AN ACTIVE APPROACH TO DIABETES SELF-MANAGEMENT

By

JESSICA YELENA BRELAND

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ABSTRACT OF THE DISSERTATION

An Active Approach to Diabetes Self-Management

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Dissertation Director:
Howard Leventhal, PhD

Type 2 diabetes affects over 20 million people in the United States and has cost the healthcare system billions of dollars. As a result, countless research hours and funds are devoted to developing and testing programs to improve the self-management skills of patients with diabetes. Some interventions produce clinically meaningful changes, but few programs are based on theoretically sound protocols, which makes it difficult to assess theory-based group or individual level variables that might be responsible for changes in self-management. The current study piloted "An Active Approach to Diabetes Self-Management," a novel diabetes self-management intervention based on the integration of two theories (the Common Sense Model of Self-Regulation and Social Cognitive Theory) with techniques from cognitive behavior therapy. The intervention was developed within a Community Based Partnership Research framework. The 4-week intervention consisted of weekly, two-hour group sessions that presented information on and experiences with diabetes self-management, including the self-monitoring of blood glucose, physical activity and nutrition. Sixteen participants participated in three groups held in the fall of 2011 and February of 2012. The primary outcome was hemoglobin A1C (A1C), which was measured before and three months after the start of the intervention. Data were also collected on diabetes self-efficacy, self-management behaviors, diabetes knowledge, general mental and physical functioning and feasibility.

Results indicated that participants with baseline A1C levels above 6.5% had a significant reduction in A1C over the course of the study. Self-efficacy and understanding of diabetes increased over the course of the study. Diabetes-related negative affect decreased over the course of the study and there was a trend towards a decrease in BMI between baseline and the end of the study. Results also indicate that the workshop was feasible with regards to participant and community staff member satisfaction, study curriculum and the group process. As described within, future iterations must amend inclusion criteria and the curriculum, improve the usability of questionnaires and increase sample size in order to further test feasibility and to determine effect and sample sizes for a larger trial.

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Introduction

Type 2 diabetes affects over 20 million people in the United States and has cost the US healthcare system billions of dollars (Centers for Disease Control and Prevention, 2011). Patients with type 2 diabetes cannot efficiently use insulin, a hormone responsible for glucose transport. This insulin insensitivity results in excess glucose in the blood stream, which is associated with a host of debilitating and costly complications, such as blindness, neuropathy and myocardial infarction. Fortunately, when the automatic processes of insulin secretion and action fail a variety of volitional behaviors can reduce blood glucose levels as well as rates of related complications. As with most forms of chronic illness, patients with diabetes are responsible for the majority of management behaviors, which include taking oral or injection medications, monitoring blood glucose and glycated hemoglobin (A1C) levels, eating a healthful diet, exercising regularly, managing cholesterol and blood pressure levels and coping with stress. Also similar to other chronic illnesses, few patients with type 2 diabetes adhere to this myriad of treatments (Deakin, McShane, Cade, & Williams, 2005).

Given these low adherence rates, countless research hours and dollars are devoted to developing and testing interventions and educational programs to improve the self-management skills of patients with diabetes. Some of these interventions produce clinically meaningful changes (e.g., HbA1c reductions between 0.3% and 1.4%; Deakin et al., 2005; Jarvis, Skinner, Carey, & Davies, 2010; Minet, Møller, Vach, Wagner, & Henriksen, 2010), but many also have a variety of limitations. In addition to the usual suspects (e.g., poor methodology, lack of minority participants), there is conflicting evidence as to whether changes in A1C are maintained over time because many studies have inadequate follow-up periods (Deakin et al., 2005). Additionally, few authors provide detailed descriptions of the techniques used to implement interventions (e.g., Lorig, Ritter, Villa, & Armas, 2009) and the reviews cited above do not provide specific details on definitions of intervention categories (e.g., defining the difference between education and intervention programs). Therefore, it is unclear whether interventions' results should be attributed to the dynamic presentation skills of specific group leaders, the interpersonal atmosphere of the group or specific techniques for behavioral change. This uncertainty is amplified by the absence of detailed theoretical models underlying the design and implementation of interventions. As a result, few studies make hypotheses about or assess theory-based group or individual level variables that might be responsible for changes in A1C, findings that might improve the content and function of existing theories of health beliefs and behaviors. Furthermore, many programs are simply too lengthy and expensive to implement outside of research settings (e.g., Farmer et al., 2007).

The intervention piloted in this study was developed to address some of these limitations. It is a brief, theoretically-based, behaviorally focused educational program designed to improve the A1C levels, self-management behaviors and health outcomes of non-insulin treated patients with type 2 diabetes. The next section describes the theories and techniques used to develop and assess the current intervention (i.e., the Common Sense Model of Self-Regulation, Social Cognitive Theory and cognitive behavior therapy). This is followed by an overview of how these theories and techniques were incorporated into the first iteration of the current intervention. Next, I discuss how the development of both interventions used a Community Based Partnership Research framework. An overview of the current intervention's curriculum as well as differences between the first and second iterations of the intervention are described in the methods section.

Theoretical Basis of the Intervention

The Common Sense Model of Self-Regulation (CSM; Leventhal et al., 2011), a model of self management in daily life, proposes that responses to control health threats are generated by a hierarchical array of control modules, some automatic, others conscious and deliberate (the latter are critical for managing changes in automatic, behavioral sequences). These modules generate the perceptions, affective responses and interpretations (automatic and volitional) that guide behavior. Deviations in somatic sensations or physical and cognitive functions from the underlying prototype of the "usual/normal self" are critical triggers for self-management. Monitoring and detecting deviations is ongoing and automatic, (e.g., unconsciously touching a sore spot), and can transition to deliberate or volitional action when deviations enter awareness; for example, actively exploring a sore spot on the skin and considering antecedent events that might have caused it. The threshold for this transition will depend upon the extent and impact of the deviation, its match to and activation of a threatening interpretation (e.g., a cancerous sore) and the presence of competing events.

Monitoring and detecting deviations is based on integrating information across five domains: *Identity*, e.g., the condition's diagnosis/label and associated symptoms; perceived *causes*, e.g., whether food, lifestyle or a virus led to symptoms; *consequences*, e.g., whether the symptoms are life threatening; *control/cure*, e.g., whether the illness can be treated; and *timelines*, e.g., whether the illness or symptoms are perceived and expected to be acute or chronic and slow or rapid in onset and cessation.

The automatic or deliberate match of deviations to one or more illness prototypes (e.g., bug bite or cancer) elicits a sequence of subjectively appropriate coping responses to remove the deviation. Both the automatic and deliberate processes are feedback systems, the automatic typically less open to outer stimuli than the deliberative. Each activated feedback system or control unit has three specific components: 1) targets or goals (i.e., set points) that are generated by the representation of the threat; 2) procedures or action sequences for removing the deviation; and 3) the appraisal of outcomes. A fourth component, the sensations or feedback of the performance itself, that is, the brain's awareness of the coping procedure (its direction, extent and intensity of effort) has recently been added (H. Leventhal, personal communication, July 11, 2011). A control system for self-management will become increasingly automatic and efficient in operation if it is "plugged" into an optimal slot in an individual's daily behavioral sequence, which requires the formation of an action plan specifying the location, time of onset and time for completion of the behavior. An action plan, an individual's mental model of the physical and social context, is moderated further by cultural beliefs, information from friends, family or physicians, and emotional states.

For patients with type 2 diabetes, many of the lower level, glucose processing feedback loops are silent. There are symptoms associated with severe hypo- or hyperglycemia, but most fluctuations in blood glucose levels are asymptomatic. As a result, patients must rely on external methods of measurement that must be used and interpreted properly in order to result in effective glucose management (e.g., if one measures the effects of exercise after 20 minutes the results are useless as it takes at least 1.5 hours to detect the effects of physical activity on blood sugar levels). The asymptomatic nature of diabetes and its treatment means that patients are not getting concrete, experience-based, "common sense" feedback about the effects of their self-management behaviors. Therefore, their representations of diabetes and its treatment may differ from information received from healthcare providers. The disconnect between prescriptions and practice can lead to confusion, frustration and ultimately the discontinuation of potentially important self-management behaviors (Peel, Douglas, & Lawton, 2007).

The current intervention addresses this confusion by using the dynamic nature of feedback systems to provide participants with concrete experiences designed to enhance diabetes self-management. In order to do this, the intervention uses empirically supported behavior change techniques that are embedded in both cognitive behavior therapy (CBT) and the conceptual framework of the CSM, including self-monitoring (e.g., Korotitsch & Nelson-Gray, 1999; Wilson & Vitousek, 1999) and behavioral assessment (e.g., Fennell, 2004; Goldfried, 1976).

The overarching goal of the treatment is to use these techniques to build and validate “diabetes self-efficacy.” Self-efficacy is a Social Cognitive Theory (SCT) concept describing an individual’s belief that he or she can effectively use a specific set of skills in a specific situation (Bandura, 1997). Both Social Cognitive Theory and the CSM conceptualize self-efficacy as a factor critical for the initiation and, more importantly, the maintenance of affective, cognitive and motivational processes for self-management. Both approaches assume that self-efficacy is built on “mastery experiences” that can be enactive, vicarious, affective/physiological or achieved through verbal persuasion (Bandura, 1997). However, because individuals base assessments of self-efficacy on their own common-sense models, the CSM suggests that self-efficacy can also be created and maintained by ineffective self-management behaviors. For example, patients who believe they only have asthma when they have symptoms are less adherent to daily maintenance inhalers because a chronic treatment does not make sense for what they consider an acute disease (Halm, Mora, & Leventhal, 2006).

The current intervention attempts to preempt similar situations in relation to diabetes self-management by providing participants with biologically valid enactive mastery experiences. The CSM and SCT suggest that these experiences are the most profound in building self-efficacy and provide a detailed set of mechanisms for their construction. The role of self-enacted experience in creating a biologically valid behavioral structure de novo is seen in a past participant’s description of what he considered the most important feature of a prior iteration of the intervention:

> "[The most important thing I learned was the] relationship between different things. And some of the things, you hear about or people tell you about it, but until you can see it concretely, you know, because I mean, I was under the impression, like I said before, that exercise would [lower blood sugar] right away and it didn't. It actually went the opposite way. And until you see that happen, you know, 5 or 6 times when you do it, because the first two times I did, I didn't believe it."

Clearly, this participant's experiences outside of the group were an important and perhaps necessary corollary to the information he acquired in the group. Multiple performances of exercise and self-assessment showed him that his "self-efficacy" included not only the ability to exercise and take blood glucose readings, but to exercise in order to control his readings (i.e., to engage in deliberative action to regulate a lower level, automatic feedback system). The current intervention uses the long-term risks of poor diabetes control and the benefits of good diabetes control as the context in which the CSM and SCT are integrated to provide participants with concrete, in session experiences with blood glucose control. Ultimately, the aim is to use these concrete experiences with deliberative actions to enhance self-efficacy in order to help participants link long- and short-term goals and create environments where self-management behaviors are performed effortlessly and automatically.

Intervention Development

The participant quoted above took part in the first iteration of the current intervention that was held in Edison, New Jersey during 2009. The original workshop was a CSM-based group treatment that promoted the self-monitoring of blood glucose (SMBG) and consisted of four sessions ranging from 2 to 2.5 hours in length. The workshop was led by a graduate student and a community social worker (Kimberly Convery) and was augmented by the presence of a physician, a registered dietician (RD) and a community health worker. Each group had up to 12 participants. Session topics and goals were as follows.

Session 1. The goal of the first session was to introduce participants to basic information about diabetes, evaluating blood sugar levels with SMBG and to introduce participants to the use of action plans for goal attainment. Actions plans were presented through the lens of the CSM (similar to their use in Leventhal, Singer, & Jones, 1965) as a way for participants to plug self-management behaviors into their existing patterns of daily life. Participants then used the action plan framework to complete the first homework assignment – monitoring blood glucose levels at least twice a day and interpreting any changes in relation to their daily foods and activities. Helping participants implement action plans included describing the importance of creating mental models of daily habits and determining start points for new behaviors. Participants were asked to visualize various stages of the process to help them delineate these start points (e.g., the location of monitors, when they would monitor, how they would record results). At the end of the session, participants chose a "buddy" to contact throughout the workshop from whom they could receive support and for whom they could provide support. Participants were provided with a handbook that presented the topics covered during the workshop.

Session 2. As with all subsequent sessions, the second session began with a review of the previous session, a review of whether participants had completed their action plans and what participants may have learned from monitoring. These discussions were intended to help participants learn how to interpret monitoring records and to help participants learn about connections between their behaviors and blood glucose levels. The end goal was to enhance their common sense models of diabetes with concrete experiences that would promote the importance and effectiveness of self-management behaviors. An additional goal was to improve participants' ability to recognize patterns in their daily lives and to use this information to create modified action plans that would seamlessly fit new behaviors into their daily schedules.

The remainder of the session was devoted to the goal of educating participants about the basics of diabetes nutrition. This was achieved through a lecture and a question and answer session led by the RD. Lecture topics were based on participants' questions and the RD's discretion. Topics usually included the importance of timing when monitoring, understanding the carbohydrate chart, caloric intake and medication. Discussions were intended to eliminate misperceptions about common foods and to demonstrate that perceptions can be misleading (e.g., low sugary taste does not always equal a low glycemic index). At the end of the session participants were led through the action plan visualization described above, but were asked to visualize and create an action plan to monitor before and two hours after an average meal and a low-carbohydrate meal. Action plans related to this assignment were complex as they involved a large set of behaviors to visualize and implement (e.g., where to shop, what to cook, when to cook, when to eat).

Session 3. After the review of the previous session and action plans, the goal of Session 3 was to educate participants about the basics of diabetes and physical activity. This was achieved through a lecture, a question and answer session and a demonstration (e.g., how to march in place and use cans for weights) led by a community health educator. Topics included the importance of individualizing exercise plans, counting all types of exercise (e.g., parking farther away from store entrances), the benefits of exercise, exercise safety, setting personal goals, and when to monitor glucose levels when incorporating exercise. These topics were chosen as they represented ways to help participants incorporate physical activity into their existing life patterns (i.e., tailoring action plans to plug behaviors into optimal slots). At the end of the session participants were asked to monitor their blood glucose levels in relation to a meal with and without physical activity and were led through an action plan visualization related to the assignment (e.g., when and where to exercise, when and where to monitor).

Session 4. After a review of the previous session and action plans and the completion of study questionnaires, the goal of Session 4 was to "put it all together." The session was participant led and facilitated by open-ended questions (e.g., how did you fit physical activity into your schedule, what do you plan to incorporate in the future?). There was no theoretical basis for the fourth session and in many ways it served as a focus group. The session ended with a review of the following workshop themes: 1) SMBG is a way to monitor the short-term effects of behaviors; 2) A1C is a long range measure of diabetes; 3) it is important to focus on relative change between SMBG readings; 4) action plans can be used for goal attainment; and 5) SMBG should serve as a cue for action.

Community-Based Partnership Research

The first iteration of the current intervention was piloted on 24 participants, few of whom completed the out of session homework assignments. Therefore, few participants reported blood glucose control mastery experiences and we saw no changes in participants' weight or self-reported A1C. Participants reported a decrease in physical activity. As a result, the academic and community staff decided to modify the intervention (as described in the methods section below). However, during this second development phase, unexpected organizational changes at the Edison Senior Center resulted in the relocation of the intervention's development to Woodbridge Township, NJ. Armed with experience and information from the intervention's first iteration, the academic team met with a community advisory group in Woodbridge to leverage the community team's experience with that of practitioners and academic researchers.

All academic and community research relationships were guided by community-based participatory research (CBPR). CBPR has led to effective prevention and treatment programs for a diverse set of problems from eating disorders (Becker, Stice, Shaw, & Woda, 2009) to domestic violence (Shoultz et al., 2006). It has also been used to develop a diabetes prevention program that is under assessment (Horowitz, Brenner, Lachapelle, Amara, & Arniella, 2009). However, few diabetes interventions describe a theoretical framework for addressing community concerns. Thus, the following section describes the ways in which the current intervention used CBPR.

Principles of CBPR: Israel and colleagues (2005) delineate nine principles of CBPR. The following section lists the principles verbatim and then describes the ways in which they were incorporated into the current intervention.

1) CBPR acknowledges community as a unit of identity. Communities can be geographical locations and/or parts of individuals' identities created by social interactions. Thus, a community can refer to a township (e.g., Woodbridge) as well as geographically dispersed groups (e.g., race or those diagnosed with diabetes). In addition to recognizing multiple definitions of community, the intervention used community identity as a motivating factor for diabetes self-management (e.g., by reframing self-management as way to strengthen the community by not draining health resources).

2) CBPR builds on strengths and resources within the community. The location of the intervention, the Woodbridge Community Center (WCC), has a variety of strengths that were used in the intervention. First, the Center's affiliation with a YMCA provided a potential location for one workshop as well as physical activity instructors and machines. Additionally, the WCC's ties with local businesses resulted in glucometer test strip donations and Woodbridge's diverse population provided the opportunity to recruit minority participants. Finally, and perhaps most importantly, the intervention made use of the considerable experience possessed by members of the community team. These staff members provided valuable information about the specific population in Woodbridge (e.g., commonly consumed foods) and for older participants in general (e.g., the importance of large type).

3) CBPR facilitates a collaborative, equitable partnership in all phases of research, involving an empowering and power-sharing process that attends to social inequalities. Given the power differential inherent in community-academic collaborations, the academic team made it a priority to continually stress that community members were an integral part of the research process. Additionally, the academic team carefully considered and if possible incorporated community concerns (e.g., including a pre and post test of diabetes knowledge). All group meetings were held at the WCC to demonstrate the academic team's commitment to embedding themselves in the community. Additionally, the intervention's food recommendations were relevant for a variety of minority groups (as opposed to assuming an Anglo diet).

4) CBPR fosters co-learning and capacity building among all partners. This principle was incorporated through the use of open communication channels. One staff member, Mrs. Convery, served as the hub between the academic and community members' concerns as she has interest and experience in both areas. Additionally, all study members were included on an email chain and the suggestions of all study members were taken seriously.

5) CBPR integrates and achieves a balance between knowledge generation and intervention for the mutual benefit of all partners. This principle involves compromise on both sides, for example, the academic staff compromised on the dates and times of the study to accommodate the daily schedule of the WCC and the community staff compromised by agreeing to exclusion criteria. These were not easy changes to make, but by having candid and respectful discussions about the merits of these suggestions, all study members were satisfied with the resulting study design.

6) CBPR focuses on the local relevance of public health problems and on ecological perspectives that attend to the multiple determinants of health. The intervention necessarily focused on a community public health problem as community members chose the topic by approaching the academic team with a diabetes-specific idea. Furthermore, the CSM and SCT inherently account for ecological perspectives (e.g., the importance of the environment in predicting behaviors).

7) CBPR involves systems development using a cyclical and iterative process. The academic team constantly checked-in with community team members about satisfaction with intervention development and incorporated staff feedback after the conclusion of the intervention and the study as a whole. Furthermore, the current intervention was a new iteration of an intervention originally conducted at the Edison Senior Citizen Center. The first workshop had theoretical (i.e., too didactic) and practical (e.g., reliance a single staff member) flaws that were addressed in the current intervention (e.g., the focus on in session experience and inclusion of multiple community members).

8) CBPR disseminates results to all partners and involves them in the wider dissemination of results. All community staff members have been informed of study results and were asked to provide formal and informal feedback on the study process and the intervention. They will also be invited to help with any publications that result from the project. For example, Mrs. Convery has already used her experience with this project to collaborate with the author on a poster presentation for a New Jersey health conference.

Wider dissemination also refers to making intervention materials available to others. One of the most popular diabetes self-management program's (i.e., Lorig et al., 2009) materials are unavailable without participation in a several week training and as such it is difficult for outside researchers to replicate and/or build upon findings. The current intervention does not wish to take this approach. Rather, it will follow the example of Hill Briggs and colleagues' (2011) who detail their problem solving treatment for diabetes self-management in a journal article and provide the manual to interested parties. In this way, the intervention and its results will be shared with patients, providers and researchers alike.

***9) CBPR involves a long-term process and commitment to sustainability*.** Throughout intervention development, the academic team stressed that in addition to determining the feasibility of the group, an additional goal was sustainability: to provide the WCC with an intervention that could be run without the academic team. A further goal was to sustain the relationship between the academic and community partners, for example, by discussing potential future studies and funding sources.

Stages of CBPR. Israel and colleagues (2005) also discuss five stages of CBPR: 1) partnership formation and maintenance; 2) community assessment and diagnosis; 3) definition of the issue; 4) documentation and evaluation of partnership process; and 5) feedback, interpretation dissemination and application of results. The way in which the current intervention addresses many of these stages is described above; however, it is important to note instances where their strict application was not possible. Community members approached the academic team for the partnership, therefore, the current intervention did not include the community assessment and diagnosis stage. Additionally, given the time-limited nature of a dissertation, it was not feasible to conduct this assessment and it may not be necessary given the high rates of diabetes and the eagerness of community members. However, as CBPR is an iterative process we may return to these stages at any time to modify the intervention as needed.

Summary of the Current Intervention and Hypotheses

The current intervention integrates two theories of health beliefs, behaviors and behavior change (the CSM and SCT) and incorporates them into an educational workshop to improve diabetes self-management that was developed within a CBPR framework. By taking this approach, the intervention addresses several limitations of previous work. First, it clearly delineates a theoretical framework making it easier for results to improve existing theories as well as eventually explain which factors of diabetes education lead to improvements in A1C levels. It also addresses a theoretical flaw in previous iterations of the workshop: not providing participants with enough practical, first-hand (i.e., enactive) experiences with diabetes self-management. Third, its brief, inexpensive and community based approach increases its sustainability (i.e. the intervention's use after the study's completion).

It was hypothesized that the intervention would result in a significant decrease in participants' A1C levels between the start and 2 months after the end of the intervention. During the same period it was hypothesized that participants would improve on measures of diabetes self-efficacy, self-management behaviors, diabetes knowledge and general mental and physical functioning. Because this was a pilot study, feasibility outcomes unrelated to statistical significance are also reported and are of primary importance (Thabane et al., 2010). It was hypothesized that the study would be feasible with regards to recruitment, participant and community staff member satisfaction, questionnaire suitability, study curriculum and the group process. It was also hypothesized that the five illness domains of the CSM would provide appropriate language to describe diabetes self-management techniques.

Methods

Population

Participants were adults over the age of 50 who self-reported a diagnosis of type 2 diabetes, were not taking insulin and could engage in mild to moderate physical activity without assistance. All participants had to be able to read, write and speak English. Participants could not be pregnant, depressed, blind or cognitively impaired. Initially participants had to be residents of Woodbridge Township, a diverse area in central New Jersey. Due to insufficient recruitment and a change in the study's location, residency requirements were eliminated.

Recruitment

Two community staff members recruited study participants for the group held in Woodbridge through a combination of posters, announcements and personal interactions. Participants for the workshops held in New Brunswick, New Jersey at the Rutgers University Institute for Health (an academic research center; IFH) were recruited by the author through a combination of flyers, community emails and community senior centers. Participants were enrolled on a first come, first served basis. The goal was to recruit at least 19 participants as data from similar studies suggested that a sample of at least 19 would provide 90% power to detect an effect size of 0.7 (similar to the effect sizes in recent and similar studies; e.g., Hill-Briggs et al., 2011; Kluding et al., 2010) at an alpha of .05.

Intervention

The intervention was implemented by a team consisting of two core leaders. The team leader (the author) was a clinical psychology graduate student with 3 years of graduate courses in the theory of health psychology and CBT and 2 years of clinical experience (10 hours per week) in an outpatient medical setting. The second leader was a social worker with over 20 years experience in creating and implementing community programs (Kimberly Convery, MSW). A first year graduate student in clinical psychology served as a back-up leader (Jessica Yu). The group leaders were supplemented by a physical activity instructor during session 2 and an RD during session 3. Questions respecting the biology and treatment of diabetes were addressed by a physician (Elaine A. Leventhal , MD, PhD) who was present during at least one session for each group.

Session content. The intervention consisted of four 2-hour group sessions. The Operations Manual and the Participant Workbook are available upon request. Session content was based on the workshop's first iteration (described in the introduction), but was modified as follows.

Session 1. The goals of Session 1 were similar to those of the previous workshop; however, current methods relied more heavily on enactive mastery experiences. For example, a pros and cons of self-management activity based on the consequence domain was used to foster motivation and problem solving was introduced through the use of scenarios so that participants could translate general problem solving skills into a diabetes specific context. Additionally, the theoretical framework of the workshop was explicitly introduced to participants with CSM-based "self-management loops" and with a description of the workshop's key tenets (i.e., knowing what one can and cannot control, the importance of timing when assessing diabetes and the importance of an experimental attitude). Both relied heavily on the timeline and control/cure domains.

As in previous groups, participants received a handbook, chose a buddy and completed a homework assignment. In order to promote adherence, the homework assignment was simplified to the use of an action plan to monitor blood glucose levels before a provided snack (Ensure), 30 minutes after the snack and 2 hours after the snack (testing strips were provided). The homework was explicitly linked to learning about controllable aspects of diabetes and the goals of the next session. Homework assignments in the current intervention did not present SMBG as a primary goal, rather the goal was to improve self-management behaviors with the option of testing the behaviors' efficacy with SMBG. This change reflected the fact that only behaviors related to food choice, medication and activity can affect glycemic control as opposed to SMBG itself (Clar et al., 2010; Malanda et al., 2012; McAndrew, Schneider, Burns, & Leventhal, 2007).

Session 2. The goal of session 2 was to review information and homework from the previous session (in a similar manner to the first iteration) and to provide participants with information regarding physical activity and diabetes. An additional goal was to increase participants' diabetes self-efficacy with regards to SMBG and physical activity through an enactive mastery experience. The activity was intended to provide participants with a concrete experience that would enhance their common sense models of diabetes and its treatment to include physical activity as an effective glycemic control method. During the activity, which was suggested by an endocrinologist, participants tested their blood sugar levels before, 30 minutes after and 1.5 hours after the same snack eaten for homework; however, they added physical activity (led by a community instructor). The session ended with a discussion of the activity as well as a discussion of action plans to increase physical activity over the coming week (i.e., the homework assignment). Participants were encouraged, but not required to record related blood glucose values as data suggested that the previous workshop highlighted SMBG at the expense of important self-management behaviors.

Session 3. The goal of session 3 was to review information and homework from the previous session, to provide participants with information regarding diabetes nutrition, and to increase participants' self-efficacy related to the preparation of healthy foods. Again, instead of relying on a lecture format (i.e., verbal persuasion), the session included healthy food taste tests and/or healthy food preparation (i.e., enactive mastery experiences) intended to augment participants' diabetes and treatment models. The RD led the mastery experiences and a pared down nutrition information session that was tailored to participants' questions. Mandatory topics included the importance of carbohydrates, the plate method and portion size. The information component of the session was shortened in order to provide more time for participants to create individually tailored action plans by reviewing their daily lives to determine when and how to modify diet. Homework combined physical activity and nutrition goals and involved developing, stating and using action plans to increase or maintain physical activity and to make at least one dietary change.

Session 4. The goal of session 4 was to review information and homework from the previous session and to consolidate any gains made during the workshop. The theory of Relapse Prevention guided the discussion (see Fairburn, 2008; Larimer, Palmer, & Marlatt, 1999 for specific techniques) and focused on how to maintain and build upon any gains made during the group by identifying and addressing lapses. Group leaders highlighted the fact that lapses are not due to a lack of “will power,” but rather can result from changes in external or internal environments. “Getting back on track” was described as requiring the reexamination of those environments to determine when and how to plug in the self-management behaviors learned during the workshop; for example, by delineating new start points or by returning to old start points and reviewing the steps in that pathway to determine (and change) ineffective steps. Leaders also stressed the fact that the chronic nature of diabetes provides ample time to make large changes, even with setbacks. Before the workshop ended, leaders elicited feedback on the group and reminded participants that they would be contacted 2 months later to fill out similar questionnaires and test A1C levels.

Measures

Primary outcome measure. The primary outcome was glycated hemoglobin (A1C), which measures average blood glucose levels over the last two to three months. A1C varies due to individual differences (e.g., pregnancy, renal failure), but is the only biomarker of diabetes associated with health outcomes and is therefore considered the best population biomarker for diabetes (Rubinow & Hirsch, 2011). A1C was measured with a finger stick blood test using a disposable A1C analyzer (99% accurate; A1CNow+, Bayer Medical Care; Tarrytown, New York) before and 2 months after the completion of the intervention.

Secondary outcomes measures. Participants completed the following self-report measures as secondary outcomes. Contact information, demographic information (with the exception of height and weight) and treatment suitability were assessed only at the baseline visit and the medication list was collected only at baseline and two-month follow-up sessions. The remainder of the measures were assessed at baseline, the final group session (post-treatment) and 2 months after the final group session (two-month follow-up). The measures are presented below in alphabetical order.

The Brief Illness Perception Questionnaire (brief IPQ). The brief IPQ (Broadbent, Petrie, Main, & Weinman, 2006) measures the five illness domains of the Common Sense Model. Each item is scored on a 0-10 scale. The items can be summed to create an overall threat score, which is measured on a 0-100 scale where higher scores indicate a more threatening perception of the illness.

Community Based Research Questionnaire. All community staff members answered multiple choice and open-ended questions about the workshop's development and outcomes. Questions were designed specifically for this study and responses were discussed at a final meeting after the final study visit. Feasible suggestions will be incorporated into future work.

Demographic Information. Demographic information included age, gender, ethnicity and education level. Height and weight were collected to calculate Body Mass Indices (BMI).

Diabetes Self-Efficacy Scale. Diabetes self-efficacy was measured with an 8-item scale developed by the Stanford Patient Education Research Center. Items assess self-efficacy in relation to a variety of behaviors necessary for diabetes self-management, for example, “How confident do you feel that you can exercise 15 to 30 minutes, 4 to 5 times a week?” Items are rated on a 10-point scale from “Not at all confident” to “Totally confident.” The authors report an internal reliability consistency of .828 (unpublished paper).

Diabetes Knowledge Questionnaire. Knowledge of diabetes was measured by multiple choice questions developed specifically for this study, for example, “When should you monitor your blood glucose levels to see the effect of physical activity?”

DUKE Health Scale. The DUKE (Parkerson, Broadhead, & Tse, 1990) measures physical and social functioning in relation to physical and mental health by producing several subscales which are scored on a 0-100 scale. For all scales, except for those measuring anxiety, depression or anxiety-depression, a higher score corresponds to better health. The depression and anxiety-depression subscales were not used in this study. Other subscale scores were used to assess potential changes in function as a result of the intervention.

General Health and Health Behaviors Questionnaire. General health and health behaviors were measured by a series of questions written or gathered specifically for this study. It included an item assessing self-assessed health as well as questions related to healthy eating, barriers to self-management behaviors, symptoms of diabetes, goals for treatment and treatment suitability.

Medication List. Participants were asked to provide a list of current medications and dosages to investigate potential effects of medication on A1C levels as well as the effects of the intervention on medication dosages.

Personal Health Questionnaire 9 (PHQ-9). The PHQ-9 (Kroenke, Spitzer, & Williams, 2001) is a nine-item measure of depression, which is validated for use in medical settings. Scores above 10 indicate depression.

Rapid Assessment of Physical Activity (RAPA). The RAPA (Topolski et al., 2006) is a measure of physical activity that has been validated for use in older adults. Scores below 6 are considered sub-optimal.

Treatment Satisfaction Questionnaire. At the end of the workshop participants answered questions regarding their satisfaction with the workshop (measured as yes or no) and whether they intended to use the skills taught in the workshop in the future (measured on a 5-point scale from not at all likely to very likely). They were also asked to give open-ended responses to questions regarding factors they would like to change about the workshop as well as factors they liked about the workshop. Feasible feedback will be included in future iterations of the workshop.

***2-Month Follow-Up Questionnaire*.** Two months after the end of the intervention, participants answered questions regarding their use of workshop skills since the end of the workshop (measured on a 5-point scale from never to very often) as well as their plans to use those skills in the future (measured on a 5-point scale from not at all likely to very likely). The questionnaire also included opened ended items on the same topics.

Feasibility Criteria

Feasibility criteria, an important component of pilot studies (Thabane et al., 2010), were operationalized and assessed as follows.

Recruitment. Successful recruitment was measured by whether the desired minimum number of participants (i.e., 19) were recruited using the methods described above.

Participant satisfaction was measured with a single quantitative item on the Treatment Satisfaction Questionnaire: “Did the workshop help you achieve your goals?” (Yes or No), by open ended items on the Treatment Satisfaction Questionnaire, by how many participants completed the workshop, their reasons for dropping out, and by participants' comments during session 4 of the workshop and the two-month follow-up session.

Community staff member satisfaction was measured with responses to the CBPR questionnaire.

Questionnaire suitability was measured by the ease with which participants completed the questionnaires created for this study and by whether the results could be analyzed and synthesized successfully by the methods described above.

Workshop curriculum. Curriculum feasibility was measured in several ways. First, by assessing whether participants reported enjoying the physical activity and nutrition demonstrations. Second, by assessing the success of the physical activity experiment (i.e., whether, on average, blood glucose levels were lower with physical activity and the snack than with the snack alone). Third, by assessing how likely participants thought they would be to use study skills in the future and whether they reported using skills between post-treatment and the two-month follow-up visit (as assessed by the Treatment Satisfaction Questionnaire and the 2-Month Follow-Up Questionnaire). Fourth, by assessing whether more than half of participants requested additional information on items listed on the Treatment Satisfaction Questionnaire. Finally, session transcripts were analyzed to identify commonly discussed topics and to determine whether the workshop sufficiently addressed these topics.

The group process. The group process refers to the ways in which group leaders and participants interacted with one another. Group process was measured by opened ended responses on the Treatment Satisfaction Questionnaire and the 2-Month Follow-Up Questionnaire and by analyzing session transcripts to determine how participants interacted and potential effects of those interactions.

The CSM. The feasibility of using the language of the CSM to describe techniques for diabetes self-management was assessed by analyzing session transcriptions to determine whether participants discussed topics related to the five illness domains (identity, timeline, cause, control/cure, and consequences).

Analyses

Outcomes for Future Trials. The purpose of this study was to test the feasibility and effectiveness of a novel intervention, thus no control group was used and statistical tests used a significance level of p = .1 for exploratory secondary analyses. Descriptive analyses confirmed that the data were not normally distributed and the sample was too small to use bootstrapping techniques (Johanson & Brooks, 2010). Therefore, change in A1C between the baseline and two-month follow-up visits was assessed with a one-tailed Wilcoxon signed-rank test. This method precluded the use of intent to treat analyses as Wilcoxon signed-rank tests ignore cases in which there is no change between time points.

Due to the small sample and non-normality of the data, the intervention's effects on the following secondary measures were assessed via Friedman's analysis of variance (ANOVA): BMI, the Brief IPQ, the Diabetes Self-Efficacy scale, items 1-3 and 6 on the Diabetes Knowledge questionnaire, the Duke Health Scale, the PHQ-9, the RAPA and items 1-2 on the 2-Month Follow-Up Questionnaire. Significant ANOVA results were followed-up with Wilcoxon signed-rank tests as suggested by Fields (2008). Changes were considered to be maintained at the two-month follow-up visit if two-month follow-up scores did not significantly differ from post-treatment scores, but did significantly differ from baseline scores.

Both intent to treat (baseline carried forward) and completer results are reported for secondary measures. The Bonferroni correction was not applied as it has been suggested that its use unnecessarily decreases power, especially in exploratory studies with small samples (Nakagawa, 2004; Perneger, 1998). Effect sizes were measured with

Pearson's *r* and were interpreted with Cohen's guidelines for social sciences (1992; 0.1, 0.3 and 0.5 correspond to small, medium and large effects, respectively).

Feasibility Outcomes. The author, Kimberly Convery and Jessica Yu independently assessed themes between and within participants' responses in session transcripts and on the following measures: Community Based Research Questionnaire, Diabetes Knowledge Questionnaire items 4-5, General Health and Health Behaviors Questionnaire, Treatment Satisfaction Questionnaire and the 2-Month Follow-Up Questionnaire Items 3+. We then compared assessments to determine themes and to assess changes in these themes over time. All other items were assessed with frequency counts or descriptive statistics.

Ethical Aspects

This research protocol was approved by the Rutgers University Institutional Review Board. All participants signed a consent form and were informed that they were participating in a pilot trial of a new treatment.

Results

Participant flow and baseline data are described first. This is followed by a description of results for the primary and secondary outcome measures. Lastly, qualitative and quantitative results for the feasibility objectives are reported, including a post-hoc exploratory analysis of differences between participants who achieved moderate to large changes in A1C and those who did not.

Participant Flow

Participant flow is demonstrated in Figures 1-3. Twenty-two participants expressed interest in the study, sixteen signed consent forms and attended the first workshop session. Two participants dropped out of treatment during the workshop and therefore did not complete the post-treatment assessment and two participants did not complete the two-month follow-up visit. Therefore, the post-treatment sample consisted

Figure 1
Flow Chart for Woodbridge

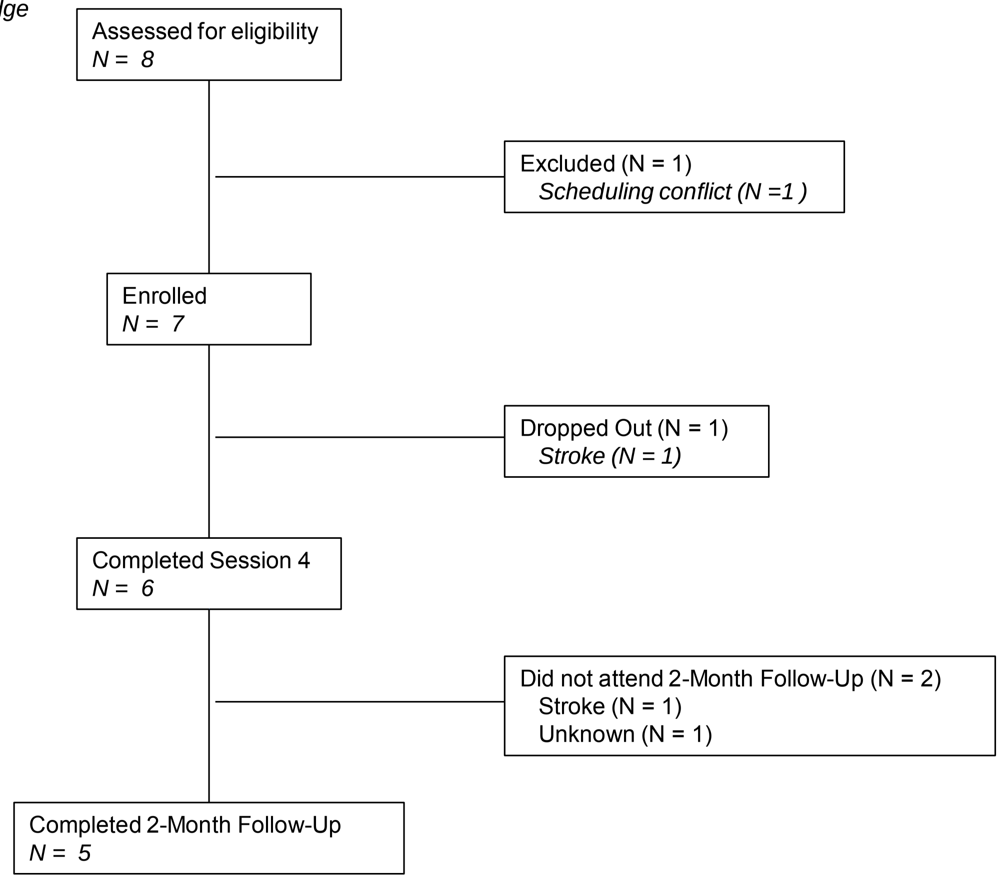


Figure 2
Flow Chart for Fall IFH Group

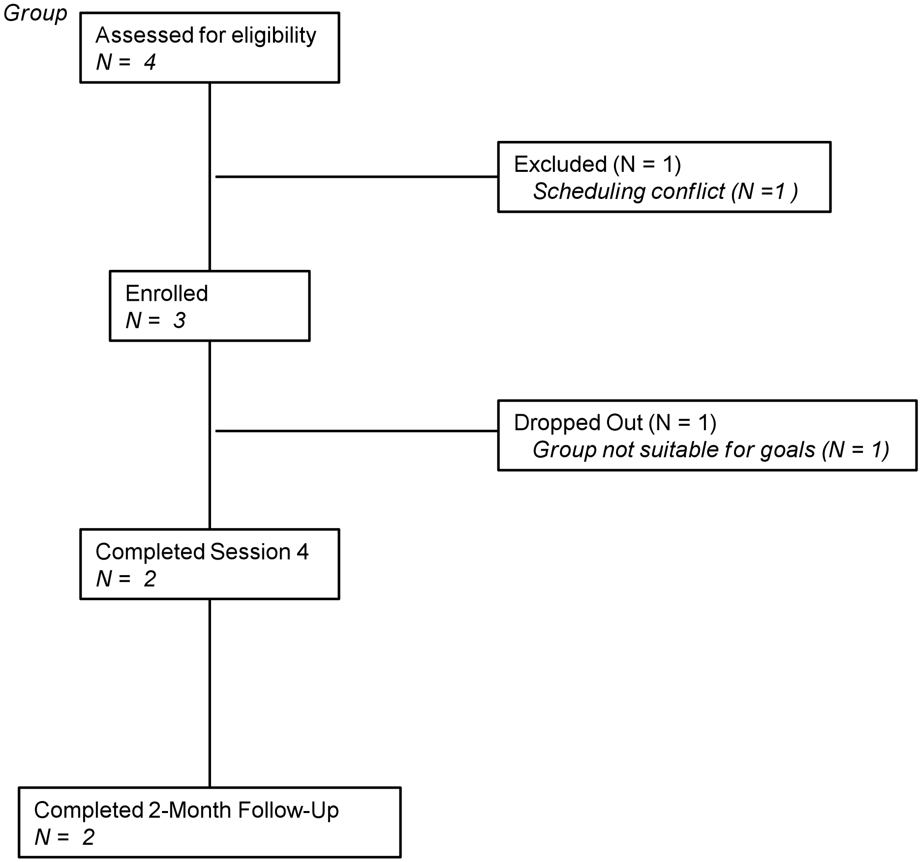
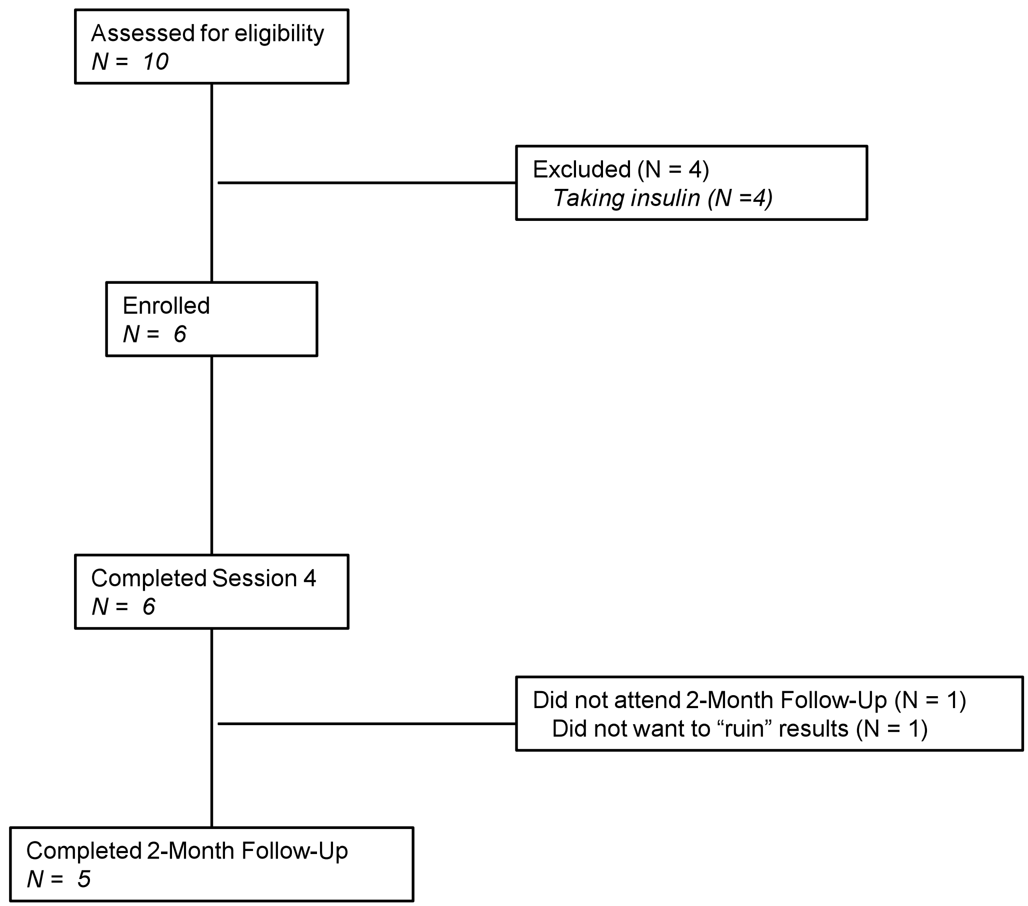


Figure 3

Flow Chart for Winter IFH Group



of 14 participants and the two-month follow-up sample consisted of 12 participants. A 12.5% drop-out rate is consistent with similar studies (Deakin et al., 2005).

Recruitment

Recruitment for groups held in Woodbridge started in August 2011 and ended in October 2011. We were unable to recruit enough participants for a group held at the Woodbridge YMCA and so the single participant interested in participating at the YMCA agreed to participate in the group at the WCC, where recruitment was also low (N=6). Recruitment for groups at IFH was conducted in September 2011 and January 2012, respectively. Interest in the IFH Fall Group was extremely low (4 potential participants expressed interest, 3 enrolled). Recruitment was slightly better for the IFH Winter Group with 10 potential participants expressing interest and 6 participating. Four potential participants at the IFH were ineligible due to taking insulin.

Baseline Data

As seen in Table 1, the sample was mostly female (75%), married (63%) and educated (69% had at least a college education). Most participants identified as Non-Hispanic White (69%), 19% identified as Asian/Pacific Islander and 6% as non-Hispanic Black. Only one participant identified as Hispanic. Almost half of all participants worked full time and all had some form of insurance. The mean age was 63.49 years (*SD* = 6.08).

Table 1 also presents differences between groups at baseline. Due to the small sample size of the first IFH group, all IFH participants were collapsed into a single group. The overall small sample size precluded chi square analyses (i.e., there were less than five cases in several cells). However, visual inspection of the groups' demographics suggests that the group held in Woodbridge had more non-White participants than the groups at IFH. Woodbridge participants also appeared to be more likely to be retired (75%) and less likely to have education beyond a bachelor's degree.

Table 1
Demographic Information

	Total		Woodbridge		IFH	
	N	Percent	*N*	Percent	*N*	Percent
Gender						
Female	12	75%	5	71%	7	78%
Male	4	25%	2	29%	2	22%
Ethnicity						
Hispanic	1	6%	0	0%	1	11%
Not Hispanic	15	94%	7	100%	8	89%
Race						
White	12	75%	3	43%	9	100%
Black	1	6%	1	14%	0	0%
Asian/Pacific Islander	3	19%	3	43%	0	0%
Marital Status						
Married	10	63%	3	43%	7	78%
Divorced	2	13%	1	14%	1	11%
Widowed	2	13%	2	29%	0	0%
Single	2	13%	1	14%	1	11%
Employment Status						
Not working/Retired	8	50%	6	86%	2	22%
Working Full Time	7	44%	1	14%	6	67%
Homemaker	1	6%	0	0%	1	11%
Health Insurance						
Medicare only	1	6%	1	14%	0	0%
Private Health Insurance/HMO	12	75%	3	43%	9	100%
Other	3	19%	3	43%	0	0%
Completed College						
Yes	11	69%	4	57%	7	78%
No	5	31%	3	43%	2	22%

Table 2 presents baseline information on study participants. The mean A1C level at baseline was 7.44% (*SD* = 1.34) and did not differ between groups. The mean BMI was in the obese range (*M* = 33.35 kg/m^2, *SD* = 6.69) and scores on the Diabetes Self-Efficacy scale suggested that participants were moderately confident in their ability to manage their diabetes (i.e., all means were above 5). Scores on the brief IPQ suggested that at baseline participants generally believed that diabetes was chronic (*M* = 7.38, *SD*

= 2.94), treatable (*M* = 7.25, *SD* = 2.46) and serious (*M* = 7.75, *SD* = 3.00). However the mean of the overall threat scores was low (*M* = 37.36, *SD* = 12.46). Participants' understanding of diabetes and their personal control over the disease was reported as moderate (understanding, *M* = 4.44, *SD* = 2.80; control, *M* = 5.31, *SD* = 1.92), and they perceived diabetes as having a moderate impact on their lives and emotions (*M* = 5.31, *SD* = 2.68). Participants' mean levels of physical activity were below recommended levels (*M* = 4.56, *SD* = 1.59). Although one third of the participants reported experiencing symptoms of hyper- and/or hypoglycemia, Duke Health Profile subscales suggest that participants were in good mental and physical health (all means below and above 50, respectively), self-assessments of health were in the good range (*M* = 2.88, *SD* = 0.72) and none reported symptoms of depression above the cut-off score (10).

Table 2
Baseline Characteristics

	Mean	*SD*		Range	
			Median	Min	Max
A1C	7.44	1.34	7.30	5.80	11.30
BMI	33.35	6.69	33.30	22.41	47.29
Diabetes Self-Efficacy Scale					
Regular eating	6.81	2.23	7.50	3.00	10.00
Following diet in the company of others	7.00	1.93	7.50	4.00	10.00
Choosing appropriate foods when hungry	6.19	2.32	6.50	1.00	10.00
Regular exercise	6.94	1.91	7.00	3.00	10.00
Prevent blood sugar from dropping during exercise	6.00	2.85	6.50	1.00	10.00
Know what to do when blood sugar levels are too high or too low	5.31	2.27	5.00	1.00	9.00
Judging when changes in illness mean one should visit the doctor	6.69	2.44	7.50	3.00	10.00
Controlling diabetes so that it does not interfere with life	6.88	2.00	7.00	3.00	10.00
Total Score	6.48	1.15	6.31	4.50	8.13

Table 2 continued

Baseline Characteristics

	Mean	*SD*	Median	Range Min	Max
Brief IPQ					
How much does illness affect your life	4.44	2.56	4.00	0.00	10.00
How long will illness continue	7.38	2.94	8.00	1.00	10.00
How much control do you feel you have over your illness	5.31	1.92	5.00	1.00	8.00
How much do you think your treatment can help your illness	7.25	2.46	7.50	1.00	10.00
How much do you experience symptoms from your illness	4.06	2.82	4.50	0.00	10.00
How concerned are you about your illness	7.75	3.00	8.50	0.00	10.00
How well do you think you understand your illness	4.44	2.80	3.50	0.00	8.00
How much does your illness affect you emotionally	5.31	2.68	6.00	0.00	10.00
Threat Score	37.36	12.46	40.00	2.00	51.00
Duke Health Profile					
Physical Health Score	56.25	18.93	55.00	20.00	90.00
Mental Health Score	86.88	15.37	90.00	50.00	100.00
Social health Score	76.88	18.15	80.00	40.00	100.00
Perceived Health Score	62.50	28.87	50.00	0.00	100.00
Self-Esteem Score	86.25	14.55	90.00	50.00	100.00
General Health Score	73.33	12.53	73.33	50.00	93.33
Anxiety Score	32.29	12.50	33.33	16.67	58.33
Pain Score	56.25	25.00	50.00	0.00	100.00
Disability Score	3.13	12.50	.00	0.00	50.00
Self Assessed Health	2.88	.72	3.00	2.00	4.00
Diabetes Knowledge Score	76.79	14.59	75.00	50.00	100.00
PHQ-9 Score	3.81	2.86	3.50	0.00	8.00
RAPA Physical Activity Score	4.56	1.59	4.00	3.00	7.00
RAPA Strength Training Score	.75	1.13	0.00	0.00	3.00

All participants reported attending the workshop to learn more about diabetes and almost all (*N* = 15) wanted to improve their diet (Table 3). Fewer were interested in increasing physical activity (*N* = 9) or meeting others with diabetes (*N* = 5), but most wanted to see how others managed diabetes (*N* = 13) and to lower blood glucose without medication (*N* = 14). Most participants reported that they believed the workshop was "very suitable" for helping them achieve their goals (*M* = 4.25, *SD* = 0.86).

Table 3
Reasons for Study Participation

	N	Percent
Get out of the house	2	13%
Learn more about diabetes	16	100%
Improve diet	15	94%
Increase physical activity	9	56%
Meet others with diabetes	5	31%
See how others manage diabetes	13	81%
Lower blood glucose without medication	14	88%

Primary and Secondary Outcomes

Primary outcome: A1C. The results of the Wilcoxon signed-rank test suggested that A1C did not differ between baseline and two-month follow-up. Post-hoc analyses demonstrated that for participants with baseline A1C levels above 6.5%, the cut-off for "excellent control" (Clar et al., 2010), A1C levels showed a medium and significant decrease between baseline (*Mdn* = 7.5; range: 6.7 -11.3) and two-month follow-up (*Mdn* = 7.1; range: 6.3-9.6), $z = -1.74$, $p < .05$, $r = -.35$.

Secondary Outcomes

Data for secondary outcomes are presented for intent to treat and completer analyses in Tables 4 and 5, respectively. Effect sizes are not reported in the tables, but demonstrate that all effects were in the medium to large range.

BMI. Intent to treat analyses suggested that BMI did not change over the course of the study. Completer analyses suggested a trend towards BMI change over the course of the study (χ^2 (2) = 5.15, $p < .1$). The Wilcoxon tests used to follow-up this finding demonstrated that BMI significantly decreased from baseline (*Mdn* = 32.30) to two-month follow-up (*Mdn* = 31.92), $z = -1.78$, $p < .05$, $r = -.36$.

Table 4

Significant Secondary Outcomes in Intent to Treat Analyses

	Median (Range)			Friedman's ANOVA	Wilcoxon Follow-Up (*Z*)		
	BL	T2	T3		T2-BL	T3-T2	T3-BL
BMI	32.30 (22.41 - 47.29)	32.38 (22.47 - 44.77)	31.92 (22.18 - 46.04)	$\chi^2(2) = 4.57$	-1.10	-0.22	-1.78**
Confidence in choosing appropriate foods	6.50 (1 - 10)	7.50 (1 - 10)	7.50 (1 - 10)	$\chi^2(2) = 8.54$**	-2.31**	-1.03	-2.20**
Confidence in responding to blood sugar levels	5.00 (1 - 10)	7.50 (3 - 10)	8.00 (1 - 10)	$\chi2(2) = 7.35$**	-2.53****	-.0.99	-2.32**
Confidence in judging when to see doctor	7.50 (3 - 10)	8.00 (3 - 10)	8.50 (3 - 10)	$\chi2(2) = 8.00$**	-2.13**	-1.02	-2.45***
Confidence in controlling diabetes so that it does not interfere with life	7.00 (3 - 10)	7.00 (4 - 10)	8.00 (3 - 9)	$\chi2(2) = 4.48$	-0.48	-1.23	-1.15*
Total Diabetes Self-Efficacy	6.31 (4.5 - 8.13)	7.19 (4.38 - 9.50)	7.44 (5.25 - 9.50)	$\chi2(2) = 6.71$**	-2.16**	-0.91	-2.49***
Control over illness	5.00 (1 - 8)	6.00 (5 - 10)	6.50 (3 - 10)	$\chi^2(2) = 6.048$**	-1.70*	-0.14	-1.63*
Understanding of illness	3.50 (0 - 8)	8.00 (2 - 10)	8.00 (0 - 10)	$\chi^2(2) = 14.04$***	-3.13****	-0.85	-2.23***
Upset by diabetes	6.00 (0 - 10)	5.00 (0 - 8)	5.00 (0 - 8)	$\chi^2(2) = 5.43$*	-1.38*	-0.57	-1.90**
Social Health Score	80.00 (40 - 100)	70.00 (40 - 100)	80.00 (40 - 100)	$\chi^2(2) = 5.09$*	-0.68	-1.93**	-1.63*

**p*<.1, **p<.05, ***p<.01, ****p<.001; BL = baseline; T2 = post-treatment; T3 = two-month follow-up

Table 5

Significant Secondary Outcomes in Completer Analyses

	Median (Range)			Friedman's ANOVA	Wilcoxon Follow-Up (*Z*)		
	BL	T2	T3		T2-BL	T3-T2	T3-BL
BMI	32.30 (22.41 - 47.29)	32.38 (22.47 - 44.77)	31.92 (22.18 - 46.04)	$\chi^2(2) = 5.15$*	-1.10	-0.47	-1.78**
Confidence in choosing appropriate foods	6.50 (4 - 10)	7.50 (5 - 10)	8.00 (4 - 10)	$\chi^2(2) = 8.58$**	-2.31**	-1.31	-2.10**
Confidence in responding to blood sugar levels	5.00 (3 - 9)	7.50 (3 - 10)	8.00 (4 - 10)	$\chi^2(2) = 5.15$*	-2.53***	-0.36	-2.32**
Confidence in judging when to see doctor	7.50 (3 - 10)	8.00 (5 - 10)	9.00 (4 - 10)	$\chi^2(2) = 8.91$**	-2.13**	-1.71*	-2.45***
Confidence in controlling diabetes so that it does not interfere with life	7.00 (4 - 10)	7.00 (4 - 10)	8.00 (7 - 9)	$\chi^2(2) = 6.72$**	-0.47	-2.53***	-1.55*
Total Diabetes Self-Efficacy	6.31 (4.50 - 8.13)	7.19 (6.25 - 9.50)	7.63 (6.25 - 9.50)	$\chi^2(2) = 7.60$**	-2.16**	-1.18	-2.49***
Control over illness	5.00 (1 - 8)	6.00 (5 - 10)	7.00 (5 - 10)	$\chi^2(2) = 5.74$*	-1.70*	-0.88	-1.63*
Understanding of illness	3.50 (0 - 8)	8.00 (5 - 10)	8.00 (6 - 10)	$\chi^2(2) = 12.91$***	-3.13****	-0.18	-2.73***
Upset by diabetes	6.00 (0 -10)	5.00 (0 -8)	5.00 (0 -8)	$\chi^2(2) = 6.19$**	-1.38*	-1.07	-.191**
Social Health Score	80.00 (40 - 100)	70.00 (40 - 100)	90.00 (40 - 100)	$\chi^2(2) = 7.40$**	-0.68	-2.56***	-1.63*

**p*<.1, **p<.05, ***p<.01, ****p<.001; BL = baseline; T2 = post-treatment; T3 = two-month follow-up

Diabetes Self-Efficacy. Total diabetes self-efficacy changed over the course of the study in both intent to treat (χ^2 (2) = 6.71, $p < .05$) and completer (χ^2 (2) = 7.60, $p < .05$) analyses. Follow-up Wilcoxon tests in the intent to treat sample demonstrated that total diabetes self-efficacy increased between baseline (*Mdn* = 6.31) and post-treatment (*Mdn* = 7.19), $z = -2.16$, $p < .05$, $r = -.38$ and that change was maintained at two-month follow-up (*Mdn* = 7.44), $z = -2.49$, $p < .05$, $r = -.44$. Results were similar in follow-up tests for the completer sample: total diabetes self-efficacy increased between baseline (*Mdn* = 6.31) and post-treatment (*Mdn* = 7.19), $z = -2.16$, $p < .05$, $r = -.44$ and that change was maintained at two-month follow-up (*Mdn* = 7.63), $z = -2.49$, $p < .05$, $r = -.51$.

Participants' confidence in choosing appropriate foods when hungry (item 3) also changed in both intent to treat (χ^2 (2) = 8.54, $p < .05$) and completer (χ^2 (2) = 8.58, $p < .05$) analyses. In the intent to treat sample, follow-up tests suggested that confidence in choosing appropriate foods increased between baseline (*Mdn* = 6.5) and post-treatment (*Mdn* = 7.5), $z = -2.31$, $p < .05$, $r = -.41$ and that change was maintained at two-month follow-up (*Mdn* = 7.5), $z = -2.20$, $p < .05$, $r = -.39$. Completer results were similar: confidence in choosing appropriate foods increased between baseline (*Mdn* = 6.50) and post-treatment (*Mdn* = 7.50), $z = -2.31$, $p < .05$, $r = -.47$ and that change was maintained at two-month follow-up (*Mdn* = 8.00), $z = -2.10$, $p < .05$, $r = -.43$.

Participants' confidence in knowing what to do when blood sugar levels are too low or too high (item 6) significantly changed over time in intent to treat analyses (χ^2 (2) = 7.35, $p < .05$) and showed a trend towards change in completer analyses (χ^2 (2) = 5.15, $p < .1$). In the intent to treat sample, follow-up tests suggested that confidence in responding to out of range blood sugar readings increased between baseline (*Mdn* = 5.00) and post-treatment (*Mdn* = 7.50), $z = -2.53$, $p < .001$, $r = -.45$ and that change was maintained at two-month follow-up (*Mdn* = 8.00), $z = -2.32$, $p < .05$, $r = -.41$. Completer results were similar: confidence in responding to out of range blood sugar readings increased between baseline (*Mdn* = 5.00) and post-treatment (*Mdn* = 7.50), $z = -2.53$, $p < .01$, $r = -.52$ and that change was maintained at two-month follow-up (*Mdn* = 8.00), $z = -2.32$, $p < .05$, $r = -.47$.

Participants' showed a significant change in their confidence to judge when changes in their illness meant visiting the doctor (item 7) in both intent to treat (χ^2 (2) = 8.00, $p < .05$) and completer (χ^2 (2) = 8.91, $p < .05$) analyses. In the intent to treat sample, follow-up tests suggested that confidence on this item increased between baseline (*Mdn* = 7.50) and post-treatment (*Mdn* = 8.50), $z = -2.13$, $p < .05$, $r = -.38$ and that change was maintained at two-month follow-up (*Mdn* = 8.50), $z = -2.45$, $p < .05$, $r = -.43$. Completer results suggested that confidence on this item increased between baseline (*Mdn* = 7.50) and post-treatment (*Mdn* = 8.00), $z = -2.13$, $p < .05$, $r = -.44$ and showed a trend towards a further increase between post-treatment and two-month follow-up (*Mdn* = 9.00), $z = -1.71$, $p < .1$, $r = -.35$.

Only completer analyses suggested that confidence in controlling diabetes so that it does not interfere with daily life (item 8) significantly changed over the course of the study (χ^2 (2) = 6.72, $p < .05$). Follow-up Wilcoxon tests suggested that it increased between post-treatment (*Mdn* = 7) and two-month follow-up (*Mdn* = 8), $z = -2.53$, $p < .01$, $r = -.52$.

Brief IPQ. Beliefs in the control domain (item 3) significantly changed over time in intent to treat analyses (χ^2 (2) = 6.05, $p < .05$) and showed a trend towards change in completer analyses (χ^2 (2) = 5.74, $p < .1$). Follow-up Wilcoxon tests in the intent to treat sample demonstrated that participants reported greater control over their diabetes between baseline (*Mdn* = 5.00) and post-treatment (*Mdn* = 6.00), $z = -1.70$, $p < .1$, $r = -.30$ and that change was maintained at two-month follow-up (*Mdn* = 6.50), $z = -1.63$, $p < .05$, $r = -.29$. Results were similar in completer analyses: control increased between baseline (*Mdn* = 5.00) and post-treatment (*Mdn* = 6.00), $z = -1.70$, $p < .1$, $r = -.35$ and that change was maintained at two-month follow-up (*Mdn* = 7.00), $z = -1.63$, $p < .1$, $r = -.33$.

Understanding of diabetes (item 7) significantly changed during the study in both intent to treat (χ^2 (2) = 14.04, $p < .01$) and completer (χ^2 (2) = 12.91, $p < .01$) analyses. Follow-up tests in the intent to treat sample demonstrated that understanding of diabetes increased from baseline (*Mdn* = 3.50) to post-treatment (*Mdn* = 8.00), $z = -3.13$, $p < .001$, $r = -.55$ and that change was maintained at two-month follow-up (*Mdn* = 8.00), $z = -2.23$, $p < .01$, $r = -.38$. Again, results were similar for completer analyses. Understanding of diabetes increased from baseline (*Mdn* = 3.50) to post-treatment (*Mdn* = 8.00), $z = -3.13$, $p < .001$, $r = -.64$ and that change was maintained at two-month follow-up (*Mdn* = 8.00), $z = -2.73$, $p < .01$, $r = -.56$.

There was a trend towards change in how upset diabetes made participants (item 8) in intent to treat analyses (χ^2 (2) = 5.43, $p < .1$) and a significant change in completer analyses (χ^2 (2) = 6.19, $p < .05$). In intent to treat analyses, follow-up Wilcoxon tests suggested that diabetes-related distress decreased between baseline (*Mdn* = 6.00) and post-treatment (*Mdn* = 5.00), $z = -1.38$, $p < .1$, $r = -.24$ and that change was maintained at two-month follow-up (*Mdn* = 5.00), $z = -1.90$, $p < .05$, $r = -.34$. In completer analyses, there was a trend towards participants reporting less diabetes-related distress between baseline (*Mdn* = 6.00) and post-treatment (*Mdn* = 5.00), $z = -1.38$, $p < .1$, $r = -.28$. Scores at the two-month follow-up visit (*Mdn* = 5.00) were significantly lower than those at baseline, $z = -1.91$, $p < .05$, $r = -.39$.

Duke Health Profile. There was a trend towards change on the Social Health Subscale in intent to treat analyses (χ^2 (2) = 5.09, $p < .1$) and a significant change in completer analyses (χ^2 (2) = 7.40, $p < .05$). Data suggested that in the intent to treat sample, participants improved their social health from post-treatment (*Mdn* = 70.00) to two-month follow- up (*Mdn* = 80.00), $z = -1.93$, $p < .05$, $r = -.34$, but two-month follow-up scores showed only a trend towards difference from baseline scores (*Mdn* = 80.00) , z = -1.63, p < .1, r = -.29. Again, results were similar in completer analyses where scores also increased from post-treatment (*Mdn* = 70.00) to two-month follow- up (*Mdn* = 90.00) , z = -5.56, p < .01, r = -.52, but that change showed only a trend towards difference from baseline (*Mdn* = 80.00) , z = -1.63, p < .1, r = -.36.

It should also be noted that most participants (N = 10; 83%) did not change diabetes-related medications between baseline and two-month follow-up. Friedman's ANOVAs suggested that no other items showed significant changes from baseline to post-treatment and/or the two-month follow-up.

Qualitative questionnaire items. As it is not possible to "carry forward" answers to qualitative items, only completer data were used.

General Health Questionnaire. At all time points most participants reported walking and/or cardio activity (e.g., biking, treadmill, elliptical) as their primary forms of physical activity and most participants maintained some form of activity between baseline and two-month follow-up. Two participants reported decreasing activity and two participants increased activity (both of whom did not engage in any activity at baseline). The most common barrier to physical activity was time, followed closely by health problems. Weather and motivation were also commonly cited barriers. Barriers changed little over the course of the study. Most participants reported increasing fruit/vegetable consumption and avoidance as their primary ways to use diet to control their diabetes. Roughly half of participants reported the cessation of avoidance as a technique to manage their diabetes. Motivation was a commonly cited barrier to healthy eating.

Brief IPQ, question 9. Participants reported similar causes for diabetes: a combination of diet, exercise and genetic risk. These responses did not change over time.

Feasibility Outcomes

An overview of feasibility outcomes is presented in Table 6.

Table 6
Feasibility Outcomes

	Feasible	Not Feasible
Recruitment		x
Patient Satisfaction	x	
Community Staff Member Satisfaction	x	
Questionnaires		x
Curriculum	x	
Physical activity and nutrition demonstrations	x	
Physical activity experiment		x
Skills	x	
Diabetes Information	x	
Common Sense Model	x	

Recruitment. Recruitment techniques proved inadequate as we were unable to recruit the minimum desired number of participants (i.e., 19), even after removing the residency restriction and recruiting a third group.

Participant satisfaction. Both quantitative and qualitative measures suggest that participants were satisfied with the workshop. All but one participant reported that the workshop helped them achieve their goals and qualitative responses to questions regarding satisfaction with the workshop at post-treatment and two-month follow-up were overwhelming positive. Further, only 12.5% of participants dropped out during the active treatment phase and only one dropped because she felt the workshop was not suitable for her goals (the other dropped for medical reasons). One of the participants did not attend the two-month follow-up session because she did not want to “ruin the study’s results,” but reported enjoying the workshop. One participant appeared dissatisfied with the workshop, as demonstrated by his abrupt departure from the two-month follow-up session. He could not be reached for further assessment.

Open-ended responses to the Treatment Satisfaction Questionnaire suggest that participants believed the workshop gave them information needed to reach their goals. A minority of participants reported specific factors (e.g., diet, exercise, action plans) and two participants felt it was too soon to tell. Most participants reported that they especially liked the group's leaders, including their attention, knowledge, interaction and support. Four participants thought group interactions were best and three participants liked teaching methods best. Some participants mentioned specific activities (e.g., nutrition or exercise) or speakers (Dr. Leventhal). Participants were split on whether they found information on food or activity most helpful, only two participants mentioned action plans or "making diabetes noisy." All but one participant intended to try some of the activities at home and they were evenly split between exercise and diet, with most participants who chose diet mentioning portion control (which was also mentioned as especially helpful).

Community Staff Member Satisfaction. Community staff member satisfaction was mixed. On one end of the spectrum was the staff member who was unable to recruit enough members to sustain a group at the YMCA and who did not respond to repeated requests for the completion of the CBPR questionnaire. On the other end of the spectrum was the satisfied staff member who left the community side and joined the academic side as a study coordinator. In the middle was the staff member who most successfully recruited members for the workshop in Woodbridge. At both time points she reported that she believed the workshop was successful and that she would be "very likely" to want to work with Rutgers in the future. She reported that she increased her knowledge about diabetes by working with academic researchers and that she liked sharing information. She would have changed the collaborative process by having a meeting or conference call in September (i.e., before the start of the groups). She reported wanting to use the diabetes workshop and materials in the future, (i.e., a group in November 2012). Further, she facilitated a joint grant application between IFH and the WCC.

Questionnaire suitability. The use of the questionnaires designed specifically for this study was not feasible. With the exception of a few direct, quantitative questions, almost all items were difficult for participants to understand and/or queried information gathered elsewhere. Further, several of the open-ended questions were difficult to analyze.

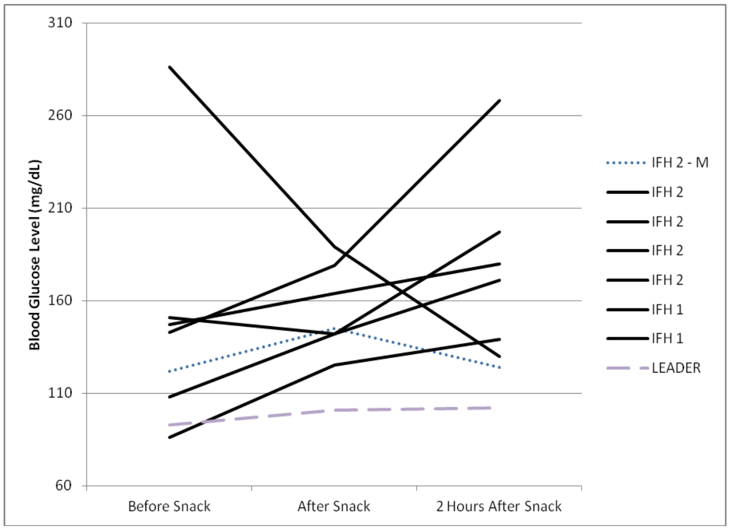
Workshop curriculum. Results regarding curriculum feasibility were mixed, but generally positive. Participants reported enjoying the physical activity and nutrition demonstrations. At least two participants reported trying some of the recipes at home, suggesting that these components of the workshop curriculum are feasible.

The physical activity/blood glucose experiment was not feasible. The goal of the group was to increase participants' blood glucose control self-efficacy by giving them concrete experiences with affecting their blood glucose levels. However, as seen in Figure 4, blood glucose levels conformed to no discernible pattern during the activity. Furthermore, Woodbridge participants helped themselves to a snack in the cool-down period, further muddying results and suggesting that they did not understand the goal of the activity (these data are not included in Figure 4).

At post-treatment the mean score for planning to use skills in the future was 4.46 (*SD* = 0.66), suggesting that participants believed they would be quite likely to use workshop skills in the future. Results were similar at the two-month follow-up visit when the mean score was 4.38 (*SD* = 0.65). Participants reported using workshop skills "quite often" (*M* = 3.92, *SD* = 1.04).

Figure 4

Blood Glucose Levels with Physical Activity



Results from the Patient Satisfaction Questionnaire showed that more than half of participants wanted more information on only one topic: foods to lower blood glucose levels. Qualitative analyses highlighted other topics that needed further attention including, oral medications, the role of stress in diabetes self-management, the effects of fasting/skipping meals, the timing of SMBG, portion sizes and the fact that people with diabetes can and must eat carbohydrates. These topics were consistently brought up in all three groups.

Session transcripts also illuminated several group differences that may have affected the feasibility of the curriculum. Several participants in the groups held in September and October (i.e., the Fall groups) noted the difficulty of having the holidays during the follow-up period. Some noted that they used the skills taught in the group to get back on track after the Holidays. For example, a participant from the Fall IFH group said,

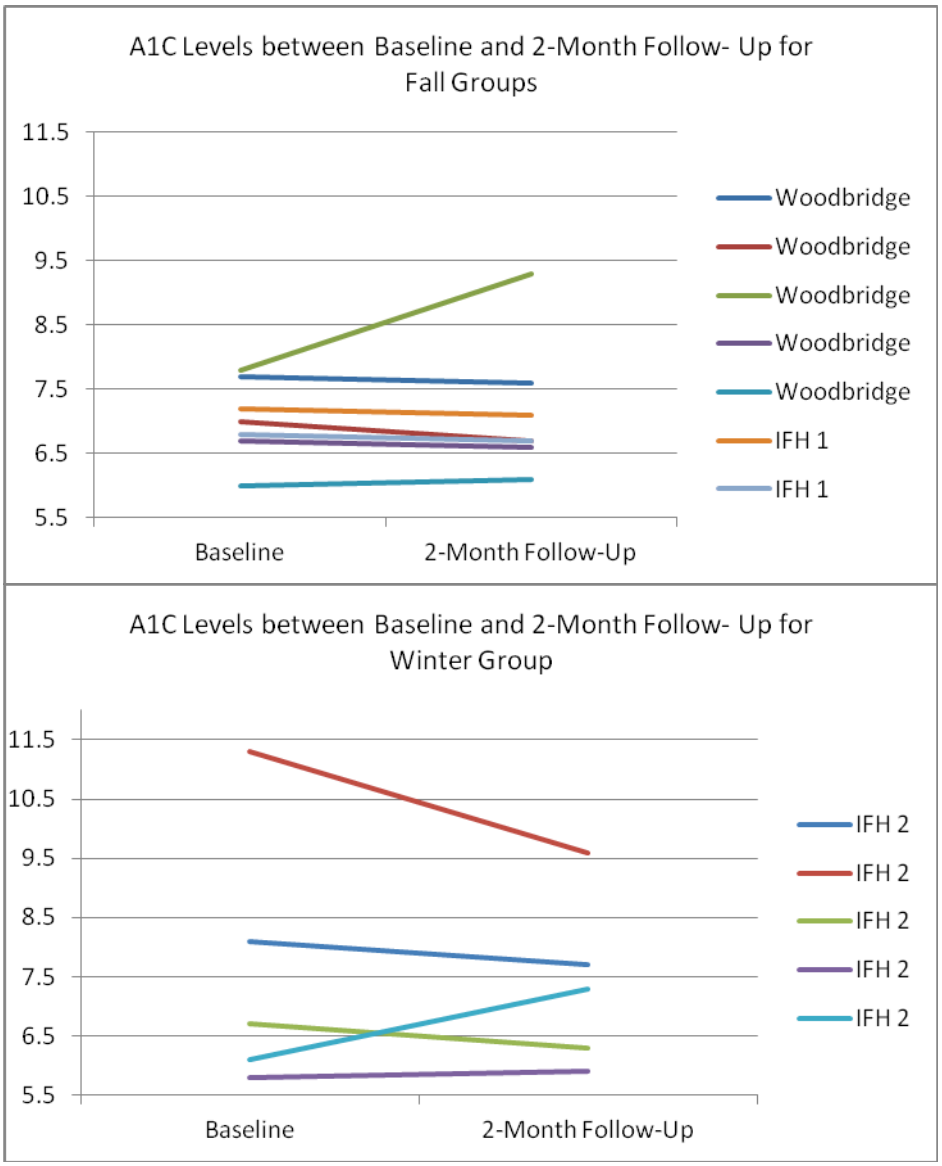
> Because of the holidays…I would eat things I knew I shouldn't be eating. I had in the back of my mind all of these things that I learned so it probably wasn't as bad as it could have been and once the holidays were over and I saw that I started to

> back slide a little bit [via SMBG], I rededicated myself to sticking to the program and saw good results.

This suggests that the workshop was feasible during the holiday season. These comments may also explain why the magnitude of change in the winter group appears larger than in the Fall groups (Figure 5).

Figure 5

Changes in A1C by Time of Year



Another group difference highlighted by session transcripts was that of location. Woodbridge participants were less educated and appeared to have more cognitive deficits than participants at IFH. For example, Woodbridge participants had difficulty understanding the concept of relapse prevention and remembering basic information over the course of the nutrition session. The text of participant speech is shorter in Woodbridge than IFH transcripts. Participants in Woodbridge tended to have less concrete action plans and were less able to alter those action plans on their own than participants at IFH. Additionally, at baseline, only one participant in Woodbridge reporting using SMBG to monitor specific foods or activities whereas all but two IFH participants reported using SMBG experimentally at baseline. These differences may explain why a visual inspection suggests that the magnitude of change is smaller in the Woodbridge group (though it could also be due to time of year as described above).

Session transcripts highlighted two themes that were common across groups. First, many participants described rigid dietary rules. As a result, eating small portions of foods with a high glycemic index was often described as “bad” or “cheating” and was followed by guilt. Several participants described this sort of rigid thinking as leading to the abstinence violation effect in which a small deviation from a plan leads to a “binge.” This suggests that the curriculum’s focus on regular eating is important. This is further supported by the fact that at least three participants reported that lessening dietary restriction reduced craving and made healthy eating easier (as expected by CBT; Fairburn, 2008).

Participants also had different beliefs about will power, which is perhaps best illustrated by the following exchange regarding the difficulty of not eating unhealthy foods in the presence of others indulging:

Participant 1: the only thing that makes me annoyed is that you can eat everything and I can’t have anything.

Participant 2: …you must have self-control, self discipline…you have to have guts
Participant 3: Guts? Where do you get it from?
Participant 2: Inside…
Participant 1: It is like they are tempting you. They are saying, go ahead, go ahead!
Participant 3: [In this class] you made us aware of what would happen if you do certain things and if you don't do certain things. [You let us decide what] we want to do…[I focused] on the things that you can do, how [to] build up self-control…[it helps] if you say, "this is something that you have to decide. You can have it as much as you want."

There is a clear difference in how these participants conceptualize self-control. Participants 1 and 2 believe it is something that one just does, something that comes from "inside." The third participant believes that self-control is necessary, but that it must be cultivated by making conscious, controllable choices (i.e., Participant 3's beliefs match the theoretical stance of the workshop). Visual inspection of the A1C data suggest that the third participant (and others who shared his beliefs) showed larger decreases in A1C than those who did not, suggesting that nuanced beliefs regarding self-control may be associated with better self-management. Further, the belief in "skill power, not will power" (Foster, Makris, & Bailer, 2005) is in line with the behavioral components of the intervention's curriculum as well as with the CSM's focus on understanding and controlling feedback systems by learning how to execute, adjust and evaluate skills.

The group process. Open-ended responses to the Treatment Satisfaction Questionnaire and the 2-Month Follow-Up Questionnaire suggest that participants enjoyed group interactions among themselves and the leaders; for example, one participant said his favorite thing about the workshop was the "good blend of demonstration, conversation and information." Another participant noted that he enjoyed the interactions among group leaders. Group leaders themselves commented on the ease of sharing presentation responsibilities and knowing that if they forgot a point the other leader(s) would step in to ensure that participants received all necessary information.

Session transcripts showed that several participants enjoyed learning how others managed their diabetes. Several also endorsed the desire to participate in support groups for diabetes once the workshop ended. The workshop provided an opportunity for participants at various stages of disease progression to share and compare notes. In this way, the group allowed participants with experience managing diabetes to reflect on and implement effective self-management strategies from the past and allowed novices to learn from the experiences of their peers and to hypothesize about their future health. Transcripts also demonstrated that participants in Woodbridge interacted less with their fellow group members, something which at least two members of the Woodbridge group cited as a program deficit.

The two larger groups (i.e., Woodbridge and the IFH Winter Group) both had individual members who strongly affected the group process. In Woodbridge, the individual participant was a negative influence – not only did he monopolize conversation by discussing his specific problems, even after being asked to hold questions to the end, but his hostile attitude (e.g., loudly leaving the two-month follow-up session) often distracted group members. Nonetheless, by acknowledging his concerns, but not his disruptive behavior, the group leaders were able to minimize his negative impact. Further, other participants used him as an example of the importance of taking control of one's actions during the fourth session.

In the IFH Winter Group the standout participant seemed to have a positive effect as she assumed the role of *de facto* peer leader. This participant spoke in a confident manner that others seemed to respect. Indeed, at the last session, she described meeting a fellow individual with diabetes, sharing information with him and then receiving a call from him a few days later in which he told her that she had "changed his life." Her persuasive style and her tacit and explicit approval of the techniques promoted in the workshop may have increased the face validity of the program for participants in the IFH Winter Group.

Treatment Successes. Post-hoc analyses classified four participants as treatment successes (i.e., they achieved moderate to large decreases in A1C over the course of the study; range: 0.3%-1.7%). Post-hoc qualitative analyses of session transcripts demonstrated that while these four participants shared many traits, these traits were often shared by other participant as well. All treatment successes flexibly applied action plans and reported subsequent changes in diet and/or physical activity, but so did many other participants. Only two treatment successes used SMBG and they varied in time since being diagnosed with diabetes (range: 3 months - 7 years), which was similar to other participants. Successful participants did not differ from most other participants in the number of reported mastery experiences or in-group participation.

The one trait on which treatment successes appeared to differ was self-efficacy – successful participants were more likely to discuss their confidence in diabetes self-management behaviors during sessions. No statistical tests were used to test this hypothesis as the samples are small and the comparisons post-hoc. However, a visual inspection of total self-efficacy scores show that successful participants went from a mean of 7.13 (SD = 1.31) to a mean of 8.10 (SD = 1.43) and that the other participants went from a mean of 6.35 (SD = 1.15) to a mean of 7.52 (SD = 1.00). Thus, the magnitude of change across groups was similar, but successful participants had higher scores of overall self-efficacy at baseline and two-month follow-up. It should be noted that the two participants who had large increases in A1C were not included in the visual inspection as one appeared increasingly cognitively impaired during the course of the study and a comparison to a group of one was deemed to be of little use.

The Common Sense Model. Participants frequently discussed all five illness domains in questionnaires and session transcripts, suggesting that the language of the

CSM is a feasible way to discuss diabetes self-management. The most commonly discussed domains were time lines (e.g., when and how to monitor, how to use/incorporate action plans) and consequences (e.g., participants reported enjoying the pros/cons exercise). These domains were not adequately assessed by the brief IPQ and therefore no follow-up statistical tests were conducted.

Most participants agreed on the causes and cures of diabetes (i.e., diet, exercise, heredity; diet, exercise and medication, respectively), but they differed greatly in their levels of control over the disease, with more successful participants reporting more control. Indeed, while describing what she liked best about the workshop, one successful participant said, “I really feel like I own this diabetes [now], it is mine, it is not the doctor’s, it is mine.” With regards to the identity domain, all participants agreed that they had a disease called diabetes, but they differed in their experiences of symptoms. As measured by the General Health Questionnaire, six participants said they had symptoms of hypoglycemia and five said they had symptoms of hyperglycemia. The symptoms described for hypo- and hyperglycemia were remarkably similar (e.g., dizziness, blurred vision) and transcripts show confusing and contradictory reports of symptoms, even by the same participants.

Discussion

The preliminary data presented above suggest that “An Active Approach to Diabetes” merits further research and that the current intervention is superior to its first iteration. The fact that A1C levels decreased in participants with baseline A1C levels above 6.5% is particularly promising as even modest decreases in A1C are associated with reductions in diabetes-related complications (Stratton, 2000). It should be noted that the workshop appeared particularly unhelpful for two of the three participants with baseline A1C levels below 6.5%. However, results related to these participants may not be generalizable as there were several mitigating circumstances (e.g., cognitive decline, a planned increase in carbohydrate consumption).

The workshop appears to positively affect participants' beliefs about several of the following four factors, which the CSM suggests are necessary for effective diabetes self-management: 1) set points generated by representations of diabetes; 2) procedures or action sequences for removing deviations; 3) the appraisal of the procedures' outcomes; and 4) sensations associated with procedures or action sequences. For example, scores on the brief IPQ suggest that participants' believed they had a better overall understanding of diabetes (factor 1) and better control over diabetes (factor 2) after the workshop. Similarly, participants reported better overall diabetes self-efficacy (which could be related to any factor) as well as increased confidence in their ability to make appropriate food choices (factor 2). Additionally, after the intervention, participants felt more confident about how to respond to out of range blood glucose readings, which suggests that they were better able to respond to and evaluate diabetes-related threats (factors, 1, 2 and 3). Increased confidence in knowing when to visit the doctor also suggests that participants were more confident in how to manage threats after the intervention. These data do not provide definitive proof that the intervention affects illness and treatment representations or that changes in illness and treatment representations affect outcomes (e.g., no tests of mediation were conducted), but they do offer preliminary support.

In addition to affecting self-efficacy and illness and treatment representations, the workshop appeared to improve some of the negative affect associated with diabetes. After the intervention participants reported being less upset by their diabetes, more confident that they could control their diabetes without it interfering in their lives and they showed a trend towards improved social health. These medium to large sized decreases are important as some forms of negative affect have been associated with decreased treatment adherence in patients with type 2 diabetes (Gonzalez et al., 2008), meaning that the current intervention could improve overall adherence to diabetes treatment regimens. Ways in which future workshops can address negative affect are described in subsequent sections.

The trend towards a decrease in BMI over the course of the study is promising and may account for some of the changes in A1C levels. Weight loss was not a primary goal of the intervention, but it is an important goal for patients with diabetes as overweight and obesity increase the risk of diabetes-related complications and weight loss has been shown to improve glycemic control (Pi-Sunyer, 2002). The decrease in BMI in the current study was most likely due to a change in participants' dietary habits as the results demonstrated no changes in physical activity behaviors. There is no simple explanation for the lack of effect on physical activity. It could be due to the fact that the in-session physical activity mastery experience did not have the intended results or the fact that fewer participants were interested in changing their physical activity at baseline. It should be noted that despite null effects on physical activity, the current intervention outperformed its previous iteration in which physical activity significantly decreased at post-treatment.

There are other areas where the workshop appeared to be ineffective. Participants reported no changes in beliefs about diabetes-related symptoms, which is unfortunate as patients who endorse symptoms related to asymptomatic conditions are less likely to adhere to treatment (e.g., Meyer, Leventhal, & Gutmann, 1985). The lack of change in symptomatology is most likely due to insufficient discussion of symptoms during the workshop. Despite a large increase in understanding of diabetes, as measured by the Brief IPQ, scores on the Diabetes Knowledge Questionnaire did not change over the course of the study. The lack of change on this questionnaire is mostly likely due to its poor construction. Both hypotheses are discussed further below.

Overall, there were few differences between completer and intent to treat analyses. However, results must be interpreted with caution due to the nature of rank-based tests and the small sample that made it impossible to assess differences between participants who completed the study and those who did not. Similarly, the statistical analyses used in this study only account for direction of change as opposed to magnitude, therefore, while results suggest that medium to large effect sizes should be used for power and sample size calculations in future work, it may be prudent to power studies for small to medium effects.

Recommended Modifications

The statistical analyses described above provide important preliminary information about the workshop's effectiveness. However, the current study is a pilot test of a novel intervention and as such primacy is not placed on statistical inferences (Thabane et al., 2010). Indeed, all results, especially null results, must be interpreted with caution given the study's small sample size and inadequate power, especially with regards to secondary analyses. The primary goal of this study was to assess the feasibility of methods for an eventual, larger trial. In the next sections I describe several specific changes suggested by the results, including practical and theoretical considerations. As the current intervention was developed within a CBPR framework, all proposed changes will be discussed with community staff members before implementation.

Recruitment. Current methods will need to be modified before the next study to improve recruitment. Designating a staff member as recruitment coordinator and providing clearer instructions for community staff members regarding the importance of recruitment (e.g., highlighting the fact that groups cannot be held if target recruitment numbers are not met) is recommended. Other factors that might improve recruitment include advertising through bulk mailings, partnering with additional health centers, providing childcare for grandchildren and paying individuals for their participation.

Efforts should also be made to recruit more minority participants as diabetes is more prevalent and deadly in these populations (Centers for Disease Control and Prevention, 2011). Many empirical articles on the recruitment and retention of minority participants stress the need for community involvement (e.g., Loftin, Barnett, Bunn, & Sullivan, 2005; Schoenfeld et al., 2000; Yancey, Ortega, & Kumanyika, 2006). The current study had involvement from a community center, but future work should expand recruitment through extra-governmental organizations, for example, by involving community religious and professional leaders (e.g., pastors or physicians who see a number of minority individuals). Face-to-face recruitment strategies are also suggested (Douglas et al., 2011), for example recruiting from places where people congregate (e.g., beauty salons).

Inclusion criteria. The inclusion criteria must be modified in at least two ways. First, participants should be required to meet a minimum A1C cutoff of 7.5%. The use of baseline A1C cutoffs is not uncommon (e.g., Hill-Briggs et al., 2011; Holtrop, Hickner, Dosh, Noel, & Ettenhofer, 2002) and is useful as it reduces interference due to floor effects and provides treatment to participants who are most in need of change (i.e., those who are in poor control of their diabetes). Its use in the current study might have increased power to detect changes in A1C. Second, participants should be evaluated with a brief, validated measure of cognitive function to assess for the presence of cognitive impairment (e.g., the Mini-Mental State Examination Folstein & McHugh, 1975). Indeed, using such a measure to exclude participants in the current study might have mitigated some of the differences between the Woodbridge and IFH groups. In the future, excluding cognitively impaired participants could improve group leaders' ability to effectively teach hypothesized mechanisms of change and will ensure that questionnaire responses provide valid information. If cognitive impairment turns out to be a significant recruitment barrier, an upper age limit could be added or the curriculum could be modified to address cognitive deficits.

Questionnaires. The questionnaires designed specifically for this study should be heavily modified or removed and replaced with existing measures. One general suggestion is to remove many of the open-ended items as they can be queried during sessions and analyzed with session transcripts. Additionally, session transcripts suggest that the inclusion of measures or items addressing dietary restriction, dietary restraint and will power are merited as participants with weak beliefs in these constructs seem to have had larger improvements in A1C. It will also be important to assess CSM domains in more detail than is currently provided by the brief IPQ either by adding questions to the IPQ (standard practice) or by developing other items or measures. At the same time, future studies must limit the overall number of questionnaires and items in order to control for the effects of multiple comparisons and use reasonable sample sizes.

Diabetes Knowledge Questionnaire. This questionnaire should be replaced with an existing measure of diabetes knowledge (e.g., the Diabetes Knowledge Test; Fitzgerald et al., 1998) to allow for easier comparisons with other work.

General Health and Health Behaviors Questionnaire. This questionnaire assessed important information (e.g., how participants tried to control their diabetes). However the open-ended responses made analysis difficult. It is recommended that the items be converted to categorical variables with an open-ended “other” option. It may preferable to use the Summary of Diabetes Self-Care Activities measure (SDSCA; Toobert, Hampson, & Glasgow, 2000), which would allow for easier publication and comparison across studies. If the SDSCA is used, questions regarding self-assessed health, treatment suitability and workshop goals should be assessed elsewhere.

Treatment Satisfaction Questionnaire. With the collection of preliminary data, several of the open-ended items on this questionnaire can be converted to categorical variables with an “other” option; for example answer choices for the question, “Which of the recommendations did you try at home?” would include a list of the skills presented in the workshop (e.g., action plans, SMBG, portion control). Additionally, at least one item regarding factors participants did not like about the workshop should be added.

2-Month Follow-Up Questionnaire. Participants’ responses to this questionnaire suggest that the questions were difficult to understand. Therefore, questions should be re-worded and presented as categorical with an “other” option, which will also aid in data analysis. Updating this questionnaire is especially important as it assesses the implementation of action plans, a hypothesized mechanism of change. Questions should be added regarding how participants make action plans and how they fit action plans into their daily lives.

Participant Satisfaction. Participants were satisfied with the workshop. However, it should be noted that while participant satisfaction may minimize attrition, high participant satisfaction and preference scores are not necessarily correlated with outcomes in primary care or psychological settings (King et al., 2005; Leykin et al., 2007; Phillips, Leventhal, & Leventhal, 2012; Renjilian et al., 2001). Nonetheless, future work on this intervention should continue to assess participant satisfaction and beliefs about treatment suitability in order to confirm its effects on attrition and outcomes.

CBPR. Despite the fact that recruitment in Woodbridge was inadequate, the community-academic partnership was successful in a broader and potentially more important sense. Open discussion of staff disagreements allowed for modifications, for example, the addition of meetings during the recruitment period, and the head staff member in Woodbridge was happy with the results. Further, the submission of a joint grant application and plans for future work demonstrate that both sites are interested in continued collaboration. This collaboration should include further integrating community partners into the research design process, for example, by spending more time discussing how to implement CSM and SCT principles.

Curriculum. The curriculum of the current intervention was based on the hypothesis that enhancing blood glucose control self-efficacy would enhance diabetes self-management. Therefore, all components of the workshop were intended to help participants develop biologically valid illness and treatment representations that would promote effective self-management. The workshop was designed to help participants achieve a coherent model of diabetes and its treatment. Results were mixed and Table 7 describes suggested changes to the curriculum that are addressed in more detail below.

Table 7
Recommended Changes to Curriculum

	Keep	Augment	Add	Remove
Blood Glucose Experiments				
Physical Activity Experiment				x
Blood Glucose Control Activity			x	
CBT Techniques				
Pros/Cons	x			
Problem Solving/Action Plans	x			
Will Power		x		
Dietary Restriction/Restraint		x		
Self-Efficacy	x			
Common Sense Model	x			
Discussion Topics				
Portion Control	x			
Medication			x	
Stress			x	
Patient-Doctor Communication			x	
SMBG		x		

Topics to remove. The physical activity experiment must be removed as the erratic results affirmed participants' models of diabetes in which blood glucose readings do not “make sense.” It is not immediately clear whether and with what to replace the physical activity experiment. On the one hand, several participants described enactive mastery experiences in which getting specific blood glucose readings in relation to specific foods or activities led to large and concrete changes in behavior. Therefore, as hypothesized by the CSM and SCT, first-hand experience with blood glucose fluctuations (e.g., seeing a spike after eating a banana) amended some participants’ common sense models of diabetes to support the belief that blood glucose levels can be controlled with specific behaviors (e.g., by eating smaller portions). As such, it seems important to continue to facilitate these enactive mastery experiences in sessions.

On the other hand, research suggests that testing the effects of physical activity on blood glucose levels may be especially difficult in short time periods as post-exercise glucose metabolism may differ between men and women, with women needing several hours before the effects of physical activity are apparent via SMBG (personal communication with B. Alderman, October, 2011). This can be seen in Figure 4 in which the male participant’s (IFH - M) results more closely align with expected outcomes. Further, the current study demonstrates that using a 1.5 hour follow-up period to see the effects of behaviors is insufficient, meaning that a 2-hour group session may not be long enough to provide participants with blood glucose mastery experiences (it may also explain a portion of the physical activity experiment’s erratic results).

If a new activity is added, it must be tested before the next study. One possible replacement would be to lengthen the nutrition session and to compare blood glucose readings between foods during that session (e.g., between white and wheat pasta). Another possibility would be to give such pre- and post-tests as homework assignments. If the pre- and post-tests were assigned as homework, it would still be necessary to pilot test assignments to ensure compelling and stable results that would engender an enactive mastery experience as opposed to the unreliable outcomes seen in the current study.

Topics to keep. Many participants referenced the pros/cons activity as a useful motivator, suggesting that the activity, and its focus on the consequence domain, should remain in the curriculum. It will also be important to continue to highlight the strategy of briefly acknowledging consequences, but constantly focusing on short-term controllable actions. Several participants reporting using this strategy to achieve change during the workshop and research in progress suggests that it is a strategy used by expert diabetes self-managers. The data also suggest that information about the other CSM domains, especially the timing of monitoring blood glucose and A1C levels, should remain in the curriculum as should information on how to use action plans (e.g., how to create environments in which self-management behaviors are completed effortlessly), portion control (e.g., consuming adequate portions of carbohydrates) and problem solving (e.g., helping participants fit action plans into their daily lives).

All of these topics share a focus on using deliberative action to regulate lower lever, automatic feedback systems. Further, many of these strategies allow participants to assess progress by tracking concrete outcomes over time. This sort of self-monitoring can motivate behavior in and of itself (Korotitsch & Nelson-Gray, 1999) and the CSM suggests that it can be used to modify illness beliefs (Leventhal et al., 2011). In the case of the current intervention, it was hypothesized that using SMBG to monitor concrete behaviors would lead to illness models in which diabetes was perceived as controllable, which would result in increased self-management self-efficacy that would promote and maintain effective self-management behaviors. Comments from several participants support this hypothesis. For example, upon seeing a 0.4% decrease in A1C at the two-month follow-up session, one participant reported that the decrease not only confirmed her belief that she was effectively "controlling" her diabetes with her current self-management behaviors, but that it also motivated her to continue using those behaviors. Another participant used A1C and SMBG tests to confirm the ineffectiveness of her self-management behaviors, which is equally important (a fact that was highlighted to the group).

Topics to add. Information should be added on medication, stress and patient-doctor communication, as described below. It is unclear whether this can achieved without at least one additional session, but it may be possible to introduce mindfulness and relaxation practices to address stress during the physical activity session and to add discussions of medication and patient-doctor communication in the space that is normally used by Dr. Leventhal to answer questions regarding these issues. Another option is to move towards a “guided self-help” format in which participants complete out of session readings on basic topics. This has been used successfully to treat binge eating disorder (Wilson, Wilfley, Agras, & Bryson, 2010) and would cut the time spent on introductory material.

It will be especially important to address medication recommendations as many participants technically adhered to physicians’ recommendations while also taking medications incorrectly. Participants described coherent, but ineffective illness and treatment representations. For example, several participants reported taking Metformin “with food” as prescribed. This is important because Metformin is only effective in the presence of food and for a relatively short period of time (i.e., it must be taken with each meal). However, instead of taking 500 mg with each meal, many participants took 1500 mg with their first meal of the day. This behavior makes “common sense,” follows doctor’s orders to take the pill “with food,” and is ineffective as it does not allow the medication to improve glucose metabolism during the second and third meals of the day. Explaining the underlying mechanisms of Metformin and similar drugs (i.e., that they need to be taken with *each* meal as opposed to with *a* meal) should amend participants incorrect treatment representations, improve their glycemic control and make treatment more cost-effective. This is also a brief intervention that could improve diabetes care in everyday clinical practice.

The data suggest that diabetes-related negative affect decreased over the course of the study, but stress was not directly addressed during sessions due to time constraints. Helping participants manage stress is important as stress produces at least two hormones, adrenaline and cortisol, that reduce glucose uptake in cells and therefore lead to higher blood glucose levels. Additionally, several participants were unaware that stress affects blood glucose levels and reported that acquiring this information helped them make sense of seemingly erratic blood glucose readings (i.e., it made their illness and treatment models more coherent). For example, one participant used this information to test whether a recent high glucose reading at a lacrosse game was due to being given a regular instead of a diet soda (as she initially suspected) or due to lacrosse-associated stress (as she now hypothesized). At the two-month follow-up session she reported that her blood sugar increased every time she watched lacrosse. As a result, she amended her model of diabetes to include lacrosse-related blood glucose spikes. She was unwilling to give up her role as a spectator, but reported that understanding the cause of those blood glucose readings improved her diabetes self-management because she no longer misattributed those high readings to other behaviors.

Most participants agreed that they would like more information on patient-doctor communication. This information can be woven into discussions of other topics (e.g., medication). It will be important for group leaders to directly explain why clear communication with one's physician is important (e.g., medications cannot work if not taken correctly). Group leaders can also ask participants about their communication concerns and use that information to guide discussion.

Topics to augment. Future workshops should increase the emphasis on the dangers of dietary restraint, dietary restriction and will power, especially given the WCC's interest in running groups during Diabetes Awareness Month in November (i.e., the holiday season). For example, it may be necessary to provide a more explicit description of the ways in which dietary restraint can increase the urge to eat unhealthfully and to ask participants to experiment with this hypothesis as a homework assignment. The CSM suggests that patients search to anchor their behaviors in concrete experiences and while it is common knowledge that fasting leads to (short term) weight loss, participants may need personal experience to believe the paradoxical fact that in some cases eating more (i.e., not fasting or heavily restricting) can lead to weight loss. This hypothesis is supported by the experiences of participants who reported being surprised that they had fewer urges to eat unhealthy foods after starting to eat on a regular schedule (i.e., 3 meals and two snacks a day). Further, discussion of this potential homework assignment would provide an opportunity for group leaders to highlight "skill power, not will power" and the idea that only concrete behaviors can affect diabetes outcomes.

Finally, the fact that Woodbridge participants were less familiar with SMBG and appeared to have smaller changes in A1C suggests that a larger focus on SMBG in groups with less SMBG experience may be beneficial. Indeed, while the efficacy of SMBG for patients with type 2 diabetes is unclear, the CSM is considered the theoretical framework that best supports its successful use (Clar et al., 2010; Malanda et al., 2012). Further, by assessing whether and how participants understand and have enactive mastery experiences with SMBG during the workshop, future studies can help confirm that CSM-based SMBG leads to glycemic control. However, any investigation of SMBG must consider the prohibitive cost of monitoring strips. The current study addressed this problem by eliciting strip donations from a community pharmacy, but this does not address the cost for participants who wish to monitor after the cessation of treatment. One solution may be to help participants complete a cost-benefit analysis of SMBG or to help them make a monthly budget that includes an appropriate number of strips. This can also be a topic during discussions of patient-doctor communication as physicians can help ensure that patients receive adequate coverage of strip costs from their health insurance companies.

The group process. Overall, participants and group leaders reported satisfaction with the group process and group leaders in Woodbridge demonstrated their ability to manage difficult situations with CBT-based techniques. In the future, group leaders should emphasize the importance of group discussion during the first session and work hard to facilitate it throughout the workshop, perhaps by promoting problem solving with group discussions about participants' problems as opposed to using preexisting scenarios. This may be especially important as the lack of group discussion among Woodbridge participants most likely decreased the number of vicarious mastery experiences in that group. Group discussions provide participants with an opportunity to test and analyze planning and action and to discuss examples of successful or unsuccessful attempts at self-management. However, the efficacy of these discussions depends upon the content – the CSM suggests that if the content is abstract it is unlikely to lead to action, whereas if the discussion of action plans is concrete and relevant to participants' daily lives it should lead to more effective self-management. In the future, group leaders must guide discussions to ensure that the focus is on concrete behaviors that highlight the importance of using controllable actions to manage diabetes.

Participants' interest in a leaderless support group may present the perfect control condition for future RCTs. More importantly, their comments demonstrate the importance of group members learning from one another (i.e., vicarious mastery experiences) and suggest that it may be beneficial to incorporate peer leaders into the workshop. Not only would this improve dissemination (Becker et al., 2009), but it could improve the program's efficacy as participants in the Winter IFH Group seemed more likely to accept and use information from someone considered a peer (i.e., the *de facto* peer leader). Interestingly, the *de facto* "peer" leader differed from the other group members in several ways; for example, she reported more experience with successful self-management and had been diagnosed for a longer period of time than most. In addition to having already acquired the skills of good diabetes self-management, she was a naturally persuasive speaker who could effectively and succinctly describe her past experiences and how they might be useful in individual participants' daily lives (which is most likely what made her seem like a peer to her group members). However, while she seemed to be viewed as a peer by group members, she was quite different from them and had a natural ability for leadership that would likely need to be taught to future peer leaders.

Fortunately, in-progress research on the CSM and expert diabetes managers suggests that this training will be relatively easy as experts report using many of the four principles highlighted by the current intervention (e.g., the importance of focusing on short term controllable action) to manage their diabetes. In this way CSM peer leaders will act like both a peer (i.e., someone with first-hand and relatable experience managing diabetes) and a leader (i.e., someone with expertise who can present that expertise in a persuasive manner) as opposed to simply being community members providing services free of charge.

The CSM. The CSM appears to be a sufficient method to explain diabetes self-management as almost all participants mentioned the five illness domains and there was a significant and large increase in understanding of diabetes from baseline to two-month follow-up. This is not surprising given the fact that the language of the CSM is the language of many medical encounters (Leventhal, Breland, Mora, & Leventhal, 2010);

however, it is necessary to confirm this hypothesis as there have been few CSM-based interventions. Participants' emphasis on the consequence, control and timeline domains validates the current intervention's promotion of this information in three of the four key skills presented as important for diabetes self-management. As described above, continuing to highlight these domains is recommended, but it may be useful to address the cause domain through out of session readings.

Further investigation of conflicting beliefs about diabetes symptoms (the identity domain) is an area ripe for research. The CSM suggests that individuals constantly search for symptoms to anchor mental models of disease and that patients who believe they have symptoms of an asymptomatic condition (hypertension) are less likely to adhere to treatment (Chen, Tsai, & Lee, 2009; Meyer et al., 1985). Little research describes the efforts of patients with diabetes as they undergo this process and session transcriptions demonstrate the difficulty of attaching symptoms to diabetes, a condition that is mostly asymptomatic, but is symptomatic in cases of extreme hypo- or hyperglycemia and in relation to many complications. For example, many participants described confusion about whether or not they should feel symptoms and others felt that the asymptomatic nature of diabetes made self-management difficult because it was not associated with any concrete changes in somatic sensations (i.e., change "felt" pointless).

The workshop was intended to help participants use SMBG as a substitute for somatic cues in diabetes self-management. However, while participants were willing to use SMBG to learn about diabetes, few were willing to use SMBG as a substitute for sensations. Few reported using SMBG to test the meaning of hypothesized symptoms and few seemed to have amended their beliefs about symptoms by the end of treatment. As a result, most remained frustrated and confused by their incoherent symptom and treatment models. Given that frustration can lead to the cessation of self-management behaviors (Peel et al., 2007), it will be important for future workshops to spend more time discussing the confusing nature of diabetes symptoms and to help participants test any reported symptoms, for example, by assigning symptom tests as homework assignments. In this way group leaders will provide participants with concrete experiences that can amend their illness and treatment models to ones more conducive to effective self-management (e.g., one in which symptoms are considered unreliable cues for self-management behaviors). This may result in even larger changes on item seven of the Diabetes Self-Efficacy scale, which assesses confidence in knowing when changes in diabetes mean visiting the doctor.

Other methodological considerations. CBT techniques proved useful in managing group sessions, describing session agendas and reviewing homework assignments. Future studies would benefit from having a licensed psychologist supervise group leaders to ensure that they effectively implement and codify CBT techniques. This will allow future work to augment the operations manual to include more detail on these techniques and will facilitate the training of new group leaders and the development of treatment fidelity measures.

Self-efficacy also proved to be an important construct as transcripts and questionnaires demonstrate that self-efficacy increased over the course of the study and that the most successful participants appeared to have the highest baseline and two-month follow-up levels of self-efficacy. However, given the short follow-up period of the current study, it is not clear whether these increases in self-efficacy will lead to the long-term mastery of diabetes self-management. Even with an infinitely long follow-up period it would be difficult to assess true diabetes mastery as, from a CSM perspective, mastery represents a seamless integration of the procedural and declarative cognitive processes required for diabetes self-management – something that is difficult to measure in a written format. A more nuanced understanding and assessment of mastery, one that goes beyond rating confidence on a 10-point scale, is needed.

In-progress work related to the CSM and expert diabetes self-managers attempts to tap into this complex process by having participants verbally describe the ways in which they manage their condition. The goal is to use these words to further understand how experts have automated the process of using cues (from start through the performance to the end), actions (again, its pieces from start to end), and outcomes to achieve diabetes mastery. The hope is to then teach these techniques, perhaps by using experts as peer leaders, in future iterations of the workshop. It remains to be seen whether it is feasible to translate the actions of diabetes mastery to words and then back to actions that are relevant to others, but the influence of the *de facto* peer leader in the IFH Winter Group suggests it is possible.

Augmenting the workshop with information from experienced diabetes self-managers, in addition to the other adjustments described above, should result in a greater number of biologically valid, enactive mastery experiences for future participants and the focus on action plans should ensure that participants can translate lessons from those experiences into their daily lives. As a result, all participants, regardless of entry-level self-efficacy scores, should be able to achieve diabetes mastery. Tracking and assessing the process of mastery attainment will be an important area of future work that may include having participants describe management activities before, during and after treatment to see if responses differ in content – more masterful participants' responses should contain descriptions of deliberately controlling automatic processes (e.g., postprandial blood glucose levels) and automating processes that were once deliberate (e.g., physical activity). It is also possible that the expert interviews will demonstrate key areas of diabetes mastery that can be assessed in study participants, for example, speed of SMBG or ease of adapting to new situations. In this way, the workshop can take an “active approach” in helping participants manage their diabetes and in combining some of today’s strongest theories, the CSM and SCT, to break the acquisition of mastery into manageable modules that can be used across conditions by clinicians and patients alike.

Limitations

The primary limitation of the current study was its small sample. Not only did the sample size reduce statistical power to see treatment effects, but the low number of participants recruited from Woodbridge made it impossible to test the CBPR framework as intended. In addition, the small sample most likely contributed to the non-normality of the data, which violated an important assumption of parametric tests and led to the use of non-parametric tests that could only account for the direction of change as opposed to the magnitude of change. Similarly, the small, non-normal sample precluded the use of statistical tests needed to answer questions related to moderators and covariates; for example it was not possible to use a multivariate analysis of variance to assess differences in changes in A1C based on baseline A1C levels (i.e., finding a significant result for A1C in a sub-group of participants with baseline A1C levels above 6.5% does not necessarily demonstrate a true group difference).

Another important limitation was the lack of a control group, which made it impossible to definitively attribute changes in A1C (or other variables) to the intervention and prevented conclusions regarding whether participants with high baseline levels of self-efficacy would have improved without the aid of the intervention. The study also conducted multiple comparisons without using the Bonferroni correction. This technique is recommended for pilot studies (Nakagawa, 2004; Perneger, 1998), but also results in increased Type I. As noted above, future work can address this limitation by limiting the number of test variables. Other limitations include the lack of more formal qualitative analyses, which may have led to incorrect conclusions from session transcripts, and the lack of minority participants, which may hamper the generalizability of results. The use of self-report on most secondary outcomes was also problematic as it may have resulted in data affected by social desirability biases.

The sole reliance on A1C as the primary outcome measure may have been another flaw as demonstrated by the case of a participant from the IFH Winter Group whose A1C increased from 6.1% at baseline to 7.2% at the two-month follow-up. She attributed this clinically significant change to an unplanned increase in stress and a planned increase in carbohydrate consumption. She increased her carbohydrate consumption, in part, on the recommendation of the intervention's physician and RD who were audibly alarmed to learn that she was consuming 30g or less of carbohydrates a day (roughly 90g/day is recommended). She reported successfully increasing her consumption of "good carbs" during the follow-up period and this probably explains her increased A1C level. However, it is unclear whether the increased A1C means she is less healthy than before she started the group – this participant had cardiovascular disease and at least one large trial has demonstrated that aggressively managing A1C levels in adults with cardiovascular disease can be deadly (The Action to Control Cardiovascular Risk in Diabetes Study Group, 2008). Future work must be designed to interpret A1C levels in relation to potential moderators, like comorbidities, not available in this study.

Conclusions

A CSM and SCT based diabetes intervention is feasible and well received by participants and academic and community staff members. Current analyses do not provide strong statistical evidence that the intervention affects A1C levels; however, preliminary results are promising. Future iterations must amend inclusion criteria, questionnaires, sample size and the curriculum as described above in order to further test feasibility and to estimate effect and sample sizes for a larger trial. The results demonstrate that diabetes self-management can be achieved through many different routes – a sole focus on diet, medication or physical activity could be as effective as any combination of the three. Future research must address these multiple pathways by using outcome measures that assess multiple routes and by using methodologies that account for individual differences.

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