

**A MINDFUL APPROACH TO DIABETES SELF-MANAGEMENT EDUCATION WITH
STRESS REDUCTION AND HEALTHY COPING FOR US VETERANS WITH
DIABETES**

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Negative emotional states impact the performance of diabetes self-care behaviors and may jeopardize metabolic control leading to acute and chronic complications. In addition, daily self-care demands commonly result in diabetes-related distress, adding to disease burden. Healthy coping is recognized as being essential to successful diabetes self-management, but little is offered during routine diabetes education to cultivate this key self-care behavioral outcome.

Approximately 40% of the US population uses some form of Complementary and Alternative Medicine. The study of Mindfulness Meditation in chronic health conditions including diabetes is an emerging science. We conducted two pilot studies of Mindfulness in relation to measures of stress and glycemic control in individuals with diabetes who are at increased risk for complications of stress: women and US Veterans.

In a preliminary mixed-methods pilot study of Mindfulness-Based Stress Reduction in six women with type 2 diabetes, two qualitative themes emerged: 1) improved coping, and 2) connecting mind and body. Quantitative analysis showed positive pre-post changes in Mindfulness, perceived stress, diabetes-related distress, and HbA1c that demonstrated moderate to large effect sizes.

A second study of US Veterans with diabetes (n=35) who were recruited from a Diabetes Education program within the Veterans Affairs Healthcare System found a high rate of retention (71%) and satisfaction among participants who received the Mindfulness intervention. Ninety-two percent of Veterans who participated in the 90-minute mindfulness training class and 30-minute booster session plus home Mindfulness practice over a 3-month period would recommend the class to other people with diabetes. Nonparametric repeated measures analysis of variance found significant improvements in diabetes-related distress, and in 3-facets of mindfulness (*observing, describing and acting with awareness*). Pairwise comparisons showed a significant improvement in diabetes self-management behaviors and attainment of goals that correlated positively with measures of diabetes-related coping and negatively with diabetes-related distress. HbA1c decreased significantly from baseline to 3 months ($8.35\% \pm 1.6$; $7.31\% \pm SD 1.22$; $z=-2.154$, $p=.03$; $d=.73$). These findings support the feasibility, acceptability, and possible benefits of a Mindfulness-based program offered as part of routine diabetes education for Veterans with diabetes, and warrant further study.

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PREFACE

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I dedicate this dissertation to my aunt and uncle, Helen Fedullo Malatack and James J. Malatack who instilled me with a love of academic learning, and to my parents Dr. Jean Fedullo Marten and Andrew Marten who inspired me with their work ethic and belief in complementary and alternative approaches to health and well-being.

1.0 ORIGINAL PROPOSAL

There are approximately 17,000 US Veterans with diabetes that receive care through the Veterans Affairs Pittsburgh Healthcare System (VAPHS) representing about 28% of total patients (DeRubertis, 2013). Self-management of diabetes is essential to achieving metabolic control and preventing acute and chronic complications, but negative emotional states can interfere with focused attention and goal-directed behaviors. Research has shown that psychological distress frequently occurs from difficulty coping with the demands of daily self-management and fear of complications (Peyrot, McMurry, & Kruger, 1999). The burden of diabetes-related distress interferes with adherence to DSM behaviors and compromises glycemic control (Fisher, et al. 2010).

Individuals with diabetes commonly experience emotional distress related to diabetes. US Veterans with diabetes are even more vulnerable to negative diabetes-related emotional states given the cumulative nature of stress and high percentage of Veterans who suffer from co-morbid depression and post-traumatic stress (Department of Veterans Affairs, Administration, Health, Program, & Group, 2012).

To address the burden of DSM and issues related to diabetes distress, Healthy Coping has been identified by the American Association of Diabetes Educators (AADE) as one of 7-self-

care behaviors essential to successful diabetes self-management (DSM) (Mulcahy et al., 2003). Yet stress management techniques that cultivate Healthy Coping are not routinely offered as part of Diabetes Self-management Education (DSME) largely due to a scarcity of evidence-based approaches that can be incorporated into usual care. Practical approaches to Healthy Coping through stress management are needed to fill this gap.

1.1 PURPOSE

The primary purpose of this pilot study is to explore the feasibility and acceptability of providing practical training in Mindfulness, an evidence-based stress management therapy, to US Veterans as part of DSME by examining its acceptance by Veterans, Diabetes Educators, and other health care providers, and the number of interested, eligible participants available for recruitment, the engagement of significant-others, systematic barriers and facilitators, and the time and resources needed to recruit, collect and analyze data. Additionally we aim to explore measurement characteristics, relevant correlations and effect sizes that will inform future clinical trials.

1.2 SPECIFIC AIMS

Aim 1: To explore the feasibility and satisfaction of implementing a Mindfulness Stress Reduction In Diabetes Education (Mind-STRIDE) intervention embedded within a routine Diabetes Self-Management Education (DSME) program for US Veterans with diabetes.

Research Question (RQ) 1: Is Mind-STRIDE a feasible and acceptable addition to routine DSME for US Veterans?

Aim 2: To explore the 3-month follow-up effects of Mind-STRIDE on mindfulness, perceived stress, diabetes-related coping, distress, self-management behaviors/goals, and glycemic control in US Veterans.

Research Questions: Will veterans who receive Mind-STRIDE demonstrate:

RQ 2.1: increased mindfulness and diabetes-related coping and decreased perceived stress and diabetes-related distress from baseline to 3-month follow-up?

RQ 2.2: greater attainment of diabetes self-management behaviors and meet more behavioral goals from baseline to 3-month follow-up?

RQ 2.3: a reduction in hemoglobin A1C (Hba1c) from baseline to 3-month follow-up?

Exploratory Aim: To explore the relationship of mindfulness with perceived stress, diabetes-related stress and coping, social support, diabetes self-management behaviors, and glycemic control in US Veterans.

1.3 DEFINITION OF TERMS

Diabetes Self-Management (DSM). DSM behaviors are self-care behaviors related to the general management of diabetes and prevention of acute and chronic complications. DSM is an ongoing process that includes mastery of skills, active problem solving, and risk reduction. DSM generally consists of healthy meal planning with regulation of carbohydrate and fat intake, planning daily activity, controlling body weight, self-monitoring blood glucose, avoiding and treating extreme blood glucose fluctuations, managing medications, and complying with periodic diabetic risk assessments (Mensing et al., 2007). The key to successful DSM is the acquisition of knowledge, psychomotor skills, and effective psychological coping to facilitate lifestyle modifications (Mendoza, Welbeck, & Parikh, 2010).

Diabetes Self-Management Education (DSME). DSME refers to a structured, purposeful program of education, training, and support defined by national standards as:

... the ongoing process of facilitating knowledge, skill, and ability necessary for diabetes self-care. This process incorporates the needs, goals, and life experiences of the person with diabetes and is guided by evidence-based standards. The overall objectives of DSME are to support informed decision-making, self-care behaviors, problem-solving, and active collaboration with the health care team to improve clinical outcomes, health status, and quality of life. (Funnell et al., 2007)

DSME is an interactive, collaborative process in which the learner with diabetes is actively engaged with the diabetes educator and diabetes care team (Mensing, et al., 2007).

AADE-7 Self-Care Behaviors. The American Association of Diabetes Educators (AADE) adopted behavioral change as the outcome of DSME in 2007. AADE-7 behaviors are the core measures of outcome performance geared toward goal-directed behavior change. They include, Healthy Eating, Staying Active, Monitoring, Taking Medications, Problem Solving, Healthy Coping and Risk Reduction.

Mindfulness. Mindfulness is a concept derived from Buddhist philosophy defined as self-regulated attention to the present moment experience with non-judgmental acceptance of one's own thoughts, feelings and sensations (Bishop et al., 2004; Kabat-Zinn, 1990). The practice of Mindfulness is often associated with mental calmness and physical relaxation. The increased awareness fostered by Mindfulness practice can reduce stress reactivity and increase coping ability over time. Mindfulness is cultivated through regular meditation practice.

Mindfulness Based Stress Reduction (MBSR). MBSR is a complementary medical therapy developed by Dr. Jon Kabat-Zinn and his team at the Stress Reduction Clinic and Center for Mindfulness in Medicine, Health Care, and Society of the University Of Massachusetts School Of Medicine. The MBSR program is an eight week program consisting of weekly 2 hour sessions that include group discussion, focused breathing, mindful movement and didactic presentations on stress theory, mindful communications, and awareness training. The program's objective is to help participants isolate and differentiate between thoughts, emotions, and physical sensations in the context of the present moment experience. The program encourages

home mindfulness practice for 40 minutes 6-days per week. MBSR has been scientifically studied in many chronic health conditions since it was developed in the early 1970's.

1.4 BACKGROUND AND SIGNIFICANCE

Metabolic control and prevention of complications depends upon DSM ([Gary, Genkinger, Guallar, Peyrot, & Brancati, 2003](#); [Norris, Lau, Smith, Schmid C.H., & Engelgau, 2002](#); [Panja, Starr, & Colleran, 2005](#)). DSME and care is patient-centered and contingent upon realization of self-management behaviors and goals ([Funnell & Anderson, 2004](#)). Issues with self-concept, diabetes burn-out, conflict with loved ones and health care providers, as well as disease-specific worries about hypoglycemia and chronic complications add to the burden of diabetes self-care ([Peyrot et al., 2005](#); [Polonsky et al., 2005](#)).

DSM itself represents a significant burden in the lives of people with diabetes ([Funnell & Anderson, 2004](#); [Russell, Suh, & Safford, 2005](#)).The management of diabetes is largely implemented by patients with intermittent instruction from health care providers ([Funnell & Anderson, 2004](#)). Appropriate DSM require a considerable amount of time that varies by the severity of disease ([Safford, Russell, Suh, Roman, & Pogach, 2005](#)). Estimates suggest that diabetes self-management requires approximately 2 hours per day to perform ([Russell, et al., 2005](#)). However, a cross-sectional study of 1,482 patients with diabetes found that more than 1/3

of people neglect to perform important elements of DSM ([Safford, et al., 2005](#)), and that men are less vigilant than women in carrying out daily self-care tasks.

1.4.1 Stress Management and Diabetes

The importance of stress management in diabetes control has been recognized ([Surwit et al., 2002](#)). *Healthy Coping* is identified as one of 7-basic Diabetes Self-Care Behaviors ([Mulcahy, et al., 2003](#)); yet, stress reduction strategies central to healthy coping are not routinely offered (Peyrot, et al., 2005). There are few practical evidence-based stress reduction programs that can be provided during routine DSME or care; therefore, usual care often consists of offering informational handouts about stress management to patients who report a high degree of stress. There is a need to incorporate evidence-based stress management programs into routine care to fill this gap.

Complementary and alternative approaches to chronic disease management including mind-body therapies have become an area of growing interest ([Tilburt et al., 2009](#)), but are not commonly used in clinical practice because of a perceived lack of clinical relevance. Previous studies of stress reduction in individuals with diabetes through relaxation techniques with and without biofeedback have had mixed results ([McGinnis, McGrady, Cox, Grower-Dowling, & 2005](#); [Surwit, et al., 2002](#)). Mindfulness-oriented interventions such as yoga, qi gong, and whole systems Ayurveda have been studied in people with diabetes primarily in India, and have shown

positive improvements in glycemic control, but these studies are generally limited by uncontrolled methods and small sample sizes ([DiNardo, 2009](#)).

1.4.2 Mindfulness and Diabetes

Mindfulness Based Stress Reduction (MBSR), has been studied in chronic pain, cancer, rheumatoid arthritis, fibromyalgia, HIV, solid organ transplantation, and psoriasis. More recently, promising findings have emerged in the field of diabetes care ([Whitebird, Kreitzer, & O'Connor, 2009](#)). An observational pilot study of MBSR in T2D (n=14) demonstrated significant decreases in Hba1c (48%, $p=0.03$, $d=0.88$), mean arterial blood pressure (6 mm Hg, $p=0.009$, $d=0.48$), and psychological distress (35%, $p=0.07$, $d=.60$) independent of weight loss, medication changes, or lifestyle modifications from baseline to 1-month follow-up ([Rosenzweig et al., 2007](#)).

In a randomized controlled trial of an Acceptance and Commitment Therapy (ACT) intervention promoting a mindful approach to difficult diabetes-related thoughts and feelings was studied in 81 patients with type 2 diabetes (T2D). Participants that received a 1-day DSME class plus the intervention were more likely to report better DSM ($p=.04$) and have target range Hba1c at 3-month follow-up than patients who received DSME alone ([Gregg & Callaghan, 2007](#)). Pre-post changes in Hba1c were significantly and independently mediated by changes in coping and DSM behaviors ($p < 0.05$).

In a larger 5-year randomized controlled trial (RCT), one-year intention to treat analysis found decreased levels of depression ($d= 0.71$; $p< .01$), improved health status ($d=0.54$; $p=.03$), and diastolic blood pressure ($d=.78$; $p<.01$) in the MBSR group ($n=53$) compared to controls ($n=57$) with per protocol analysis showing greater stress reduction ($d=.64$; $p=.02$) in the MBSR group. The Diabetes and Mindfulness Study (DiaMind), a clinical trial of Mindfulness Based Cognitive Therapy (MBCT), similar to MBSR, in people with T1D and T2D ($n=139$) in the Netherlands, found reductions in emotional distress and increased health-related quality of life. No significant effect on HbA1c or diabetes-related distress was found, although patients in the MBCT group who had higher levels of diabetes distress at baseline showed a decreased trend ($d =.70$, $p=.07$).([van Son et al., 2013](#)).

Clearly, the study of Mindfulness is an emerging scientific field, and its application to healthy coping in persons with diabetes has not been examined. Exploring suitable interventions that incorporate mindfulness into DSME may provide diabetes educators with an important tool for assisting patients to control stress, improve glycemic control, and ultimately decrease modifiable risks for chronic complications. By routinely offering stress management/healthy coping training as part of DSME, patients at risk for psychological distress can be identified and supported. Dissemination of the results from this study may help to support the *Healthy Coping* outcome of AADE-7 Self-Care Behaviors and influence the use of Mindfulness as a stress management strategy throughout the VA system and elsewhere. The goal to incorporate a mindful stress management intervention into DSME for US Veterans and to target healthy coping by using the AADE-7 Self-Care Behavior assessment tool is innovative.

1.4.3 Conceptual Model

The conceptual framework for this study is underpinned by bio-psychosocial stress theory (Bernard & Krupat, 1994; Goldstein & McEwen, 2002; Lazarus & Folkman, 1987; Peyrot, McMurry, & Kruger, 1999; Selye, 1956). The conceptual model (Figure 1) is derived from the Model of Shared Psycho-Biological Pathways (APPENDIX A), which posits that a psychosocial intervention such as Mind-STRIDE can influence psychological (i.e., mindfulness,

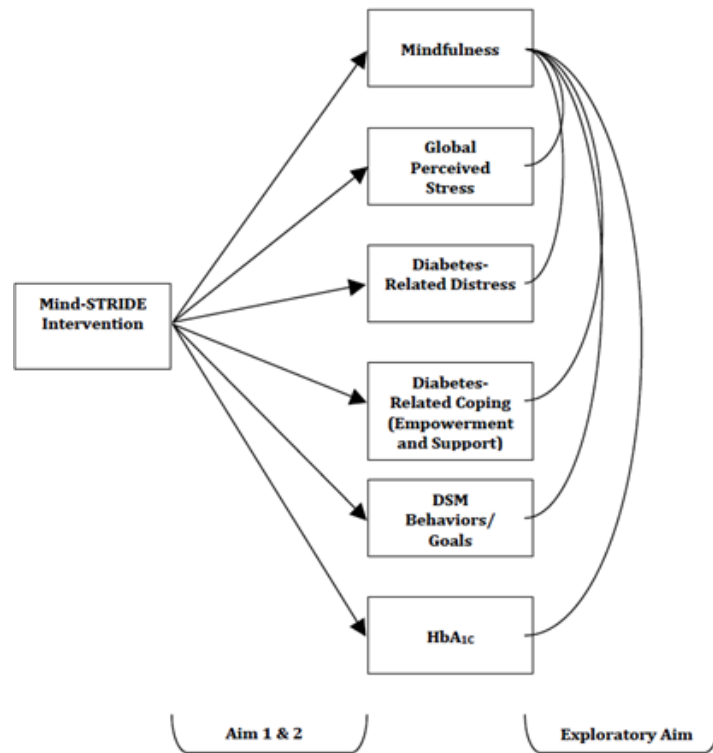


Figure 1. Conceptual Model

healthy coping, and stress reduction), behavioral (i.e., DSM), and biological (i.e., HbA_{1c}) pathways.

1.4.4 Preliminary Studies

This researcher conducted four preliminary studies in preparation for this dissertation proposal. The first paper was a systematic review article of mind-body therapies performed in individuals with diabetes that was published in *Diabetes Spectrum* 2009 (APPENDIX B). This study provided much of the background for the current study. Using the search terms meditation, yoga, relaxation techniques, breathing exercises, diabetes type 1 or type 2, hyperinsulinism, and hemoglobin A, glycosylated, a query of three databases (Medline, CINAHL, and AMED) yielded 12 English language studies performed in adult participants between 1985 and 2007. Of these 12 studies, only one pilot study (Rosenzweig et al., 2007) looked at Mindfulness in persons with diabetes. This literature review helped to identify the gap in knowledge regarding the use of Mindfulness as a treatment strategy for diabetes.

The second study was a survey conducted in 51 US Veterans with T2D from December 2008 to March 2009 at the Veterans Affairs Pittsburgh Healthcare System (VAPHS) Diabetes Clinic. (APPENDIX C). This survey assessed feasibility and Veteran interest in participating in an 8-week MBSR research study at the University Drive (UD) location in Pittsburgh. Of those polled, 31 Veterans (61%) reported having an interest in attending the MBSR program.

Respondents were mainly white (84%; 16% African American) men (98%) over the age of 55 years (78%). Sixty-one percent of respondents requested printed information on stress management; 78% identified location as being a decisive factor for participation in a multiple-session study. Goal of the 31-interested respondents were as follows: general stress reduction (48%); to improve diabetes control (23%); to improve weight and overall health (20%); to improve self-esteem (3%); to learn something new (6%). Twenty respondents had no interest in the proposed MBSR program. Reasons for no interest included: location/lack of transportation (40%); having no stress or controlled stress (45%) or no interest in MBSR (15%). The 9 respondents who stated they had no or controlled stress were all over age 55 years. We concluded from this survey that there is general interest in a stress management program among Veterans with diabetes, but that multiple sessions present a barrier to participation especially for Veterans who have to travel to Pittsburgh. These findings were presented in a poster presentation at the 2009 Eastern Nursing Research Society (ENRS) conference in Providence, RI (APPENDIX D).

The third preliminary study was a prospective observational study of MBSR performed in 2010 that supported the feasibility of conducting an experimental study of MBSR in women with T2D (Manuscript 1). Moderate effect sizes for perceived stress, diabetes related distress and Hba1c were found. Efforts to recruit individuals with T2D from the community who had an interest in and were available to participate in an existing 8-week stress reduction program proved challenging, costly, and did not address diabetes-specific issues, which participants thought would enhance a future program.

The fourth preliminary study was a review of the prevalence and recent findings for use of complementary and alternative medicine (CAM) therapies in diabetes care (APPENDIX E). This systematic review of CAM publications from 2010 to 2012 found that approximately 40% of the adult US population seeks to improve chronic disease management through use of CAM. We concluded from this review that although there have been promising results of CAM therapies reported in individuals with diabetes, more rigorous study is needed.

1.5 RESEARCH DESIGN AND METHODS¹

1.5.1 Research Design

The proposed investigation is a quantitative randomized controlled interventional pilot study with a repeated measures pre-post design.

1.5.2 Setting

The proposed study will be conducted at VAPHS, UD Division. VAPHS is an integrated healthcare system affiliated with the University of Pittsburgh that serves the Veteran

¹The Research Design and Methods were modified for the current study after the original proposal. See Manuscript 2 for the modified research methodology and statistical analysis plan.

population throughout the tri-state area of Pennsylvania, Ohio and West Virginia and consists of 3-divisions: 1) A medical, surgical outpatient primary and tertiary care facility at UD, 2) A behavioral health outpatient and tertiary care facility newly relocated at UD, and 3) H.J. Community living and Veterans recovery center located in Aspinwall PA, a nearby suburb of Pittsburgh. VAPHS also includes 5-community based outpatient clinics (CBOC).

VAPHS provides health care to approximately 17,000 US Veterans with diabetes, 28% of total patients served (Frederick DeRubertis, personal communication, September, 2013). The UD location is the only VA location in the tri-state area that has a Department of Endocrinology and Metabolism. Veterans from the tri-state area of Pennsylvania, Ohio and West Virginia are referred to UD for diabetes care and DSME. The Diabetes Nurse Educator receives approximately 250 DSME referrals annually. Classes are held Tuesday mornings from 9 AM to 12 PM throughout the year in a spacious and comfortable conference room.

The VA DSME program meets national standards and maintains recognition by the America Diabetes Association (ADA) Education Recognition Program (ERP) (Funnell, et al., 2007). The curriculum utilizes elements of AADE-7 Behavioral Guidelines. The Diabetes Nurse Educator and Dietitian Educator teach the class. The conference room is reserved for the purpose of diabetes education for the entire day, and will be available for delivery of the Mind-STRIDE intervention following the DSME class. VA transportation is provided free of charge to all Veterans traveling from the CBOC's and affiliate health centers who wish to take advantage of this service.

1.5.3 Population

VAPHS serves adult male and female Veterans of all races and ethnicities. Demographic data of Veterans from Allegheny County provides a snapshot of a primarily older (76% between ages 45 and 85 years; 41% between ages 65 and 85 years), non-Hispanic white (83%) male (92.4%) population (VETDATA, 2012).

Sample

The target sample of 60 participants, 30 participants per group, will be recruited from Veterans who have been referred for DSME by their VA healthcare providers. Since this is a feasibility pilot study we will not attempt to adjust recruitment quotas for race, gender, or ethnicity, but anticipate that we will have access to a sample population similar to the demographic composition of the general population of the VAPHS.

1.5.4 Sampling Procedures

The diabetes nurse educator will provide information about the study by phone to potential candidates with HbA1c >7% who have been referred for DSME (Appendix F). VAPHS Endocrinology Department requires that an HbA1c be obtained prior to all diabetes management consults and referrals. HbA1c results are available to care providers in the VA Computerized

Patient Record System (CPRS). The lead-time between referral and scheduled attendance in DSME class is approximately 14 days.

Veterans interested in study participation will be asked for their permission for the investigator to call them to provide more information about the study. During this phone call, the researcher will explain the study in greater detail. Potential participants who remain interested will be asked to provide verbal consent for eligibility screening. A waiver of informed consent for phone screening will be obtained as per IRB requirements (Appendix G). Interested eligible candidates will be enrolled when they sign the Informed Consent (Appendix H). After informed consent is obtained, participants will be randomly assigned to the Mind-STRIDE intervention group or DSME alone Control Group. A randomization algorithm will be used for the randomization procedure to two groups stratified by insulin use and partner participation. Group assignment will be determined via sealed envelopes opened in sequence.

Inclusion criteria. Competent male and female Veterans with previous diagnosis of T1D or T2D for at least 6 months, HbA1c >7%, who have been on a stable medication regimen for at least 30 days and have been referred for DMSE meet inclusion criteria. Eligible participants must be able to read, write and understand spoken English.

Exclusion criteria. Veterans are excluded who currently practice some form of Mindfulness such as yoga or meditation, have had documented serious physical or mental illness within the previous 30 days, are unwilling to be randomized to the intervention or control groups, anticipate relocating from the Pittsburgh area within the next 3 months, are deemed incompetent or have cognitive impairment (as documented in the Computerized Patient Record

System, CPRS), or actively abuse alcohol or drugs, or have other physical or mental conditions that may interfere with the ability to comprehend the informed consent and/or actively participate in the study. Pregnant women are also excluded from participation.

Sample Size Justification

A sample size of 26 participants in each group will achieve 80% power to detect an effect size as low as .2 for between and within interaction effects and .34 for between interaction effects for a two way mixed analysis of variance (ANOVA) with α set at .05 (Buchner, Erdfelder, Faul, & Lang, 2009). Correlation power analysis also performed for the exploratory aim determined that a total sample size of 50 will achieve 80% power to detect a moderate difference of -0.45849 between the null hypothesis correlation of 0.0 and the alternative hypothesis correlation of 0.45849 using a two-sided hypothesis test with a significance level of .01. The sample size will be increased by 20% to a total of 30 participants per group for attrition.

1.5.5 Instruments (APPENDIX I)

Demographic questionnaire. This questionnaire includes age, race, and ethnicity, duration of diabetes, marital status, occupation, employment status, and level of education.

Satisfaction. Satisfaction with the Mind-STRIDE class and home practice will be assessed using a 6-item questionnaire on a 5-point Likert scale (“Strongly disagree” to “Strongly Agree”). Sample items are, “This class was interesting and easy to understand.” and “I plan to continue

practicing mindful stress management that I learned in class.” This instrument was adapted from a satisfaction survey previously used for an educational diabetes intervention (Charron-Prochownik, Hannan, Sereika, Becker, & Rogers-Fischl, 2006).

Adherence to home practice. Each participant’s adherence to home mindfulness practice will be assessed as number of weekly home practice sessions performed and the number of home practice diaries completed.

Mindfulness. Mindfulness will be measured by the “5-Facet Mindfulness Questionnaire” (FFMQ), a validated questionnaire consisting of 39 items on a 5-point Likert scale (“Never or very rarely true” to “Very often or always true”) based on a factor analytic study of 5-independently developed mindfulness questionnaires. It measures 5-facets representing elements of mindfulness: *observing*, which refers to noticing or attending to internal and external experiences, such as thoughts, sensations, emotions, sounds, sights, and smells; *describing*, which refers to the ability to describe one’s emotions and feelings; *acting with awareness*, which includes attending to one’s activities in the present moment; *non-judging* of inner experience, which refers to taking a non-evaluative attitude toward thoughts and feelings; and *non-reactivity* to inner experience, which includes allowing thoughts and feelings to come and go, without getting caught up in or carried away by them. Each factor consists of 7 or 8 items. The five facets demonstrated adequate to good internal consistency (α ranging from 0.75 to 0.91) when tested in experienced meditators and non-meditators (Baer, Smith, Hopkins, Krietemeyer, & Toney, 2006).

Global perceived stress. The Perceived Stress Scale (PSS-10) is a 10-item shortened version of the earlier 14-item self-report instrument that provides a global measure of perceived stress in daily life. Items are presented on a 4-point Likert scale (“never” to “very often”). PSS-10 measures frequency of stress feelings during the preceding month, and is a reliable measure of life-events stress measures and social anxiety (Cohen, Kamarck, & Mermelstein, 1983). The Cronbach’s α for the PSS was .84 or .86 and the test-retest reliability was .55 in 6 weeks in previous studies performed in college students.

Diabetes-related distress. “Problem Areas in Diabetes” scale (PAID). The PAID questionnaire comprises 20 items describing common negative feelings associated with having diabetes, e.g. “Feeling scared when you think about living with diabetes?”; “Not having a clear and concrete goal for your diabetes care?” that are answered on a 5-point Likert scale (Not a problem to Serious problem). Item scores are summed to provide a total score of emotional distress, with higher scores denoting greater distress. The PAID scale has high internal reliability (Cronbach’s $\alpha >.90$) and has shown effect sizes between 0.30 and 0.65 across different psychosocial, educational, and medical interventions (Fisher, Glasgow, Mullan, Skaff, & Polonsky, 2008).

Diabetes-related coping. Diabetes-related coping is assessed by 2 measures:

a. “*Diabetes Empowerment Scale Short Form*” (*DES-SF*), a brief overall assessment of diabetes related psychosocial self-efficacy that consists of 9-items on a 5-point Likert scale (“Strongly agree” to “Strongly disagree”) adapted from the original 37 item DES scale. (R. M. Anderson, Funnell, Fitzgerald, & Marrero, 2000). Cronbach’s α of the DES-SF = 0.84 and

content validity are supported in a study of 229 individuals with diabetes who completed a 6-week DSME program (Anderson R.M., Fitzgerald J.T., Gruppen, Funnell, & Oh, 2003),

b.Support Attitudes Sub-scale of the Diabetes Care Profile (DCP), a self-administered questionnaire that assesses social and psychological factors related to diabetes and its treatment. The DCP Support Attitudes Subscale consists of 4 questions: 1 single answer multiple-choice question and 3 other questions, each with 6 sub-questions, on a 5-point Likert scale (“Strongly disagree” to “Strongly agree”). Cronbach’s α for the Support Attitudes Subscale was .69 and .73 demonstrating reliability. The Social Attitudes Subscale significantly ($p \leq .01$) correlated with The Social Provisions Scale ($r=.51$), CES depression scale ($r=-.35$) and the Happiness and Satisfaction scale ($r=.25$) demonstrating concurrent validity (Fitzgerald, Davis, Connell, Funnell, & Hiss, 1996).

DSM behaviors. DSM behaviors measured by 4-items on a 5- point Likert scale (“None of the time” to “All of the time”) also adapted from the DCP (Fitzgerald, et al., 1996) will be used to measure DSM adherence related to diet, activity, self-monitoring of blood glucose, medication use and scheduled contact with health. The DCP is a 234-item 16-scale assessment designed to measure psychosocial factors related to diabetes and its treatment. Reliability and validity of the DCP was tested in US Veterans with T2D recruited from three VA hospitals in the Southwestern US. Cronbach’s α ranged from .63 to .95 in non-Hispanic Whites (n-238). Mean values on the DCP scales were consistent within and across ethnicities lending support for its construct validity.

DSM goals. DSM goals are measured by the AADE-7 Self-Care Behavioral Assessment. Behavioral assessment and of goals met for each of 7-self-care behavioral domains scored on a 10 point Likert scale (Not met to Achieved). This tool was created to assess core measures of outcome performance for DSME and was intended for use in individuals and populations, but to our knowledge this assessment has not previously been used in a research setting, and no psychometric testing has been performed.

Glycemic Control. Glycemic control is measured by HbA1c, an estimate of average glycemic control over the preceding 2 months (Koenig, Peterson, Kilo, & et.al, 1976; Nathan, Singer, Hurxthal, & Goodson, 1984). Normal range HbA1c is 4.5 to 5.7% for non-diabetic individuals. The recommended range for most individuals with diabetes is less than 7%. All HbA1c tests will be obtained by finger-stick by trained staff following standard operating procedures at in the VAPHS Diabetes or Primary Care clinics. National Glycohemoglobin Standardization Program certified methods were followed for the Siemens S025110 DCA Vantage Analyzer using latex immune-agglutination inhibition methodology. Coefficient of Variation (CV) = 2.9 to 5.4% in lay field testing compared to high pressure liquid chromatography (HPLC) performed at a reference laboratory at the University of Missouri Medical Center (Siemens Healthcare Diagnostics, Ltd., UK).

1.5.6 Intervention

We adapted the Mind-STRIDE stress-management protocol from MBSR, (Kabat-Zinn, 1990), the Diabetes ACT Manual (Gregg, Hayes, & Callaghan, 2007), and AADE-7 Self-Care Behaviors (Mulcahy, et al., 2003). This 90-minute intervention will be delivered by this researcher who is a Nurse Practitioner and Certified Diabetes Educator with previous training in MBSR. The Mind-STRIDE intervention will be delivered immediately following the DSME class. The intervention consists of a didactic presentation, group activities and discussion, and 15 minutes of mindfulness practice (APPENDIX J). Mind-STRIDE participants will be instructed to perform 10 minutes of home mindfulness practice 6 days per week, and will be provided with an audio recording to guide their home practice that contained 3 Mindfulness meditations recorded by this researcher. Mind-STRIDE participants will also be provided with paper diary sheets to document the date, duration and a brief description of their experience with each home practice session. The diaries will provide written feedback of subjects' adherence to daily Mindfulness practice. Control group participants will be given the opportunity to receive the Mind-STRIDE intervention following completion of the study. All participants will receive phone calls every 2 weeks to answer questions, to help maintain their engagement in the study, and to remind them of scheduled study visits (APPENDIX K). Mind-STRIDE participants will also receive one 30 minute Mindfulness booster session following the routine 1-month DSME follow-up visit with the dietitian (APPENDIX L). This session will consist of group discussion

regarding home mindfulness practice, a didactic presentation on problem solving, and brief group meditation practice.

1.5.7 Procedures for Data Analysis

Data analysis will be performed using IBM SPSS version 19 Statistical Package (SPSS Inc., Chicago, IL, 2010).

Data Screening Procedures. Analysis will be performed initially to test the effectiveness of the randomization assignment using t-tests (parametric) or Mann-Whitney U (non-parametric) for continuous outcomes and chi square tests for categorical values and percentages to detect significant baseline differences between groups. Significant group differences in gender, BMI, or Hba1c will be used as covariates in mixed effects modeling. All randomized participants will be included in the analysis regardless of follow-up status according to the intention to treat principle (Lachin, 2000).

Normality and Outliers. Data will be checked by proofreading, assessment of range and contingency table assessment before proceeding to formal analysis. Data entry and coding will be rechecked if discrepancies are detected. The data will then be evaluated for extreme or discrepant values first univariately then multivariately. Outliers will be evaluated to determine if they are members of the intended sampled population versus an extreme value of the target population. Dichotomous values with disproportionate split will be considered outliers.

Graphically, histograms, box plots and normality probability plots will be used to help visualize data points that are removed from the rest of the distribution of data. ID number in SPSS will be used to identify aberrant cases. Statistically, cases with Z scores on one or more variables that are >3.29 will be considered potential univariate outliers.

Scatterplots will be used to visualize multivariate outliers, however, scatterplots are of limited value when ≥ 3 variables are looked at simultaneously. Mahalanobis distance will be statistically generated in SPSS using a dummy DV to run the procedure. Outliers will be assessed in each group at each time point.

Once the outliers are identified and on which variable or variables the outlier is discrepant, it will be decided whether to modify the scores or to delete outliers that are discrepant or erroneous. The examination of outliers will also determine to which kinds of cases the results of this study will apply. Outliers that are part of the target population will remain in the analysis and steps will be taken to reduce the impact through transformations.

The underlying assumption of Normality will be assessed by looking at measures of skewness and kurtosis, ideally looking for values close to zero. Measures greater than 3 after being divided by their standard error will be considered generally significant. With the small sample size of this study, an alpha level of .01 will be used to evaluate significance of skewness and kurtosis. The Shapiro-Wilk test will be used to provide further evidence for normality in which a non-significant test statistic indicates that the data are from a normally distributed sample. Graphically, normal and detrended probability plots will be used to observe if data points

fall in a straight line indicating normality. Frequency histograms will also be generated to observe for dispersion of the data.

Linearity, Homoscedasticity Non-additivity, Sphericity and Multicollinearity.

Linearity will be grossly assessed by bivariate scatterplots looking for a desired oval-shaped distribution. Residual plots (standard residuals vs. predicted values) will also be assessed. If nonlinear, variables will be transformed to enhance linearity with the use of dummy variables.

Homoscedasticity. Homoscedasticity will be examined by the Levene test and by Spread and Level plots looking for a desired cluster of the data points around the horizontal line suggesting that the group variance is constant. If homoscedasticity is not found, power transformation of the variables will be considered to stabilize the variance and strengthen the analysis.

Violations of Additivity, an assumption of repeated measures ANOVA, will be assessed by the Tukey test for non-additivity (Huck, 2004). We will transform the data as recommended if the non-additivity test is significant. However, we will not assess for the assumptions of Sphericity and Compound Symmetry because these assumptions do not apply to within group ANOVA having only two levels such as in pre-posttests (Algina & Kesselman, 1997).

If assumptions are not met, data transformations will be performed and compared. Constants may be added if the original distribution contains values less than one; log and square root transformations will be compared. The direction of the skew will be considered in deciding whether to use the transformed data. The decision to use transformed data will include keeping the interpretation as simple as possible for the target audience.

Multicollinearity (for regression analysis). Careful screening for multicollinearity will be performed in SPSS by generating conditioning indices and Tolerance and Variance Inflation Factors (VIF) statistics. Using Belsey et al.'s criteria, a conditioning index greater than 30 for a given dimension in addition to variance proportions greater than .5 for a least 2 variables will be considered suggestive of multicollinearity (Tabachnick & Fidell, 2007). Likewise variables having a VIF greater than .9 will be interpreted as multicollinear suggesting statistical instability and will be dealt with by averaging the collinear variables. Tolerance of 0 (1- the squared multiple correlation of the variable) will be interpreted as having singularity. In this case, the variable will be examined for an obvious source of singularity and will be deleted from the analysis

Homogeneity of Regression Slopes (for ANCOVA). To determine if the slope homogeneity assumption is upheld, we will perform an F-test to test the interaction between pre-test and post-test scores. A non-significant finding will lead us to conclude that the covariates relate similarly to the dependent measure for each group and that ANCOVA is a tenable approach (Huck, 2004). If the result is significant, then we will transform the data and retest the assumption using transformed data. If the assumption remains violated, ANCOVA will not be performed.

Independence of Covariate and Treatments (for ANCOVA). To meet this assumption, we will ensure that all baseline data is collected prior to the delivery of the Mind-STRIDE intervention.

Missing Data. Data will be analyzed for data Missing Completely at Random (MCAR). If data is not MCAR, we will assume it is Missing at Random (MAR) given the voluntary nature of the study. Data decisions will be made to impute missing data using statistical software. (Tabachnick & Fidell, 2007). We will take measures to avoid missing data by reassuring participants that all responses will be confidential and that there are no wrong answers. We will also review all assessments for completeness during the session in which it is collected. We will phone participants every two weeks to help keep them engaged in the study and remind them of scheduled assessment visits.

Data Analysis Procedures for Specific Aim 1

Aim 1: To explore the feasibility and satisfaction of implementing the Mind-STRIDE intervention embedded within a routine (DSME) program for US Veterans with diabetes.

Research Question (RQ) 1: Is Mind-STRIDE a feasible and acceptable addition to routine DSME for US Veterans?

We will explore rate of recruitment and retention of participants. Recruitment rates will be calculated as the percentage of participants recruited from the total number of eligible patients who attended DSME classes at UD during the recruitment period. The percentage of eligible patients who were enrolled in the study will also be computed. Retention will be defined as completion of baseline and 3 month follow-up visits. Adherence to home Mindfulness practice will be measured as the number of home practice diaries completed. Acceptance and satisfaction with the Mind-STRIDE program will be determined by satisfaction scores and participant

comments recorded in the home practice diaries and investigator field notes. Participant family and significant others will be invited to participate, and the number of those who attend will be recorded. Logs will be kept of all necessary resources and expenditures required to conduct the study.

Data Analysis Procedures for Aim 2

Aim 2: To explore the 3-month follow-up effects of Mind-STRIDE on mindfulness; perceived stress, diabetes-related coping and distress, social support and self-management behaviors/goals; and glycemic control in US Veterans with diabetes compared to controls who received DSME alone.

Research Questions: Compared to Controls, will veterans who receive Mind- STRIDE demonstrate:

RQ 2.1: greater mindfulness and diabetes-related coping and decreased perceived stress and diabetes-related distress from baseline to 3-month follow-up?

RQ 2.2: attain greater diabetes self-management behaviors and meet more behavioral goals from baseline to 3-month follow-up?

RQ 2.3: achieve a greater reduction in hemoglobin A1C (HbA1c) from baseline to 3-month follow-up?

General Linear Modeling or Generalized Linear Modeling (nonparametric), will be used for Two Way Mixed ANOVA for Aim 2. Each intermediate variable and (HbA1c), the primary dependent variable, will be analyzed at baseline and at 3-months following the Mind-STRIDE

intervention (the independent variable). Group by time effects will be analyzed to compute point estimates, confidence intervals, and effect sizes for the between group effect (group assignment) and within group effect (time) and for within and between interaction effects. Repeated measures will be used to find the best covariance structure and explore possible correlations.

If significant within group correlations greater than 0.2 are found, repeated measures analysis of covariance (ANCOVA) will be performed to achieve greater power. Covariates will be screened for significant between group differences using t-tests or a non-parametric equivalent, and additional assumptions of ANCOVA will be examined prior to being entered into the model.

Data Analysis Procedures for the Exploratory Aim

Exploratory Aim. To explore the relationship of mindfulness with perceived stress, diabetes-related coping, distress, social support, and self-management behaviors, and glycemic control in US Veterans.

Because of the small sample size exploration of the relationships between all variables is statistically limited. For example, methods that examine co-variation such as path analysis or structural equation modeling (SEM), require larger sample sizes to have statistical stability and are not appropriate for this small pilot study. Therefore, scatter plots will be generated to observe for the magnitude and direction of relationships; and relationships will be quantified using Pearson product moment or Spearman correlations if nonparametric. Linear regression will be performed to estimate correlations and to explain the proportion of variance between variables.

Mind-STRIDE, the independent variable, potential independent covariates (mindfulness, perceived stress, diabetes –related stress and coping, social support and DSM behaviors) and the primary dependent variables (Hba1c) will be explored; then, multivariate regression will be performed to approximate best model fit. Possible moderation and mediation effects of potential covariates on the dependent variables will be explored. Potential moderators will be determined as significant interactions effects in a hierarchical multiple regression model (Baron & Kenny, 1986). To test for mediation, we will perform the Sobel test if requirements for mediation are met and the assumption of normality is not violated (Baron & Kenny, 1986). In cases of non-normality, which is very likely in this small sample, the Bootstrapping method will be used instead (Shrout & Bolger, 2002). We may also test for Moderated Mediation for different groups or levels of continuous moderator variables when appropriate (Mullan, Judd, & Yzerbyt, 2005).

1.5.8 Procedures for data collection

Data will be collected by seven self-report questionnaires and the AADE-7 Self-care Behavioral Assessment completed by the Dietitian:

- The Demographic questionnaire will be completed at baseline.
- The FFMQ, PPS-10, PAID, DES-SF, and Satisfaction questionnaires will be completed at baseline, 1 month, and 3 months.
- The Support Attitudes and DSM behavior questionnaire will be completed at baseline and 3 months.

- AADE-7 Self –behavioral assessment will be completed by the Dietitian during the 1 month and 3 month follow-up visits.

Hba1c values within 1 month of DSME class will be extracted from CPRS. Each participant will be provided with 12-postage-paid pre-addressed envelopes and will be asked to mail in home practice diaries each week, even if they did not make any entries. Hba1c values will be obtained from CPRS within 1-month of the Baseline and 3-month research visits. VAPHS care standards require that Hba1c be obtained every 3 months in patients receiving treatment for diabetes as part of usual care.

Each participant will establish DSM goals during DSME class in collaboration with the Diabetes Nurse Educator. At 1 month and 3 month follow-up, the Dietitian Educator will re-assess DSM goals that were actually attained using the AADE-7 Self-Care Behavior Form. Themes from the goal setting discussions will be documented in field notes.

1.5.9 Study Limitations and Potential Difficulties

This study is limited in the ability to make generalizations because it is a small pilot study being conducted at one site consisting of self-selected participants. Since most of the data will be subjective responses, there is a possibility of bias and assessment effect. Action will be taken to

reduce this risk by reminding participants that their truthful responses on the questionnaires and home practice diaries are important to the quality of the research being conducted.

It is also possible that the study will be limited by missing data from participants who do not complete the study. We will reduce this risk by taking the following actions to improve participant retention in the study: 1) Phone calls will be made to all participants every 2 weeks. If the participant cannot be reached, a message will be left on their answering machine. If they do not have an answering machine a letter will be sent. 2) Participants will be reminded of all upcoming research sessions. 3) Lunch will be provided to all participants between the DSME session and the Mind-STRIDE intervention. 4) All participants will receive an MP-3 player containing an audio recording of the mindfulness home practice exercise. The Mind-STRIDE group will receive the MP-3 player during the Mind-STRIDE session; the Control group will receive the MP-3 player following completion of the study. 5) All participants will receive a ten-dollar check at the end of the study as reimbursement for their time.

Table 1. Time Table for Project Activities

Time after proposal defense	0-20	20- 32	32-48	48-52
Recruitment/data collection	X			
Consult with statistician	X	X	X	X
Data entry/verification	X	X		
Data analysis		X	X	
Preparation of Final Report			X	X

1.5.10 Research Participant Risk and Protection

Eligible candidates over age 18 assented by the diabetes nurse educator will be contacted by phone. The study was explained in detail and phone consent for screening will be obtained from interested candidates. A HIPAA waiver will be requested as required by the VAPHS IRB. Prior to the DSME class, details of the study will be provided to interested eligible candidates in person and all questions were answered. After the study is fully explained, all questions will be answered and informed consent was obtained. Prior to study modification, participants will be randomized to the Mind-STRIDE group or a control group. There will be no restriction of enrollment based on gender, racial group or ethnicity.

The potential risks to research participants in this study will be minimal and include possible discomfort as a result of discussing personal feelings in a group setting, and physical or psychological discomfort from remaining silent and in a still position for 10 to 15 minutes during Mindfulness practice. We will take measures to reduce these risks by protecting participant confidentiality and by de-identifying all data. Electronic data will be stored in a password protected file on the VAPHS network drive. All hard copies will be stored in locked cabinets within a locked study office at VAPHS, UD. We will create a comfortable and safe space for the Mind-STRIDE class and will maintain a non-threatening and reassuring environment. Lastly, we will provide Mind-STRIDE participants with alternative postures and suggestions for relieving

tension and/ or discomfort during mindfulness practice sessions. Findings of the study will be available to all participants after data analysis is completed.

1.5.11 Human Participants

a. Participants in this study will include US Veterans with type 1 or T2D, over age 18 years, with Hba1c > 7%, who have been referred for DSME at VAPHS, UD.

Inclusion criteria: Competent male and female US Veterans with previous diagnosis of diabetes, Hba1c > 7%, who have been on a stable medication regimen for at least 30 days and have been referred for DMSE. Eligible participants must be able to read, write and understand spoken English.

Exclusion criteria: Veterans who currently practice some form of Mindfulness such as yoga or meditation, have had a documented history of serious physical or mental illness in the past 30 days, are unwilling to be randomized, are pregnant or actively trying to get pregnant, or anticipate relocating from the Pittsburgh area within the next 3 months, have CPRS-documented incompetence, cognitive impairment or alcohol or drug use that could potentially have interfere with the ability to comprehend the informed consent and/or actively participate in the study.

b. The collected data will be used for research purposes. These data include self-report questionnaires and home practice diaries. Demographic data will be collected from the computerized patient record that will included age, race, and ethnicity, duration of diabetes,

marital status, occupation, and employment status. HbA1c results performed within 1 month of baseline and 3-month follow-up visits will be collected from CPRS.

c. It is possible that the study will be limited by missing data from participants who do not complete the study or study questionnaires. We will take the following actions to improve participant retention in the study: 1) Phone calls will be made to participants every 2 weeks. If the participant is not reached, a message will be left on their answering machine. If they do not have an answering machine, a letter will be sent. 2) Participants will be reminded of all upcoming research visits. 3) Lunch will be provided to all participants between the DSME session and the Mind-STRIDE intervention. 4) Participants will receive equipment necessary to listen to the home practice audio recording. 5) All participants will receive a ten-dollar check after completion of each research visit as reimbursement for their time.

d. The potential risks to research participants in this study are minimal and include possible breach of confidentiality, discomfort discussing personal feelings in a group setting, and physical or psychological discomfort from remaining silent and in a still position for 10 to 15 minutes during mindfulness practice.

e. We will take measures to reduce these risks by protecting participant confidentiality and by de-identifying all data. Electronic data will be stored in a password protected file on the VAPHS network drive. All hard copies will be stored in locked cabinets within a locked study office at VAPHS, UD. We will create a comfortable and safe space for the Mind-STRIDE class and will maintain a non-threatening and reassuring environment. Lastly, we will provide Mind-

STRIDE participants with alternative postures and suggestions for relieving tension and, or discomfort during mindfulness practice sessions.

f. This is a minimal risk study. The time commitment for the Mind-STRIDE group will be approximately 2.5 hours on-site at VAPHS UD plus 10 minutes of home mindfulness practice 6-days per week for 12 weeks, equaling an additional 12 hours for a total of 14.5 hours over a 3-month period. The time commitment for Control participants will be approximately 1.5 hours over the same time period. The benefit of study participation for Mind-STRIDE participants will be to receive information on a stress management technique that may help them perceive less stress and improve coping and DSM skills. The benefit for all participants will be that their participation in this study will result in information pertinent to finding new strategies for stress management as part of routine DSME. Complementary mind-body therapies have the potential of providing cost effective, non-pharmacologic options for reducing diabetes-related stress and improving glycemic control. This study will offer a low risk approach to investigating the benefits of Mindfulness, a mind-body modality that has shown promise in chronic disease management including diabetes.

2.0 SUMMARY OF THE STUDY

The current feasibility pilot study was conducted at VAPHS University Drive division, from September 1, 2012 to June 1, 2013 to explore the addition of a Mindfulness stress management component embedded within routine DSME to facilitate Healthy Copy, one of 7-key self-care behavioral outcomes. We developed a MINDful STRess Reduction In Diabetes Education program called Mind-STRIDE, loosely based on MBSR and the ACT Manual for Diabetes Self-management that incorporated practical stress-management training instruction into routine DSME offered to US Veterans at VAPHS.

A small observational feasibility pilot study (Manuscript 1) was conducted in 6-women who participated in an 8-week community MBSR program in preparation for development of the Mind-STRIDE intervention and current pilot study. The preliminary pilot study informed the current study by supporting the acceptance of Mindfulness in higher-risk individuals with diabetes, and highlighted the importance of creating a diabetes-specific intervention. The results of this preliminary pilot study also provided effect size estimates that informed sample size calculations and power analysis, and helped to delineate outcome measures and the research setting requirements for the present Veterans' study.

In preparation for the current study, this primary investigator conducted a Veterans' survey (APPENDIX D), participated in a community MBSR program, and attended a week-long MBSR teacher training at the Omega Institute in Rhinebeck NY taught by Dr. Jon Kabat-Zinn and Dr. Saki Santorelli, the originators of MBSR from the University of Massachusetts Medical School.

Following approval of the original proposal, the content validity of the Mind-STRIDE intervention was corroborated by a clinical psychologist, who is also an experienced MBSR teacher and practitioner. Audio taped practice sessions were held at the UPMC Center for Integrative Medicine to ensure proficiency in presenting the material in an authentic and cogent manner. To ensure fidelity of the intervention, Mind-STRIDE sessions were audio taped and evaluated by a member of the research team to ensure that essential talking points and mindfulness practice segments were consistently presented. This researcher also prepared audio recordings to guide participants with home practice. The recording includes voice-overs for three different mindfulness practices, *Mindful Breathing/Body Scan*, *Mindful Movement*, and *Three-Minute Breathing Space*.

There was a 6-month delay in the start of the study because of lengthy review by the VA Institutional Review Board (IRB). (IRB documents appear in APPENDIX M). Although the study had been accepted for expedited review, institution-specific procedures and information security issues created the need for multiple revisions; for example, the information security officer prohibited the provision of MP-3 players to study participants, and a modification to use read-only computerized disks was finally approved. In addition, scanning of study questionnaires that had been formatted as "teleforms" to ensure data entry accuracy was not permitted off-site,

and since the VA did not have scanning capabilities, further protocol modifications were required. The IRB approved the original proposal in August of 2012. The research team was oriented and the first participants were enrolled in September, 2012.

Initially recruitment was slow. There was a limited number of Veterans who met inclusion criteria, and there was poor class attendance, sometimes resulting in class cancellations. Several DSME classes were cancelled between November 2012 and January 2013 during the holiday season, further adding to recruitment problems. DSME class enrollment for each class had typically been open to ten Veterans, but it was not uncommon for just two or three of those who were registered to show-up. In an effort to increase class attendance, class registration was eventually increased to thirteen per class, which improved class size somewhat.

2.1 STUDY MODIFICATION

Shortly after the study started, VAPHS initiated a program to deliver DSME via Computerized Video Teleconferencing from the UD Division to outlying CBOC's. As a result of this initiative, the number of monthly DSME classes held at University Drive was decreased by 50%. Since Veterans who received DSME via video teleconferencing represent a different condition, and were not eligible for recruitment, the study was modified to a one group quasi-experimental repeated measures design by consensus of the dissertation committee. We had considered adding a non-participant comparison group of Veterans who completed DSME at University

Drive during the previous 6-months; however, we were apprised by the VA IRB that the approval process for this chart review would likely take more than 6-months. Since the only outcome variable available for comparison from this chart review would have been HbA1c, which was not the primary outcome, we decided not to pursue a comparison group for the purposes of this feasibility study. The VA IRB granted approval for the revised specific aims and protocol in April of 2013. The modified research design and methods and findings are detailed in the Results Manuscript (Manuscript 2).

3.0 MANUSCRIPT # 1

Exploring Mindfulness Based Stress Reduction in Women with Type 2 Diabetes: A mixed methods pilot study

3.1 ABSTRACT

The purpose of this study is to explore the feasibility of introducing Mindfulness Based Stress Reduction (MBSR) as means of controlling stress and cultivating coping skills in women with type 2 diabetes (T2D). Healthy coping is identified as a key behavior of successful diabetes self-management, yet stress reduction strategies central to healthy coping are not routinely offered during routine diabetes self-management education. Research has linked psychological stress with higher diabetes risks in women than men, indicating need to explore effective stress management tactics for women with diabetes.

In this mixed-methods pilot study, we explored the feasibility of offering MBSR, an 8-week psycho-educational program, to women with T2DM. Dispositional mindfulness (MAAS),

perceived stress (PSS), diabetes-related stress (PAID), quality (PSQI and metabolic control (A1C; lipids) were measured pre, post and 1-month following a standard 8-week MBSR intervention. Qualitative data were gathered by structured interviews and analyzed by concept analysis.

All participants stated they would recommend MBSR to others with diabetes, and 5/6 participants (83%) intended to continue mindfulness practice in their daily lives. Three qualitative themes emerged: 1) improved coping, and 2) connecting mind and body. Quantitative analysis showed positive pre-post changes in mindfulness, perceived stress, diabetes-related stress, and Hba1c that demonstrated moderate effect sizes and were sustained at 1-month except for Hba1c. These findings support feasibility and acceptability of providing MBSR to women with T2D and suggest possible benefits that warrant further study.

3.2 INTRODUCTION

Daily self-management can be a source of stress for millions of people living with diabetes. Healthy coping is one of 7-behaviors identified as being essential to diabetes self-care. A key to healthy coping is a person's ability to manage their response to stress in order to be more aware, balanced, and able to solve problems more effectively. Yet stress reduction strategies that cultivate healthy coping are not generally offered during routine diabetes education and care.

Previous studies associating psychological stress and diabetes risk have consistently shown a higher correlation in women than in men (Heraclides, Chandola, Witte, & Brunner, 2012; Meisinger et al., 2002). Furthermore, there are gender differences in mortality, morbidity and psychological well-being in women who have diabetes compared to men (Auryan & Itamar, 2008). Women with diabetes have a higher risk of adverse outcomes from cardiovascular events compared to men with diabetes and women who do not have diabetes (Travani, Bertuzzi, Gallus, Negri, & LaVecchia, 2002), suggesting that DSM and metabolic control may be especially important for women.

It is known that the presence of diabetes doubles the odds of co-morbid depression (R. J. Anderson, Freedland, Clouse, & Lustman, 2001) and the risk may be greater in women. Analysis of data on 1,810 adults with diabetes from the 1999 National Health Interview Survey (NHIS) showed that female gender is an independent risk factor for major depression and is correlated with poorer metabolic control in younger women (Egede & Zheng, 2003). During pregnancy and up to one year following childbirth, women with diabetes are twice as likely to be diagnosed with or treated for depression compared with pregnant women who do not have diabetes (Kozhimannil, Pereira, & Harlow, 2009).

In a study of 280 adults with type 1 diabetes (T1DM) women were found to use significantly less active coping mechanisms than men, report more depressive symptoms, and have poorer psychological adjustment to diabetes (Enzlin, Mathieu, & Demyttenaere, 2002). Depression in persons with diabetes can be two-fold, whereby depression and diabetes-related distress may coexist (Fisher et al., 2010). Studies have shown that diabetes-related distress is

positively correlated with HbA1c and is an independent and major contributor to poor DSM adherence in women who take insulin (Polonsky et al., 1995).

Finally, there is evidence that although stress management interventions may improve psychological well-being, findings related to glycemic control have been inconsistent (DiNardo, 2009; McGinnis, et al., 2005; Surwit, et al., 2002). Mindfulness Based Stress Reduction (MBSR) has shown early evidence of positive results in patients with type 2 diabetes (Hartmann et al., 2012; Rosenzweig et al., 2010; Rosenzweig, et al., 2007; Teixeira, 2010; van Son, et al., 2013). There are few evidence-based stress reduction training programs available, therefore usual care currently consists of providing informational handouts.

The purpose of this study is to explore the feasibility of offering MBSR, an 8-week psycho-education program of mindfulness training, to women with T2D as a means of decreasing perceived and diabetes-related stress and improving metabolic control.

3.3 METHODS

This study is a prospective mixed-methods feasibility pilot of MBSR in community women volunteers with T2D. The University of Pittsburgh Institutional Review Board granted approval, and informed consent was obtained from participants.

3.3.1 Mindfulness Intervention

The MBSR program closely followed the curriculum developed at the Stress Reduction Clinic and the Center for Mindfulness in Medicine, Health Care, and Society of the University Of Massachusetts Medical School. The MBSR program consisted of 8 weekly 2-hour sessions that includes group discussion, focused breathing, mindful movement and didactic presentations on stress theory, mindful communications, and awareness training. The program's objective was to help the participant to isolate and differentiate between thoughts, emotions, and physical sensations in the context of the present moment experience. The program also encouraged home mindfulness practice 40 minutes 6 days per week.

Two trained and experienced MBSR teachers (a psychologist and a licensed clinical social worker) delivered the intervention separately to different groups according to the standard MBSR curriculum. Adherence to the MBSR program was measured by class attendance and completion of daily home practice log sheets that documented the date, duration and felt-experience of home practice. Participants were instructed to return the log sheets to the researchers via mail or email each week during the duration of the study regardless of whether daily entries were completed.

3.3.2 Measures

Quantitative outcomes included subjective and biological data. Subjective measures included the Perceived Stress Scale (PSS-10) (Cohen, et al., 1983), Problem Areas in Diabetes Scale (PAID) (Fisher, et al., 2008) and the Mindfulness Attention Awareness Scale (MAAS) (Brown & Ryan, 2003). Biological measures included blood pressure, Body Mass Index (BMI), fasting blood glucose, lipids panel, and Hba1c. Laboratory values were obtained by finger-stick in a certified lab at the University of Pittsburgh School of Nursing using Bayer A1C+ Now™ assay and Cholestech LDX™ Lipid + Glu cassettes.

3.3.3 Analysis

Descriptive statistics were used to analyze baseline data that included demographic and general health information. Data were analyzed using SPSS (v19.0. Armonk, NY: IBM Corp.) Quantitative outcomes were measured pre-post and 1-month follow-up and are described as mean change and effect size. Because of the small sample size, parametric analysis was not possible. Change scores were used to calculate group by time effects. Qualitative data were gathered through home practice diaries and semi- structured interviews conducted at the follow-up visit. Qualitative data were coded and categorized using constant comparative method (Strauss & Corbin, 1998).

3.4 RESULTS

3.4.1 Participant Characteristics

Six (43%) of 14-screened candidates were enrolled in the study; eight eligible candidates chose not to participate due to time conflicts with the MBSR class schedule. All 6 participants completed the 12-week study. At baseline, mean age was 55.7 years (range=42-69), A1C was 6.9% (range=6.0-8.7%), and duration of diabetes was 4.9 years (range=2–10). Participants were primarily Caucasian (86%), college educated (71.4%), had multiple co-morbid conditions (>4; 86%); 4 participants had prior interest in mind-body therapies, i.e. yoga, meditation (57%), but none had previous MBSR experience.

3.4.2 Adherence to Mindfulness Practice

Participants attended an average of 6 weekly group sessions (range= 3-8 sessions); 4 participants attended 100% of sessions. One participant hospitalized for complications of an unrelated chronic illness during the course of the study missed several classes, but completed the study. 100% of participants maintained daily home practice diaries. One month following the

intervention, 2 participants continued to submit home practice diaries. 83% (5) participants completed 1-month follow-up. One participant stated she was not able to complete the follow-up visit due to personal reasons.

3.4.3 Quantitative Results

Pre-post changes in the hypothesized direction were observed. There were small to large effect sizes between the MBSR intervention and mindfulness ($d=.28$), perceived stress ($d=.95$), diabetes related distress ($d=.35$), and A1C ($d=.4$) that were sustained or increased at 1 month follow up except for A1C (Table 1). Group-by-time effects showed trends in positive directions for mindfulness, perceived stress, and diabetes-related distress (Figure 2). However, negative trends were observed for Hba1c ($d= .4$) and sleep quality ($d=.2$) from post-intervention at 1 month follow-up (Figure 3).

3.4.4 Qualitative Results

Five women who completed the 1 month follow-up visit were highly satisfied with the program, planned to continue using the techniques they learned, and would recommend it to other persons with and without diabetes. Four women reported greater awareness in their daily lives as a result of attending the program. Two concepts emerged from the qualitative data regarding the MBSR

intervention: 1) Improved coping, and 2) Connecting mind and body. Participant statements that support these concepts appear in Table 2.

3.5 DISCUSSION

Stress affects metabolic control in people with T2D through the interplay of physiologic and behavioral mechanisms. Increased psychological stress places women at particularly increased risk for diabetes related distress and complications. Healthy coping is an important diabetes self-management behavior that may help mitigate the adverse effects of stress in women with diabetes. This mixed-methods pilot study suggests that MBSR is a feasible and potentially beneficial integrative therapy for women with T2D.

Our finding that MBSR results in improved psychological coping among persons with T2D is consistent with other studies in patients with diabetes (Hartmann, et al., 2012; Rosenzweig, et al., 2007; Teixeira, 2010). Minimal effective MBSR dose has been a matter of interest, as researchers and clinicians seek to provide brief interventions to patients who may not have the availability to attend the traditional 8-week session programs (Klatt, Buckworth, & Malarkey, 2009). Expert opinion has posited that at least 3 sessions are required for efficacious effects. However, a 2007 randomized controlled trial of 81 patients with Type 2 Diabetes (T2D) found that subjects who received a 1-day acceptance and mindfulness intervention based on

Acceptance and Commitment Therapy (ACT) plus usual DSME were more likely to report better DSM ($p=.04$) and have target-range HbA1c at 3 month follow-up ($p< .001$) than participants who received DSME alone (Gregg & Callaghan, 2007). In this study, pre-post changes in HbA1c were significantly and independently mediated by changes in coping and DSM behaviors ($p < .05$). Mindfulness meditation instruction or practice was not included in this intervention.

Despite research supporting the general health benefits of complementary and alternative therapies, integrative mind-body therapies such as MBSR are seldom used in clinical practice because of a perceived lack of clinical relevance. Therefore, further clinical studies demonstrating the feasibility of incorporating evidence-based mind-body therapies into routine diabetes education and care are important.

Although this study is limited by small self-selected sample size that precludes causal inference, qualitative and quantitative results suggest that MBSR is positively received and may benefit women with T2D. All women participants completed the MBSR program. Several women continued daily MBSR practice even after the study's conclusion. Participants unanimously agreed that MBSR was helpful, and that they would recommend the MBSR training to friends and acquaintances with and without diabetes.

Women who self-selected to participate in this study had multiple co-morbid conditions, suggesting that women with more complicated health histories may be more apt to seek and participate in complementary health therapies. In fact, many of the women participants reported having had a special interest in mind-body modalities prior to participation in the study.

Women in this study found that MBSR improved their capacity for coping. Two women were to “breathe-through” neuropathic discomfort possibly by attaching less suffering to the perception of pain. (*“I know it’s still there, but it seems easier to tolerate”*). This is consistent with previous long term studies in chronic pain (Kabat-Zinn, Lipworth, Burney, & Sellers, 1987) that have shown sustained benefits of MBSR that varied according to disease specific conditions and amounts of home practice (Rosenzweig, et al., 2010).

The negative impact of stress in diabetes calls for practical, structured therapies to enhance healthy coping that can be routinely provided as an adjunct to usual DSME and care. MBSR and other mindfulness therapies may help to improve DSME and the ability to cope with the chronic demands and stress of the disease. MBSR presents a structured mind-body approach to chronic disease management that can be integrated into diabetes care and may help to improve psycho-biological and behavioral outcomes.

3.5.1 Conclusion

In conclusion, the findings of this mixed-methods pilot study support the feasibility and acceptability of studying MBSR in women with T2D. Further study of MBSR and its relationship to coping is warranted in a larger, more diverse sample of women and other groups at risk for stress-related complications.

Table 2. Quantitative Results and Mean Change

Variable	Measure	Pre to post $\Delta \pm SD$	<i>d</i>	Pre- follow-up $\Delta \pm SD$	<i>d</i>
Mindfulness	MAAS	3.5 ± 14.1	.28	7.5 ± 17.3	.58
Perceived Stress	PSS-10	3.7 ± 3.4	.95	2.8 ± 4.3	.72
Diabetes-related Distress	PAID	7.3 ± 15.1	.35	11.9 ± 14	.69
Sleep quality	PQSI	.33 ± 16	-.07	1.2 ± .98	-.22
Glycemic Control	Hba1c	.37 ± .58	.40	-.73 ± 2.3	-.40

d (.2=small effect; .5=moderate effect; .8=large effect)
MAAS = Mindfulness Awareness and Awareness Scale
PSS-10= Perceived Stress Scale 10-item
PAID= Problem Areas in Diabetes Scale
PQSI= Pittsburgh Quality Sleep Index

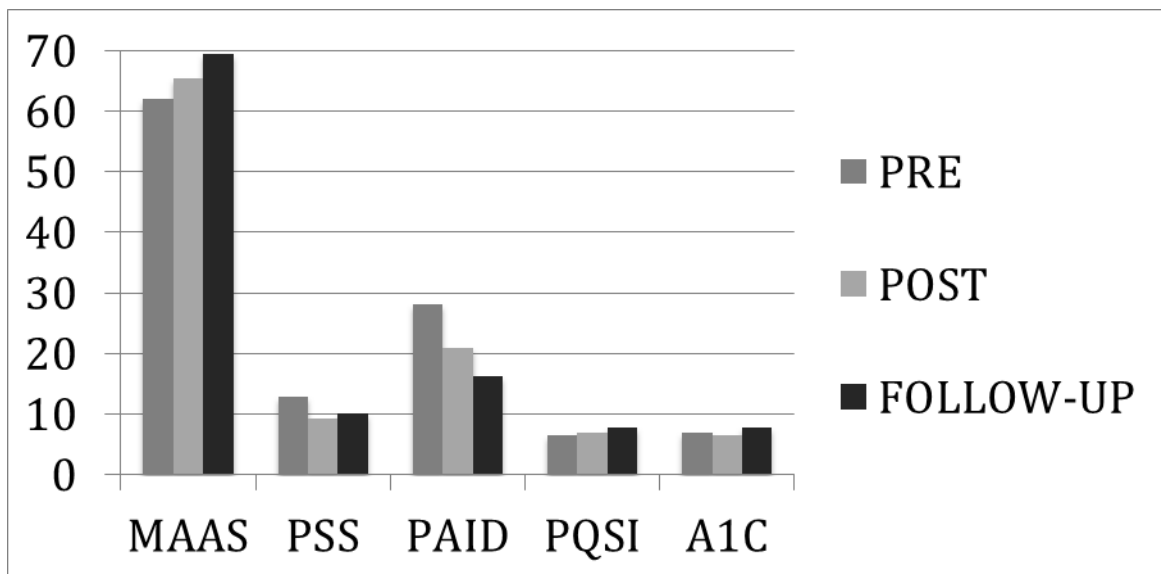


Figure 2. Group by Time Effects

Table 3. Qualitative Comments and Statements

Concept	Representative Statement
Coping	<p>“...more confident ...” “easier to cope”</p> <p>“...lowered my reaction to things...”</p> <p>“...it makes it easier to calm down and deal with aggravation and pain of diabetes...”</p>
Connecting mind and body	<p>“...able to visualize what is going on internally...”</p> <p>“...motivated me to exercise and take better care of myself.”</p> <p>“...I can now ‘breathe through’ my neuropathic pain”</p>

4.0 MANUSCRIPT # 2

A Mindful Approach to Diabetes Self-Management Education with Stress Reduction and Healthy Coping for US Veterans with Diabetes

4.1 ABSTRACT

Daily stressors of diabetes self-management (DSM) present ongoing challenges to individuals with diabetes. Healthy Coping has been identified one of seven key diabetes self-care behaviors; yet, stress reduction strategies central to healthy coping are not routinely offered, and few evidence-based strategies exist. There has been growing interest in mindful approaches to diabetes care. We explored the effects of a psycho-educational mindfulness-intervention with home practice on diabetes related coping, distress, self-management behaviors/goals, and glycemic control in US veterans.

Veterans with diabetes (N=35) were recruited from a recognized Diabetes Education program within the Veterans Affairs Healthcare System. Psycho-behavioral and glycemic outcomes were explored in participants who received diabetes education that included the

mindfulness intervention. Outcome variables were measured at baseline, 1-month and 3-month follow-up. A recruitment rate of 62.5% was observed with retention of 71% of participants; 92% of participants agreed or strongly agreed that they would recommend a Mindfulness class to other persons with diabetes. At 3-months, significant inverse correlations were found for diabetes-related distress and 3 facets of mindfulness: acting with awareness ($r_s = -.539$; $p < .01$), non-judgment ($r_s = -.534$, $p < .01$), and non-reactivity ($r_s = -.524$; $p < .01$) that had not been present at baseline. Nonparametric repeated measures analysis found significant pre-post improvements for diabetes-related distress ($X^2_{(2)} = 8.603$, $n=16$, $p = .01$) and the *observing* ($X^2_{(2)} = 6.035$, $n=17$, $p = .05$), *describing* ($X^2_{(2)} = 7.968$, $n=17$, $p = .02$), and *acting with awareness* ($X^2_{(2)} = 6.0$, $n=17$, $p = .05$) facets of Mindfulness. Hba1c decreased significantly from baseline to 3 months ($8.35\% \pm 1.6$; $7.31\% \pm 1.22$; $z = -2.154$, $p = .031$; $d = .73$) consistent with prior studies of DSME. These findings support the feasibility, acceptability, and possible benefits of a Mindfulness-based diabetes education intervention for US Veterans and warrant further study.

4.2 INTRODUCTION

It has been estimated that 25% of US Veterans who receive care through the Veterans Affairs Healthcare (VAH) System have diabetes, affecting more than one million Veterans at any given time (Diabetes-QUERI Executive Committee, June, 2013). Self-management of diabetes is essential to achieving metabolic control and preventing acute and chronic complications, but

negative emotional states can interfere with focused attention and goal-directed behaviors. Research has shown that psychological distress frequently occurs as a result of difficulty coping with the daily demands of self-management and fear of complications. The burden of diabetes-related distress often interferes with adherence to DSM behaviors and compromises glycemic control.

Individuals with diabetes commonly experience emotional distress related to diabetes, which can co-exist with depression and also can occur independently of it (Fisher, et al., 2010). Moreover, research suggests that stress is additive (McEwen, 2002) and that there is a bi-directional relationship between activation of the physiological stress response and deregulation of glucose metabolism (Novak et al., 2013; Pan, Lucas, Sun, & et al., 2010). US Veterans with diabetes are even more vulnerable to negative emotional states given the cumulative nature of stress and the high percentage of Veterans who suffer from co-morbid depression and post-traumatic stress (Department of Veterans Affairs, et al., 2012).

To address the burden of DSM and issues related to diabetes-distress, Healthy Coping has been identified by the American Association of Diabetes Educators (AADE) as one of 7-self-care behaviors essential to successful diabetes self-management (DSM) (Mulcahy, et al., 2003). Yet stress management techniques that cultivate healthy coping are not routinely offered as part of Diabetes Self-management Education (DSME) largely due to a scarcity of evidence-based approaches that can be incorporated into usual care. Practical approaches to stress management and healthy coping are a needed to fill this gap.

DSME provides practical instruction to individuals with diabetes to increase their knowledge and skills to perform key self-care behaviors, but does not commonly provide training in stress management essential to healthy coping. More people with diabetes are looking to complementary and integrative therapies to help improve their health and quality of life (DiNardo M.M., Gibson J.M., Siminerio L., Morell A.R., & Lee, 2012; Tilburt, et al., 2009). Mindfulness, an evidence-based stress management therapy, has been studied in diabetes and other chronic health conditions, and may represent a practical approach to filling this void. Scientific inquiry of mindfulness in diabetes has been limited, and to our knowledge mindfulness has not been explored in US Veterans with diabetes (DiNardo, 2009; HAIG Report, 2011).

Guided by bio-psychosocial stress theory that posits that the inter-relationship of mind, body, and behavior influence an individual's physiologic and functional health, we performed a pilot study to explore the feasibility and acceptability of providing mindfulness meditation training to US Veterans as part of DSME. Our primary aim was to explore its acceptance by US Veterans, diabetes educators, and other health care providers, the number of interested, eligible participants available for recruitment, the engagement of significant others, systematic barriers and facilitators, and the time and resources needed to recruit, collect and analyze data. As a secondary aim, we sought to explore the 3-month follow-up effects of Mind-STRIDE on mindfulness, perceived stress, diabetes-related coping, distress, self-management behaviors/goals, and glycemic control. An exploratory aim was to examine correlations between each facet of Mindfulness with perceived stress, diabetes-related distress and coping, social support, diabetes self-management behaviors, and glycemic control.

4.3 BACKGROUND

4.3.1 Diabetes Self-Management

Metabolic control and prevention of diabetic complications depend upon DSM and the realization of self-management behaviors and goals (Funnell & Anderson, 2004). DSM generally consists of healthy meal planning with regulation of carbohydrate and fat intake, planned daily activity, weight management, self-monitoring of blood glucose, avoidance and treatment of extreme blood glucose fluctuations, medication management, and compliance with regular diabetic risk assessments (Mensing, et al., 2007). The rigorous demands of daily self-management represents a significant burden in the lives of many people with diabetes (Funnell & Anderson, 2004; Russell, et al., 2005). This is because the patient is responsible for making decisions and implementing day-to-day self-care with intermittent instruction from health care providers (Funnell & Anderson, 2004). Moreover, performance of DSM requires a considerable amount of time each day that varies by severity of disease (Safford, et al., 2005). Estimates suggest that daily diabetes self-management can require 2 hours to perform (Russell, et al., 2005). However, a cross-sectional study of 1482 patients with diabetes found that more than 1/3 of patients neglect to perform important elements of DSM, with men being less vigilant than women in carrying out daily self-care tasks (Safford, et al., 2005).

4.3.2 Stress and Diabetes

The importance of stress management in diabetes control is known (Surwit, et al., 2002). The key to successful DSM is to provide the individual with knowledge, psychomotor skills, and effective psychological coping to facilitate lifestyle modifications (Mendoza, et al., 2010). Healthy coping is recognized as one of 7-key Diabetes Self-Care Behaviors (Mulcahy, et al., 2003); yet, stress reduction strategies central to healthy coping are not routinely offered. There are few practical stress reduction programs that can be provided as part of routine DSME; therefore, usual care often consists of offering informational handouts rather than providing practical instruction and training.

4.3.3 Mindfulness based therapies in diabetes

Complementary mind-body approaches to chronic disease management have become a growing area of interest in health care (Tilburt, et al., 2009). One such therapy, Mindfulness, a concept derived from Buddhist philosophy, is defined as self-regulated attention to the present moment experience with non-judgmental acceptance of one's own thoughts, feelings and sensations (Bishop, et al., 2004; Kabat-Zinn, 1990). Mindfulness is often associated with a state of calmness and increased awareness that supports an individual's ability to cope. Mindfulness is cultivated through regular meditative practice and self-regulation.

Mindfulness Based Stress Reduction (MBSR), an evidence-based psycho-educational program that has been studied in many chronic health conditions for 40 years, has more recently been studied in diabetes. MBSR is a group program consisting of eight weekly 21/2-hour sessions that include discussions, focused breathing, mindful movement, and didactic presentations on the physiologic stress response, mindful communications, and awareness training. The program's objective is to help the participant to isolate and differentiate between thoughts, emotions, and physical sensations in the context of the present moment experience. The program also includes a one-day retreat and encourages home mindfulness practice for 40 minutes 6 days per week.

A 2009 review of mind-body therapies in diabetes by this researcher and others found just one study of mindfulness (DiNardo, 2009; Whitebird, et al., 2009). The science of integrative mind-body therapies in general and mindfulness in diabetes in specific is an emerging field, and there have been noteworthy studies conducted in recent years.

A small 2007 observational pilot study of MBSR in T2D ($n=14$) demonstrated significant decreases in HbA1c ($d=.88$, $p=.03$), mean arterial blood pressure ($d=.48$, $p=.01$), and psychological distress ($d=.60$, $p=.07$) independent of weight loss, medication change or change in level of activity (Rosenzweig, et al., 2007). In a larger 5-year randomized controlled trial (RCT), one-year intention to treat analysis found decreased levels of depression ($d=.71$, $p=.01$), improved health status ($d=.54$, $p=.03$), and diastolic blood pressure ($d=0.78$, $p<.01$) in the MBSR group ($n=53$) compared to controls ($n=57$) with per protocol analysis showing greater stress reduction ($d=.64$; $p=.02$) in the MBSR group. The Diabetes and Mindfulness Study

(DiaMind), a Dutch clinical trial of Mindfulness Based Cognitive Therapy (MBCT)(Teasdale J. D. et al., 2000), similar to MBSR, in people with T1D and T2D ($n=139$) found reductions in emotional distress and increased health-related quality of life. No significant effect on HbA1c or diabetes-related distress was found, although those in the treatment group who had higher levels of diabetes distress at baseline showed a decreased trend ($d = .70, p = .07$).(van Son, et al., 2013).

Studies using functional magnetic resonance imaging (fmri) to view the brains of mindfulness meditation practitioners have provided intriguing evidence of physiologic changes in areas of the brain including the pre-frontal cortex and amygdale that regulate focus and attention (Luders, Clark, Narr, & Toga, 2011; Moore, Gruber, Derosé, & Malinowski, 2012). Although these studies were not performed specifically in participants with diabetes, findings provide hypotheses about how Mindfulness might improve performance of DSM behaviors by strengthening cognitive focus and awareness.

In a 2007 randomized controlled study of 81 patients with Type 2 Diabetes (T2D), participants who received a 1-day DSME class plus an “acceptance and mindfulness” intervention utilizing Acceptance and Commitment Therapy (ACT) were more likely to report better DSM ($p = .04$) and have target range HbA1c at 3-month follow-up than patients who received DSME alone (Gregg & Callaghan, 2007). Changes in HbA1c were significantly and independently mediated by changes in coping and DSM behaviors ($p < .05$). The study did not include mindfulness training, nor did it assess the level of diabetes-related stress among participants; but importantly, it demonstrated the efficacy of a one session mindfulness-based intervention coupled with DSME.

Despite evidence supporting the general health benefits of MBSR, it like other complementary and alternative therapies, is seldom used in clinical practice because of a perceived lack of clinical relevance (Tilburt, et al., 2009). Clinical studies, such as this one, are needed to demonstrate the feasibility of incorporating evidence-based integrative therapies into standard care to fill this gap. Further study of interventions that incorporate mindfulness into DSME may provide diabetes educators with an important tool for assisting patients to manage stress, improve glycemic control, and ultimately decrease modifiable risks for diabetic complications. By routinely providing stress management and healthy coping training as part of DSME, patients at risk for psychological distress, burnout, and non-adherence can be identified and supported. The current study taps into the *Healthy Coping* dimension of AADE-7 Self-Care Behaviors for US Veterans with diabetes and may influence further studies of Mindfulness as a Healthy Coping component of DSME throughout the VA system and elsewhere.

4.3.4 Conceptual Framework

The conceptual model for the current study is guided by bio-psychosocial stress theory (Bernard & Krupat, 1994; Goldstein & McEwen, 2002; Lazarus & Folkman, 1987; Selye, 1956), which posits that a psychosocial intervention such as Mind-STRIDE can influence biological outcomes (i.e., HbA1c) through psychological (i.e., mindfulness, healthy coping, and stress reduction) and behavioral (i.e., DSM) pathways.

4.4 RESEARCH DESIGN AND METHODS

The current study is a quasi-experimental feasibility pilot study having a pre-post intervention design conducted from September 2012 to September 2013. We adapted a MINDful STress Reduction In Diabetes Education (Mind-STRIDE) program from MBSR (Kabat-Zinn, 1990), and the Diabetes ACT Manual (Gregg, et al., 2007). This 90-minute intervention was delivered immediately following a DSME class conducted at an urban Veterans Affairs Healthcare facility by a Nurse Practitioner, Certified Diabetes Educator with training in MBSR. The intervention consisted of a didactic presentation, group activities and discussion, and 20 minutes of Mindfulness practice. The didactic presentation included an explanation of stress theory and an introduction to basic tenets of mindfulness, including “beginner’s” mind, non-attachment, non-judgment and compassion. Participants were asked to set an intention of performing 10-15 minutes of home mindfulness practice 6 days per week, and were provided with an audio tape recording to guide their home practice. Participants also received paper diaries to record their experience with each home practice session. Participants received a 30-minute booster session after one month that lasted 30 minutes and consisted of discussion and ten minutes of mindfulness practice.

4.4.1 Sample

A target sample consisted of US Veterans who had a diagnosis of diabetes for at least 6-months, an Hba1c > 7%, had been on stable diabetes medications for at least 1 month and were referred for DSME by their healthcare provider. Current Mindfulness meditation practitioners, Veterans having a documented history of recent serious physical or mental illness within the past 30 days, and Veterans with documented incompetence, cognitive impairment, or substance abuse were excluded.

4.4.2 Measures

Demographic information was obtained at baseline with a self-report questionnaire. Four additional self-report questionnaires (FFMQ, PSS-10, PAID, and DES-SF) were administered at baseline prior to the DSME class and also at the 1-month and 3-month follow-up visits. Hba1c and three other questionnaires (DSM, and Diabetes Social Attitudes) were collected at baseline and at 3-month follow-up only. The AADE-7 Self-care Behavioral Assessment was performed at the 1-month and 3-month follow-up visits.

Feasibility was computed as rates of recruitment and retention. We also examined factors related to enrollment and attrition, systematic barriers and facilitators, and kept records regarding significant other involvement, and needed resources.

Satisfaction. a). *Participant Satisfaction* was measured by a 6-item questionnaire on a 5-point Likert scale (“Strongly agree” to “Strongly disagree”) and by participant comments from home practice diaries and investigator field notes (Table 1). b). *Diabetes Educator Satisfaction* was assessed by answers to 4-open ended questions and one Likert-type question (the questions are described in the Results section).

Adherence to home mindfulness practice was assessed by completed home practice diaries.

The 5-Facet Mindfulness Questionnaire (FFMQ) is a validated mindfulness instrument consisting of 39 items on a 5-point Likert scale (“Never or very rarely true” to “Very often or always true”) based on a factor analytic study of 5- independently developed Mindfulness questionnaires. It measures 5-facets representing elements of mindfulness: observing, which refers to noticing or attending to internal and external experiences, such as thoughts, sensations, emotions, sounds, sights, and smells; describing, which refers to the ability to describe one’s emotions and feelings; acting with awareness, which includes attending to one’s activities in the present moment; non-judging of inner experience, which refers to taking a non-evaluative attitude toward thoughts and feelings; and non-reactivity to inner experience, which includes allowing thoughts and feelings to come and go, without getting caught up in or carried away by them. The five facets demonstrated adequate to good internal consistency (α ranging from .75 to .91) when tested in experienced meditators and non-meditators (Baer, et al., 2006).

The Perceived Stress Scale (PSS-10) is a 10-item self-report instrument that provides a global measure of perceived stress in daily life. Items are presented on a 4-point Likert scale

(“never” to “very often”). PSS-10 measures frequency of stress feelings during the preceding month, and is a reliable measure of life-events stress measures and social anxiety (Cohen, et al., 1983). The Cronbach’s α for the PSS was .84 or .86 and the test-retest reliability was .55 in 6 weeks in previous studies performed in college students.

Problem Areas in Diabetes scale (PAID) comprises 20 items describing common negative feelings associated with having diabetes, e.g. “Feeling scared when you think about living with diabetes?”; “Not having a clear and concrete goal for your diabetes care?” that are answered on a 5-point Likert scale (Not a problem to Serious problem). Item scores are summed to provide a total score of emotional distress, with higher scores denoting greater distress. The PAID scale has high internal reliability (Cronbach’s $\alpha > .90$) and has shown effect sizes between .30 and .65 across different psychosocial, educational, and medical interventions (Fisher, et al., 2008).

Diabetes Empowerment Scale Short Form (DES-SF) is a brief overall assessment of diabetes related psychosocial self-efficacy that consists of 9-items on a 5-point Likert scale (“Strongly agree” to “Strongly disagree”) (R. M. Anderson, et al., 2000). Cronbach’s α of the *DES-SF* = .84, and content validity are supported in a study of 229 individuals with diabetes who completed a 6 week DSME program (Anderson R.M., et al., 2003).

Support Attitudes Sub-scale of the Diabetes Care Profile (DCP) is a self-administered questionnaire that assesses social and psychological factors related to diabetes and its treatment. The DCP Support Attitudes Subscale consists of 4 questions: 1 single answer, multiple choice question and 3 other questions, each with 6 sub-questions, on a 5-point Likert scale (“Strongly

disagree” to “Strongly agree”). Cronbach’s α for the Support Attitudes Subscale was .69 and .73 demonstrating reliability. The Social Attitudes Subscale significantly ($p \leq .01$) correlated with The Social Provisions Scale ($r=.51$), CES depression scale ($r=-.35$) and the Happiness and Satisfaction scale ($r=.25$) demonstrating concurrent validity (Fitzgerald, et al., 1996).

DSM behaviors are measured by 4-items on a 5- point Likert scale (“None of the time” to “All of the time”) also adapted from the DCP (Fitzgerald, et al., 1996) to measure DSM adherence related to diet, activity, self-monitoring of blood glucose, medication use and scheduled contact with health. Reliability and validity of the DCP was tested in US Veterans with T2D recruited from three VA hospitals in the Southwestern US. Cronbach's α ranged from .63 to .95 in non-Hispanic Whites ($n=238$).

DSM goals are measured by AADE-7 Self-Care Behavioral Assessment. Behavioral assessment of goals met for each of 7-self-care behavioral domains; Healthy eating, Being active, Monitoring blood glucose, Taking medications consistently, Problem solving, Healthy coping and Risk reduction. Items are scored on a 10-point Likert scale (Not met to Achieved). This tool was created to assess core measures of outcome performance for DSME and was intended for use in individuals and populations, but to our knowledge, it has not previously been tested in a research setting, and its psychometric properties have not been determined.

Glycemic Control is measured by HbA1c, an estimate of average glycemic control over the preceding 2 months (Koenig, et al., 1976). All HbA1c tests were obtained by finger-stick by trained staff using the Siemens S025110 DCA Vantage Analyzer that uses latex immuno-agglutination inhibition methodology (CV=2.9-5.4% compared to high pressure liquid

chromatography that is performed in most standard labs) (Siemens Healthcare Diagnostics, Ltd., UK). Hba1c, generally ranges from 4.5-5.7 in healthy individuals, and the recommended value for most individuals with diabetes is <7%.

4.4.3 Procedures for Data Analysis

Data analysis was performed using IBM SPSS version 21 Statistical Package (SPSS Inc., Chicago, IL, 2010).

Descriptive Statistics. Demographic and outcome data were examined for measures of spread, distribution and central tendencies. Variable distributions were examined for normality and influential outliers.

Normality and Outliers. Data were checked by proofreading, assessment of range and contingency table assessment before proceeding to formal analysis. Data entry and coding was rechecked when discrepancies are detected. The data were then evaluated for extreme or discrepant values. Outliers were evaluated to determine if they were part of the intended sampled population. Graphically, histograms, box plots and normality probably plots were used to help visualize data points. ID number in SPSS was used to identify aberrant cases. Statistically, cases with Z scores on one or more variables that were >3.29 were considered potential univariate outliers.

The underlying assumption of normality was assessed by looking at measures of skewness and kurtosis, ideally looking for values close to zero. Measures greater than 3 after

being divided by their standard error were considered generally significant. With the small sample size of this study, an alpha level of .01 was used to evaluate significance of skewness and kurtosis. The Shapiro-Wilk test was used to provide further evidence for normality in which a non-significant test statistic indicated that the data were from a normally distributed sample. Graphically, normal and detrended probability plots were used to observe if data points fell in a straight line indicating normality. Frequency histograms were also generated to observe for dispersion of the data.

Missing Data. We reviewed each assessments for completeness during the session in which it is collected whenever possible. Participant cases with missing data were compared to those with complete data to examine for differences in baseline characteristics. For any participant case in which a questionnaire was missing less than 30% of items at a specific time point, we substituted the mean score for each missing item (Tabachnick & Fidell, 2007). Any questionnaire that had greater than 30% missing items was considered missing, and that individual case was not included in the analysis for that outcome at that time point.

4.4.3.1 Data Analysis Procedure for the Primary Aim

We explored the rates of recruitment and retention of participants and examined factors associated with enrollment and attrition. Recruitment rates were calculated as the percentage of participants recruited from the total number of eligible patients who attended DSME classes during the recruitment period. The percentage of eligible Veterans who were enrolled in the

study was computed. Retention was defined as completion of baseline and 3 month follow-up visits. Adherence to home Mindfulness practice was measured as whether any home practice diaries were completed. Acceptance and satisfaction with the Mind-STRIDE program was determined by satisfaction scores and participant comments recorded in the home practice diaries and investigator field notes. Records were maintained regarding participation of significant others and for ongoing systematic and procedural issues pertinent to resources, costs and study time-frame.

4.4.3.2 Data Analysis Procedures for the Secondary Aim

Non-parametric analysis was performed for Aim 2, because of the small sample size, ordinal level data, and potential for non-normality. Non-parametric tests are less sensitive to outliers and do not rely on the assumptions of normality for validity; however they tend to be less robust than their parametric equivalents (Lomax, 2001). Differences over time were analyzed using the Friedman Test, the non-parametric equivalent of the omnibus test or one-way repeated measures analysis of variance (ANOVA). The Friedman test determines whether each individual's median score differs significantly across all levels of the factor, in this case time, after taking into account the dependency among scores introduced by the repeated measures design (Green & Salkind, 2008).

Regardless of the outcome of the omnibus test, pairwise post-hoc comparisons were performed using Wilcoxon-signed rank tests with α set at $\leq .05$. The post hoc tests included the comparison of the three time points, thus three tests were performed for each outcome.

The Wilcoxon-signed rank test, a nonparametric equivalent to the paired t-test, was also performed for all measures collected at only two time points. Like the Friedman test, it is based on median ranked scores. Typically, a Bonferroni correction would be performed when doing multiple comparisons to avoid Type-I error inflation; however, a less conservative approach ($\alpha \leq .05$) was used because of the exploratory nature of this study in which the emphasis was on the magnitude of the effects rather than on the level of significance.

To examine the magnitude of the intervention on pairwise pre-post differences, effect sizes were computed using Cohen's d , which reflects the strength of the association of two variables in a statistical sample; d of 0.2 was considered a "small" effect, 0.5 a "medium" effect, and 0.8 or greater was considered a "large" effect (Cohen, 1988). It was important to compute effect sizes in this feasibility study to measure the magnitude of the differences between time points. Statistical significance does not reflect the clinical importance of the change over time; therefore, the effect size was calculated to examine an objective and standardized assessment of the observed effects. Because several outcomes were measured in the current investigation, the calculation of the standardized effect allowed for the comparison of clinical significance among all measures (Field, 2005). The effect size estimates will also inform sample size calculations for future analysis plans in more confirmatory studies. It is also sensible for researchers to report effect size estimates for use in meta-analytic studies that summarize multiple investigations with

the same research questions by synthesizing effect sizes (Field, 2005; Morgan, Reichert, & Harrison, 2002).

4.4.3.3 Data Analysis Procedures for the Exploratory Aim

To explore the associations between each facet of mindfulness with global perceived stress, diabetes-related distress and coping, performance of diabetes self-management behaviors, and HbA1c at baseline and 3-months following the Mind-STRIDE intervention.

Baseline and 3-month correlations for each facet of mindfulness with all other outcome variables were presented as Spearman Rank-Order (Spearman's *rho*) correlations with α set at 0.05. Spearman's *rho* is a nonparametric test that measures monotonic relationships of ranked variables according to the direction of the correlation. As such, it is not sensitive to outliers and is suitable to use for non-normal distributions and ordinal data as with Likert scales (Huck, 2004). Point biserial correlations were presented for home practice adherence with all other outcome variables with α set at 0.05. Home practice adherence is scored dichotomously as 0 for no diaries and 1 for at least 1 diary completed. Correlation results are interpreted as 1.0 indicating a perfect positive correlation and -1.0 indicating a perfect negative correlation with a result of 0.0 indicating no relationship. Generally, correlations below 0.5 are considered low; 0.5 are moderate, and correlations close to 1.0 are considered high (Huck, 2004).

4.5 RESULTS

4.5.1 Participant Characteristics

Mind-STRIDE participants were generally obese (BMI 32 kg/m²), older (62 ± 9.47 yrs), White (68.6%) males (94.3%) with T2D (80%) who attended some college. A complete summary of participant demographics is presented in Table 3.

4.5.2 Feasibility and Acceptability

We explored feasibility by examining the number of potential eligible candidates who were referred to and attended DSME class at VAPHS UD campus from September 1, 2012 to June 1, 2013. There were 56 potentially eligible candidates who attended DSME class during the period of recruitment who had an HbA1c > 7%. Of these, 43 provided assent to the Diabetes Educator. After hearing more about the study, this investigator screened 38 eligible candidates; of these, 35 met inclusion criteria and were enrolled in the study. The rate of recruitment was 62.5%. Reasons offered by those who declined participation in the study included being “too busy”, not wanting to return to VAPHS UD despite assurances that efforts would be made to arrange study visits on the same day as another appointment. Other reasons for declining participation included having “no stress”, that the study was “too involved” and not being “able to commit” at this time.

Of the 35 participants who were enrolled in the study, seven participants had been randomized to a control group prior to the study modifications and were not included in the

statistical analysis; four control group participants completed all 3 assessments. Twenty of 28 Veterans in the intervention group completed the study with a retention rate of 71%. The combined overall retention rate for both groups was 69%. A summary of attrition appears in Table 2.

Although each participant was encouraged to bring a significant other to the Mind-STRIDE program, only three participants were accompanied by a support person. Several participants commented, however, that they received encouragement and support from their spouse regarding participation in the program.

4.5.2.1 Participant Satisfaction

To assess participant satisfaction, Mind-STRIDE participants completed Satisfaction questionnaires at each study time point, with the following results:

- 100%- agreed or strongly agreed that class was interesting and easy to understand
- 96% - agreed or strongly agreed that they learned something new, and planned to continue practicing mindfulness
- 92%-agreed or strongly agreed that they would recommend a mindful stress management class to other people with diabetes
- 78% agreed or strongly agreed that the CD made home practice easier

Comments taken from satisfaction questionnaires, home practice diaries and investigator field notes appear in Table 4.

4.5.2.2 Adherence to Home Practice

Only 39% ($n=11$) of participants completed a total of 45 weekly home practice diaries. The number of weekly diaries completed per participant ranged from 1-diary to 12-diaries. The reported duration of home practice ranged from a “few minutes to 30 minutes per day” two to six days per week. Several participants reported that they practiced at home on a regular basis, but they did not complete diaries, and were coded 0 for adherence. One participant acknowledged having no interest in Mindfulness or home practice, but completed the study “to benefit other veterans”.

4.5.2.3 Diabetes Educator Satisfaction

We explored the acceptance and satisfaction of the diabetes nurse educator and dietitian educator who coordinate and teach the DMSE class and assisted with recruitment and assessment procedures. The diabetes educators answered 5-open ended questions about their participation and observations: 1) “What if anything about the study was difficult or burdensome for you?” 2) “If the study were to be repeated what if anything would you suggest changing?” 3) “What if any benefit did you observe in the Veterans who participated in the Mind-STRIDE study?” 4) “How do you feel about including stress management training as part of DSME?” 5) “On a scale of 0 to 10, 0 being “it was not worthwhile” to 10 “it was extremely worthwhile”, how would you describe the study?”

The educators agreed that the start of the study was the most difficult aspect due to administrative and scheduling problems. Attempts to gain phone assent from potential study

candidates was also burdensome. Both thought that cumbersome research activities i.e. obtaining informed consent and the completion of baseline questionnaires would be better completed in advance of the class. Both thought it was too soon to tell if participants would have any long-term benefits. However, the dietitian noted that several study participants bonded with the other Veterans in their intervention cohort, and seemed to benefit from interactions at follow-up assessment visits. Both educators believe that stress management training should be included in DSME since it is not currently part of the curriculum. When asked how they would rate the study, one of the diabetes educators answered “8”, and the other answered “9” out of 10, indicating a very favorable evaluation of their experience except for they identified as systematic administrative hassles.

4.5.3 Within Group Effects

The Friedman Test found significant positive effects over time found for diabetes-related distress ($X^2_{(2)} = 8.603, n = 16, p = .01$) and the *observing* ($X^2_{(2)} = 6.035, n = 17, p = .05$), *describing* ($X^2_{(2)} = 7.968, n = 17, p = .02$), and *acting with awareness* ($X^2_{(2)} = 6.0, n = 17, p = .05$) facets of Mindfulness. Wilcoxon-Signed Ranked pairwise comparisons were significant for diabetes-related distress from baseline to 3 months ($Z = -2.67, p = .01, d = .75$) and from 1 month to 3 months ($Z = -3.042, p < .01, d = .64$) with moderately large effect sizes. No significant pairwise comparisons were found for *observing* or *acting with awareness*; however, there was a positive trend for *observing*

from 1 month to 3 months ($Z = -1.822, p = .07, d = .37$). There were significant increases in *describing* from baseline to 1 month ($Z = -2.110, p = .04, d = .28$) and from baseline to 3 months ($Z = -1.970, p = .05, d = .32$) with small to medium effect sizes.

Significant baseline to 1- month improvements were found for global perceived stress ($Z = -2.05, p = .04, d = .47$) and for *non-reacting* ($Z = -1.98, p = .04, d = .24$) with medium to small effect sizes respectively. Significant baseline to 3-month improvements were observed for diabetes support needs ($Z = -1.945, p = .05, d = .51$), DSM behaviors ($Z = -2.089, p = .04, d = .51$), AADE-7 goals of *Healthy Eating* ($Z = -2.427, p = .02, d = .96$), *Taking Medications* ($Z = -2.207, p = .03, d = .56$), and the composite AADE-7 score ($Z = 2.765, p = .01, d = .67$), and for HbA1c ($Z = -2.154, p = .03, d = .73$), all demonstrating medium to large effects sizes. All other effect size calculations for paired comparisons were $< .5$. A summary of nonparametric repeated measures analyses and effect size estimates appears in Tables 6 to 9.

4.5.4 Correlations

Adherence to home practice as measured by home practice diaries did not correlate with any facet of Mindfulness. When Spearman's *rho* correlations were applied at baseline, there was a significant inverse relationship between diabetes coping (empowerment) with both global perceived stress ($r_s = -.37, p = .03$) and with diabetes-related distress ($r_s = -.45, p = .01$). There was also an inverse association between global perceived stress and DSM ($r_s = -.389, p = .03$). Not

surprisingly, diabetes support needs positively correlated with *support received* ($r_s = .498, p < .01$).

Also at baseline, there were medium correlations noted between 3-mindfulness facets, *acting with awareness* with *describing* ($r_s = .484, p < .01$) and with *non-judgment* ($r_s = .589, p < .001$); and for *describing* with *non-judgment* ($r_s = .592; p < .001$). *Acting with awareness* positively correlated with diabetes support needs ($r_s = .359; p = .04$). There were no other significant baseline correlations for the Mindfulness facets.

Notably at 3 months, significant correlations emerged between four of the mindfulness facets: *acting with awareness* was inversely correlated with global perceived stress ($r_s = -.59; p < .01$) and diabetes-related distress ($r_s = -.539; p = .01$), and was positively correlated with diabetes empowerment ($r_s = .421; p = .05$) and DSM ($r_s = .464; p = .02$). “*Describing*” was also positively correlated with diabetes empowerment ($r_s = .499; p = .02$); “*non-judgment*” correlated inversely with global perceived stress ($r_s = -.590; p < .01$) and with diabetes-related stress ($r_s = -.534, p = .01$), and positively with diabetes coping (empowerment) ($r_s = .429; p = .04$) and DSM ($r_s = .465; p = .02$). *Non-reactivity* inversely correlated with diabetes-related distress ($r_s = -.524; p = .01$).

A significant inverse correlation was found between diabetes-related distress and DSM at 3-months ($r_s = -.427; p = .04$). Positive correlations were found at 3-months for diabetes support needs with support received ($r_s = .792; p < .001$), and for support received with support attitudes ($r_s = .547; p = .01$). A complete summary of Spearman’s *rho* bivariate correlations appears in Tables 10 to 12.

4.6 DISCUSSION

This pilot study demonstrates the feasibility and acceptability of introducing Mindfulness and Mindfulness training into DSME for US Veterans. The retention rate of over 70% and the high level of satisfaction among Mind-STRIDE participants and diabetes educators support the likelihood that a larger controlled study can be successfully implemented. There is precedent for successful meditation programs within the VAH System (Lang et al., 2012), and according to the VA commissioned Haig Report (2011), there are 125 VA facilities that provide CAM or refer patients to CAM providers.

In addition to demonstrating feasibility and relevance, the results of this study as well as our previous pilot study (Manuscript 1) support the Model of Shared Psychobiological Pathways by demonstrating improvements in psychological (Mindfulness, stress and coping), behavioral (DSM and goals) and biological (Hba1c) outcome measures associated with a psychosocial intervention (Mind-STRIDE). Further application of this model to the study of Mindfulness in diabetes in larger samples may help to examine possible complex modifying and mediating effects.

The Friedman Test found positive pre to post effects for diabetes-related distress and for the *observing, describing, and acting with awareness* facets of mindfulness. When pairwise comparisons were examined for Mindfulness facets of *observing, describing, and acting with awareness*, significance was detected only for *describing* from baseline to one month that was sustained at 3 months. It is possible that small significant effects could have been detected for

other facets of mindfulness in a larger, sufficiently powered sample. Closer study of the *non-judgment* facet, for example, would be of particular interest in the Veteran population where non-judgment has been inversely associated with PTSD symptoms (Wahbeh, Lu, & Oken, 2011). In the current study, moderate correlations were observed between *non-judgment*, *acting with awareness*, and *describing* at baseline and 3 months.

Changes in *describing* are noteworthy because of positive post-intervention correlations found between *describing* and diabetes empowerment, one of our surrogate measure of coping. Interestingly, the DiaMIND study omitted this facet because “describing one’s emotions and feelings” was not considered a primary focus of the intervention (van Son, et al., 2013). In the present study, pairwise comparison of diabetes support attitudes revealed a significant increase in support needs from pre to post intervention. A possible explanation for this may be that with increased Mindfulness, an individual with diabetes may become more aware of his/her self-care needs and feel more empowered to communicate these needs to others. Further study of effects of Mindfulness on diabetes support attitudes may provide insights into interpersonal aspects and communication styles between individuals with diabetes and their spouses or significant others.

Perhaps, the most clinically meaningful finding of this study was seen in the mitigation of diabetes-related distress over time. Diabetes-related distress is known to affect self-management, and is considered a key barrier to glycemic control, but little is known about the effects of DSME on diabetes-related distress (Steed, Cooke, & Newman, 2003). The DESMOND trial, a multisite clinical trial conducted in the United Kingdom that investigated 3-year follow-up effects of a diabetes education and self-management program in primary care, found no difference in PAID

scale scores between those who received the diabetes education program and Controls who did not receive it (Khunti et al., 2012).

In the present study, an inverse correlation was demonstrated between diabetes-related distress, diabetes empowerment, and DSM that underscores the importance of this covariate relationship. Significant pre to post improvements observed for the Healthy Eating and Taking Medications self-care behavioral goals are particularly important in terms of adherence.

Surprisingly, there was a significant but non-sustained decrease in global perceived stress from baseline to 1-month, approaching a medium effect size at 1 month ($d=.47$) and at 3-months ($d=.37$). This is not consistent with previous mindfulness research including our own pilot study (Manuscript 1), in which significant changes were sustained and had a large effect size. A non-sustained change was also found for the *non-reactivity* facet of Mindfulness. It is not known if improvement in global perceived stress or *non-reactivity* would have been sustained with a more traditional 8-week mindfulness program or with additional booster sessions.

4.6.1 Limitations

The current study has several limitations. The self-selected homogeneous sample limits the ability to generalize conclusions based on the findings; the sample was skewed toward older, White, males who had some college education. A more diverse sample may have yielded different results.

Participants signed informed consent and were randomized on the same day as the DSME class, which afforded the researcher little or no control over scheduling. Since we had learned from our previous survey that repeated trips to University Drive are undesirable and burdensome for many Veterans, we planned to perform all research activities on the day of the intervention. But completion of these activities in addition to participating in the 3-hour DSME class plus the 90-minute Mind-STRIDE intervention proved to be taxing for some older veterans, and was a deterrent for some eligible candidates.

In addition, having a control group as originally planned would have allowed for between group comparisons. Although efficacy was not an aim of this feasibility study, it is not possible to conclude that the Mindfulness intervention contributed any additional benefit to DSME without a comparison group. For example, the observed decrease in Hb_{a1c} of >1% ($8.4 \pm SD 1.60\%$ to $7.3 \pm SD 1.22\%$) is consistent with changes in Hb_{a1c} previously associated with DSME in the literature (Norris, et al., 2002). However, although it is not known whether Mind-STRIDE enhanced the efficacy of the DSME class, in view of the observed improvement in glycemic control, it is not likely that the additional Mindfulness program with expectations for home practice detracted from its beneficial effects. In addition, a pre-post change in Hb_{a1c} ($d=.4$) was found in our preliminary pilot study of women with T2D in which MBSR was provided without DSME.

Other limitations include use of non-parametric analysis, which is not as robust as the parametric equivalents, but was necessary to use for this study because of the characteristics of the small homogeneous sample. Furthermore, most of the outcome data were collected by self-

report, and even though the instruments were previously shown to be psychometrically valid and reliable, the effects of measurement reactivity in this population are uncertain.

4.6.2 Recommendations and Implications

Pilot studies are important for exploring process measures that inform the implementation of future investigations. This study has raised several process issues and methodological questions. Working with key leaders in clinical research sites to streamline recruitment procedures and help navigate the system would enhance studies such as this one that involve minimal risk. Resources available within the VAH were very conducive to conducting similar studies as this one, in respect to its comprehensive computerized medical records system and high standards for usual care.

Although most of the study participants were willing to explore the process and practice of Mindfulness, some participants seemed to be much more engaged than others. It is not clear from this study, how to identify Veterans that might benefit from a Mindfulness intervention. In addition different types of meditation or more frequent opportunities for group practice may be more effective for some Veterans.

Twenty percent of participants in this study did not find the home practice CD helpful. By assisting participants find more personally appealing meditation aids, it might be possible to enhance the home practice experience and facilitate more precise measurements of adherence. In addition, few Veterans completed the paper diaries even when they reported having engaged in

regular practice. The paper diaries lacked utility and appeal, although a few of the Veterans found that using them was therapeutic. Measurement of home practice adherence could be improved with use of technology, perhaps by uploading a meditation application to a personal digital device that would serve both as a meditation timer and a real time documentation tool. Other accoutrements such as meditation blankets or pillows might boost home practice adherence for some people.

In terms of analysis, a larger sufficiently powered, controlled study would allow for between-group comparisons as well as exploration of mediation and moderation effects for complex covariance structures with the use inferential statistics. Block design random assignment methods would facilitate recruitment, and would require sufficient lead time and control over participant scheduling.

We found the FFMQ to be a useful measure for capturing multiple dimensions of mindfulness, and the observed covariation between 3 of the facets, *describing*, *acting with awareness*, and *non-judgment*, provide an area for further inquiry. Moreover, the effect size calculations for pairwise pre-post intervention effects for each FFMQ facet derived from this study will help to inform sampling procedures for future studies of Mindfulness in this population. Furthermore, the performance of formal psychometric testing to determine the validity and reliability of the FFMQ in the Veteran population would have important implications for future research. Additionally, psychometric testing of the AADE-7 Self-behavioral Assessment would also have important research implications for this widely-used clinical instrument.

On the other hand, while psychometrically sound self-report instruments serve an important purpose in bio-behavioral research, their validity when used for repeated assessment is limited by measurement bias. Finding relevant and innovative techniques for measuring physiologic stress and metabolic processes would provide more meaningful measurements of stress and glucose tolerance.

4.6.3 Conclusion

In conclusion, this study demonstrated feasibility and acceptability of embedding a one-session mindful stress reduction program within routine DSME to support the goal of Healthy Coping in US Veterans with diabetes. Observations of decreased diabetes-related distress and a positive association of specific facets of mindfulness with coping and improved DSM behaviors warrant further study.

Table 3. Summary of Attrition

Group	Baseline Hba1c (%)	Time-point	Drop-out	Reason
MS	12.5	Baseline	yes	Poor vision; disorganize thoughts; nothing new
CG	9.9	1 mo	no	Admitted to outside hospital for major surgery
CG	11.0	1 mo	no	Lost to follow-up
CG	10.3	1 mo	no	Admitted to skilled nursing facility ¹
MS	9.8	1 mo	yes	Moved to another state
MS	8.3	1 mo	no	Family issue
MS	12.7	1 mo	no	Admitted to skilled nursing facility ²
MS	10.2	3 mo	yes	Difficulty with home practice; bipolar disorder
MS	10.1	3 mo	no	Unknown
MS	8.6	3 mo	no	Unknown
MS	8.8	3 mo	no	Admitted to skilled nursing facility ³

* Mind-STRIDE (MS); Control Group (CG)

¹ prior CVA; ² prior ischemic foot ulceration; ³ COPD exacerbations

Table 4. Demographics (n=28)

Variable	Mean± SD	Median (range)	% (n)
Hba1c (%)	8.83 ± 1.76	8.1 (7.1-13.9)	
BMI (kg/m ²)	33.2 ± 7.04	33.1 (21.2- 49.9)	
Age (yrs)	62.8 ± 9.65	64 (40 - 76)	
Sex (Male)			94.4 (27)
Race (White)			67.9 (19)
DM (T2D)			78.6 (22)
Duration of DM (yrs)	18.2 ± 17.53	13 (.5- 55)	
Married			67.9 (19)
Number of People Household			
Live Alone			14.3 (4)
Live with one other			42.9 (12)
Education			
High School Graduate			39.3 (11)
Some College			25 (7)
Bachelor's Degree			17.9 (5)
Graduate Degree			10.7 (3)
Employment Status			
Full-time			14.3 (4)
Part-time			7.1 (2)
Retired			42.9 (12)
Disabled			17.9 (5)

Table 5. Categorized Summary of Participant Feedback

Category	Comments
<u>Mindfulness as a personal resource</u>	
	<i>“Provides another tool to help keep you on track”</i>
	<i>“Helps make things easier”</i>
	<i>“It definitely helps me feel better, a great tool”</i>
	<i>“It got me through a really tough day when my wife was sick and my car broke down.</i>
	<i>“Extension of principles from anger management to practical use in diabetes program for control.”</i>
	<i>“This presentation/study is very useful and I would strongly suggest this type of study to Veterans that I counsel (unemployed veterans).”</i>
	<i>“I find it very helpful as it helps you to concentrate on things that will help you to feel better about yourself”</i>
	<i>“This should help some people if they are willing to commit to doing this.”</i>
	<i>“Good way to help people understand their bodies.”</i>
	<i>“More classes. Very helpful - interesting. Need more involvement.”</i>
<u>Awareness</u>	
	<i>“This helped become more aware.”</i>
	<i>“This class is showing me a different approach in dealing with my thinking!”</i>
	<i>“I was surprised how much I did not hear until I took this class. Just never paid attention to surroundings. Took most things for granted.”</i>
	<i>“This program has given me the thought about what is meaningful in life!”</i>
<u>Home Practice</u>	
	<i>“Interruptions during my home study disrupted the thoughts I was having.”</i>
	<i>“I have problems with attention deficit at home. My mind wanders even though I try to stay focused.”</i>
	<i>“It helps when you do it on a continuing daily basis; I found different times of day work best.”</i>
	<i>“Mindfulness recordings are very helpful.”</i>
<u>Relaxation</u>	
	<i>“It relaxes me.” “I fall asleep.”</i>
	<i>“The breathing was a great way to control thought. Stretches very helpful for tension release.”</i>
<u>Social support</u>	
	<i>“I was skeptical but my wife said ‘Give it a try’; I’m glad I did.”</i>
	<i>“My wife and I have been doing it together.”</i>
	<i>“I think it was good talking with others about what they think and feel, that I am not the only one with these feelings.”</i>
<u>Behavior change</u>	
	<i>“My wife asked me why this motivates me... after all this time.”</i>
	<i>“Curious to continue this process and see my personal experiences and results!”</i>
	<i>“I’m sticking with it, because I want to help myself do better.”</i>
<u>Assessments</u>	
	<i>“Too many questions on questionnaires.”</i>

Table 6. Friedman test ($df=2$)

Variable	n	Mean ranks			χ^2
		(Base)	(1 mo.)	(3mo.)	
Mindfulness (FFMQ)	17				
Observing		(2.06)	(1.59)	(2.35)	6.04*
Describing		(1.50)	(2.09)	(2.41)	7.97*
Acting with awareness		(1.53)	(2.15)	(2.32)	6.00*
Non-judging		(1.65)	(2.00)	(2.35)	4.50
Non-reactivity		(1.68)	(2.21)	(2.12)	3.10
Global Perceived Stress (PSS-10)	16	(2.22)	(1.91)	(1.88)	1.25
Diabetes Related Distress (PAID)	16	(2.31)	(2.28)	(1.41)	8.60*
Diabetes Empowerment (DES-SF)	15	(1.60)	(2.10)	(2.30)	4.18

* $p \leq 0.05$

Table 7. Wilcoxon-Signed-Ranked Test for Pairwise Comparisons (FFMQ, $n=17$)

Variable	Mean ranks (neg.) (pos.)		Z	d
<u>Mindfulness (FFMQ)</u>				
<i>Observing</i>				
Base to 1-mo	(5.17)	(7.55)	-.976	.21
Base to 3-mo	(7.08)	(7.81)	-.629	.17
1 month to 3-mo	(11.8)	(6.79)	-1.82	.37
<i>Describing</i>				
Base to 1-mo	(5.17)	(7.55)	-2.11*	.28
Base to 3-mo	(10.0)	(8.15)	-1.97*	.32
1 month to 3-mo	(10.2)	(7.50)	-.363	.07
<i>Acting with Awareness</i>				
Base to 1-mo	(12.4)	(7.96)	-1.284	.18
Base to 3-mo	(11.6)	(7.92)	-.877	.24
1 month to 3-mo	(9.17)	(8.10)	-6.75	.06
<i>Non-judgment</i>				
Base to 1-mo	(7.50)	(8.25)	-1.282	.21
Base to 3-mo	(9.25)	(7.55)	-1.309	.30
1 month to 3-mo	(11.7)	(7.55)	-.309	.07
<i>Non-reactivity</i>				
Base to 1-mo	(7.50)	(8.83)	-1.976*	.24
Base to 3-mo	(4.90)	(8.31)	-1.473	.28
1 month to 3-mo	(8.07)	(7.94)	-.199	.01

* $p < .05$

**** $p < .01$**

Table 8. Wilcoxon-Signed Ranked Tests for Pairwise Comparisons

Variable	<i>n</i>	Mean ranks		<i>Z</i>	<i>d</i>
		(neg.)	(pos.)		
<u>Diabetes Related Distress (PAID)</u>	16				
Base to 1-mo		(9.67)	(7.00)	-.984	.13
Base to 3-mo		(9.96)	(4.13)	-2.666**	.75
1 month to 3-mo		(8.73)	(3.25)	-3.042**	.64
<u>Global Perceived Stress</u>	16				
Base to 1-mo		(9.60)	(4.80)	-2.050*	.47
Base to 3-mo		(9.56)	(4.74)	-1.5.11	.37
1 month to 3-mo		(7.44)	(7.58)	-.440	.02
<u>Diabetes Empowerment (DES-SF)</u>	15				
Base to 1-mo		(8.00)	(7.30)	-1.290	.18
Base to 3-mo		(6.88)	(7.75)	-1.589	.43
1 month to 3-mo		(8.10)	(6.31)	-.351	.13

* $p < .05$

** $p < .01$

Table 9. Wilcoxon-Signed-Ranked Tests (Baseline to 3-mo)

Variable	<i>n</i>	Mean ranks		<i>Z</i>	<i>d</i>
		(neg.)	(pos.)		
<u>Diabetes Support Attitudes (DCP)</u>	16				
Support Needs		(5.20)	(9.40)	-1.945	.51
Support Received		(5.67)	(9.56)	-1.479	.54
Support Attitudes		(6.33)	(9.11)	-1.254	.28
<u>Diabetes Self-Management (DCP)</u>	20	(6.33)	(11.08)	-2.089*	.51
<u>AADE-7 Goals Achieved</u>	15				
Healthy eating		(3.00)	(6.67)	- 2.427*	.96
Being active		(3.25)	(7.57)	-1.790	.39
Monitoring		(7.17)	(4.79)	- .628	.02
Taking medications		(0.00)	(3.50)	- 2.207*	.56
Problem solving		(7.75)	(4.21)	- .845	.09
Healthy coping		(4.00)	(4.67)	-1.409	.51
Risk reduction		(0.00)	(1.50)	-1.342	.27
Composite Score		(4.25)	(8.04)	- 2.765**	.67
<u>Glycemic Control (Hba1c)</u>		(10.61)	(8.30)	-2.154*	.73

**p* < .01
***p* < .001

Table 10. Spearman's *rho* Correlations with Participant Baseline Characteristics

Variable	Obs	Des	Act aware	Non-judge	Non-react	PSS	PAID	DES-SF	Sup Needs	Sup Rec	Sup Att	DSM	HbA1c
Age	-.11	-.03	-.07	-.08	-.08	-.27	-.15	.37*	-.21	.05	-.02	.55**	.14
Race	.40**	-.01	.15	.01	-.15	-.10	-.15	.01	.01	-.10	.03	-.15	.48**
BMI	.36*	-.01	.01	.10	.19	.16	.18	-.15	-.25	-.21	.24	-.15	.08
DM yrs.	-.31	.14	.02	-.04	.19	-.01	.23	.02	-.01	.11	-.32	.31	-.67
DM type	.25	-.21	-.07	-.07	.19	.06	.07	-.08	-.01	-.32	.10	-.44*	.34*
#in Home	-.05	.20	.13	.11	-.06	.12	-.04	-.13	.03	.32	.23	.29	-.23

* = $p < .01$

** = $p < .001$

Race (1=white; 2= black)

DM Type (1-T1D; 2=T2D)

in Home= number of people living in household

Obs= observing mindfulness facet

Des= describing mindfulness facet

Act aware= acting with awareness mindfulness facet

Non-judge= non-judgment mindfulness facet

PSS= Perceived Stress Scale

Table 11. Spearman's *rho* Correlations (Baseline)

Variable	Des	Act aware	Non-judge	Non-react	PSS	PAID	DES-SF	Sup Needs	Sup Rec	Sup Att	DSM	Hba1c
Obs.	.13	.27	-.07	-.23	-.08	-.24	.32	-.10	.03	.14	-.17	-.11
Des.		.48**	.59**	.26	-.10	-.26	.16	.04	.22	.13	.03	-.12
Act/Aware			.59**	.23	-.18	-.21	-.08	-.36*	.21	.02	.13	.14
Non-judge				.22	-.24	-.14	-.01	-.28	-.02	.10	.08	.17
Non-react					-.07	-.14	-.13	.15	-.11	-.24	-.24	-.08
PSS						.62**	-.37*	.29	.12	.05	-.39*	.18
PAID							-.45**	.24	-.05	-.25	-.23	.16
DES-SF								-.17	.17	.09	.26	-.19
Sup Needs									.50*	-.25	-.32	.08
Sup Rec										.18	.01	-.14
Sup Att											.11	-.01

* = $p < .01$

** = $p < .001$

Obs= observing mindfulness facet

Des= describing mindfulness facet

Act aware= acting with awareness mindfulness facet

Non-judge= non-judgment mindfulness facet

PSS= Perceived Stress Scale

PAID=Problem Areas in Diabetes Scale

DES-SF- Diabetes Empowerment Short Form

Sup Needs= Support Needs subscale of the Diabetes Support Attitudes Scale

Sup Rec= Support Needs subscale of the Diabetes Support Attitudes Scale

DSM= Diabetes Self-Management Questionnaire adapted from Diabetes Care Profile

Table 12. Spearman's *rho* correlations (3-mo.)

Variable	Des	Act	Non- aware	Non- judge	PSS react	PAID	DES- SF	Sup SF	Sup Needs	Sup Rec	DSM Att	Hba1c
Mindfulness												
<i>Obs</i>	.40	.11	.04	.21	-.05	-.04	.11	.27	.30	.19	-.30	-.03
<i>Des</i>		.23	.30	.16	-.18	-.12	.50*	-.01	.21	.35	.08	.12
<i>Act/aware</i>			.84**	.17	-.59**	-.54**	.42*	.03	.08	.32	.46*	-.04
<i>Non-judge</i>				.12	-.59**	-.53**	.43*	-.12	.04	.31	.47*	-.13
<i>Non-react</i>					-.30	-.52**	-.04	-.29	-.34	-.05	.12	-.01
PSS-10						.21	-.65**	.04	-.11	-.01	-.40	-.09
PAID							-.03	.10	.04	-.35	-.43*	-.01
DES-SF								.22	.29	.16	.54**	.12
Sup Needs									.78**	.44	-.13	.02
Sup Rec'd										.55**	.26	-.18
Sup Att.											.26	-.05

* = $p < .01$

** = $p < .001$

Obs= observing mindfulness facet

Des= describing mindfulness facet

Act aware= acting with awareness mindfulness facet

Non-judge= non-judgment mindfulness facet

PSS= Perceived Stress Scale

PAID=Problem Areas in Diabetes Scale

DES-SF- Diabetes Empowerment Short Form

Sup Needs= Support Needs subscale of the Diabetes Support Attitudes Scale

Sup Rec= Support Needs subscale of the Diabetes Support Attitudes Scale

DSM= Diabetes Self -Management Questionnaire adapted from Diabetes Care Profile

5.0 ADDITIONAL RESULTS

There were seven participants assigned to the Control Group prior to revision of the study design; four Control participants completed the study. Although the Control Group was not included in the statistical analysis, the same descriptive statistics were collected as was for the Mind-STRIDE group. Descriptive statistics are presented in Tables 13 and 14.

Table 13. Control Group Demographics (n=7)

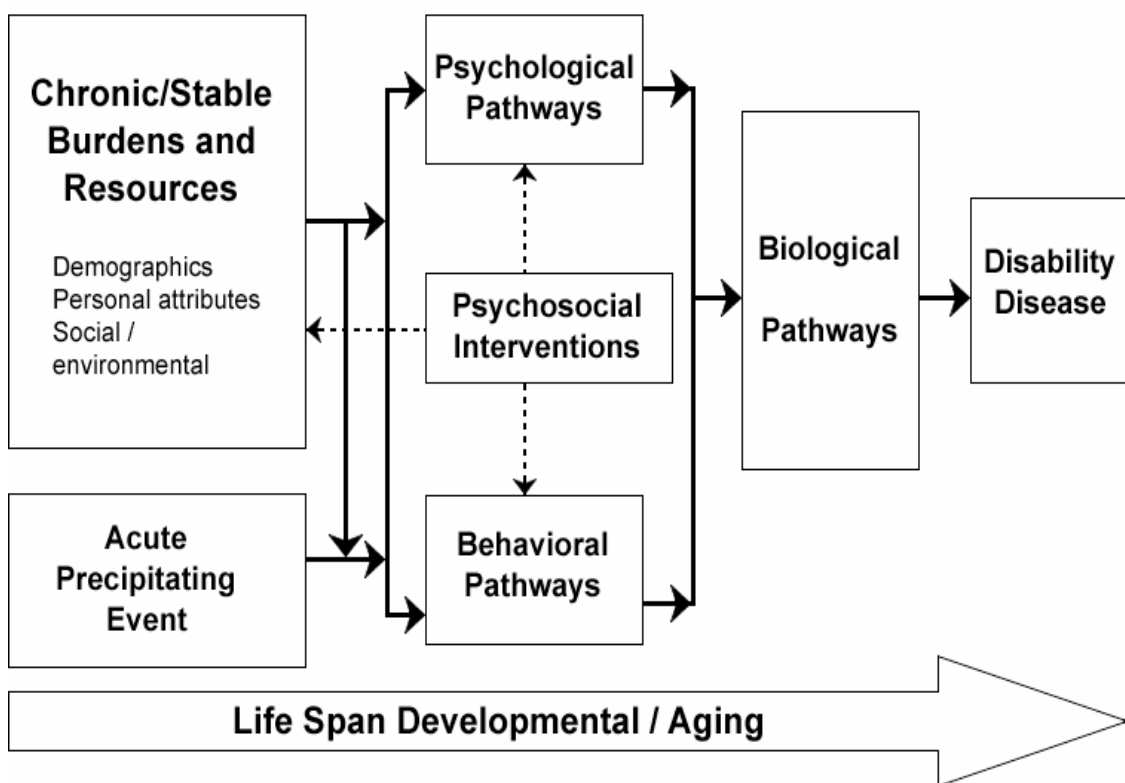
Variable	Mean± <i>SD</i>	Median (range)	% (n)
Hba1c (%)	9.7 ± 1.7	9.9 (7.4-12.3)	
BMI (kg/m ²)	30.7 ± 5.5	32 (21 - 37)	
Age (yrs.)	60.6 ± 9.2	63 (48 - 72)	
Sex (Male)			85.7 (6)
Race (White)			71.4 (5)
DM (T2D)			100 (7)
Duration of DM (yrs.)	14.7 ± 14.7	13 (.5- 55)	
Married			42.9 (3)
Number of People Household			
Live Alone			57.1 (4)
Live with one other			42.9 (3)
Education			
High School Graduate			28.6 (2)
Some College			57.1 (4)
Bachelor's Degree			14.3 (1)
Graduate Degree			0
Employment Status			
Full-time			28.6 (2)
Part-time			14.3 (1)
Retired			42.9 (3)
Disabled			14.3 (1)

Table 14. Descriptive Statistics for Control Group at Baseline and 3-mo

Variable	Baseline (<i>n</i> =7) Median (range)	3-mo (<i>n</i> =4) Median (range)
Mindfulness		
<i>Observing</i>	39.5 (35-44)	30 (27-33)
<i>Describing</i>	31 (29-33)	31 (27-35)
<i>Acting with Awareness</i>	24.5 (21-28)	20 (13-27)
<i>Non-judgment</i>	25.5 (19-32)	26.5 (23-30)
<i>Non-reactivity</i>	28 (26-30)	26.5 (26-27)
Diabetes Related Distress (PAID)	13.8 (5-22.5)	10.6 (5-16.25)
Perceived Stress (PSS-10)	22.5 (20-25)	18 (11-25)
Diabetes Empowerment (DES-SF)	33 (29-37)	35.5 (33-38)
Diabetes Support Attitudes (DCP)		
Support Needs	2.5 (2-3)	3.67 (3-5)
Support Received	4.17 (3-5)	3.92 (3-5)
Support Attitudes	4.17 (4-5)	
Diabetes Self-Management (DCP)	8 (4-12)	22.5 (22-23)
Glycemic Control (HbA1c)(%)	9.9 (7.4-12.3)	7.1 (5.8-8.3)

APPENDIX A: CONCEPTUAL FRAMEWORK

Model of Shared Psychobiological Pathways



APPENDIX B: MANUSCRIPT #3

Mind-Body Therapies in Diabetes Management
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November 18, 2013

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Diabetes Association is to prevent and
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Background and Clinical Problem

Practitioners of meditation have long believed in its ability to treat stress and chronic disease. The physiological basis of this belief has never been fully described, but as current research continues to reveal the intricacies of neuro-endocrine pathways, meditation, yoga, and other mind-body therapies are considered to be promising options in the treatment of diabetes.

The prevalence of diabetes is increasing dramatically worldwide.¹ Negative effects of physiological and emotional stress on blood glucose control have been described in the literature.^{2,3} Mind-body therapies, such as meditation, yoga, *qi-gong*, and other relaxation techniques, have been studied in diabetes as a means of decreasing stress-related hyperglycemia.⁴⁻⁸ The objective of many mind-body therapies is to facilitate attainment of a physiological state that counteracts the stress response and develops into a permanent set of traits among practitioners.

Physiological and emotional stress activate neuro-endocrine and sympathetic pathways via the hypothalamic-pituitary-adrenal axis and medullary adrenal sympathetic system.^{9,10} Circulating catecholamines and glucocorticoids affect the structure and function of a variety of tissues and induce inflammatory cytokines that lead to increased glucagon production and decreased uptake and disposal of glucose in peripheral muscles.¹¹ Cytokines, primarily interleukin 6, have been strongly implicated in oxidative stress and inflammatory processes that lead to insulin resistance and vascular complications.¹¹⁻¹³

The relaxation response promotes regulation of cortisol and other stress hormones.¹⁴ Structured programs of meditation, such as Transcendental Meditation and Mindfulness-Based Stress Reduction (MBSR), train participants in focused attention and diaphragmatic breathing to invoke this response. Other relaxation therapies involve progressive muscle relaxation, biofeedback, and a variety of behavioral stress management techniques, such as guided imagery.

Yoga is a traditional Indian practice that includes diaphragmatic breathing and *asanas* (body postures that promote physical comfort and mental composure). Yoga experts believe that some *asanas* exert positive effects on various endocrine glands.¹⁵ *Qi-gong* is an ancient Chinese form of “moving meditation” similar to *t'ai chi* that combines slow diaphragmatic breathing with spiral and circular body movements.¹⁶

Case Study

K.M. is a 57-year-old black woman with hypertension, hyperlipidemia, and a 5-year history of type 2 diabetes treated with metformin and a sulfonylurea who presents for follow-up of diabetes. Her A1C has been > 7.5% for the past year. Her serum creatinine is noted to have increased to 1.6 mg/dl since the last appointment with her primary care provider. She complains

of a lot of stress at home. She has been intolerant of thiazolidinedione medications because of edema and weight gain. She has not been able to lose weight despite multiple attempts at dieting and has difficulty exercising because of pain related to osteoarthritis in her hips and knees. Her health insurance does not cover many newer diabetes medications, and she cannot afford high-cost medications. She is fearful of needles and wants to avoid injections.

Physical exam reveals a BMI of 32 kg/m² and blood pressure of 138/84 mmHg. Acanthosis nigricans is noted at the skin folds of her posterior neck. Her waist circumference is 40 inches. Her heart and lung examination are normal, and her abdomen is obese and non-tender without masses. The remainder of her physical examination is unremarkable. Pertinent laboratory values include A1C of 7.8%, fasting plasma glucose (FPG) of 168 mg/dl, and serum creatinine of 1.6 mg/dl.

Clinical Question

Are there any cost-effective, non-pharmacologic therapies in addition to weight loss and exercise that may help improve glycemic control in adults with diabetes?

PICO Format

1. Population: adults with diabetes
2. Intervention: meditative therapies for glycemic control
3. Comparison: non-meditative therapies for glycemic control
4. Outcomes of interest: A1C and FPG

Search Strategy

To conduct an integrated review of the literature, three databases (Medline, CINAHL, and AMED) were queried using the search terms meditation, yoga, relaxation techniques, breathing exercises, diabetes type 1 or type 2, hyperinsulinism, and hemoglobin A, glycosylated. This search yielded 20 citations written in English between 1974 and 2007. Articles written in English, using adult samples, and published after 1985 were reviewed. Before 1985, most of the work done in this area was qualitative or anecdotal. Articles were retrieved from the Health Science Library System at the University of Pittsburgh in Pennsylvania.

The search was limited to two dependent variables: A1C and FPG. A1C is an accepted measure of glycemic control in diabetes that estimates the average blood glucose level from the previous 3 months. The American Diabetes Association (ADA) recommends maintaining an A1C < 7% to decrease the risk of microvascular complications. FPG provides a measure of glycemic control in terms of pancreatic β -cell function and insulin resistance.¹⁶

Results and Critical Appraisal

All study interventions took place in outpatient settings without interruption or change in the participants' current diabetes therapy. Improvements in A1C consistently correlated with improvements in FPG. No adverse effects were reported in any of the studies. All but one study were performed in adults with type 2 diabetes, and one study was done in adults with type 1 diabetes. Additionally, all but one of the studies used a group intervention; however, possible cohort effects were not addressed by the authors. A comparison of the studies is found in [Table 1](#).

Table 1. Comparison of Studies Included in Integrative Review

Citation	Design (duration)	n (study population)	Setting	Meditative Interventions	Non-Meditative Interventions	Variable of Interest	Outcome	Evidence Grade
Rosenzweig et al., 2007 ¹⁷	POS (12 weeks)	14 (T2D)	Academic health center United States	MBSR		A1C	NS at week 8 P = 0.03 at week 12	B
Khatri et al., 2007 ⁷	RCT (3 months)	101 (MSX)	Outpatient clinic India	Yoga	Usual care	A1C FPG	P < 0.001 P < 0.001	A
Elder et al., 2006 ¹⁸	RCT (6 months)	60 (T2D)	Health maintenance organization United States	Ayurvedic protocol	DMED	A1C FBG	P = 0.006* P = 0.001* *(for baseline A1C > 6.5%)	A
Singh et al., 2004 ⁴	POS (40 days)	24 (T2D)	Outpatient clinic India	Yoga		A1C FPS	P < 0.05	B
Malhotra et al., 2005 ⁶	POS (40 days)	20 (T2D)	Outpatient clinic India	Yoga		FPG	P < 0.05	B
McGinnis et al., 2005 ¹⁹	RCT (3 months)	39 (T2D)	Outpatient clinic United States	RT + BF (individual)	ED	A1C FPG	P < 0.01 P < 0.05	A
Bijlani et al., 2005 ⁵	POS (10 days)	98 (T2D/mixed cardiovascular risk)	Outpatient clinic India	Yoga + ED		FPG	P < 0.001	B
van Rooijen et al., 2004 ²⁰	RCT (12 weeks)	149 (T2D/Black African women)	Hospital outpatient clinic S. Africa	RT + ED	Aerobic exercise + ED	A1C	P = 0.052	C
Stenstrom et al., 2003 ²³	RCT (14 weeks; interrupted time series)	36 (T1D)	Academic health center Sweden	Stress Management	Usual care	A1C	NS	A
Surwit et al., 2002 ²¹	RCT (1 year)	108 (T2D)	Academic outpatient clinic United States	RT + DMED	DMED	A1C	P < 0.05	A
Citation	Design (duration)	n (study population)	Setting	Meditative Interventions	Non-Meditative Interventions	Variable of Interest	Outcome	Evidence Grade
Tsujuchi et al., 2002 ⁸	RCT (4 months; interrupted time series)	26 (T2D)	Outpatient clinic Japan	<i>Qi-gong</i>	Usual care	A1C	P < 0.05	A
Jablon et al., 1997 ²⁴	RCT interrupted time series	20 (T2D)	VA outpatient clinic United States	RT + BF	Usual care	FPG	NS	A

BF, biofeedback; DMED, diabetes education; ED, education; MBSR, mindfulness-based stress reduction; MSX, metabolic syndrome X; NS, nonsignificant; POS, prospective observational study; RCT, randomized controlled trial; RT, relaxation techniques; T1D, type 1 diabetes; T2D, type 2 diabetes; VA, Veterans Administration.

Table 1.

Comparison of Studies Included in Integrative Review

Three observational studies performed in India using multi-modality yoga interventions observed positive improvements in glycemic control, prompting the investigators to conclude that the physiological mechanism should be further explored.⁴⁻⁷ A 2007 prospective observational pilot study on MBSR in type 2 diabetes demonstrated decreased A1C and psychological distress independent of weight loss and lifestyle modification.¹⁷ This was the first study to investigate MBSR in a cohort of individuals with diabetes.

Secondary analysis of a randomized controlled trial (RCT) of 60 adults with type 2 diabetes was performed by Elder et al. using whole-systems analysis to evaluate a traditional multi-modality Indian Ayurvedic intervention protocol that incorporated daily meditation. The Vedic intervention was associated with decreased A1C and mean FPG only in participants whose baseline A1C was > 6.5%.¹⁸ The results of this study were confounded by the other independent variables that included exercise, diet, and an herbal supplement.

Five other small RCTs showed trends toward positive improvements in A1C and FPG.^{7,8,19-21} Control groups were variable and often included a second intervention, such as general health education, diabetes education, or exercise. A South African study that compared an intervention of education plus aerobic exercise to one of education plus relaxation therapy in Black African women showed small but similar improvements in A1C in both groups, which the authors attributed to study effect.²⁰

Studies of relaxation techniques with and without biofeedback had mixed results. Surwit et al. studied 108 subjects with type 2 diabetes for 1 year following a five-session group intervention of relaxation therapy plus diabetes education. There was a 0.5% reduction in A1C relative to control subjects, with 32% of the treatment group having a $\geq 1\%$ reduction in A1C compared to 12% of control subjects.²¹ Reductions in A1C of as little as 0.6% have been associated with a significant reduction in risk of complications in type 2 diabetes.²²

Another study of relaxation therapy plus biofeedback demonstrated improved glycemic control that was sustained for 3 months and was associated with decreased depression and anxiety scores.¹⁹ However, a Swedish study of relaxation therapy in adults with type 1 diabetes failed to show an improvement in A1C despite improvement in mood.²³ Similar findings were reported in a RCT of relaxation therapy plus biofeedback in which there was no improvement in FPG or other measures of glucose tolerance despite reductions in psychological and physiological stress.²⁴

Improvements in A1C with *qi-gong* were associated with improved mood and decreased C-peptide.⁸ The authors suggest that the observed reduction in C-peptide may suggest an underlying mechanism of decreased insulin resistance with *qi-gong*.

Summary Evidence Grading System for Clinical Practice Recommendations

Based on the ADA evidence grading system for clinical practice recommendations, in which A is clear evidence from RCTs, B is supportive evidence from well-conducted cohort studies, C is from poorly controlled studies, and E is from expert consensus or clinical experience, four studies met criteria for level B and one study met criteria for level C. Although seven studies met most of the criteria for level A, none were large multi-center trials. All the RCTs reviewed had relatively small sample sizes and lacked scientific rigor, limiting their ability to make generalizable conclusions but provided convincing evidence for further inquiry. Four of eight RCTs reviewed for this article compared the effects of meditative therapies to those of usual care using conventional treatment regimens. Four others were confounded by additional non-meditative interventions. Larger RCTs that investigate the mechanisms of action and compare effects of specific mind-body interventions on diabetes control are warranted.

Case Study Revisited

Because K.M.'s serum creatinine had increased above 1.4 mg/dl, metformin was discontinued. Her sulfonylurea dose was increased. She was referred to a registered dietitian for medical nutrition therapy and was advised to enroll in a yoga class being offered at the YWCA in her neighborhood. She was asked to return for follow-up in 3 months. If her A1C remains > 7%, further adjustments to her diabetes medication regimen will be considered.

Clinical Question Revisited/Implications for Practice

There are data to suggest that mind-body therapies may have an overall positive effect on glucose control. However, there is currently no conclusive evidence to support this hypothesis. No adverse effects were reported in any of the studies that were reviewed. Based on these studies, it appears that yoga, meditation, *qi-gong*, and relaxation therapy are safe techniques that may be of benefit in the treatment of diabetes but require further study.

Meditation, yoga, and other mind-body therapies are becoming more popular and accessible through local health clubs and wellness centers. These therapies may represent cost-effective self-care strategies for improving glucose control through regulation of neuro-endocrine processes that impair glucose metabolism. Until more research is available and the effects of these techniques are more clearly defined, mind-body therapies could be recommended only as potentially helpful adjuncts to conventional diabetes therapy.

Footnotes

***Editor's note:** The articles published in this department present patient cases using an evidence-based practice framework presented with "PICO" components: population, intervention, comparison, and outcome; a description of the search strategy employed for the integrative review; a summary of the results and critical appraisal of the search; and an evaluation of the scientific and medical evidence base for recommendations.*

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[Abstract/FREE Full Text](#)

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[Abstract/FREE Full Text](#)

22. [↵](#)

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[Abstract/FREE Full Text](#)

23. [↵](#)

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[CrossRefMedline](#)

24. [↵](#)

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[CrossRefMedline](#)

APPENDIX C: VETERANS' SURVEY

Researcher: "We are thinking of starting classes to teach veterans how to reduce stress. We need to learn from people like you how interested you are in attending such classes. May I ask you a few questions to get your opinion?" (If veteran says, "No," say "O.K., no problem." If veteran says "Yes," ask the questions below).

A type of meditation called "Mindfulness" is aimed at reducing stress and increasing a person's level of awareness. Doing this type of stress reduction has shown improvement in signs and symptoms for some people who have chronic health problems. This stress reduction program involves eight weekly two-hour classes that include group discussions, breathing exercises, meditation, and gentle yoga.

Would you be interested in attending mindful stress reduction classes if they were offered?

____ Yes ____ No

If yes, what would you want to gain? _____

If no, why not?

Are there any factors that influence your decision? (such as location, time of day, or parking)

Would you be interested in receiving printed information on mindful stress reduction techniques?

____ Yes ____ No

APPENDIX D: ABSTRACT EASTERN NURSES RESEARCH SOCIETY

22ND ANNUAL SCIENTIFIC SESSIONS, MARCH 24-26, 2010, PROVIDENCE RHODE

ISLAND (POSTER PRESENTATION)

The Effect of Mindfulness Based Stress Reduction on Stress, Glycemic Control and Insulin Resistance in Type 2 Diabetes

Theoretical Framework: Diabetes increases the risk of stroke and cardiac death two to four fold and leads to debilitating micro-vascular complications that can be delayed or prevented by maintaining blood glucose control. Mindfulness Based Stress Reduction (MBSR) and other mind-body therapies have been associated with improved metabolic control in type 2 diabetes, but the underlying mechanisms of these approaches are not fully understood. Insulin Resistance (IR) is considered an underlying link between type 2 diabetes and vascular complications. Activation of the neuro-endocrine stress response increases IR and pancreatic beta cell burden, which may contribute to the progression of type 2 diabetes. The practice of MBSR may decrease IR and blood glucose by neutralizing the neuro-endocrine stress response.

Purpose: To explore the effect of Mindfulness Based Stress Reduction (MBSR) on perceived and physiologic stress, insulin resistance (IR), and blood glucose control in type 2 diabetes.

Preliminary Findings: A preliminary feasibility/acceptability survey of 25 patients with type 2 diabetes performed at a diabetes clinic showed that 60% of respondents would be interested in attending an 8- week MBSR course if the location was convenient.

Methods: A pilot study using a randomized controlled design of the relationship of an 8- week MBSR intervention with stress, IR, and glycemic control in 15 adults with type 2 diabetes vs. 15 attention controls receiving general health education. Outcome measures will include mean arterial blood pressure, cytokines IL-6 and IL-10, the Perceived Stress Scale, the Appraisal of Diabetes Scale, The Freiberg Mindfulness Questionnaire, IR (HOMA-IR) and glycemic control (home blood glucose monitoring and hemoglobin A1C). Baseline scores will be compared to post-intervention and 12- week follow- up scores between groups. Regression analysis will be conducted to explore the relationship between variables.

Conclusions and implications: This study will serve as the basis for a larger study of MBSR and metabolic control in individuals with diabetes.

APPENDIX E: MANUSCRIPT #4

Complementary and Alternative Medicine in Diabetes Care
Current Diabetes Reports, **December, 2012**, vol. 2, no. 6, 749-61

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Complementary and Alternative Medicine in Diabetes Care

Monica M. DiNardo · Jolynn M. Gibson ·
Lara Siminerio · Allison R. Morell · Edward S. Lee

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Abstract Growing numbers of people with diabetes in the U.S. and worldwide use complementary and alternative medicine (CAM) while receiving conventional medical therapy as a means of managing disease and improving quality of life. Although herbal and natural products are the most commonly used forms of CAM, mind–body approaches are also gaining popularity and scientific interest. Current findings suggest that CAM may help to promote an integrative, participatory model of diabetes care that relies upon provider knowledge of evidence-based therapies and patient disclosure of CAM use. Emerging evidence of positive findings with some natural products and mind–body therapies have been reported in glycemic parameters, markers of cardiovascular risk, and quality of life in individuals with type 2 diabetes; however, further investigation in well-designed, adequately powered studies is needed before use of CAM modalities can be recommended as part of clinical care.

Keywords Complementary and alternative medicine · Herbal supplements · Nutritional supplements · Mind–body therapies · Diabetes mellitus · Type 2 diabetes · Prediabetes · Insulin resistance

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Introduction

Use of complementary and alternative medicine (CAM) is a growing phenomenon among people with chronic illnesses, including diabetes mellitus [1, 2]. A recent report indicated that approximately 40 % of adults and 12 % of children in the U.S. used CAM during the previous year [3]. As in the general population, CAM users who have diabetes tend to be more educated and to have a higher income and are mostly female [2, 4–6]. U.S. adults spent \$33.9 billion in out-of-pocket expenses for CAM products and visits to CAM practitioners in 2007 [7]. The estimated global CAM market is projected to be \$113 billion [8].

CAM has its roots in traditional healing practices of many cultures and is generally divided into four categories: (1) natural products (vitamins, herbal medicines, dietary supplements), (2) mind–body medicine (yoga, meditation, deep-breathing exercises, acupuncture), (3) manipulative and body-based practices (massage therapy, spinal manipulation), and (4) other (whole medical systems, energy fields, movement therapies, traditional healers) [1].

The National Center for Complementary and Alternative Medicine (NCCAM) currently lists three “key points”

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regarding CAM use in diabetes: (1) In general, there is currently insufficient scientific evidence to prove that dietary supplements substantially benefit users with type 2 diabetes (T2D) or its complications; (2) CAM therapies do not replace conventional therapy; and (3) CAM users should report CAM use to their health care providers to ensure safe care [1].

According to NCCAM, CAM is difficult to define because the field is very broad, is constantly changing, and encompasses a group of systems, products, and practices that are generally unfamiliar to practitioners of conventional medicine. Most CAM use is “complementary”—that is, used together with conventional medicine, rather than “alternative,” used in place of conventional therapies [2, 5, 6, 9, 10, 11•]. The evolving field of *integrative medicine* combines treatments from both conventional medicine and CAM for which there is some high-quality evidence of safety and effectiveness.

In this article, we summarize studies related to the application of CAM in diabetes as an update of current evidence over the past 3 years. There were 41 articles identified in a query of Pub Med in April 2012 for human research publications in English language peer-reviewed journals from 2010 to 2012. Most of the studies were performed in adults with T2D or prediabetes, although a few studies included individuals with T1D.

Epidemiologic Studies

During the past 3 years, epidemiologic studies of CAM use among individuals with diabetes and prediabetes have been reported worldwide (Table 1). In general, CAM use was found to be motivated by a desire to prevent, cure, or limit progression of diabetes, to improve quality of life, and to take a more active role in personal health care [2, 4, 10, 12]. CAM users with diabetes commonly consider these therapies to be safe when used in conjunction with conventional therapies, and some believe that conventional medicine by itself was not working [5].

In a 2008 survey of parents of children with T1D, parents identified “hope for improving well-being” (92 %) as the primary reason for using CAM as part of their child’s health care [13]. A more recent survey of 467 participants in the SEARCH for Diabetes in Youth study found that participants who used a “CAM diet” reported improved quality of life (QOL), but those using supplements and stress-reduction activities reported decreased QOL [11•]. The temporal sequence between CAM use and assessment of QOL in this study was not specified, and the effects of CAM on QOL in this population remain unclear.

Moreover, CAM users with diabetes commonly report having difficulty communicating with their medical

providers about CAM use and fear disapproval [4, 5, 9, 10, 12]. In one U.S. survey of 806 “Taking Control of Your Diabetes” seminar attendees (2004–2006), 73 % had disclosed the use of CAM to their medical providers, with Hispanic participants being nearly four times less likely to report CAM use [12]. Diabetes was a predictor of CAM use after controlling for ethnicity (OR=2.37; 95 % CI: 1.18, 4.77), and ethnicity played a role in determining which types of CAM were used.

Clinical Studies

Natural Products

Overall, herbal and natural products are the most commonly used types of CAM in persons with T2D [8•, 12, 14•]. Several small experimental investigations have reported effects of natural foods on glycemic parameters, insulin resistance, lipids, and oxidative stress in people with T2D (Table 2). A randomized controlled study (RCT) of 114 patients with T2D treated with oral medications compared participants ($n=56$) who received polyphenol-rich supplement containing pomegranate extract, green tea extract, and ascorbic acid with placebo controls ($n=58$). As compared with controls, pre–post changes were found in the treatment group for serum malondialdehyde (MDA), a by-product of lipid peroxidation, (-0.57 ± 0.55 ; $p<.001$), low-density lipoprotein cholesterol (LDLc) (-15.74 ± 29.76 ; $p<.001$), high-density lipoprotein cholesterol (HDLc) (4.51 ± 9.16 ; $p<.001$), antioxidant capacity (0.45 ± 0.62 ; $p<.001$), and total glutathione (GSH) (761.86 ± 652.71 ; $p<.001$) [15]. The researchers concluded that these results suggest that polyphenol-rich supplements may be beneficial in reducing cardiovascular risks in persons with T2D.

Berberine, an herb used in Chinese medicine for antibiotic properties, has shown glucose- and lipid-lowering properties in previous laboratory and anecdotal studies [16]. A recent RCT of berberine investigated its potential mechanisms of action in 60 patients with T2D and dyslipidemia [17•]. Comprehensive metabonomic analysis found significant decreases in the concentrations of 13 fatty acids following berberine administration, 10 of which differed statistically from placebo. These findings suggest a possible role of berberine in the treatment of T2D by targeting free fatty acid metabolism [17•].

A single-blind placebo-controlled study ($n=60$) investigated the effects of ground garlic tablets (300 mg of 0.6 % *allium sativum* three times per day) + metformin, as compared with metformin + placebo in patients with T2D. This RCT found significantly decreased percent change in FPG levels from baseline to 24 weeks in the treatment group, as compared with controls (-3.12 % vs. 0.59 %, $p<.005$).

Table 1 Global prevalence, demographics, and factors related to complementary and alternative medicine (CAM) use in diabetes

Location	Sample	Study design	% CAM use	CAM modalities used	Reasons for CAM use in DM	Factors associated with CAM use
Australia	<ul style="list-style-type: none"> • n=69 CAM Users 	<ul style="list-style-type: none"> • Multicenter cross-sectional • 2008 	46.3 %	<ul style="list-style-type: none"> • Multivitamins (40 %) • Cinnamon (25 %) • Co-enzyme q10 (25 %) • Prayer (25 %) 	<ul style="list-style-type: none"> • Treat DM (62.5 %) • General health and DM (37.5 %) 	<ul style="list-style-type: none"> • Born overseas (63 %; p=0.044) • Age, gender, wealth, duration of DM were not associated with rate of CAM use
<i>Manya et al. 2012</i>	<ul style="list-style-type: none"> • T1D/ T2D • Female 43 % • age ≥18 years 	<ul style="list-style-type: none"> • Questionnaire 				
Austria	<ul style="list-style-type: none"> • n=198 	<ul style="list-style-type: none"> • Cross-sectional 	34 % T1D	<ul style="list-style-type: none"> • 1/3 used biologically-based tx: 1. Vitamin and mineral supplements 2. Herbal medicines 3. Cinnamon 	<ul style="list-style-type: none"> • Prevention (36 %) • Improved QOL/well-being (13 %) • Expected positive impact on DM (4 %) 	<ul style="list-style-type: none"> • Educational level influenced type of supplement used
<i>Fabian et al. 2011</i>	<ul style="list-style-type: none"> • CAM Users • T1D, T2D • female >50 % 	<ul style="list-style-type: none"> • Structured Interviews • University clinic 	31 % T2D			
Canada	<ul style="list-style-type: none"> • n=400,055 	<ul style="list-style-type: none"> • Cross-sectional (CCHS)* 	8 % Diabetes visited a CAM practitioner	<ul style="list-style-type: none"> Those with DM used: • Acupuncture • Reflexology 	<ul style="list-style-type: none"> • Not measured 	<ul style="list-style-type: none"> • Asthma, diabetes and migraine headache are significant predictors of CAM use • Types of CAM services varied by chronic disease • Participants with DM were less likely to use CAM services than the general population
<i>Metcalfe et al. 2010</i>	<ul style="list-style-type: none"> • DM participants • female=47 % • mean age: 62.9±14.7 years 	<ul style="list-style-type: none"> • 2001–2007 • Interviews 				
Israel	<ul style="list-style-type: none"> • n=3,742 	<ul style="list-style-type: none"> • 2005–2006 	46.9 %	<ul style="list-style-type: none"> • Herbal remedies : 38.8 % (T2D) • Manual/movement therapies: 28.6 % (T2D) • T2D & non-DM users reported similar use of folk/traditional medicine: 39 %–46 % and nutritional supplements 37 %–41 % 	<ul style="list-style-type: none"> • Not measured 	<ul style="list-style-type: none"> • Those with T2D had higher rate of CAM use in the previous year (p<0.05) • CAM use was associated with higher self-assessed religiosity in Jewish participants
<i>Ben-Arye et al. 2010</i>	<ul style="list-style-type: none"> • DM /CAM Users • (T2D=485) • female >50 % • age <60 years 	<ul style="list-style-type: none"> • Cross-sectional • Convenience sample • Questionnaire 				

Table 1 (continued)

Location	Sample	Study design	% CAM use	CAM modalities used	Reasons for CAM use in DM	Factors associated with CAM use
Jordan <i>Wazaiyy et al. 2011</i>	<ul style="list-style-type: none"> • $n=1,000$ CAM Users • (T2D=158; T1D=8) • female 59.6 % • age 51–60 years 	<ul style="list-style-type: none"> • Cross-sectional survey • Semistructured questionnaire by pharmacist 	16.6 %	<ul style="list-style-type: none"> • Herbal remedies (16.6 %) 1. Green Tea (20.5 %) 2. Aniseed (19.9 %) 3. Ginger (18.7 %) 	<ul style="list-style-type: none"> • Symptom relief (69.3 %) • Curing disease (18.1 %) • Slow disease progression (9.6 %) • ↓ Medication side effects (3 %) 	<ul style="list-style-type: none"> • Recommended by <ol style="list-style-type: none"> a. Family (41.6 %) b. Friends (26.5 %) c. Media (27.1 %) • ≥High School Education 83.7 %
Korea <i>Kim et al. 2011</i>	<ul style="list-style-type: none"> • $n=2,752$ CAM users-$n=677$ T2D • Male (57.2 %) • Female (42.8 %) 	<ul style="list-style-type: none"> • Cross-sectional study using the KNDP** database • 2005 • Questionnaire 	24.6 %	<ul style="list-style-type: none"> • Natural products: <ol style="list-style-type: none"> 1. Red ginseng 2. Herbal medicine 3. Silkworm 	<ul style="list-style-type: none"> • Not measured 	<ul style="list-style-type: none"> • Higher income • Diabetic neuropathy • Self-monitoring of blood glucose (SMBG) (Average annual cost of CAM \$793)
Malaysia <i>Hasan et al. 2011</i>	<ul style="list-style-type: none"> • $n=230$ CAM Users • (DM-$n=114$; T1D=89; T2D=25) • female 47.4 % • mean age=56.05±10.3 years 	<ul style="list-style-type: none"> • Case-control study • Interview 	49.6 %	<ul style="list-style-type: none"> • Herbal medicine (64.9 %) • Vitamins (57.9 %) • Ginseng (12.3 %) • Yoga (7.9 %) 	<ul style="list-style-type: none"> • Quality & Safety of CAM (63.2 %) • Complementary treatment for diabetes (53.5 %) • Family Hx of CAM use (21.9 %) 	<ul style="list-style-type: none"> • Decreased FBG (44 %, $p=0.045$) • Influenced of: <ol style="list-style-type: none"> a. Friends (39.5 %) b. Family (28.1 %) c. Advertisement (21 %) d. Health professionals (11.4 %) • Indian ethnicity (49.2 %) • Married (85.2 %) • Secondary school education (59.6 %)
Nigeria <i>Ogbera et al. 2010</i>	<ul style="list-style-type: none"> • $n=263$ CAM users: 	<ul style="list-style-type: none"> • Cross-sectional 	46 %	<p>Biological-based therapies only: local herbs, garlic, ginger, aloe vera, vitamins, and bitter leaf</p> <p>Most Common:</p>	<ul style="list-style-type: none"> • Blood glucose lowering (however, no benefit of CAM use noted, as compared with non-CAM user) 	<ul style="list-style-type: none"> • Age, literacy, use of insulin • Recommended by family members, neighbors or others with DM

Table 1 (continued)

Location	Sample	Study design	% CAM use	CAM modalities used	Reasons for CAM use in DM	Factors associated with CAM use
Taiwan	<ul style="list-style-type: none"> • (T1D/T2D) • Female-male ratio 2:1 • Age 60±10.7 years • Illiterate (3.5 %) 	<ul style="list-style-type: none"> • Interview 	<ul style="list-style-type: none"> • Before T2D dx: 22.7 % • After T2D dx: 61 % 	<ul style="list-style-type: none"> 1. Vitamins 2. Bitter leaf 3. Garlic 	<ul style="list-style-type: none"> • People around them believed in it (49.2 %) • Participant believed in CAM (38.6 %) 	<ul style="list-style-type: none"> • Primary source of CAM information: <ol style="list-style-type: none"> 1. Family (39 %) 2. Friends (27 %) 3. Media (19 %) 4. Physician (6 %) • ≥High school graduate (53.1 %)
<i>Chang et al. 2011</i>	<ul style="list-style-type: none"> • T2D • Female (55.8 %) • Age ≥18 years 	<ul style="list-style-type: none"> • Retrospective, Cross-sectional • Three regions of Taiwan: metropolitan, urban and rural • Structured interview • 2006–2007 		<ul style="list-style-type: none"> CAM modalities with the most significant increase AFTER diagnosis: <ol style="list-style-type: none"> 1. Nutritional supplements ($p < .001$) 2. Chinese herbal medicines ($p < .001$) 3. Diet modifications ($p = .003$) 4. Manipulative-based therapies ($p < .001$) 5. Biofield therapy ($p < .001$) 6. Bioelectromagnetic-based therapies ($p = .001$) 7. Supernatural healing therapies ($p < .001$) 8. Mind-body therapies ($p = .04$) 		
USA	<ul style="list-style-type: none"> • $n = 806$ • T1D/T2D • Male (71.4 %) • Age >45 years (84.6 %) 	<ul style="list-style-type: none"> • Cross-sectional • Questionnaire administered at (IKOYD)*** conferences in six U.S. cities • 2004–2006 	92.9 %	<ul style="list-style-type: none"> • Pharmacologic (81.9 %) a. Multivitamins (45.3 %) b. Vit E (35.7 %) c. Green tea (30.9 %) • Nonpharmacologic (80.3 %): CAMS <ol style="list-style-type: none"> a. Exercise (66.8 %) b. Prayer/meditation (35.9 %) 	<ul style="list-style-type: none"> • Feel better/stronger (77.2 %) [$p < 0.001$] • Control diabetes (69.9 %) • CAM effectiveness (68.4 %) • Decrease blood sugar (64.6 %) 	<ul style="list-style-type: none"> • Higher education ($p = .001$) • DM was a predictor of CAM use • Ethnic differences did not predict CAM prevalence but played a role in forms of CAM use <ul style="list-style-type: none"> • 73 % disclosed CAM use to medical provider • Hispanics were 4 times less likely to disclose CAM use to medical provider
<i>Villa-Caballero et al. 2010</i>						

Table 1 (continued)

Location	Sample	Study design	% CAM use	CAM modalities used	Reasons for CAM use in DM	Factors associated with CAM use
USA McCarty et al. 2010	• n=467 CAM users:	• Cross-sectional multisite • Interview	36.4 %	• CAM diet • Stress-reduction activities		• More barriers to treatment • CAM diet users reported higher QOL • Users of supplements and stress-reduction activities reported poorer QOL
	• T1D (9.6 %)/T2D	• SEARCH for Diabetes in Youth Survey Participants		• Supplements		• Older age • Longer duration of DM • Parental education >Bachelors Degree • Parental income >50,000
	• 13.8 (±3.9)	• 2006				
	• Female 55.9 %					
	• Caucasian 86.5 %					
	• Comorbidity 22.4 %					

*CCHS Canadian Community Health Survey

**KNDP Korean National Diabetes Program

Additionally, the treatment group had significant pre–post improvements in mean total cholesterol (6.2 mg/dl, –2.82 %, $p \leq .005$), LDLc (3 mg/dl, –2.18 %, $p \leq .005$), triglycerides (5.2 mg/dl, –3.12 %, $p < .005$), and HDLc (2.36 mg/dl, 6.72 %, $p < .005$) [18]. Previous studies of garlic in persons with T2D had mixed results, however [19–21]. The exact mechanisms of action of garlic as an antidiabetic agent are still not clear. *Allicin*, the principally bioactive compound in garlic, may play a role in increasing circulating insulin levels [21]. One proposed mechanism for the antilipidemic effects of garlic is inhibition of HMG-CoA reductase [22, 23].

Cinnamon, a rich source of polyphenols used for centuries in Chinese medicine, has been shown to affect blood glucose and insulin signaling [24]. A meta-analysis of clinical studies of cinnamon use (as whole cinnamon and/or cinnamon extract) in individuals with T2D and prediabetes included eight clinical trials. Random-effects modeling found statistically significant reduction of fasting plasma glucose (FPG) (-0.49 ± 0.2 mmol/L $p = .03$), leading the authors to conclude that cinnamon improves FPG in people with T2D or prediabetes [25••]. A clinical trial by Akilen et al. further supports the favorable effects of cinnamon. In this study, 58 individuals with treated T2D and HbA1c >7 % were randomly assigned to receive either 2 g of cinnamon daily or placebo for 12 weeks. Significant decreases in HbA1c (8.3 %–7.9 % vs. 8.6 %–8.7 %; $p < .005$) and mean change in systolic (–3.4 vs. 0.4 mmHg; $p < .001$) and diastolic (–5 vs. –0.7 mmHg; $p < .001$) blood pressures were observed in the cinnamon group, as compared with placebo. There were no significant differences in serum lipids within or between groups [26].

Portulaca oleracea L. (PO, commonly known as “pigweed”) rich in omega 3 fatty acids, glutathione, flavonoids, polysaccharides, antioxidants, vitamins, and minerals, was compared with metformin in a small 8-week double-blind RCT ($n = 30$) [27]. After 2 months, significant within-group decreases in serum lipids, liver function tests, fasting and postprandial blood glucose, insulin, body weight, and BMI and increases in HDL and albumin were reported in the PO group. Comparable changes were seen in the metformin group. Body weight and blood glucose values were obtained by self-report; all other tests were derived by laboratory analysis.

Several other small studies of natural food products were performed in people with T2D, prediabetes, and related complications (Table 2). A combination of *Epigallocatechin gallate* (the main component of green tea extract) and amla (an extract from the Indian gooseberry) showed improvements in plasma glucose levels, LDL/HDL ratio, and measures of oxidative stress in patients with T2D and uremia [28•]; turmeric was found to lower urine protein and urinary IL-8 in patients with diabetic nephropathy [29]. Studies of *Rauvolfia-citrus* tea, a Nigerian folk medicine, [30], broccoli sprouts

Table 2 Summary of recent studies of natural complementary and alternative medicine products

Modality	Type of study	Sample size (n –) [mean age ± SD]	Duration of study	Primary outcomes (*p<.05; **p<.001)
Epigallocatechin gallate + Amla <i>Huang et al. 2011</i>	Quasi-experimental healthy volunteers (n=15) served as “normal” controls	n=13 (DM/ +uremia) [49±17 years]	3 months	Plasma glucose* HDL*, LDL/HDL ratio*, and antioxidant defense* HbA1c Lipids: HDL**LDL/HDL ratio* Hepatic and renal functions C-reactive protein* Plasma antioxidant/oxidative status*
Flaxseed/ flaxseed oil <i>Taylor et al. 2010</i>	RCT, 3 parallel groups: Milled flaxseed Flaxseed oil No flaxseed control	n=34 (T2D, well-controlled) [52.4±1.5 years]	12 weeks	Fasting plasma glucose (FPG)F HbA1c Insulin Phospholipid fatty acid
Turmeric <i>Khajehdehi, P., et al. 2011</i>	Randomized, double blind, placebo controlled	n=40 (T2D/ nephropathy) [52.6±9.7 years]	2 months	Glycemia Lipids Serum creatinine Urine protein** Urinary IL-8 excretion*
Gymnema sylvestre <i>Om Santal Adivasi (OSA0) Al-Romayyan et al 2010</i>	Observational	n=11 (T2D) [50.1±3 years]	60 days	Fasting blood glucose (FBG)** Postprandial BG* Body weight, BMI Serum insulin** C-peptide*
Beberine <i>Gu et al. 2010</i>	RCT double-blinded, placebo controlled	n=60 (T2D /dyslipidemia) [51±9 years]	3 months	FBG** 2-h OGTT plasma glucose** HbA1c** LDL**, total cholesterol** Triglycerides*
Phenol-containing antioxidants <i>Fenercioglu, et al. 2010</i>	RCT placebo controlled	n=114 (new onset T2D) [53±7 years]	3 months	FBG HbA1c Lipids (LDL, HDL)** Plasma malondialdehyde (MDA)** Total glutathione (GSH)* Antioxidant capacity**
Almonds <i>Wien et al. 2011 Li et al. 2011</i>	RCT parallel-group RCT crossover	n=65 (prediabetes) [54 years) n=20 (T2D, mild dyslipidemia) (58 years)	16 weeks 12 weeks	Serum insulin Insulin Resistance (HOMA)* Beta cell function (HOMA) Serum lipids (LDL)* Adiposity Glycemic control Lipids
Broccoli Sprouts		n=81	4 weeks	FBG*

Table 2 (continued)

Modality	Type of study	Sample size (n –) [mean age ± SD]	Duration of study	Primary outcomes (*p<.05; **p<.001)
<i>Bahadoran et al. 2011</i>	RCT double-blind parallel group, placebo controlled	T2D [18–60 years]		Serum total antioxidant capacity (TAC)** Total oxidant status (TOS) Oxidative stress index(OSI)** MDA** Oxidized low LDLc* Total cholesterol
Cinnamon <i>Akilen et al. 2010</i> <i>Davis et al. 2011</i>	RCT, double blinded, 2-parallel groups Meta-analysis	n=58 T2D [54 years] 8 clinical trials (T2D; Prediabetes)	12 weeks	HbA1c* Blood pressure** FBG Waist circumference BMI Lipids FBG*
Garlic <i>Ashraf et al. 2011</i>	Single-blind placebo controlled	n=60 T2D [40±5.04] (Garlic + Metformin) [35±4.58] (placebo)	24 weeks	FBG* (at week 12) Total cholesterol*; triglycerides*; HDL*, LDL*
Whole/fractionated yellow pea flour <i>Marinangeli et al. 2011</i>	Single-blind, cross-over (white wheat flour control)	n=23 T2D/overweight/ hyperlipidemia [51±8] (men) [52±3] (women)	28 days (28-day wash-out)	Fasting insulin* Insulin resistance (HOMA)* Body composition* (Android:gynoid fat, women) Urinary enterolactone FBG, pp glucose Fasting lipids
Portulaca Oleracea PO L Seeds <i>El-Sayed, 2011</i>	RCT double blind	n=30 T2D/obesity [40±3.2 years]	56 days	Serum insulin** Total cholesterol**;HDL**;LDL*; Triglycerides* ALT**, AST**,GGT**, ALP Total and direct bilirubin** Albumin** Body weight**, BMI**
Rauvolfia-citrus tea <i>Campbell-Tofie et al., 2011</i>	Double-blinded RCT pilot	n=23 [64±7 years]	4 months	FBS* 2 hr-pp glucose* HbA1C* Fatty acid profile*
Tomato <i>Shidfar et al. 2011</i>	Quasi-experimental	n=32 T2D male [52.7±5.6 years]	8 weeks	Serum glucose Apolipoproteins A-I, B Homocysteine Blood Pressure

[31], almonds [32, 33], and fractionated yellow pea flour [34] reported significant results in glycemic parameters, insulin resistance, lipids, or oxidative stress. Studies of tomatoes [35] and flaxseed/flaxseed oil [36] did not find statistically significant results (Table 2).

Although many studies of natural products reported promising findings, the clinical significance of these findings remains unclear. Future studies would benefit from larger sample sizes, examinations of long-term effects/side effects, and clear evaluation of effect size. Furthermore, drug interactions are a major concern with all natural supplements and make pharmacovigilance and patient disclosure essential [37, 38].

Mind-Body Medicine

Yoga

Recent studies of yoga, an ancient Indian practice of breath control, simple meditation, and body postures have been conducted in participants with T2D. In an RCT, 123 T2D patients were randomized to receive yoga plus standard care or standard care alone, stratified by chronic diabetes complications. The following comparison of pre–post changes in the yoga versus standard care controls showed improvements in body weight and measures of glycemia and oxidation: BMI (-0.5 ± 0.1 vs. 0.3 ± 0.2 kg/m²; $p < .001$), FPG (-0.8 ± 0.3 vs. 0.4 ± 0.1 mmol/L; $p < .001$), postprandial plasma glucose (-1.1 ± 0.4 vs. 0.3 ± 0.4 mmol/L; $p < .03$), HbA1c (-0.1 ± 0.2 vs. 0.5 ± 0.3 %; $p < .001$), MDA (-10.8 ± 1.4 vs. 1.6 ± 1.6 μ mol/L; $p < .001$), and GSH (0.8 ± 0.1 vs. -0.8 ± 1.2 μ mol/gmHb; $p < .001$) [39]. Another RCT compared a comprehensive yogic breathing intervention plus usual medical treatment ($n=27$) versus usual medical treatment alone ($n=22$) on glycemic control and QOL in individuals with T2D (HbA1c range: 6 %–9 %). Although there was a nonsignificant trend toward glycemic improvement in the yogic treatment group, significant improvements were reported in physical ($p < .01$), psychological ($p = .02$), and social ($p = .03$) domains and total QOL ($p = .01$), as assessed by World Health Organization QOL BREF [40]. More research is warranted before generalizations about the effectiveness of yoga in persons with T2D can be made.

Meditation

Approximately 21 million U.S. adults practice mindfulness or some form of meditation [8*]. Mindfulness comes from Buddhist tradition and is defined simply as “non-judgmental awareness of the present moment experience” [41]. The objective of mindfulness is the attainment of a balanced state of awareness that develops over time into a permanent set of traits among practitioners and counteracts stress.

Mindfulness Based Stress Reduction (MBSR), an 8-week program of body awareness and meditation, has been scientifically studied in the U.S. and elsewhere since the 1970s in many chronic conditions, including chronic pain, depression, and diabetes [42–44].

A recently published 1-year intention-to-treat analysis from the Heidelberg Diabetes and Stress-Study, a 5-year RCT of MBSR in individuals with T2D on depression and microalbuminuria, found lower levels of depression on the Patient Health Questionnaire (Cohen’s $d=0.71$, $p = .007$), and improved mental health status (SF-12; $d=0.54$, $p = .03$) and diastolic blood pressure ($d=0.78$, $p = .004$) in the MBSR group ($n=53$), as compared with controls ($n=57$), demonstrating moderate to large effect sizes. No change in microalbuminuria was found. Per-protocol analysis found greater stress reduction (PHQ stress scale) in the intervention group ($d=0.64$, $p = .02$) [45].

Another RCT in 20 older participants (age 50–94) with T1D or T2D and self-reported symptoms of peripheral diabetic neuropathy were randomized to a group that received 4 weeks of mindfulness training + home practice ($n=10$) versus an attention control group ($n=10$) that received nutrition information and maintained food logs [46]. No statistically significant differences in QOL were found. Pre-post differences in adjusted means favoring improved pain QOL were demonstrated in the mindfulness group (adjusted mean 25.38 to 21.62 \pm 11.42; Cohen’s $f=0.07$), approximating a small effect size.

Arguably the most intriguing research emerging in mind-body medicine involves several recent studies using functional magnetic resonance imaging, EEG, and other techniques that have reported characteristic changes in brain physiology in long-term meditators, as well as those who received as little as 8 weeks of meditation training [47, 48]. Although none of these observational studies was performed in people with diabetes per se, these findings may have important psycho-biological implications for diabetes self-management and warrant further study.

Acupuncture and Related Therapies

Acupuncture, which involves the insertion of needles in the body at specific locations in prescribed combinations, is one component of traditional Chinese medicine. Other components include moxibustion, in which an ember of dried mugwort is placed near or on the skin to stimulate acupuncture points, herbal therapies, breathing and movement exercises (qi gong and tai chi), and massage and manipulation. Each of these treatments is believed to complement the others but can be independently useful in restoring a person’s balance of mind, body, and spirit and thereby promote healing [49].

The traditional practice of acupuncture is organized around several hundred acupuncture points and 20 connecting channels or “meridians,” through which life energy, or *qi*

(pronounced *chee*), is believed to flow. This differs from the modern understanding of acupuncture, which ascribes the mechanism of action principally to the effect of needle stimulation on the nervous system, but is able to provide a framework for empirical study. Previous studies have described effects of acupuncture that include local changes in inflammatory mediators, endocrine responses, and modulation of the immune system [50].

Unfortunately, RCTs of acupuncture are methodologically problematic, because acupuncture has no adequate control condition. Some studies have used active “sham” controls, some involving insertion of needles, albeit using different techniques or body locations. An earlier qualitative study comparing traditional Chinese and Japanese style acupuncture in the treatment of diabetic neuropathy, highlighted the difficulty in standardizing acupuncture for a clinical study, not only because of the different styles of acupuncture, but also because treatments in daily practice are tailored to the individual on the basis of their presentation on a given day, in the context of their personal history [51].

Recent systematic reviews acknowledge methodological problems in studies of acupuncture and moxibustion performed in persons with T2D and insulin resistance. One recent paper reviewed the findings of 234 English language publications published between 1979 and 2009 on acupuncture for the treatment conditions having a component of insulin resistance. The quality of the evidence was found to be insufficient to generate conclusions due to underpowered studies, short duration, and the fact that most of the clinical trials were not placebo controlled. Even so, measurable effects on blood glucose and other glycemic markers were found and warrant further study [52••]

A systematic review of moxibustion in T2D found high risks of bias in all five studies, four of which were RCTs [53]. Two RCTs compared the effectiveness of moxibustion versus acupuncture with that of moxibustion plus acupuncture. The combined treatment showed the most beneficial effects on blood glucose, urine glucose, and HbA1c. Despite these favorable results, it was concluded that due to the scarcity of trials and low methodological quality, further study is necessary [53].

A 2010 pilot study that compared 42 individuals with diabetic peripheral neuropathy who received 15 days of acupuncture with 21 individuals who received “sham acupuncture” found significant differences in vibratory perception between groups ($p < .05$) and from pre to post in the acupuncture group ($p < .01$). Measures of motor and sensory function showed significant improvement in the acupuncture group, which were not present in the sham group. In addition, acupuncture was found to be significantly more effective than sham acupuncture for treatment of lower extremity pain, numbness, altered temperature, and upper extremity rigidity [54].

In another recent RCT, the effect of transcutaneous electrical nerve stimulation (TENS) on acupuncture points on serum

glucose, serum insulin, and insulin resistance during surgical anesthesia for elective hysterectomy was measured in 60 women without diabetes [55]. In this study, participants were randomized to either TENS treatment that received 30 min of electrical stimulation or placebo, in which the electrical contact pads were placed on the points but were not stimulated electrically. Normal hyperglycemic response to surgical stress, as measured every 30 min by plasma glucose, was significantly blunted in patients who received the actual treatment. Plasma insulin and insulin resistance (HOMA) were higher in the control group. More studies having similar scientific rigor are needed in persons with diabetes to provide evidence for practical applications of acupuncture in diabetes management and the prevention of acute hyperglycemia.

Qi gong and T'ai chi

A 2009 review article found available studies to be of low methodological quality and collectively without sufficient evidence to suggest that qi gong is an effective treatment for T2D [56]. In a more recent RCT in which individuals with untreated fasting hyperglycemia ($n=41$) were randomized to a 12-week qi gong intervention, positive changes were observed in the qi gong group relative to controls (95 % CI) in body weight (-3.04 kg [-4.42 , -1.66]; $p < .001$), waist circumference (-4.78 cm [-6.36 , -3.20]; $p < .001$), leg strength (2.66 [1.12, 4.12]; $p < .001$), HbA1c (0.23 % [-0.45 , -0.01]; $p = .04$), insulin resistance (HOMA) (-1.26 [-2.17 , -0.35]; $p = .008$), and fasting insulin (-18.61 [-32.23 , -5.00]; $p = .009$) [57]. Logistic regression demonstrated that the qi gong intervention was a significant predictor of reduced weight, decreased waist circumference, decreased insulin resistance, and improved leg strength. In this study, the effect of qi gong on insulin resistance was mediated by reduced body weight.

Another RCT of qi gong ($n=32$) in persons with T2D taking oral medications who were randomly assigned to the qi gong intervention ($n=11$), a control group ($n=10$), or an active comparison group receiving progressive muscle relaxation (PMR) ($n=11$) [58] found a significant reduction in FPG in the qi gong group (184.9 ± 35.3 to 161.9 ± 40.5 mg/dL; $p < .003$), but not in the control and PMR groups. Nonsignificant trends toward improvement in HbA1c and insulin resistance were also noted in the qi gong group.

An overall review article of 35 systematic reviews of t'ai chi in chronic diseases including T2D, found no convincing evidence that t'ai chi is effective in any condition except for fall prevention and improvement of psychological health in older individuals [59]. However, in a recent hospital-based RCT ($n=104$) of obese participants with T2D who were randomized to receive a 12-week program of gentle t'ai chi versus conventional exercise (CE) [60], significant postintervention improvements were found in the t'ai chi group in BMI

(33.5 ± 4.8 vs. 31.3 ± 4.2 ; $p = .038$), triglycerides (214 ± 47 vs. 171 ± 34 mg/dL; $p = .012$), HDLc (38 ± 16 vs. 45 ± 18 mg/dL; $p = .023$), MDA (2.66 ± 0.78 vs. 2.31 ± 0.55 μ mol/L; $p = .035$), and C-reactive protein (0.39 ± 0.19 vs. 0.22 ± 0.15 mg/dL; $p = .014$). HbA1c values in the t'ai chi group did not decrease ($8.9 \% \pm 2.7 \%$ vs. $8.3 \% \pm 2.2 \%$; $p = .064$). No improvements were observed in the CE group.

In any case, one advantage of qi gong and t'ai chi may be that these practices can be performed at almost any level of exercise tolerance, in comparison with traditional exercise, and represent an appealing option for increasing movement and activity for some persons with T2D including older and obese individuals.

Manipulative and Body-Based Practices

Recent small observational studies of body-based practices have had mixed results in persons with T2D. Studies by Edwards et al. [61] and Wandell et al. [62] found no significant differences in well-being, QOL, or glycemic outcomes with therapeutic massage. However, a quasi-experimental study of far-infrared sauna therapy in older community volunteers with T2D (mean age, 66.5 years; range, 50–75) found positive pre-to-post changes in physical health, general health, social functioning, and QOL indices of the SF-36 and improved visual analogue scales for stress and fatigue following 3 sessions/week for 10 weeks [63]. Inconsistent associations between body-based therapies and improved QOL suggest individual differences that could be explored further.

Ayurvedic and Whole-System Therapies

Ayurveda has its origins in ancient Indian medicine and uses a multipronged approach of diet modification, herbal preparations, yoga, and breathing exercises to restore the equilibrium and good health.

Gymnema sylvestre (GS), the extract from a rainforest plant known as *gurmar* (meaning "sugar destroyer" in Hindi) has been used to treat diabetes in Ayurvedic medicine for centuries. GS has been shown to directly stimulate beta cell secretion of insulin [64, 65], but the crude formulation has been associated with degradation of the beta cell membrane. A recent well-designed pilot study of *Om Santal Adivasi* (OSA®), a novel high molecular weight GS extract not shown to have deleterious cell membrane effects, found significant pre-post increases in insulin and C-peptide that corresponded to significant reductions in fasting and postprandial glucose in 10 of 11 study participants with T2D [66•].

A Cochrane review of whole-system CAM therapies in T2D included one study of whole systems Ayurvedic treatment and six trials of proprietary herbal mixtures (Diabecon, Inolter, Cogent DB, Pancreas, and Hyponidd) [67•]. The

reviewed studies involved a total of 354 participants and controls with treatment ranging from 3 to 6 months in duration. The study of whole system Ayurvedic treatment did not provide HbA1c or FPG data, but secondary analysis reported possible glycemic benefits for individuals with baseline HbA1c values above 6.5 %.

Significant glucose-lowering effects were found with use of three of the herbal mixtures (Diabecon, Inolter, and Cogent DB), as compared with placebo or no additional treatment controls. Diabecon and Inolter are multiherbal mixtures that contain GS and several other herbs used to regulate glucose and lipid metabolism. The beneficial glycemic effects have been attributed to the synergistic action of the herbal ingredients [68, 69]. Cogent DB is a mixture of nine herbs mostly from the Neem tree that has been shown in animal studies to decrease blood glucose, possibly due to down-regulation of hepatic enzyme activity [70].

There were no serious toxic effects or deaths reported in the articles reviewed. The authors concluded, however, that due to methodological deficiencies and small sample sizes, there is insufficient evidence at present to recommend the use of these types of interventions in routine clinical practice [67•].

Conclusions

Although many recent studies report positive findings of CAM in T2D, the future direction of CAM use in clinical diabetes management is contingent upon more rigorous investigations in adequately powered longitudinal studies that examine the magnitude of effects. Nevertheless, millions of people with diabetes worldwide are gravitating toward CAM, and there is a trend toward integrating the wisdom of Eastern healing practices with conventional Western medicine. Patients are in need of guidance in navigating the seemingly endless array of products and therapies that may or may not complement their conventional treatments. By remaining apprised of emerging evidence and incorporating nonthreatening inquiries about CAM use into routine clinical dialogue, health-care providers can promote safe practice and assist patients in making informed choices. CAM holds promise for offering an integrative, participatory model of diabetes care, but more rigorous study is needed.

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APPENDIX F: PRE-SCREENING PHONE CALL

Hello, this is XX. I am a Diabetes Educator from VA Pittsburgh. Your provider referred you for diabetes self-management education class and I am calling to schedule you for the class.....

After patient is scheduled for class,

I would also like to tell you about a study that is being done at the VA Pittsburgh regarding stress and diabetes management. Stress can make diabetes management more difficult, and this research will study a type of stress reduction therapy in patients with diabetes who receive diabetes education. Are you interested in learning more about the study?

If no, thank you

If yes, will you give permission for the Primary Investigator, Monica DiNardo to call you to tell you more about the study and study participation? What is a good way and time of day for her to reach you? Monica can be reached at ###-###-####

APPENDIX G: WAIVER OF INFORMED CONSENT

Hello, my name is Monica DiNardo. I am a nurse practitioner, diabetes nurse educator and researcher at the VA Pittsburgh.

The Diabetes Educator told me that you said you were interested in hearing more about a research study on stress in diabetes at the VA Pittsburgh when she called you to schedule you for diabetes class.

Stress can make diabetes management more difficult for some people. The purpose of this research study is to find out if a stress management program called Mind-STRIDE helps veterans cope better with diabetes. Mind-STRIDE is based on a method of stress reduction called “Mindfulness”, which has been studied in other many other health problems by other researchers. Mindfulness is the practice of paying attention on purpose to the present moment to reduce feelings of stress over time and is similar to meditation, but it is not religious. It is an integrative medical treatment, which means it does not take the place of your usual diabetes care, but is added to your usual diabetes medications and treatment.

Veterans who attend the diabetes education classes and are interested in participating in the study will be enrolled in the study. One half of the participants will receive an instructional class with a group discussion and practice session. The stress management class will be held

following the diabetes class and will last about 1 ½ to 2 hours. Participants will be asked to practice stress management at home for 10 to 15 minutes, 6 days per week, using an audio-taped recording to guide their practice.

Some people who volunteer to participate in the study will not get the stress management class, but will be part of a comparison group instead. People in the comparison group will be able to take the stress management class after 3 months if they choose to do so.

Everyone who volunteers to be in the study will be asked to check the best answers on several lists of questions before the diabetes class starts. It will take about 20-30 minutes to complete the questions. People who volunteer for the study will be asked to answer some questions again 1 month and 3 months later, and will also receive a phone call from the research team every 2 weeks for the next 3 months during the study.

Choosing to participate or not in this study is completely voluntary and will not affect the care you receive from your health care providers at the VA. You will still be enrolled in the diabetes class even if you don't participate in the study.

All study participants will receive refreshments on the day of class and will be reimbursed for their time.

Possible risks may be that participants may feel uncomfortable talking about their feelings of diabetes in a group setting or become uncomfortable sitting quietly still for the 15 minute mindfulness sessions. A possible benefit may be that participants will gain skills that help them manage stress and diabetes better.

Do you think you might be interested in participating in the stress management study?

If yes:

- 1) We will ask you to arrive for diabetes class 1 hour earlier at 8AM. At that time we will ask you to sign a consent form for study participation. After your informed consent is signed, we will let you know what group you will be in, and will ask you to fill out the questionnaires.
- 2) You may contact me, the Primary Investigator, at 412 360-1121 with any questions.
- 3) Do you plan on attending diabetes class with a family member or friend?
- 4) If you have any questions about research participant rights, you may call the VA Research Office at ###-###-####.
- 5) All records that identify potential participants by name will be kept confidential and stored in a locked and password protected file at the VA.

Thank you very much.

APPENDIX H: INFORMED CONSENT

Subject Name: _____ Last 4 SSN: _____ Date: _____

Title of Study: A Mindful Approach to Diabetes Self- Management Education with Stress Reduction and Healthy Coping for US Veterans with DiabetesCo-Principal Investigators: Monica DiNardo,CRNP,PhD(c); R. Harsha Rao, MD
VAMC: Pittsburgh (646)**LAY TITLE: Evaluating a Mindful Stress Management Program Added to Routine Diabetes Self-management Education for US Veterans with Diabetes****STUDY CONTACT INFORMATION:**If you have a general question about this research study, or if you have any concerns or complaints related to this research study, you may call **Monica DiNardo CRNP, Co-Principal Investigator , (412) 360-1121 or any of the investigators listed below.**If you experience any illness, injury or other medical problem that you feel may be related to this study, please call **Monica DiNardo CRNP, Principal Investigator (412) 360-1121 or Janice Beattie, Research Nurse (412) 360-1394 Monday to Friday 8 AM to 4:30 PM.** In the case of a medical emergency contact your local emergency medical service or go to your local emergency room.**Co- Principal Investigators**Monica DiNardo CRNP, CDE, VAPHS, University Drive Division (412)360-1121
Harsha Rao, MD, Co-Principal Investigator, VAPHS, University Drive Division (412) 360-1394**Research Nurse**

Janice Beattie RN, CD, VAPHS, University Drive Division (412)360-1394

STUDY SPONSOR:American Association of Diabetes Educators (AADE)
Additional information regarding the study sponsor can be provided upon request.**PURPOSE OF THE RESEARCH STUDY:** The purpose of this research study is to evaluate the satisfaction and short term effects of adding a Mindfulness Stress Reduction In Diabetes program to standard diabetes self-management education classes. The Mind-Stride program is a 90-minute program that uses a techniques called "mindfulness", a type of stress reduction used to help manage stress by some people with long-standing health problems. You are being asked to participate in this research study because you have diabetes and have been referred for diabetes self-management education classes by your care provider. You are eligible for this research study because your hemoglobin HbA1c (an estimate of

Subject Name: _____ Last 4 SSN: _____ Date: _____

Title of Study: A Mindful Approach to Diabetes Self- Management Education with Stress Reduction and Healthy Coping for US Veterans with DiabetesCo-Principal Investigators: Monica DiNardo, CRNP, PhD(c); R. Harsha Rao, MD
VAMC: Pittsburgh (646)

your 3-month average blood glucose) is above 7%. An HbA1C of 7% or below is the goal for most people with diabetes.

There will be approximately 40 participants in this research study at the VAPHS.

DESCRIPTION OF THE RESEARCH STUDY:

STUDY PROCEDURES- If you indicate that you are interested in study participation by signing this informed consent, you will be enrolled in the Mind-STRIDE study and will receive a special stress management training program following the diabetes self-management education class. The Mind-STRIDE study consists of 3 visits over a 12 week period.

The first visit will last approximately 2 hours **in addition** to the diabetes education class. Participants will fill out a series of questionnaires about their level of stress, support from friends and family, and problems with diabetes self- management. It will take about 20-30 minutes to complete these questions. Study participants will then participate in a 90-minute stress reduction training program, which consists of group discussion, gentle stretching exercises performed while seated in a chair, and a 10- minute guided mindful breathing practice. Participants will be also be asked to practice mindful breathing at home 15 minutes per day 6 days per week totaling about 1 ½ hours per week for the 12 week duration of the study. Participants will receive a compact disc (CD) to use at home to guide home practice. A portable CD player will be loaned to participants who do not have access to one at home. Study participants will be asked to describe their practice sessions on a home practice diary log sheet that will be provided to them by the researcher. Log sheets will not contain the participants' names or any identifiable information like phone number, and the participant will be identified by study number only. Participants will be asked to mail the log sheets to the researcher every 2 weeks in a postage-paid envelope provided by the researcher.

Mind-STRIDE sessions will be audio-taped so that the group discussion can be accurately described by the researchers. Only members of the research team will have access to the audio-recordings. The audio-recordings will be saved on a secure Network at the VAPHS, and will be maintained indefinitely.

FOLLOW UP VISITS

VA FORM 10-1086 JUNE 1990 (revised 02/2013)

Subject's Initials _____

Subject Name: _____ Last 4 SSN: _____ Date: _____

Title of Study: A Mindful Approach to Diabetes Self- Management Education with Stress Reduction and Healthy Coping for US Veterans with DiabetesCo-Principal Investigators: Monica DiNardo, CRNP, PhD(c); R. Harsha Rao, MD
VAMC: Pittsburgh (646)

The 1 month and 3 month follow up visits will take 30 minutes in addition to a 30 minute dietitian appointment. At these visits participants will meet with a dietitian to review what was learned in the diabetes class. Participants will also meet with the researcher for an additional 20-30 minutes to review Mind-STRIDE, discuss home practice and participate in a 10-minute stress reduction exercise. All participants will then complete another series of questionnaires that will take 20-30 minutes to complete. These questionnaires will be similar to the first set of questionnaires. Each follow-up visit will last 60-90 minutes. Every effort will be made to schedule follow-up visits at a time that is convenient for participants.

Participants may receive a brief phone call from the research team every 2 weeks to answer any questions. These phone calls will last no more than 5 -10 minutes. If you do not answer your telephone, with your permission, the researcher will leave a brief message on your answering machine. Do you grant permission for the researcher to leave messages regarding your participation in this study on your answering machine?

_____ yes _____ your initials.

_____ no _____ your initials.

END OF STUDY PROCEDURES,- Participation in the Mind-STRIDE study **ends after the 3rd set of questionnaires is completed.** Participation in the study will last 12 weeks (3 months) and all procedures will take place at VAPHS, University Drive Division.

If you agree, information from this research study will be kept for future research on diabetes education and stress management. Only the Principal Investigators will have access to this information, which will be stored in an electronic file on the VA Network Drive, and will not contain any information that can identify you or link you to the research information. Do you agree to allow future use of your information from this study?

_____ yes _____ your initials.

_____ no _____ your initials.

VA FORM 10-1086 JUNE 1990 (revised 02/2013)

Subject's Initials _____

Subject Name: _____ Last 4 SSN: _____ Date: _____

Title of Study: A Mindful Approach to Diabetes Self- Management Education with Stress Reduction and Healthy Coping for US Veterans with Diabetes

Co-Principal Investigators: Monica DiNardo, CRNP, PhD(c); R. Harsha Rao, MD
VAMC; Pittsburgh (646)

If you agree, you may be re-contacted by the Primary Investigator for future research within the VA looking at long term results of the Mind-STRIDE program. Do you agree to be re-contacted by the Primary Investigator for this future research?

_____ yes _____ your initials.

_____ no _____ your initials.

All participants will be mailed a summary of the results of the finalized study if requested.

RISKS AND BENEFITS:

The risks of this research study are minimal and include but are not limited to loss of confidentiality. Other possible risks include embarrassment and/or physical discomfort when participating in group discussions, silent breathing or gentle stretching practice. Other inconveniences/limitations include the significant time commitment to attend an extra clinical visit, complete daily log sheets and answer questionnaires.

Privacy and Confidentiality: Every effort will be made to make sure that the information about you obtained from this study will be kept strictly confidential. As private information is collected about you as part of this study, there is a risk to your privacy and confidentiality. The research staff will take every precaution to protect your identity and the confidentiality of the information collected about you. Any electronic or hard/paper copies of the information collected about you will be stored in a secured location. Any copies that contain information that could be used to identify you (such as your name, address, etc.) will be stored separately from study information (such as your completed questionnaires). Only those individuals who are authorized to review your information will have access to it. Your data will be coded with only a study number.

Your information may also be disclosed to the VA Pittsburgh Healthcare System Research and Development Office Staff in order to perform duties related to research administration. Additionally, your information may be shared with the VA Pittsburgh Healthcare System

VA FORM 10-1086 JUNE 1990 (revised 02/2013)

Subject's Initials _____

Subject Name: _____ Last 4 SSN: _____ Date: _____

Title of Study: A Mindful Approach to Diabetes Self- Management Education with Stress Reduction and Healthy Coping for US Veterans with DiabetesCo-Principal Investigators: Monica DiNardo, CRNP, PhD(c); R. Harsha Rao, MD
VAMC: Pittsburgh (646)

Institutional Review Board (the committee that oversees human research) in order to ensure the protection of human subjects, staff of the VAPHS Research Compliance Office in order to perform audit and compliance duties, and federal agencies, such as the VA Office of Research Oversight (ORO), the Office for Human Research Protections (OHRP) and the Government Accounting Office (GAO), in order to meet VA and other federal or local regulations. Additionally, any medical information may be shared with your healthcare provider(s) with your consent, and possibly without your consent if permissible under federal laws and regulations. Finally, you consent to the publication of the study results so long as the information about you is anonymous and/or disguised so that your identity will not be disclosed.

You may not directly benefit from participating in this study. Your participation may help medical research determine if it is feasible and beneficial to offer mindful stress management as a part of diabetes education. The potential benefits of study participation are learning a stress reduction technique and contributing to new knowledge about acceptability and short term effects of offering this type of stress reduction technique when offered as part of routine diabetes education.

ALTERNATIVES TO PARTICIPATION:

There may be other stress reductions studies that you qualify for. Talk to your provider about such options. You have the alternative not to participate in this research study.

NEW FINDINGS: You will be informed of any significant new findings during the course of the study, which may affect your willingness to continue to participate.

INVESTIGATOR INITIATED WITHDRAWAL: The investigator(s) may stop your participation in this study without your consent for reasons such as: it will be in your best interest; you do not follow the study plan; or you experience a study-related injury.

VOLUNTARY PARTICIPATION/RIGHT TO WITHDRAW: Your participation in this study is voluntary. You do not have to take part in this study, and your refusal to participate will involve no

VA FORM 10-1086 JUNE 1990 (revised 02/2013)

Subject's Initials _____

Subject Name: _____ Last 4 SSN: _____ Date: _____

Title of Study: A Mindful Approach to Diabetes Self- Management Education with Stress Reduction and Healthy Coping for US Veterans with DiabetesCo-Principal Investigators: Monica DiNardo, CRNP, PhD(c); R. Harsha Rao, MD
VAMC: Pittsburgh (646)

penalty or loss of rights to which you are entitled. You may withdraw from this study at any time without penalty or loss of VA or other benefits to which you are entitled.

Should you choose to withdraw from the study, please notify the research team.

Your diabetes clinician may be involved as an investigator in this research study. As both your health care provider and a research investigator, s/he is interested both in your medical care and the conduct of this research study. You are under no obligation to participate in this or any other research study offered by your doctor. Before you agree to participate in this research study, or at any time during your participation in this study, you may discuss your care with another doctor who is not associated with this research study.

MEDICAL TREATMENT: In the event that you sustain injury or illness as a result of your participation in this VA approved research study, conducted under the supervision of one or more VA employees, all medical treatment (emergent as well as medical treatment beyond necessary emergent care) will be provided by the VA. Except in limited circumstances, the necessary medical care must be provided in VA medical facilities.

However, if such injury or illness occurred as a result of your failure to follow the instructions for this study, you may not be eligible for free care unless you have independent eligibility for such care under Federal Law.

FINANCIAL COMPENSATION: If you sustain an injury or illness as a result of participating in this research study, you may be eligible to receive monetary compensation for your damages pursuant to applicable federal law. If you believe that you are injured as a result of participation in this study, please contact the Principal Investigator. If compensation is available the Principal Investigator will provide you with an explanation as to what that compensation consists of, or where you can obtain further information regarding it.

COST AND PAYMENTS: If you are a veteran subject, eligible for veteran services, there will be no cost to you for your participation in this study. However if you are receiving medical care and services from the VA that are not part of this study, and you are a veteran described in federal regulations as a "category

Subject Name: _____ Last 4 SSN: _____ Date: _____

Title of Study: A Mindful Approach to Diabetes Self- Management Education with Stress Reduction and Healthy Coping for US Veterans with DiabetesCo-Principal Investigators: Monica DiNardo, CRNP, PhD(c); R. Harsha Rao, MD
VAMC: Pittsburgh (646)

7" veteran, you may be required to make co-payments for the care and services that are not required as part of this research study.

All participants will be paid \$10 by check to reimburse participants for time and travel. The check will be mailed to you after each set of questionnaires are completed at Visit #1, 1-month follow-up and 3-month follow-up. You should expect to receive the check within 30 days after completing each set of questionnaires. Due to limitations in the Financial Management System, payments made to you will generate Internal Revenue Service (IRS) Form 1099 regardless of amount. Payments will be reported to the IRS as income and your social security number will be used for this purpose.

RECORD RETENTION: Your research records will be retained in accordance with the Veterans Health Administration (VHA) Records Control Schedule.

RESEARCH SUBJECTS' RIGHTS: You have read or have had read to you all of the above. Ms. DiNardo or her authorized representative has explained the study to you and answered all of your questions. The risks, discomforts, and possible benefits of this research study, as well as alternative treatment choices, have been explained to you.

A description of the study has been provided to you, including an explanation of what this study is about, why it is being done, and the procedures involved. You have the right to ask questions related to this study or your participation in this study at any time. You should be giving your consent only under conditions in which you have sufficient opportunity to carefully consider whether or not to participate in this study. Your consent should not be given under conditions that pressure you or try to influence your decision in any way.

Your rights as a research subject have been explained to you, and you voluntarily consent to participate in this research study. You will receive a copy of this signed consent form.

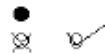
If you have any questions about your rights as a participant in this study, or wish to speak more about the study with someone not associated with the research study, you can call the Associate Chief of Staff for Research and Development at (412) 954-5394.

APPENDIX I: INSTRUMENTS

Instrument Number:

1	0	3	1
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Shade circles like this: ●
Not like this: ○



Study # _____

Demographics

ID Number:	<input type="text"/>	Administration Date:	<input type="text"/>	/	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
			(month)		(day)		(year)			

(FOR STAFF USE ONLY)

INSTRUCTIONS: For each of the following questions, please respond with the answer that is best describes you. Please provide an answer for each question.

1. Your age:

<input type="text"/>	<input type="text"/>	<input type="text"/>	(years)
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2. Your birth date:

<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
			(month)			(day)			(year)

3. Your zipcode:

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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4. Your sex:

- 1 Male
- 2 Female

5. What year were you first told you had diabetes?

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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6. What is your marital status?

(Choose one response only.)

- 1 Never married
- 2 Currently married
- 3 Living with partner/significant other
- 4 Separated
- 5 Widowed
- 6 Divorced

7. What is your ethnic origin /race?

(Choose all that apply to you.)

- 1 White
- 2 Black or African American
- 3 Native American
- 4 Hispanic
- 5 Asian
- 6 Native Hawaiian or other Pacific Islander
- 7 Arabic
- 8 Other: _____
- 9 Unknown

(office use only)

<input type="text"/>	<input type="text"/>
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ID Number: _____
(for internal use only)

Date: __ / __ / __
(for internal use only)

8. Where do you live most of the year?
(Choose one response only.)

- 1 Your home, apartment, or condo
- 2 Senior citizen apartment /condo
- 3 Home of a relative /friend
- 4 Retirement home
- 5 Adult foster care
- 6 Nursing home
- 7 Other: _____

(office use only)	

9. How many people live with you?
(Choose one response only.)

- 0) 0 (I live alone)
- 1) 1 person
- 2) 2 people
- 3) 3 people
- 4) 4 people
- 5) 5 or more people

10. How much schooling have you had? (Years of formal schooling completed.)
(Choose one response only.)

- 1 8th grade or less
- 2 Some high school
- 3 High school graduate or GED
- 4 Some college or technical school
- 5 College graduate (Bachelor's degree)
- 6 Graduate degree

ID Number: _____
(for internal use only)

Date: __ / __ / __
(for internal use only)

**11. Which of the following best describes your current employment status?
(Choose one response only.)**

- 1 Working full-time, 35 hours or more a week
- 2 Working part-time, less than 35 hours a week
- 3 Unemployed or laid off AND looking for work
- 4 Unemployed AND NOT looking for work
- 5 Homemaker
- 6 In school
- 7 Retired
- 8 Disabled; unable to work
- 9 Something else? Please specify: _____

(office use only)
<input type="checkbox"/>
<input type="checkbox"/>

12. Emergency Room

- a. *In the past year, have you been seen in the Emergency Room?* 1 Yes 2 No
- b. *In the past 6 months, have you been seen in the Emergency Room?* 1 Yes 2 No
- c. *In the past 3 months, have you been seen in the Emergency Room?* 1 Yes 2 No

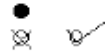
13. Hospital Admission

- a. *In the past year, have you been admitted to the hospital?* 1 Yes 2 No
- b. *In the past 6 months, have you been admitted to the hospital?* 1 Yes 2 No
- c. *In the past 3 months, have you been been admitted to the hospital?* 1 Yes 2 No

Instrument Number:

1	0	3	2
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Shade circles like this: ●
 Not like this: ○



Study # _____

Baseline Satisfaction Questionnaire

ID Number:	<input type="text"/>	Administration Date:	<input type="text"/>	/	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	<input type="text"/>
			(month)		(day)		(year)		
Visit Number:	1								
	Baseline								

(FOR STAFF USE ONLY)

INSTRUCTIONS: For each of the following statements, choose the response that most closely matches your opinion.

	Strongly Disagree	Disagree	Do Not Agree nor Disagree	Agree	Strongly Agree
	1	2	3	4	5
1. This class was interesting and easy to understand.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2. I learned something new in this class.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
3. I plan on using the method of mindful stress management I learned in class.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
4. I would recommend this mindful stress management class to other people with diabetes.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

COMMENTS: _____

(office use only)

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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Instrument Number:

1	0	4	2
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Shade circles like this: ●
 Not like this: ○

Study # _____

Satisfaction Questionnaire
 (for Month 1 and Month 3 Visits)

ID Number:

Administration Date: / /

(month) (day) (year)

Visit Number: 2 3
 1 Month 3 Month ("Post")

(FOR STAFF USE ONLY)

INSTRUCTIONS: For each of the following statements, choose the response that most closely matches your opinion.

	Strongly Disagree	Disagree	Do Not Agree nor Disagree	Agree	Strongly Agree
	1	2	3	4	5
1. This class was interesting and easy to understand.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2. I learned something new in this class.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
3. I found home mindfulness practice to be helpful.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
4. The home practice CD helped make home practice easier to do.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
5. I plan to continue practicing mindful stress management that I learned in class.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
6. I would recommend a mindful stress management class to other people with diabetes.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

COMMENTS: _____

(office use only)

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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Instrument Number:

1 0 3 3

ID Number:

10 empty boxes for ID number

Study # _____

Week #

2 empty boxes for week number

Mindfulness Diary (Home Practice Diary)

Day of the Week	Date	# of Minutes Practiced	What did I notice?
<input type="radio"/> Su <input type="radio"/> M <input type="radio"/> Tu <input type="radio"/> W <input type="radio"/> Th <input type="radio"/> F <input type="radio"/> Sa	<input type="text"/> / <input type="text"/> / <input type="text"/> <small>(month) (day) (year)</small>	<input type="text"/>	
<input type="radio"/> Su <input type="radio"/> M <input type="radio"/> Tu <input type="radio"/> W <input type="radio"/> Th <input type="radio"/> F <input type="radio"/> Sa	<input type="text"/> / <input type="text"/> / <input type="text"/> <small>(month) (day) (year)</small>	<input type="text"/>	
<input type="radio"/> Su <input type="radio"/> M <input type="radio"/> Tu <input type="radio"/> W <input type="radio"/> Th <input type="radio"/> F <input type="radio"/> Sa	<input type="text"/> / <input type="text"/> / <input type="text"/> <small>(month) (day) (year)</small>	<input type="text"/>	
<input type="radio"/> Su <input type="radio"/> M <input type="radio"/> Tu <input type="radio"/> W <input type="radio"/> Th <input type="radio"/> F <input type="radio"/> Sa	<input type="text"/> / <input type="text"/> / <input type="text"/> <small>(month) (day) (year)</small>	<input type="text"/>	
<input type="radio"/> Su <input type="radio"/> M <input type="radio"/> Tu <input type="radio"/> W <input type="radio"/> Th <input type="radio"/> F <input type="radio"/> Sa	<input type="text"/> / <input type="text"/> / <input type="text"/> <small>(month) (day) (year)</small>	<input type="text"/>	
<input type="radio"/> Su <input type="radio"/> M <input type="radio"/> Tu <input type="radio"/> W <input type="radio"/> Th <input type="radio"/> F <input type="radio"/> Sa	<input type="text"/> / <input type="text"/> / <input type="text"/> <small>(month) (day) (year)</small>	<input type="text"/>	
<input type="radio"/> Su <input type="radio"/> M <input type="radio"/> Tu <input type="radio"/> W <input type="radio"/> Th <input type="radio"/> F <input type="radio"/> Sa	<input type="text"/> / <input type="text"/> / <input type="text"/> <small>(month) (day) (year)</small>	<input type="text"/>	

Instrument Number:

1	0	3	8
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Shade circles like this: ●
 Not like this: ○



Study # _____

Five Facet Mindfulness Questionnaire

ID Number:	<input type="text"/>	Administration Date:	<input type="text"/>	/	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	<input type="text"/>
			(month)		(day)		(year)		
Visit Number:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>						
	Baseline	1 Month	Post						
(FOR STAFF USE ONLY)									

INSTRUCTIONS: Please read each of the following statements. Using the scale provided, choose the response that best describes your own opinion of what is generally true for you.

	Never	Very Rarely	Rarely	Sometimes	Often	Very Often
	1	2	3	4	5	6
1. When I'm walking, I deliberately notice the sensations of my body moving.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2. I'm good at finding words to describe my feelings.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
3. I criticize myself for having irrational or inappropriate emotions.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
4. I perceive my feelings and emotions without having to react to them.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
5. When I do things, my mind wanders off and I'm easily distracted.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
6. When I take a shower or bath, I stay alert to the sensations of water on my body.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
7. I can easily put my beliefs, opinions, and expectations into words.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
8. I don't pay attention to what I'm doing because I'm daydreaming, worrying, or otherwise distracted.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
9. I watch my feelings without getting lost in them.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
10. I tell myself I shouldn't be feeling the way I'm feeling.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

ID Number: _____
(for internal use only)

Date: ___ / ___ / ___
(for internal use only)

	Never 1	Very Rarely 2	Rarely 3	Sometimes 4	Often 5	Very Often 6
11. I notice how foods and drinks affect my thoughts, bodily sensations, and emotions.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
12. It's hard for me to find the words to describe what I'm thinking.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
13. I am easily distracted.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
14. I believe some of my thoughts are abnormal or bad and I shouldn't think that way.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
15. I pay attention to sensations, such as the wind in my hair or sun on my face.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
16. I have trouble thinking of the right words to express how I feel about things.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
17. I make judgments about whether my thoughts are good or bad.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
18. I find it difficult to stay focused on what's happening in the present.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
19. When I have distressing thoughts or images, I "step back" and am aware of the thought or image without getting taken over by it.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
20. I pay attention to sounds, such as clocks ticking, birds chirping, or cars passing.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
21. In difficult situations, I can pause without immediately reacting.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
22. When I have a sensation in my body, it's difficult for me to describe it because I can't find the right words.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
23. It seems I am "running on automatic" without much awareness of what I'm doing.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
24. When I have distressing thoughts or images, I feel calm soon after.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
25. I tell myself that I shouldn't be thinking the way I'm thinking.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

ID Number: _____
(for internal use only)

Date: ___ / ___ / ___
(for internal use only)

	Never 1	Very Rarely 2	Rarely 3	Sometimes 4	Often 5	Very Often 6
26. I notice the smells and aromas of things.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
27. Even when I'm feeling terribly upset, I can find a way to put it into words.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
28. I rush through activities without being really attentive to them.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
29. When I have distressing thoughts or images, I am able just to notice them without reacting.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
30. I think some of my emotions are bad or inappropriate and I shouldn't feel them.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
31. I notice visual elements in art or nature, such as colors, shapes, textures, or patterns of light and shadow.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
32. My natural tendency is to put my experiences into words.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
33. When I have distressing thoughts or images, I just notice them and let them go.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
34. I do jobs or tasks automatically without being aware of what I'm doing.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
35. When I have distressing thoughts or images, I judge myself as good or bad, depending on what the thought /image is about.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
36. I pay attention to how my emotions affect my thoughts and behavior.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
37. I can usually describe how I feel at the moment in considerable detail.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
38. I find myself doing things without paying attention.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
39. I disapprove of myself when I have irrational ideas.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Instrument Number:

1	0	3	9
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Shade circles like this: ●

Not like this: ○



Study # _____

Perceived Stress Scale (10 Item)

ID Number:	<input type="text"/>	Administration Date:	<input type="text"/>	/	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
			(month)		(day)		(year)			
Visit Number:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>							
	1	2	3							
	Baseline	1 Month	Post							
(FOR STAFF USE ONLY)										

Instructions: The questions in this scale ask you about your feelings and thoughts *during the last month*. In each case, please indicate how often you felt or thought a certain way by filling in the circle that corresponds to your response.

	Never 0	Almost Never 1	Sometimes 2	Fairly Often 3	Very Often 4
1. <i>In the last month</i> , how often have you been upset because of something that happened unexpectedly?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2. <i>In the last month</i> , how often have you felt that you were unable to control the important things in your life?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
3. <i>In the last month</i> , how often have you felt nervous and "stressed"?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
4. <i>In the last month</i> , how often have you felt confident about your ability to handle your personal problems?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
5. <i>In the last month</i> , how often have you felt that things were going your way?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
6. <i>In the last month</i> , how often have you found that you could not cope with all the things that you had to do?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
7. <i>In the last month</i> , how often have you been able to control irritations in your life?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
8. <i>In the last month</i> , how often have you felt that you were on top of things?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
9. <i>In the last month</i> , how often have you been angered because of things that were outside of your control?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
10. <i>In the last month</i> , how often have you felt difficulties were piling up so high that you could not overcome them?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Instrument Number:

1	0	3	5
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Shade circles like this: ●

Not like this: ⊗



Study # _____

Problem Areas in Diabetes (PAID) Questionnaire

ID Number:	<input type="text"/>	Administration Date:	<input type="text"/>	/	<input type="text"/>	/	<input type="text"/>	<input type="text"/>
			(month)		(day)		(year)	
Visit Number:	<input type="radio"/>	<input type="radio"/>						
	1	3						
	Baseline	Post						

(FOR STAFF USE ONLY)

INSTRUCTIONS: Which of the following diabetes issues are currently a problem for you? For each question, fill in the circle next to the response that gives the best answer for you. Please provide an answer for each question.

	Not a Problem	Minor Problem	Moderate Problem	Somewhat Serious Problem	Serious Problem
	0	1	2	3	4
1. Not having clear and concrete goals for your diabetes care?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2. Feeling discouraged with your diabetes treatment plan?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
3. Feeling scared when you think about living with diabetes?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
4. Uncomfortable social situations related to your diabetes care (e.g., people telling you what to eat)?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
5. Feelings of deprivation regarding food and meals?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
6. Feeling depressed when you think about living with diabetes?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
7. Not knowing if your mood or feelings are related to your diabetes?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

ID Number: _____
(for internal use only)

Date: ___ / ___ / ___
(for internal use only)

	Not a Problem	Minor Problem	Moderate Problem	Somewhat Serious Problem	Serious Problem
	0	1	2	3	4
8. Feeling overwhelmed by your diabetes?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
9. Worrying about low blood sugar reactions?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
10. Feeling angry when you think about living with diabetes?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
11. Feeling constantly concerned about food and eating?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
12. Worrying about the future and the possibility of serious complications?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
13. Feelings of guilt or anxiety when you get off track with your diabetes management?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
14. Not "accepting" your diabetes?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
15. Feeling unsatisfied with your diabetes physician?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
16. Feeling that diabetes is taking up too much of your mental and physical energy every day?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
17. Feeling alone with your diabetes?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
18. Feeling that your friends and family are not supportive of your diabetes management efforts?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
19. Coping with complications of diabetes?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
20. Feeling "burned out" by the constant effort needed to manage diabetes?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Instrument Number:

1	0	3	4
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Shade circles like this: ●

Not like this: ○



Study # _____

Diabetes Empowerment Form (DES-SF) (Short Form)

ID Number:	<input type="text"/>	Administration Date:	<input type="text"/>	/	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
		(month)			(day)			(year)		
Visit Number:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>							
	1	2	3							
	Baseline	1 Month	Post							
(FOR STAFF USE ONLY)										

INSTRUCTIONS: For each of the following statements, choose the response that gives the best answer for you.

In general, I believe that I . . .

	Strongly Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Strongly Agree
	1	2	3	4	5
1. know what part(s) of taking care of my diabetes that I am dissatisfied with.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2. am able to turn my diabetes goals into a workable plan.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
3. can try out different ways of overcoming barriers to my diabetes goals.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
4. can find ways to feel better about having diabetes.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
5. know the positive ways I cope with diabetes-related stress.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
6. can ask for support for having and caring for my diabetes when I need it.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
7. know what helps me stay motivated to care for my diabetes.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
8. know enough about myself as a person to make diabetes care choices that are right for me.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Instrument Number:

1	0	4	0
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Shade circles like this: ●

Not like this: ○



Study # _____

Social Support

ID Number:	<input type="text"/>	Administration Date:	<input type="text"/>	/	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	<input type="text"/>
			(month)		(day)		(year)		
Visit Number:	<input type="radio"/>	<input type="radio"/>							
	1	3							
	Baseline	Post							
(FOR STAFF USE ONLY)									

INSTRUCTIONS: For each of the following statements, choose the one response that best describes how much you agree or disagree with each statement.

1. I want a lot of help and support from my family or friends in:

(Choose only one response per line.)

	Strongly Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Strongly Agree	Does Not Apply
	1	2	3	4	5	(-2)
a. following my meal plan.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
b. taking my medicine.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
c. taking care of my feet.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
d. getting enough physical activity.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
e. testing my sugar.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
f. handling my feelings about diabetes.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

2. My family or friends help and support me a lot to:

(Choose only one response per line.)

	Strongly Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Strongly Agree	Does Not Apply
	1	2	3	4	5	(-2)
a. follow my meal plan.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
b. take my medicine.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
c. take care of my feet.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
d. get enough physical activity.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
e. test my sugar.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
f. handle my feelings about diabetes.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

ID Number: _____
(for internal use only)

Date: ___ / ___ / ___
(for internal use only)

3. My family or friends:

(Choose only one response per line.)

	Strongly Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Strongly Agree	Does Not Apply
	1	2	3	4	5	(-2)
a. accept me and my diabetes.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
b. feel uncomfortable about me and my diabetes.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
c. encourage or reassure me about my diabetes.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
d. discourage or upset me about my diabetes.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
e. listen to me when I want to talk about my diabetes.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
f. nag me about diabetes.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

4. Who helps you the most in caring for your diabetes?

(Choose one response only.)

- 1 Spouse
- 2 Other family members
- 3 Friends
- 4 Paid helper
- 5 Doctor
- 6 Nurse
- 7 Case Manager
- 8 Other health care professional
- 9 No one

Diabetes Care Profile Sub-scale, University of Michigan Diabetes and Research Training Center
<http://www.med.umich.edu/umdrct/props/survey.html#dcp>

Instrument Number:

1	0	3	6
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Shade circles like this: ●

Not like this: ○



Study # _____

Diabetes Self-Management Behaviors

ID Number:	<input type="text"/>	Administration Date:	<input type="text"/>	/	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	<input type="text"/>
			(month)		(day)		(year)		
Visit Number:	<input type="radio"/>	<input type="radio"/>							
	1	3							
	Baseline	Post							

(FOR STAFF USE ONLY)

INSTRUCTIONS: Thinking about the different parts of a diabetic treatment plan, please answer the following questions.

- In the past 3 months, would you say you were following your diet plan?
 - 0 Not part of treatment plan
 - 1 None of the time
 - 2 Little of the time
 - 3 Some of the time
 - 4 Most of the time
 - 5 All of the time
- In the past 3 months, would you say you were checking your blood sugar level as needed?
 - 0 Not part of treatment plan
 - 1 None of the time
 - 2 Little of the time
 - 3 Some of the time
 - 4 Most of the time
 - 5 All of the time
- In the past 3 months, would you say you were taking diabetes pills and /or insulin (shots) as recommended?
 - 0 Not part of treatment plan
 - 1 None of the time
 - 2 Little of the time
 - 3 Some of the time
 - 4 Most of the time
 - 5 All of the time
- In the past 3 months, would you say you were exercising regularly as recommended?
 - 0 Not part of treatment plan
 - 1 None of the time
 - 2 Little of the time
 - 3 Some of the time
 - 4 Most of the time
 - 5 All of the time
- In the past 3 months, would you say you have kept your scheduled doctor /clinic visits for your diabetes care?
 - 0 Not part of treatment plan
 - 1 None of the time
 - 2 Little of the time
 - 3 Some of the time
 - 4 Most of the time
 - 5 All of the time
- In the past 3 months, have you been seen in the Emergency Room? 1 Yes 2 No
- In the past 3 months, have you been admitted to the hospital? 1 Yes 2 No



Instrument Number:

1	0	3	7
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Study # _____

AADE7™ Self-Care Behaviors

ID Number:	<input type="text"/>	Administration Date:	<input type="text"/> / <input type="text"/> / <input type="text"/>
		(month)	(day) (year)
Visit Number:	<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3	Baseline 1 Month Post	(FOR STAFF USE ONLY)

Goal Setting		Follow Up		Goal Review Documentation	
Date -- / -- / --	Goal: Healthy Eating <input type="radio"/> Make better food choices <input type="radio"/> Reduce portion size <input type="radio"/> Follow meal plan Goal individualization: _____	Month <input type="radio"/> 1 mo. <input type="radio"/> 3 mo.	Achieved Rate 0-10: <input type="text"/> / <input type="text"/>	<input type="radio"/> Achieved <input type="radio"/> Continued <input type="radio"/> Modified _____ _____ _____	
Date -- / -- / --	Goal: Being Active <input type="radio"/> Exercise longer <input type="radio"/> Exercise more often <input type="radio"/> Follow exercise plan Goal individualization: _____	Month <input type="radio"/> 1 mo. <input type="radio"/> 3 mo.	Achieved Rate 0-10: <input type="text"/> / <input type="text"/>	<input type="radio"/> Achieved <input type="radio"/> Continued <input type="radio"/> Modified _____ _____ _____	
Date -- / -- / --	Goal: Monitoring <input type="radio"/> Follow monitoring schedule <input type="radio"/> Monitor more often <input type="radio"/> Monitor health status Goal individualization: _____	Month <input type="radio"/> 1 mo. <input type="radio"/> 3 mo.	Achieved Rate 0-10: <input type="text"/> / <input type="text"/>	<input type="radio"/> Achieved <input type="radio"/> Continued <input type="radio"/> Modified _____ _____ _____	

ID Number: _____
(for internal use only)

Goal Setting		Follow Up		Goal Review Documentation		
Date	Goal: Taking Medication	Month	Achieved	<input type="radio"/> Achieved <input type="radio"/> Continued <input type="radio"/> Modified		
-- / -- / --	<input type="radio"/> Increase taking medications on time <input type="radio"/> Miss fewer medications <input type="radio"/> Take medications as prescribed Goal individualization: _____	<input type="radio"/> 1 mo. <input type="radio"/> 3 mo.	Rate 0-10: <table border="1" style="display: inline-table; vertical-align: middle;"> <tr> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> </tr> </table>			_____ _____ _____

Date	Goal: Problem Solving	Month	Achieved	<input type="radio"/> Achieved <input type="radio"/> Continued <input type="radio"/> Modified		
-- / -- / --	<input type="radio"/> Identify potential problems <input type="radio"/> Plan problem situation treatment <input type="radio"/> Prevent problem situations Goal individualization: _____	<input type="radio"/> 1 mo. <input type="radio"/> 3 mo.	Rate 0-10: <table border="1" style="display: inline-table; vertical-align: middle;"> <tr> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> </tr> </table>			_____ _____ _____

Date	Goal: Healthy Coping	Month	Achieved	<input type="radio"/> Achieved <input type="radio"/> Continued <input type="radio"/> Modified		
-- / -- / --	<input type="radio"/> Cope with diagnosis of disease <input type="radio"/> Adapt to lifestyle changes <input type="radio"/> Get support from family /friends Goal individualization: _____	<input type="radio"/> 1 mo. <input type="radio"/> 3 mo.	Rate 0-10: <table border="1" style="display: inline-table; vertical-align: middle;"> <tr> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> </tr> </table>			_____ _____ _____

Date	Goal: Reducing Risks	Month	Achieved	<input type="radio"/> Achieved <input type="radio"/> Continued <input type="radio"/> Modified		
-- / -- / --	<input type="radio"/> Stop smoking <input type="radio"/> Get health checkups <input type="radio"/> Perform daily self-care activities Goal individualization: _____	<input type="radio"/> 1 mo. <input type="radio"/> 3 mo.	Rate 0-10: <table border="1" style="display: inline-table; vertical-align: middle;"> <tr> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> </tr> </table>			_____ _____ _____

Diabetes Educator Name and Initial Index: _____

APPENDIX J: MIND-STRIDE INTERVENTION

Baseline questionnaires except Satisfaction questionnaire will be administered prior to the session (10 minutes)

- I. Introduction -didactic presentation of stress in diabetes introducing concepts of mindfulness, stress and distress (10 minutes)
 - a. Pain vs. Suffering
 - b. Acceptance
- II. Activity #1: Assessing your feelings about your own diabetes self-management, adapted from the Diabetes ACT Therapist Manual (15 minutes)
 - a. Use of white board
- III. Activity #2: Mindful eating exercise- adapted from Mindfulness-Based Stress Reduction Protocol – (10 minutes)
 - a. Sensory clarity
 - b. Emotion vs. thought vs. intentions
- IV. Activity #3: Gentle stretching and body awareness (may be performed while seated) (2-3 minutes)
- V. Activity #4: Mindfulness activity: Body Scan (20 minutes). CDR / players will be distributed and demonstrated.
- VI. Group Discussion: Focused attention; body awareness (10 minutes)
 - a. Incorporating mindfulness into daily life
- VII. Group Discussion: Reacting vs. responding to stress (10 minutes)
 - a. Disentangling
 - b. Triangle of Awareness
- VIII. Wrap-up: summarizing what took place. Provide home diaries. Schedule follow-up visit. Administer Satisfaction questionnaire. (15 minutes)

APPENDIX K: TELEPHONE SCRIPT

Hello this is _XXXX_ from the Diabetes and Stress Management Study at the VA.
Do you have a moment to talk?

If yes,

I just called to ask how things are going with your diabetes management.

How would you rate your stress level since we last spoke?

(0= no stress; 10 = the most stress you ever encountered

(For Intervention Group participants):

How has the home stress management practice been going?

I just want to remind you to mail in your home practice diary this week.

Do you have any questions?

I would also like to remind you of your next research visit on -----.

I'll plan on calling you again in 2 weeks.

Thank you.

If there is no answer, the following message will be left on the answering machine:

Hello this is XXXX from the research study at the VA Pittsburgh.

I am just checking in with you to see how you are doing.

If you have any questions or want to discuss anything, feel free to call me at -----.

(For Intervention Group participants):

Please remember to send in your weekly log sheet in the envelopes provided.

I would also like to remind you of your next research visit on-----.

I'll plan on calling you again in 2 weeks.

Thank you.

If there is no answering machine, a letter will be sent with the above message.

APPENDIX L: 1-MONTH BOOSTER SESSION

- I. Discussion (10 minutes): Tell me about your home practice?
 - i. Probes:
 - 1. How often have you been practicing?
 - 2. What has it been like for you?
 - 3. How has your diabetes self-management been going?
 - 4. How have you been coping with stress?

- II. Mindfulness Activities (10 minutes):
 - i. Brief sitting meditation

- III. Didactic (10 minutes)
 - i. Mindfulness in daily living
 - ii. Problem solving

APPENDIX M: IRB DOCUMENTS



PHS

VA Pittsburgh Healthcare System

VA Pittsburgh
Healthcare System
University Drive
Pittsburgh, PA 15240

October 13, 2011

Monica DiNardo, MSN, APNP, BC, CDE
Doctoral Student
University of Pittsburgh
School of Nursing
440 Victoria Building
3500 Victoria Street
Pittsburgh, PA 15261

Dear Ms. DiNardo,

I support your efforts to conduct a project for your doctoral dissertation and AADE grant submission entitled, "A Holistic Approach to Diabetes Self-Management Education, Healthy Coping and Stress Reduction for US Veterans with Diabetes" at the Veterans Affairs Pittsburgh Health Care System (VAPHS).

Your goal to adapt our current diabetes education program to include a mindfulness-based stress management intervention to improve coping skills and decrease diabetes-related distress in our Veteran with diabetes is very timely and promising. There are approximately 10,000 Veterans with diabetes cared for by the VAPHS, representing about 25-28% of our total patient population. Furthermore, the Computerized Patient Record System (CPRS) at the VA is an excellent resource that will allow timely access to hemoglobin A1C values and facilitate communication with patients and primary care providers.

This project may raise awareness of the Veterans with diabetes of the importance of self-care behaviors in reducing modifiable risks of this disorder, and empower them to make informed decisions regarding diabetes self-management. The information obtained from this study could be instrumental to improving current educational protocols which in turn may ultimately help to prevent diabetes-related complications in our Veterans.

Sincerely,

Frederick DeRubertis, MD
Vice President, Medical Specialty Service Line, VAPHS

www.va.gov/pittsburgh
Phone: 412-688-6000
1-888-4 VA PITT
(1-888-432-7488)
Fax: 412-688-2121

**DEPARTMENT OF
VETERANS AFFAIRS**

MEMORANDUM

Responsible Mentor Certification

To: VA Pittsburgh Healthcare System Institutional Review Board

From: R Harsha Rao MD

Date: 5-30-2012

Subject: A Mindful Approach to Diabetes Self Management Education with Stress Reduction and Healthy Coping in US Veterans with Diabetes Co-PI's Monica DiNardo CRNP, PhD(c), R Harsha Rao MD

I certify that I am willing to serve in the capacity of Responsible Mentor for the above referenced project. I understand that as the Responsible Mentor my responsibilities include providing assistance to Monica DiNardo to ensure that this project is appropriately managed and that all requirements related to Human Research Protections are applied according to local and national policies/procedures. Furthermore, I certify that I understand that in order to serve in the capacity of Responsible Mentor, I must meet the VAPHS IRB Principal Investigator qualifications as described below:

A PI must be either compensated by VA, work without compensation (WOC), or may be an employee assigned to VA through the Intergovernmental personnel Act (IPA) of 1970. Furthermore, for studies deemed greater than minimal risk by the IRB, the PI must have a significant physical presence at the VAPHS- either related to clinical responsibilities or in relation to other research activities.



Signature

July 26, 2012

From: Steven H. Graham, MD, PhD

To: [Monica DiNardo](#)

Study# [Pro00000360](#)
Re: A Mindful Approach to Diabetes Self- Management Education with Stress Reduction and Healthy Coping for US Veterans with Diabetes

The memo is being sent as written notification that the above named research project has been approved by all relevant committees, subcommittees, or other entities and may now be initiated.

Please be reminded that Continuing Review is required by the appropriate subcommittees prior to the approval expiration date. Please refer to the subcommittee approval letter(s), attached, for the date of expiration.

Sincerely,

Steven H. Graham, MD, PhD

VA PITTSBURGH HEALTHCARE SYSTEM
7180 Highland Drive
Pittsburgh, PA 15206
[412-954-5381](tel:412-954-5381)
<http://www.pittsburgh.va.gov/Research/professionals.asp>

July 26, 2012

From: **Research & Development Committee, VA Pittsburgh Healthcare System #646**

To: [Monica DiNardo](#)

Study#

[Pro00000360](#)

Re: A Mindful Approach to Diabetes Self- Management Education with Stress Reduction and Healthy Coping for US Veterans with Diabetes

The above named project was approved by the R&D Committee. All necessary subcommittee approvals have been obtained.

Sincerely,

Gretchen Haas, PhD

VA PITTSBURGH HEALTHCARE SYSTEM
7180 Highland Drive
Pittsburgh, PA 15206
412-954-5381
<http://www.pittsburgh.va.gov/Research/professionals.asp>

04/10/2013

IRB APPROVAL - Amendment

From: Linda Fried

To: Monica DiNardo

Amendment # [Ame3_Pro00000360](#) for Study#: [Pro00000360](#) ; A Mindful Approach to
Re: Diabetes Self- Management Education with Stress Reduction and Healthy Coping for US
Veterans with Diabetes

The following items were reviewed and approved through Expedited Review:

Study		Application
Study	Design	Figure
Consent Form – Version date: 04/08/2013		

Expedited Approval was granted on 04/09/2013.

Sincerely,
Linda Fried
Electronically Signed

VA PITTSBURGH HEALTHCARE SYSTEM
7180 Highland Drive
Pittsburgh, PA 15206
412-954-5381
<http://www.pittsburgh.va.gov/Research/professionals.asp>

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