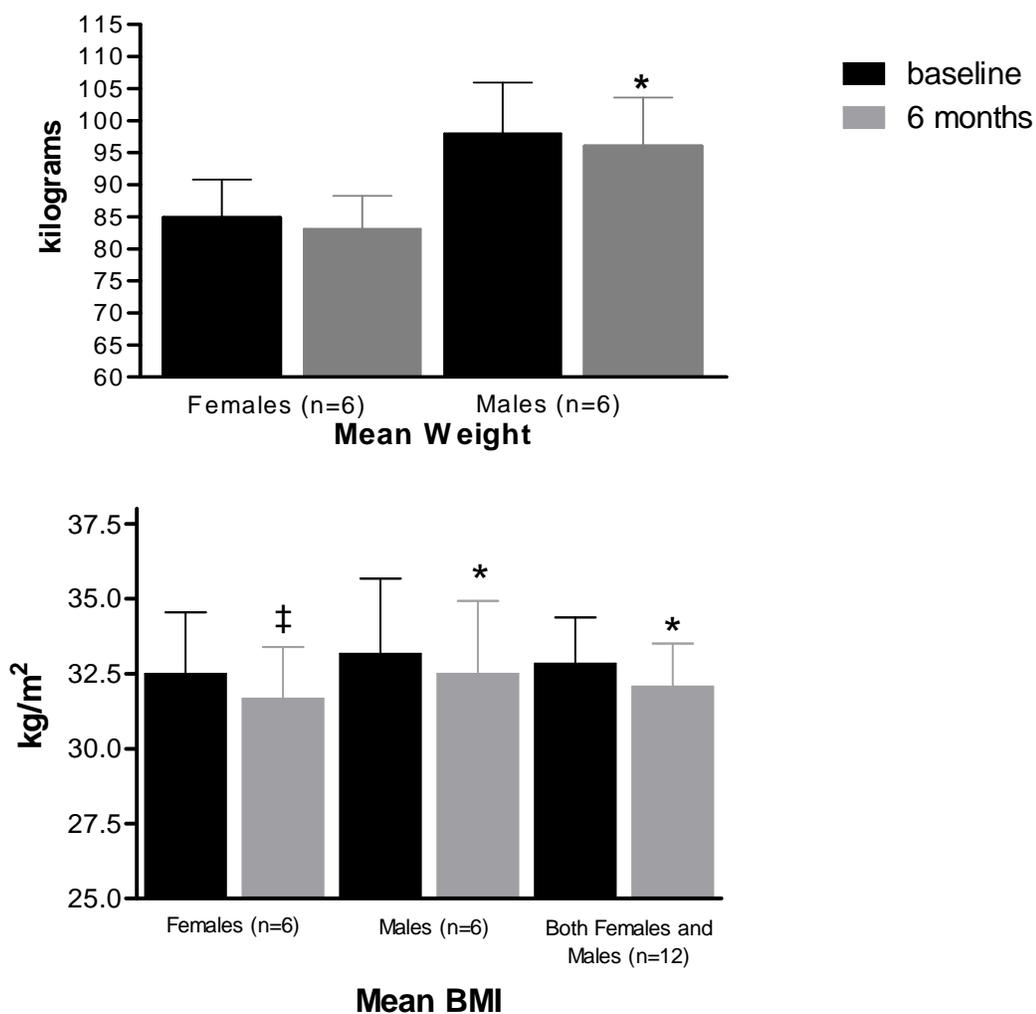


Figure 3.3 shows mean weight and BMI at baseline and 6 months for females (n=6), males (n=6), and all intervention participants (n=12). Weight and BMI were measured using a weight a balance-beam weight and stadiometer scale. Both females, males, and all intervention participants had significant decreases in weight and BMI post-intervention. Values are expressed as the mean \pm SEM. * Significant difference of $p \leq 0.05$ post-intervention. ‡ Significant difference of $p \leq 0.1$ post-intervention.

Figure 3.4 Mean HbA_{1c} Scores Pre- and Post-Intervention

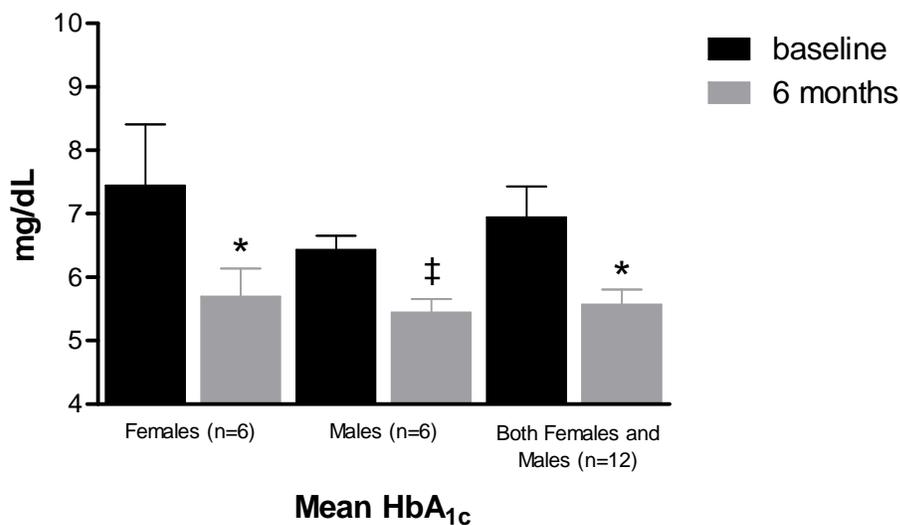


Figure 3.4 shows mean glycosylated hemoglobin levels (HbA_{1c}) at baseline and 6 months for females (n=6), males (n=6), and for all intervention participants (n=12). HbA_{1c} scores were assessed using a Micromat II HbA_{1c} CLIA Waived Test (Bio-rad, Hercules, CA). Both females, males, and all participants had significantly lower scores for HbA_{1c} post-intervention. Values are expressed as the mean \pm SEM. * Significant difference of $p \leq 0.05$ post-intervention. ‡ Significant difference of $p \leq 0.1$ post-intervention.

Figure 3.5: Mean Lipoprotein and Lipid Levels Pre- and Post-Intervention

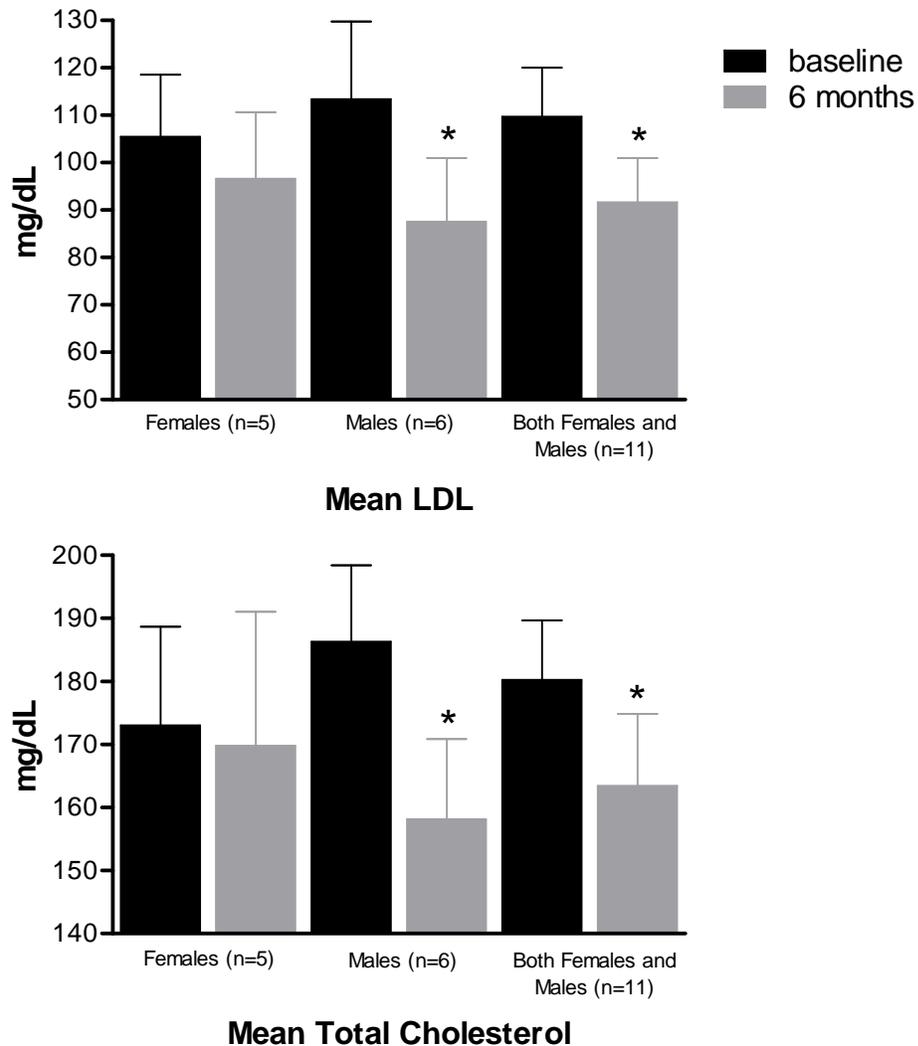


Figure 3.5 shows mean plasma low density lipoprotein levels and total cholesterol at baseline and 6 months for females (n=5), males (n=6), and all intervention participants (n=11). Plasma samples were analyzed for high density lipoproteins (HDL), low density lipoproteins (LDL), triglycerides (TG), and total cholesterol using an Ortho Vitros DT60 (Johnson & Johnson; Rochester, NY). No significant differences were found for HDL and TG post-intervention (data not shown). Significant decreases were found for LDL and total cholesterol post-intervention in males only and all intervention group participants. Values are expressed as the mean \pm SEM. * Significant difference of $p \leq 0.05$ post-intervention.

Figure 3.6: Mean Systolic and Diastolic Blood Pressure Pre- and Post-Intervention

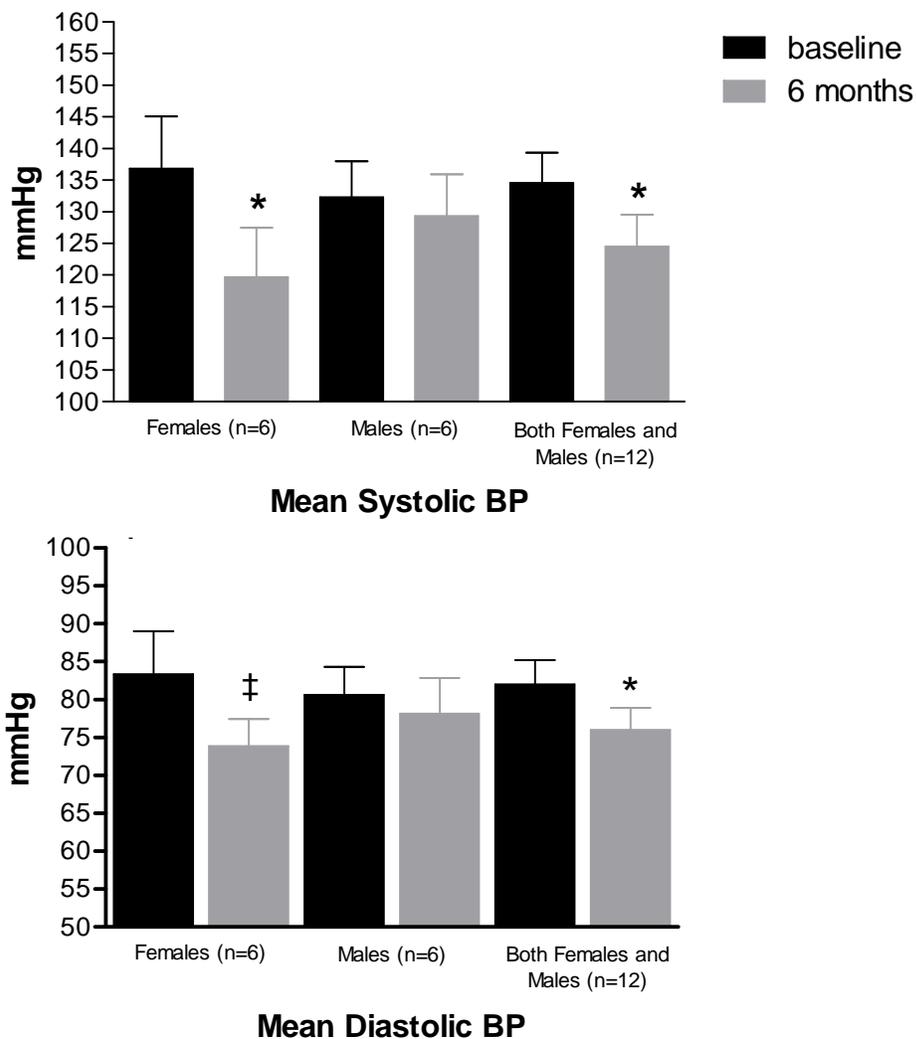


Figure 3.6 shows mean systolic and diastolic blood pressure at baseline and 6 months for females (n=6), males (n=6), and all intervention participants (n=12). An Omicron HEM-712C Automatic Inflation Blood Pressure and Heart Rate Monitor (Omicron, Philadelphia, PA) was used to assess systolic and diastolic blood pressures. Blood pressure was measured three times per participant with a two minute waiting period between each assessment and averages were obtained. Females showed a significant decrease in both systolic and diastolic blood pressure post-intervention. Values are expressed as the mean \pm SEM. * Significant difference of $p \leq 0.05$ post-intervention. ‡ Significant difference of $p \leq 0.1$ post-intervention.

Chapter 4

Description of a Resilience and Diabetes Self-Management Intervention for African American Adults with Type 2 Diabetes and Lessons Learned

4.1 Abstract

Purpose: The purpose of this chapter is to describe a resilience and diabetes self-management education intervention that was pilot tested in African American adults with type 2 diabetes and to discuss lessons learned. *Methods:* An introduction to resilience theory and resilience education is included followed by a detailed description of the resilience and diabetes self-management education intervention. The preliminary study results are then summarized and a discussion of the lessons learned is presented. *Results:* Twenty-two participants were recruited to participate in the intervention. Using convenience sampling methodology, 16 participants elected to participate in the intervention and 6 participants chose to be in the waitlisted control group. Twelve subjects from the intervention group (6 females; 6 males) completed the study and no subjects from the waitlisted control group returned for post-data collection. At six months preliminary analyses using paired t-tests indicated that the resilience and diabetes education intervention significantly improved diabetes empowerment, management of the psychosocial aspects of diabetes, readiness to change, setting and achieving goals, and several physiological markers including weight, BMI, HbA_{1c}, blood lipids, blood pressure, IGF-1 and PBMC proliferation. Additionally, several lessons learned emerged from conducting the pilot study, including: recruitment and retention strategies; recommendations for remaining culturally sensitive to participant resources; considerations for improving the cultural competency of the education curriculum; the

use of complementary and alternative medicine practices by African Americans with T2DM; and approaches for increasing participant self-assessment and goal-setting skills.

Conclusions: Though further studies are needed, interventions that emphasize improving the psychological well-being of African Americans with type 2 diabetes, such as resilience education, may facilitate greater reductions in metabolic abnormalities, improved quality of life outcomes, and increased long-term compliance to standard diabetes self-management. By pilot testing the resilience and diabetes education curriculum, the investigators have learned several useful lessons that may improve the cultural competency and overall effectiveness of the intervention for future studies. In addition, the lessons learned may aid other diabetes educators who face similar challenges in developing and implementing a diabetes self-management education intervention for African American adults.

4.2 Introduction

Research indicates that African Americans with type 2 diabetes (T2DM) are less likely to adhere to standard diabetes self-management regimens than non-Hispanic whites (7, 34, 61), resulting in poorer blood glucose control as well as a higher risk for the development of microvascular and macrovascular complications (59, 250, 258). Several studies in diabetes self-management have shown that individuals reporting greater psychological well-being have better self-directed diabetes care and quality of life than those reporting poor psychological well-being (66, 82, 124, 151, 162, 185). Interestingly, African Americans are documented to have higher levels of perceived stress, depression, and anxiety than non-Hispanic whites (132) which may be attributed to an elevated

exposure to chronic stressors (e.g., low socioeconomic status, less education, low literacy, lack of social support, racial bias, higher levels of crime and violence, lack of resources, lack of health insurance and lack of quality healthcare) (255). In addition, the Diabetes Attitudes, Wishes and Needs (DAWN) study found that more than 40% of individuals with diabetes reported poor psychological well-being and 85.2% experienced diabetes-related emotional stress (181). Unfortunately, the DAWN study also found that approximately one third of healthcare providers did not feel capable of adequately addressing the psychological needs of diabetes patients (182, 221). Therefore, African Americans with T2DM are at a particular disadvantage for experiencing poor psychological well-being and poor quality of life. Diabetes educators must focus on developing culturally competent educational strategies that address the psychological needs of African Americans with T2DM in order to improve adherence to diabetes self-management and overall health outcomes.

Resilience education is a novel supplement to standard diabetes self-management education and addresses the psychological needs of African Americans with T2DM. The construct of resilience presents a paradigm shift in the literature away from problem-focused and disease-focused models toward understanding the strengths and virtues that aid individuals to grow and thrive in the face of change and disruption. Therefore, resilience can be envisioned as existing along a continuum with vulnerability, implying that resilient individuals are more resistant to adverse thoughts and behaviors and display positive adaptations despite adversity (122). For purposes of this study, resilience is defined as the ability to effectively cope with stressful situations and change in ways that sustain healthy levels of psychological and physiological functioning (173).

A great deal of research has been conducted to determine the characteristics of resilient individuals. Several positive character strengths identified by the literature that correlate with resilience include, but are not limited to: optimism, hope, positive affect, happiness, faith, determination, wisdom, gratitude, forgiveness, hardiness, problem-solving skills, and responsibility (238). However, it is necessary for researchers to distinguish the traits that are outcomes of resilience from those that produce resilience through moderating or mediating resistance to stress by enhancing adaptive behaviors. For instance, Kobasa's work in regard to hardiness, which is operationalized as high life stress with a low rate of illness, found that one's sense of commitment, challenge, and control were the protective factors that mediated the positive adaptations and resistance to stress (135). Other possible protective factors that may mediate or moderate resistance to stress include, but are not limited to: self-esteem, self-efficacy, social support, a sense of empowerment, positive life events, self-leadership, and adaptive coping strategies (166, 204).

Improving one's adaptive coping skills is very important for helping individuals build resilience. Coping is defined by Lazarus and Folkman as "constantly changing cognitive and behavioral efforts to manage specific external and/or internal demands that are appraised as taxing or exceeding the resources of the person - p. 141 (140)." Research indicates that adaptive coping strategies strongly correlate with beneficial psychological and physiological health outcomes (140, 166, 227). Adaptive strategies include problem-focused coping and rational reappraisals (140). Problem-focused coping involves directing activities toward minimizing the impact of the stressor and leads to the belief that the stressor is controllable. Problem-focused coping may include other adaptive

coping strategies such as seeking social support, planning, and active coping. Rational reappraisal is a concept drawn from Lazarus and Folkman's transactional model of stress and coping in an effort to minimize perceived threats (140). In this model, objective environmental events, or stressors, require an adaptive response from the individual. The adaptive response elicited is dependent upon a series of primary and secondary appraisals. During the primary appraisal, the individual assesses the potential threat posed by the event; judging its significance as 1) positive, challenging, and controllable; 2) negative, threatening and stressful; or 3) irrelevant. Then a secondary appraisal occurs in which personal strengths or resources are assessed that may help resolve or manage the event. Rational reappraisals are well established in the literature as contributors to enhancing stress-tolerance and thus resilience (140). In evaluating coping strategies among African American T2DM patients, those using greater problem-solving coping strategies are reported to have better glycemic control than those using maladaptive coping strategies (41, 66, 82, 116, 185, 239).

Maladaptive coping strategies include emotion-focused coping strategies such as avoidance, denying, blaming, and wishful thinking (49) (27). Maladaptive coping has often been associated with higher levels of perceived stress, depression, negative affect, and lower quality of life (52). For instance, denying and blaming are considered to be dysfunctional because it often leads to alienation by others and thereby reduces social support. Likewise, blaming oneself and being overly critical of the self can lead to reduced self-esteem. Wishful thinking is considered maladaptive because it usually results in not managing the stressful situation or irrational and unrealistic approaches for coping with the stressor. However, Lazarus makes the clear point that classifying the

discrete actions of problem-focused or emotion-focused coping as either completely adaptive or completely maladaptive is problematic because all strategies have an adaptive potential for coping with stress (140). For instance, emotion-focused and avoidance coping may be considered adaptive coping methods in low-control short-term situations. Likewise, in highly uncontrolled chronic diseases, such as cancer, short-term denial is often found to be an effective tool for readjustment to certain aspects of being diagnosed with the disease (157). However, in chronic diseases that are controllable, such as T2DM, using maladaptive coping strategies are most likely adverse for achieving optimal health and well-being. Therefore, one must consider the situational characteristics and variables involved in the presiding stressor.

In addition to using effective coping strategies during stressful experiences, resilience has also been described as a motivational force that drives individuals to pursue self-actualization, altruism, wisdom and balance (193). The energy source that propels individuals to move through disruption and chaos is unique to each person. However, motivational forces have been identified to come from both intrinsic and extrinsic sources (69). Intrinsic sources include needs, wants, interests, knowledge, beliefs, values, genetics and instinct. Extrinsic sources include relationships, finances, available resources, rewards or punishments, and actual or perceived social consequences. Thus, increasing an individual's knowledge regarding diabetes or determining the needs of an individual for achieving positive behavior change as well as enhancing ones social support and utilization of community resources may lead to greater motivation that empowers one to adhere to diabetes self-management.

Many researchers have concluded that resilience is a process that can be taught to individuals and is not necessarily a skill that an individual is born with or without (253). This notion is reiterated by the fact that personality traits are believed to remain constant over time, whereas resilience is modifiable (8). Therefore, many clinicians have developed resilience education programs based upon the empirical research surrounding stress and coping. The aim of resilience education is typically threefold: 1) to help individuals enhance their protective factors by improving their adaptive coping skills and positive character strengths and reducing maladaptive coping behaviors; 2) to reduce perceived threat and increase perceived coping resources; and 3) to help individuals identify and maximize the motivating forces that empower one to seek harmony and thus achieve growth and thriving (193).

Interventions to improve resilience have been evaluated in children, older adults, trauma victims, patients with chronic illness, and college student populations, as well as in workplace settings (193, 227). In many studies resilience education was found to improve psychosocial traits, purpose in life, and workplace performance and has decreased perceived stress, depression, symptoms of illness, and sick-days lost (193). In fact, our previous research has shown that a theory-based resilience education intervention, *Transforming Lives Through Resilience Education*, was effective in reducing stress, depressive symptoms, and symptoms of illness, and increasing effective coping strategies in college students (227, 229). Yet, few studies have examined the effects of resilience education in minority populations with chronic illnesses. Recently, a resilience education approach was used to improve health outcomes in individuals with T2DM who had previously received standard diabetes education (40). This study found

that resilience education significantly promoted higher levels of resilience, as evidenced by improved coping skills, improved diabetes empowerment, having fun in life, healthful eating, and physical activity, and significantly reduced diabetes-related stress in the intervention group as compared to the control group at six months (41). However, the study was unable to significantly improve glycosylated hemoglobin scores and waist measurements at six months. This study also did not include African American subjects in the study population though other races were represented. Given these data and the fact that African Americans experience high levels of perceived stress, resilience education simultaneously administered with standard diabetes self-management education may help low SES African Americans with T2DM to enhance their level of resilience and improve their adherence to healthful behaviors. Here we describe the resilience and diabetes self-management intervention pilot tested in a church-based group of African American adults with T2DM (n=16) and present lessons learned.

4.3 Methods

Overview of intervention:

What follows is a detailed description of the resilience and diabetes self-management intervention, *The Diabetes Coaching Program: Transforming Lives Through Resilience Education (DCP)*, that was pilot tested in a convenience sample of 22 African American adults with T2DM. All twenty-two participants were invited to attend the intervention. Sixteen individuals (8 females; 8 males) attended the first education session and were designated as the intervention group. The remaining six individuals (4 females; 2 males) did not attend the first meeting session, but expressed interest in

attending a one-day resilience and diabetes education seminar at the conclusion of the study as well as returning for post-data collection and therefore were designated as the waitlisted control group. The intervention group participants attended four two-hour weekly formal instruction sessions followed by eight 1.5-hour biweekly support group meetings. The four class sessions were a combination of a previously tested resilience education curriculum (227, 229) and a standard diabetes self-management education curriculum. The resilience curriculum was based on the transactional model of stress and coping (140) and a modified version of the International Diabetes Center Type 2 Diabetes BASICS manual (194) was used to guide the diabetes knowledge and self-management curriculum which was in accordance with National Standards of Diabetes Self-Management Education (94). In addition, participants kept a daily journal throughout the extent of the intervention to document their diabetes self-management goals and progress. The intervention lasted a total of six months and was conducted at a predominantly African American church in East Austin, Texas. The resilience education curriculum was taught by a health education professor (i.e., Dr. Mary Steinhardt) and the diabetes self-management education curriculum was taught by a nutritional sciences doctoral candidate student (i.e., Madonna Mamerow).

Session One:

The first session of the resilience education curriculum, *Transforming Stress Into Resilience*, introduced a resilience model derived from the work of O’Leary and Ickovics (173) and Carver (50) and was used to reinforce the core content of the intervention. As shown in Figure 4.1, the resilience model illustrates four common reactions to stress

including “give up,” “put up,” “bounce up,” and “step up.” “Give up” describes individuals who become overwhelmed by stressful situations and succumb to the mounting pressures. Individuals in this category are considered to be the least resilient when faced with stress compared to those in other categories. The second type of reaction is “put up” and describes individuals who struggle to overcome stressful situations. These individuals react better to stress than those who give up, but their sense of well-being remains diminished. Those who are classified as “bounce up” are considered to be resilient and make a complete recovery from the stressful situation back to their previous level of functioning. The final category, “step up,” describes individuals that thrive in the face of adversity and not only recover from the stressful situation, but achieve an even greater level of functioning and well-being from having experienced the disruption.

Using this resilience model, associations were made between the four reactions to stress and two broad categories of coping strategies, problem-focused coping and emotion-focused coping. Problem-focused coping strategies (i.e., active coping, planning, positive reframing, acceptance, social support) were associated with “bounce up” and “step up” and were recommended for overcoming stressful situations that were within one’s control. Emotion-focused coping strategies (i.e., denial, behavioral disengagement, self-distraction, self-blame, venting) were only recommended as a short-term response to feeling overwhelmed or when the stressful situation was not within one’s control and were associated with “give up” and “put up” if used long-term.

Immediately following the resilience curriculum, was the first session of the diabetes curriculum, *An Introduction to Type 2 Diabetes*, which provided a description of T2DM and the role insulin plays in blood glucose regulation. T2DM symptoms were

discussed as well as the importance of controlling blood glucose. A glucometer kit was then distributed to all participants, along with a month supply of test strips, lancets, and alcohol preparation swabs. Additional testing supplies were distributed as necessary thereafter for the remainder of the intervention. Participants were instructed on how to use the blood glucose meter and lancet device, how to interpret the results, and important times of the day to monitor their blood glucose levels. At the end of the session, participants practiced checking their blood glucose and were asked to monitor, at minimum, their fasting blood glucose levels each day throughout the extent of the study.

Session Two:

A responsibility model was introduced in session two of the resilience curriculum, *Taking Responsibility*, which drew a line between taking or not taking responsibility for one's actions and behaviors. Individuals that function "above the line" feel they have the ability to impact their life circumstances and take responsibility for their actions and behaviors. These individuals also display high levels of self-esteem. In contrast, individuals that fall "below the line" feel powerless to influence their life circumstances and respond to stressful situations by denying, blaming, making excuses, and shaming which further decrease their circle of influence and self-esteem (60). Participants were then taught a five step process for taking responsibility and achieving "above the line" responses to stress.

The final part of the second session, *Your Diabetes Food Plan and Physical Activity*, taught participants how a proper diet and exercise plan can help manage blood glucose levels. First, participants learned the difference between meal planning and

dieting. This concept emphasized controlling blood glucose levels rather than focusing on weight reduction, and highlighted the importance of planning regularly scheduled mealtimes to avoid hypoglycemic and hyperglycemic conditions. Participants were then instructed on how to create and maintain a healthful diabetes food plan that was suitable for each of their individual lifestyles. Constituents of a balanced diet were introduced and demonstrations with food models were used as visual aids for selecting correct portion sizes. Participants also learned how to count carbohydrate exchanges and determined the number of carbohydrates needed per meal. An activity on reading food labels followed which helped participants develop skills for counting carbohydrates. The session was concluded with a discussion on the importance of participating in regular exercise and the amount of physical activity needed each day.

Session Three:

An ABCDE thinking model based on the work of Albert Ellis (78) was described in session three of the resilience curriculum, *Focusing on Empowering Interpretations*, and taught participants how to change negative thoughts or interpretations into ones that were more empowering. According to this model, “**A**” stands for the **activating** event or stressor; “**B**” stands for the negative **belief** or thought about the activating event; “**C**” stands for the **consequence** that results from the belief, usually how one feels and behaves; “**D**” stands for **disputing** the negative beliefs about the activating event and reinterpreting the situation in a manner that helps one to feel more empowered (if necessary, “**D**” can also stand for briefly **distracting or distancing** oneself from the stressful event); and “**E**” stands for the amount of **energy** one is able to devote to

managing the activating event. This model was then used to illustrate how negative thoughts and disempowering interpretations to stressful events can cause individuals to fall below the line on the responsibility model, whereas positive interpretations can lead to above the line behaviors.

The diabetes curriculum of session three, *Helpful Tips for Food Planning and Physical Activity*, provided strategies for achieving the diet recommendations and physical activity requirements presented in session two. Suggestions for accomplishing optimal food planning were distributed into seven categories: 1) How to choose a variety of foods; 2) Controlling portion sizes; 3) Establishing regular mealtimes; 4) Eating less fat; 5) Tips for dining-out and special occasions; 6) Getting enough water; and 7) Moderating alcohol intake. Strategies for controlling blood glucose levels during sick-days were also discussed during this session. Participants then discussed plans for incorporating more physical activity into their daily routines and were encouraged to set small and achievable exercise goals in order to eventually accomplish at least thirty minutes of moderate exercise each day. Participants were also advised to choose only activities they found enjoyable in order to avoid burn-out and boredom with an exercise regimen.

Session Four:

The final session of the resilience curriculum, *Creating Meaningful Connections*, focused on enhancing participants' levels of social support and informed participants of the positive effects that social support can have on thinking, behavior, health, and well-being (176). This session also introduced the concept of self-leadership based on the

Internal Family Systems model, which identifies an individual as possessing an internal community or “family” of multiple sub-personalities (e.g., the achiever, the caretaker, the critic) that are directed by a core Self (210) (211). Many times certain sub-personalities are forced into more extreme roles than necessary, usually as a result of emotional pain or stress, which causes the parts of the internal system to struggle with one another. However, when the Self is leading, the various sub-personalities operate together more harmoniously and the individual progressively experiences more of nine characteristics (i.e., calm, clarity, curiosity, compassion, confidence, courage, creativity, connectedness, contentment). Therefore, the Self can be thought of as our core identity that is not attached to any specific agenda and provides a safe and nurturing environment within us. As the Self leads, an individual takes responsibility, focuses on empowering interpretations, creates meaningful connections, and thus becomes more resilient and thriving.

The concluding topic of session four, *Living Well with Diabetes*, emphasized that complications resulting from diabetes can be postponed or avoided altogether with appropriate glycemic control. Several complications of diabetes were described along with the signs and symptoms that may be experienced with each disorder. The complications presented included heart disease, hypertension, dyslipidemia, retinopathy, neuropathy, renal disease, erectile dysfunction, wound healing and diabetic foot problems. The session also discussed the impact of emotional stress on blood glucose levels and overall health outcomes.

Bi-Weekly Support Groups:

Eight, 1.5-hour, biweekly support group meetings were conducted following the four instructional sessions to reinforce participant skills and knowledge regarding diabetes self-management and to provide a supportive atmosphere to promote healthful behavior changes. Journal entries were reviewed and an informal approach was employed to encourage the participants to openly discuss any problems or difficulties faced in their diabetes self-management regimen. Exchange of healthy recipes and exercise suggestions were also discussed by the participants as well as plans for goal setting and problem solving. In addition, participants submitted their glucometers to an instructor to analyze the previous week's test results using a computer software program. The instructor then provided individual recommendations to each participant for improving glycemic control and reinforced the importance of daily blood glucose monitoring. Each support group session was concluded with 15-30 minutes of physical activity, usually walking at a local high school track near the intervention site. Each participant established his or her own level of intensity. For instance, some participants chose to walk and at times some individuals elected to jog. The duration of the physical activity was dependent upon each participant's own willingness, desire, and/or ability to perform the activity. Therefore, the goal of the physical activity component was to motivate individuals to begin incorporating more physical activity into their daily routines.

4.4 Results

Twelve intervention group participants completed the study and no waitlisted control participants returned for the post-intervention data collection. The retention rate

was 75% for the intervention group and 54.5% when all study participants were considered (e.g., both the intervention and waitlisted control group participants). Therefore, only general trends were determined for the intervention group using paired t-tests. The participation rate was 100% for the resilience and diabetes education classes, which included make up sessions for missed classes; and 56.6% attended the support group sessions. Results indicated that the resilience and diabetes education intervention significantly enhanced diabetes empowerment, management of the psychosocial aspects of diabetes, readiness to change, setting and achieving goals, and female self-reported physical activity levels at six months ($p < 0.05$). Several physiological variables demonstrated significant decreases at six months including BMI, male body weight, HbA_{1c}, LDL cholesterol, total cholesterol, blood pressure and female insulin-like growth factor-1 (IGF-1) levels ($p < 0.05$). In addition, peripheral blood lymphocytes showed significantly increased proliferative ability post-intervention ($p < 0.05$). No significant improvements were found for resilience, coping skills, self-leadership, perceived stress, depressive symptoms, negative affect, HDL cholesterol, fasting blood glucose, and triglycerides although resilience, perceived stress, HDL cholesterol, and fasting blood glucose were slightly improved.

4.5 Lessons Learned

This pilot study was the first stage of many in the development of a culturally competent resilience and diabetes education intervention for African American adults with T2DM, and to our knowledge is the first study to ever evaluate a resilience education approach in this specific population. Although no direct improvements were

found in resilience or markers of psychological well-being, the intervention did demonstrate several beneficial psychosocial improvements at six months including improved diabetes empowerment, management of the psychosocial aspects of diabetes, readiness to change, and setting and achieving goals, which were all key components of the resilience curriculum. Likewise, participants were taking more responsibility for their lifestyle choices by monitoring blood glucose more frequently, eating healthfully and getting more exercise, which was evidenced by the significant improvements found in HbA_{1c} scores, cholesterol levels, and self-reported activity levels at six months. Participants also discussed an increased sense of social support and strategies for coping with stressful situations in their daily lives and self-management routines, which were also important aspects of the resilience curriculum. These preliminary data suggest that the collective components of the intervention have the potential to facilitate a vast number of positive health outcomes for African Americans with T2DM. By conducting the pilot study the investigators also learned several valuable lessons based upon their experiences and the preliminary results that may help improve the cultural competency of the current intervention as well as the outcomes of future long-term studies. The following insights may also help guide diabetes educators when developing and implementing a diabetes self-management intervention for African American adults.

Strategies for Improving Recruitment and Retention

Literature indicates that recruitment and retention of African American subjects is challenging for many investigators (259). Low recruitment numbers, slow accrual rate of subjects, and lack of retention may partly explain why African Americans are

underrepresented in clinical research studies (144). In this pilot study, recruitment efforts were targeted at predominantly African American church congregations due to a large body of literature which indicates the church setting as an ideal venue for health promotion activities among ethnic minorities (39, 130, 147, 174, 208). Several characteristics which render the church setting as an optimal location include: having well-established nursing and health ministries which are highly receptive to collaborative efforts with healthcare professionals and healthcare services; access to a large population of individuals at risk for or diagnosed with T2DM; and involvement in leading health promotion activities, such as organizing health fairs and health prevention screenings (39).

Lesson #1: Identify a key opinion leader within the African American community to assist in recruitment of subjects and implementation of the intervention; utilize multiple strategies for recruiting participants; and begin planning early for the recruitment process.

The investigators found that recruiting subjects from African American churches can be a very fruitful experience if relationships are established between the researcher and a leader from the church nursing or health ministry early in the recruitment process. Since churches typically have a hierarchical organizational structure for gaining approval to recruit subjects and implement education programs, having an advocate or liaison from the church, such as a nursing ministry leader, can help the researcher navigate through any policy or procedural issues in a more timely and efficient manner, especially since policies and procedures can vary from church to church. For example, a researcher may

need to receive permission or assistance from several individuals within the church administration prior to beginning the recruitment process, including: committee chairs that may have questions regarding the research plan; the pastor or deacon; and the church secretary who will need time to prepare the church bulletin to advertise the study as well as any announcements to be made during worship services. In conversations with several local church administrators, at least three months preparation time is usually preferred for organizing, scheduling, and planning the advertisement of a new education program prior to beginning the recruitment process. Therefore, investigators should begin contacting church leadership well in advance of the study's start date. Likewise, if the investigator plans to recruit participants from multiple churches, he or she should coordinate the efforts among the churches; otherwise announcements could be made weeks or even months apart at the different churches, which could affect the start date of the study as well as the interest of individuals wishing to participate in the study.

Previous literature also advises taking no longer than one month for the accrual of human subjects in order to maintain low attrition rates (144). However, a slower accrual rate has been reported for African American subjects than for other ethnicities (144) and was a major challenge in the present study. Therefore, once a relationship is established with the church, the investigators recommend implementing multiple recruitment strategies early in the recruitment process to insure a larger number of subjects in a shorter period of time. For example, in the present study a nursing ministry leader volunteered to be interviewed about the DCP by a local radio station with a large African American listening audience. This proved to be an effective method for recruiting a larger number of individuals more quickly to the study and several additional radio

announcements were broadcast. Additionally, flyers were distributed at a pharmacy, recreation center, and library located near the church. The investigators also found that study participants reported feeling more comfortable enrolling for a research study when the church was involved with the recruitment process.

Establishing a relationship with an active member of the church is also beneficial to the overall ebb and flow of the research study once it is underway. By working closely with a knowledgeable church member, the investigator has an insider's advantage and can better prepare for unforeseen circumstances and cultural sensitivity issues. For example, an active church member may help the investigator to schedule meeting times and secure meeting rooms with the church administration or simply inform the researcher of special events occurring at the church that may interfere with research meeting times. In addition, he or she can instruct the investigator as to any cultural traditions which should be adhered to when inside the church or when attending church services. Therefore, being well-informed about the cultural intricacies and activities of the church can optimize the recruitment and research experience for both the investigator and the church. Moreover, conducting a well-organized study can lead to increased participant self-efficacy with the intervention and decreased attrition (259).

Lesson #2: Offer incentives for participation and maintain frequent contact with all study participants, including control subjects, to improve retention rates.

After the recruitment process was complete, the investigators implemented several strategies to increase retention of subjects. In the present pilot study, the intervention group participants were compensated with a maximum of \$100 cash, which

was dispersed in \$20 cash increments throughout the study and data collections; a Bayer Ascensia Glucometer Kit; test supplies for six months; and a copy of their lab results from each data collection. In addition, refreshments were provided during meetings to offer examples of healthy snacks for diabetes patients, and to insure that participants maintained proper blood glucose levels during the two-hour class sessions, which were held after work and during dinner time when participants were available to meet. The investigators also gave reminder phone calls to the participants about upcoming meetings, which also gave the investigators an opportunity to check-in with participants on their progress throughout the week and to provide encouragement and support. Intervention participants were also given a dinner banquet at the conclusion of the intervention to celebrate their progress and to thank them for their dedication to the Diabetes Coaching Program. The overall retention rate for the intervention group was 75% (n=12); participation was 100% for the resilience and diabetes education classes, which included make up sessions for missed classes; and 56.6% attended the support group sessions. Attrition was due to relocation, job related conflicts with the class schedule, and lack of interest. These numbers reflect average rates of retention compared to the previous literature.

Incentives for the waitlisted control group, included: monetary compensation of \$40 cash dispersed in \$20 amounts after completion of the pre-and post-data collections; a copy of their laboratory results; and the opportunity to attend a one-day seminar over the resilience and diabetes education curriculum. However, no waitlisted control subjects returned for post-data collection. This attrition rate was the greatest limitation of the pilot study and was most likely due to the convenience sampling method used in the study.

Since all participants were invited to participate in the DCP classes and support group sessions and these six individuals did not initially choose to participate, then one may speculate that these individuals may not have been highly committed to the study from the beginning, which was confirmed by three participants who expressed lack of interest when contacted for post-data collection. Therefore, using a randomized cross-over study design may help to increase retention of control group participants for future studies. However, high attrition may have also been attributed to small sample size and the inability to contact three of the waitlisted control participants post-intervention due to disconnected phone numbers. Additionally, after the initial data collection was performed, no further contact was made with the control participants in order to avoid influencing normal diabetes self-management practices. The investigators therefore recommend maintaining contact with the control group participants throughout the study to increase retention rates. Periodic check-ins with the control group may also help to maintain participant interest and serve as a means of updating participant contact information. Another method for possibly increasing retention rates in the control group may be to collect pedometer information for physical activity assessments throughout the extent of the study, which would also strengthen the reliability and validity of self-reported physical activity data as well as help to maintain waitlisted control participants' interest in the study.

Strategies for Remaining Culturally Sensitive to Participant Resources

According to the 2005 U.S. Census Bureau, African Americans are overrepresented among the poor with nearly 25% falling at or below the poverty line (71)

and approximately 19.7% lacking health insurance (71). Because of these statistics a large number of African Americans have limited access to transportation, medical and mental healthcare, education, and other resources (181). Therefore, a major emphasis of the present pilot study was to remain sensitive to participant resources in order to improve long-term adherence to diabetes self-management.

Lesson #3: Conduct the intervention within the community setting of participants at a location near public transportation and educate participants about the resources that are available within their community that will help with the management of their diabetes.

In keeping consistent with the chronic care model (183) and current literature on patient empowerment (20), the intervention only utilized resources that participants had easy and open access to within the community (e.g., churches, neighborhood walking trails, high school tracks, local grocery stores, etc.). For example, when educating the participants on exercise, the investigators identified local high school tracks, parks, and community recreation centers that were available to the public for personal exercise free of charge. Participants were also encouraged to start a walking group in the neighborhood or go for a walk after church with fellow parishioners. In addition, during the support group sessions participants went for a 15-30 minute walk through the neighborhood or at a local high school track. These strategies provided participants with the skills and knowledge necessary to make healthy lifestyle choices upon completion of the study rather than the need for expensive gym memberships, personal trainers, and nutritionists that would not be practical for low income African Americans. This may explain why

individuals reported significantly increased levels of physical activity at six months. Likewise, the church community served as an outlet for social support to the individuals participating in the intervention. By remaining culturally sensitive to the social environment of African Americans patient empowerment is increased, which may lead the long-term compliance to lifestyle changes such as diet and exercise can be enhanced as well as the cost effectiveness of the intervention.

Another strategy implemented by the investigators to remain culturally sensitive to participant resources was to conduct the program at a location within the participants' community environment (i.e., a local church) where access to public transportation was readily available. Several participants in this pilot study were either unable to drive or did not have transportation to and from the intervention site. Therefore, it was imperative for participation and retention of subjects that the intervention site be located near a bus stop or within a relatively short distance from home so that family members could drive the participant to and from the study site. Conducting the study within the participants' community also allowed the participants to stay in close proximity to their regular daily activities. For instance, after DCP meetings several participants immediately went to choir practice or to the men's worship group meetings. This saved participants additional bus fares as well as extra trips for family members. Many participants also stated feeling more comfortable attending class sessions within their community environment rather than traveling to an unfamiliar location. Thus, familiarity with the environment may also be an important factor for African Americans when participating in a diabetes self-management program.

Lesson #4: Provide self blood glucose monitoring supplies to participants and educate participants about cost effective strategies for obtaining testing supplies in the future.

Some participants reported difficulty affording glucometers and testing supplies. Therefore, glucometer kits and testing supplies were provided to insure that each participant would be able to learn how to properly test their blood glucose as well as monitor their blood glucose throughout the study. Participants were also allowed to keep the glucometers upon completion of the study. Since affordability of testing supplies was a major concern for participants, the investigators also provided participants with information on how to more economically manage their diabetes in an effort to empower the participants to continue monitoring their blood glucose upon completion of the study. For instance, participants were informed that many pharmaceutical companies offer free glucometer kits with a prescription from a healthcare provider and were instructed to ask their healthcare provider or pharmacist about offers to obtain free glucometers in the future. The participants were also given information about wholesale distributors that sold testing supplies to individuals at reduced rates. Many participants seemed encouraged by this information and expressed feeling more able to afford the necessary equipment for proper diabetes self-management.

Strategies for Improving the Cultural Competency of the Education Curriculum

Although diabetes self-management education is documented to be the safest and most effective form of treatment currently available to diabetes patients (254), many traditional self-management interventions have demonstrated ineffective results among ethnic minority groups. These results have been attributed, in part, to culturally

inappropriate or inadequate education curriculums (45, 138, 257). For instance, traditional approaches fail to incorporate important cultural issues such as a group's beliefs, values, customs, traditional foods, dietary patterns, language, and literacy levels (46). Since African Americans continue to display a disproportionate burden for development of T2DM as compared to whites (13), culturally competent diabetes self-management education programs are necessary for producing more effective results as well as long-term adherence to diabetes self-management regimens. Therefore, a major goal of the investigators was to determine the efficacy and acceptance of the resilience and diabetes self-management curriculum among African American adults with T2DM in order to improve the overall cultural competence of the intervention.

Lesson #5: Tailor the resilience curriculum to utilize more diabetes specific language to provide participants with a clear understanding of how the resilience curriculum can help to improve diabetes self-management and coping with diabetes-related distress.

Initially, the investigators struggled with decisions about how to best incorporate the resilience curriculum into the diabetes self-management education curriculum. Because the resilience curriculum had never been tested in African American adults with T2DM, decisions were made to keep each of the curriculums as separate components during the class sessions. Participants reported satisfaction with this format and requested that the resilience component continue to be taught separately from the diabetes self-management curriculum. However, at post-data collection the participants surprisingly did not report improved resilience, coping skills, or self-leadership even though they

displayed positive behavioral changes and physiological improvements that would suggest otherwise. Therefore, the investigators recommend: 1) tailoring the resilience curriculum toward more diabetes-specific language and examples; 2) presenting coping skill strategies in relation to diabetes self-management; and 3) using modified versions of the psychosocial process variable survey instruments that include more diabetes-specific language.

Lesson #6: Simplify the education curriculum and disperse the information over more class sessions that utilize more visual aids.

Participants also reported feeling overwhelmed by the quantity of information presented during each class session and recommended increasing the number of classes to allow for more discussion time and activities. This statement is consistent with previous literature which recommends that when working with low-socioeconomic status and low-literacy level populations, the more simple the behavior change is conceptualized the more likely the intervention will be accepted (16). Therefore, the information from the original four class sessions was divided into eight weekly class sessions. The classes were also improved to include more in-class activities and visual aids to strengthen the class instruction, as well as accommodate individuals of low-literacy and participants that had difficulty reading due to poor eye-sight from diabetes-related complications. In addition, the investigators are currently developing a participant education manual and facilitator guide to provide more organization and structure to the class sessions instead of distributing handouts at each session.

Lesson #7: Focus the education curriculum toward controlling carbohydrate intake rather than weight loss and utilize more hands-on activities to demonstrate portion control, such as utilizing food models and simple meal-planning methods.

Many participants in the present study were also concerned about losing weight and felt discouraged due to failed attempts in the past. However, research suggests that diabetes patients focus on food planning and monitoring blood glucose levels rather than attempting to lose weight (47). Therefore, class instruction emphasized blood glucose control rather than weight loss by teaching participants about proper carbohydrate intake and portion control. These methods allowed participants to see immediate successes when glucose scores were within acceptable ranges. However, during class sessions regarding proper carbohydrate intake, many participants found counting carbohydrates to be a difficult concept to apply and reported reluctance in using exchange lists for monitoring carbohydrate consumption. In a study by Ziemer, et. al., a meal-plan system emphasizing healthy food choices was found to be equally as effective as using an exchange based meal-plan in urban African Americans with T2DM (261). Furthermore, in the Soul Food Light study conducted by Anderson-Loftin, et. al., ethnic food models proved to be a successful mechanism for teaching portion control and carbohydrate counting (16). Therefore, in addition to the exchange list system, participants were taught proper diabetes food planning methods using My-Pyramid concepts and were given demonstrations on portion control using plastic food models. Participants reported greater satisfaction with these methods and stated that the visual aids helped them to better understand the exchange list concept.

Lesson #8: Suggest healthful modifications to “soul foods” and southern cuisines that allow for flavor to be retained.

Study participants also desired to learn ways to make healthy modifications to their family recipes in order to preserve cultural traditions. In particular, participants wanted foods to retain flavor. These desires were consistent with previous literature that meals are social events for African Americans and that food preferences are typically rooted in traditions (16). Therefore, two additional lessons are currently being incorporated into the curriculum to enhance dietary self-management for future studies. First, a lesson was incorporated for modifying “soul foods” and southern cuisines, which are typically high in saturated fat, cholesterol, and salt. In this lesson, participants are given an opportunity to modify a favorite recipe based upon easy to use charts that show healthy substitutions for fat, cholesterol, sodium, and sugar. Secondly, a grocery store tour is being incorporated to allow participants to apply skills for reading food labels and determining healthier selections, such as looking for low-sodium items and selecting fresh or frozen fruits and vegetables over canned goods.

Lesson #9: Address the underlying fears that motivate certain adverse health behaviors regarding diabetes self-management.

Throughout the intervention the investigators also noted several reasons given by participants for not monitoring or controlling blood glucose levels that should be addressed during class sessions and monitored during support group sessions. First, some participants reported intentionally maintaining high blood glucose levels to prevent hypoglycemic conditions, which were considered to be much worse experiences than the

symptoms experienced during hyperglycemic conditions. Secondly, some participants reported not testing blood glucose levels for fear of bad test results or simply because the lancet device hurt. Therefore, the investigators addressed these underlying fears by helping participants to develop coping skills for dealing with out-of-range test results as well as more empowering viewpoints for knowing their test scores. An effort was also made to provide one-on-one coaching to participants who had difficulty with out-of-range test results, especially participants with hypoglycemic scores. Additionally, testing techniques were demonstrated to participants that were considered to be less painful options and group participants were asked to provide additional techniques they recommended for less painful testing.

Lesson #10: Provide a supportive atmosphere and encourage the involvement of family members.

Finally, social support was reported as a major benefit of the DCP classes and support groups. Participants often stated that they “no longer felt alone” with their disease and felt a sense of unity with others who shared in their same struggles that did not judge them. They also indicated that the supportive atmosphere of the group helped them to openly talk to family members about their fears and struggles. In addition, participants expressed a desire to have family members attend the classes with them, not only for support, but also because they wanted family members to become educated about diabetes. Many participants specifically mentioned wanting their children present whom they feared would develop diabetes and/or were struggling with mental health issues.

Complementary and Alternative Medicine Practices of African Americans with T2DM

Throughout the course of the intervention many participants discussed non-conventional therapeutic approaches for managing and/or coping with their diabetes, including: dietary and herbal supplementations, vitamins, and prayer. These approaches are classified as complementary and alternative medicines (CAM) and is defined by the National Center for Complementary and Alternative Medicine (NCCAM) as “a group of diverse medical and healthcare systems, practices, and products that are not presently considered to be part of conventional medicine. (29)” CAM therapies include, but are not limited to: whole medicine systems such as homeopathic, naturopathic, traditional Chinese medicine and Ayurveda; mind-body medicine such as cognitive-behavioral therapy, mindfulness, meditation, and prayer; biologically-based practices such as dietary and herbal supplementation; manipulative and body-based medicine such as massage, acupuncture or chiropractic and osteopathic medicine; and energy medicine such as Reiki, qi gong, and touch therapies.

Literature indicates that African Americans report using CAM therapies more often than Asians, Hispanics, or whites when vitamins and prayer are included. However, if vitamins and prayer are excluded, African Americans are the least likely group to use CAM therapies (29). These results may be due to differences in personal and/or financial resources among ethnic groups. For instance, the education level of an individual may influence whether or not one is able gain knowledge about additional CAM therapies. In addition, some individuals may not be able to afford other types of CAM therapy (24, 26). Furthermore, diabetes patients are twice as likely to use dietary CAM therapies than

other chronic disease patients (76). Reasons identified by diabetes patients for using CAM therapies include: disliking the side effects of conventional medical treatments; the high cost of prescription drugs; feeling unable to control one's healthcare; and discontent with healthcare providers (26).

Lesson #11: Include a discussion of home remedies and nutritional supplements that participants believe improve their blood glucose control and provide recommendations regarding the use of any CAM therapies mentioned.

In the present pilot study, many participants discussed the use of nutritional therapies that they felt helped to control their diabetes. These therapies included: multivitamin supplements, mineral water, cinnamon, garlic, honey, Noni juice and Clementine oranges. The use of many of these same nutrition therapies were also documented by Popoola in a study regarding the holistic medicine practices of African Americans and Nigerians with diabetes (187). Due to the possible impact of such therapies on the efficacy of conventional medical treatments, diabetes educators should remain astute to the current empirical evidence regarding alternative dietary practices when conducting diabetes self-management education interventions with African Americans and provide information regarding any possible contraindications.

Lesson #12: Respect the participants' religious beliefs and determine strategies for incorporating one's beliefs into health promotion activities.

Many participants in the present study also discussed prayer and faith in God as a mechanism to cope with life stressors and diabetes. Numerous studies in coping

conducted with African Americans have also found spirituality and faith in God to be an important factor for general health promotion, disease adjustment, and stress-related coping (130, 147, 186, 206, 236, 242). Survey results from the present study using the Brief COPE scale (51) confirmed high mean scores for religious-focused coping at pre- and post-test (pre-test $\mu= 3.67\pm0.54$; post-test $\mu=3.63\pm0.53$). Likewise, a descriptive study conducted by Jones, et. al., on the use of CAM by rural African Americans with T2DM, reported religion, spiritual beliefs, prayer and/or faith in God as the most significant element for treatment and/or coping with diabetes (126). Given the literature surrounding faith-based coping among African Americans, diabetes educators may want to assess whether religion and/or spiritual beliefs are important to the patient and determine ways to incorporate such beliefs into a holistic approach for living well with diabetes.

Approaches for Increasing Participant Self-Assessment and Goal-Setting Skills

Self-assessment and goal-setting are reported to be important components for promoting positive and sustainable behavior changes among adults. Due to the chronic nature of T2DM and the necessity of proper daily self-management in preventing and/or delaying diabetes-related complications, goal-setting and self-assessment may help promote greater adherence to diabetes self-management. In a recent literature review of goal-setting interventions by Shiltz, et. al. (217), goal-setting was found to significantly increase positive diet and exercise behavior changes among adults. Specifically, the review identified proximal goal-setting to be more effective in achieving positive diet and exercise behavior changes than setting distal goals. Significant positive results in

behavior change were also found when one's goals were supported by another individual. Likewise, self-assessment as well as goal-feedback and tracking were reported as important factors for promoting goal self-efficacy and attainment. Therefore, the investigators of the present study implemented several strategies to enhance proximal goal-setting and self-assessment among participants.

Lesson #13: Daily guided journal activities for participants helped them identify barriers in their self-care regimen, set and achieve health-related goals, and track their progress over time.

Journaling was one method used in the present study to increase participant self-assessment and goal-setting. Journaling is documented to improve behavior awareness and mindfulness (251); aid in setting and achieving goals (212, 217); increasing personal reflection (216, 251); identifying and/or reducing stressors (154); and can serve as a social support strategy (146). Therefore, participants were asked to complete a guided journal activity each day throughout the extent of the study. As shown in Figure 4.2, each journal entry was one page in length and included an inspirational quote, a section to record a health-related goal, a ten-item checklist to evaluate healthy lifestyle choices, and a section for personal reflection of one's behaviors and emotions. The 10-item checklist also served as a quick and convenient self-assessment of physical activity, nutrition habits, sleep habits, and blood glucose monitoring for each day. Items on the checklist were each worth a value of ten points and were tallied for a daily score. Seventy points or higher was considered a passing score. Many participants reported that the journal helped them to identify barriers and difficulties experienced in their diabetes self-management

regimen as well as setting and achieving their diabetes-related goals each day. Survey results from the present study using the Diabetes Empowerment Scale-Short Form (DES-SF) (18) confirmed significantly enhanced scores for setting and achieving goals at six months ($p= 0.023$). Thus, the components of the journal system used in this study not only reinforced the core components of the resilience and diabetes self-management curriculum, but also served as a means to promote goal-setting and self-assessment as well as goal-feedback and tracking. However, the investigators recommend determining the literacy level of clients or study participants when implementing a journal system.

Lesson #14: Evaluating participants' blood glucose results and providing recommendations increased participants' accountability and helped participants problem-solve out-of-range blood glucose scores.

A second strategy that may have contributed to the significantly increased goal-setting and achievement among participants at six months was evaluating each participant's weekly blood glucose test results. According to the ADA, if 50% or more of daily blood glucose readings are within normal acceptable ranges the patient can expect an HbA_{1c} score within the normal acceptable range. Therefore, participants were given the proximal goal of achieving 50% or more of their daily blood glucose readings within the normal accepted ranges each week in order to achieve the distal goal of an acceptable HbA_{1c} value at the conclusion of the study. During each meeting session the participants' blood glucose readings from the previous week were downloaded into the WinGlucoFacts version 1.3 PC program and analyzed for daily patterns and out-of-range scores. The investigators typically noticed daily patterns for each individual and then

asked the participants to recall meals, daily activities, and perceived stress levels that may have led to any out of range test results. This information allowed the investigators to establish an active partnership with the participant for improving glycemic control. For instance, Monday was found to be an extremely stressful workday for one participant and mealtimes were missed except for occasional snacks and a large meal after work which led to poor blood glucose control on that day. By highlighting such behaviors, the participants gained an increased awareness of how their blood glucose levels were affected by their lifestyle choices and stress levels and were able to make the appropriate adjustments to their diet and physical activity. In addition, participants reported that having another person evaluate their blood glucose scores each week motivated them to regularly test their blood glucose. Therefore, accountability to another individual was an important motivator for checking blood glucose regularly and reflects literature findings that goal-support is important in sustaining positive behavior changes (217).

4.6 Conclusion

The resilience education component of the diabetes self-management intervention may help health care providers address the psychological needs of African Americans with T2DM. However, it is mandatory that practitioners and diabetes educators remain culturally sensitive to the many influences that affect the behaviors of African Americans with diabetes in order to maintain long-term adherence to diabetes self-management. Currently, the present intervention is being revised to become more culturally relevant to the needs of African Americans with T2DM based upon the lessons learned described in this chapter.

Figure 4.1: Resilience Model Taught in the Intervention

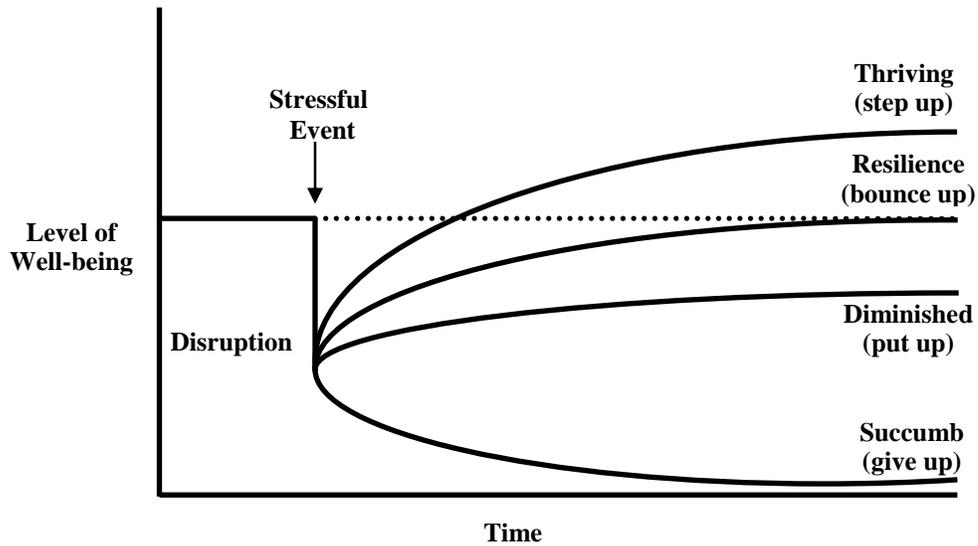


Figure 4.1 is the resilience model taught in the intervention, *The Diabetes Coaching Program: Transforming Lives Through Resilience Education*, and is based on the work of O’Leary and Ickovics (173) and Carver (50). The above diagram was extracted from Steinhardt, M.A. and Dolbier, C.L., 2008.

Figure 4.2: Example Journal Page

**“You can if you think you can.”
~ Norman Vincent Peale**

Date _____

Today’s Goal
I will take responsibility towards achieving optimal health and well-being today by...

Directions: Use the resilience curriculum to help you score 70 or higher; give yourself 10 points for each box you check.

- Monitor blood glucose
- Choose *whole grain* or *high fiber* bread, pasta, & cereal
- Eat five fruits & veggies in a variety of colors
- Choose fat-free or reduced fat foods most often
- Choose low sodium and sugar-free products
- Drink four 16 oz bottles of water (*or more*)
- Reduce your calories by 300-500 kcal
- Exercise 30 minutes (*or more*)
- Sleep 7-8 hours
- Accomplish today’s goal

Personal Reflection
As I reflect on my behavior and feelings today I am aware of ...

Figure 4.2 shows an example of a journal page from the journal instrument used in the intervention to promote goal-setting and self-assessment as well as goal-feedback and tracking. The journal also was used to reinforce core concepts taught in the DCP.

Chapter 5

Discussion

5.1 Introduction

African Americans display a disproportionate prevalence for the development of T2DM compared to the general population. Even with the many advances made in understanding and treating T2DM the number of new cases reported each year continues to grow. The most effective, safest, and least costly treatment for preventing, managing, and/or impeding the progression of T2DM is lifestyle change therapy, which is the foundation of standard diabetes self-management. However, African Americans are less likely to adhere to the necessary lifestyle changes, including diet, exercise, and blood glucose monitoring, than non-Hispanic whites. The literature indicates that individuals experiencing poor psychological well-being are less likely to adhere to diabetes self-management regimens than those with good emotional health. Interestingly, African Americans are reported to display higher levels of perceived stress, depression, and anxiety than non-Hispanic whites. Therefore, it is important that diabetes educators address the psychological needs of African Americans with T2DM in order to improve adherence to diabetes self-management and health outcomes. Resilience education is a novel approach for addressing the psychological needs of African American adults with T2DM. Resilience education aims to improve an individual's ability to cope with change and stressful situations in ways that maintain healthy levels of psychological and physiological functioning despite disruption or chaos. Therefore, the overall goal of this

dissertation was to investigate the feasibility of a resilience and diabetes self-management education intervention in African American adults with T2DM.

5.2 Summary of Results

The first objective of the study was to examine the effectiveness of the resilience and diabetes education intervention to improve psychosocial process variables, including resilience, coping strategies, self-leadership, and diabetes empowerment. Results indicated that the intervention was able to improve diabetes empowerment as well as its three subscales: managing the psychosocial aspects of diabetes; readiness to change; and setting and achieving goals. In addition, male participants reported greater significant increases for diabetes empowerment and each of its three subscales than female participants.

The second objective of the study examined the short-term effectiveness (six months) of the intervention to alter potential contributing factors to the metabolic abnormalities associated with T2DM, including psychological well-being, biological markers, and health behaviors. No improvements were found in markers of psychological well-being post-intervention including perceived stress, symptoms of depression, and negative affect. Biological markers assessed included markers of neuroendocrine function (i.e., cortisol, insulin, and IGF-1) and markers of immune function (i.e., PBMC proliferation and CRP). Cortisol levels showed no significant changes post-intervention, whereas IGF-1 levels significantly decreased by 11.9% in female participants post-intervention. Unfortunately, insulin levels could not be obtained due to highly skewed data results. PBMC proliferation was significantly enhanced by 60.1% in females and

61.5% in males post-intervention, and no significant changes were observed in CRP levels post-intervention. However, CRP levels were found to be highly elevated at baseline and at six months, indicating vascular damage. Finally, self-reported physical activity was assessed as a measure of health behavior and was significantly increased for females post-intervention, but not males.

The final objective of the study was to examine the short-term effectiveness (six months) of the intervention to delay the disease progression of obesity, T2DM, and CVD by reducing metabolic risk factors. First, we assessed weight and BMI as markers of obesity. All participants had a BMI of 25 or greater. Significant reductions were found in weight and BMI for males at six months, amounting to a 1.9% mean weight loss. Female participants showed a significant decrease in BMI post intervention, but did not show a significant decrease in body weight though a 2.1% mean weight loss was observed. Next, HbA_{1c} levels were assessed as a marker of T2DM. At baseline the mean glycosylated hemoglobin score for the participant group was near 7% (, which is an acceptable score for individuals with diabetes to maintain. At six months, participants improved to within the ranges expected for non-diabetic adults (i.e., 4-6%). Thus, significant decreases in HbA_{1c} levels were observed in females with a 1.9% decrease and males with a 0.9% decrease post-intervention. Finally, lipidemia and blood pressure were assessed as markers of CVD. Female participants showed normal to near normal ranges for all lipids and lipoprotein values at baseline, except for HDL cholesterol which was lower than normal. Males however, displayed elevated LDL cholesterol and TG levels as well as a lower than normal HDL cholesterol value at baseline. Females and males also demonstrated prehypertensive systolic and diastolic blood pressure at baseline, with

females showing slightly higher mean systolic and diastolic blood pressure than males. Therefore, LDL and total cholesterol were significantly decreased in males by 14.8% and 8.1%, respectively at six months, whereas females showed significant decreases in systolic and diastolic blood pressure by 12.5% and 11.4%, respectively at six months. No changes were found in HDL levels or TG levels for either females or males. A synopsis of the significant changes observed at six months is shown in Table 4.1.

5.3 Discussion and Future Directions

This pilot study was the first stage of many in the development of a culturally competent resilience and diabetes self-management intervention for African American adults with T2DM, and to our knowledge is the first study to ever evaluate a resilience education approach in this specific population. Although no direct improvements were found in resilience, affective coping strategies, self-leadership or markers of psychological well-being, the intervention did demonstrate several beneficial psychosocial improvements at six months including improved diabetes empowerment, management of the psychosocial aspects of diabetes, readiness to change, and setting and achieving goals, which were all key components of the curriculum. Likewise, participants were taking more responsibility for their lifestyle choices by monitoring blood glucose more frequently, eating healthfully and getting more exercise, which was evidenced by the significant improvements found in HbA_{1c} scores, cholesterol levels, and self-reported activity levels at six months. One may also speculate that because individuals were taking more responsibility for their health care, that participants were utilizing more problem-focused coping strategies to manage their diabetes. Participants also discussed an

increased since of social support and felt they new better ways of coping with stressful situations in their daily lives and self-management routines, as well as how stress can effect their diabetes self-management and blood glucose levels. Therefore, instruments that use more diabetes specific language to determine the outcomes of psychosocial process variables and psychological well-being may be better assessment tools when working with diabetes patients. Likewise, gearing the resilience curriculum to include more diabetes specific language and examples for coping with diabetes-related health issues may improve results on psychosocial process variables. These preliminary data suggest that the collective components of the intervention have the potential to facilitate a vast number of positive health outcomes for African Americans with T2DM. However, because of the limited number of subjects recruited for this pilot study, results should be interpreted cautiously. By conducting the pilot study the investigators also learned several valuable lessons based upon their experiences and the preliminary results that may help improve the cultural competency of the current intervention as well as the outcomes of future long-term studies. These insights included strategies for increasing recruitment numbers and reducing attrition rates; improving the overall cultural competence of the education curriculums; the utilization of alternative medical therapies by African Americans; and approaches for increasing participant self-assessment and goal-setting.

Since this pilot project was a collaborative translational study of the effects of resilience and diabetes self-management education on clinical outcomes, several improvements need to be made in the assessment of biological variables for future studies. First improvements could be made to broaden the scope of the study to evaluate the impact of resilience and diabetes education on the metabolic syndrome. Therefore,

additional outcome variables should be incorporated to meet the NCEP ATP III guidelines of metabolic syndrome, including measures of abdominal obesity and insulin resistance. Measuring waist-to-hip ratio or using DEXA imaging would have given a more reliable and valid assessment of percent body fat and fat distribution, which are much more accurate assessments of metabolic load than body mass index. An added benefit of using DEXA imaging is that bone density can also be determined, which may lend more information for evaluating immune function. Glucose tolerance, serum insulin, and insulin resistance must also be evaluated in future studies, not only because these variables are determinates of diabetes, but also to gain a better understanding of the status of the participants' diabetes and how well participants are managing their diabetes. Likewise, these measures could provide more insight into the interactions of the metabolic, neuroendocrine, and immune systems in relation to stress responses and disease development. Further assessments of lymphocyte apoptosis, T-lymphocyte subsets, and lymphocyte insulin receptor generation capacity could also help to better explain the improvements found in PBMC proliferation at six months. Likewise, assessing IGF-1 binding proteins and cortisol binding globulin as well as serum concentrations of catecholamines may also give greater insight into the influence of chronic stress on T2DM development and progression in relationship to endocrine function.

5.4 Conclusion

In conclusion, examining the interactions of psychosocial and behavioral factors with biological systems is imperative to understanding the health differences observed

among racial and ethnic groups because the biological level serves as the pathway to disease and death. However, our results indicate that our original model as outlined in Figure 1.1 is not as linear or simplistic as originally illustrated. For instance, psychosocial process variables, psychological well-being, health behaviors, and demographic variables may interact among themselves as well as with the neuroendocrine and immune systems, leading to either resistance or vulnerability to disease, as shown in Figure 4.1. Likewise, once resistance or vulnerability is established additional communication may result with the neuroendocrine and immune systems, as well as with other variables. Therefore, the resilience and diabetes education intervention may not act solely through psychosocial process variables to accomplish the results observed in this study. Investigating the role of resilience and diabetes self-management education within the frameworks of various biopsychosocial models may further elucidate the mechanisms by which the curriculum influences health outcomes in African Americans with T2DM. Nonetheless the results of this pilot study demonstrated that resilience education in combination with diabetes self-management may have the potential to generate a vast number of positive psychological and physiological health outcomes in African Americans with T2DM.

As Hans Selye, the renowned “Father of Stress,” long ago suggested, “If we could prove that the organism had a general nonspecific reaction-pattern with which it could meet damage caused by a variety of disease-producers, this defensive response would lend itself to a strictly objective, truly scientific analysis. By clarifying the function of the mechanism of response through which Nature herself fights injuries of various kinds, we might learn how to improve upon this reaction whenever it is imperfect - p. 31 (215).” Clearly, more work is needed to determine how psychosocial factors influence biological

systems and lead to either vulnerability or resistance to disease. However, resilience and diabetes education may be one means for improving upon the “reaction” whenever it is less than perfect in African American adults with T2DM.

Table 5.1: Synopsis of Significant Changes at 6 months

Measures	Significant Changes		
	Females (n=6)	Males (n=6)	Females and Males (n=12)
Psychosocial Process Variables			
Resilience (CD-RISC)	NC	NC	NC
Coping Strategies (Brief COPE)	NC	NC	NC
Support	NC	NC	NC
Avoidant	NC	NC	NC
Problem-Solving	NC	NC	NC
Hopeful	NC	NC	NC
Self-Leadership (SLS)	NC	NC	NC
Diabetes Empowerment (DES)	↑	↑↑↑	↑↑↑
Managing Psychosocial Aspects	↑↑	↑↑↑	↑↑↑
Readiness to Change	NC	↑↑	↑↑↑
Setting and achieving goals	NC	↑	↑↑
Psychological Well-being Variables			
Perceived Stress (PSS)	NC	NC	NC
Depressive Symptoms (CES-D)	NC	NC	NC
Negative Affectivity (PANAS)	NC	NC	NC
Physical Activity Variable			
Physical Activity (BIAR)	↑↑	NC	↑
Biological Markers			
Cortisol (µg/dL)	NC	NC	NC
IGF-1 (ng/dL)	↓↓ (11.9%)	NC	not applicable
PBMC Proliferation (%)	↑ (60.1%)	↑↑ (61.5%)	↑↑↑ (61.9%)
CRP (mg/L)	NC	NC	NC
Metabolic Risk Factors			
Weight (kg)	NC	↓↓ (1.9%)	not applicable
BMI	↓ (2.5%)	↓↓ (2.1%)	↓↓↓ (2.3%)
HbA1c (%)	↓↓ (1.8%)	↓ (0.9%)	↓↓↓ (1.3%)
HDL (mg/dL)	NC	NC	not applicable
LDL (mg/dL)	NC	↓↓↓ (22.8%)	↓↓↓ (14.8%)
TG (mg/dL)	NC	NC	NC
Total Cholesterol (mg/dL)	NC	↓↓↓ (15.1%)	↓↓↓ (8.1%)
Systolic Blood Pressure (mmHg)	↓↓↓ (12.5%)	NC	↓↓ (7.5%)
Diastolic Blood Pressure (mmHg)	↓ (11.4%)	NC	↓↓ (7.3%)

↑ = significant increase p≤0.1

↓ = significant decrease p≤0.1

↑↑ = significant increase p≤0.05

↓↓ = significant decrease p≤0.05

↑↑↑ = significant increase p≤0.01

↓↓↓ = significant decrease p≤0.01

NC = no change

Table 5.1 shows the significant changes observed by gender and for females and males together following the six month resilience and diabetes education intervention. The percentage of increase or decrease observed for each physiological variable is shown in parentheses.

Figure 5.1: Biopsychosocial Interactions Model

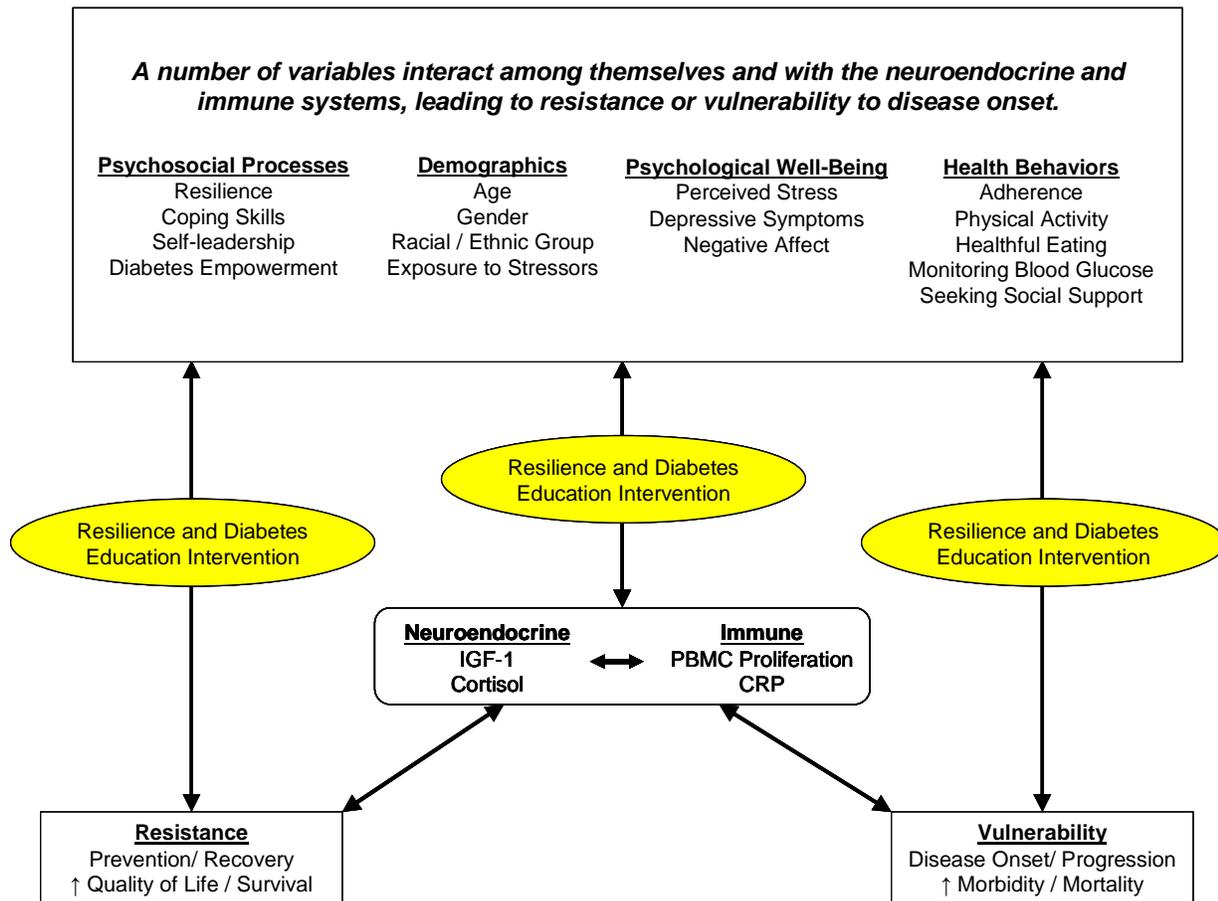


Figure 5.1 shows a biopsychosocial model which illustrates that numerous variables can interact among themselves and with the neuroendocrine and immune systems, leading to resistance or vulnerability to disease onset. This by no means is a comprehensive list of all the variables influencing disease progression or resistance, but represents some of the variables highlighted by this study. Furthermore, the resilience and diabetes education intervention is shown as potentially influencing this cross-talk at several points. At these points, an individual has the opportunity to adapt with prevention or recovery which leads to increased quality of life and survival; remain at the same level of functioning; or reintegrate with loss of function and further disease progression.

Appendix A IRB Approval Letter



OFFICE OF RESEARCH SUPPORT & COMPLIANCE

THE UNIVERSITY OF TEXAS AT AUSTIN

P.O. Box 7426, Austin, Texas 78713 (512) 471-8871 - FAX (512) 471-8873
North Office Building A, Suite 5.200 (Mail code A3200)

FWA # 00002030

Date: **11/02/06**

PI(s): **Madonna M Mamerow** Department & Mail Code: **HUMAN ECOLOGY** **A2700**
Mary A Steinhardt **KINESIOLOGY & HEALTH-BEL** **D3700**

Dear: **Madonna M Mamerow**
IRB APPROVAL – IRB Protocol # 2006-09-0093

**Title: A Resilience Intervention in African American Adults with
Type 2 Diabetes**

In accordance with Federal Regulations for review of research protocols, the Institutional Review Board has reviewed the above referenced protocol and found that it met approval under an Expedited category for the following period of time: **11/01/2006 - 10/31/2007**

Expedited category of approval:

 (1) Clinical studies of drugs and medical devices only when condition (a) or (b) is met. (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review). (b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

 X (2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows: (a) from healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or (b) from other adults and children², considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

 (3) Prospective collection of biological specimens for research purposes by Non-invasive means.
Examples:

- (a) hair and nail clippings in a non-disfiguring manner;
- (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;
- (c) permanent teeth if routine patient care indicates a need for extraction;
- (d) excreta and external secretions (including sweat);
- (e) uncannulated saliva collected either in an un-stimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue;
- (f) placenta removed at delivery;
- (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;
- (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the Process is accomplished in accordance with accepted prophylactic techniques;
- (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;
- (j) sputum collected after saline mist nebulization.

(4) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications). Examples:

- (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy;
- (b) weighing or testing sensory acuity;
- (c) magnetic resonance imaging;
- (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;
- (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

(5) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt).

(6) Collection of data from voice, video, digital, or image recordings made for research purposes.

(7) 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).

Please use the attached approved informed consent

You have been granted Waiver of Documentation of Consent
According to 45 CFR 46.117, an IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

- The research presents no more than minimal risk
- AND**
- The research involves procedures that do not require written consent when performed outside of a research setting
- <OR>**
- The principal risks are those associated with a breach of confidentiality concerning the subject's participation in the research
- AND**
- The consent document is the only record linking the subject with the research
- AND**
- This study is not FDA regulated (45 CFR 46.117)
- AND**
- Each participant will be asked whether the participant wishes documentation linking the participant with the research, and the participants wishes will govern.

You have been granted Waiver of Informed Consent
According to 45 CFR 46.116(d), an IRB may waive or alter some or all of the requirements for Informed consent if:

- The research presents no more than minimal risk to subjects;
- The waiver will not adversely affect the rights and welfare of subjects;
- The research could not practicably be carried out without the waiver; and
- Whenever appropriate, the subjects will be provided with additional pertinent information they have participated in the study.

___ This study is not FDA regulated (45 CFR 46.117)

RESPONSIBILITIES OF PRINCIPAL INVESTIGATOR FOR ONGOING PROTOCOLS:

- (1) Report **immediately** to the IRB any unanticipated problems.
- (2) Proposed changes in approved research during the period for which IRB approval cannot be initiated without IRB review and approval, except when necessary to eliminate apparent immediate hazards to the participant. Changes in approved research initiated without IRB review and approval initiated to eliminate apparent immediate hazards to the participant must be promptly reported to the IRB, and reviewed under the unanticipated problems policy to determine whether the change was consistent with ensuring the participants continued welfare.
- (3) Report any significant findings that become known in the course of the research that might affect the willingness of subjects to continue to take part.
- (4) Insure that only persons formally approved by the IRB enroll subjects.
- (5) Use **only** a currently approved consent form (remember approval periods are for 12 months or less).
- (6) **Protect the confidentiality of all persons and personally identifiable data, and train your staff and collaborators on policies and procedures for ensuring the privacy and confidentiality of participants and information.**
- (7) Submit for review and approval by the IRB all modifications to the protocol or consent form(s) prior to the implementation of the change.
- (8) Submit a **Continuing Review Report** for continuing review by the IRB. Federal regulations require **IRB review of on-going projects no less than once a year** (a Continuing Review Report form and a reminder letter will be sent to you 2 months before your expiration date). Please note however, that if you do not receive a reminder from this office about your upcoming continuing review, it is the primary responsibility of the PI not to exceed the expiration date in collection of any information. Finally, it is the responsibility of the PI to submit the Continuing Review Report before the expiration period.
- (9) Notify the IRB when the study has been completed and complete the Final Report Form.
- (10) Please help us help you by including the above protocol number on all future correspondence relating to this protocol.

Thank you for your help in this matter.

Sincerely,

Lisa Leiden, Ph.D., Chair
Institutional Review Board

Protocol # Approval dates: - 2006-09-0093

11/01/2006

10/31/2007

Appendix B

Informed Consent to Participate in Research The University of Texas at Austin

Participant # _____

IRB# 2006-09-0093

You are being asked to participate in a research study. This form provides you with information about the study. The Principal Investigator (the person in charge of this research) or her representatives will also describe this study to you and answer all of your questions. Please read the information below and ask questions about anything you don't understand before deciding whether or not to take part. Your participation is entirely voluntary and you can refuse to participate without penalty or loss of benefits to which you are otherwise entitled. You can stop participating at any time; simply tell the researcher.

Title of Research Study: A Resilience Intervention in African American Adults with Type 2 Diabetes

Principal Investigators:

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Purpose:

If you decide to participate in this study, you will be one of approximately 30 people helping us to test the effectiveness of our course titled, *The Diabetes Coaching Program: Transforming Lives Through Resilience Education* to improve diabetes self-management. Information you provide about how the course helps you to manage your stress and diabetes self-care will help us to revise and refine our curriculum to meet the needs of African American adults with type 2 diabetes.

Procedures:

Before the study begins, you will be asked to give a sample of blood and fill-out a survey, as well as have your height, weight, blood pressure, and heart rate assessed (considered the first data collection). The day before giving the blood sample you will be asked to fast for eight hours with the only exception being water. You should also withhold taking insulin or oral hypoglycemic doses until after the blood draw. Food and drinks will be available for you immediately after your blood is drawn and before you take the survey. Depending upon the results of these assessments you may be excluded

from the study. If you are included in the study, we will collect this information again six months later (considered the second data collection).

Once you have been included in the study, you will be assigned to attend one of two courses being conducted. The first course will begin in the November of 2006 and the second course will begin in May 2007 after the second data collection is complete.

If you are selected to begin the course in November 2006: You will be expected to attend four weekly classes to be held at Olivet Baptist Church (dates to be announced). All classes will be taught by Dr. Mary Steinhardt, Madonna Mamerow, and a diabetes educator and will take two hours to complete. Topics for each class include:

Class One: Transforming Stress into Resilience

Class Two: Taking Responsibility

Class Three: Focusing on Empowering Interpretations

Class Four: Creating Meaningful Connections

After all the materials are presented for the above classes, Madonna Mamerow, Dr. Steinhardt, and a diabetes educator will conduct nine, two-hour, bi-weekly support group meetings to help you with any difficulties and barriers you may be having in your diabetes self-management routine. During our next to last meeting, a two-hour focus group session will be conducted and we will ask the participants to discuss the most beneficial parts of the day's session as well as make suggestions for improving the class. The discussion will be recorded with audio tape and will be retained for future analysis by the principal investigator and her co-investigators. The recorded comments made by you and other participants will be used to improve the course to meet the needs of African American adults with type 2 diabetes.

If you are selected to begin the course in May 2006: You will be given the opportunity to attend a five-hour seminar to be held at Olivet Baptist Church on a Saturday afternoon (date to be announced). The seminar will be taught by Dr. Mary Steinhardt, Madonna Mamerow, and a diabetes educator. This seminar will include similar information as presented during the November classes.

Time Commitment:

If you are selected to begin the course in November 2006: The entire study will take approximately 32 hours of your time over a six month period beginning in November 2006 and ending in May 2007 (first data collection, 2 hours; four weekly class sessions, each 2 hours; second data collection, 2 hours; nine bi-weekly support group meetings, each 2 hours; and one focus group session, 2 hours).

If you are selected to begin the course in May 2006: The entire study will take approximately 9 hours of your time over a six month period beginning with the first data collection in November 2006 and ending in with the Saturday Seminar in May 2007 (first data collection, 2 hours; Saturday seminar, 5 hours; second data collection, 2 hours).

Possible discomforts and risks:

The potential risks of the study are no more than what you are expected to experience outside of the study. However, it is possible that you may experience some distress in becoming more aware of the stressors in your current diabetes self-management routine, as well as the ways you cope with these stressors. If participation in the study leads you to ask for additional information, Dr. Steinhardt is a licensed professional counselor and will provide that information or refer you to the appropriate resources in the community.

Blood will be obtained by venipuncture. This method involves inserting a needle into a vein in the arm and withdrawing a sample of blood. It is routinely used to obtain blood for physical examinations. Venipuncture is accompanied by minor discomfort at the site of the needle entry and may result in slight bruising and a feeling of faintness. In this study a registered nurse with two or more years of experience will obtain 18 mL (about two tablespoons) sample of your blood that will be analyzed for cholesterol levels, glycosylated hemoglobin levels, blood glucose levels, immune function, and neuroendocrine function.

In order to manage or deal with blood borne infectious diseases, we will use a sterile environment and sterile techniques including: using gloves and lab coats and changing gloves between each participant's blood draw, swabbing the site of the needle stick with an alcohol prep, using vacutainer needles and tubes and disposing of all used equipment in a biohazard container or sharp objects container. In the event of an accidental needle-stick, the nurse will inform us and we will direct you to see a physician. *However, The University of Texas at Austin has no program or plan for continuing medical care and/or hospitalization for research-related injuries or for financial compensation.*

We do not anticipate any risk or discomfort during the blood pressure, heart rate, weight, or height assessments. If we detect values that are extremely high or low during any of your physical assessments or clinical labs, we will inform you and will direct you to speak with your physician as soon as possible. A copy of your results will be faxed to your physician upon his or her request.

Possible benefits to you or others:

By participating in this study, you are helping us to better understand how we can improve our resilience curriculum to meet the needs of African American adults with type 2 diabetes. No inferences will be drawn about you specifically. By participating in this study, you will have the opportunity to learn more about coping with the chronic condition of type 2 diabetes and will be introduced to behavioral changes that you can make in your lifestyle that may help you to meet your diabetes self-care goals.

Compensation for your participation:

For your participation you will receive a Diabetes Coaching Program Journal, monetary compensation, and your laboratory test results before and after the study for glycosylated hemoglobin, cholesterol, blood glucose, and blood pressure.

If you are selected to begin the course in November 2006: You will receive a total compensation of up to \$80 cash if you complete the entire study. The \$80 amount will be dispersed in \$20 increments throughout the study as follows:

- 1) You will receive \$20 after completing all four class sessions.
- 2) You will receive \$20 after completing three support group sessions.
- 3) You will receive \$20 after completing six support group sessions.
- 4) You will receive \$20 after completing the second data collection.

To receive the full compensation of \$80 you must complete all five study requirements listed above. If you miss one or more of these study requirements you will receive only compensation for those requirements you complete.

You will also receive an *Ascensia Contour* blood glucose meter donated by Bayer Corporation if you are selected for the November 2006 course.

If you are selected to begin the course in May 2007: You will receive a total compensation of up to \$40 cash. The \$40 amount will be dispersed in \$20 increments throughout the study as follows:

- 1) You will receive \$20 after completing the five hour seminar.
- 2) You will receive \$20 after completing the second data collection.

To receive the full compensation of \$40 you must complete all three study requirements listed above. If you miss one of these study requirements you will receive only compensation for those requirements you complete.

Contacts and Questions:

If you have any questions about the study please ask now. If you have questions later or want additional information, please call Madonna Mamerow, Dr. Mary Steinhardt, or Dr. Christopher Jolly. Their contact information is listed at the top of the first page of this consent form.

In addition, if you have questions about your rights as a research participant, please contact Lisa Leiden, Ph.D., Chair, The University of Texas at Austin Institutional Review Board for the Protection of Human Subjects, 512-471-8871.

How will your privacy and the confidentiality of your research records be protected?

Only the principle investigator, co-investigators, and the University of Texas Institutional Review Board have the legal right to review your records. Any information collected about you including survey data, clinical test results, journal records, or audio recordings will not be released without your consent unless required by law or a court order. If the results of this research are published or presented at scientific meetings, your identity will not be disclosed

The confidentiality of your survey, blood samples, clinical results, and any audio recordings from class will be protected by: 1) coding the items with a number so that no personally identifying information is visible on them; 2) storing all information collected in a locked file cabinet in Dr. Mary Steinhardt's office or Dr. Chris Jolly's Office; 3) and erasing the audio tapes after the analysis is complete.

You have been informed about this study's purpose, procedures, possible benefits and risks, and you have received a copy of this form. You have been given the opportunity to ask questions before you sign, and you have been told that you can ask other questions at any time. You voluntarily agree to participate in this study. By signing this form, you are not waiving any of your legal rights.

****Printed Name of Subject** **Date**

****Signature of Subject** **Date**

****Signature of Principle Investigator** **Date**

Appendix C Survey Instrument

Diabetes Program Survey

Thank you for your willingness to complete this survey. Your individual responses will be strictly anonymous. There will be no link between your name and your survey responses.

As you complete the survey, please keep the following points in mind:

- 1) there are no right or wrong answers
- 2) just give your own honest opinion
- 3) responses should indicate what you do or feel rather than what you think most people do or feel
- 4) try not to let your answers to one question influence your answers to other questions; treat each item separately from every other item
- 5) please try to be as accurate in your responses as possible; sometimes none of the answers fit exactly, please choose the answer that comes the closest
- 6) please answer every item on the survey

How long have you been diagnosed with type 2 diabetes? _____ months _____ years

What is your age? _____

Please circle your gender? 1. Female 2. Male

In addition to type 2 diabetes, please circle whether or not you have any other significant diseases or disorders such as cancer, end-stage renal disease, Alzheimer's disease, congestive heart failure, HIV/AIDS, etc.?

1. Yes 2. No

If yes, please specify _____

Please circle whether you are currently pregnant?

1. Yes 2. No

Do you plan to become pregnant in the next six months?

1. Yes 2. No

Please circle whether or not you are currently participating in another diabetes disease management program?

1. Yes 2. No

Please circle your education level:

- | | |
|-------------------------------|--------------|
| 1. Some high school | 5. Bachelors |
| 2. High school diploma or GED | 6. Masters |
| 3. Technical or trade school | 7. Doctorate |
| 4. Some college | |

Please circle your family's current yearly income before taxes:

- | | |
|-------------------------|-------------------------|
| 1. \$19,999 or less | 4. \$60,000 to \$79,999 |
| 2. \$20,000 to \$39,999 | 5. \$80,000 to \$99,999 |
| 3. \$40,000 to \$59,999 | 6. \$100,000 or more |

Please list **all** medications you are currently taking.

Please indicate how much you agree with the following statements as they apply to you during the **past month**. If a particular situation has not occurred recently, answer according to how you think you would have felt. **RESILIENCE**

Indicate how much you agree with the following statements as they apply to you during the past month:	NOT TRUE AT ALL	RARELY TRUE	SOME-TIMES TRUE	OFTEN TRUE	TRUE NEARLY ALL THE TIME
1. I am able to adapt when changes occur.	0	1	2	3	4
2. I have at least one close and secure relationship which helps me when I am stressed.	0	1	2	3	4
3. When there are no clear solutions to my problems, sometimes fate or God can help.	0	1	2	3	4
4. I can deal with whatever comes my way.	0	1	2	3	4
5. Past successes give me confidence in dealing with new challenges and difficulties.	0	1	2	3	4
6. I try to see the humorous side of things when I am faced with problems.	0	1	2	3	4
7. Having to cope with stress can make me stronger.	0	1	2	3	4
8. I tend to bounce back after illness, injury, or other hardships.	0	1	2	3	4
9. Good or bad, I believe that most things happen for a reason.	0	1	2	3	4
10. I give my best effort, no matter what the outcome may be.	0	1	2	3	4
11. I believe I can achieve my goals, even if there are obstacles.	0	1	2	3	4
12. Even when things look hopeless, I don't give up.	0	1	2	3	4
13. During times of stress/crisis, I know where to turn for help.	0	1	2	3	4
14. Under pressure, I stay focused and think clearly.	0	1	2	3	4
15. I prefer to take the lead in solving problems, rather than letting others make all the decisions.	0	1	2	3	4
16. I am not easily discouraged by failure.	0	1	2	3	4
17. I think of myself as a strong person when dealing with life's challenges and difficulties.	0	1	2	3	4
18. I can make unpopular or difficult decisions that affect other people, if it is necessary.	0	1	2	3	4
19. I am able to handle unpleasant or painful feelings like sadness, fear and anger.	0	1	2	3	4
20. In dealing with life's problems, sometimes you have to act on a hunch, without knowing why.	0	1	2	3	4
21. I have a strong sense of purpose in life.	0	1	2	3	4
22. I feel in control of my life.	0	1	2	3	4
23. I like challenges.	0	1	2	3	4
24. I work to attain my goals, no matter what roadblocks I encounter along the way.	0	1	2	3	4
25. I take pride in my achievements.	0	1	2	3	4

Please indicate what you did and how you felt when experiencing stressful events during the past month. Obviously, different events bring out somewhat different responses, but think about what you usually did when you were under stress. COPING SKILLS

Indicate <u>during the past month</u> what you did and how you felt when experiencing stressful events.:	NOT AT ALL	A LITTLE BIT	A MEDIUM AMOUNT	A LOT
1. I concentrated my efforts on doing something about the situation I was in.	1	2	3	4
2. I tried to come up with a strategy about what to do.	1	2	3	4
3. I tried to see it in a different light, to make it seem more positive.	1	2	3	4
4. I accepted the reality of the fact that it happened.	1	2	3	4
5. I made jokes about it.	1	2	3	4
6. I tried to find comfort in my religion or spiritual beliefs.	1	2	3	4
7. I tried to get emotional support from others.	1	2	3	4
8. I tried to get advice or help from other people about what to do.	1	2	3	4
9. I turned to work or other activities to take my mind off things.	1	2	3	4
10. I said to myself "this isn't real".	1	2	3	4
11. I said things to let my unpleasant feelings escape.	1	2	3	4
12. I used alcohol or other drugs to make myself feel better.	1	2	3	4
13. I just gave up trying to deal with it.	1	2	3	4
14. I criticized myself.	1	2	3	4
15. I took action to try to make the situation better.	1	2	3	4
16. I thought hard about what steps to take.	1	2	3	4
17. I looked for something good in what happened.	1	2	3	4
18. I learned to live with it.	1	2	3	4
19. I made fun of the situation.	1	2	3	4
20. I prayed or meditated.	1	2	3	4
21. I got comfort and understanding from someone.	1	2	3	4
22. I got help and advice from other people.	1	2	3	4
23. I did something to think about it less, such as went to the movies, watched TV, read, daydreamed, slept, or went shopping.	1	2	3	4
24. I refused to believe that it happened.	1	2	3	4
25. I expressed my negative feelings.	1	2	3	4
26. I used alcohol or other drugs to help me get through it.	1	2	3	4
27. I blamed myself for things that happened.	1	2	3	4
28. I gave up the attempt to cope.	1	2	3	4

Read the following statements carefully and circle the response that best describes how frequently you experienced each statement during the past few weeks. SELF-LEADERSHIP

How frequently did you experience the following during the <u>past few weeks</u> :	NEVER/ ALMOST NEVER	RARELY	SOME- TIMES	OFTEN	ALWAYS/ ALMOST ALWAYS
1. I felt a sense of inner peace.	1	2	3	4	5
2. I was clear about what I wanted from life.	1	2	3	4	5
3. I felt an inner sense of confidence.	1	2	3	4	5
4. I embraced life's challenges.	1	2	3	4	5
5. I felt disconnected from myself.	1	2	3	4	5
6. I experienced feeling calm in my body.	1	2	3	4	5
7. I treated myself with kindness.	1	2	3	4	5
8. I had a hard time trusting my own instincts.	1	2	3	4	5
9. I felt alone in the world.	1	2	3	4	5
10. I maintained an inner steadiness even under pressure.	1	2	3	4	5
11. I delighted in exploring and discovering new things.	1	2	3	4	5
12. I felt agitated.	1	2	3	4	5
13. I felt there was a real purpose for my life.	1	2	3	4	5
14. I could handle present situations.	1	2	3	4	5
15. I could think creatively about my problems.	1	2	3	4	5
16. I felt loved.	1	2	3	4	5
17. I felt at ease.	1	2	3	4	5
18. I had faith in myself.	1	2	3	4	5
19. I felt I belonged in this world.	1	2	3	4	5
20. I met life's challenges with courage.	1	2	3	4	5

DIABETES EMPOWERMENT

In general, I believe that I:	STRONGLY AGREE	AGREE	NEUTRAL	DISAGREE	STRONGLY DISAGREE
1. ...know what part(s) of taking care of my diabetes that I am satisfied with.	1	2	3	4	5
2. ...know what part(s) of taking care of my diabetes that I am dissatisfied with.	1	2	3	4	5
3. ...know what part(s) of taking care of my diabetes that I am ready to change.	1	2	3	4	5
4. ...know what part(s) of taking care of my diabetes that I am not ready to change.	1	2	3	4	5
5. ...can choose realistic diabetes goals.	1	2	3	4	5
6. ...know which of my diabetes goals are most important to me.	1	2	3	4	5
7. ...know the things about myself that either help or prevent me from reaching my diabetes goals.	1	2	3	4	5
8. ...can come up with good ideas to help me reach my goals.	1	2	3	4	5
9. ...am able to turn my diabetes goals into a workable plan.	1	2	3	4	5
10. ...can reach my diabetes goals once I make up my mind.	1	2	3	4	5
11. ...know which barriers make reaching my diabetes goals more difficult.	1	2	3	4	5
12. ...can think of different ways to overcome barriers to my diabetes goals.	1	2	3	4	5
13. ...can try out different ways of overcoming barriers to my diabetes goals.	1	2	3	4	5
14. ...am able to decide which way of overcoming barriers to my diabetes goals works best for me.	1	2	3	4	5
15. ...can tell how I'm feeling about having diabetes.	1	2	3	4	5
16. ...can tell how I'm feeling about caring for my diabetes.	1	2	3	4	5
17. ...know the ways that having diabetes causes stress in my life.	1	2	3	4	5
18. ...know the positive ways I cope with diabetes-related stress.	1	2	3	4	5
19. ...know the negative ways I cope with diabetes-related stress.	1	2	3	4	5

In general, I believe that I:	STRONGLY AGREE	AGREE	NEUTRAL	DISAGREE	STRONGLY DISAGREE
20. ...can cope well with diabetes-related stress.	1	2	3	4	5
21. ...know where I can get support for having and caring for my diabetes.	1	2	3	4	5
22. ...can ask for support for having and caring for my diabetes when I need it.	1	2	3	4	5
23. ...can support myself when dealing with my diabetes.	1	2	3	4	5
24. ...know what helps me stay motivated to care for my diabetes.	1	2	3	4	5
25. ...can motivate myself to care for my diabetes.	1	2	3	4	5
26. ...know enough about diabetes to make self-care choices that are right for me.	1	2	3	4	5
27. ...know enough about myself as a person to make diabetes care choices that are right for me.	1	2	3	4	5
28. ...am able to figure out if it is worth my while to change how I take care of my diabetes.	1	2	3	4	5

The questions in this scale ask you about your feelings and thoughts during the last month. In each case, you will be asked to indicate how often you felt or thought a certain way. **PERCEIVED STRESS**

How often have you felt or thought in the following ways during the last month?	NEVER	ALMOST NEVER	SOME-TIMES	FAIRLY OFTEN	VERY OFTEN
1. In the last month, how often have you been upset because of something that happened unexpectedly?	0	1	2	3	4
2. In the last month, how often have you felt that you were unable to control the important things in your life?	0	1	2	3	4
3. In the last month, how often have you felt nervous & “stressed”?	0	1	2	3	4
4. In the last month, how often have you felt confident about your ability to handle your personal problems?	0	1	2	3	4
5. In the last month, how often have you felt that things were going your way?	0	1	2	3	4
6. In the last month, how often have you found that you could not cope with all the things that you had to do?	0	1	2	3	4
7. In the last month, how often have you been able to control irritations in your life?	0	1	2	3	4
8. In the last month, how often have you felt that you were on top of things?	0	1	2	3	4
9. In the last month, how often have you been angered because of things that were outside of your control?	0	1	2	3	4
10. In the last month, how often have you felt difficulties were piling up so high that you could not overcome them?	0	1	2	3	4

Below is a list of some of the ways you may have felt or behaved. Please indicate how often you have felt or behaved this way during the past few weeks. DEPRESSION

<i>DURING THE PAST FEW WEEKS...</i>	Rarely or none of the time (less than 1 day)	Some or a little of the time (1-2 days)	Occasionally or a moderate amount of time (3-4 days)	All of the time (5-7 days)
1. I was bothered by things that usually don't bother me.	0	1	2	3
2. I did not feel like eating; my appetite was poor.	0	1	2	3
3. I felt that I could not shake off the blues even with help from my family or friends.	0	1	2	3
4. I felt like I was just as good as other people.	0	1	2	3
5. I had trouble keeping my mind on what I was doing.	0	1	2	3
6. I felt depressed.	0	1	2	3
7. I felt that everything I did was an effort.	0	1	2	3
8. I felt hopeful about the future.	0	1	2	3
9. I thought my life had been a failure.	0	1	2	3
10. I felt fearful.	0	1	2	3
11. My sleep was restless.	0	1	2	3
12. I was happy.	0	1	2	3
13. I talked less than usual.	0	1	2	3
14. I felt lonely.	0	1	2	3
15. People were unfriendly.	0	1	2	3
16. I enjoyed life.	0	1	2	3
17. I had crying spells.	0	1	2	3
18. I felt sad.	0	1	2	
19. I felt that people disliked me.	0	1	2	3
20. I could not get "going".	0	1	2	3

This scale consists of a number of words that describe different feelings and emotions. Read each item and then indicate to what extent you generally feel this way, that is, how you feel on average.

NEGATIVE AFFECT

Indicate how you feel on average:	NOT AT ALL	A LITTLE	MODERATELY	QUITE A BIT	VERY MUCH SO
1. interested	1	2	3	4	5
2. distressed	1	2	3	4	5
3. excited	1	2	3	4	5
4. upset	1	2	3	4	5
5. strong	1	2	3	4	5
6. guilty	1	2	3	4	5
7. scared	1	2	3	4	5
8. hostile	1	2	3	4	5
9. enthusiastic	1	2	3	4	5
10. proud	1	2	3	4	5
11. irritable	1	2	3	4	5
12. alert	1	2	3	4	5
13. ashamed	1	2	3	4	5
14. inspired	1	2	3	4	5
15. nervous	1	2	3	4	5
16. determined	1	2	3	4	5
17. attentive	1	2	3	4	5
18. jittery	1	2	3	4	5
19. active	1	2	3	4	5
20. afraid	1	2	3	4	5

Please check below the category that best describes your physical activity for the past month.
Physical Activity Questionnaire

_____ 0 = no physical activity

_____ 1 = moderate to vigorous physical exercise 1 time/week for at least 20 minutes

_____ 2 = moderate to vigorous physical exercise 1-2 time/week for at least 20 minutes

_____ 3 = moderate to vigorous physical exercise 3 time/week for at least 20 minutes

_____ 4 = moderate to vigorous physical exercise 5 time/week for at least 30 minutes

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Vita

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