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COMBINING THE COMMON SENSE MODEL, COGNITIVE BEHAVIORAL PRINCIPLES, AND REAL WORLD EXPERIENCE TO PROMOTE TYPE 2 DIABETES SELF-MANAGEMENT

By

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ABSTRACT OF THE DISSERTATION

Combining the Common Sense Model, Cognitive Behavioral Principles, and Real World Experience to Promote Type 2 Diabetes Self-Management By JESSICA SAMANTHA YU

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Type 2 diabetes mellitus (T2DM) is a chronic and progressive medical condition that has reached pandemic levels, currently affecting 368 million people worldwide. With previous research demonstrating that T2DM is largely irreversible, the focus is now on developing and disseminating structured diabetes self-management education and support (DSME) programs to help patients live as healthfully as possible without exacerbating their illness. In recent years, several DSME interventions have demonstrated clinically meaningful changes in T2DM patients; however, there appears to be little translation of these programs from research into real world settings because these settings often lack clear blueprints for how to create or implement DSME programs that best fit their organizational needs and structure. Thus, the current study aimed to address this research-practice gap through the development of a brief, theoretically-driven, and behaviorally-focused group-based DSME curriculum for use in real world settings. Phase 1 of the study entailed concentrated efforts to join behavioral health researchers, community health leaders, and T2DM experts in combining the Common Sense Model of Self-

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Regulation (a prominent health behavior theory), cognitive behavioral principles, and current guidelines from the American Diabetes Association into a novel DSME curriculum. Phase 2 of the study then focused on implementing the resulting four-session curriculum, *An Active Approach to Diabetes Self-Management*, in local community centers and examining its early acceptability, feasibility, and effectiveness in producing clinical and psychosocial outcomes of interest. A total of 22 adults with T2DM, ranging in age from 35 to 87 years, were recruited from four community organizations and entered into four separate groups. Results indicate statistically significant improvements in participants' glycemic control, diabetes knowledge, and diabetes self-efficacy over the course of the study. In addition, results indicate that both participants and community liaisons were highly satisfied with the intervention. These findings contribute to the field's growing knowledge of how best to capitalize on clinical, research, and real world expertise to design thoughtful and practical DSME programs.

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Introduction

A Global Pandemic

Type 2 diabetes mellitus (T2DM) is a chronic and progressive medical condition characterized by an abnormality in the pancreatic hormone insulin that causes an individual's body to fail to either produce enough insulin or properly use insulin, resulting in an excess of glucose in the bloodstream (National Institute of Diabetes and Digestive and Kidney Diseases [NIDDK], 2012). Approximately 28 million Americans (adults and children combined), or 9% of the United States population, are affected by T2DM (Centers for Disease Control [CDC], 2014). Across the globe, this number rises to approximately 368 million people, or 8% of the world's population (International Diabetes Federation [IDF], 2014). These prevalence rates have already exceeded expert epidemiological projections from the turn of the century (e.g., Boyle et al., 2001; Wild et al., 2004), and are expected to climb to increasingly astonishing levels – a projected *592 million people* worldwide – by 2035 (Guariguata et al., 2014).

Beyond the fact that hundreds of millions of people are affected by T2DM, the medical and economic burdens associated with T2DM are staggering. Diabetes is associated with increased cardiovascular risk, kidney and liver disease, nerve damage, visual disturbance, foot damage, and skin problems (Mayo Clinic, 2014). Worldwide, epidemiological data indicate that diabetes is a leading cause of blindness, kidney failure, and non-traumatic lower limb amputations (World Health Organization [WHO], 2010). It is also the seventh-leading cause of death, with estimates that the overall risk of death among people with diabetes is at least twice that of people without (Roglic et al., 2005). With such complex disease profiles, medical expenses for people with T2DM are double

those for their non-diabetic peers, adding up to almost \$13,700 per year in the U.S. (American Academy of Clinical Endocrinologists [AACE], 2007; ADA, 2014) and costing the national healthcare system over \$245 billion annually (ADA, 2014). Outside the U.S., the global health expenditure on diabetes totals over \$376 billion annually (Zhang et al., 2010). Thus, as many have argued before, T2DM is a problem of global, pandemic proportion (e.g., Jarvis, Skinner, Carey, & Davies, 2010).

The Irreversibility of T2DM

In 2006, with mounting evidence of T2DM's status as a true pandemic with myriad economic, medical, and personal consequences, the United Nations General Assembly (2007) voted to pass a resolution calling for all nations to develop policies for the prevention and treatment of diabetes. In response, several research groups have, over the years, aimed to develop improved biomedical and lifestyle interventions for patients with T2DM. Studies examining the efficacy and effectiveness of these interventions have made one thing clear: T2DM, as a chronic and progressive disease, is unlikely to be reversed.

The defining feature of T2DM is a glycated hemoglobin level (hereon referred to as "HbA1c") greater than or equal to 6.5% (ADA, 2015). HbA1c is a measure of an individual's average blood glucose level over the previous 2-3 months and considered the biomarker of choice for diabetes (Caveney & Cohen, 2011). People without diabetes typically have HbA1c levels less than 5.7% and those at risk for diabetes have levels between 5.7 and 6.4% (ADA, 2015). Researchers examining the reversibility of T2DM have therefore defined complete remission from T2DM as achieving an HbA1c of less

than 5.7%, and found that very few people – less than 2% – ever meet and maintain this level.

The results of two recent studies in particular illuminate the irreversibility of T2DM. In the first, Karter and colleagues (2014) examined the 7-year incidence of diabetes remission among 122,781 adults with T2DM receiving routine clinical care (e.g., pharmacologic treatment) within the Kaiser Permanente Northern California healthcare system. Defining complete remission as having HbA1c less than 5.7% for at least 12 months with the absence of pharmacologic treatment during that period, the authors found that only 0.14% of patients reverted from T2DM to non-T2DM status. Further, they found that only 0.007% of patients sustained this status for a prolonged period of at least five years. Comparing the rates of death and T2DM remission in their sample of adults, Karter et al. (2014) made this sobering conclusion: "The chances of dying were higher than the chances of any remission" (p. 3191).

One could argue that Karter et al.'s study speaks only to the effectiveness of treatment-as-usual, rather than more intensive and specialized interventions, in achieving diabetes remission. However, Look AHEAD, the largest and longest-running randomized controlled trial (RCT) of behavioral weight loss in the U.S. to date demonstrates that even the most incentivized and specialized interventions also fail. In the trial, 4,503 overweight adults with T2DM were randomized to either an intensive lifestyle intervention (ILI) or treatment-as-usual (TAU). ILI was comprised of four years of regularly scheduled individual and group coaching focused on caloric restriction and increased physical activity, with dietary products and fitness classes provided free of charge and prizes awarded to participants who met their weight loss goals. TAU was

comprised of optional diabetes education and support offered three times per year (Look AHEAD Research Group, 2006). Gregg et al. (2012) examined the frequency of remission throughout the study, with complete remission defined as HbA1c less than 5.7% without the need for diabetes medication at the time of assessment. Although the authors reported a statistically significant difference in complete remission rates between ILI and TAU participants at the end of the active phase of treatment, it must be made clear that these rates were quite low -0.7% for ILI and 0.2% for TAU. In addition, of participants achieving remission at any point in the study, one-third to one-half returned to T2DM status each year (Gregg et al., 2012).

It is important to note that intensive interventions such as the ILI in Look AHEAD have been shown to produce positive effects, including reduced HbA1c, clinically meaningful weight loss, increased physical activity, and reduced caloric intake (Look AHEAD Research Group, 2010; 2014), all of which may improve patients' diabetes status and outcomes. However, these interventions have yet to help reverse T2DM in all but a handful of patients. Some clinician researchers have therefore argued that an even more drastic measure – bariatric surgery – be taken to treat overweight patients with T2DM, who may be most at risk for diabetes-related complications. Results from a multi-site study of T2DM remission and relapse in 4,434 T2DM patients following bariatric surgery, however, found that while 68% of patients experienced complete remission following surgery, this remission lasted a median of just 8.3 years, with 31% of those who remitted re-developing diabetes within five years (Arterburn et al., 2013). Thus, even with the most invasive and intensive interventions, remission remains elusive for people with T2DM.

The Importance of Self-Management in T2DM

Given that remission is so elusive for people with T2DM, clinicians, researchers, and policy makers in the field have more recently focused on developing and disseminating structured diabetes self-management education and support (DSME) programs to help patients learn how to control their blood glucose, prevent acute complications, and reduce the risk of long-term complications (ADA, 2015). In other words, health professionals are increasingly interested in using DSME to help those with T2DM live as healthfully as possible with diabetes – as opposed to free of diabetes – without making it worse. Currently, the American Diabetes Association's (2015) clinical practice guidelines recommend that patients with T2DM receive structured DSME when first diagnosed and as needed thereafter – and that DSME strive to be patient-centered, theoretically-driven, and skills-based. Specifically, DSME should aim to empower patients with the confidence, knowledge, and skills to manage their diabetes on a day-today basis by focusing on key components of self-management, such as healthy eating, physical activity, blood glucose monitoring, and psychosocial assessment and care (ADA, 2015).

In recent years, many DSME interventions have been developed based upon the above guidelines, tested in RCTs, and demonstrated clinically meaningful changes in T2DM patients. Many of these interventions follow a group-based format, as there is evidence that group-based education is more cost effective and likely to stimulate behavioral and lifestyle changes for patients with diabetes than individual education (Tang, Funnell, & Anderson, 2006). These include the empowerment-based approach advocated by Funnell, Tang, and Anderson (2007), the problem-solving approach

championed by Hill-Briggs and colleagues (2011), and the Chronic Disease Self-Management Program developed by Lorig and colleagues (2013) – all of which educate and motivate patients to engage in important self-management behaviors for T2DM in relatively brief, patient-centered, and skills-based interventions. For example, Funnell et al.'s (2011) empowerment-based DSME program consists of six weekly, two-hour, group sessions focused on having participants review their own diabetes status (e.g., by examining recent HbA1c, blood pressure, lipid profile, and weight results) and helping them work through the process of creating lifestyle changes to achieve self-identified goals. Hill-Briggs et al.'s (2011) problem-solving intervention consists of nine, 90minute, group sessions, the first of which provides participants with information on diabetes, its complications, and key self-management behaviors, and the rest of which help patients identify barriers to effective self-management, set realistic goals, and prepare to take action toward these goals. Lorig et al.'s (2013) Chronic Disease Self-Management Program consists of six group sessions focused on building participants' self-efficacy as it pertains to health-related behaviors and symptoms, such as healthy eating, exercise, medication use, doctor-patient communication, and decision-making.

Studies utilizing these approaches for T2DM self-management have examined their efficacy and effectiveness in culturally diverse and ethnic minority populations (e.g., Anderson et al., 2005; Philis-Tsimikas et al., 2004), in various clinical, community, and online settings (e.g., Lorig, Ritter, Villa, & Armas, 2009; Lorig, Ritter, Laurent, et al., 2010; Lorig, Ritter, Ory, & Whitelaw, 2013), and with both health professionals and peers as leaders (e.g., Tang et al., 2011). These studies have found that, post-intervention, participants report increased diabetes knowledge and self-care (Anderson et al., 2005; Fitzpatrick, Schumann, & Hill-Briggs, 2013; Philis-Tsimikas et al., 2004), witness improvements in their HbA1c and other physical health measures (Anderson et al., 2005; Hill-Briggs et al., 2011; Lorig et al., 2013; Philis-Tsmikas et al., 2004), endorse increased quality of life (Lorig et al., 2013), and endorse high satisfaction with the intervention (Hill-Briggs et al., 2011).

Beyond these specific approaches and studies, there is additional evidence that group-based DSME indeed improves patients' diabetes-related outcomes. In their Cochrane review, Deakin et al. (2005) examined the results of 11 studies involving 1,532 adults with T2DM and found that group-based DSME, compared to routine treatment, wait list control, or no intervention, was more likely to help participants increase their diabetes knowledge and reduce their HbA1c, body weight, blood pressure, and need for diabetes-related medication. More recently, Steinsbekk and colleagues (2012) pooled data from 21 studies involving 2,833 adults who were randomly assigned to either group-based DSME or routine care, and found that those who engaged in group-based DSME were more likely to experience statistically significant pre- to post-treatment reductions in their HbA1c, as well as improvements in their diabetes knowledge, self-efficacy, and self-management behaviors.

Taken together, the results of these and other studies (e.g., Harris et al., 2014; Kluding et al., 2010) demonstrate that group-based DSME can help patients with T2DM achieve desired clinical and psychosocial outcomes. While some studies have failed to find these effects, this is likely due to problematic inclusion criteria or intervention design. For example, Lorig and colleagues (2009) allowed T2DM participants already in "good control" of their diabetes, with HbA1c less than 7% (NIDDK, 2014), to enter their study, which may have resulted in a floor effect that did not allow the researchers to find much evidence of HbA1c improvement. Khunti et al. (2012) condensed their six-hour group-based DSME program for newly diagnosed participants into one- or two-day programs and found that it was no more effective than routine care in improving participants' HbA1c, depression, and quality of life – likely because the intervention was too brief and left little time for participants to practice and obtain feedback on their selfmanagement behaviors. On the other hand, Tang et al. (2011) found that an 88-week DSME program aimed at helping participants understand the chronicity of their disease and the necessity of lifelong self-management was simply too long for participants, discouraging regular attendance and thereby limiting their ability to learn how to engage in effective self-management. Thus, group-based DSME may be shown most effective when interventions target those patients most in need of help and provide adequate time for patients to learn and practice self-management behaviors.

A Wide Research-Practice Gap in T2DM Self-Management

Despite the published successes of many DSME interventions, there is one alarming fact. This is that only 7% of adults with T2DM can be considered effective selfmanagers, as only 7% routinely engage in the behaviors that have heretofore been described as important and necessary for optimal glycemic control (Griffin et al. 1998; Deakin et al., 2005). And this fact raises the question: If multiple studies have demonstrated that structured DSME can help patients reduce their HbA1c and improve their diabetes-related health and quality of life, then why are so few patients considered effective self-managers?

The answer lies in the wide gap between DSME research and practice. As previously described, countless studies have examined the efficacy and effectiveness of DSME programs in a wide range of settings – including research offices, community health centers, primary care clinics, and faith-based organizations (Harris et al., 2014; Samuel-Hodge et al., 2006) –, yet there appears to be little sustained translation of these programs from research into real world settings. Community surveys indicate that only 10-50% of real world patients have access to DSME (Haas et al., 2012; Peyrot, Rubin, Funnell, & Siminerio, 2009). The reasons for this are multi-faceted; however, two reasons stand out. First, specific programs or protocols made available by researchers for use in clinical and community settings are often perceived by staff as too dense, long, and time-intensive (Farmer et al., 2007; Peyrot & Rubin, 2008) – and therefore may not be seen as suitable to offer. Second, when clinical and community settings instead attempt to design a DSME program that may better fit their organizational needs and structure, they often lack a clear blueprint for how to create DSME programs within their environments. Few research groups clearly describe the process of developing and delivering DSME, which includes detailing the theoretical models that serve as the basis for intervention design and implementation (Deakin, 2005) and describing the specific skills and techniques employed by facilitators to promote health behavior change (Lorig, Ritter, Villa, & Armas, 2009). Without such a blueprint, real world health educators and professionals may be at a loss for how to develop much-needed DSME programs.

The Current Study

Thus, the current study aimed to improve the current state of T2DM selfmanagement education and support by addressing both the previously outlined successes and limitations of structured DSME in the development of a brief, theoretically-driven, and behaviorally-focused group-based DSME curriculum for use in real world settings. In particular, the study drew upon three principles and theories, briefly outlined below and further delineated in the following section, in creating and testing a group-based intervention focused on enhancing the self-care behaviors of T2DM patients.

Common Sense Model of Self-Regulation. A prominent health behavior theory, the Common Sense Model of Self-Regulation (CSM; Leventhal et al., 2011) addresses how people conceptualize their illnesses and make decisions regarding treatment. CSM posits a hierarchically organized model of illness that begins with an individual's *representation* of illness that then guides his or her *coping* responses and finally his or her *appraisal* of effective or ineffective coping responses (Nerenz & Leventhal, 1983). This model can serve as a "common sense" feedback loop for individuals dealing with some type of health threat or illness, as the symptoms (a component of illness representations) individuals experience can drive them to engage in behaviors (e.g., taking medication, a means of coping) that reduce symptomatology and increase the experience of health. The feedback loop for individuals with T2DM, however, is not so simple because T2DM is considered a "silent" illness – that is, the symptoms of elevated blood glucose are barely discernable. Thus, individuals with T2DM do not undergo the typical common sense feedback loop that allows them to experience how their selfmanagement behaviors may decrease symptomatology. Therefore, individuals with T2DM must learn how to replace the typical feedback loop with a diabetes-specific feedback loop that will enable them to develop effective self-management strategies. Previous studies have utilized CSM to develop self-management interventions for

illnesses such as asthma, cancer, and heart disease (Leventhal et al., 2011; McAndrew et al., 2008).

Cognitive Behavioral Therapy. While CSM provides a framework for helping patients conceptualize their illness and its treatment, it does not necessarily define the concrete skills and tools required to elicit health behavior change. Cognitive behavioral therapy (CBT) does define these skills and tools (also referred to as "principles" and "strategies"), and has been shown to be effective for a number of disorders, including depression, eating disorders, and irritable bowel syndrome (e.g., National Institute for Clinical Excellence [NICE], 2004; Lackner et al., 2010). The core principles and strategies of CBT cut across its specific treatments for various disorders and include regular self-monitoring of behaviors, out-of-session homework assignments to increase individual self-efficacy, and patient-provider collaboration in goal-setting and problem solving (Wilson & Vitousek, 1999). These principles and strategies have been integrated into interventions for a wide variety of chronic diseases and medical problems (White, 2001), and may prove useful in helping T2DM patients and DSME facilitators understand exactly how to increase or improve self-care and self-management behaviors.

Community-Based Participatory Research. Community-based participatory research (CBPR; e.g., Israel, Eng, Schulz, & Parker, 2005; Becker, Stice, Shaw, & Woda, 2009) is an applied and collaborative approach that enables community stakeholders to participate in all aspects of research in order to adequately address pressing public health concerns, improve intervention design and implementation, and increase the translation of research findings into real world clinical care and policy change (NIH Office of Behavioral and Social Sciences Research, 2015). Given the research-practice gap in DSME, CBPR principles – specifically, engaging community leaders and stakeholders in intervention development, participant recruitment, and intervention delivery – were used to aid in the development of a program likely to be implemented beyond the research setting.

Study Phases. With the overall goal of developing a novel DSME program for adults with T2DM, the current study was divided into two phases. The aim of Phase 1 was to describe the process of integrating CSM and CBT into a group-based DSME program titled *An Active Approach to Diabetes Self-Management*. The aim of Phase 2 was two-fold: 1) to build community-research partnerships; and 2) to leverage these partnerships to examine the early effectiveness of *An Active Approach to Diabetes Self-Management* in improving diabetes-related clinical and psychosocial outcomes within the sample of adults successfully recruited for the study.

Method

Study Overview

To develop *An Active Approach to Diabetes Self-Management*, the current study was comprised of two inter-related phases. Phase 1 entailed concentrated efforts to join T2DM patients, researchers, community health leaders, and diabetes experts in combining the health behavior theory of CSM, the behavioral strategies of CBT, and current ADA guidelines into a novel DSME curriculum. Phase 2 then focused on implementing the resulting group-based DSME curriculum in local community centers and examining its early acceptability, feasibility, and effectiveness in producing clinical and psychosocial outcomes of interest.

Phase 1: Intervention Development

To describe the methodology underlying the development of *An Active Approach to Diabetes Self-Management* (hereon referred to as "*An Active Approach*"), this section includes: 1) a brief overview of the expert consultation group formed to guide the development of *An Active Approach*; 2) a description of CSM as the theoretical framework for *An Active Approach*; 3) a description of CBT principles and strategies used to enact behavior change in *An Active Approach*; and 4) a description of the overall intervention.

Expert Consultation. CBPR principles suggest that community members and researchers work together to optimally combine real world experience and scientific knowledge to improve community health (NIH OBSSR, 2015). In developing health promotion programs, a critically important action step is to invite community partners and health experts to join an advisory board or consultation group that will help develop, oversee, and structure the particular program (Partnership for Prevention, 2008). Therefore, at the outset of developing the current, second, generation of An Active Approach (See Breland, 2012 for a description of the original iteration of the intervention), an expert consultation group was formed, with the goal of having an interdisciplinary group of experts in CBT, CSM, community health, diabetes care, nutrition, and fitness guide the development of the DSME curriculum. The group included the principal investigator (J.Y., a student of CBT and CSM), the author of CSM (Howard Leventhal, Ph.D.), a social worker with over two decades of experience creating and implementing community health programs (Kimberly Convery, MSW), a local community health educator (Fern Kulman, MPH, RN), an Internal Medicine physician with over 30 years of experience treating adults with T2DM (Elaine Leventhal, M.D.,

Ph.D.), a certified diabetes educator, clinical nutritionist, and registered dietitian (Lauren Bernstein, M.S., R.D., C.D.E.), and a fitness instructor (Steffanie Gallante, M.Ed.).

Members of this expert consultation group were kept up-to-date on the development of *An Active Approach* and approached at various points throughout the overall study to provide feedback on the intervention's structure, curriculum, and session activities. Each member's unique background and expertise were incorporated into the intervention's design. For example, K.C. and F.K.'s experiences with community health programming led to *An Active Approach* becoming a four-session "workshop", as this length and title were considered acceptable and familiar to potential recruitment sites and participants. E.L.'s experience as a physician treating T2DM patients was invaluable in deciding to focus the intervention predominantly on nutrition, exercise, medication adherence, and doctor-patient communication. In addition, L.B.'s experiences as a diabetes educator, nutritionist, and dietitian helped determine what information and activities would be most important to include in *An Active Approach's* session on nutrition.

Common Sense as a Theoretical Framework. The Common Sense Model of Self-Regulation (Leventhal et al., 2011) proposes that an individual's regulation of physical health and illness is influenced by his or her subjective experience and perception of symptoms, mood, and dysfunction. Each subjective experience is matched to some prototype of illness, with the default prototype being that of an acute illness. The prototype of an acute illness begins with a *representation* of that illness (e.g., symptoms) that then drives an individual's *action plan* for coping behavior (e.g., taking medications). This action plan is defined by a series of *sensations* associated with the coping behavior (e.g., opening a pill bottle, swallowing a pill). Later, the individual determines whether his or her action plan has been effective through an *appraisal* of outcomes (e.g., reduction of symptoms). Thus, this sequence of events, *illness representation—action plan—sensations—appraisal of outcomes*, serves as the individual's automatic and common sense feedback loop for illness and is accessed whenever he or she experiences some type of health threat. The problem with using this feedback loop for T2DM is that diabetes is an asymptomatic, chronic illness rather than a symptomatic, acute illness – and therefore, a T2DM patient who focuses on waiting for and responding to perceived symptoms of high blood glucose stands little chance of learning the behaviors necessary for long-term, effective self-management.

Given its focus on understanding how people self-regulate health and illness, the CSM provides *An Active Approach* with a sound theoretical framework for illness perception and management. The goal of integrating CSM into DSME is to replace patients' automatic and common sense feedback loop for acute illness with one that focuses on conscious, deliberate, and volitional self-management behaviors for chronic illness (McAndrew et al., 2008). Doing so requires two parallel processes: 1) modifying an individual's illness representation; and 2) adding information to an individual's action plan. Rather than use his or her subjective experience of symptoms as an illness representation that prompts coping behavior, the T2DM patient must be taught to view external methods of diabetes measurement, such as his or her daily blood glucose readings or quarterly HbA1c levels, as the illness representation. In addition, rather than have the T2DM patient focus on a singular coping behavior that can be appraised relatively quickly, the T2DM patient must be taught to engage in a variety of self-

management behaviors. In learning these behaviors, he or she must learn not only what to do (e.g., change diet, exercise, or take medication), but also what to expect (e.g., decreased HbA1c) and when to expect it (e.g., in 2-3 months). Furthermore, this action plan must be carefully integrated into daily life in order to become automatic over time.

The CSM is integrated into An Active Approach in two ways. One is by delineating it into four themes that participants are asked to remember throughout the intervention. First, participants are asked to understand what they can and cannot control in T2DM. They are told that they can control behaviors such as eating healthfully, engaging in physical activity, and taking their medications – but that they cannot control the automatic bodily functions, like insulin secretion, that are the hallmark of T2DM. Second, participants are asked to understand the various *time lines associated with diabetes self-management*. They are encouraged to view self-management as a progression from short- to long-term goals, beginning with the immediate goals of managing their blood glucose levels through healthy eating, exercise, and medication adherence; moving to intermediate goals of regularly visiting their physicians to track their HbA1c; and ending with long-term goals of avoiding severe diabetes-related complications like blindness, kidney disease, and death. Third, participants are asked to understand the various time lines associated with diabetes self-assessment. Participants learn how immediate feedback comes in the form of daily or momentary blood glucose monitoring, whereas long-term feedback on diabetes control comes in the form of quarterly HbA1c readings. Fourth, participants are asked to adopt an experimental attitude to self-management – to understand that their individual self-management strategies must be catered to their individual desires and needs.

The other way in which CSM is integrated into *An Active Approach* is by educating participants about the default in the automatic, common sense, feedback loop and encouraging them to adopt a diabetes-specific feedback loop. In the first session of the intervention, participants are taught that any health problem can be managed if an individual can identify what the problem is, how to treat it, and whether the treatment works – and how this easily applies to a relatively simple problem like a headache. They are then introduced to the concept of T2DM as an asymptomatic, chronic illness that makes it difficult to "feel" and treat high blood sugar, and provided with an illustration of a diabetes feedback loop that uses blood glucose readings – rather than any subjective symptoms that may or may not be related to these readings – as the impetus for effective and lifelong self-management.

Cognitive Behavioral Principles to Promote Health Behavior Change.

Cognitive behavioral therapy is a collaborative, structured, and short-term psychological treatment that focuses on understanding how patients' thoughts, feelings, and behaviors maintain their presenting problems – and on modifying these maladaptive patterns in order to promote effective problem solving, health, and wellness (White, 2001). The cornerstone of CBT is an active learning environment in which the patient is viewed as a partner in assessment and treatment – as someone who is an expert is his or her own illness experience but requires coaching to learn new strategies and techniques to overcome the particular illness (Scott, Mansell, Salkovskis, Lavender, & Cartwright-Hatton, 2010). Applied to chronic illness self-management, this means encouraging patients to observe and describe their own diagnoses, symptoms, and behaviors that may exacerbate illness, and providing them with concrete skills and strategies to promote

health. As New (2010) writes, it means creating a learning environment that is personal, motivational, and reinforcing:

Learning activities for adults must involve them in the learning process, motivate them, promote their self-determination, meet their learning needs, allow them to share personal knowledge and experiences, promote competence, reinforce positive behaviors, and help them to identify consequences of behaviors (p. 317).

CBT outlines several skills and strategies that are incorporated into the structure of treatment sessions to increase patient motivation and assist in behavior change. These include orienting the patient to treatment, helping the patient determine his or her treatment goals, setting specific agendas for treatment sessions, and using behavioral experiments, modeling, problem-solving, and homework to help patients practice new and adaptive behaviors. Orientation to treatment occurs at the outset of treatment, and is a way to obtain patients' "buy-in" for treatment. Patients are informed of what treatment entails, why it works, and what to expect from it – and as a result, patients are more likely to understand the treatment and be motivated to do what is asked of them. *Goal setting* also occurs at the outset of treatment. Patients are asked to define observable, measurable, and achievable goals that enable providers to assess progress and identify positive change. Agenda setting, behavioral experiments, modeling, and problem-solving then occur within treatment sessions to teach patients exactly how to achieve behavior change, whereas *homework* – in particular, *self-monitoring* – is assigned between sessions to encourage patients to practice behavior change in their everyday lives (Cully & Teten, 2008).

To provide both T2DM patients and group facilitators with the concrete tools necessary for effective diabetes self-management, each of the aforementioned skills and strategies is integrated into each session of *An Active Approach*. At the very beginning of

the first group session, participants receive an orientation to the four-session DSME program. They are introduced to the overall goal of the program, as well as to the specific topics addressed in each session. They are also asked to commit to actively participating in the group, which means attending each session, completing all activities, and discussing both successes and problems with the facilitator and other group members. In the first session, participants are also asked to think of their individual goals and engage in a pros-and-cons exercise to motivate them to work towards their goals. Throughout *An Active Approach*, each session begins with the setting of an agenda for the day, includes different activities and experiments to teach participants specific self-management strategies, and incorporates active discussion of participants' positive and negative experiences with self-management in order to reinforce effective behavior and problem-solve ineffective behavior. In addition, each session ends with homework, related to the day's lesson, that will help participants integrate effective self-management strategies into their daily routines.

An Active Approach to Diabetes Self-Management. Guided by CBPR, CSM, CBT, the most recent ADA guidelines for structured DSME, and participant feedback from an earlier iteration of the intervention (Breland, 2012), *An Active Approach to Diabetes Self-Management* is now a four-session workshop that aims to provide T2DM patients with the confidence, knowledge, and skills to effectively manage their condition. It is meant to address the needs of both newly diagnosed patients and those who have been long diagnosed and wish to "re-boot" their self-management. The workshop follows the format of group-based DSME, with four to seven participants and one to two facilitators per group. In the current study, J.Y. facilitated all groups, with either K.C. or E.R. co-facilitating and E.L. serving as a medical expert on hand to answer any specific questions about diabetes medical care. Sessions are held weekly, with each session lasting two hours. Sessions are designed to be active and collaborative, with material presented via handouts, demonstrations, hands-on learning experiments, and dynamic discussion between facilitators and group members. Each session is briefly outlined below (See Appendix B for the full intervention manual).

Session 1. Session 1 focuses on introducing participants to An Active Approach, providing them with basic information on T2DM, increasing their motivation for selfmanagement, and discussing the key components of self-management. In this session, participants are provided with a handbook to use throughout the intervention. The handbook can be considered a "workbook" and includes session agendas, relevant information, written exercises, and homework. Participants are asked to introduce themselves to one another and discuss their diabetes diagnosis, duration, and workshop goals. They are asked to write down these goals and assess their motivation, via a pros and cons exercise, for self-management in their handbooks. They are introduced to the diabetes-specific feedback loop and informed of the key self-management strategies they will learn in the program (self-monitoring, eating well, exercising, taking medications, and communicating with doctors). They are taught how to properly monitor their blood glucose and asked to practice this for homework. At the end of this session, they are also asked to begin keeping a daily record of their eating in preparation for the following session's focus on nutrition.

Session 2. Session 2 focuses on introducing participants to diabetes nutrition and meal planning. In this session, participants' daily food records are reviewed to assess

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whether participants are following three key guidelines for a healthy diabetes diet: 1) eating regularly (e.g., every 4 hours); 2) limiting carbohydrates; and 3) exercising portion control. In-session activities then demonstrate to participants how to incorporate strategies to meet each of these guidelines into their self-management routines. For example, a grocery bag with various breakfast, lunch, dinner, and snack items is brought in to teach participants how to read nutrition labels to determine carbohydrate counts and the Plate Method (ADA, 2015) is taught to help participants control portion sizes. At the end of this session, participants are asked to continue keeping their daily food records and to use the guidelines learned in session to plan one breakfast, one lunch, and one dinner before the next session.

Session 3. Session 3 focuses on teaching participants about the importance of physical activity. In this session, participants' daily food records and sample meals are first reviewed to provide participants with feedback on their efforts to eat healthfully. Then, the importance of regular physical activity is discussed, with an emphasis on understanding what types of exercise, whether structured (e.g., jogging) or unstructured (e.g., gardening, walking pets), participants see as most achievable, appropriate, and enjoyable for them. Next, a fitness demonstration, tailored to the abilities of the particular group of participants, provides participants with an example of a type of exercise they may incorporate into their daily self-management routines. At the end of this session, participants are asked to continue keeping their daily food records and to meet individual exercise goals for the week.

Session 4. Session 4 focuses on teaching participants how to maintain effective self-care behaviors in the future. In this session, participants' individual homework and

progress throughout the workshop is first reviewed. Next, participants are engaged in an active discussion of other self-care behaviors (e.g., medication adherence and stress management) and how to communicate with their health care providers about their long-term self-management.

Phase 2: Implementing and Testing *An Active Approach to Diabetes Self-Management*

To describe the methodology underlying the implementation and testing of *An Active Approach to Diabetes Self-Management*, this section includes: 1) the protocol used to build community-research collaborations with specific intervention sites; 2) a description of participant inclusion and exclusion criteria; 3) a summary of the measures given to participants; and 4) the data analytic strategy utilized to assess outcomes of interest.

Community-Research Collaboration. To examine the acceptability, feasibility, and early effectiveness of *An Active Approach* within community settings in the area surrounding New Brunswick, NJ, the study team began by establishing a community-research collaboration protocol to identify potential partnerships. First, the team generated a list of potential organizational partners, largely based upon the advice of K.C. and F.K., whom together had over 40 years of experience leading community-based health programs. Second, J.Y. sent identified key personnel within each potential organizational partner introductory e-mails describing the study and intervention and requesting an in-person meeting to discuss the study in more detail. Third, J.Y. met with key personnel who responded to this initial e-mail to discuss their organizations' specific

health programming needs, how *An Active Approach* could meet these needs, and, if appropriate, potential recruitment strategies.

Once a collaborative relationship was formed with a specific organization, a unique recruitment protocol was established for that organization. Whenever possible, active – rather than passive – recruitment methods were used, as research has demonstrated that active methods are more likely to attract eligible participants for health-related interventions (Raynor et al., 2009). Active methods are those in which researchers take the initiative to identify and approach potential participants (e.g., by phone), whereas passive methods are those in which potential participants must identify themselves (e.g., by responding to an advertisement). In the current study, key personnel most often utilized the approach of identifying community members they believed would be eligible for the study, providing them with a study advertisement, following up about their interest, and then directing them to J.Y. for official entry.

Participants. Study inclusion and exclusion criteria were similar to those used in other studies of behavioral interventions for T2DM (e.g., Cummings et al., 2013) and designed to be minimally restrictive in order to increase the ecological validity of the study. Individuals aged 18 years and older with a diagnosis of T2DM were eligible for the study if they met the following additional inclusion criteria: 1) had an HbA1c level greater than or equal to 7.0%; 2) had the ability to read, write, and speak English; 3) obtained medical clearance from their primary care physician to participate in an educational group for diabetes self-management; and 4) identified a physician who would be overseeing their overall health and medical treatment for diabetes. Individuals who met the inclusion criteria were excluded if they: 1) were pregnant; 2) had a current

diagnosis of cancer; 3) reported cognitive impairment that could interfere with their ability to understand intervention materials; 4) endorsed active suicidal ideation or intent; or 5) were currently engaged in an alternative diabetes education program. Use of insulin or oral medications for T2DM was not exclusion criterion, as the need for medication and insulin to help patients meet their target blood glucose levels is a routine part of diabetes treatment and medication adherence is considered a necessary self-management behavior (ADA, 2015).

Measures. The study consisted of three assessment time points: baseline (BL), end-of-treatment (EOT; at the close of Session 4), and follow-up (FU; 2.5-months following EOT). The primary outcome measure was the mean (average) reduction, from BL to FU, in participants' HbA1c. Secondary outcome measures included increases in participants' diabetes knowledge, diabetes self-efficacy, and overall health and quality of life from BL to EOT, as well as participants' satisfaction with the intervention at EOT.

Demographic Information. A demographic questionnaire was provided to participants at BL. It included questions regarding participants' age, gender, race, ethnicity, education, work status, and household income, as well as questions regarding participants' duration of illness, use of medication, and engagement in previous diabetes education.

HbA1c. As the ADA (2015) recommends that T2DM patients measure their HbA1c approximately every 3 months to determine whether they have reached or maintained their glycemic targets, participants' HbA1c levels were measured at BL and FU using a disposable HbA1c analyzer commercially available as a home-test and shown to be 99% accurate (A1cNow+, Bayer Medical Care; Tarrytown, NY).

Diabetes Knowledge Test. Participants' knowledge of T2DM was assessed at BL, EOT, and FU using the Diabetes Knowledge Test (DKT; Fitzgerald et al., 1998). The DKT is a well-established measure designed to assess patients' broad-based knowledge of diabetes and its treatment. The first 14 items only were included in the study, as the last seven items pertain specifically to insulin users or individuals with type 1 diabetes mellitus. The 14 items are presented as multiple-choice questions regarding patients' understanding of diabetes-related problems, how to accurately assess blood glucose, and how food and physical activity affect blood glucose levels. For example, the DKT asks participants to choose the correct responses for the following items: "The diabetes diet is...?"; "HbA1c is a test that is a measure of your average blood glucose level for the past...?"; and "Numbness and tingling may be symptoms of ...?" An individual's DKT score is the total number of correct responses, with the highest score possible in the current study equal to 14. The DKT has been shown to have a reliability of $\alpha = 0.70 - 0.70$ 0.71 in clinical and community samples (Michigan Diabetes Research and Training Center, 2015).

Diabetes Self-Efficacy Scale. Participants' self-efficacy regarding their T2DM self-management was assessed at BL, EOT, and FU using the Diabetes Self-Efficacy Scale (DSES; Stanford Patient Education Research Center, ongoing). The DSES includes eight items that measure patients' confidence in engaging in a variety of behaviors widely regarded as necessary for effective self-management. For each item, patients are asked to rate their confidence on a scale of 1 to 10, with 1 meaning "not at all confident" and 10 meaning "totally confident." Sample items include: "How confident do you feel that you can eat your meals every 4 to 5 hours every day, including breakfast every day?"; "How

confident do you feel that you can exercise 15 to 30 minutes, 4 to 5 times a week?"; and "How confident do you feel that you can control your diabetes so that it does not interfere with the things you want to do?" An individual's DSES score is the average of all responses, with the maximum score possible equal to 10. The DSES has been shown to have a reliability of $\alpha = 0.83$ (Lorig, Ritter, Villa, & Armas, 2009).

DUKE Health Profile. Participants' overall health and functioning was assessed at BL, EOT, and FU using the DUKE Health Profile (DUKE; Parkerson, Broadhead, & Tse, 1990). The DUKE includes 17 items that are divided into six domains of health (physical, mental, social, general, perceived health, and self-esteem) and four domains of dysfunction (anxiety, depression, pain, and disability). Response options vary per item. Items related to individuals' mental, social, and perceived health are most often presented as statements for which they must choose from one of the following options: "Yes, describes me exactly"; "Somewhat describes me"; or "No, doesn't describe me at all." Sample statements include: "I like who I am"; "I am happy with my family relationships"; and "I am basically a healthy person." Items related to patients' physical health are most often presented as questions for which patients must report the intensity of any physical limitation as "none", "some", or "a lot". Sample questions include: "Today, would you have any physical trouble or difficulty walking up a flight of stairs?" and "During the past week, how much trouble have you had with hurting or aching in any part of your body?" Each domain is scored independently as an average of the responses specific to that domain; the general score is an average of an individual's physical, mental, and social scores. The maximum score possible for all domains is 100. The DUKE has been shown to have a reliability of $\alpha = 0.55 - 0.78$ in clinical and community

samples (Parkerson et al., 1990). In the current study, physical, mental, social, general, and perceived health scores only were examined.

Patient Health Questionnaire-9 Item Version. Due to the elevated risk of depression in individuals with diabetes compared to those without diabetes (ADA, 2015), participants' depressive symptomatology was assessed at BL, EOT, and FU using the Patient Health Questionnaire-9 Item Version (PHQ-9; Kroenke, Spitzer, & Williams, 2001). On the PHQ-9, patients are asked how often, over the previous two weeks, they have been bothered by any depressive symptoms, including depressed mood, apathy and anhedonia, hopelessness, worthlessness, and suicidal ideation or intent. Responses range from 0, meaning "not at all", to 3, meaning "nearly every day". An individual's PHQ-9 score is the total of all responses, with the maximum possible score equal to 27. A PHQ-9 score of 5-9 indicates minimal depressive symptoms, 10-14 indicates mild depressive symptoms, 15-19 indicates moderately severe depressive symptoms, and greater than 20 indicates severe depressive symptoms (Kroenke & Spitzer, 2002). The PHQ-9 is widely used in clinical practices and research trials, and has been shown to have a reliability of $\alpha = 0.89$ (Kroenke, Spitzer, Williams, & Lowe, 2010).

Client Satisfaction Questionnaire. Participants' satisfaction with the intervention served as a measure of intervention acceptability and was assessed at EOT using the 8-item Client Satisfaction Questionnaire (CSQ; Larsen, Attkisson, Hargreaves, & Nguyen, 1979). The CSQ has been used to measure client and patient satisfaction across a wide variety of clinical, human services, education, and governmental programs. Response options differ for each item, but all are based on a 4-point scale. Sample items include: "To what extent did this program meet your needs?" (with possible responses of 1 =

"only a few of my needs met"; 2 = "most of my needs met"; 3 = "almost all of my needs met"; and 4 = "all of my needs met"); and "How satisfied are you with the amount of help you received in this program?" (with possible responses of 1 = "quite dissatisfied"; 2 = "mildly dissatisfied"; 3 = "most satisfied"; and 4 = "very satisfied"). An individual's CSQ score is the total of all responses, with a maximum score of 32. The CSQ has been shown to have a reliability of $\alpha = 0.83$ (Larsen, Attkisson, Hargreaves, & Nguyen, 1979).

Intervention Feasibility. Formation of successful community-research partnerships, participant referral, participant attendance, and participant retention were used to assess intervention feasibility.

Data Analyses. All data analyses were performed in SPSS Version 23.0. First, participant demographics were examined using frequencies, means, and standard deviations. Second, a repeated measures *t*-test was conducted to examine the effect of participation in *An Active Approach* on participants' mean HbA1c between BL and FU. Third, one-way, repeated measures analyses of variance (ANOVAs) were conducted to examine the effect of participation in *An Active Approach* on participants' diabetes knowledge, diabetes self-efficacy, and overall health and quality of life between BL, EOT, and FU, as assessed by the DKT, DSES, and DUKE. Finally, mean EOT score for client satisfaction, as assessed by the CSQ, was reviewed. All tests were conducted as intent-to-treat analyses, with the baseline observation carried forward (BOCF) approach used to handle missing data.

Results

Results of the implementation and acceptability, feasibility, and early effectiveness testing of *An Active Approach* are presented in this section in the following

order: 1) a description of the community-research collaborations formed; 2) a flowchart of participant referral, eligibility, and entrance into the study; 3) an overview of participant demographics; and 4) a summary of primary and secondary outcomes regarding changes in participants' HbA1c, diabetes knowledge, diabetes self-efficacy, health and quality of life, and overall intervention satisfaction.

Community-Research Collaboration

Table 1 (See Appendix A for all Tables and Figures) documents all the organizations identified, key personnel contacted, and collaborations formed within the community surrounding New Brunswick, NJ. Based upon the advice of the expert consultation group's two community health experts, K.C. and F.K., a total of eight organizations were identified as possible collaborative sites. Four of the organizations were university affiliates and four were community centers or neighborhood institutions. Of these eight organizations, four actively collaborated with the research team to recruit participants and hold workshops within their respective sites.

Two of the four organizations were direct referrals of F.K. and affiliates of the Woodbridge Township Department of Health and Human Services. Maple Tree Manor, located in Avenel, NJ, is a low-income housing facility for county residents ages 60 and over. Its Housing Director had a long history of working with other agencies to bring various health, leisure, and social activities to her residents, and became an early advocate of *An Active Approach*. After meeting with the P.I. to discuss the aims of and inclusion criteria for the study, she personally identified and recruited eligible participants. Evergreen Senior Center, located in Colonia, NJ, is a community center that specifically caters to Woodbridge Township's aging population. Its Director had a proven

record of working with other individuals and organizations to provide members with a number of educational, recreational, and social programs. After meeting with the study P.I. to learn about *An Active Approach*, she developed an initial advertisement to gauge her population's interest and instructed her unit's social workers – who function as case managers for community members requiring assistance navigating the county's vast resources – to identify individuals they believed could benefit from the DSME group.

Parker at Stonegate ("Parker") was a direct referral of K.C. Primarily an assisted living residence in Highland Park, NJ, Parker runs an active outreach program that invites adults ages 55 and over from the community to utilize its fitness center and attend a variety of health and wellness seminars. With previous experience collaborating with Rutgers University investigators, Parker's Director of Research and Education was particularly interested in contributing to health intervention research, and recruited other staff members, including the organization's Health and Wellness Coordinator, to advertise the study among able residents, community members, and day workers.

Finally, the Rutgers University Occupational Health Department – which was a new contact for the research team – provides clinical care for university faculty and staff and boasts a number of health promotion programs, including nutritional and smoking cessation counseling. After an initial meeting with the study P.I., the Department's Administrative Manager came to view *An Active Approach* as another health promotion program to advertise throughout the university. She invited the P.I. and other study team members to university flu clinics and encouraged them to advertise the study in various university bulletins.

Participant Referral, Eligibility, and Entrance

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Figure 1 illustrates participant flow into the study. Each collaborative site independently recruited participants for An Active Approach, with all recruitment procedures, assessments, and intervention sessions occurring on-site. Maple Tree Manor initially identified five potential participants for the study. All five were eligible and entered into the study, completing all study procedures. Evergreen Senior Center initially identified 10 potential participants for the study. Seven were available and eligible, entered into the study, and completed all study procedures. Parker at Stonegate identified five potential participants. Four were eligible and entered into the study, with three completing all study procedures. Finally, Rutgers University Occupational Health initially identified 15 potential participants. Six were available and eligible, entered into the study, and completed all study procedures. Thus, from an initial pool of 35 potential participants, a total of N = 22 adults with T2DM across the four collaborative sites participated in the study. The majority (n = 16; 72.7%) attended all four sessions of an Active Approach and all but one completed all BL, EOT, and FU measures. The one participant who did not complete the study attended just two group sessions, citing personal reasons that interfered with her ability to continue actively engaging in the intervention and study.

Participant Demographics

Table 2 summarizes participants' baseline demographic information. Participants were predominantly female (86.4%) and ranged in age from 35 to 87 years, with a mean age of 67.45 ± 11.72 years. They were mostly Non-Hispanic (95.5%) and Caucasian (81.8%). Almost half of participants (45.5%) were currently married. Their education levels varied, with one participant (4.5%) having completed grade school only, half

(50.0%) having completed high school or an equivalent, and the rest (45.5%) having pursued some type of higher education. Given the mature age of the sample, half of participants (50.0%) were retired; however, approximately one-third (31.8%) reported that they were continuing to work full-time. Income varied widely, from less than \$10,000 to greater than \$100,000, with half of participants (50.0%) reporting a current household income of less than \$60,000. Of note, those who reported an income of less than \$20,000 reported that they and/or their partners had no personal income and relied on family or governmental assistance.

With respect to T2DM status, participants' mean HbA1c at baseline was $7.41\% \pm 0.40\%$, with a range between 7.0% and 8.4%. On average, participants had lived with diabetes for 9.65 ± 8.15 years. This duration did vary, with five participants (22.7%) reporting that they had received their diagnosis within the past year and another five (22.7%) reporting that they had lived with their diagnosis for 15 or more years. Almost half (45.5%) reported receiving some previous diabetes education, which included a structured diabetes group, nutrition counseling, and individual coaching. Over 80% of participants were currently taking a diabetes-related medication, including insulin (13.6%) or oral medication (77.3%).

Primary and Secondary Outcomes

Table 3 summarizes participants' mean BL, EOT, and FU scores for all primary and secondary outcomes. Overall, results indicate significant improvements in participants' HbA1c, diabetes knowledge, diabetes self-efficacy, and depressive symptomatology over the course of the study. Where violations of sphericity were detected by Mauchly's Tests during the conduct of the one-way, repeated measures ANOVAs for the secondary outcome measures, Greenhouse-Geisser corrected results are reported.

HbA1c. Results of the repeated measures *t*-test used to assess change in participants' HbA1c over the course of the study indicate a reduction in mean HbA1c from BL (M = 7.41, SD = 0.40) to FU (M = 7.16, SD = 0.41). This reduction was statistically significant, t(21)=4.03, p < 0.01, and represents a medium to large effect size, d = 0.63.

Diabetes Knowledge. Results of the one-way, repeated measures ANOVA, with Greenhouse-Geisser correction, used to assess change in participants' diabetes knowledge over the course of the study indicate a statistically significant increase in mean DKT scores over time, F(1.26, 26.44) = 22.66, p < 0.001. Post-hoc tests using Bonferroni correction reveal that the difference in mean DKT scores between BL (M = 10.32, SD = 2.28) and EOT (M = 12.55, SD = 1.14) was statistically significant, p < 0.001; however, that difference in scores between EOT and FU (M = 12.95, SD = 1.05) was not, p = 0.249, indicating that improvements between BL and EOT were maintained at FU.

Diabetes Self-Efficacy. Greenhouse-Geisser corrected results of the one-way, repeated measures ANOVA used to assess change in participants' diabetes self-efficacy over the course of the study also reveal a statistically significant increase in DSE scores over time, F(1.34, 28.06) = 16.86, p < 0.001. Post-hoc analyses with Bonferroni correction demonstrate that the difference in scores between BL (M = 6.99, SD = 1.72) and EOT (M = 8.60, SD = 1.07) was statistically significant, p < 0.01, but that between EOT and FU (M = 8.66, SD = 0.92) was not, p = 1.00, indicating that improvements between BL and EOT were maintained at FU. Health and Quality of Life. Results of the one-way repeated measures ANOVAs used to assess change in participants' health and quality of life over the course of the study indicate no significant change in DUKE scores between BL, EOT, and FU. Participants' mean Mental Health score did not significantly differ between assessment time points, F(2, 42) = 1.87, p = 0.167; participants' mean Physical Health score did not significantly differ between the time points, F(2, 42) = 0.516; and their mean Social Health score did not significantly differ between the time points, F(2, 42) = 0.20, p = 0.82. In addition, there was no significant change in participants' Perceived Health score over the course of the study, F(2, 42) = 1.79, p = 0.18.

Depressive Symptomatology. Results of the one-way, repeated measures ANOVA, with Greenhouse-Geisser correction, show a statistically significant decrease in PHQ-9 scores between BL and FU, F(1.37, 28.82) = 4.70, p < 0.05. Post-hoc tests with Bonferroni correction indicate that the difference was significant between BL (M = 2.95, SD = 2.79) and EOT (M = 1.45, SD = 1.54), p < 0.05, but not between EOT and FU (M =2.18, SD = 2.00), p = 0.10, suggesting that improvements in depressive symptomatology were maintained from EOT to FU.

Client Satisfaction. Mean CSQ score at EOT was 31.64 ± 0.79 , indicating high treatment satisfaction.

Discussion

The aim of the current study was two-fold: 1) to combine the health behavior theory of CSM, the principles and strategies of CBT, and the tenets of CBPR to create a theoretically-based and behaviorally-focused T2DM self-management group appropriate for dissemination and implementation within community settings; and 2) to examine the acceptability, feasibility, and early effectiveness of the resulting curriculum in collaborative sites within the area surrounding New Brunswick, NJ. To achieve these aims, the study was conceptualized as having two separate, but inter-related, phases. Phase 1 was focused on forming an expert consultation group, comprised of community members and researchers with varied levels of experience in CBT, CSM, community health, diabetes care, nutrition, and fitness – and leveraging the expertise of this group to integrate CSM, CBT, and current ADA guidelines into a novel DSME curriculum, *An Active Approach to Diabetes Self-Management*. Phase 2 then focused on building community-research collaborations and examining the effectiveness of *An Active Approach* in improving the clinical and psychosocial outcomes of community adults with T2DM.

Efforts to bridge the research-practice gap in health-related fields typically involve some kind of translational research to move evidence-based findings from clinical trials into real world practice settings. This process often progresses in a unidirectional manner (Rubio et al., 2010), such that interventions are adapted to fit within the structure of real world clinical and community settings only *after* they have been proven effective in research studies. Although this method is meant to ensure that treatments work before they become widely available, it may in fact impede their dissemination and implementation when even the most evidence-based interventions are seen as poor fits for their intended settings. For example, an intervention may be considered too costly, time-intensive, or resource-intensive for a particular site; it may be viewed as misaligned with a site's philosophy or structure; or a site may be unclear as to whether and how to modify an intervention in order to implement it (Glasgow & Emmons, 2007). These barriers, however, are less likely to be present if the intervention is developed in consultation with one or more individuals who understand the site's organization, needs, and practices.

Thus, the formation of a multi-disciplinary consultation group to guide the development of *An Active Approach* from the outset of the study proved to be an invaluable step, enabling the research team to optimally balance the principles of CSM and CBT with the real world experiences of community health settings. In one specific example, it enabled the research team to develop teaching material and in-session activities that provided clear and concrete instructions for participants to improve their eating habits in order to become more effective T2DM self-managers. In developing the material for An Active Approach's nutrition session, the research team initially intended to use CSM and CBT to provide participants with general principles, rather than strict rules, for healthy eating. Specifically, the research team intended to encourage participants to adopt an experimental attitude to first self-monitor and observe unhealthy patterns in eating, then use immediate feedback from blood glucose monitoring to understand how different foods have differential effects on blood glucose, and finally determine how to eat for maximal glycemic control. The research team did not intend to provide any specific menus or meal plans, or to label any foods as "good", "bad", "right", or "wrong", because the team viewed each participant's eating behaviors and needs as unique. However, the consultation group's community health experts and diabetes educator advised that, based upon their experience, participants would desire more than general principles – they would want concrete information on exactly what to eat, when to eat, and how to eat. With this in mind, the research team worked with these experts to

insert specific healthy eating ideas and strategies, consistent with CSM and CBT principles, into the curriculum. The result was the addition of three specific strategies for grocery shopping, meal planning, and glycemic control – carbohydrate counting, the Plate Method, and eating on a regular schedule –, as well as the provision of sample menus and snack suggestions to help participants better envision healthy eating.

Similar to how detailing the process of designing a DSME curriculum can provide clinical and community settings with a clear blueprint for how to create their own DSME programs, it is now clear that including specific strategies, sample menus, and snack suggestions in An Active Approach provided participants with their own blueprints for *how exactly* to eat. In addition to the quantitative data demonstrating that participants' diabetes self-efficacy, including their confidence in following a diabetic-friendly diet, increased after attending An Active Approach, qualitative data show how including carbohydrate counting, the Plate Method, and eating on a regular schedule in a way that was consistent with CSM and CBT's emphases on active experimentation and learning increased participants' engagement in and excitement for healthy eating. After in-session "grocery shopping" demonstrations showing participants how to read nutrition labels, count carbohydrates, and assess portion size, participants appeared to have "A-ha!" moments. They went home and experimented with one or more strategies – and the result was personalized learning. They returned to the following session with empty food cartons to demonstrate how they had read the nutrition labels on their favorite oatmeal packets and microwaveable meal containers. They proudly shared photos of their dinner plates, with each plate divided carefully using the Plate Method such that half the plate was devoted to vegetables, a quarter to lean protein, and a quarter to grains or starches.

They discussed how they posted their favorite recipe tips, from the curriculum and from each other, on Facebook. In sum, the combination of CSM, CBT, and real world tips and tricks seemed to enable participants to think, "*This* is how to eat."

Beyond helping to balance CSM, CBT, and real world experience in An Active Approach, consultation group members also helped the research team forge successful community-research collaborations. The CBPR literature has long highlighted the importance of identifying advocates, champions, and leaders within community organizations to help push program and intervention dissemination and implementation forward, as forming relationships with such individuals builds trust between researchers, community partners, and community members (Horowitz, Robinson, & Seifer, 2009). The consultation group's community health experts became An Active Approach's first advocates, champions, and leaders – and helped the research team find additional advocates through their vast social and occupational networks. For instance, F.K., in her role as the Woodbridge Township's Department of Health and Human Service's Public Health Officer, was eager to bring a chronic disease self-management program to the area's residents. She personally contacted key staff members at various township agencies to assess interest in An Active Approach, introduced the research team to those who responded, and even organized initial meetings between the research team and interested agency staff. Because she was a well-known public health figure within the Woodbridge community, her endorsement of An Active Approach mattered. Agency staff trusted her judgment, and as a result, became more trusting of the research team. They also then became An Active Approach's next advocates, introducing the intervention to

their colleagues, recruiting participants for the study, and helping to retain participant and staff engagement throughout the study.

At the same time, the process of working with the consultation group's community health experts to bring An Active Approach into real world settings also highlights the tension that can develop between scientific and community partners when creating, disseminating, and implementing new interventions. In CBPR, questions often arise as to who "owns" an intervention, who in the community has the right to participate in an intervention, or how to share research findings (Minkler, 2004). To avoid any harsh feelings or miscommunication, CBPR experts strongly recommend drafting formal or informal memorandums of understanding (MOU) at the very beginning stages of collaboration to clarify such issues in advance (Minkler, 2004). In the current study, the IRB-approved study protocol served as a formal MOU between the research team and collaborating sites to clarify study procedures, inclusion and exclusion criteria, and assessment measures, while ongoing conversations between the research team and key personnel at collaborating sites served as informal MOUs to clarify specific recruitment and retention strategies. Nevertheless, both parties experienced disagreement over relatively minor matters throughout the course of the study. Such matters included where to include sites' organizational seals on study advertisements, whether to recruit solely during the community's health awareness periods (e.g., Diabetes Awareness Month in November), whether to allow sites' own health educators to facilitate sessions, what refreshments to provide participants during group sessions, and how to thank participants for their time in the study. Such disagreements at times led to frustration on either or both sides, but ongoing dialogue between the research team and collaborating sites to clarify

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each side's position and needs helped settle matters while maintaining a good working relationship between both parties.

Ultimately, it was this good working relationship that produced what Phase 2 of the current study demonstrates may be an acceptable, feasible, and effective group-based DSME program for implementation within community health settings. Results of the examination of *An Active Approach's* effectiveness among participants in the study's four collaborating sites provide evidence that the intervention has the potential to engage community adults with T2DM in becoming active and effective self-managers of their illness. Each collaborative site took the initiative to secure space, time, and participants for the intervention, highlighting *An Active Approach's* acceptability and feasibility amongst the sites. Quantitative data from primary and secondary outcome measures highlight *An Active Approach's* acceptability, feasibility, and effectiveness among participants.

Most notably, participants' mean HbA1c decreased over the course of the study – and this result is not only statistically significant, but also clinically meaningful. Nineteen participants, or over 85% of the total sample, were able to maintain or reduce their HbA1c, meaning that they were able to either improve or at the very least not worsen their diabetes. More importantly, eight participants, or over one-third of the total sample, were able to reduce their HbA1c to 7% or below, indicating excellent glycemic control (ADA, 2015). In addition to demonstrating improved glycemic control, results also indicate that participants witnessed improvements in their diabetes knowledge and selfefficacy after participating in *An Active Approach*. For half of participants, *An Active Approach* was their first foray into attending a structured DSME program, and therefore, they had ample room to increase their understanding of the diagnosis, progression, and management of T2DM. For the other half, *An Active Approach* was an opportunity to regain or solidify knowledge that may have initially been gained in a previous DSME group, one-on-one counseling, or nutritionist visit. Both groups of participants, in oral and written feedback provided to the research team at EOT and FU, reported new learning and greater confidence in managing their condition.

Surprisingly, participants' mean PHQ-9 scores did not indicate clinically significant depressive symptomatology at any point in the study. The highest PHQ-9 scores at BL, EOT, and FU were 9, 4, and 7, respectively, indicating no more than minimally depressive symptomatology among this sample of participants. The comorbidity of depression and diabetes has been well documented, with epidemiological studies showing that the two conditions occur together twice as often as would be predicted by chance alone (Holt, de Groot, & Golden, 2014). The exact nature of their relationship is still a matter of debate, as previous research has suggested that depression may be both a risk factor for and consequence of diabetes (Renn, Feliciano, & Segal, 2011). In either case, elevated depressive symptomatology appears to worsen diabetes self-management (Bogner, Morales, de Vries, & Cappola, 2012), such that reducing depression is often the first step toward increasing patient adherence and compliance in T2DM self-management interventions (e.g., Bogner et al., 2012; Safren et al., 2014).

In the current study, it may have been that participants' connection with their respective collaborative sites served as a protective factor against depression. Three of the study's four collaborative sites worked diligently to offer a plethora of enjoyable, pleasurable, and health-stimulating activities and resources within socially supportive

environments. The majority of participants took advantage of these opportunities, reporting that they regularly attended their sites' fitness classes, game nights, and holiday celebrations, and made appointments with their sites' health coaches and social workers when necessary. Several participants also reported volunteering at their sites in an effort to keep themselves mentally stimulated, physically active, and socially connected. Participants' engagement in such activities may have kept depression at bay and also manifested in their relatively moderate to high quality of life ratings throughout the study. Participants' Physical, Mental, Social, and General Health scores as assessed by the DUKE were comparable to normative data gathered from thousands of medically insured Americans (Corcoran & Fisher, 2013).

Furthermore, participants' burgeoning connections with each other may have had additional positive impacts on their mood, which may in turn have had positive effects on their self-management. Previous research has shown that improved mood and social support improve treatment outcomes for a number of chronic illnesses and mental health conditions (e.g., DiMatteo, 2004; Grave, Hellzen, Romild, & Stordal, 2012; Markowitz, Gonzalez, Wilkinson, & Safren, 2011). In the current study, participants appeared to develop close relationships with one another. They carpooled to sessions, became Facebook friends, exchanged contact information, and called and e-mailed one another between sessions with advice and questions. They became their own support group – and the cheerleading and coaching they provided each other may have further helped to improve their self-management and mood.

Finally, both qualitative and quantitative data demonstrate *An Active Approach's* acceptability among participants and feasibility for implementation in community

settings. Participants joined the group and remained in the group. They responded to the CSQ in a way that indicated high satisfaction with the intervention, and they provided oral and written feedback detailing their appreciation of the education, information, and support provided by group facilitators. They wrote that facilitators were "at their best at all times," "made learning and sharing better," and approached sessions in an "easy, non-judgmental" manner that was "positive and encouraging." Moreover, participants appreciated *An Active Approach* 's availability in community settings so much that they pushed for some continuity of the program. For example, participants from the Evergreen Senior Center asked Evergreen's Director to continue holding monthly diabetes support groups so participants and other community members could meet regularly to share progress and problem solve self-management issues. In addition, participants from Parker at Stonegate asked their Director of Health and Wellness to consider offering additional and expanded diabetes workshops.

Limitations

The previously outlined successes of the design, dissemination, and implementation of *An Active Approach to Diabetes* notwithstanding, several limitations of the current study should be acknowledged. First, the sample size was relatively small and participants were predominantly Caucasian, female, and of older age, potentially limiting the study's generalizability. Second, participants' BL HbA1c levels and DUKE and PHQ-9 scores indicate a less severe sample, also limiting the study's generalizability. Third, follow-up assessments were conducted just 2.5 months after the final group session, obscuring any conclusions about *An Active Approach's* long-term effect on selfmanagement. And fourth, the study's reliance on self-reported changes in behaviors, as opposed to objective observations of such changes, may lead to questions about whether and how participants truly became effective self-managers.

Conclusions and Future Directions

Despite the limitations noted above, the study nevertheless had its strengths. These include the richness of data obtained from careful tracking of *An Active Approach's* development, efforts to build collaborative relationships, recruitment strategies, participant outcomes, and participant feedback. Furthermore, the study provides an important blueprint for DSME program development, implementation, and evaluation in community settings, thus helping to bridge the research-practice gap in diabetes education. It contributes to the field's growing knowledge of how best to work with community partners to design thoughtful and practical group-based DSME curricula that meet the competing demands of intervention consumers, developers, and hosts.

Building on the findings from the current study, future work should aim to continue *An Active Approach's* dissemination and implementation in nearby community settings to gather additional data on its acceptability, feasibility, and effectiveness. Importantly, this work should examine whether *An Active Approach* evolves into a sustainable program within the current study's four collaborative sites, as this may be the truest test of the intervention's practicality and worth in the real world. In addition, this work should take into account the limitations previously outlined by: 1) establishing additional collaborative relationships to recruit a more diverse sample; 2) making concerted efforts to recruit more severely diabetic patients who are arguably in most need of DSME; 3) including objective measures of self-management behavior change, using methods such as standardized dietary and physical activity assessment instruments available from the National Collaborative on Childhood Obesity Research Measures Registry (2010); and 4) planning for additional follow-up assessments to examine the intervention's long-term effectiveness. Such work has broad and important implications for the true reach of this novel self-management intervention.

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APPENDIX A:

TABLES AND FIGURES

Table 1

Organization Type	Site Name	Personnel Contacted	Collaboration Formed?
University Affiliates	New Jersey Agricultural Experiment Station	Community Health Sciences Educator	No
	New Jersey Institute for Food, Nutrition, and Health	Director	No
	RU Healthy	Lead Nutritionist	No
	Rutgers University Occupational Health Department	Administrative Manager	Yes
	Evergreen Senior Center	Division Director	Yes
	Maple Tree Manor	Housing Director	Yes
Community Centers and Organizations	Parker at Stonegate	Director of Research and Education	Yes
	YMCA of Metuchen, Edison, Woodbridge, and South Amboy	Community Connections Coordinator	No

Area institutions and key personnel contacted to form community-research collaborations.

Table 2

Age: <i>M (SD)</i>	67.45 (11.72)	
Gender: <i>n</i> (%)		
Female	19 (86.4)	
Male	3 (13.6)	
Ethnicity: <i>n</i> (%)		
Hispanic	1 (4.5)	
Non-Hispanic	21 (95.5)	
Race: <i>n</i> (%)		
Caucasian	18 (81.8)	
Not Caucasian ^a	4 (18.1)	
Marital Status: n (%)		
Single	1 (4.5)	
Married	10 (45.5)	
Separated or Divorced	4 (18.2)	
Widowed	7 (31.8)	
Highest Education: n (%)	, <i>,</i> , , , , , , , , , , , , , , , , ,	
Grade School Only	1 (4.5)	
High School or GED	11 (50.0)	
Associate's Degree or 2-Year College	4 (18.2)	
Bachelor's Degree or 4-Year College	3 (13.6)	
Master's Degree	2 (9.1)	
Doctoral Degree	1 (4.5)	
Current Work: n (%)		
Part-Time	1 (4.5)	
Full-Time	7 (31.8)	
Homemaker	2 (9.1)	
Retired	11 (50.0)	
Household Income: n (%)		
<\$10,000	4 (18.2)	
\$10,000-\$19,999	3 (13.6)	
\$20,000-\$29,999	1 (4.5)	
\$30,000-\$39,999	0 (0)	
\$40,000-\$49,999	1 (4.5)	
\$50,000-\$59,999	2 (9.1)	
\$60,000-\$69,999	4 (18.2)	
\$70,000-\$79,999	2 (9.1)	
\$80,000-\$89,999	1 (4.5)	
\$90,000-\$99,999	2 (9.1)	
>\$100,000	2 (9.1)	

Participant baseline demographics (N = 22)

Table 2 (continued)

Participant baseline demographics (N = 22)

HbA1c: <i>M</i> (<i>SD</i>)	7.41 (0.40)				
Duration of Illness: M (SD)	9.65 (8.15)				
Previous Diabetes Education: n (%)					
Yes	10 (45.5)				
No	12 (54.5)				
Current Diabetes Medication: n (%)					
Yes	18 (81.8)				
No	4 (18.2)				

^a The non-White racial categories (Black, Asian, Native Hawaiian or Pacific Islander, American Indian or Alaska Native, and Other) used by the U.S. Census were collapsed into the single category "Not Caucasian".

Table 3

	Baseline (BL) M ± SD (Range)	End of Treatment (EOT) M ± SD (Range)	2.5 Month Follow-Up (FU) M ± SD (Range)	Statistical Significance of <i>t</i> -test or Overall Repeated Measures Comparison
HbA1c	7.41 ± 0.40 (7.0 - 8.4)	-	7.16 ± 0.41 (6.4 - 8.4)	<i>p</i> < 0.001
Diabetes Knowledge Test	10.32 ± 2.28 (6 - 14)	12.55 ± 1.14 (10 - 14)	12.95 ± 1.05 (11 - 14)	<i>p</i> < 0.001
Diabetes Self-Efficacy	6.99 ± 1.72 (2.00 - 8.75)	8.60 ± 1.07 (5.5 - 10.0)	8.66 ± 0.92 (6.5 - 9.8)	<i>p</i> < 0.001
DUKE				
Physical	60.00 ± 18.77 (10 - 90)	59.55 ± 23.60 (0 - 90)	61.36 ± 21.89 (20 - 100)	<i>p</i> = 0.516
Mental	77.73 ± 16.88 (50 - 100)	82.27 ± 14.45 (50 - 100)	83.18 ± 14.60 (50 - 100)	<i>p</i> = 0.194
Social	78.18 ± 16.51 (60 - 100)	77.27 ± 19.07 (40 - 100)	81.82 ± 16.51 (50 - 100)	<i>p</i> = 0.159
General	71.97 ± 12.20 (50 - 90)	73.06 ± 13.56 (40 - 96.67)	75.48 ± 11.52 (53.33 - 100)	<i>p</i> = 0.086
Perceived	61.36 ± 30.60 (0 - 100)	56.82 ± 23.38 (0 - 100)	68.18 ± 24.62 (50 - 100)	<i>p</i> = 0.165
PHQ-9	2.95 ± 2.79 (0 - 9)	1.45 ± 1.54 (0-4)	2.18 ± 2.00 (0 - 7)	<i>p</i> < 0.01
Client Satisfaction	-	31.64 ± 0.79 (30 - 32)	-	_

Participants' mean BL, EOT, and FU scores for all primary and secondary outcome measures (N = 22).

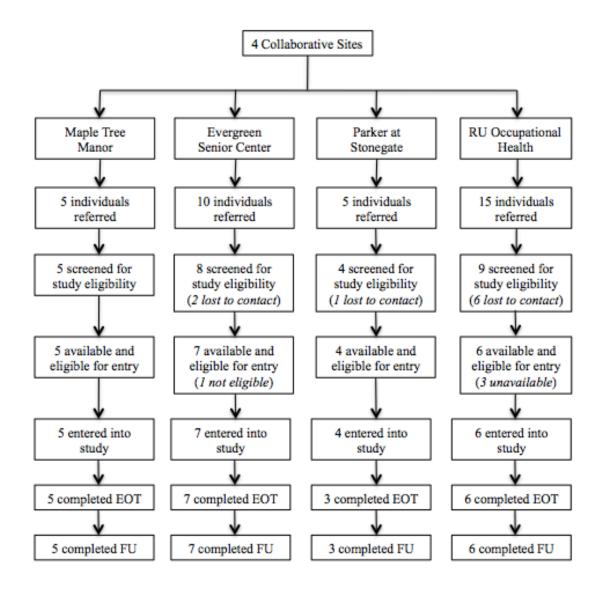


Figure 1. Participant flow into the study.

APPENDIX B:

PARTICIPANT HANDBOOK

AN ACTIVE APPROACH TO DIABTES SELF-MANAGEMENT

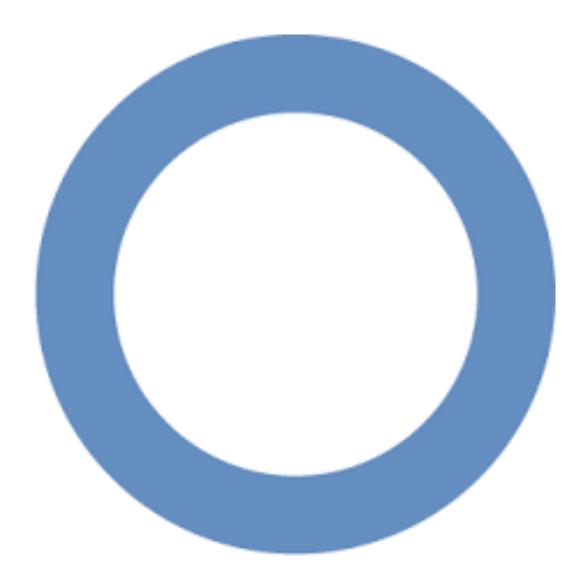


TABLE OF CONTENTS

- **1. Session 1: Program Overview**
- 2. Session 2: Nutrition
- **3. Session 3: Physical Activity**
- 4. Session 4: Special Topics and Wrap-Up
- 5. Appendix

SESSION 1: PROGRAM OVERVIEW



Agenda

- 1. Group Introductions
- 2. Overview and Group Guidelines
- 3. Individual Goals
- 4. Workshop Themes
- 5. Risks and Benefits of Diabetes Self-Management
- 6. Diabetes 101
- 7. Learning from Your Body: Self-Monitoring
- 8. Assignments

Overview

Welcome to "An Active Approach to Diabetes Self-Management"! This four-session workshop is designed to assist you in becoming an expert diabetes self-manager. Over the next four weeks, you, your group members, and your facilitators will work together to provide you with the confidence, knowledge, and skill to take control of your diabetes, overall health, and quality of life.

Each of the four sessions in this workshop is devoted to a specific topic:

- 1. Session 1 Diabetes 101
- 2. Session 2 Nutrition
- 3. Session 3 Physical Activity
- 4. Session 4 Special Topics and Wrap-Up

Throughout the workshop, we encourage you to actively participate by asking questions, expressing any concerns, and sharing your success. Remember that even though we are here to teach you about self-management, you are the expert in your own diabetes experience. Therefore, we hope to learn as much from you as you learn from us!

Group Guidelines

To make the most out of this workshop, we ask that you commit to the following:

- 1. Attend each and every session.
- 2. Complete all in- and out-of-session activities.
- 3. Keep all personal information discussed during the workshop confidential.

Workshop Goals

Before we begin, let's take a moment to come up with some concrete goals. Use the space provided here to list your goals.

My Workshop Goals:

Workshop Themes

Excellent! Now that you have outlined your goals for this workshop, let's see how these goals fit into the following four workshop themes.

To become an expert diabetes self-manager, we firmly believe in helping you understand what you can and cannot do about your diabetes. Therefore, we focus on helping you learn:

- 1. What you can and cannot control when managing your diabetes.
 - a. You can control behaviors like eating healthfully, engaging in physical activity, and taking your medication.
 - b. You cannot control automatic bodily functions like insulin secretion or digestion.
- 2. The various time lines associated with diabetes selfmanagement.
 - a. Short-term goals include managing your blood glucose level through healthy eating, exercise, and medications.
 - b. Intermediate goals include regularly visiting your doctor and tracking your HbA1c levels.
 - c. Long-term goals include avoiding diabetes-related complications like blindness, kidney disease, and death.
- 3. The various time lines associated with diabetes selfassessment.
 - a. Immediate feedback on the effects of food and activity on your blood sugar is provided through blood glucose monitoring.
 - b. Long-term feedback on your diabetes control is provided through your HbA1c readings.

- 4. How to have an experimental attitude towards selfmanagement.
 - a. Everyone's body is different, so it is important for you to try out different activities, foods, and techniques to figure out what is right for you.

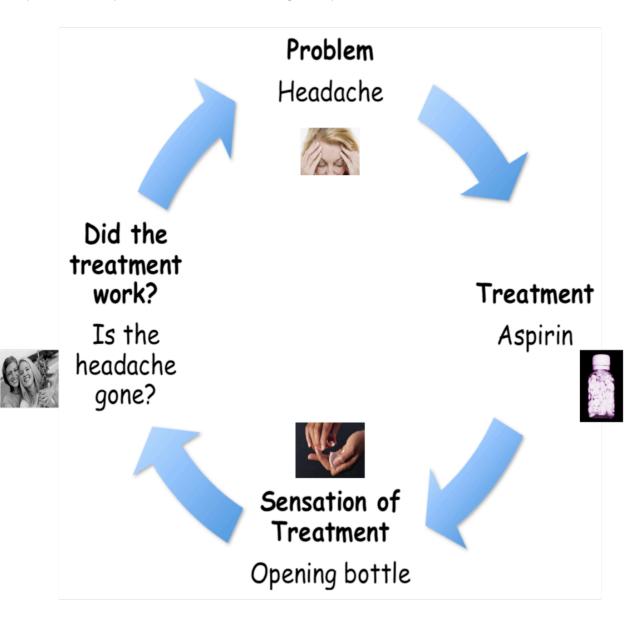
Risks and Benefits of Diabetes Self-Management

Now, are you ready to become an expert self-manager? Complete the table below to compare the risks and benefits of learning how to manage your diabetes.

	Risks of not managing diabetes	Benefits of managing diabetes
For your everyday health		
For your family and friends (both everyday activities and long-term health)		

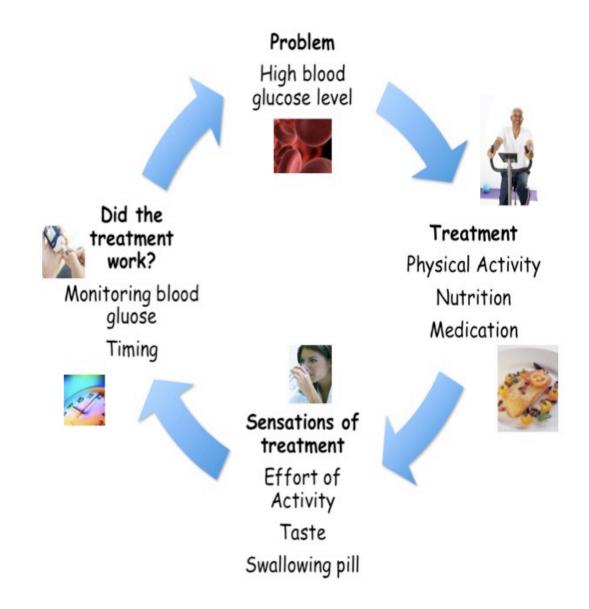
A Basic Self-Management Feedback Loop

To manage any health problem, it is important to know four basic things: (1) What the problem is; (2) How to treat the problem; (3) The sensations associated with treatment; and (4) Whether the treatment works. As you can see below, this process is relatively simple if the problem is something simple, like a headache.



Blood Glucose Feedback Loop

Blood glucose self-management is difficult because many parts of the loop are difficult to feel - for example, you cannot feel high blood glucose levels and you cannot tell whether a treatment works unless you know when to monitor the results. Our goal is to help you learn about this feedback system so that you can effectively manage your diabetes.

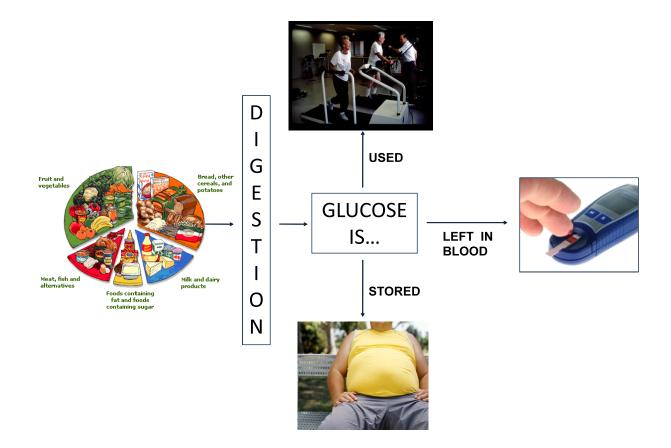


Diabetes 101: Back to the Basics of Diabetes

In the following section, we provide answers to some common questions about diabetes self-management.

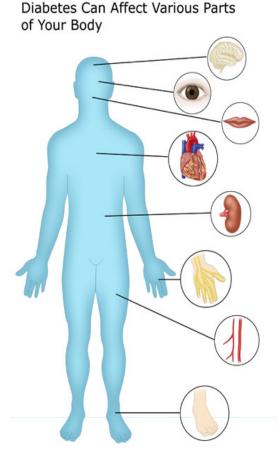
What is Diabetes?

As you can see in the chart below, after you eat, food is digested and converted into glucose (a kind of sugar). That glucose can then be used and/or stored by your cells or left in your blood. For glucose to be used or stored, your body must be sensitive to insulin, a hormone produced by your pancreas. Insulin's main job is to take glucose from your blood into your cells.



Initially, people who have type 2 diabetes suffer from insulin insensitivity. This means that despite normal or elevated insulin production, your cells do not recognize insulin and therefore do not allow it or the glucose it carries to enter your cells. To make matters worse, because the insulin is not being used, over time, your pancreas may stop producing insulin altogether. This is the point at which your doctor may prescribe insulin as a treatment for your diabetes.

There are two main effects of your body not recognizing insulin. First, your cells do not get enough energy because the insulin cannot bring glucose to the cells. Second, because insulin cannot bring glucose into the cells, there is a lot of glucose left over in your blood. As you can see in the chart below, this damages the blood vessels and nerves that run all over your body.



http://www.deo.ucsf.edu/images/charts/5.a.jpg

When you monitor your blood glucose levels with a glucometer, you are monitoring the glucose in your bloodstream. As a person with type 2 diabetes, your goal should be to keep those blood glucose levels as similar to those of a person who does not have diabetes as possible. You can accomplish this with physical activity, nutrition and/or medication.

What is Hemoglobin A1c?

Diabetes affects your blood glucose and something referred to as "HbA1c". Your blood glucose level is a measure of the amount of glucose in your bloodstream at the exact moment you monitor with your glucometer. The American Diabetes Association (ADA) recommends that people with type 2 diabetes try to keep your blood glucose between 80 and 120 mg/dL before meals or when waking up and between 100 and 140 mg/dL at bedtime.

Hemoglobin A1c (also known as HbA1c or just A1c, on the other hand, gives you a sense of your average glucose control over the last 2 to 3 months by telling you the percentage of red blood cells in your body that have glucose molecules attached. The more glucose in your blood, the higher that number will be. For people without diabetes, that number is usually between 4.5% and 5.5%. The American Diabetes Association (ADA) recommends that if you are under the age of 65 and have diabetes that your A1c level be below 7%. However, every person's body is unique. You and your physician should decide what a normal A1c level is for **you**.

The ADA also came up with a great analogy to help people understand A1c. They compare it to a batting average in baseball, "Both A1c and the batting average tell you about a person's overall success. Neither a single day's blood test results nor a single game's batting record gives the same big picture." At a minimum you and your doctor should be measuring and discussing your A1c batting average at least twice a year.

Summing up...

Information about the consequences of diabetes can be scary! So, try to remember that while complications of diabetes are serious, the fact that diabetes is a chronic condition means that you have time to learn to control your diabetes and avoid negative outcomes.

Learning from Your Body: Self-Monitoring

One way to control diabetes is by investigating the impact of various foods and physical activities on your blood sugar levels and modifying your eating habits and physical activity accordingly.

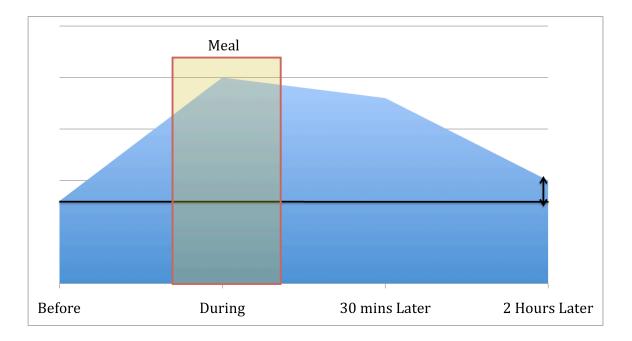
Here are some key points to keep in mind when evaluating your blood sugar levels:

- Blood glucose monitoring is NOT a way to monitor diabetes!
 a. That's what A1c levels are for.
- 2. Blood glucose monitoring **IS** a way to evaluate the effects of various foods and activities on your blood sugar.
- 3. If you monitor once a day, you are monitoring your activities and eating habits over the last day.
- 4. If you want to see the effects of specific foods or activities, you must focus on the <u>change</u> between pre-meal and post-meal readings or the <u>change</u> between pre-activity and post-activity readings.
- 5. Flexibility is key. By acting as your own personal scientist you can constantly learn new things about the effects of nutrition and physical activity on your body. So:
 - Think your lunch is healthy? --- Test it!
 - Think there is no point in walking around the block after dinner? --- Test it!

- Think that lunch made your blood glucose high? ---Test it!
- 6. Everyone's blood glucose readings will be different. While there are ranges of appropriate glucose readings for waking or after a meal, there is no one number we can give to guide you.
 - a. That is why you have to act like a scientist and test, test, test!
- 7. You can also monitor the meaning of symptoms you associate with diabetes.
 - a. While it may seem like all headaches indicate low blood sugar, that may not be true. The only way to find out if your symptoms are linked to your blood sugar is to test!

Timing

To get accurate information from your blood glucose meter, it is necessary to recognize the importance of timing when monitoring. This is why one of the workshop's goals is to help you learn the time lines associated with diabetes self-management. As you can see on the chart on the next page, as you eat a meal (or engage in activity) your blood sugar rises. Once you stop eating, your blood sugar level starts to fall, but you will get very different blood sugar readings depending on when you monitor your blood sugar levels because it takes time for your body to store and/or use glucose.



As this chart shows, it is important to monitor 1.5 to 2 hours after meals/activities because it is only then that your body has used and/or stored all the glucose that it can. This way you get a true reading of the amount of glucose left in your blood stream.

Using Blood Glucose Readings

Blood glucose readings aren't useful unless you use them! Knowing a specific reading only helps you manage your diabetes if you use that reading to structure your self-management behaviors. For example, if you notice that a certain food leads to large increases in blood sugar, consider swapping it out for a healthier option or increasing your physical activity.

Frustration

We understand that monitoring blood glucose can be frustrating because the readings don't always make sense. That is why part of becoming an expert diabetes self-manager is accepting the fact that blood sugar readings can be erratic, even when your diabetes is under control. It can help to remember that single readings mean nothing about your worth as a person. Also, instead of using day-to-day readings to assess your diabetes status, remember to focus on the A1c levels you get from your doctor.

Some closing thoughts on blood sugar monitoring

- 1. Monitoring is important because it allows <u>you</u> to evaluate how specific foods and activities affect <u>your</u> body.
 - a. You can then use that information to change your selfmanagement behaviors
- 2. Monitoring doesn't have to be done forever.
 - a. You should monitor now because you need to learn how foods and activities affect your blood sugar levels. However, over time, this knowledge will become automatic and won't require as much thought and testing.
 - i. Think about learning how to drive a car.
 - ii. When you first started, you had to pay close attention to tasks like putting the car into gear, signaling or deciding when to turn. It was a very conscious process.
 - iii. Over time, driving became an automatic process. Now, instead of thinking about how to turn the car on, when to switch gears or how to signal, you just drive!
 - iv. Self-management can follow a similar course, so don't get discouraged!

For Next Week

In next week's session, we will focus on diabetic-friendly nutrition. In preparation for our nutrition session, we want you to do the following:

• Monitor your blood glucose before and twice after a typical meal.

• Keep a daily diary of your meals and snacks.

Action plans may help you in carrying out these tasks. Fill in the action plan templates below:

Goal 1: To monitor blood glucose before, 30 minutes after, and 2 hours after a typical meal.

How to implement this plan:

When to implement this plan:

Where to implement this plan:

Goal 2: To keep a daily diary of meals and snacks.

How to implement this plan:

When to implement this plan:

Where to implement this plan:

Problem Solving

Sometimes, things get in the way of our ability to complete tasks. If that happens, it may be helpful to think of the following problem solving steps:

- Write down a clear description of one problem to work on. What is the problem about? When does the problem occur? Where? Who is involved? Try to break up complicated problems into several smaller ones and consider each one separately.
- 2. <u>Set a realistic goal.</u> What would you like to happen? Choose a clear and achievable goal.
- 3. <u>Brainstorm.</u> List as many solutions as you can think of. Don't rule anything out.
- 4. <u>Consider the advantages and disadvantages (pros and cons)</u> <u>for each potential solution.</u> What are the benefits of each solution? What are the difficulties and obstacles?
- 5. <u>Choose the solution that seems best.</u> Which solution seems the most feasible and has the least impact on your time, effort, money, other people's effort, etc.?
- 6. <u>Develop an action plan.</u> Write down exactly *what* you will do and *when* you will do it.
- 7. <u>Review and evaluate your progress.</u> Make needed changes and see if they work.

Buddy System

If you want, you can pick a partner, exchange phone numbers and call each other mid-week, for the next 4 weeks, to offer encouragement. Just a quick and simple phone call. It may go something like this: "Hi, Jessica, this is X, how are you making out with recording your sugars? Excellent! I'm doing _____. See you next week. Good-bye!" The buddy system is not required, but past workshop members have found it helpful. Your buddy's name: _____ Your buddy's phone number: _____

In Closing...

We covered a lot in session one, but please keep in mind that the aim throughout all sessions is to assist you in becoming your own expert in diabetes management. Of course, we must be mindful that expertise does not come quickly, it takes time, but with the right skills and patience it is definitely possible!

SESSION 2: NUTRITION



AGENDA

- 1. Review of Session 1
- 2. Review of Daily Diaries and Self-Monitoring
- 3. Diabetes and Nutrition
- 4. Group Activity Carbohydrate Counting and Portion Control
- 5. New Assignments

Diabetic-Friendly Eating

Many people with diabetes believe that they absolutely cannot have carbohydrates, starches, and sugars - and therefore cannot have some of their favorite foods. **That is not true!** There is no "perfect" way to eat, but there are ways to eat more healthfully. In particular, eating regularly, limiting your portion sizes while eating a variety of foods, and counting carbohydrates will help you keep your blood glucose in its target range and help lower your risk for diabetes-related complications like heart disease and stroke.

Regular Eating

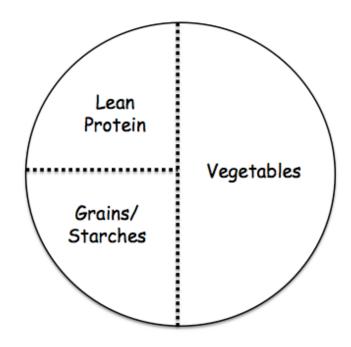
If you have diabetes, it is important to eat on a regular schedule, even if you are not hungry. Doing so will help stabilize your blood glucose level and ensure that you get as many of the nutrients you need to maintain your health.

In general, eating on a regular schedule means eating every 4-5 hours. For the typical adult, this means having **three meals and two to three snacks** each day. A typical eating schedule might look like this:

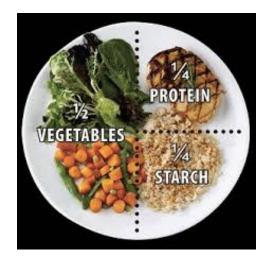
- 7:00 AM Breakfast
- 10:00 AM Snack
- 12:30 PM Lunch
- 4:00 PM Snack
- 7:00 PM Dinner
- 9:00 PM Snack

Portion Control and Food Variety Portion Control

A simple way to control your portion sizes while making sure you eat a variety of foods is to follow the "Plate Method". To follow the Plate Method, the first thing you need is a 9-inch plate. As you prepare your meal, think of dividing the plate into three sections that look like this:



Then, place your food in the appropriate spot to ensure that you are eating a healthy, balanced meal. Half of the plate should be devoted for vegetables, $\frac{1}{4}$ of the plate for lean protein, and another $\frac{1}{4}$ for grains and starches. The only exception is breakfast, when you will leave the vegetable portion of your plate empty. Here is an example of a balanced meal using the Plate Method.



Food Variety

The Plate Method will help you make sure to have a variety of foods throughout the day. Here are a few additional tips on specific nutrients that will increase your chances of having a healthy, balanced meal.

<u>Carbohydrates</u>

Simple carbohydrates (carbs) instantaneously dump glucose into your blood stream. When choosing carbs, try to choose complex carbs instead. Complex carbs are better than simple carbs because they gradually release glucose and will therefore help you maintain your energy and blood sugar. Complex carbs are found in fiber-rich foods such as vegetables, fruits, whole grains, and beans.

<u>Fats</u>

There are three major types of fats: trans fats, saturated fats, and unsaturated fats. Trans fats result from hydrogenation (like margarine). Saturated fats are the fats used in fried foods. Polyunsaturated fats are in peanut and vegetable oil. Monounsaturated fats are best -- they have good cholesterol and can be found in products like olive oil.

Counting Carbohydrates

Counting the carbohydrates in your meals and snacks is another great way to help keep your blood glucose in the right range. In general, you should aim to keep your carbohydrate intake within or below the following:

- 45-60 grams at each meal
- 15-20 grams at each snack

To understand what 15-20 grams of carbohydrates look like and how to read nutrition labels when counting carbohydrates, review the attached resource (Appendix II) from the American Diabetes Association ("All About Carbohydrate Counting").

Group Activity

Let's practice counting carbohydrates in common foods. Doing so will help you make healthy choices when grocery shopping, preparing meals, and eating out.

For Next Week

To review today's session and to prepare for next week's session, which focuses on physical activity, we want you to do the following:

- Prepare one breakfast, one lunch, and one dinner according to the guidelines provided today. Take a photo of each!
- Keep a daily diary of your meals, snacks, and any physical activity.

Action plans may help you in carrying out these tasks. Fill in the action plan templates below:

Goal 1: Prepare one breakfast, one lunch, and one dinner according to the diabetic guidelines provided.

How to implement this plan:

When to implement this plan:

Where to implement this plan:

Goal 2: To keep a daily diary of meals, snacks, and physical activity.

How to implement this plan:

When to implement this plan:

Where to implement this plan:

SESSION 3: PHYSICAL ACTIVITY



AGENDA

- 1. Review of Session 2
- 2. Review of Meals and Daily Diaries
- 3. Diabetes and Physical Activity
- 4. Fitness Demonstration
- 5. New Assignments

Benefits of Physical Activity

Regular physical activity is really important for people with diabetes. It helps control blood glucose, weight, and blood pressure. It can raise "good" cholesterol and lower "bad" cholesterol. It keeps your joints flexible, strengthens your bones, and helps reduce stress. Physical activity also stimulates healthy heart and blood flow, reducing the risk of heart disease and nerve damage for people with diabetes.

There are several ways to include physical activity into your daily routine. You can increase your activity throughout the day by gardening, taking the stairs, or walk around while watching TV. Alternatively, you can block out time for activities like dancing, swimming, or riding a bicycle. See below for more suggestions. Whatever you do, it is important to work up to about 30 minutes of exercise, 5 days a week.

Suggestions for Exercise

There are all types of physical activity - and to incorporate regular physical activity into your daily routine, you need to choose those types that match your interests, physical capabilities, and environment. Below are some examples of physical activity.

- 1. Day-to-Day Activities
 - Taking the stairs instead of an elevator
 - Parking farther away from a building and walking
 - Raking leaves
 - Cleaning the bathroom
- 2. Flexibility Exercises
 - Gentle stretching
 - Yoga to increase flexibility and reduce tension
- 3. Strength Training
- 4. Aerobic Exercises

- Swimming pool exercises can be less stressful on the joints
- Dancing
- Walking/Running
- Biking

Healthy Activity Tips

Before engaging in any physical activity, keep these tips in mind:

- 1. Get your doctor's approval.
 - People with diabetes need their MDs to check multiple systems to ensure readiness for physical activity (e.g., blood pressure, HbA1c, circulation, kidneys, eyes and feet)
- 2. Individualize your exercise plan.
 - Everyone should have a different exercise plan because every person is different.
- 3. Get comfortable exercising.
 - Make sure your shoes fit well.
 - Make sure your socks stay clean and dry; cotton socks are best.
 - Check your feet for redness or sores after exercising.
 - Call your doctor if you have sores that do not heal.
- 4. Be aware of your blood glucose level before, during, and after physical activity.
 - Before physical activity, if blood glucose is below 100, have a small, healthy, carbohydrate snack.
 - If your blood glucose is above 250-300 before physical activity, do not exercise.
- 5. Set your own personal goals.
 - Keep goals realistic, each short-term goal can be a stepping stone to larger, longer-term goal.
 - For example, increasing from 10 minutes of sustained physical activity to 15 minutes.

 Adding an extra day to the weekly schedule of physical activity, such as making Monday the swimming pool day, Wednesday the yoga day, and Friday the mall walking day

Incorporating Physical Activity into Your Action Plans

This week we hope you will use the information you learned in session to increase your physical activity. Again, we encourage you to make an action plan to increase the probability that you follow through on your desire to increase activity. You can use the template below:

Goal: To increase physical activity.

How will you implement your plan:

When will you carry out your plan:

Where will you carry out your plan:

SESSION 4: WRAP-UP



AGENDA

- 1. Review of Session Three
- 2. Examining Progress
- 3. Planning for the Future
- 4. Some Facts to Remember Us By

Have You Achieved Your Goals?

Look back at the first page in this handbook, have you achieved any of your goals for the program? If so, list them below:

Also list how you achieved those goals:

What else would you like to achieve?

The next section will help you plan to achieve those goals in the future.

Planning for the Future

Diabetes is a chronic illness and therefore diabetes selfmanagement is an ongoing process. That's why it's important to think about how you want to use the skills you learned in this workshop in the future. As always, we think an action plan is a good way to decide how to maintain any changes you've made. We've provided a template below:

Goal:

How will you implement your plan:

When will you carry out your plan:

Where will you carry out your plan:

Getting Back on Track

Since self management is an ongoing process, there will inevitably be times when you forget to do physical activity or eat unhealthy foods. That's ok and to be expected! The key is to notice warning signs that you're getting off track so that you can get back on track. You can list those warning signs below: Once you have listed the warning signs, it's important to think about how you will deal with those difficult situations so that you get back on track with your self-management. You can list your plans for getting back on track below:

Some facts to remember us by...

- 1. Focus on the parts of the diabetes you can control in the short-term, like nutrition and physical activity, because these will affect your health in the long-term.
- 2. Monitor your blood glucose as a way to see the effects of short term behaviors.
 - a. But, remember to assess those measurements using the appropriate time lines!
 - i. For example, focusing on changes between readings to learn about specific behaviors
 - b. Also remember to use abnormal readings as a cue for action.
 - For example, increasing your activity level, changing your eating habits or calling your doctor
- 3. HbA1c, not blood glucose monitoring, is a way to assesses intermediate goals and see the effects of your self-management behaviors over 2-3 months.
- 4. Remember to keep working at your self-management goals until they become easy and automatic.
- 5. You now have the tools to become an expert diabetes manager!

APPENDIX I: More Information about Diabetes

Why is it important to be a healthy weight?

Maintaining a healthy weight is a good idea whether you have diabetes or not. Being overweight puts you at a greater risk for heart disease and high blood pressure (which is more likely to lead to strokes in people with diabetes). It also makes it harder for your body to use insulin.

Why is it important to check my feet every day?

Excess glucose in your bloodstream can damage the nerves and blood vessels in your feet. This damage can cause numbness which means you won't always know when you've injured your foot. Untreated foot injuries can lead to serious infections and ultimately result in amputation. The best way to protect against these outcomes is to check your feet everyday. You can use a mirror if you're not flexible enough to see the bottom of your feet on your own. The ADA recommends checking for the following signs, comparing one foot to the other:

- 1. A change in the size or shape of the foot
- 2. A change in skin color (becoming red or blue)
- 3. A change in skin temperature (warmer or cooler)
- 4. An open area of skin (blister or sore) with or without drainage
- 5. An ingrown toenail
- 6. Structural deformities of the foot (hammer toes or bunions)
- 7. Corns or calluses
- 8. Pain, burning, tingling, or numbness in your feet

It is also important to wear comfortable shoes and athletic socks. Finally, make sure to tell your doctor if you notice any changes. What are diabetes medications, and how do they work? You can also control your diabetes through oral medication (pills). Below are descriptions of the main classes of oral medication for type 2 diabetes. Some of these drugs, like thiazolidinediones, are controversial so you should always talk to your doctor if you have questions about your medication. Generic names are followed by brand names in parentheses. These descriptions were taken from the American Diabetes Association (ADA) website (www.diabetes.org) as well as the National Institute of Diabetes and Digestive and Kidney Diseases (diabetes.niddk.nih.gov).

Sulfonylureas. These pills cause beta cells in the pancreas to make more insulin. This class includes the following drugs and are usually taken twice a day before meals: chlorpropamide (Diabinese), glimepiride (Amaryl), glipizide (Glucotrol, Glucotrol XL), and glyburide (DiaBeta, Glynase, Micronase).

Meglitinides. These pills also cause beta cells to release insulin. This class includes the following drugs that are usually taken before each of three meals: repaglinide (Prandin), nateglinide (Starlix). They are taken before each of three meals.

Because sulfonylureas and meglitinides stimulate the release of insulin, they can cause hypoglycemia (low blood glucose).

Biguanides. These pills decrease the amount of glucose produced by the liver. They also make muscle tissue more sensitive to insulin so that more glucose can be absorbed. This class includes the following drugs: metformin (Glucophage, Glucophage XR, Glumetza, Fortamet, and Riomet).

Thiazolidinediones. These pills help insulin work better in the muscle and fat and also reduce glucose production in the liver. This class includes the following drugs: pioglitazone (Actos), rosiglitazone (Avandia).

DPP-4 Inhibitors. DPP-4 Inhibitors work by preventing the breakdown of a naturally occurring compound in the body, GLP-1. GLP-1 reduces blood glucose levels in the body, but is broken

down very quickly so it does not work well when injected as a drug itself. By interfering in the process that breaks down GLP-1, DPP-4 inhibitors allow it to remain active in the body longer, lowering blood glucose levels only when they are elevated. DPP-4 inhibitors do not tend to cause weight gain and tend to have a neutral or positive effect on cholesterol levels. This class is made up of: sitagliptin (Januvia).

Alpha-glucosidase inhibitors. Alpha-glucosidase inhibitors help your body lower blood glucose levels by blocking the breakdown of starches, such as bread, potatoes, and pasta, in the intestine. They also slow the breakdown of some sugars, such as table sugar. Their action slows the rise in blood glucose levels after a meal. This class includes the following drugs: acarbose (Precose), miglitol (Glyset). They should be taken with the first bite of a meal.

It is important to remember that pills don't work for everyone, especially if you have had type 2 diabetes for more than 10 years. It is also important to note that pills can sometimes stop working out of the blue. That is why, even when you're on medication, nutrition and physical activity are important parts of selfmanagement.

What are some useful websites about diabetes?

- <u>www.aade.org</u> is the website of the American Association of Diabetes Educators and provides helpful information for both patients and providers.
- <u>www.diabetes.org</u> is the website of the American Diabetes Association, which is a great resource for all your diabetes needs.

APPENDIX II: Additional Handouts

Daily Diary

Date: Time	Meal or Snack	Blood Glucose	Comments

Date:

Starchy Vegetables List

Common Non-Starchy Vegetables

- Amaranth or Chinese spinach
- Artichoke
- Artichoke hearts
- Asparagus
- Baby corn
- Bamboo shoots
- Beans (green, wax, Italian)
- Bean sprouts
- Beets
- Brussels sprouts
- Broccoli
- Cabbage (green, bok choy, Chinese)
- Carrots
- Cauliflower
- Celery
- Chayote
- Coleslaw (packaged, no dressing)
- Cucumber
- Daikon
- Eggplant
- Greens (collard, kale, mustard, turnip)
- Hearts of palm
- Jicama
- Kohlrabi
- Leeks
- Mushrooms
- Okra
- Onions
- Pea pods
- Peppers
- Radishes
- Rutabaga
- Salad greens
- Sprouts
- Squash (cushaw, summer, crookneck, spaghetti, zucchini)

- Sugar snap peas
- Swiss chard
- Tomato
- Turnips
- Water chestnuts
- Yard-long beans

Common Starchy Vegetables

- Parsnip
- Plantain
- Potato
- Pumpkin
- Acorn squash
- Butternut squash
- Green Peas
- Corn

Fiber-Rich Grains

- Bulgur (cracked wheat)
- Whole wheat flour
- Whole oats/oatmeal
- Whole grain corn/corn meal
- Popcorn
- Brown rice
- Whole rye
- Whole grain barley
- Whole faro
- Wild rice
- Buckwheat
- Buckwheat flour
- Triticale
- Millet
- Quinoa
- Sorghum

All About Carbohydrate Counting (ADA Toolkit No. 14 - Please download from www.diabetes.org)

> Carbohydrate Food List and Sample Meal Plans (Diabetes 101 - Please download from www.uofmhealth.org/diabetes101)

APPENDIX C:

MEASURES

Demographic Questionnaire

Basic Information

ID: _____

Interview Date:

Gender:

- □ Male
- □ Female

Date of Birth: _____

Marital Status:

- □ Married
- □ Separated/Divorced
- \square Widowed
- \Box Single

Ethnicity:

- □ Hispanic
- □ Non-Hispanic

Race (Check all that apply):

- □ White
- □ Black or African American
- □ Asian
- □ Native Hawaiian or Pacific Islander
- □ American Indian or Alaska Native
- □ Other _____

Highest education level:

- \Box No degree/grade school only
- □ High school diploma or GED
- □ Associate's Degree/2-year college
- □ Bachelor's Degree/4-year college
- □ Master's Degree
- □ Doctorate (MD, PhD)
- □ Other _____

Current work situation:

- □ Unemployed
- □ Currently working part-time
- □ Currently working full-time
- □ Homemaker
- \Box Retired
- \Box Disabled or on sick leave
- □ Other _____

Combined family income:

- □ \$150,000 or more
- □ \$100,000 to \$149,000
- □ \$90,000 to \$99,999
- □ \$80,000 to \$89,999
- □ \$70,000 to \$79,999
- □ \$60,000 to \$69,999
- □ \$50,000 to \$59,999
- □ \$40,000 to \$49,999
- □ \$30,000 to \$39,999
- □ \$20,000 to \$29,999 □ \$10,000 to \$19,999
- \Box Less than \$10,000

When were you first diagnosed with type 2 diabetes?

Have you previously received diabetes self-management education or support?

- □ Yes
- □ No

If "yes" to the above, please provide a brief description below:

Diabetes Knowledge Test

For each of the following questions, please circle the correct response.

- 1. The diabetes diet is:
 - a. the way most American people eat.
 - b. a healthy diet for most people.
 - c. too high in carbohydrates for most people.
 - d. too high in protein for most people.
- 2. Which of the following is highest in carbohydrates?
 - a. Baked chicken
 - b. Swiss cheese
 - c. Baked potato
 - d. Peanut butter
- 3. Which of the following is highest in fat?
 - a. Low fat milk
 - b. Orange juice
 - c. Corn
 - d. Honey
- 4. Which of the following is a "free food"?
 - a. Any unsweetened food
 - b. Any dietetic food
 - c. Any food that says "sugar free" on the label
 - d. Any food that has less than 20 calories per serving
- 5. Glycosylated hemoglobin (HbA1c or A1c) is a test that is a measure of your average blood glucose level for the past:
 - a. day
 - b. week
 - c. 6-10 weeks
 - d. 6 months
- 6. Which is the best method for test blood glucose?
 - a. Urine testing
 - b. Blood testing
 - c. Both are equally good
- 7. What effect does unsweetened fruit juice have on blood glucose?
 - a. Lowers it
 - b. Raises it
 - c. Has no effect

- 8. Which should NOT be used to treat low blood glucose?
 - a. 3 hard candies
 - b. ¹/₂ cup orange juice
 - c. 1 cup diet soft drink
 - d. 1 cup skim milk
- 9. For a person in good control, what effect does exercise have on blood glucose?
 - a. Lowers it
 - b. Raises it
 - c. Has no effect
- 10. Infection is likely to cause:
 - a. an increase in blood glucose
 - b. a decrease in blood glucose
 - c. no change in blood glucose
- 11. The best way to take care of your feet is to:
 - a. look at and wash them each day
 - b. massage them with alcohol each day
 - c. soak them for one hour each day
 - d. buy shoes a size larger than usual
- 12. Eating foods lower in fat decreases your risk for:
 - a. nerve disease
 - b. kidney disease
 - c. heart disease
 - d. eye disease

13. Numbness and tingling may be symptoms of:

- a. kidney disease
- b. nerve disease
- c. eye disease
- d. liver disease
- 14. Which of the following is usually NOT associated with diabetes:
 - a. vision problems
 - b. kidney problems
 - c. nerve problems
 - d. lung problems

We would like to know how confident you are in doing certain activities. For each of the following questions, please choose the number that corresponds to your confidence that you can do the tasks regularly at the present time. 1 = Not at all confident, 10 = Totally confident.

- 1. How confident do you feel that you can eat your meals every 4 to 5 hours every day, including breakfast every day?
 - 1 2 3 4 5 6 7 8 9 10
- 2. How confident do you feel that you can follow your diet when you have to prepare or share food with other people who do not have diabetes?
 - 1 2 3 4 5 6 7 8 9 10
- 3. How confident do you feel that you can choose the appropriate foods to eat when you are hungry (for example, snacks)?
 - 1 2 3 4 5 6 7 8 9 10
- 4. How confident do you feel that you can exercise 15 to 30 minutes, 4 to 5 times a week?
 - 1 2 3 4 5 6 7 8 9 10
- 5. How confident do you feel that you can do something to prevent your blood sugar level from dropping when you exercise?
 - 1 2 3 4 5 6 7 8 9 10
- 6. How confident do you feel that you know what to do when your blood sugar level goes higher or lower than it should be?
 - 1 2 3 4 5 6 7 8 9 10
- 7. How confident do you feel that you can judge when the changes in your illness mean you should visit the doctor?
 - 1 2 3 4 5 6 7 8 9 10
- 8. How confident do you feel that you can control your diabetes so that it does not interfere with the things you want to do?
 - 1 2 3 4 5 6 7 8 9 10

DUKE Health Profile

Here are some questions about your health and feelings. Please reach each question carefully and check ($\sqrt{}$) your best answer. You should answer the questions in your own way. There are no right or wrong answers.

	Yes, describes me exactly	Somewhat describes me	No, doesn't describe me at all
1. I like who I am.			
2. I am not an easy person to get along with.			
3. I am basically a healthy person.			
4. I give up too easily.			
5. I have difficulty concentrating.			
6. I am happy with my family relationships.			
7. I am comfortable being around people.			

TODAY, would you have any physical trouble or difficulty:

	None	Some	A lot
8. Walking up a flight of stairs?			
9. Running the length of a football field?			

<u>DURING THE PAST WEEK</u>, how much trouble have you had with:

	None	Some	A lot
10. Sleeping?			
11. Hurting or arching in any part of your body?			
12. Getting tired easily?			
13. Feeling depressed or sad?			
14. Nervousness?			

DURING THE PAST WEEK, how often did you:

	None	Some	A lot
15. Socialize with other people (talk or visit with			
friends or relatives)?			
16. Take part in social, religious, or recreation			
activities (meetings, church, movies, sports,			
parties)?			

DURING THE PAST WEEK, how often did you:

	None	1-4 Days	5-7 Days
17. Stay in your home, a nursing home, or hospital			
because of sickness, injury, or other health			
problem?			

Patient Health Questionnaire-9 Item Version

Over the last 2 weeks, how often have you been bothered by any of the following problems? Circle your answer.

	Not at all	Several days	More than half the days	Nearly every day
1. Little interest of pleasure in doing things	0	1	2	3
2. Feeling down, depressed, or hopeless	0	1	2	3
3. Trouble falling or staying asleep, or sleeping too much	0	1	2	3
4. Feeling tired or having little energy	0	1	2	3
5. Poor appetite or overeating	0	1	2	3
 Feeling bad about yourself – or that you are a failure or have let yourself or your family down 	0	1	2	3
7. Trouble concentrating on things, such as reading the newspaper or watching television	0	1	2	3
 Moving or speaking so slowly that other people could have noticed? Or the opposite – being so fidgety or restless that you have been moving around a lot more than usual 	0	1	2	3
9. Thoughts that you would be better off dead or of hurting yourself in some way	0	1	2	3
TOTAL SCORE				

If you checked off <u>any</u> problems, how <u>difficult</u> have these problems made it for you to do your work, take care of things at home, or get along with other people?

Not difficult at all	Somewhat difficult	Very difficult	Extremely difficult
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Client Satisfaction Questionnaire

Please help us improve our program by answering some questions about the services you received. We are interested in your honest opinion, whether they are positive or negative. Please answer all the questions. We also welcome your comments and suggestions. Thank you very much; we appreciate your help.

- 1. How would you rate the quality of the service you received?
 - _____ Excellent

____ Good

____ Fair

- _____Poor
- 2. Did you get the kind of service you wanted?
 - _____ Definitely not
 - _____ Not really
 - _____Yes, generally
 - _____ Yes, definitely
- 3. To what extent has our program met your needs?
 - _____ Almost all of my needs met
 - _____ Most of my needs met
 - _____ Only a few of my needs met
 - _____ All of my needs met
- 4. If a friend were in need of similar help, would you recommend our program to him or her?
 - _____ Definitely not
 - ____ Not really
 - _____Yes, generally
 - _____Yes, definitely
- 5. How satisfied are you with the amount of help you have received?
 - _____ Quite dissatisfied
 - _____ Mildly dissatisfied
 - _____ Mostly satisfied
 - _____ Very satisfied
- 6. Have the services you received helped you to deal more effectively with your problems?
 - _____ Helped a great deal
 - _____ Helped somewhat
 - _____ Did not really help
 - _____ No, they seemed to make things worse

- 7. In an overall, general sense, how satisfied are you with the service you have received?
 - _____ Very satisfied
 - _____ Mostly satisfied
 - _____ Mildly satisfied
 - _____ Quite dissatisfied

8. If you were to seek help again, would you come back to our program?

- _____ Definitely not
- _____ No, not really
- _____Yes, generally
- _____ Definitely
- 9. Additional comments or suggestions: