# EFFECTS OF A MINDFULNESS INTERVENTION DELIVERED WITHIN DIABETES EDUCATION ON DIABETES-RELATED OUTCOMES IN MILITARY VETERANS

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**RESEARCH PLAN**

## 1.0 Background

Diabetes affects one million Veterans who receive care through the Veteran Affairs Hospital Administration (VHA), and is associated with higher mortality and morbidity. [1] Effective diabetes self-care is a critical and complicated aspect of disease control in diabetes that largely contributes to metabolic control and prevents micro-vascular and macro-vascular complications including hypoglycemia, eye disease, kidney failure, and limb threatening foot infections, cardiovascular disease, and stroke. [2] Diabetes self-management requires daily execution of self-care behaviors and the subsequent realization of related self-care goals.[3] Numerous studies have documented the association between diabetes self-management and improved diabetes outcomes.[2, 4-7] Diabetes self-management is largely implemented by patients themselves with intermittent instruction from health care providers, [8] and typically consists of an ongoing, demanding daily regimen of (a) healthy meal planning with regulation of carbohydrate and fat intake and control of body weight, (b) planning daily physical activity, (c) self-monitoring blood glucose and avoiding and treating extreme blood glucose fluctuations, (d) managing medications (which may include multiple daily injections), (e) complying with periodic diabetic risk assessments, and (f) managing stress.[9] The key to successful self-management of diabetes is the acquisition of knowledge, psychomotor skills, and effective psychological coping to facilitate lifestyle modifications and performance of these key self-care tasks. [10] The amount of time required to perform diabetes self-management varies by diabetes type and severity, and requires an average commitment of about 2 hours per day. [11]

## 1.1 The Demands of Diabetes Self-Management Create Diabetes–Related Distress.

The demands of diabetes self-management often result in an independent type of psychological anguish known as diabetes-related distress (DRD). DRD arises from perceived inability to keep up with the requirements and complexities of diabetes self-management[12] and is associated with decreased adherence, such that 30% of people with diabetes, particularly men, neglect to perform important elements of self-care [11]. If prolonged, a lapse in diabetes self-management ultimately predisposes individuals to poorer metabolic control, and higher rates of diabetes-related morbidity and mortality. [6, 13] Moreover, decreased adherence to self-management behaviors often creates interpersonal strain with significant others and with health care providers.[14]

Although the symptoms of DRD are similar to that of clinical depression, with which it may co-occur, it is important for health care providers to distinguish between the two conditions in order to provide appropriate therapeutic options. The reported prevalence of depressive symptoms among patients with diabetes ranges from 20 to 40%.[15, 16] Patients with diabetes and comorbid depression display higher functional impairment,[17] more lost work time,[18] poorer diabetes self-management, and more comorbidities[17] than patients with diabetes alone. However, it has been argued that DRD, and not clinical depression, may account for many of these reported findings, and is more strongly and independently related to behavioral and clinical measures of diabetes self-care than is depression.[19-21] Fisher et.al have demonstrated that although depressive symptoms are prevalent in individuals who have diabetes, most of these people are not clinically depressed; instead, they are distressed about their diabetes, and feel a lack of self-efficacy about self-managing the disease.[22]

## 1.2 Diabetes Self-Management Education (DSME) is the Cornerstone of Diabetes Self-Management.

DSME is the primary vehicle through which diabetes self-management is promoted, and focuses on supporting behaviors that facilitate achievement of effective diabetes self-care behaviors and goals as identified by the American Association of Diabetes Educators AADE7™ (Figure 1). [23] Multiple studies and meta-analyses have found DSME to be highly cost-effective for improving metabolic and psychosocial outcomes. [5, 24, 25] *Healthy coping,* defined as the conscious effort to master, minimize, and tolerate stress, including personal and interpersonal conflict, is the seventh, and typically least developed and least addressed, self-care behavior (see Figure 1). Traditionally, DSME

1. Healthy Eating
2. Staying Active
3. Monitoring
4. Taking Medications
5. Problem Solving
6. Reducing Risks
7. Healthy Coping

**Figure 1. AADE-7™ Self-Care Behaviors**

programs reference the importance of stress management, but stop short of providing practical support for developing necessary coping skills that
facilitate diabetes self care and diabetes control.[26, 27] For example, the VA's DSME course booklet, *Self-Care Skills for Patients with Diabetes* (VA, Department of Defense clinical practice guideline, 2011), encourages patients to find ways to manage stress management by "limiting, changing, or avoiding stressful situations and making time to relax and exercise" in order to achieve and maintain blood glucose control. Despite this recommendation, useful stress management support tools are not offered as part of the training.

**1.3 Mindfulness is a Promising Tool for Stress Reduction.**
Mindfulness-based stress reduction strategies are promising tools for supporting comprehensive diabetes self-management. Mindfulness is a secular concept adapted from Eastern philosophy that refers to self-regulated attention to the present moment experience with engagement of the five senses and an attitude of non-judgment.[28, 29] Mindfulness facilitates emotional regulation and modifies the way an individual reacts to difficult situations through the practice of attention, acceptance, and awareness.[29] Emotional regulation and the acquisition of new perspectives lead to feelings of self-efficacy by allowing difficult situations to be reflected upon and responded to thoughtfully and without distraction by pre-occupations with bodily sensations or intrusive thoughts and behaviors.[30] Although mindfulness is not a relaxation technique in the traditional sense, increased awareness fostered by mindfulness practice has been associated with a state of physical and mental calmness that lowers stress-reactivity and strengthens coping behaviors.[31, 32] Mindfulness is cultivated and strengthened through the practice of meditation.

Compelling neuro-physiologic research of meditation using functional magnetic resonance imaging, EEG, and other brain mapping techniques has shown characteristic changes in the brain physiology of individuals who had as little as 8 weeks of meditation training [33] and involve characteristic changes in the prefrontal cortex, occipito-temporal regions, and cortical insulae that correspond to areas of the brain involved in learning, memory, regulation of emotion, and executive functioning. [34-37] These findings suggest mechanisms for how the practice of mindful meditation may enhance emotional regulation and mental focus that are very important for effective diabetes self-management. These cognitive processes control present-moment orientation, attention control, attention switching, how one views one's own thoughts (metacognition), insight about one's attitudes and beliefs (metacognitive awareness), changing one's perspective on events/thoughts (cognitive restructuring), exposure and desensitization (as opposed to avoidance behaviors), and acceptance. [30, 38 39]

**1.4 Mindfulness can be used to Support Chronic Disease Self-Management.**
Mindfulness-Based Stress Reduction (MBSR) is the standard-bearer for mindfulness interventions that are specific to chronic disease management. MBSR is a complementary mind-body medical therapy developed by Dr. Jon Kabat-Zinn and his team at the University of Massachusetts School of Medicine. Similar to the Chronic Disease Self-Management Program (CDSMP), MBSR typically includes eight weekly 2-hour sessions and also a half-day meditation retreat. Weekly classes include group discussion, breath-focused meditation, gentle yoga, and didactic presentations on stress theory, mindful communications, and awareness training. One of the program's objectives is to help participants become more aware of in-the-moment emotions, and physical sensations. Meditation instruction and practice provide the foundation for MBSR, which has been scientifically studied in many chronic health conditions since the early 1970's including chronic pain,[40] cancer [41], rheumatoid arthritis,[42] fibromyalgia,[43] human immunodeficiency virus (HIV),[44] solid organ transplantation,[45] psoriasis[46], post-traumatic stress disorder (PTSD)[47, 48] and more recently in diabetes.[49,50-52]

During the past decade, an emerging body of research supports promising results of mindfulness-inspired interventions for reducing disease burden for individuals with diabetes. As with numerous other chronic health conditions, this approach has shown improved psychological stress and quality of life, but the effects on metabolic outcomes in diabetes have been inconsistent and warrant further study. More specifically, a seminal 2007 observational pilot study of MBSR in patients with Type 2 diabetes (T2DM) demonstrated significant pre- to post improvements in HbA1c, mean arterial blood pressure, and psychological distress, independent of weight loss, medication changes or lifestyle modification[50]. In partial contrast, two subsequent longitudinal, multisite trials of MBSR conducted in people with type 1 diabetes (T1DM) and T2DM, the Heidelberger Diabetes and Stress study [49] and the Diabetes and Mindfulness Study (DiaMind) [52] did not find effects on HbA1c, but did detect significant reductions in emotional distress. Furthermore, in our own pilot work examining the effects of brief targeted mindfulness training as part of DSME (as opposed to intensive MBSR) for Veterans with diabetes, we found significant improvements in DRD and diabetes self-management that

correlated with improved diabetes self-efficacy, as well as a 1% reduction in HbA1c. These findings raise questions about the role of mindfulness as it applies to variables in the diabetes self-care paradigm (i.e. DRD, diabetes self-efficacy, and diabetes self-management behaviors) and impact on diabetes outcomes such as glycemic control.

### 1.5 Our Conceptual Framework Includes Previously Unexamined Variables Related to Mindfulness and Diabetes Outcomes.

The conceptual framework for this study (Figure 2) is underpinned by bio-psycho-social stress theory [14, 53-57] that posits a psychosocial intervention such as Mind-STRIDE can influence psychological (i.e., mindfulness, diabetes self-efficacy, and DRD), behavioral (diabetes self-management), and biological (glycemic control) outcomes in the setting of an individual's accumulated life stresses ("allostatic load") and personal resources (i.e., genetic pre-disposition and social support). In our conceptual model, mindfulness, diabetes self-efficacy and DRD (the primary outcome) are independently and synergistically affected by Mind-STRIDE, the independent variable, as is diabetes self-management. Glycemic control, the distal secondary outcome, is affected by both changes in diabetes self-management and through down-regulation of Hypothalamic-Pituitary-Adrenal Axis (HPA) feedback activity resulting in decreased insulin resistance and increased blood glucose disposal.[58] Although measurement of neuro-endocrine biomarkers is outside of the scope of this psycho-educational study, we include HPA axis activation in the conceptual model as an unmeasured covariate, because of its relevance to the relationship between stress and metabolic glycemic control.

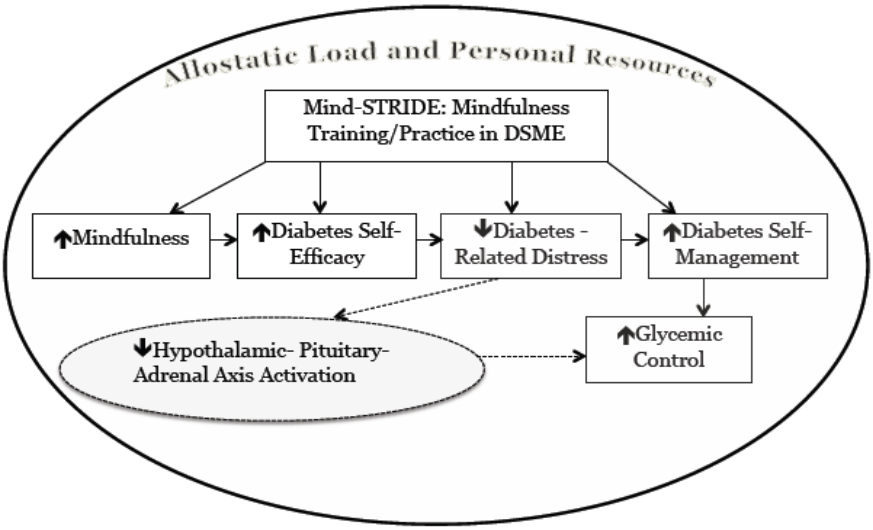



**Figure 2. Study Conceptual Model of Allostatic Load, Personal Resources, and Diabetes Control**

### 1.6 Confirmatory and Expanded Research is Needed Prior to Implementation of Mindfulness Interventions in Diabetes Care of Veterans.

More research is needed to confirm and elucidate the impact of mindfulness on multiple aspects of diabetes self-care and outcomes, particularly in special populations such as Veterans, where Complementary and Alternative Medicine (CAM) initiatives are increasingly being utilized as a group of cost-effective, non-pharmacologic interventions. First, while the effects of mindfulness interventions on glycemic control remain unclear based on results of the aforementioned limited number of studies, these studies do suggest, though not definitively, that mindfulness may be specifically efficacious for reducing DRD, which directly reflects diabetes quality of life and reduced disease burden. Additional research is therefore needed to expand upon previous studies and elucidate the relationship between mindfulness and reduction of DRD, and to examine *additional relationships* involved in the complex landscape of diabetes self-care, and ultimately, glycemic control. More specifically, the large-scale trials did not examine the effects of mindfulness on other related variables commonly understood to impact diabetes self-care, such as diabetes self-efficacy and individual diabetes self-management behaviors.

Furthermore, these questions particularly warrant closer examination in the Veteran population for several reasons. Veterans are a unique population that may have even greater clinical responsiveness to a mindfulness intervention due to their higher prevalence of diabetes and diabetes-related burden than in the general US population (11% vs. 8%), and greater physical and psychological vulnerability to stress-related conditions. For example, there is progressively more depression and post-traumatic stress in modern era Veterans compared to previous generations of Veterans and to the US population at large.[59] In addition, Veterans experienced more childhood trauma compared to the non-military population that has been linked to lifelong emotional difficulties, and may have even led some Veterans to enlist in the military as a form of escape.[60, 61]

In order to support the testing of patient-centered, feasible, and sustainable interventions, we assert that the next phase of mindfulness research in diabetes needs to assess the efficacy of brief mindfulness training embedded in the context of routine DSME and care, where it has a natural, conceptual fit with the promotion of Healthy Coping, one of the 7 core pillars of DSME (Figure 1). While successful programs such as the aforementioned CDSMP have been applied to patients with diabetes to facilitate self-care and stress reduction,[62] programs such as this that entail a series of lengthy community-based or online sessions that occur outside of routine healthcare visits may not be practical or appealing to many of the Veterans who receive care through VHA.

To address this issue, we developed and pilot-tested single session mindfulness training with one booster called Mindful Stress Reduction in Diabetes Education (Mind-STRIDE), which is incorporated into routine DSME. At the VA Pittsburgh Healthcare System (VAPHS), a certified nurse diabetes educator and a dietitian teach DSME in one comprehensive 3-hour participatory group class. The Mind-STRIDE program was adapted from core MBSR tenets and activities presented in Kabat-Zinn's book, Full *Catastrophe Living: Using Wisdom of Your Body and Mind to Face Stress, Pain, and Illness,*[29] and also *The Mindfulness Based Stress Reduction Workbook* [63] (Table 1).

**Table 1. Summary of Mind-STRIDE: MBSR Topics and Content adapted from the work of Jon Kabat-Zinn**

| Topic | Content | Method |
|---|---|---|
| 1. Foundations of Mindfulness Practice: Attitudes and Commitment | Paying attention; Non-judging; Patience; Beginner's Mind; Trust; Non-striving; Acceptance; Letting go | White-board presentation and class activity, reinforced at booster and with home practice recording |
| 2. The Power of Breathing: An Ally in Healing | Diaphragmatic Breathing; Sitting Meditation: Nourishing the Domain of Being | Class instruction and practice of mindful breathing reinforced at booster and by home practice recording |
| 3. Being in Your Body | Body Scanning Technique | Class instruction and practice reinforced by home practice recording |
| 4. Cultivating Strength, Balance and Flexibility | Reconnecting with the Body through Mindful Movement | Class instruction and practice of yoga-type chair exercises reinforced by home practice recording |
| 5. Mindfulness in Daily Life | Recognizing "auto-pilot" and avoidance behaviors; Formulating strategies for staying in the present moment | Class discussion reinforced with home practice |
| 6. Understanding Stress | Overview of pathophysiology of stress and its effects on diabetes | White board class presentation |
| 7. Responding vs. Reacting to Stress | Understanding the Triangle of Awareness: disentangling thoughts, sensations, and emotions. | Class discussion reinforced by paper hand-outs |
| 8. Diabetes Stress and Food Stress | Discovering ways in which diabetes is stressful. The role of food in diabetes stress | Class discussion, reinforced at booster and home practice |

The Mind-STRIDE curriculum was adapted with expert guidance of Dr. Carol Greco, Co-Investigator, who is a highly trained and experienced MBSR teacher. Mind-STRIDE includes meditation training and practice, mindful movement (seated yoga postures) and discussions similar to those presented in the traditional MBSR program that are aimed at increasing body and sensory awareness, disentangling thoughts, and decreasing emotional reactivity. (See Appendix 2 for additional class materials)**.**

Our goal is to build upon the preliminary and pilot work described below by further assessing the efficacy of Mind-STRIDE in a full-scale RCT examining its impact on mindfulness, diabetes self-efficacy, diabetes self-management, and glycemic control among Veterans with diabetes.

### 1.7 Relevant Research—Preliminary Studies

We have conducted two surveys and two pilot studies in preparation for the current RCT proposal that demonstrate Veteran preference for accessible and personalized interventions, as well as Mind-STRIDE's feasible and outcome-driven approach that warrants efficacy testing.

#### *1.7.1 MBSR for United States (US) Military Veterans with Diabetes: A Survey of Interest among Veterans (PI: Monica DiNardo, PhD, RN)*

The purpose of this descriptive study was to determine Veteran interest in learning more about stress management and participating in an 8-week MBSR program at VAPHS. We conducted a survey of 51 US Veterans with T2DM from December 2008 to March 2009 at the VAPHS Diabetes Clinic. Respondents were mainly white (84%), men (98%), 55 years of age or older (78%). Of those polled, 31 Veterans (61%) reported having an interest in attending the MBSR program. Sixty-one percent requested printed information on stress management; 78% identified the MBSR program's location as being a decisive factor to their willingness to participate in a multiple-session study. These 61% of interested respondents identified wanting to attend the program for the following reasons: for general stress reduction (48%); to improve diabetes control (23%), to manage weight and overall health (20%), to improve self-esteem (3%); and/or to learn something new (6%). Twenty respondents (39%) had no interest in attending the proposed MBSR program; reasons for no interest included: lack of transportation/unable to commit to eight weekly sessions (40%); having no stress or stress under control (45%) or no interest in this type of program (15%). These findings were presented in a poster presentation at the 2009 Eastern Nursing Research Society (ENRS) conference in Providence, RI.

*Implications for the proposed study*. From this survey we gained a sense of the demographic characteristics and interests of patients who receive care at VAPHS Diabetes Specialty clinic. Although their degree of interest in attending a stress management program at VAPHS was high, we concluded that recruitment for a multi-session face to face program at VAPHS would be difficult, since the travel and time commitment was a barrier for many of the Veterans who were surveyed.

### *1.7.2 Stress Reduction in Diabetes Education: A Survey of Interest among Diabetes Educators (PI: Monica DiNardo, PhD, RN)*

The purpose of this descriptive survey was to assess Diabetes Educators' a) perceptions of stress among their patients, and b) willingness to include mindfulness stress management training as part of DSME. We conducted a survey of Diabetes Educators who attended a meeting of the Western Pennsylvania Association of Diabetes Educators in November 2014. Of the 28 diabetes educators who completed the survey, 18 (64%) were Registered Nurses, 11 of whom were Certified Diabetes Educators, five were Advanced Practice Nurses, and two were Bachelor prepared nurses; and 10 (36%) were Registered Dietitian/Certified Diabetes Educators. The average number of years as a Diabetes Educator was 15 years (range 6 months -32 years). Thirteen of 28 (46%) respondents personally practice yoga, meditation, or another mind-body approach to manage their own stress. Of the 28 respondents, 22 (79%) reported that their patients often or very often complain that their stress is a barrier to diabetes self-management and blood glucose control. Thirteen of 28 (46%) of the diabetes educators surveyed teach group DSME classes, and four of them consistently provide stress management education as part of their group classes. Reasons given for not currently providing stress management training within DSME were time constraints, lack of expertise, limited scientific evidence, and lack of inclusion in the pre-existing DSME curriculum. Nineteen of 28 diabetes educators (68%) surveyed would consider adding brief mind-body stress management training as part of group DSME as long as it was evidence-based, time - efficient, and was written into their model of care.

*Implications for the proposed study*. We concluded from this survey that patients frequently inform diabetes educators that stress is a barrier to diabetes self-care and blood glucose control. In general, there was interest among the diabetes educators surveyed for adding a brief mind-body stress reduction intervention to DSME, and that brief, evidence based mindfulness programs relevant to DSME are needed.

### *1.7.3 Exploring Mindfulness Based Stress Reduction on Women with Type 2 Diabetes: A Mixed Methods Pilot Study (PI: Monica DiNardo, PhD, RN)*

The aims of this 2010 prospective observational pilot study of women with T2DM (n=6) was to a) explore the acceptability of MBSR in women with T2DM who attended a community health center MBSR program, and b) identify the best strategies, outcome measures, and the logistics for conducting a successful MBSR program. The 8-week MBSR intervention consisted of weekly two-hour sessions and a half-day silent retreat taught by Dr. Carol Greco, Co-Investigator. We gathered pre-post data on HbA1c, blood pressure, body mass index (BMI), waist circumference, lipid profile, and C-reactive protein (CRP), a marker of non-specific inflammation. Mindfulness (Mindfulness Attention Awareness Scale, MAAS), global perceived stress, (Perceived Stress Scale<PSS-10), diabetes stress (Problem Areas in Diabetes Scale, PAID), quality of life (SF-36), and metabolic

control (HbA1c) were measured at baseline, at completion of the 12-week intervention, and one-month post-intervention follow-up at 16 weeks. At baseline, participants' mean age was 55.7 years, mean HbA1c was 6.9%, and mean duration of diabetes was 4.9 years. Participants were primarily white (86%), college educated (71.4%), and had multiple co-morbid conditions (>4; 86%).

Six of 14-screened candidates were enrolled in the study; the remaining eight eligible candidates did not enroll due to time conflicts with the MBSR class schedule. All enrolled participants completed the 12-week study. Even with this very small sample, we found significant pre-post intervention changes in improved mindfulness, decreased perceived stress, decreased diabetes stress, and a 1% decrease in HbA1c. These changes were sustained at 1-month post intervention follow-up except in HbA1c. Qualitative data were gathered by structured interviews at 16 weeks post -intervention to explore participants' experience with the MBSR program and its perceived importance to their diabetes self-care. All of the participants reported very high satisfaction with the program and would recommend MBSR to other people with and without diabetes. Five of the six participants intended to continue practicing mindfulness in their daily lives. The participants unanimously recommended adding diabetes-specific content to future MBSR programs. Concept analysis was performed using grounded theory methodology,[64] and two qualitative themes were identified: 1) Improved coping (e.g.*"…more confident …" "easier to cope"*; *"…lowered my reaction to things…"; "…it makes it easier to calm down and deal with aggravation and pain of diabetes…"), and* 2) Connecting mind and body (e.g. *"…able to visualize what is going on internally…"*; *"…motivated me to exercise and take better care of myself*; *I can now 'breathe through' my pain").*

*Implications for the proposed study*. MBSR was positively received and showed promise of benefit to women with T2DM. These findings support the feasibility of conducting an experimental study of MBSR in women with T2DM, and found positive changes in perceived stress, diabetes related distress, and HbA1c. Efforts to recruit community participants with T2DM who were available to participate in an 8-week program proved challenging however. Furthermore, the generic community MBSR program did not address diabetes-specific issues important to these study participants. We utilized what we learned from these findings to overcome barriers to our diabetes-specific mindfulness intervention, Mind-STRIDE. As a result of this small pilot study, the PI collaborated with Dr. Greco to design an accessible one-session intervention that incorporates fundamental tenets of MBSR and addresses diabetes-specific concerns, including mindful eating and using self-compassion to deal with interpersonal difficulties surrounding self-management issues.

### *1.7.4 A Mindful Approach to Diabetes Self-Management Education with Stress Reduction and Healthy Coping for US Veterans with Diabetes (PI: Monica DiNardo, PhD, RN)*

The purpose of this pilot study was to determine the feasibility and acceptability of our Mind-STRIDE intervention in a prospective observational study in a sample of Veterans with T1DM and T2DM at VAPHS. Study participants were recruited from DSME classes at VAPHS. Participants who had diabetes for at least six months, took a stable regimen of diabetes medications for at least one month, and had a baseline HbA1c greater than 7% were eligible to participate. Regarding feasibility and acceptability, we tracked participant recruitment and retention, and measured Veteran and Diabetes Educator satisfaction with Mind-STRIDE by self-report rating scales and interviews. Secondarily, we assessed the effects of Mind- STRIDE on perceived stress (PSS-10), DRD (PAID) , and self-efficacy (Diabetes Empowerment Scale, DES-SF), diabetes self-management (AADE-7™Self-care Behaviors), and HbA1c over time, from baseline to 3-month post intervention.

In this study, 60% (28/47) of eligible Veterans agreed to participate, and 71% (20) of enrolled participants completed the three-month study. At least half of the participants who dropped out did so because of comorbid medical or behavioral conditions (Table 2). Our sample was unemployed or retired (82%) older males (mean age 63 years) who were overweight (mean BMI 33 kg/m$^2$) and had T2DM; 54% were college educated. Median diabetes duration was 18.2 years (range 6 months - 55 years), and mean baseline HbA1c was 8.8%.

**Table 2. Participant Attrition Summary**

| Participant | Baseline HbA1c (%) | Time point | Reason for Attrition |
|---|---|---|---|
| 1 | 12.5 | Baseline | Poor vision; unable to complete questionnaires |
| 2 | 9.8 | 1 mo | Moved to another state |
| 3 | 8.3 | 1 mo | Family crisis |

| | | | |
|---|---|---|---|
| 4 | 12.7 | 1 mo | Admitted to skilled nursing facility |
| 5 | 10.2 | 3 mo | Bipolar disorder difficulty with home practice |
| 6 | 10.1 | 3 mo | Unknown |
| 7 | 8.6 | 3 mo | Unknown |
| 8 | 8.8 | 3 mo | Admitted to skilled nursing facility |

There was a high level of acceptance among clinicians and Veteran participants. Clinician acceptance of Mind-STRIDE was measured by a brief structured interview and 10 point rating scale (1= this program was not useful at all; 10 = this program was excellent and met the needs of the class). The course instructors rated the program 8.5 out of 10, and thought the program was pertinent to "what's missing" in DSME. Veteran participant satisfaction with Mind-STRIDE was assessed with a 4-item satisfaction questionnaire and free-text comment section; 96% of participants strongly agreed that they learned something new and planned to continue practicing mindfulness meditation in the future; 92% would recommend Mind-STRIDE to other people with diabetes. Daily paper and pencil diary entries assessed participant acceptance, experience, and frequency of home practice. Eleven (39%) of the participants completed home practice diaries indicating an average home practice frequency and duration of 12 minutes three times per week.

Qualitative data were gathered from the free -text comment section of participant satisfaction questionnaires and the home practice diaries to provide insight into Veteran satisfaction and acceptance of their experience with Mind-STRIDE. Qualitative data was coded by two coders using modified Grounded Theory, and was organized by theme with 100% agreement. Participant quotes and themes appear in Table 3.

**Table 3. Summary of Mind-STRIDE Participant Feedback: Themes and Supporting Veteran Quotes from Satisfaction Questionnaires and Home Practice Journals**

<u>Mindfulness as a personal resource</u>

- "Provides another tool to help keep you on track."
- "Helps make things easier."
- "It definitely helps me feel better, a great tool."
- "It got me through a really tough day when my wife was sick and my car broke down. Extension of principles from anger management to practical use in diabetes program for control."
- "This presentation/study is very useful and I would strongly suggest this type of study to Veterans that I counsel (unemployed Veterans)."
- "I find it very helpful as it helps you to concentrate on things that will help you to feel better about yourself."
- "This should help some people if they are willing to commit to doing this."
- "Good way to help people understand their bodies."
- "More classes. Very helpful - interesting. Need more involvement."

<u>Awareness</u>

- "This helped become more aware."
- "This class is showing me a different approach in dealing with my thinking!
- "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…"
- "This program has given me the thought about what is meaningful in life! Stress relief is certainly important and attainable! Thinking about everyday thoughts and feelings are important!"
- "Good way to help people understand their bodies."
- "Class was good and made me consider my thought processes."

<u>Home Practice</u>

- "Interruptions during my home study disrupted the thoughts I was having."
- "I have problems with attention deficit at home. My mind wanders even though I try to stay focused."
- "It helps when you do it on a continuing daily basis; I found different times of day work best."
- "Mindfulness recordings are very helpful."

<u>Social support</u>

- "I was skeptical but my wife said 'Give it a try. I'm glad I did."
- "My wife and I have been doing it together."
- "I think it was good talking with other diabetics about what they think and feel, that I am not the only one with these feelings.

<u>Behavior change</u>

- "My wife asked me why this motivates me… after all this time."
- "Curious to continue this process and see my personal experiences and results!"
- "I'm sticking with it, because I want to help myself do better.

Nonparametric repeated measures analysis and post-hoc pairwise comparisons were applied to the quantitative data using the Friedman's Test and Wilcoxon Signed Rank Test respectively and demonstrated a statistically significant reduction in DRD from baseline to 3-months post intervention ($p < .01$; $d = .7$). Significant improvements in diabetes self-management ($p < .05$; $d = .5$), and a 1% reduction in HbA1c ($p < .05$; $d = .7$) were also observed. After 3-months of mindfulness practice, significant correlations were found between psychological outcomes and specific elements of Mindfulness that were not present at baseline (Table 4).

**Table 4. Post-intervention Correlations between Mindfulness Facets and Psychological Outcomes**

| Mindfulness (FFMQ) | Perceived Stress (PSS-10) | Diabetes Distress (PAID) | Diabetes Self-Efficacy (DES-SF) |
|---|---|---|---|
| Observing | -.05 | -.04 | .11 |
| Describing | -.18 | -.12 | .50* |
| Acting with awareness | -.59** | -.54** | .42* |
| Non-judgment | -.59** | -.53** | .43* |
| Non-reactivity | -.30 | -.52** | -.04 |

*$p<.05$; **$p<0.1$

*Implications for the proposed study*. We pilot-tested the feasibility of operationalizing Mind-STRIDE within existing DSME classes. Rates of recruitment and retention were generally good, Veteran satisfaction and engagement and staff satisfaction and enthusiasm were high. However, only 39% of participants completed diaries, therefore we concluded that the use of paper home practice diaries was inefficient for tracking home practice. We believe hand-held digital devices will be easier and more appealing to the participants and therefore will increase participation in this exercise. These devices can be used for more portable and convenient access to the audio-recorded guided meditations and for real-time documentation of home meditation practice; and they can also serve as a home practice journal. This pilot study paved the way for taking the next step, testing the effects of the intervention on glycemic control and intermediary psycho-behavioral outcomes in the proposed RCT.

## 2.0 Significance

One in four US veterans who receive care through the VHA have diabetes, which means that at any given time more than one million Veterans look to the VHA for diabetes care and self -management support.[1] Management of diabetes depends upon self-management behaviors to regulate metabolic control and prevent or delay micro-vascular and macro-vascular complications. Advanced micro-vascular complications of diabetes are the leading causes of blindness, non-traumatic amputations, and end-stage kidney disease in the US and in VHA. VHA patients have a higher rate of diabetes (11% vs. 8%) compared to the general US population. Advanced macro-vascular complications such as myocardial infarction and stroke contribute to higher mortality rates in VA patients with diabetes, which average 5% compared to 2.6% among patients without diabetes, and is a major cause of deaths and inpatient admissions outside of VHA[1]. Diabetes is one of the top medical conditions requiring hospital admissions and 30-day readmissions, and therefore is a significant contributor to escalating health care costs.[65]

The anticipated impact of this study is to decrease DRD and enhance self-efficacy to improve diabetes self-care behaviors through mindfulness and potentially improve glycemic control among Veterans. Because DRD interferes with self-care behaviors, our program has potential for significantly impacting and advancing the health and health care of Veterans because it targets a serious and prevalent problem that is not currently well-addressed within the context of diabetes care. The proposed mindfulness study will extend knowledge of the feasibility and effects of providing a practical, low cost, mind-body intervention that can be offered as a part of routine DSME, and has already been successfully pilot-tested in a sample of Veterans who found it acceptable and helpful. This is not surprising in that approximately 21 million US adults, including Veterans, practice mindfulness or some form of meditation.[66] Mindfulness is increasingly incorporated into Complementary CAM initiatives in VHA. Mindfulness is one of the top five most frequently used mind-body CAM modalities at VA facilities. Studies of mindfulness meditation in Veterans with PTSD have shown improvements in PTSD symptoms and improvements in quality of life. [47, 67] Over 5,000 Veterans have been treated with mindfulness meditation at VA facilities for anxiety, PTSD, depression and stress management.[68] Over half of VHA facilities have existing procedures for mindfulness in place and offer mindfulness therapy primarily to Veterans

receiving outpatient care. However, mindfulness meditation has not been studied or applied to the care of patients with diabetes within VHA.

The proposed study supports VHA National Nursing Strategic Plan (2013-18) goal 1a(4) by testing the integration of a new nurse-led initiative into a patient-centered program of specialty care. This proposal also corresponds with VHA Blueprint for Excellence (9-2014) transformational action 7.2 by testing a program that will enhance VA Research on CAM. Empowering Veterans to improve their own wellbeing is one of the driving strategies behind VA CAM research. VHA has funded 13 mind-body studies in partnership with the National Center for Complementary and Alternative Medicine that target pain and PTSD in active duty personnel and in Veterans and their families. However, currently, there are no planned VA studies of mindfulness-based therapies for diabetes.

Considering the cumulative effects of stress and the number of military Veterans who suffer from co-morbid depression and PTSD, [57, 69] Veterans with diabetes are at particular risk for negative consequences of diabetes distress. Mind-STRIDE re-directs the current intervention paradigm for DSME and diabetes care, and could pay-off with a ready-to-use program choice for Veterans that offers effective psycho-behavioral self-management support through patient-aligned care. Considering that our Co-Investigators are prominent VA, national, and international leaders, Dr. Rao and Dr. Siminerio in the field of diabetes care and education, and Dr. Bormann and Dr. Greco in meditation and mindfulness, the likelihood of uptake of findings and recommendations from the proposed research is high. Mind-STRIDE has minimal potential for harm, and holds promise for enhancing the physical and psychological health of Veterans to better equip them to "*manage their own lives and achieve their own goals.*"[1] We also anticipate that in the future, programs similar to Mind-STRIDE might have applicability for supporting Veterans' self-management goals in prevention and maintenance of other chronic conditions. In fact, this study is closely aligned with currently and previously NRI- funded mindfulness and meditation trials for PTSD[67] and cardiovascular risk in women (The Mindful Hearts Trial). Together these nurse-led studies will build upon one another to make substantial contributions to the emerging literature and science of mindfulness and meditation in Veterans who are at risk for and suffer from chronic diseases.

### 2.1 Innovation

Our intervention is noteworthy and novel in four ways:

a) **Content:** Mind-STRIDE is an original VA pilot-tested intervention adapted from an evidence-based Mindfulness training model, MBSR
b) **Accessibility:** Our program incorporates a brief, accessible mindfulness-based intervention provided at the point of diabetes care, and tests the efficacy of a potentially new diabetes care process geared toward uptake and sustainability
c) **Design:** Our study is the first to apply a qualitative analysis of mindfulness in people who have diabetes, which actively supports the design and implementation of a new patient– centered diabetes paradigm
d) **Measurement:** Our study is the first to utilize common technology (digital tablets) to capture adherence to home mindfulness practice in real time, as well as utilize existing VA Tele-Health technology for verification of home blood glucose data

## 3.0 RESEARCH DESIGN AND METHODS

### 3.1. Design

This study is a 2-arm single-site mixed-methods randomized controlled efficacy trial of a mindfulness intervention to reduce DRD among Veterans with diabetes. Participants will be randomized to one of two study conditions: the experimental group (DSME+ Mind-STRIDE) and the usual care group (DSME-Alone). Research assessments will occur at baseline (T1), 12- weeks (T2), and at 24 weeks (T3) for both study arms. Satisfaction assessments will be conducted in the experimental group following the Week 4 booster. Qualitative telephone interviews will be conducted at 15 weeks in a subgroup of purposively sampled participants in the experimental group.

### 3.2 Setting

This study will be conducted at the University Drive (UD) campus of VA Pittsburgh Healthcare System (VAPHS), an integrated healthcare system affiliated with the University of Pittsburgh that serves the Veteran population throughout the tri-state area of Pennsylvania, Ohio, and West Virginia. VAPHS is a major tertiary care institution comprised of two facilities and is the hub to five smaller "spoke" facilities in the region; it provides specialty diabetes care to five regional Community-Based Outpatient Clinics (CBOCs), for which it provides diabetes specialty care services. VAPHS provides outpatient health care to approximately 17,000 US Veterans with diabetes annually, 28% of the total number of patients served. The UD location is the only VA location in the tri-state area of Southwestern Pennsylvania, Southeastern Ohio and Northern West Virginia that has a Diabetes Specialty clinic and offers group DSME classes (Additional information about VAPHS is found in the *Facilities and Resources* section.) The Diabetes Clinic is housed within the multi-disciplinary Medical clinic in the hospital facility at UD, and is staffed by four board certified endocrinologists, two nurse practitioners (one is the PI), three certified diabetes nurse educators, and a dietitian. The staff diabetes educators and dietitian provide individual diabetes education in the outpatient clinic by appointment in addition to teaching the comprehensive group DSME classes. Group classes are held twice monthly throughout the year in a conference room at UD and are offered twice monthly via direct video-conferencing from UD to Veterans gathered at spoke facilities. The coordinating diabetes nurse educator co-teaches the DSME class with the dietitian and received over 300 DSME referrals from primary care and specialty clinic providers at UD and 160 referrals from spoke facility providers in 2014. The VA DSME program meets national standards and maintains recognition by the America Diabetes Association (ADA) Education Recognition Program (ERP) .[24]

### 3.3 Population and Sample

The target population for this study is male and female Veterans who have a diagnosis of T1DM or T2DM. We will use the following inclusion and exclusion criteria for our study sample:

*Criteria for inclusion:*

a) DSME class enrollment*
b) Fluency in reading and writing English**
c) Diagnosis of diabetes for at least 6 months *
d) HbA1c >7.5% within past 3 months *
e) Stable diabetes medications for at least 60 days*
f) Problem Areas in Diabetes Scale (PAID) score > 10 (described below, Section 3.8)**
g) Telephone access with voice mail to receive research related messages**
h) Willingness to utilize VA Home Tele-Health for documentation of home blood glucose readings**
i) Willingness to be randomized to the experimental or usual care group**
j) Willingness to have the qualitative interview audio-recorded (if randomized to experimental group)**

*Criteria for exclusion:*

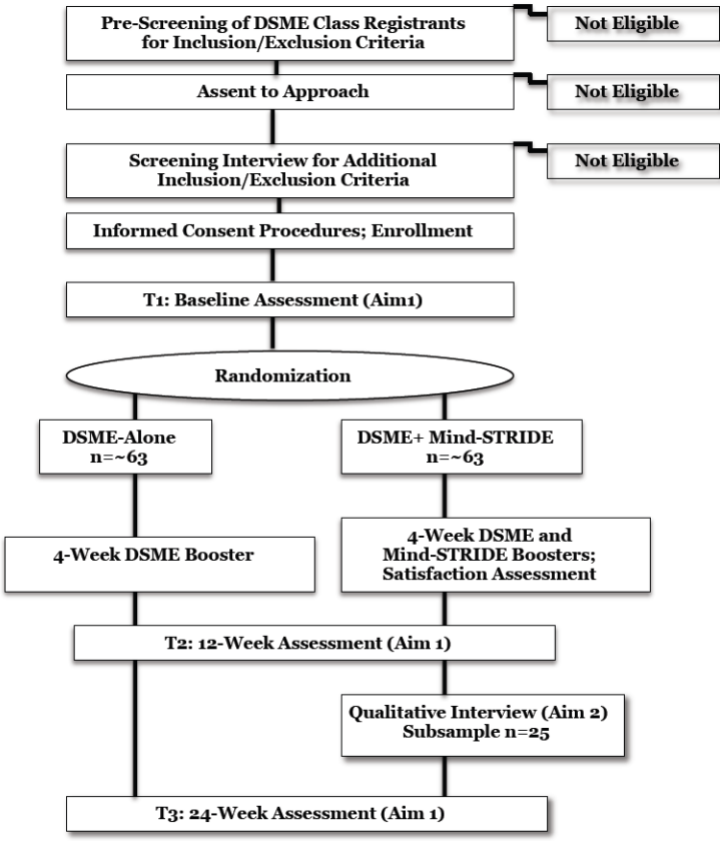
a) Active meditation practice **
b) Documented cognitive impairment including active psychosis, dementia or other organic mental disorders, that may interfere with the ability to comprehend the informed consent and/or actively participate in the study*
c) Previous attendance of VA DSME class within the past 12 months *
d) Planned relocation from the Pittsburgh area within the next 6 months**

**Determined by pre-screening of VA computerized Patient Record System (CPRS)*
***Determined by telephone screening interview*

### 3.4 Procedures

An overview of the study design and procedures appears in Figure 3. All participants enrolled in DSME will be pre-screened by the Research Assistant, pursuant to IRB approved HIPPA Waiver, for inclusion and exclusion criteria. Prior to the DSME class, the staff diabetes educator will contact eligible candidates to obtain assent. The Research Assistant or Research Coordinator will then contact assenting participants for telephone screening for additional inclusion/exclusion criteria pursuant to an IRB approved Waiver of Documentation of

Informed Consent for Screening. After informed consent procedures are completed, enrolled participants will complete Baseline (T1) pencil-and paper research assessments administered in-person by the Research Assistant. After completion of T1 assessments, participants will be randomly assigned to either the experimental condition (DSME+ Mind-STRIDE) or the usual care condition (DSME -Alone) (See Randomization Procedure). Subsequent post-intervention research assessments will be completed at week 12 (T2) and week 24 (T3), and will consist of biological measures (height, weight, blood pressure, and laboratory assessment of HbA1c) performed by clinical staff, and completion of paper and pencil assessments administered in person by the Research Assistant or Research Coordinator. In the DSME + Mind-STRIDE group, participants will also complete the participant satisfaction assessment administered by the Interventionist following the 4-week booster. A purposively sampled subset of 25-participants will complete a qualitative telephone interview at 15-weeks (between T2 and T3).




Participants in both groups will attend the 4-week DSME follow-up booster visit with the staff dietitian who is not part of the study team. The study interventionist will deliver the Mind-STRIDE booster to participants in the experimental group immediately following that dietitian visit. The Interventionist will administer the satisfaction questionnaire to Mind-STRIDE participants after completion of the booster session, and will ensure confidentiality by asking participants to seal completed surveys in provided envelopes. In addition, all participants will receive a monthly post-card from the study team to help promote engagement and retention in the study. All participants will receive reimbursement for participation in the study following each assessment ($50 at T1, $75 at T2, and $100 at T3) and will also receive a digital tablet as remuneration for their participation. DSME + Mind-STRIDE participants will receive the tablet following the initial Mind-STRIDE intervention; DSME–Alone participants receive the tablet following completion of T3.

**Figure 3. Study Design and Procedures**

### 3.4.1 Randomization Procedure

After screening and written informed consent procedures have been completed, all eligible research participants entering the study will complete baseline procedures. After baseline assessments are completed, participants will be randomized into one of two groups: 1) DSME + Mind-STRIDE (the experimental group), or 2) DSME-Alone (usual care). The study statistician will perform the randomization process using statistical software with a random-number generator to create a list of group assignments before study recruitment begins. Randomization will occur in blocks of 4 or 6, and the group assignments will be created based on the specific number of expected eligible participants.

## 3.5 Description of Usual Care and Experimental Conditions

Participants in both conditions will continue their usual diabetes care as per their diabetes care providers. They will self-monitor their blood glucose according to instructions provided by their diabetes care providers, and will transmit data from their home blood glucose meters using standard VA issued Home Tele-Health equipment that is available and offered to all patients.

### 3.5.1 Usual Care Condition (DSME-Alone)

Patients randomized to the Usual Care Condition (DSME-Alone) will receive the standard 3-hour DSME class that includes a didactic presentation, discussion, and interactive activities using a booklet and power point slides covering the following topics:

*a)* An overview of diabetes pathophysiology, HbA1c, major elements of DSM; distinguishing between T1DM and T2DM
*b)* Eating Healthy - identifying nutrients, reading food labels, choosing healthy portion sizes
    - Activity: "My Healthy Eating Plan"- creating a personal eating plan
*c)* Being Active- Being safe while make physical activity a regular part of your day, sample walking schedules
    - "My Activity Lifestyle Plan: getting started"-setting goals for daily activity
*d)* Monitoring- Glucose testing tips; managing hypoglycemia and hyperglycemia
*e)* Medications-Tips for taking medication safely; diabetes oral medications, classes and actions; insulin use, action and storage, injection site selection, use of a syringe or pen
    - Activity: "Keep Track of Your Insulin Doses"- writing down insulin doses
*f)* Sick Day Management- maintaining insulin regimen; knowing what to eat when you're sick, guidelines for short–term illness, when to call your Health Care Team, when and how to get care immediately
*g)* Living well with Diabetes- care of your heart, kidneys, eyes, and feet; care of your emotional health and travel tips
    1. Activity: "Tracking Diabetes Health" – documenting recent lab results, goals, targets, recent exams, and vaccines.

Participants in the Usual Care (DSME-Alone) condition also receive a 30- minute booster with the staff dietitian in which basic self-management skills and goals from DSME class are reinforced.

### 3.5.2 Experimental Condition (DSME +Mind-STRIDE)

Participants randomized to the Experimental Condition (DSME +Mind-STRIDE) will receive the same 3-hour DSME group class (described above) plus the 1-hour Mind-STRIDE intervention delivered by the Study Interventions that includes the following topics and activities:

*a)* Group discussion: exploring the stress of living with diabetes (5 minutes)
*b)* Meditation practice: Being in your body, "Body Scan Technique" (10 minutes)
*c)* Group activity ("the raisin-eating exercise"): promoting awareness and differentiation between thoughts, judgements, and sensory perceptions (5 minutes)
*d)* Didactic presentation and group discussion of stress theory; stress and diabetes; responding vs. reacting to stressful situations (15 minutes)
*e)* Mindful movement (chair yoga) (5 minutes)
*f)* Didactic presentation of mindfulness and mindful approaches to diabetes self-management, (10 minutes)
*g)* Group discussion: mindfulness in everyday life, mindful eating (5 minutes)
*h)* Group activity: setting intentions/commitment for daily home mindfulness practice. Tablets are distributed. (5 minutes)

The DSME + Mind-STRIDE group will also receive one 30 minute Mind-STRIDE booster session with the Study Interventionist in addition to the DSME booster with the staff dietician. The Mind-STRIDE booster consists of:

a) 20 minutes of discussion/reinforcement of mindfulness concepts
b) 10 minutes of guided mindfulness meditation practice

The DSME+ Mind-STRIDE group will be encouraged to engage in at least 15 minutes of home mindfulness practice 6 days per week consisting of:

a) 15-minutes of mindful meditation practice
b) One daily mindfulness activity (e.g. mindfully eating one meal)
c) Real-time tracking of home meditation practice using *Mindfulness Coach,* a VA-developed and supported application (Figure 4).


**Figure 4. VA Mindfulness Coach Application**

d) Optional journaling to reflect the home practice experience answering the question "What did you notice?"

Participants have the option of using 3-pre-loaded audio recordings on the tablets that were created by the PI and Dr. Greco to guide their home practice and reinforce the guiding mindfulness principles taught during the intervention. Participants will also access the pre-loaded *Mindfulness Coach* application for additional home practice support and to document home meditation practice. Recorded materials will be downloaded at each research visit. None of the data stored on the tablets will contain identifiable information, and personal use of the tablets' internet features will be blocked during the course of study

### 3.6 Variables and Measures

#### 3.6.1 Quantitative Measures

**Diabetes-Related Distress (DRD),** the primary outcome, will be measured with the Problem Areas in Diabetes scale (PAID). The PAID questionnaire will also be used for Screening to determine inclusion criteria of moderate to high baseline DRD (PAID score>10). It comprises 20 items that describe 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, scores range from 0-100, with higher scores denoting greater distress. Scores over 40 denote burn-out, while scores of 10 or less may reflect denial. 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.[19]

**Mindfulness-** Two validated measures, a multi-faceted measure, the Five Facet Mindfulness Questionnaire (FFMQ), and a one-dimensional measure, the Revised Cognitive and Affective Mindfulness Scale (CAMS-R), will measure mindfulness. The FFMQ and CAMS-R measures self-reported mindfulness differently and are being used to address the complexity of assessing the construct. Mindfulness will be measured as a secondary outcome for Aim1.

The 5-Facet Mindfulness Questionnaire (FFMQ) is 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. Higher scores reflect greater levels of each factor. Each factor consists of 7 or 8 items. The five facets demonstrated adequate to good internal consistency (alpha ranging from 0.75 to 0.91) when tested in experienced meditators and non-meditators. [70]

The Revised 12-item Cognitive and Affective Mindfulness Scale (CAMS-R) is a one-dimensional, 12-item inventory on a 4 point Likert scale ("Rarely/Not at all" to "Almost always") that measures mindfulness during general daily occurrences on four components of mindfulness (i.e., attention, awareness, present-focus, and acceptance/non-judgment) and yields one total score. Higher scores denote greater mindfulness. The internal consistency of the CAMS-R in this sample is adequate (alpha= .76), and there is evidence of convergent and discriminant validity with concurrent measures of mindfulness, distress, well-being, emotion-regulation, and problem-solving approaches.[71]

**Self-Efficacy** will be measured with the Diabetes Self-Efficacy Scale (DSES). This self-administered questionnaire consists of 8-items on a 10 point Likert scale (*1= Not confident at all; 10 = Totally confident*) that measures self-efficacy in diabetes self-management activities, with higher score denoting greater diabetes self-efficacy. Content validity of the DSES was supported in a study of 186 subjects who completed a six-week community diabetes education and lifestyle program. The internal consistency reliability of this instrument is high (alpha=.83).[72]

**Diabetes Self-Management** will be measured with the Self-Care Inventory Revised (SCI-R), a psychometrically sound 15-item self-administered survey that measures perceived adherence to recommended diabetes self-care behaviors of adults with T1DM and T2DM. Higher scores reflect greater diabetes self-management behaviors. It was tested in 3 separate studies in 554 adults with diabetes and found to have high internal consistency (r=.63). Its construct validity is supported by correlations with diabetes distress (r=-.36); self-esteem (r=.25) self-efficacy (r=.47), depression (r=-.22) anxiety (r=-.24) and HbA1c (r=-.37). Responsiveness analysis showed SCI-R scores improved with diabetes psycho-education with a medium effect size of 0.62 and a Guyatt responsiveness statistic of 0.85.[73]

**Glycemic control,** i.e., HbA1c, the secondary (distal) metabolic outcome, will be assessed at each time point: T1, T2, and T3. All tests will be performed at VAPHS laboratories according to National Glyco-hemoglobin Standardization Program approved methods using high performance liquid chromatography (Tosoh Bioscience South San Francisco, CA).

**Potential Covariates**

**Frequency and duration of mindfulness practice** will be measured by participant entries using the VA Mindfulness Coach Application. This application is a user -friendly method for timing and tracking meditation practice (in minutes) that also includes guided meditations and formats for personalized meditation sounds and music.

**Depression** will be measured with the Patient Health Questionnaire (PHQ-9), a widely used brief 9-item instrument adapted from the longer PHQ for measuring the severity of symptoms of depression over the past two weeks. The assessment can be administered repeatedly, and can reflect improvement or worsening of symptoms. Response options are on a 4-point Likert scale (0="Not at all"; 3="Nearly every day"). Item 9 assesses for the presence and duration of suicidal ideation. A tenth non-scored question assigns weight to the degree to which depressive problems have affected the patient's level of function. The validity of PHQ-9 was tested in 15 studies in primary care and obstetrical clinics. PHQ scores ≥ 10 had a sensitivity of 88% and a specificity of 88% for major depression. PHQ-9 scores of 5, 10, 15 and 20 represent mild, moderate and moderately severe and severe depression respectively. We will follow VAPHS policy for suicide assessment/ crisis treatment for those with positive responses to item 9.[74]

**Post-Traumatic Stress** will be measured with the psychometrically valid PTSD checklist for DSM-5 (PCL-5) a 20-item self-report measure that assesses the 20 DSM-5 symptoms of PTSD over the past month on a scale of 0 ("Not at all") to 4 ("Extremely"). Higher scores reflect greater PTSD. Evidence for the PCL for DSM-4 suggests that a 5-10 point change represents reliable change (i.e., change not due to chance) and a 10-20 point change represents clinically significant change. Change scores for PCL-5 are currently being determined. It is expected that reliable and clinically meaningful change will be in a similar range, but is subject to further validation.

**Social Support** will be measured with The 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: one single answer multiple-choice question and three other questions, each with 6 sub-questions, on a 5-point Likert scale ("Strongly disagree" to "Strongly agree"). Higher subscale scores reflect greater social support or social support needs. Cronbach's alpha for the Support Attitudes Subscale was .69 and .73 demonstrating reliability. The Social Attitudes Subscale is 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.[75]

**Comorbidity** will be measured with the Charlson Self-Report Comorbidity Index, a reproducible and valid 16-item self-report questionnaire that includes items corresponding to each element of the medical record-based Charlson index, a commonly used comorbidity risk assessment. Higher scores reflect greater comorbidity. The questionnaire was tested in 170 hospital inpatients and compared to Charlson scores abstracted from these patients' medical records. Responses are dichotomous yes or no answers to the questions, "Has a doctor or other health care provider ever told you that you have…" Test-retest reliability assessed with the intra-class correlation coefficient was 0.91 for the questionnaire and 0.92 for the chart-based Charlson index. Spearman

correlation between these two measures was 0.63. The correlation between comorbidity measures was weaker in less educated patients, but overall offers practical advantages over intensive medical-record based assessments particularly for use as a screening tool. Scores above 75 are considered to represent high comorbidity.[76]

**Demographic characteristics** will be measured with an investigator-created questionnaire developed specifically for this study and includes age, race, ethnicity, duration of diabetes, diabetes medications, changes to diabetes medications within the past 60 days, marital status, occupation, employment status, and highest level of education completed.

**Patient satisfaction** with DSME+ Mind-STRIDE class will be measured with the Patient Satisfaction Questionnaire (PSQ), an 8-item, self-report questionnaire used to measure general satisfaction with overall healthcare services and mental health care in particular. [77] It has high internal consistency with alphas ranging from .90 to .94. The items have been modified slightly to apply to our intervention. Instrument reproduced with permission of C. Clifford Attkisson, developer.

### 3.6.2Data Collection

A summary of the timeline for data collection procedures appears in Table 5.

**Table 5. Variables and Measures Timeline**

| Variables | Measures* | Screen | T1 (Pre) | Week 4 Booster | T2 (Week 12) | 15-week Interview | T3 (Week 24) |
|---|---|---|---|---|---|---|---|
| Anthropomorphic measures | BMI (kg/M$^2$) | | X | | X | | X |
| Blood Pressure | BP mm/Hg | | X | | X | | X |
| Co-Morbidity | Charlson Self-Report index | | X | | | | |
| Demographics | Investigator Questionnaire | | X | | | | |
| Depression | PHQ-9 | | X | | X | | X |
| Diabetes Self-Efficacy | DSES | | X | | X | | X |
| Diabetes Self-Management | SCI-R | | X | | X | | X |
| DRD | PAID | X | | | X | | X |
| Glycemic Control | HbA1c | X | | | X | | X |
| Mindfulness | FFMQ, CAMS-R | | X | | X | | X |
| PTSD | PLC-5 | | X | | X | | X |
| Satisfaction (DSME+ Mind-STRIDE only) | PSQ | | | X | | | |
| Social Support | DCP Support Attitudes Scale | | X | | X | | X |
| Veteran Satisfaction and Experience with Mind-STRIDE (Experimental group sub-sample) | Qualitative Telephone Interview | | | | | X | |

### 3.6.3 Participant Burden

The total estimated time it will take to participate in the study beyond that of usual care over the 24 week study duration for the DSME-Alone group is approximately 5-hours, and 30-hours for the DSME+ Mind-STRIDE group, with the bulk of time occurring during the first 6 weeks for screening, assessments, and class and booster attendance. This time estimate for the usual care DSME-Alone group includes: screening and informed consent processes (2 hours) and three 1-hour assessments (3 hours). The time estimate for the experimental group also includes the (1 hour) Mind-STRIDE intervention, the 4-week Mind-STRIDE booster session (30-minutes), home mindfulness practice (~24 hours). Journaling with each home practice session is encouraged, but is optional and will depend on each individual. Journaling can take as little as 1 minute or up to several minutes (~3 hours). Qualitative telephone interviews will also be conducted in a subset of 25 purposively sampled experimental group participants (40 –minutes).

### 3.7 Data Analysis

### 3.7.1 General Analytic Approach for Aim 1:

Aim 1: To compare the effects of the intervention (DSME+ Mind-STRIDE) with those of usual care (DSME-alone) on diabetes distress, diabetes self-efficacy, and DSM in military Veterans over time.

Hypotheses. From baseline to 24-week post-intervention, DSME+ Mind-STRIDE compared to DSME-Alone will:

1. Significantly reduce DRD (primary outcome)
2. Significantly increase mindfulness, diabetes self-efficacy and diabetes self-management (secondary behavioral outcomes)
3. Significantly decrease HbA1c (distal metabolic outcome)

**Independent variable:** The Mind-STRIDE intervention, which includes mindfulness stress reduction, mindfulness meditation training and home practice.

**Dependent variables:** The primary outcome on which the analysis is powered is DRD measured by the PAID scale. Secondary outcomes include diabetes self-efficacy, diabetes self-management, mindfulness, and glycemic control, measured by HbA1c.

**Analysis:** To assess whether there are group differences over time, we will use separate linear (or non-linear depending on outcome) mixed models for each outcome (diabetes distress, primary), diabetes self-efficacy, diabetes self-management, mindfulness and glycemic control (secondary) for 3 time points (baseline, 12 weeks post-intervention, and 24 weeks post-intervention). The base model will include fixed effects for treatment group DSME+ Mind-STRIDE, DSME-Alone group, time, and the interaction between treatment group and time. To the extent possible, post-hoc analyses to explore the possible relationships between mindfulness and diabetes-related distress (as well as the interaction between them) on the distal secondary outcome, glycemic control will be performed.

**Power analysis:** Power calculations for Aim 1, hypothesis 1 of this study were based on a repeated measures design (2 sided $\alpha = .05$) with 2 treatment groups (DSME+ Mind-STRIDE; DSME-Alone) and 3 time points (baseline, 12 weeks post intervention, 24 weeks post-intervention). We computed sample size estimates that were powered to detect an overall treatment group difference in DRD (PAID scale score) as well as a treatment group difference over time (interaction between treatment group and time). Based on our pilot work, a medium effect size (d= .6) gives a clinically meaningful change in PAID score. Using a medium (d=.5) effect size, and estimates of the correlations between observations on the same subject of r=.5, powering at 80% gives a sample size estimate of 86 (~43 per group). To account for possible clustering due to the randomization occurring in groups of n=5 participants, the required total sample size (86) was inflated by a factor of $(1+ (5-1) * p)$, where $p$ is the intra-cluster correlation coefficient.[78, 79] A conservative estimate of the intra-cluster correlation of $p=0.05$, gives an increased sample size of 104 (~52 per group). To ensure a sample of 104 at study completion, 126 Veterans will need to be recruited over the 2-year study period. This number of 126 Veterans is approximately 20% of the usual number of Veterans referred for DSME over two years and is within what is considered reasonable to recruit based on our pilot data. Sample size estimates were computed in Stata Statistical Software: Release 12 (College Station, TX: StataCorp LP; 2011).

Ada Youk PhD, Associate Professor of Biostatistics at the University of Pittsburgh Graduate School of Public Health, will oversee statistical analysis for Aim 1. Analyses for Aim 1 will be performed using Stata statistical software. Diabetes distress (the primary outcome) and secondary outcomes (mindfulness diabetes self-efficacy, diabetes self-management, and HbA1c) will be assessed for normality and appropriate data transformations will be used if necessary. Descriptive statistics will be computed to determine central tendency, data sparseness, and existence of outliers for all other continuous variables. Frequency distributions will be generated for categorical variables to identify data sparseness, and categories with small frequencies will be merged when appropriate. In addition, we will consider categorization of continuous predictors if the distributions are skewed or violate assumptions of linearity. Differences in covariates by treatment group will be tested using chi-square (or Fisher's exact) statistics for categorical variables and t-test (or Mann-Whitney) for continuous variables. Graphical procedures will be used to assess simple change in the outcomes over time. For the main analyses for Aim 1, we will test study hypotheses by using linear mixed models (or non-linear

mixed models where appropriate), which account for repeated measures and assess change over time (baseline, 12 weeks, 24 weeks). The linear mixed model allows for missing data if data are missing at random. Demographic variables with a univariate association with the outcome ($p<0.10$) or differed by treatment group at baseline ($p<0.05$) will be considered for inclusion in a multivariate model. Covariates will be retained in the final multivariable models if significant at $p<0.05$. All tests will be two-sided. All analyses will be conducted as intent-to-treat analyses and include all patients in the groups to which they were randomized, regardless of adherence and/or subsequent withdrawal.

*Missing Data.* We will review all assessments for completeness during the session in which it is collected to attempt to minimize missing data for Aim 1. We will attempt to assess the missing data mechanism for missing data due to lost to follow-up or withdrawal. If there are significant differences in baseline variables between those subjects that have complete outcome data and those that do not, we will adjust for those covariates as part of the modeling. [80] If no systematic differences are found or if the missing data is intermittent, the missingness will be handled as part of the regression modeling. Using linear mixed linear models allows the use of all available data, including data from those who are missing one or more of the assessments. We will also perform completers only analyses and see if these differ compared to the modeling using all of the available data to assess sensitivity to the missingness.

### 3.7.2 General Analytic Approach for Aim 2

Aim 2: To identify Veteran satisfaction and experiences with DSME +Mind-STRIDE.

We will use Convergent Parallel Design (Figure 5) to develop a more complete understanding of the research questions by obtaining different but complementary quantitative (Aim 1) and qualitative (Aim 2) data.[81] Collecting and analyzing two independent strands of data at the same time in a single phase will enable us to prioritize the methods equally while keeping the data analysis independent. We will then mix the results at the point of interface, looking for convergence, divergence, contradictions or relationships of the two sources of data that will inform the overall interpretation of study results.

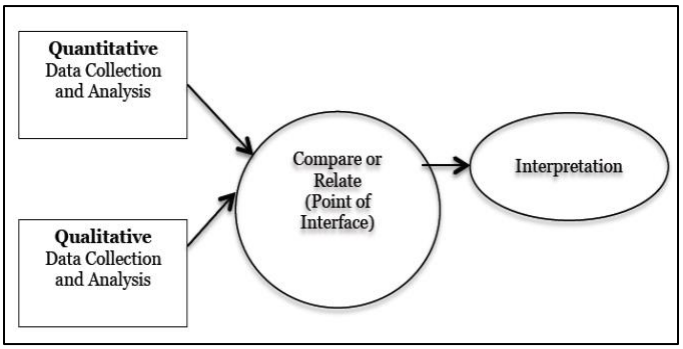



**Figure 5. Convergent Parallel Design**

Specifically, audio recordings will be made using digital recording devices that are Federal Information Processing Standard (FIPS) 140-2 compliant. All interviews will be audio-recorded using a VAPHS-approved encrypted digital recorder. Audio recordings will be protected per VAPHS policy. Trained interviewers will conduct semi-structured interviews developed specifically to address Qualitative-Aim 2. A standardized telephone interview guide (Appendix 4) will ensure sufficient uniformity across the interviews in topics covered and in sequencing to allow comparisons. As further interview preparation, we will pilot test the interview guides with 2-4 patients. The pilot will assist in determining whether refinement or modification of questions is needed, allowing us to make necessary revisions.[82] If the interview guides are not significantly modified as a result of the pilot, the information gathered from the people who participated in the pilot will be added to the information obtained from participants in the full study.

The semi-structured interview guide will contain open-ended questions (including clarifying questions) that also will provide the flexibility to explore topics and elicit patient experiences in greater depth—with probing questions according to varied patient experiences. Participant interviews will be aimed at exploring Veteran satisfaction and experiences with the Mind-STRIDE class provided within DSME. The interview will also explore their experience with mindfulness training and home mindfulness practice in general and relative to diabetes management. When possible, DSME+ Mind-STRIDE participants will be asked additional questions guided by observations recorded in their journals to enable more contextual exploration of their mindfulness experience. The interviews will (1) provide detailed "thick" descriptions about Veteran experiences with Mind-STRIDE and mindfulness practice that do not rely on predefined quantitative study instrument categories,[83] and (2) provide patients the opportunity to elaborate about moment to moment experiences associated with mindfulness practice . The interviews will take approximately 20-30 minutes and will be audio-recorded and transcribed verbatim by a trained transcriptionist at the Center for Health Equity Research and Promotion

(CHERP). Results of interviews will be summarized into topics discussed, as well as the range of thematic issues, concerns, or foci of the patient. We will also record the frequencies of topics and themes that emerge. Recordings will be stored according to VA information security specifications**.**

A sub-sample of 25 DSME+ Mind-STRIDE participants will be selected for the interviews by purposive sampling with maximum variation in order to represent a wide range of age groups, race/ethnicity, and severity/type of diabetes.[84]. Verbatim transcripts from interviews with 25 DSME+ Mind-STRIDE participants are sufficient for thematic saturation—which requires a minimum of 12-20 participants of each "type." [85] The transcribed data will be de-identified and imported into ATLAS.ti (Scientific Software, Berlin, Germany) for data management and analysis.[86] Two coders are standard and necessary in qualitative research to ensure reliability of the coding scheme.[87] Dr. Rodriguez will train the coders (existing study staff) to develop qualitative codebooks for the patient interviews.

Keri Rodriguez PhD, Research Health Scientist and CHERP Core Investigator at VAPHS, will oversee qualitative data analysis for Aim 2. Using a modified grounded theory approach for data analysis, trained coders will use the constant comparative method to compare newly gathered data with previously collected data to develop categories of responses.[84] Initially, the two coders will employ an iterative process of close readings and discussion of a sample of interview transcripts to identify emergent concepts, categories, themes and relationships in the data and develop an initial set of codes to be applied to subsequent transcripts. The broad areas of foci will include Veteran satisfaction and experiences of mindfulness training and practice. As the coders examine more transcripts, they will refine their coding sub-categories and develop a coding scheme. In the case of disagreements, they will further develop rules to distinguish codes. If necessary, the coders will consult with the research team to refine the criteria. Both coders will then each code 100% of the transcripts independently.[87] We will use a system of audit trails to document the creation of all codes and Kappa statistics will be computed to assess inter-coder agreement. The coders will meet and process any differences in coding for each interview until agreement is achieved. If the two coders discussed a discrepancy and are unable to come to a consensus, a resolution will be reached with Dr. Rodriguez's and the PI's adjudication. The codes determined through this consensus process will be recorded in a master file, which will become the basis for the final analysis. This process of coding will maintain narrative coherence with inter-coder reliability kappa scores > 0.75.[88]

### 3.8 Timeline

Dr. DiNardo, the Principal Investigator (PI), will be oversee the details of the study including hiring and training staff, testing the data entry system, creating study manuals, and recruiting and consenting subjects. She will lead weekly meetings with the Research Team and bi-monthly meetings with Co-Investigators so that issues can be addressed in a timely manner. The Mentoring team is highly experienced in conducting clinical trials, and will guide the investigator in reaching charted milestones on the timeline. See Gantt chart (Table 6).

**Table 6. Study Timeline**

| **Study Activity** | **Year 1** | | | | **Year 2** | | | | **Year 3** | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Q1 | Q2 | Q3 | Q4 | Q1 | Q2 | Q3 | Q4 | Q1 | Q2 | Q3 | Q4 |
| Conduct monthly team meetings | X | X | X | X | X | X | X | X | X | X | X | X |
| Hire staff | X | X | | | | | | | | | | |
| Create procedure manual | X | X | | | | | | | | | | |
| Create data entry system | X | X | | | | | | | | | | |
| Recruit participants | | X | X | X | X | X | X | X | X | | | |
| Deliver intervention | | X | X | X | X | X | X | X | X | X | | |
| Collect data | | | X | X | X | X | X | X | X | X | X | |
| Analyze data | | | X | X | X | X | X | X | X | X | X | |
| Prepare and submit publications a presentations | | | | | | | | | X | X | X | X |

### 3.9 Study Design Considerations

Several aspects of the study design warrant consideration. First, the 3-year duration of the study prevents extended follow-up of more than 6 months. However, based on previous research of DSME and mindfulness interventions, we expect to be able to detect changes in the outcomes specified, and the 6-month time period is consistent with typical clinical follow-up periods. Second, there is potential for adjustment of diabetes medications during the study by care providers. To account for this, medication will be tracked and verified in CPRS, and controlled for in the analysis. Finally, generalizability is limited due to the relatively small sample size and single VAMC site. However, our site is a large academic medical center serving a range of diabetes severity in a Veteran population drawn from urban, suburban, and rural areas in the region. Additionally, the proposed study includes a qualitative component, for which the purpose is not generalizability, but rather gaining an understanding of a phenomenon of interest in a specific group of participants.[87]

Particular advantages of our study design and approach include the fact that the intervention has been pilot-tested at VAPHS and fit into the already existing DSME format and therefore can realistically be implemented without delay. Additionally, to the extent possible, one trained diabetes educator will deliver the DSME component and one trained mindfulness instructor will deliver the Mind-STRIDE intervention to all groups in order to decrease instructor bias. In order to sustain engagement in the study, all participants will receive monthly postcards from the research study. Control group participants will receive postcards with healthy tips for living with diabetes, and experimental group participants' postcards will include these tips plus mindfulness tips and quotations. And finally, our mixed-methods methodology will provide a more comprehensive evaluation of the program and inform potential implementation at other VAMCs in the future.

To assure that the mindfulness training is delivered in a standardized way, a course manual will be developed and instructor guidelines will be followed. Pursuant to IRB approved authorization, all Mind-STRIDE sessions will be audiotaped using a VA-approved encrypted audio-recorder. Dr. Greco, our mindfulness expert, will develop a fidelity-rating guide for the intervention. Dr. Greco will train the Study Coordinator to use this guide to assess the fidelity of each audio-recorded session, so that the interventionist can be made aware of any discrepancies from the course manual, and they can be corrected in a timely fashion.

## 4.0 Dissemination/Implementation

Study findings will be disseminated to the following intended groups as soon as the final study report has been completed: Veterans, VA healthcare providers and researchers, and non-VA diabetes researchers and diabetes stakeholders outside of the VA. Strategies for disseminating findings to each group are described below with an estimated timeline of planned dissemination in year three of the study.

### 4.1 Veterans

Study findings will be disseminated to Veterans using the following methods:

a) Articles in VA newsletters, magazines, and other Veteran-related publications
b) Presentations at health fairs and community outreach event

### 4.2 VA Healthcare Providers and Researchers

Study findings will be disseminated to VA providers locally, regionally, and nationally through the following mechanisms:

a) Publications in peer-reviewed scientific journals (e.g., *Diabetes Care, The Diabetes Educator, Applied Nursing Research, Journal of Alternative and Complementary Therapies*).
b) In-person presentations at conferences and workshops (e.g., *The American Diabetes Association Scientific Meetings; The American Academy of Nurse Practitioner Annual Meeting; American Association of Diabetes Educators Annual Meeting), The Society of Behavioral Medicine Annual Meeting*
c) Webinars, teleconferences, and nursing grand rounds

d) Creation and dissemination of an educational videotape (included in the budget)

## 5.0 Project Management Plan

### 5.1 Qualifications of Investigators

This project combines an outstanding, productive, and uniquely qualified team of investigators including nurse researchers and national experts that have the diversity of experience and expertise necessary for the successful completion of the proposed program of research (see Biosketches). The Primary Investigator has assembled an outstanding research team of mentors and co-investigators with whom she has worked with closely in clinical and clinical research settings related to diabetes management, education, and healthy behavior change. A comprehensive table of mentoring plan activities is included in **Appendix 5.**

**Monica DiNardo PhD, ANP, CDE, the PI**, is a new investigator and an experienced certified adult nurse practitioner and diabetes educator who has maintained a clinical practice at VA Pittsburgh Healthcare System since 2008 and completed her PhD at the University of Pittsburgh School of Nursing in 2013. Dr. DiNardo attended the Mindfulness Based Stress Management Trainer course taught by Dr. Jon Kabat-Zinn at the Omega Institute in Rhinebeck, New York. She has conducted two feasibility pilot studies of mindfulness interventions for individuals with diabetes, one of which was conducted at the VA Pittsburgh Healthcare System. She will oversee all aspects of the proposed study in collaboration with the co-investigators and the guidance of her strong mentoring team.

### 5.2 Mentors

**Lauren Broyles PhD, RN (Nurse Co-Mentor, Co-Investigator)** is a VA Research Health Scientist, HSR&D Career Development Awardee, and Core Investigator in the Veterans Affairs Pittsburgh Healthcare System's Center for Health Equity Research and Promotion (CHERP) and investigator in the VISN 4 MIRECC. She is Principal Investigator of an NRI-funded RCT examining the efficacy of a nurse-delivered behavioral intervention for alcohol use. Dr. Broyles is an Assistant Professor of Medicine, Clinical and Translational Science, and Nursing at the University of Pittsburgh (Pitt). Dr. Broyles mentoring experience includes serving as Co-Director for the Pittsburgh site of the VA Office of Academic Affiliations Advanced Inter-professional Fellowship in Addictions Treatment and as Director of the "Ramp to K" career development program for junior investigators at Pitt. Dr. Broyles will serve as Primary Nursing Co-mentor for Dr. DiNardo. She will meet with Dr. DiNardo weekly and provide direct guidance and oversight of all facets of the Mentoring Plan (Appendix 5). She offers expertise in grant writing, manuscript, preparation, and navigating the research environment and resources at VAPHS, CHERP, and in the VA Nursing Research arena.

**Jill Bormann PhD, RN, FAAN (Senior Nurse Co-Mentor, Co-Investigator)** is a highly respected nurse scientist with the VHA System and recipient of the 2014 Secretary's Award for Excellence in Nursing. Dr. Bormann is Associate Nurse Executive and Research and Clinical Nurse Specialist in Adult Psychiatric-Mental Health Nursing at the VA San Diego Healthcare System and Clinical Professor at San Diego State University School of Nursing. Dr. Bormann's research interests include Veterans with PTSD. Dr. Bormann pioneered a program of research on health-related outcomes of the Mantram Repetition Program (MRP), a spiritually integrated meditation intervention for the management of symptoms related to trauma-related stress. Dr. Bormann will serve as Senior Nurse Co-Mentor. Dr. Bormann brings expertise and experience in successful clinical implementation trials of meditation and mind-body research at VA. She will serve as implementation expert for the study. She will also assist with selection of grant and career opportunities in Complementary and Alternative Medicine, and will help to guide Dr. DiNardo's research trajectory. She will attend weekly telephone meetings with the PI and Mentoring team. She will be engaged in execution and evaluation of the Mentoring Plan. (Appendix 5)

**Natalia Morone MD, MS (Mentor, Co-Investigator)** is an Associate Professor of Medicine and Clinical and Translational Science at the University of Pittsburgh School of Medicine as well as Staff Physician at the Geriatric Research Education and Clinical Center of the VAPHS. Her research focus is in mindfulness interventions for chronic pain in older adults. Dr. Morone has been Principal Investigator for an NIH/NIA RO1 clinical trial of mindfulness for older adults with chronic pain, and has published extensively on mindfulness

for pain as well as stress reduction. She has also completed two qualitative studies of the effects of mindfulness meditation on pain and stress. Dr. Morone is a general internist and has an active clinical practice. She also co-directs the Career Education and Enhancement for Health Care Research Diversity program at the University of Pittsburgh, which is committed to providing a solid foundation on which to build a successful research career for under-represented minorities. Dr. Morone has expertise in conducting clinical research in mindfulness and will provide guidance and oversight of the proposed study. She will assist with manuscript preparation, preparation of presentations, and preparation for future grant writing. Dr. Morone will meet with the PI and mentoring team weekly, and will be actively engaged in the Mentoring Plan. (Appendix 5)

**5.3 Co-Investigators/ Members of Core Research Team**

**Ada Youk PhD (Co-Investigator)** is an Associate Professor at the University of Pittsburgh Graduate School of Public Health and an Affiliate Investigator/Senior Biostatistician in the Veterans Affairs Pittsburgh Healthcare System's Center for Health Equity Research and Promotion (CHERP) in the Biostatistics and Informatics Core (BIC). Dr. Youk has almost 20 years of experience with grant-writing, study design, data analysis, and paper and presentation development. Her main areas of research are statistical methodology for missing data, longitudinal data analysis, health disparities, health services research, clinical research, and regression modelling. She has extensive experience with analyzing data from large, longitudinal, prospective epidemiology studies and randomized clinical trials which primarily involve time to event modeling and mixed effects modeling. Dr. Youk teach courses in analysis of cohort studies, applied regression analysis, scientific communication skills, mathematical methods for statistics, and mixed models in the Graduate School of Public Health. Dr. Youk will guide, direct, and oversee the randomization of study participants and analyses for each study aim and will contribute to the interpretation of data and the development of manuscripts reporting study findings. Dr. Youk will also personally conduct, validate, and document select complex analyses and participate in weekly meetings with the investigative team, as well as separate weekly meetings to direct and oversee the work of the programmer analyst. Dr. Youk will provide ongoing methodological and analytic guidance throughout the entirety of the RCT study as well contribute to presentations and manuscripts. She will meet with the PI and core research team weekly.

**Keri Rodriguez, PhD (Co-Investigator)** is a full-time Research Health Scientist and CHERP Core Investigator at VAPHS. Dr. Rodriguez has extensive experience in the development and implementation of qualitative methods and in the interpretation of qualitative data. Her work includes a VA HSR&D Merit Review Entry Program award focused on patient-provider communication and decision making in heart failure, and a Minority Supplement from the National Cancer Institute supported her work as co-investigator on the "Communication Regarding Quality of Life Between Oncologists and Patients with Advanced Cancer project; both projects include substantial qualitative data components. She has served as Co-Investigator on nurse-led projects with Dr. Broyles related to health behavioral change in Veterans. Dr. Rodriguez will provide oversight for the qualitative methods employed by this project. Specifically, she will assist with development of the qualitative assessment and data management tools, and provide input on the coding process. She will work with Drs. DiNardo and Morone to train the project staff that will be performing the qualitative coding. She will oversee the development of documented coding audit trails and assist with development of the qualitative codebook. Dr. Rodriguez will participate in the regular weekly project team meetings and meetings of those working on the qualitative methods. She will participate in the data analysis and interpretation of the qualitative data as well as the preparation of manuscripts and presentations related to the qualitative data.

**5.4 Co-Investigators with Focused Advisory Roles**

**Carol Greco PhD (Co-Investigator)** is a licensed clinical psychologist at the UPMC Center for Integrative Medicine and Assistant Professor of Psychiatry at the University of Pittsburgh School of Medicine. Dr. Greco coordinates the Mindfulness-Based Stress Reduction (MBSR) program at UPMC and has been engaged in research of Mind-body interventions for pain control and stress management in patients with chronic illness. Dr. Greco has completed five teacher-training programs in MBSR at the University of Massachusetts Medical School's Center for Mindfulness. She teaches MBSR at the University of Pittsburgh Medical Center Shadyside Center for Integrative Medicine. Since 2004, she has taught a total of 17 eight-session MBSR classes to approximately 300 individuals. She also has expertise in patient-reported outcomes instrument development, particularly in the area of non-specific factors that contribute to healing/positive outcomes. Dr. Greco has served as MBSR expert regarding program development and will assist with training of the mindfulness

interventionist, and will oversee assessment of intervention fidelity. She will be instrumental in interpretation of clinical significance. She will meet with the PI and study team twice monthly, and will be available for ad hoc telephone meetings with the PI and mentoring team as needed particularly during the first year of the study.

**Linda Siminerio PhD, RN, CDE (Co-Investigator)** is Professor of Medicine, Executive Director, University of Pittsburgh Diabetes Institute, Assistant Professor of Nursing, University of Pittsburgh School of Nursing. Dr. Siminerio is the Director of the Adult Clinical Services Division of the University of Pittsburgh Diabetes Institute. She is a nationally prominent advocate for diabetes care, education and funding, and is Chair of the National Diabetes Education Program (NDEP). She is former Vice President of the American Diabetes Association (ADA) and Chair of the International Diabetes Federation (IDF) translation research program, and served as Chair of the IDF World Congress. She was Principal Investigator for a Department of Defense (DOD) regional diabetes initiative grant. Her main academic focus is in translation research and diabetes quality improvement, self-management, community interventions, and overcoming barriers to diabetes care in underserved populations. She has organized the 2nd largest network of ADA recognized Diabetes Self-Management Education programs in the US. She will serve as Diabetes Self-Management Education expert and will help to oversee assessment and interpretation of diabetes self- care outcomes. She will meet with the PI and study team twice monthly, and will be available for ad hoc telephone meetings as needed. She will help with preparation of manuscripts and presentations, and overall dissemination of study findings.

**R.Harsha Rao, MD (Co-Investigator)** is a board certified endocrinologist, Associate Professor at the University of Pittsburgh School of Medicine, and Clinical Director of the VAPHS Division of Endocrinology and Diabetes. Dr Rao is active in clinical practice and leads the multidisciplinary Diabetes Management Clinic at VAPHS. He also serves as Director of the University of Pittsburgh Endocrinology Fellowship. Dr. Rao worked with Dr. DiNardo on her previous feasibility pilot study, and will serve as clinical diabetes expert for this grant. His position as Clinical Director and daily contact with the PI will afford him access to decisions and resources that will help to support the proposed study. He will meet with the PI and study team twice monthly, and will be available for ad hoc telephone meetings with the PI and mentoring team as needed particularly during the first year of the study.

**Carolyn Thorpe PhD, MPH (Co-Investigator)** is Assistant Professor in the University of Pittsburgh School of Pharmacy and a Core Investigator at Veterans Affairs Pittsburgh Healthcare System's Center for Health Equity Research and Promotion (CHERP). She is a health services researcher and behavioral scientist with interests in quality medication prescribing and adherence in older adults with T2DM and multiple comorbidities, and has published on the topic of coping in this population. Dr. Thorpe's projects are aimed at medication adherence in older adults. The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), the Agency for Healthcare Research and Quality (AHRQ), and the Department of Veterans Affairs has supported her work. Methodologically, Dr. Thorpe is experienced in a wide range of both quantitative and qualitative methods. She has extensive expertise in VA utilization data and the development and evaluation of behavioral and health systems interventions. She will serve as consultant on interpretation of medication adherence and coping measures, and will meet with the PI twice monthly, and will be available for ad hoc meetings as necessary.

### 5.5 Summary

In conclusion, the proposed mixed methods RCT aims to evaluate the efficacy of a mindfulness intervention designed to reduce DRD and support diabetes self-care management. The results have the potential to support self-care disease management in millions of Veterans with diabetes through a low-cost, non-pharmacologic intervention that can be easily incorporated into routine DSME. The intervention and study design are supported by solid preliminary and pilot data generated by the PI, who is supported by a highly experienced, interdisciplinary mentoring team of experts in resource-rich VA research and clinical environments. The NRI is the ideal mechanism for supporting the PI, Dr. DiNardo's development as a nurse investigator prepared to conduct independent research focused on high priority, VA mission-oriented areas of investigation.