



Kindness Matters: A Randomized Controlled Trial of a Mindful Self-Compassion Intervention Improves Depression, Distress, and HbA_{1c} Among Patients With Diabetes

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Anna M. Friis,¹ Malcolm H. Johnson,¹
Richard G. Cutfield,² and
Nathan S. Consedine¹

OBJECTIVE

Mood difficulties are common among patients with diabetes and are linked to poor blood glucose control and increased complications. Evidence on psychological treatments that improve both mood and metabolic outcomes is limited. Greater self-compassion predicts better mental and physical health in both healthy and chronically ill populations. Thus, the purpose of this randomized controlled trial (RCT) was to evaluate the effects of self-compassion training on mood and metabolic outcomes among patients with diabetes.

RESEARCH DESIGN AND METHODS

This RCT tested the effects of a standardized 8-week mindful self-compassion (MSC) program ($n = 32$) relative to a wait-list control condition ($n = 31$) among patients with type 1 and type 2 diabetes. Measures of self-compassion, depressive symptoms, diabetes-specific distress, and HbA_{1c} were taken at baseline (preintervention), at week 8 (postintervention), and at 3-month follow-up.

RESULTS

Repeated-measures ANOVA using intention to treat showed that MSC training increased self-compassion and produced statistically and clinically significant reductions in depression and diabetes distress in the intervention group, with results maintained at 3-month follow-up. MSC participants also averaged a clinically and statistically meaningful decrease in HbA_{1c} between baseline and follow-up of >10 mmol/mol (nearly 1%). There were no overall changes for the wait-list control group.

CONCLUSIONS

This initial report suggests that learning to be kinder to oneself (rather than being harshly self-critical) may have both emotional and metabolic benefits among patients with diabetes.

¹University of Auckland, Auckland, New Zealand
²Waitemata District Health Board, Auckland, New Zealand

Corresponding author: Anna M. Friis, a.friis@auckland.ac.nz or annamfriis@gmail.com.

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Major depression is estimated to affect at least 12% of patients with diabetes (1), with subclinical mood symptoms and distress apparent in nearly one-third (31%) of those living with this chronic condition (2). In addition to predicting a higher negative affect, the emotional burden of distress about managing one's diabetes may be a qualitatively different experience from depression per se (3,4). Although both distress and depression are linked to poor glycemic control, evidence suggests that distress rather than depression may be a better predictor of metabolic outcomes (3,5). Of note, given the scale and impact of mood disturbance among patients with diabetes, evidence for psychological interventions that successfully treat depression and distress and, ideally, concurrently improve metabolic outcomes is limited.

Several reasons exist to continue the search for psychotherapeutic interventions to improve mental and physical health outcomes among patients with diabetes. A meta-analysis of randomized controlled trials (RCTs) for treating depression in diabetes showed that psychotherapeutic treatments are moderately effective for depression and that cognitive behavior therapy (CBT) in particular had a small effect on glycemic control (6). Although the number and sample sizes of studies included in this meta-analysis were relatively small (10 of the 14 studies investigated samples ranging from 13 to 60 participants), a more recent study of 87 adults with depression and uncontrolled type 2 diabetes found that CBT focused on adherence and depression improved these outcomes as well as glycemic control (7). On the other hand, in their RCT, Hermanns et al. (8) found that diabetes-specific CBT reduced depression and distress in a mixed sample ($n = 214$) of patients with type 1 and 2 diabetes but had no between-group effect on HbA_{1c} , and a large-scale meta-analysis and review showed no effects of psychological interventions on glycemic control among adults with type 1 diabetes (9). Overall, the wide variation in methodologies and inclusion criteria, including the fact that most trials also included other supportive treatments such as diabetes education alongside the intervention, means that drawing conclusions about the efficacy of current

psychological treatment approaches and/or their metabolic effects remains difficult.

Given the prevalence and health-related implications of mood difficulties among patients with diabetes and the lack of conclusive evidence for current psychological interventions or their effects on glycemic indices, the search for behavioral interventions that can meet patient needs on a broad scale must continue. One promising approach to improving well-being in clinical settings is the practice of self-compassion, an ancient idea arising alongside research into the health benefits associated with mindfulness. Studies of mindfulness interventions among patients with diabetes have shown consistent improvements in psychological outcomes, including depression, but effects on metabolic control have been varied (10). Fundamentally, self-compassion-based treatments are based on the notion that significant portions of psychological distress are created by the tendency to be self-critical about actual or perceived failures. Self-compassion incorporates mindfulness as a core component (11) while also attempting to encourage a sense of common humanity (recognizing that everyone goes through difficult times) and self-kindness (responding to one's suffering with gentleness and understanding instead of judgment and criticism). Unlike mindfulness, self-compassion directly trains the capacity for active soothing and self-comforting in times of suffering. Patients learn to treat themselves in the same way they might treat distress in a beloved other, providing gentle comfort and tending to their own needs for self-care.

For a patient population in which the relentless demand for healthy blood glucose control presents daily opportunities for failure and, thus, attacks on the self, the practice of self-kindness may reduce psychological suffering with subsequent, flow-on metabolic benefits. Evidence in both healthy and patient populations (12) has linked greater self-kindness with better mood, and a meta-analysis of nearly 80 studies has shown a large effect size ($r = 0.47$) in the relationship between self-compassion and well-being (13). Although evidence from diabetes is scanty, one study found that self-compassion predicted less diabetes-specific distress and buffered the link between diabetes

distress and poor metabolic outcomes (5).

Drawing from studies that show that self-compassion can be increased through training (14), the current investigation tested whether an 8-week group-based self-compassion intervention would improve psychological and physical health outcomes among patients with diabetes. We expected that self-compassion would increase over the training period and that the training would reduce both depression and diabetes-specific distress in the intervention arm. We also expected that these gains would be sustained at 3-month follow-up and that self-compassion training would reduce HbA_{1c} levels across the same time period.

RESEARCH DESIGN AND METHODS

This RCT contrasted a standardized mindful self-compassion (MSC) intervention with a wait-list (treatment-as-usual) control. Participants were 63 patients with either type 1 or type 2 diabetes. They were aged 18–70 years (mean 42.87, SD 14.30), fluent in English, and able to attend a minimum of six of eight scheduled treatment sessions. Exclusion criteria were self-reported inability to read and write English. Participants were recruited between July 2014 and September 2014 at three hospital sites in Auckland, New Zealand. Recruitment was through self-referral to the trial or following recommendations from a patient's physician or diabetes nurse; the study was widely advertised through numerous local diabetes centers. All participants provided written informed consent.

Procedure

Participants in the intervention condition ($n = 32$) were assessed at baseline (T_1), at week 8 (T_2), and 3 months after training had concluded (T_3). Participants in the wait-list control condition ($n = 31$) completed identical measurements at the same three time points. Each time they provided data, participants received \$20 vouchers to cover the costs associated with traveling to laboratories for blood testing. Participants received an additional \$20 voucher for each MSC session they attended to cover transportation and parking costs. Treatment groups began in August 2014 and were completed by October 2014.

Treatment Allocation

A trained researcher blind to the hypotheses and study design and without participant contact used randomization software to allocate treatment assignments. Patients were told that they would be participating in a program based on evidence that learning to treat oneself with kindness and understanding when faced with difficult feelings and circumstances could be good for mental and physical health. They were told that they might be allocated to either a skills training workshop or a wait-list control. No further information about the MSC program was provided.

Intervention

MSC is a protocol-standardized intervention aimed at increasing mindfulness and self-compassion and reducing the suffering associated with experiential avoidance (14). Sessions were delivered to groups of 8–12 people during eight weekly sessions, each lasting 2.5 h. Adherence to the standard MSC protocol was strict, without specific reference to diabetes as a particular source of suffering. The intervention was delivered by the first author, a New Zealand-registered health psychologist trained to teach the program according to manualized MSC protocols. Clinical supervision was conducted weekly through Skype conference with MSC trainers across the intervention period. All participants received a standardized e-mail 2 days after each weekly session that summarized the week's teachings and encouraged them to practice what they had learned during the previous session.

The central components of MSC are formal meditation together with formal and informal self-compassion practices aimed at developing the cognitive, behavioral, and physical capacities to soothe and comfort oneself when distressed (see Supplementary Data).

Wait-list Condition

Participants in the wait-list control condition received medical treatment as usual.

Assessments

Age, sex, ethnicity, and health status were assessed through self-report, as were time since diagnosis and type of diabetes.

Outcome Measures

Self-compassion was assessed using the Self-Compassion Scale (SCS) (11), a

26-item, 5-point Likert scale questionnaire comprising positive subscales of self-kindness, common humanity, and mindfulness and negative subscales of self-judgment, isolation, and overidentification. Studies have demonstrated satisfactory psychometric properties (15). Factor analysis has confirmed the six-factor structure of the scale and the single higher-order component of self-compassion. Reliabilities for the aggregate total score in the current study were $T_1 = 0.91$, $T_2 = 0.91$, and $T_3 = 0.93$.

Depression

Symptoms of major depressive disorder were assessed with the 9-item Patient Health Questionnaire (PHQ-9) (16). By using a 2-week time window, responders rated symptoms on a scale of 1 (not at all) to 4 (almost every day). A summed score was calculated. The PHQ-9 is widely used and has excellent psychometric properties. It was validated with patients with diabetes in both primary and specialized outpatient clinics (17). α -Reliabilities for the current study are $T_1 = 0.81$, $T_2 = 0.87$, and $T_3 = 0.85$.

Diabetes-specific distress is a common condition and is consistently linked to poor biobehavioral disease management (18). The 17-item Diabetes Distress Scale (DDS) has a consistent factor structure and good internal reliability and validity (18). The DDS contains items from four established domains of diabetes-related distress: emotional burden, physician-related distress, regimen-related distress, and interpersonal-related distress. A total score is calculated, with a mean item score of ≥ 3 considered to be high distress and worthy of clinical attention; higher scores on the DDS have been associated with greater HbA_{1c} (18). α -Reliabilities for the total scale are $T_1 = 0.87$, $T_2 = 0.90$, and $T_3 = 0.92$.

Glycemic control (indicated by HbA_{1c} values at the three time points) was assessed using values reported by Lab Tests Auckland Ltd., an accredited medical testing laboratory, by using the COBAS Integra platform (Roche Diagnostics). HbA_{1c} reflects mean blood glucose levels over the previous 2–3 months and is the standard assessment of glycemia (19).

Sample Size Calculation

The sample size calculation, based on 2 (group) \times 3 (time) mixed-model repeated-measures ANOVA, was estimated from a

review and meta-analysis of psychological interventions among patients with diabetes (5) in which the effects of treatment on glycemic control were substantially smaller than the moderate effects found for depression. A priori analyses with an f effect size of 0.25 and α -probability of 0.05 suggested a minimum sample of 44 participants. Allowing for dropout and retention (20,21), 63 participants were recruited. The sample size calculations were performed with GPower 3.1 software.

Statistical Analyses

The Consolidated Standards of Reporting Trials (CONSORT) guidelines for randomized trials were followed, and intention-to-treat analyses were conducted with SPSS Statistics 20 software (IBM Corporation). Individual missing values were imputed by using the means of the relevant subscale for the SCS and DDS or the total scale mean for the PHQ-9. For missing HbA_{1c} values ($n = 6$ of 189), the most recently recorded value was carried forward. For the four participants who withdrew from the study, measurements from the time point before withdrawal were carried forward for analysis, and all multivariate assumptions were met. As a further check, per-protocol analyses were conducted, revealing a very similar pattern of results for both biological and subjective outcomes. Independent samples t tests and χ^2 analyses were used to test for possible group differences in demographic and clinical variables at baseline (T_1).

A series of 2 (group) \times 3 (time) mixed-model ANOVAs tested the expectations that 1) randomization to the self-compassion training would increase self-compassion as well as reduce depression, distress, and HbA_{1c} relative to the wait-list control and 2) these gains would be maintained at 3-month follow-up. Effect sizes are reported as partial η^2 (η_p^2) coefficients. To further interpret any time-by-group interactions, a series of t tests examined possible differences between baseline and postintervention (T_1 and T_2), between postintervention and 3-month follow-up (T_2 and T_3), and between baseline and 3-month follow-up (T_1 and T_3).

Clinically Meaningful Improvement

Clinically meaningful improvements in outcomes were defined as reductions

between T_1 and T_3 of 1) at least 5 points on the baseline PHQ-9 score (22), 2) at least 1 point on the DDS mean (23), and 3) at least 0.5% (5.5 mmol/mol) in HbA_{1c} scores (24). χ^2 analyses were used to test between-group differences in the proportion of participants showing clinically significant improvement.

RESULTS

Recruitment and Attrition

As indicated in the CONSORT diagram (Fig. 1), 84 patients indicated an initial interest in participation. Of these, 71 were randomized (15% noneligible), and 63 ultimately provided data for the study (32 in the MSC condition, 31 in the wait-list control [89% of eligible]). χ^2 analysis showed no group differences in attrition: Of the 63 participants who provided baseline data, 4 withdrew (2 from each condition).

Baseline Characteristics

Table 1 provides an overview of the study sample, stratified by group. No differences were found between the two groups at baseline in demographic or diabetes-specific characteristics other than time since diagnosis. However, between-group differences were seen at baseline on psychological and clinical metrics; PHQ-9, DDS, and HbA_{1c} scores were greater and SCS scores were lower in the MSC group than in the wait-list control group. A greater proportion of intervention participants had clinically significant diabetes distress, but no differences between groups were found in the proportion with clinically significant depression (Table 2). Because of these baseline differences, primary analyses were replicated by ANCOVA in which baseline values were covaried and T_2 and T_3 values entered as repeated measures. Results were essentially unchanged.

Changes in Self-Compassion

The ANOVA showed a main effect of time ($F[2,60] = 13.07$, $P < 0.001$, $\eta_p^2 = 0.30$) but not of group ($F[1,61] = 0.02$, $P > 0.05$); however, there was an interaction between time and group ($F[2,60] = 0.06$, $P = 0.001$, $\eta_p^2 = 0.21$). Plot inspection, confirmed with t tests (Table 3), showed that self-compassion increased in the MSC group between T_1 and T_2 , with gains maintained at T_3 . No changes were found in the wait-list control group at any time (Fig. 2).

Changes in Depressive Symptoms

The ANOVA testing for changes in depressive symptoms showed an effect for time ($F[2,60] = 12.40$, $P < 0.001$, $\eta_p^2 = 0.29$). As with the SCS scores, there was no main effect for group ($F[1,61] = 2.40$, $P > 0.05$), but there was a significant time-by-group interaction ($F[2,60] = 7.07$, $P < 0.05$, $\eta_p^2 = 0.19$). Plot inspection confirmed by t tests (Table 3) showed that the intervention reduced depression scores in the MSC group between T_1 and T_2 , with results maintained at T_3 . There were no changes in depression scores in the wait-list control group between any time point (Fig. 2).

Changes in Diabetes Distress

The ANOVA showed effects for both time ($F[2,60] = 27.30$, $P < 0.001$, $\eta_p^2 = 0.48$) and group ($F[1,61] = 3.92$, $P = 0.05$, $\eta_p^2 = 0.06$) as well as an interaction between time and group ($F[2,60] = 12.24$, $P < 0.001$, $\eta_p^2 = 0.29$). Plot inspection, confirmed with t tests (Table 3), showed that the intervention reduced distress in the MSC group between T_1 and T_2 , with improvements maintained at T_3 . Although there were no changes evident in the wait-list control group between T_1 and T_2 , there was an overall reduction in distress scores between T_1 and T_3 (Fig. 2).

Changes in HbA_{1c}

Results showed an effect for time ($F[2,60] = 13.25$, $P < 0.001$, $\eta_p^2 = 0.31$) but not group ($F[1,61] = 2.66$, $P > 0.05$). The general reduction in HbA_{1c} over time was qualified by an interaction between time and group ($F[2,60] = 5.1$, $P < 0.05$, $\eta_p^2 = 0.15$). Inspection of the interaction plot, confirmed by t tests (Table 3), showed that although HbA_{1c} did not change between T_1 and T_2 in the MSC group, scores reduced by >10 mmol/mol (nearly 1%) between T_1 and T_3 . There was no change overall between T_1 and T_3 for the wait-list control group (Fig. 2).

Clinically Significant Change

Analyses demonstrated group differences in the proportion of participants showing clinically meaningful improvement between T_1 and T_3 . In the MSC group, 20 (62.5%) participants recorded a clinically meaningful decrease in PHQ-9 depression scores compared with 5 (16.1%) in the wait-list control group ($\chi^2 [1, n = 63] = 12.28$, $P < 0.001$,

$\phi = -0.47$). Equally, 15 (46.9%) participants in the MSC group recorded clinically meaningful reductions in distress compared with 3 (9.7%) in the wait-list control group ($\chi^2 [1, n = 63] = 8.93$, $P < 0.05$, $\phi = -0.41$). For HbA_{1c} , 21 (65.6%) participants in the MSC group recorded a clinically meaningful decrease compared with 9 (29%) in the wait-list control group ($\chi^2 [1, n = 63] = 7.05$, $P < 0.05$, $\phi = -0.37$).

CONCLUSIONS

To our knowledge, this report represents the first investigation into the possible utility of self-compassion training in improving mood and metabolic outcomes among patients with type 1 and type 2 diabetes. As expected, the 8-week MSC intervention increased self-compassion, a finding consistent with a prior RCT of the MSC protocol and other evidence suggesting that self-compassion can be learned (14). The current study extends these findings to a diabetes population, a difficult-to-treat patient group among whom harsh self-criticism is not only common (25) but also a likely correlate of mood and behavioral self-management difficulties. As such, finding that the intervention showed the expected benefits in terms of reducing depression and diabetes-specific distress is important. Perhaps most notably and consistent with our final hypothesis, self-compassion training also reduced HbA_{1c} , suggesting that the MSC intervention affected both subjective and objective metrics, an extension of most prior psychosocial RCTs among patients with diabetes (26).

Given the absence of compassion-specific studies among patients with diabetes, this discussion considers these findings in relation to prior studies that incorporated aspects of mindfulness or acceptance, a class of psychosocial intervention that may also engender compassion alongside acceptance of difficult thoughts and feelings (4,27). We consider possible explanations for the benefits of self-compassion, evaluate the clinical possibilities for compassion-based therapies in diabetes, and offer directions for future research and clinical practice.

First, the finding that the MSC program reduced depression adds to the overall evidence for psychosocial interventions among patients with diabetes

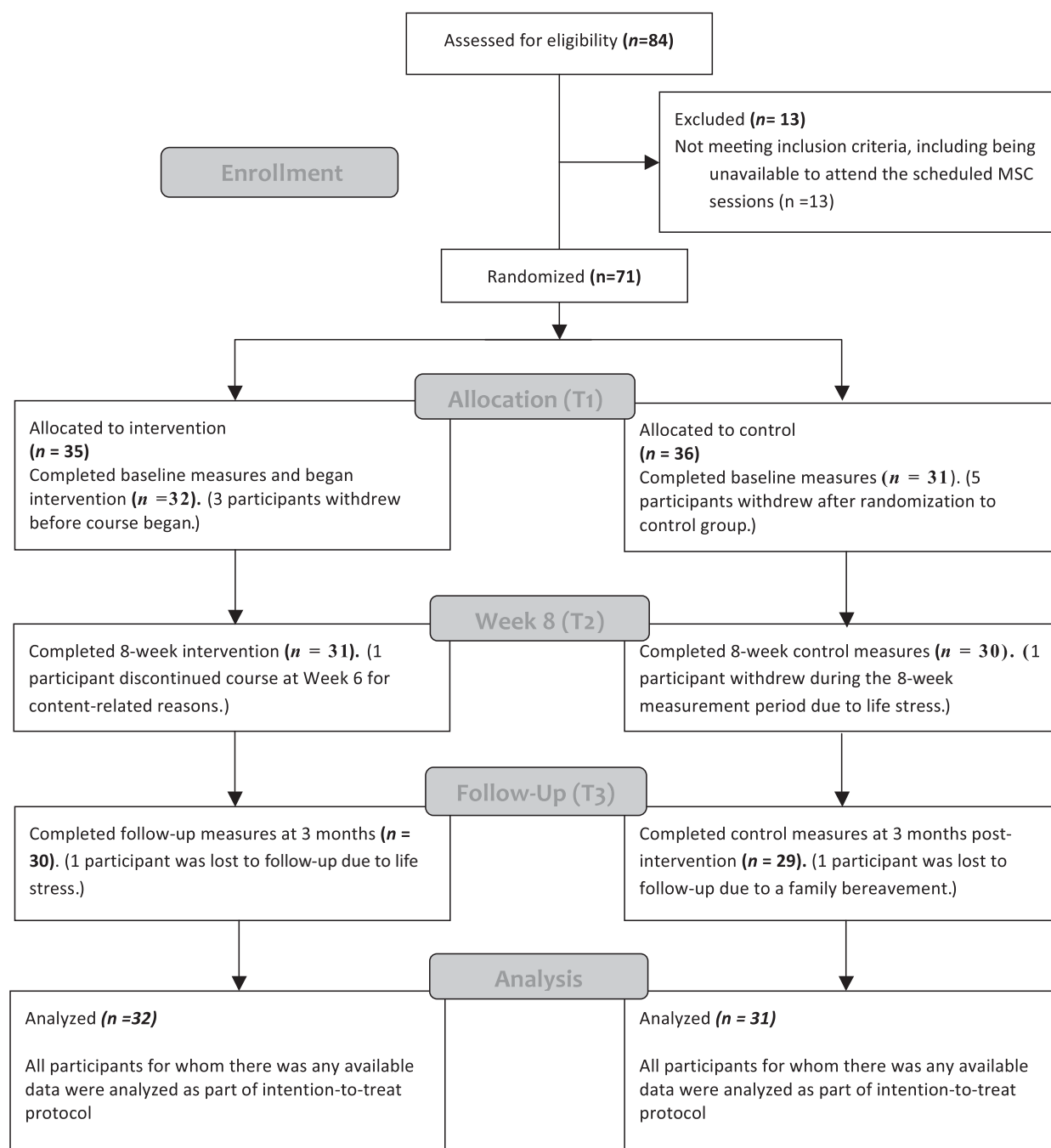


Figure 1—CONSORT diagram showing the flow of participants with diabetes through each stage of the MSC RCT.

(6–9) and is consistent with several mindfulness-based RCTs (4,20,21) and uncontrolled studies (28,29). However, although mindfulness is a foundation of MSC, self-compassion is broader in scope than mindfulness alone, concurrently emphasizing self-kindness (rather than self-criticism) and common humanity (compared with isolation), qualities also associated with well-being (13). A recent pilot study among breast cancer survivors (another group in which

mood disorders are common) of an 8-week cognitively based compassion intervention also reported reduced depression after sessions emphasizing self-kindness and common humanity (30), providing preliminary evidence for the efficacy of this type of training.

Second, that the training reduced diabetes distress is likewise consistent with prior mindfulness interventions (4,20,21). Although diabetes-related topics were not explicitly referred to

during the MSC program, all participants were patients with diabetes. As such, the emphasis on mindful acceptance of difficulty as being normal (i.e., “other people in my situation feel like this”) and active soothing of stressed or uncomfortable emotional states (“may I be kind to myself in this moment”) likely elicited diabetes-related thoughts, with the MSC practices then proving helpful in reducing the associated distress. This interpretation is consistent with the

Table 3—Results of *t* tests between T₁ and T₂, T₂ and T₃, and overall differences between T₁ and T₃ for MSC and wait-list control groups separately

Measure	T ₁ and T ₂	Difference	T ₂ and T ₃	Difference	T ₁ and T ₃	Difference
SCS						
MSC	<i>t</i> (31) = 4.70**	0.58 (0.12)	<i>t</i> (31) = 0.88	0.11 (0.14)	<i>t</i> (31) = 5.10**	0.70 (0.14)
Wait-list	<i>t</i> (30) = 1.93	0.25 (0.13)	<i>t</i> (30) = −1.92	−0.24 (0.12)	<i>t</i> (30) = 0.14	0.01 (0.10)
PHQ-9						
MSC	<i>t</i> (31) = −3.85*	−4.86 (1.27)	<i>t</i> (31) = −0.95	1.3 (1.35)	<i>t</i> (31) = −5.92**	−6.14 (1.04)
Wait-list	<i>t</i> (30) = −1.96	−2.44 (1.25)	<i>t</i> (30) = 1.74	2.03 (1.17)	<i>t</i> (30) = −0.38	−0.41 (1.10)
DDS17						
MSC	<i>t</i> (31) = 4.56**	0.83 (0.18)	<i>t</i> (31) = −1.12	−0.23 (1.18)	<i>t</i> (31) = −7.23**	−1.06 (0.15)
Wait-list	<i>t</i> (30) = −0.36	−0.06 (0.17)	<i>t</i> (30) = −0.90	−0.19 (0.21)	<i>t</i> (30) = −2.11*	−0.25 (0.20)
HbA _{1c}						
MSC	<i>t</i> (31) = −1.47	−2.81 (1.91)	<i>t</i> (31) = −3.63*	−7.41 (2.04)	<i>t</i> (31) = −4.65**	−10.22 (2.20)
mmol/mol						
%	<i>t</i> (31) = −1.47	−0.26 (0.18)	<i>t</i> (31) = −3.63*	−0.68 (0.19)	<i>t</i> (31) = −4.65**	0.94 (1.14)
Wait-list						
mmol/mol	<i>t</i> (30) = 1.58	1.20 (1.25)	<i>t</i> (30) = −3.27*	−3.71 (1.14)	<i>t</i> (30) = −1.20	−1.74 (1.45)
%	<i>t</i> (30) = 1.58	0.18 (0.11)	<i>t</i> (30) = −3.27*	−0.34 (0.10)	<i>t</i> (30) = −1.20	−0.16 (0.13)

Data are mean (SE) unless otherwise indicated. **P* < 0.05. ***P* < 0.001.

among people with greater levels of distress and depression (and poorer glycemic control). In addition, we note a failure of randomization with between-

group baseline differences in the key clinical markers of depression, distress, and HbA_{1c} as well as in self-compassion. Although the analytic approach should

accommodate such differences, findings must nonetheless be interpreted with caution because they may be limited to those with more room to improve in

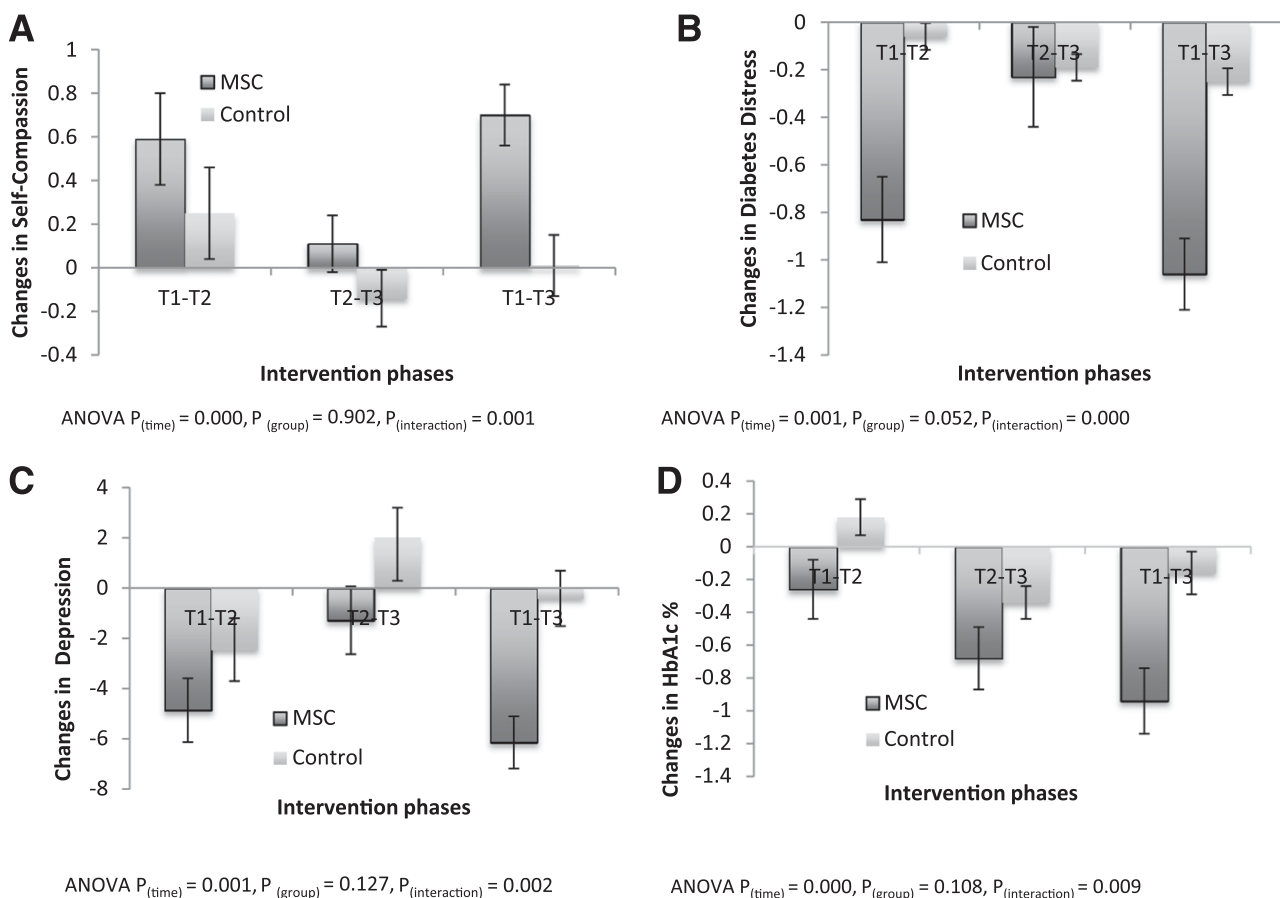


Figure 2—Mean difference scores in outcome measures of self-compassion (A), diabetes distress (B), depression (C), and HbA_{1c} (D) for each group between T₁ and T₂ (baseline and postintervention), T₂ and T₃ (postintervention and 3-month follow-up), and T₁ and T₃ (baseline and 3-month follow-up).

terms of greater baseline levels of depression and distress, among whom higher HbA_{1c} can be expected (2).

Finally, the absence of an active control group means nonspecific factors, including group support or simply meeting with a teacher and fellow patients with diabetes in a supportive way over a period of 8 weeks, may be responsible for the observed effects. Caution must therefore be applied in attributing these results to the effects of the MSC intervention specifically, and findings must again be considered preliminary. Notwithstanding these limitations, this first RCT of a stand-alone psychological intervention (i.e., without the inclusion of diabetes-specific education or material) found differences in both psychological and physiological metrics (HbA_{1c}) in what is a typically hard-to-treat population.

Offsetting these limitations, however, is a low dropout rate (6.30%), which is unusual for distressed patients with diabetes where levels of ~30% dropout are common (20,21,39). Participants were clearly motivated to attend the MSC sessions and to stay involved in the program until completion. Wait-list control participants were also motivated to attend sessions, with nearly two-thirds subsequently taking part in the MSC program immediately following the conclusion of the experimental protocol.

Future Directions

Living with diabetes involves relentless self-care responsibilities that can be understandably overwhelming for patients. Opportunities for negative self-evaluation and self-criticism of failures in diabetes self-management abound. Although some evidence exists for the effectiveness of mindfulness-based interventions in this patient group, developing the capacity to actively soothe and comfort oneself during suffering (i.e., self-compassion) may also be useful in mitigating the harmful effects of self-criticism. Such benefits might conceivably extend to other chronically ill populations in which issues with self-regulation and mood are common. Randomized trials with large sample sizes, an active control group, and longer-term follow-up of both psychological and metabolic outcomes using easily replicable protocols are needed.

In summary, these data show that a standardized, 8-week self-compassion intervention improves both mental health

and metabolic outcomes in patients with diabetes. The increased capacity to be kind and understanding to oneself in the face of difficult feelings may be an important focus for training as part of reducing the suffering linked to depression and distress and improving the key clinical marker of effective diabetes management: HbA_{1c}.

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