

# Effects of an integrated mindfulness intervention for veterans with diabetes distress: a randomized controlled trial

Monica M DiNardo <sup>1</sup>, Carol Greco,<sup>2,3</sup> Angela D Phares,<sup>1</sup> Nicole M Beyer,<sup>1</sup> Ada O Youk,<sup>1,4</sup> D Scott Obrosky,<sup>1</sup> Natalia E Morone,<sup>5</sup> Jason E Owen,<sup>6</sup> Shaddy K Saba,<sup>7</sup> Stephen J Suss,<sup>2</sup> Linda Siminerio<sup>8</sup>

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For numbered affiliations see end of article.

## Correspondence to

Dr Monica M DiNardo;  
mdinardo21@gmail.com

## ABSTRACT

**Introduction** US military veterans have disproportionately high rates of diabetes and diabetes-related morbidity in addition to being at risk of comorbid stress-related conditions. This study aimed to examine the effects of a technology-supported mindfulness intervention integrated into usual diabetes care and education on psychological and biobehavioral outcomes.

**Research design and methods** Veterans (N=132) with type 1 or 2 diabetes participated in this two-arm randomized controlled efficacy trial. The intervention arm received a one-session mindfulness intervention integrated into a pre-existing program of diabetes self-management education and support (DSMES) plus one booster session and 24 weeks of home practice supported by a mobile application. The control arm received one 3-hour comprehensive DSMES group session. The primary outcome was change in diabetes distress (DD). The secondary outcomes were diabetes self-care behaviors, diabetes self-efficacy, post-traumatic stress disorder (PTSD), depression, mindfulness, hemoglobin A1C (HbA1C), body weight, and blood pressure. Assessments were conducted at baseline, 12 weeks, and 24 weeks. Participant satisfaction and engagement in home practice were assessed in the intervention group at 12 and 24 weeks.

**Results** Intention-to-treat group by time analyses showed a statistically significant improvement in DD in both arms without significant intervention effect from baseline to 24 weeks. Examination of distal effects on DD between weeks 12 and 24 showed significantly greater improvement in the intervention arm. Improvement in DD was greater when baseline HbA1C was <8.5%. A significant intervention effect was also shown for general dietary behaviors. The secondary outcomes diabetes self-efficacy, PTSD, depression, and HbA1C significantly improved in both arms without significant intervention effects. Mindfulness and body weight were unchanged in either group.

**Conclusions** A technology-supported mindfulness intervention integrated with DSMES showed stronger distal effects on DD compared with DSMES control. Examination of longer-term outcomes, underlying mechanisms, and the feasibility of virtual delivery is warranted.

**Trial registration number** NCT02928952.

## INTRODUCTION

The risk of diabetes among US military veterans is 2.5 times greater than among non-veterans,<sup>1</sup> contributing to higher morbidity

## Significance of this study

### What is already known about this subject?

- Diabetes distress related to the burden of diabetes self-care is an independent predictor of diabetes outcomes.
- Emerging studies of mindfulness-based interventions have shown efficacy in reducing diabetes distress, but research is limited in populations at risk, including US military veterans.

### What are the new findings?

- A targeted mindfulness intervention integrated into conventional diabetes care is feasible, acceptable, and more efficacious for improving general dietary behaviors and for reducing diabetes distress after 12 weeks compared with conventional care.
- Reductions in diabetes distress were greater with baseline hemoglobin A1C <8.5% (69 mol/mol), which may be relevant in selecting appropriate patients for mindfulness-based diabetes interventions.
- Use of mobile technologies may help persons remain engaged in mindfulness practice and contribute to longer-term positive diabetes outcomes.

### How might these results change the focus of research or clinical practice?

- These results might influence standards of diabetes care to include mindfulness training as an adjunct to diabetes self-management education and support for suitable candidates.
- Replication of these results with virtual delivery might help expand access to mindfulness-based educational programs for veterans and other persons at risk of diabetes and diabetes distress.

and mortality.<sup>2</sup> This disproportionate risk is linked to overweight and obesity, socioeconomic disparity, physical disability, and mental health comorbidity, which adversely affect nutrition and health behaviors.<sup>3 4</sup> Type 2 diabetes is also associated with exposure to dioxin ('Agent Orange'), a defoliant used during the Vietnam War. Additionally, high rates of mental health problems such

as post-traumatic stress disorder (PTSD) and depression negatively impact veterans' health.<sup>5,6</sup>

Best practice for treatment of diabetes requires regular medical follow-up and ongoing diabetes self-management education and support (DSMES) to promote lifestyle modifications, pharmacological interventions, and self-monitoring.<sup>7</sup> Of persons with diabetes, 36% experience diabetes distress (DD),<sup>8</sup> an underaddressed condition of conventional diabetes care.<sup>9</sup> DD is a predictor of diabetes self-management and clinical outcomes including higher hemoglobin A1C (HbA1C) related to emotional distress from complex self-care demands and the stress of living with diabetes.<sup>10</sup> The prevalence of DD in veterans is unknown, but is likely to be substantial considering their prevalence of comorbid stress-related conditions.

Research on mindfulness-based interventions (MBI) has demonstrated positive effects in multiple health conditions,<sup>11</sup> including studies by Veterans Health Administration investigators primarily with veterans who have PTSD and mood disorders.<sup>12</sup> There have been few randomized controlled trials (RCT) of mindfulness in diabetes<sup>13,14</sup> and none has been conducted with veterans. This gap is unfortunate as mindfulness seems to be particularly beneficial for individuals like veterans who may be emotionally or cognitively depleted and stressed by daily diabetes self-management tasks.<sup>15</sup> This study thus aimed to test the hypothesis that integrating an MBI into diabetes care more effectively reduces DD compared with conventional diabetes care and education alone. The secondary outcomes included diabetes self-care, diabetes self-efficacy, PTSD, depression, mindfulness, HbA1C, blood pressure, and body weight. The intervention Mind-STRIDE (Mindful STress Reduction In Diabetes Education) was developed and feasibility-tested by the investigators in an observational pilot (n=28) that supported feasibility, acceptability, and fidelity of the intervention warranting efficacy testing.<sup>16,17</sup>

## RESEARCH DESIGN AND METHODS

### Setting, population, and sample

This study was conducted at VA Pittsburgh Healthcare System (VAPHS), which provides diabetes care to approximately 24 000 veterans annually. Veterans were recruited between November 2016 and October 2019 from the DSMES class roster, via brochures and fliers, and by mass mailing with an 'opt-out' option. Eligibility criteria included a diagnosis of diabetes, positive screen for DD, HbA1C >7%, and willingness to be randomized. Veterans with type 1 diabetes (T1D) and type 2 diabetes (T2D) were included since the intervention and the DSMES target DD and behavior change relevant to both phenotypes. Randomization would minimize potential confounding effects by distributing phenotypes between study arms. Candidates were prescreened for baseline DD using the Problem Areas in Diabetes (PAID-5) scale<sup>18</sup> and the Diabetes Distress Scale (DDS-2).<sup>19</sup> We added the DDS-2 as a second screening tool after the first five

veterans were screened because some were unreceptive to the terms 'feeling scared' and 'feeling depressed' in the PAID-5 scale. Exclusion criteria included attendance of the DSMES session within the past year, having a current mindfulness practice, and cognitive impairment assessed by International Statistical Classification of Diseases and Related Health Problems codes (ICD9, ICD10) and patient problem lists maintained in electronic medical records within the Veterans Health Administration (VHA) Computerized Patient Record System that indicated any type of dementia, cognitive impairment, or cognitive decline.

### Procedures

Each participant provided informed consent before taking part in the two-arm efficacy trial. Participants completed baseline procedures immediately prior to the DSMES session. They were then randomized as a group using random block sizes of 4 or 6 (generated by a computerized algorithm) to receive either Mind-STRIDE integrated with DSMES or DSMES control. All participants continued to receive ongoing diabetes management from their VA healthcare practitioners. To promote engagement and retention between scheduled inperson research assessments and to ensure equal attention across both arms, all participants received phone calls from either the research assistant or the interventionist (depending on study arm) at weeks 2, 8, and 18. All participants were reimbursed \$50 after baseline and 12-week assessments and \$75 after study completion.

### The control condition

All participants attended a one-session comprehensive 3-hour DSMES group session routinely offered through the VAPHS diabetes clinic. The DSMES session addresses foundational knowledge, skills-building, and problem-solving necessary for diabetes self-care in accordance with the Association of Diabetes Care and Education Specialists National Standards<sup>7</sup> and VA/Department of Defense Clinical Practice Guidelines.<sup>20</sup> The session was facilitated by two certified diabetes care and education specialists, a nurse and a dietitian, who were not part of the research team and who were blinded to randomization status. After 4 weeks, all participants attended a 30 min DSMES follow-up visit as part of the usual DSMES procedure, where they reviewed diabetes self-care goals with the dietitian. The control arm received only the DSMES session and the DSMES follow-up visit.

### The Mind-STRIDE intervention

The 90 min intervention was delivered immediately following the DSMES session to those in the intervention arm. The investigators adapted Mind-STRIDE from Mindfulness-Based Stress Reduction (MBSR), the gold standard mindfulness program for persons with chronic health conditions,<sup>21</sup> and from qualitative findings from their pilot work.<sup>22</sup> A summary table of topics adapted from MBSR appears in online supplemental files 1; 2.

The intervention consisted of group discussion, a didactic presentation of chronic stress and diabetes, formal meditation practice, and activities targeting sensory, cognitive, and behavioral awareness. Each intervention was audio-recorded and facilitated by one of three interventionists (SJS, SKS, ADP) who had completed an MBSR or health coaching course and were trained to facilitate Mind-STRIDE by the investigators. The research coordinator (NMB) and/or the principal investigator (MMD) reviewed each audio recording within 1 week to ensure fidelity. The 30 min Mind-STRIDE booster was coordinated with the DSMES follow-up visit at 4 weeks. During the booster, the interventionist provided individualized feedback on home practice to Mind-STRIDE participants and guided a short meditation practice.

Intervention participants were encouraged to practice formal mindfulness (breath-focused meditation) or informal mindfulness (mindful attention to the present moment in everyday life) for 10–15 min at least 5 days per week over the course of the study to allow longitudinal assessment of participation and outcomes. These parameters were based on findings from the Mind-STRIDE pilot that showed veterans were more likely to practice mindfulness when sessions were of short (10–15 min) duration.<sup>16</sup> A frequency of 5 days per week, similar to that of MBSR, was chosen to encourage the cultivation of a regular mindfulness practice.<sup>21</sup>

Home practice was supported by the investigator-developed Mind-STRIDE workbook and a publicly available VA mobile application (app), *Mindfulness Coach*. The workbook includes weekly home practice guidance and journaling sections that incorporate structured activities and guided meditations for weeks 1–15 and unstructured, independent practice options during weeks 16–24. *Mindfulness Coach* was developed at the VA National Center for PTSD for veterans with PTSD and is available to the general public on both iOS<sup>23</sup> and Android<sup>24</sup> platforms. The app contains general information on initiating a mindfulness practice, practice tracking features, and guided meditations (eg, Body Scan). *Mindfulness Coach* has been downloaded more than 900 000 times since 2014.<sup>25</sup> Its use without additional clinical support has been associated with significant positive changes in mindfulness mastery.<sup>26</sup> The Mind-STRIDE research team collaborated with one of the app developers (JEO) to add diabetes-specific information and investigator-recorded guided meditations to the ‘Practice Now’ file of the app and to allow collection of real-time app usage data. These data were stored without identifiers on the VA App Connect server. Mind-STRIDE participants downloaded the app on a loaned iPad or their personal mobile device. Six technology-adverse participants were provided with an audio CD containing the same recordings (and loaned CD players if requested) in lieu of the app.

### Sample size assessment

Power calculations were based on a repeated measures design (two-sided,  $\alpha=0.05$ ) with two treatment groups

and three timepoints. A sample size of 104 (52 per group) would provide 80% power to detect an overall group difference in DD and treatment group difference in DD over time (ie, interaction between group and time), using medium effect size ( $d=0.50$ ) and correlation of  $r=0.5$  for repeated observations per subject. The sample size was inflated by a factor of  $(1+(n-1)*\rho)$ , using an intraclass correlation coefficient value of 0.05 and group size of  $n=5$  to adjust for correlations that might occur due to group randomization.

### Outcomes and measures

Participant characteristics including sex, race, and ethnicity were gathered by self-report questionnaires at baseline (T1). Other potential covariates including comorbidity and changes in diabetes medications were accessed from the VA Corporate Data Warehouse (CDW). Comorbidity was measured by the *Charlson Comorbidity Index (CCI)*.<sup>27</sup> Diabetes medication data (30 days prior to enrollment through study completion) were retrieved from the CDW. *Diabetes medication change* was assessed as the addition (yes/no) or discontinuation (yes/no) of a unique class of diabetes medications. Participants were queried at 12 weeks (T2) and 24 weeks (T3) about diabetes medication changes within the past 90 days. Responses were cross-checked with CDW data.

Primary and secondary outcome measures were gathered at T1, T2, and T3.

#### Primary outcome: DD

The 20-item PAID scale measures DD across four domains on a 5-point Likert scale: emotional burden, practitioner-related, regimen-related, and interpersonal. PAID has shown high reliability (Cronbach’s  $\alpha=0.95$ ) and construct validity with measures of emotional distress, disordered eating, fear of hypoglycemia, and short-term and long-term complications in persons with T1D and T2D. Higher scores indicate greater DD.<sup>28</sup>

#### Secondary outcomes

##### Diabetes self-care

The 14-item Survey of Diabetes Self-Care Activities (SDSCA) assesses daily performance of diabetes self-care activities over the previous 7 days across seven domains: general diet, nutrient-specific special diet, physical activity, blood glucose monitoring, foot care, medication adherence, and smoking. It has shown acceptable interitem correlation (mean=0.47), moderate test–retest correlations (mean=0.40), and low correlations among domains (mean  $r=0.23$ ). Higher scores denote more frequent behaviors.<sup>29</sup>

##### Diabetes self-efficacy

The eight-item Diabetes Self-Efficacy Scale measures self-efficacy in diabetes self-management activities on a 10-point Likert scale by asking how confident the individual is in their ability to manage specific diabetes self-care activities. It has high internal reliability (Cronbach’s  $\alpha=0.85$ ), is sensitive to change, and has been validated

by associations to other health indicators. Higher scores denote greater diabetes self-efficacy.<sup>30</sup>

### Post-traumatic stress

The six-item PTSD Checklist (PCL-6) is an abbreviated version of the psychometrically valid civilian version (PCL-C) designed for use in general medical settings. PCL-6 is highly sensitive to clinically significant change in PTSD symptoms (0.92) and has adequate test–retest reliability (Cronbach's  $\alpha=0.78$ ). Higher scores reflect greater PTSD symptoms.<sup>31</sup>

### Depression

The Patient Health Questionnaire (PHQ-8) contains eight items that assess key symptoms of depression. It has shown high reliability (Cronbach's  $\alpha=0.89$ ) and is highly correlated with the extensively validated PHQ-9 (which includes an additional item on suicidality).<sup>32</sup> Scores of 5, 10, 15, and 20 represent mild, moderate, moderately severe, and severe depression, respectively.<sup>33</sup>

### Mindfulness

The 15-item Mindfulness Attention Awareness Scale (MAAS) measures attentive awareness to the present moment on a 6-point Likert scale. Cross-validation studies have confirmed a single-factor model, satisfactory inter-item reliability (Cronbach's  $\alpha=0.87$ ), and convergent and discriminatory validity. Higher scores denote higher levels of mindfulness.<sup>34</sup>

### Hemoglobin A1C

Blood samples were drawn at the VAPHS laboratory prior to each research assessment and were analyzed according to National Glycohemoglobin Standardization Program-approved methods using high-performance liquid chromatography (Tosoh Bioscience, South San Francisco, California). Each increment of 0.5% over 7% represents increased risk of diabetes complications.<sup>35</sup>

### Mean arterial pressure

The research staff took two manual blood pressure readings during each research visit after participants were seated for 5 min. Mean arterial pressure (MAP) was calculated as the average systolic blood pressure + 2 (average diastolic blood pressure) divided by 3.

### Anthropometric characteristics

Height was obtained from the electronic medical record. Weight was measured by the research staff at baseline and prior to each research assessment using a digital scale (Taylor Model 7340). Body mass index (BMI) was calculated at baseline as  $\text{kg}/\text{m}^2$ .

### Patient satisfaction

The eight-item investigator-developed satisfaction survey measured general satisfaction with the Mind-STRIDE intervention using a 4-point Likert scale. Higher scores denote greater satisfaction.

### Participant engagement

Home practice data were compiled from the Mindfulness Coach app, workbook journal entries, satisfaction questionnaires, and phone calls. App usage data were extracted directly from the VA App Connect server, checked against usage patterns from other data sources, and prepared for analysis using Microsoft Excel. Frequency and duration of formal and informal mindfulness practice were described as the average number of days per week and the average number of minutes per session. After reviewing the data, participants were categorized based on median values as 'more engaged' if they practiced at least two times per week with less than 3 consecutive weeks of unrecorded practice; 'less engaged' if they practiced less than twice per week or had a lapse in recorded practice of more than 3 consecutive weeks; or 'not engaged' if they did not practice or dropped out of the study.

### Statistical analysis

Descriptive statistics were computed to determine central tendency, data sparseness, and existence of outliers for all continuous variables. Differences in baseline characteristics by treatment group were assessed using  $\chi^2$  (or Fisher's exact) statistics for categorical variables and t-test (or Mann-Whitney) for continuous variables. In an intention-to-treat analysis, linear mixed models with fixed effects for group, time, and their interaction and random effect for participant were used to determine the effect of the intervention compared with control over 24 weeks. The same analyses were applied separately from weeks 12 to 24 to identify distal effects. Stratified analyses for DD were performed by level of glycemic control. Analyses for DD were also stratified by level of engagement in the intervention arm. All models were adjusted for age and duration of diabetes. Insulin use was also considered as an adjustment variable, but when included the models were unchanged. Missing data were minimal, but the use of a linear mixed model allows for missing data when data are missing at random. All tests were two-sided (at  $\alpha=0.05$ ).

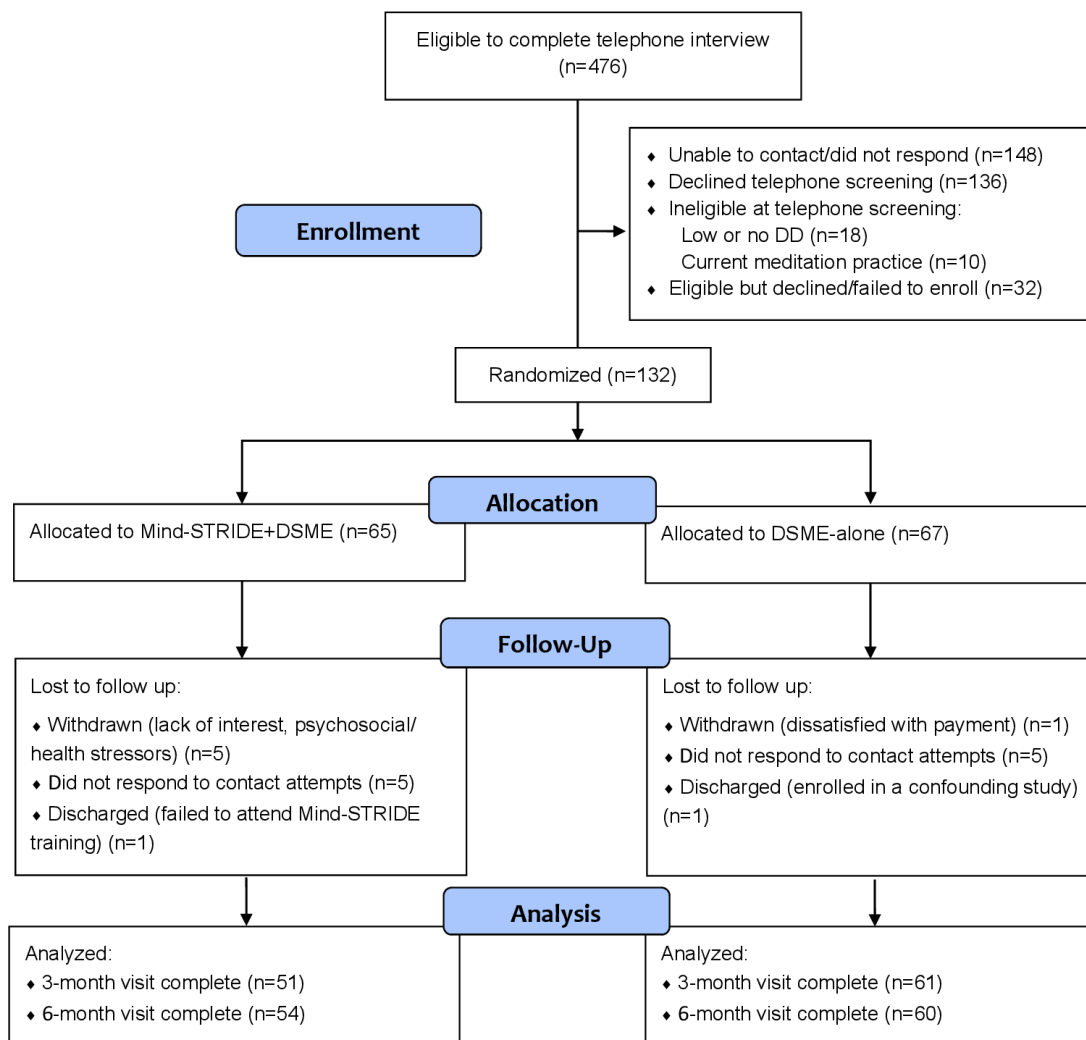
## RESULTS

### Participant flow

There were 476 veterans eligible for prescreening. Of those 192 were prescreened, 164 met the eligibility criteria, and 132 were randomly assigned to receive either Mind-STRIDE ( $n=65$ ) or control DSMES ( $n=67$ ). Retention rates were 83% ( $n=54$ ) and 90% ( $n=60$ ) in the intervention and control group, respectively (see figure 1 for Consolidated Standards of Reporting Trials chart).

### Participant characteristics

As shown in table 1, participants tended to be older ( $60.7\pm 10.6$  years), white (67.4%) and men (91.7%) who were obese or overweight (mean BMI  $34.3\pm 10.6$   $\text{kg}/\text{m}^2$ ). The baseline mean HbA1C was  $8.6\%\pm 1.6\%$  and the duration of diabetes was  $13.0\pm 10.4$  years. More



**Figure 1** CONSORT flow diagram. CONSORT, Consolidated Standards of Reporting Trials; DD, diabetes distress; DSME, Diabetes Self-management Education; Mind-STRIDE, Mindful STress Reduction In Diabetes Education

than two-thirds of the participants ( $n=93$ , 70%) were using insulin; the remainder were using oral or injectable non-insulin diabetes medications. The mean CCI score was 2.9, indicating mild to moderate risk of 1-year mortality. There was no difference in the number of diabetes medication changes between randomized groups ( $p=0.96$ ).

### Primary outcome: DD (PAID)

There were statistically significant reductions in DD over time in both the intervention arm ( $p<0.0001$ ) and control arm ( $p<0.001$ ) (table 2). Group by time interaction for DD was not statistically significant ( $p=0.15$ ) over 24 weeks.

Group by time analyses between distal weeks 12 and 24 showed a statistically significant decrease in DD ( $p=0.02$ ) for the intervention group but not the control group ( $p=0.96$ ) (figure 2). Analyses for DD stratified by baseline HbA1C categories showed a statistically significant group by time effect in DD with baseline HbA1C  $<8.5\%$  ( $p=0.01$ ), but not with HbA1C  $\geq 8.5\%$  ( $p=0.80$ ).

### Secondary outcomes

As shown in table 2, among diabetes self-care activities (SDSCA), all three dietary domains improved in both arms. There was a significant group by time effect for general diet ( $p=0.003$ ). Foot care improved in both groups. MAP and exercise improved in the control arm without significant group by time effects. Diabetes self-efficacy, PTSD, and depression improved significantly in both groups without significant group by time effects. However, scatter plots showed non-significant trends toward improvement between the distal timepoints of 12 and 24 weeks (figure 2). Mindfulness did not change in either arm.

There were statistically significant reductions in HbA1C over time in both groups without significant group by time effects. Examination of small, non-significant trends using scatter plots shows sustained HbA1C less than 8% in the intervention arm between distal timepoints, while HbA1C trended above 8% in the control arm (figure 2). Changes in body weight were not statistically significant in either group; however, one control participant lost a large amount of weight.

**Table 1** Participant characteristics and scale scores at baseline

Characteristics	Total (N=132)	Intervention (n=65) Mean (SD)	Control (n=67) Mean (SD)	P value*
Race, n (%)				
White	89 (67.4)	45 (69.2)	44 (65.7)	0.66
Black	43 (32.6)	20 (30.8)	23 (34.3)	
Gender, n (%)				
Male	121 (91.7)	60 (92.3)	61 (91.0)	1
Female	11 (8.3)	5 (7.7)	6 (9.0)	
Marital status, n (%)				0.36
Currently married/living with partner	57 (43.2)	26 (40.0)	31 (46.3)	
Divorced/separated	48 (36.4)	29 (44.6)	19 (28.4)	
Never married	19 (14.4)	6 (9.2)	13 (19.4)	
Widowed	8 (6.1)	4 (6.2)	4 (6.0)	
Education, n (%)				0.29
Some high school	1 (0.8)	1 (1.5)	0 (0.0)	
High school graduate or equivalent certification	25 (18.9)	10 (15.4)	15 (22.4)	
Some college or technical school	73 (55.3)	41 (63.1)	32 (47.8)	
College graduate (bachelor's degree)	22 (16.7)	8 (12.3)	14 (20.9)	
Graduate degree	11 (8.3)	5 (7.7)	6 (9.0)	
Work status, n (%)				0.52
Retired	57 (43.2)	27 (41.5)	30 (44.8)	
Disabled	31 (23.5)	15 (23.1)	16 (23.9)	
Working full time or part time	32 (24.2)	18 (27.7)	14 (20.9)	
Unemployed or laid off	10 (7.6)	4 (6.2)	6 (9.0)	
Other	2 (1.5)	1 (1.5)	1 (1.5)	
Type 2 diabetes, n (%)	124 (94)	62 (95)	62 (93)	0.72
Insulin use, n (%)	93 (70)	46 (71)	47 (70)	0.78
Age, years (SD)	60.7 (10.6)	60.6 (10.5)	60.7 (10.8)	0.95
Mean arterial pressure, mm Hg (SD)	99.9 (12.8)	99.5 (12.0)	100.3 (13.6)	0.72
Weight, kg (SD)	107.3 (36.7)	103.3 (18.2)	111.2 (48.1)	0.81
BMI, kg/m <sup>2</sup> (SD)	34.3 (10.6)	33.2 (5.6)	35.3 (13.8)	0.26
HbA1C, % (SD) (n=131)	8.6 (1.6)	8.6 (1.5)	8.7 (1.6)	0.68
Diabetes duration, years (SD)	13.0 (10.4)	12.1 (9.7)	13.8 (11.1)	0.34
Charlson Comorbidity Index score (SD)	2.9 (1.9)	2.9 (1.7)	3.0 (2.0)	0.79
Mindful Attention Awareness Scale score (SD)	4.3 (0.9)	4.4(0.9)	4.3 (0.9)	0.43
PTSD Checklist score (SD)	13.6 (5.7)	13.2 (5.7)	13.9 (5.7)	0.49
Depression, PHQ-8 score (SD)	8.7 (5.7)	8.2 (5.7)	9.1 (5.8)	0.39
Self-efficacy for diabetes score (SD)	6.0 (2.0)	6.2 (1.9)	5.8 (2.0)	0.21
Diabetes distress, PAID score (SD)	36.8 (20.2)	34.5 (19.3)	39.1 (20.9)	0.19
Diabetes patient education survey, SDSCA score (SD)				
General diet	3.4 (2.0)	3.3 (2.1)	3.5 (1.9)	0.44
Specific diet (n=131)	3.1 (1.6)	3.3 (1.6)	3.0 (1.5)	0.25
Spacing carbohydrates	2.8 (2.2)	2.9 (2.5)	2.6 (2.0)	0.5
Exercise	2.7 (2.1)	2.8 (2.1)	2.5 (2.1)	0.37
Blood glucose (n=130)	4.8 (2.6)	4.7 (2.7)	4.9 (2.5)	0.57
Foot care	3.8 (2.4)	3.6 (2.3)	4.0 (2.4)	0.25
Smoking status	2.8 (6.0)	2.8 (5.8)	2.6 (6.1)	0.91
Medication (n=69)	6.4 (1.7)	6.3 (1.3)	6.4 (1.1)	0.96

\*Continuous variables were assessed by t-test and categorical variables by Fisher's exact test.

BMI, body mass index; HbA1C, hemoglobin A1C; PAID, Problem Areas in Diabetes; PHQ-8, Patient Health Questionnaire; PTSD, post-traumatic stress disorder; SDSCA, Survey of Diabetes Self Care Activities.

**Table 2** Results of longitudinal modeling to assess change over time by group

Outcome	Intervention (n=65)* β (95% CI)	Control (n=67)* β (95% CI)	P value for test of group by time interaction†
Diabetes distress (PAID)	12 weeks: -9.99 (-13.31 to 6.68) 24 weeks: -13.94 (-17.16 to -10.72) P<0.0001	12 weeks: -9.78 (-13.02 to -6.53) 24 weeks: -9.86 (-13.12 to -6.60) P<0.0001	0.15
HbA1C (%)‡	12 weeks: -0.66 (-1.04 to -0.27) 24 weeks: -0.65 (-1.03 to -0.26) P=0.0006	12 weeks: -0.75 (-0.12 to -0.37) 24 weeks: -0.62 (-1.00 to -0.24) P=0.0001	0.91
Diabetes self-efficacy	12 weeks: 0.75 (0.22 to 1.27) 24 weeks: 1.06 (0.55 to -1.57) P=0.0001	12 weeks: 0.61 (0.21 to 1.02) 24 weeks: 0.74 (0.33 to 1.14) P=0.0007	0.60
PTSD (PCL-C)	12 weeks: -1.09 (-2.30 to 0.12) 24 weeks: -1.79 (-2.97 to -0.60) P=0.012	12 weeks: -1.22 (-2.19 to -0.25) 24 weeks: -1.13 (-2.11 to -0.16) P=0.020	0.57
Depression (PHQ-8)	12 weeks: -1.76 (-3.12 to -0.40) 24 weeks: -2.30 (-3.63 to -0.96) P=0.002	12 weeks: -2.05 (-2.91 to -1.18) 24 weeks: -1.87 (-2.74 to -1.00) P<0.0001	0.67
Mindfulness (MAAS)	12 weeks: 0.12 (-0.13 to 0.38) 24 weeks: 0.14 (-0.10 to 0.39) P=0.451	12 weeks: 0.16 (-0.04 to 0.35) 24 weeks: 0.19 (-0.01 to 0.39) P=0.120	0.94
Mean arterial blood pressure (MAP) (mm Hg)	12 weeks: -1.08 (-4.21 to 2.04) 24 weeks: -0.27 (-3.32 to 2.79) P=0.784	12 weeks: -4.44 (-7.77 to -1.11) 24 weeks: -3.68 (-7.04 to -0.33) P=0.020	0.23
Body weight (kg)	12 weeks: -0.82 (-2.02 to 0.38) 24 weeks: -0.59 (-1.77 to 0.59) P=0.377	12 weeks: -5.69 (-13.56 to 2.19) 24 weeks: -6.09 (-14.02 to 1.83) P=0.236	0.30
General diet (SDSCA)	12 weeks: 1.34 (0.78 to 1.90) 24 weeks: 1.67 (1.12 to 2.22) P<0.0001	12 weeks: 0.69 (0.24 to 1.13) 24 weeks: 0.45 (0.0 to 0.90) P=0.009	0.003
Specific diet (SDSCA)	12 weeks: 0.44 (-0.001 to 0.89) 24 weeks: 0.74 (0.30 to 1.17) P=0.003	12 weeks: 0.59 (0.28 to 0.90) 24 weeks: 0.62 (0.31 to 0.94) P=0.0001	0.63
Spacing carbohydrates (SDSCA)	12 weeks: 0.84 (0.11 to 1.57) 24 weeks: 1.51 (0.80 to 2.22) P=0.0002	12 weeks: 0.88 (0.32 to 1.43) 24 weeks: 0.84 (0.28 to 1.40) P=0.002	0.22
Exercise (SDSCA)	12 weeks: 0.38 (-0.17 to 0.94) 24 weeks: 0.63 (0.09 to 1.17) P=0.072	12 weeks: 0.52 (0.07 to 0.98) 24 weeks: 0.68 (0.21 to 1.14) P=0.011	0.93
Blood glucose testing (SDSCA)	12 weeks: 0.31 (-0.20 to 0.82) 24 weeks: 0.51 (0.01 to 1.01) P=0.134	12 weeks: -0.08 (-0.63 to 0.47) 24 weeks: -0.39 (-0.94 to 0.15) P=0.336	0.06
Foot care (SDSCA)	12 weeks: 0.94 (0.32 to 1.56) 24 weeks: 1.12 (0.52 to 1.73) P=0.0005	12 weeks: 0.69 (0.21 to 1.16) 24 weeks: 0.75 (0.27 to 1.22) P=0.003	0.63
Smoking status (SDSCA)	12 weeks: -23.06 (-53.77 to 7.65) 24 weeks: -4.10 (-33.97 to 25.78) P=0.301	12 weeks: 0.96 (-24.29 to 26.21) 24 weeks: 18.04 (-7.45 to 43.54) P=0.307	0.35
Medication taking (SDSCA)	12 weeks: -0.23 (-0.61 to 0.14) 24 weeks: -0.12 (-0.49 to 0.25) P=0.474	12 weeks: -0.36 (-0.82 to 0.10) 24 weeks: -0.15 (-0.63 to 0.32) P=0.314	0.91

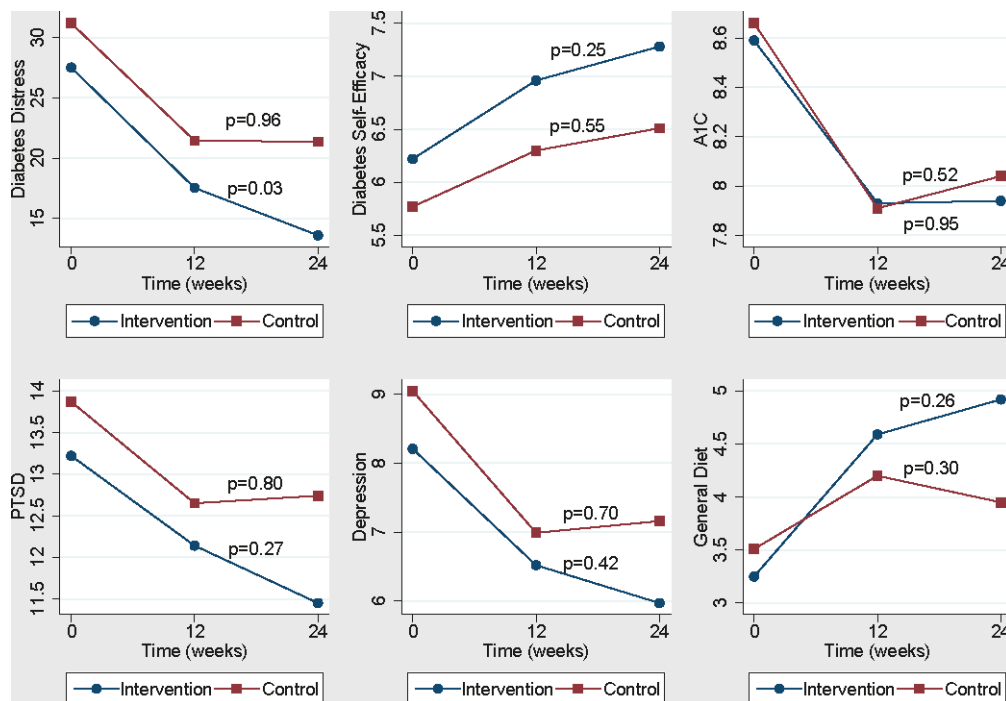
All models are adjusted for age and duration of diabetes.

\*Estimates, CIs and p values based on linear mixed model with a fixed effect for time and a random effect for record identification.

†P values based on linear mixed model with fixed effects for intervention arm, time and interaction between them, and random effect for veteran.

‡Modeled with n=131 (one participant did not have baseline HbA1C drawn).

HbA1C, hemoglobin A1C; MAAS, Mindfulness Attention Awareness Scale; MAP, mean arterial pressure; PAID, Problem Areas in Diabetes; PCL-C, PTSD Checklist Civilian Version; PHQ-8, Patient Health Questionnaire; PTSD, post-traumatic stress disorder; SDSCA, Survey of Diabetes Self Care Activities.



**Figure 2** Adjusted group means over time. PTSD, post-traumatic stress disorder.

### Satisfaction

Of the 53 participants from the intervention arm who completed the satisfaction questionnaires after study completion, 96% (n=51) reported that Mind-STRIDE helped them manage diabetes more effectively, while 91% (n=48) stated that Mind-STRIDE was the type of program they would have attended even if it were not part of a research study. Additionally, 77% (n=41) said it met their stress management needs and 94% (n=50) would recommend it to a fellow veteran or friend with diabetes. Of the 41 participants who responded to additional questions added to the survey, 98% (n=40) indicated that they were satisfied or highly satisfied that a mindfulness intervention was incorporated into their diabetes care and 29% (n=12) reported that they had sought out additional mindfulness resources. In addition, 37% (25 of 67) of the control group opted to receive the mindfulness training after completing the study, indicating interest in this type of program.

### Home practice engagement

Mind-STRIDE participants practiced mindfulness an average of 3 days per week and 20 min per occasion. About half (33 of 65) were more engaged (51%), 32% (21 of 65) were less engaged, and 17% (11 of 65) were not engaged or dropped out. Of those who were more engaged, 70% (23 of 33) used the app and 18% (6 of 33) used the CD, while 33% (7 of 21) of those who were less engaged used the app and none used the CD. More engaged participants practiced a combination of formal and informal mindfulness. Less engaged participants generally practiced informally. Within-group analyses showed a statistically significant reduction in DD in both more engaged and less engaged categories over time, with

greater effects in the more engaged category ( $B=-15.33$  (95% CI  $-19.74$  to  $-10.92$ ),  $p<0.0001$  vs the less engaged category  $B=-9.38$  (95% CI  $-13.76$  to  $-5.00$ ),  $p=0.001$ ).

### CONCLUSIONS

This study integrated a mindfulness intervention into conventional diabetes care and education to target DD in veterans. Statistically significant improvements in most outcomes were observed in both the intervention and control arms over 24 weeks. Since DSMES is a critical component of diabetes care,<sup>7</sup> it likely accounts for improved outcomes in the control arm. However, research has shown that the durability of DSMES effects is variable,<sup>36–39</sup> and the value of multifaceted programs that integrate psychobehavioral interventions into DSMES is increasingly being recognized.<sup>14 40 41</sup> This study showed a statistically and clinically significant reduction in DD after 12 weeks compared with DSMES control. In addition, a significant group by time intervention effect was observed for general dietary behaviors, and there were non-significant distal trends toward improvement in other secondary outcomes that may suggest longer-lasting effects with the intervention.

Our findings reiterate those from a systematic review and meta-analysis of eight RCTs involving 841 participants with diabetes that showed increased longer-term efficacy of MBI in mitigating DD compared with shorter term.<sup>42</sup> The meta-analysis also identified five factors that influence the effect size (Cohen's d) of MBI on DD: higher baseline DD ( $d=0.48$ ), MBSR-based design ( $d=0.58$ ), group format ( $d=0.36$ ), home practice assignments ( $d=0.42$ ), and assessment of longer-term effects ( $d=0.56$ ). Mind-STRIDE incorporates each of these five



factors, which may account for its efficacy in reducing DD between weeks 12 and 24 compared with control.

Although studies have identified DD as a positive predictor of HbA1C in persons with diabetes,<sup>10</sup> PAID scores did not correlate with HbA1C in this sample of veterans. A table of baseline associations with DD is shown in the online supplemental materials. Although the burden of diabetes self-management, directly associated with DD, is likely to increase with the addition of new therapies and care tasks as metabolic outcomes worsen, some persons may not internalize feelings of distress in response to this burden. Further, participants with higher HbA1C may have a variety of challenges that influence their response to these types of interventions, such as conflicting priorities, low literacy, or social determinants of health that were not assessed. The aforementioned meta-analysis<sup>42</sup> provides context for MBI effects on DD and HbA1C, reporting greater reductions in DD when baseline HbA1C was <8% and the duration of follow-up was >6 months. This aligns with the results of our stratified analyses that found stronger intervention effects on DD after 12 weeks and when baseline HbA1C was <8.5%. Accordingly, baseline HbA1C and its correlation to DD may be relevant considerations for future mindfulness studies with veterans and other persons with diabetes.

The effects on other secondary outcomes are also noteworthy. Nutrient-specific and special diet domains of the SDSCA improved significantly in both arms without a significant intervention effect, possibly due to new knowledge gained from dietary counseling provided by the DSMES dietitian. In contrast, general diet improved in both groups, with a significant intervention effect that may reflect behavioral changes related to increased mindful attention to healthy eating. Interestingly, previous research<sup>43</sup> found a 12 min mindful attention exercise mitigated the relationship between hunger and calorie-dense junk food consumption, resulting in healthier food choices. According to those researchers, mindful attention may be a metacognitive component of mindfulness that can modulate motivational states and play a central role in eating behaviors. Weight loss was not observed in either group despite reported improvements in dietary behaviors. This could be because modest dietary improvements may not translate to sufficient caloric reductions for weight loss, particularly in individuals with metabolic dysregulation.

The secondary outcomes diabetes self-efficacy, PTSD, and depressive symptoms improved in both arms without significant intervention effects. This is not surprising since prior DSMES and MBI research has shown positive outcomes in these areas, attributed to stress reduction, social support, and increased feelings of well-being.<sup>7 12 44</sup> It is striking, however, that these improvements continued to trend after 12 weeks in the Mind-STRIDE intervention arm compared with DSMES control, suggesting longer-lasting effects when an MBI is integrated with DSMES.

It is difficult to theorize about mechanisms, however, since measurement of mindfulness is challenging.<sup>45 46</sup>

For example, a systematic review of 85 studies showed that brief mindfulness interventions positively impacted health-related outcomes, but it is unclear if these effects were mediated by changes in mindfulness.<sup>47</sup> Accordingly, previously reported baseline analyses from the current study showed a significant inverse association between mindfulness (MAAS) and DD, whereby greater mindfulness predicted lower DD.<sup>48</sup> However, our longitudinal analyses showed that MAAS scores did not increase alongside reductions in DD as would have been expected. It is possible that MAAS and other such instruments may not be sensitive to changing states of mindfulness.

Nonetheless, Mind-STRIDE is timely and responsive to veterans' interest in mindfulness. In a survey of 185 veterans, 58% were interested in learning about mindfulness and 30% had practiced mindfulness during the past year.<sup>49</sup> Over 75% of those who practiced reported perceived benefit. However, Martinez *et al*<sup>50</sup> identified numerous barriers to veteran participation in traditional 8-week MBSR programs, including misinformation from healthcare practitioners (eg, MBSR may diverge with religious beliefs), scheduling conflicts, limited access, aversion to group activities, inability to commit to home practice, and difficulty understanding its concepts. Mind-STRIDE addresses several of these barriers by tailoring an MBSR-inspired intervention with home practice support that can be integrated into current diabetes care processes.

### Strengths and limitations

This RCT addressed existing gaps in knowledge regarding the efficacy of mindfulness interventions in veterans with DD, the effects of mindfulness as an adjunct to diabetes care and education, and the use of a mobile app to support and track engagement. Unlike similar studies that primarily relied on self-report, this study also used objective measures, increasing the validity of our findings. Mind-STRIDE and DSMES were delivered by consistent teams of interventionists and educators, which decreased potential instructor bias. The interventionists had basic experience with MBSR, but extensive experience or certification was not required. Thus, trained members of diabetes care teams like psychologists, social workers, nurses, dietitians, or health coaches can readily facilitate this type of intervention in conjunction with conventional diabetes care and education. Satisfaction was high and over two-thirds of the participants remained engaged over 6 months.

We note several limitations. Although a retention rate of 86% is acceptable, 31% of Mind-STRIDE participants either dropped out or did not engage in mindfulness practice. Perhaps more frequent telephonic support or additional booster(s) would have conferred greater benefits beyond the DSMES control. The study was also conducted in person at one VA site, thus limiting accessibility and generalizability. Despite specific recruitment efforts, there were few female participants. Finally, the

duration of the study did not allow for examination of distal effects beyond 24 weeks.

In summary, a technology-supported, MBSR-inspired mindfulness intervention integrated with DSMES significantly reduced DD after 12 weeks compared with DSMES control. Effects were greater when baseline HbA1c was moderately elevated (<8.5%). Examination of long-term outcomes, underlying mechanisms, and feasibility of virtual delivery is warranted.

#### Author affiliations

<sup>1</sup>Center for Health Equity Research and Promotion, VA Pittsburgh Healthcare System, Pittsburgh, Pennsylvania, USA

<sup>2</sup>Department of Psychiatry, University of Pittsburgh School of Medicine, Pittsburgh, Pennsylvania, USA

<sup>3</sup>Center for Complementary Medicine, University of Pittsburgh Medical Center, Pittsburgh, Pennsylvania, USA

<sup>4</sup>Graduate School of Public Health, University of Pittsburgh, Pittsburgh, Pennsylvania, USA

<sup>5</sup>Department of Medicine, Boston University School of Medicine, Boston, Massachusetts, USA

<sup>6</sup>National Center for PTSD, VA Palo Alto Health Care System, Palo Alto, California, USA

<sup>7</sup>Suzanne Dworak-Peck School of Social Work, University of Southern California, Los Angeles, California, USA

<sup>8</sup>Department of Medicine, University of Pittsburgh School of Medicine, Pittsburgh, Pennsylvania, USA

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#### ORCID iD

Monica M DiNardo <http://orcid.org/0000-0001-7764-1031>

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