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Effects of a Mindfulness-Based Weight Loss Intervention on Long-Term Psychological Well-Being Among Adults with Obesity: Secondary Analyses from the Supporting Health by Integrating Nutrition and Exercise (SHINE) Trial

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Abstract

Objective: This study tested whether a mindfulness-based intervention for obesity that included components aimed at emotion regulation and mindful eating improved psychological outcomes including stress, anxiety, positive emotion, and depression, during the intervention period and at longer-term follow-up.

Methods: Adults with obesity (*N*=194) were randomized to a 5.5-month diet-exercise weight loss intervention with or without mindfulness training focused on emotion regulation and mindful

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Author Contributions

ARH: Contributed to the study conception, analyzed and interpreted the data, and drafted and critically revised the manuscript. SJSH: Contributed to the study conception, assisted with data analysis and interpretation, and drafted and critically revised the manuscript. JD: Designed and executed the study, assisted with data interpretation, and drafted and critically revised the manuscript. PJM: Executed the study and drafted and critically revised the manuscript. WH: Assisted with data analysis and interpretation, and drafted and critically revised the manuscript. MA: Assisted with data management and drafted and critically revised the manuscript. JK: Designed intervention components and critically revised the manuscript. ESE: Designed the study and critically revised the manuscript. AEM: Drafted and critically revised the manuscript. FMH: Designed and executed the study, secured grant funding, and drafted and critically revised the manuscript. Ashley E. Mason and Frederick M. Hecht contributed equally as senior co-authors. All authors have read and approved the final manuscript.

Ethics Statement

All procedures performed in studies involving human participants were approved by University of California, San Francisco in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed Consent Statement

Informed consent was obtained from all individual participants included in the study.

Trial Registration: Clinicaltrials.gov: NCT00960414

Conflict of Interest Statement

The authors declare that they have no conflicts of interest.

eating. Participants completed self-report measures of mindfulness and psychological well-being, which were planned secondary outcomes, at baseline, mid-intervention (3 months), and at 6-, 12-, and 18-months post-baseline (maintenance period). Mixed effects models and linear regression were used to test between- and within-group changes in psychological well-being. Finally, this study explored whether changes in mindfulness (from baseline to each 6- and 18-months post-baseline) mediated the effects of intervention arm on changes in psychological outcomes during those respective time periods. This study explored whether changes in mindfulness from baseline to 6 months mediated the effects of intervention arm on changes in psychological outcomes from baseline to 18 months.

Results: Participants randomized to the mindfulness arm had significant increases in positive emotions at all follow-up times compared to controls. There were statistically significant increases in mindfulness, psychological flexibility, and reflection, as well as decreases in anxiety and depressive symptoms at 12 months compared to control participants. These changes remained significant for psychological flexibility and reflection at 18 months. There were no significant differences in perceived stress. Among mindfulness participants, greater increases in mindfulness from 6–18 months was associated with greater positive emotions and psychological flexibility as well as lower perceived stress, anxiety, depressive symptoms, and rumination at 18 months, adjusting for 6-month values. Mediation analyses indicated that randomization to the mindfulness intervention arm was associated with 6-month increases in mindfulness, and these increases were in turn associated with improved psychological outcomes at 6 months and 18 months. Changes from baseline to 18 months did not mediate 18-month changes in psychological outcomes.

Conclusions: Mindfulness training in emotion regulation and mindful eating may provide greater longer-term psychological well-being benefits in non-clinical populations with obesity compared to conventional diet-exercise interventions.

Keywords

mindfulness; obesity; psychological well-being; randomized controlled trial; depression; anxiety

Recent estimates suggest that more than 37% of American adults meet criteria for obesity, a complex and multifactorial condition with many psychological comorbidities (Flegal et al., 2016). Compared to adults without obesity, individuals with obesity are at a 55% higher risk of developing depression (Luppino et al., 2010). Individuals with excess weight are also at greater risk for symptoms of anxiety (Gariepy et al., 2010) and psychosocial stress (Torres & Nowson, 2007). These psychological states are often exacerbated by pervasive weight stigma and discrimination (Tomiyama et al., 2018). Strengthening emotion regulation skills may improve health behavior change and maintenance (Michie et al., 2011), while increasing positive affect can bolster health behaviors such as physical activity, sleep hygiene, and adherence to medications (Pressman et al., 2019).

Current behavioral weight loss interventions may not adequately address psychological well-being and emotion regulation in this population (Rand et al., 2017). As individuals with obesity may use food as a form of avoidance or as a coping mechanism for distress (Rand et al., 2017), interventions that do not adequately address emotion regulation and psychological well-being may have difficulty maintaining long-term weight reduction in individuals prone

to emotion-related overeating (Rand et al., 2017). Weight loss interventions that focus solely on psychotherapy promote little long-term weight loss, although individuals with obesity who do lose weight experience reduced depressive symptoms (Blaine et al., 2007). These findings suggest that behavioral interventions that target both emotion and eating regulation in individuals with obesity might improve the long-term durability of weight loss and decreased emotion-related eating, as well as providing improvements in psychological well-being.

This study is a secondary analysis of a randomized, controlled trial that tested the effects of adding mindfulness-based intervention components to nutrition and exercise-based strategies for weight loss over a 5.5-month intervention period. The trial followed participants for 1.5 years from the start of the intervention. Prior publications report on changes in weight and metabolic parameters (Daubenmier et al., 2016; Mason et al., 2018). Specifically, comparisons of the mindfulness to control arm favored the mindfulness arm in weight loss at 12 months but these differences were not statistically significant. There were statistically significant between-group differences in changes in fasting glucose at 12 months favoring the mindfulness intervention arm. Subsequent analyses of eating behavior (Mason et al., 2016a; Mason et al., 2016b) found that relative to participants in the control arm, participants in the mindfulness arm had significant reductions in reward-driven eating at 6 months (post-intervention), which, in turn, predicted weight loss at 12 months. Contrary to the original hypotheses, perceived stress did not mediate the effect of intervention arm on weight loss at 12 or 18 months. Additionally, the mindfulness intervention arm, compared to the control intervention arm, had increases in mindful eating, and increases in mindful eating were associated with decreased consumption of sweets and lower fasting glucose.

Although prior reports have focused on weight loss, metabolic outcomes, and eating behavior, this study tested whether the mindfulness-based arm would improve aspects of psychological well-being. Mindfulness-based interventions (MBIs) teach individuals to cultivate present-moment awareness of internal experiences with acceptance and nonjudgment (Kabat-Zinn, 1994). In so doing, MBIs target improved emotion regulation skills and may promote better psychological well-being. The practice of mindful eating aims to enhance awareness and self-regulation of eating behavior as well as thoughts, feelings and sensations that trigger maladaptive eating patterns. A growing literature suggests mindful eating interventions reduce emotional (O'Reilly et al., 2014) and binge eating (Godfrey et al., 2015), yet few studies have examined the effects of mindful eating on psychological well-being outcomes. The studies that have examined these relationships have been either correlational (Winkens et al., 2018) or small in sample size (Dalen et al., 2010). One larger study found that a mindful eating intervention for binge eating decreased depressive symptoms in the intervention compared to the control arm (Kristeller et al., 2014). However, this study only included follow-up at four months. Research is limited on the long-term effects of MBIs in general on psychological well-being; one review found that only 11% (5/47) of studies had follow-up of one year or longer (Goyal et al., 2014). The goal of this analysis is to examine the psychological benefits of including mindfulness-based components in a weight loss program. Additionally, this study tracks psychological well-being outcomes over a year long period after the main intervention period. Because there exist many elements of mindfulness-based stress reduction in this program, the current

analysis may also extend knowledge of the effects of programs which include these elements on psychological outcomes.

The study's indicators of positive psychological well-being were positive emotions, psychological flexibility, and reflection. Positive emotions are beneficial for overall health (Fredrickson, 2004) and psychological flexibility allows for the perspective shifting and goal-setting needed to engage in healthy behavior (Kashdan & Rottenberg, 2010). Reflection is an adaptive form of self-focus motivated by curiosity (Trapnell & Campbell, 1999) that is associated with problem-solving and reduced depression (Treynor et al., 2003). The study's indicators of negative psychological well-being were perceived stress, anxiety and depressive symptoms, and rumination. Perceived stress is associated with harmful health behaviors, disease, and shortened life span (Cohen et al., 1988; Schneiderman et al., 2005). Anxiety and depressive symptoms are also each associated with a host of negative health outcomes (Niles & O'Donovan, 2019), including disordered eating (Singh, 2014) and worsened health status (e.g., Graham-Engeland et al., 2018). Rumination, a perseveration of negative thought content, leads to both symptom magnification and poorer clinical outcomes (Sansone & Sansone, 2012).

The present study hypothesized both that a mindfulness-based weight loss intervention would result in greater increases in positive psychological well-being and greater decreases in negative psychological well-being compared to the control intervention and that improvements in psychological well-being outcomes would be mediated, in part, through increases in mindfulness. The study thus examined between- and within-group changes in self-reported mindfulness and indicators of psychological well-being both during the intervention (from baseline to 3 months) as well as post-intervention (6, 12, and 18-month timepoints).

Methods

Participants

Participants learned about the study via fliers, newspaper advertisements, online postings, and referrals at University of California, San Francisco (UCSF) clinics. Recruitment materials stated the study was a comparison of two weight-loss interventions and each involved a change in diet, exercise, and stress management, and did not specifically advertise that mindfulness would be taught in one of the intervention arms. This was done to mask participants to the hypothesis that mindfulness training would improve psychological and physical health, and to reduce potential disappointment after being assigned to the active control intervention arm. Inclusion criteria included: BMI 30–45.9 kg/m^2, age 18 years or older, abdominal obesity (waist circumference > 102 cm for men and > 88 cm for women). Exclusion criteria included: diabetes (fasting glucose ≥ 126 mg/dL or hemoglobin A1c > 6.5% or between 6.0% and 6.5% with an abnormal oral glucose tolerance test), active bulimia or a strong history of bulimia, a substance use disorder or mental health concern that, in the opinion of the investigators, would make engagement in the group intervention difficult, initiation of a new class of psychiatric medication in the prior two months, currently on a specific weight loss diet, previous mindfulness-based stress reduction

or mindful eating training, and current mindfulness meditation practice. Additional details regarding eligibility criteria can be found elsewhere (Daubenmier et al, 2016).

Researchers enrolled 194 participants in the study and randomized 100 participants to the mindfulness intervention arm and 94 randomized to the active control intervention arm (see Figure 1). Randomization resulted in demographic characteristics and self-reported psychological measures among intervention arms at baseline as noted in Table 1. The sample was predominately female (80% overall).

Procedures

The Supporting Health by Integrating Nutrition and Exercise (SHINE) clinical trial was conducted from July 2009 to October 2013; the detailed protocol and primary outcomes have been reported elsewhere (Daubenmier et al., 2016). The SHINE trial was an individually randomized group-treatment trial in which we randomized participants in a 1:1 ratio to 5.5-month diet-exercise intervention arms with or without mindfulness training. Participants completed assessments at baseline and 3, 6, 12, and 18 months after intervention initiation. A computer-generated random allocation sequence randomized participants; randomization assignments were only revealed to study staff after entering a participant number into a study database. At each assessment time point, participants completed self-report measures using the Survey Monkey web-based questionnaire system. The UCSF Institutional Review Board reviewed and approved study procedures, and all participants provided written informed consent and were compensated for participation in assessments.

Interventions.

In an effort to limit the expectancy effects related to arm assignment, participants were blinded to the exact content of each arm prior to randomization. The trial was described as testing two approaches to weight loss and stress reduction, without mentioning “mindfulness” in the recruitment materials or consent form. Participants randomized to the mindfulness arm only learned about the mindfulness content once the intervention groups began. Intervention group sizes ranged from 10 to 22 participants, with two-thirds of the groups having 15 to 18 participants. Over approximately 5.5 months, the mindfulness intervention groups received 16 two and a half hour sessions (12 weekly, three biweekly, and one monthly) and one additional all-day session. The active control groups received the same number of sessions, but the group sessions were reduced from 2.5 to 2.0 h after session 9 to reduce participant burden while ensuring perceptions of benefit. Both arms received the same diet-exercise guidelines: encouragement of modest calorie reduction (500 kcal/day), decreasing calorically dense, nutrient-poor foods such as refined carbohydrates, and increasing fresh fruits and vegetables, healthy oils, and proteins; and encouragement of increased daily activity. Participants were given pedometers to establish daily average steps and were then instructed to set attainable goals for increasing daily steps. As previously reported (Daubenmier et al., 2016), class attendance was similar for the mindfulness and control arms (74.7% vs. 71.2%, respectively; $p = .55$), as was 18-month retention (81% vs. 71%, respectively; $p = .13$).

Mindfulness intervention.

The mindfulness-based weight loss intervention was modeled after Mindfulness-Based Stress Reduction (MBSR) (Kabat-Zinn, 1990) and utilized several mindfulness practices to target stress management and emotion regulation, eating, and exercise. The mindfulness practices included teaching body scan meditation, mindful yoga, and sitting mindfulness meditation, drawn from how these are taught in MBSR. Mindful eating practices were drawn from the Mindfulness-Based Eating Awareness Training (MB-EAT) program (Kristeller & Wolever, 2011). Mindful eating practices focused on awareness and self-regulation of emotions, physical hunger, stomach fullness, taste satisfaction, food cravings, and other eating triggers in the context of reduced caloric intake (Kristeller et al., 2014; Kristeller & Bowman, 2015). Both intervention arms received guidance on incorporating walking into daily practice for exercise. In the mindfulness groups this included learning mindful walking practices (Dreyer & Dreyer 2006). Home practices included mindfulness exercises, such as sitting meditation, eating mindfully, gentle yoga, and brief “mini-meditations,” which participants were asked to practice about 30 minutes per day. Participants received course material handouts and audio recordings with guided mindfulness practices. Experienced mindfulness instructors and registered dietitians co-led the sessions. Each class session opened with a mindfulness practice (sitting, yoga, or loving kindness meditation) followed by a discussion of the practice and review of progress and challenges over the previous week.

Active control intervention.

Participants in the active control condition received cognitive-behavioral-based methods for stress management, which drew on a standard-of-care weight loss program (Schwartz & Brownell, 2004). Active control participants also received instruction in progressive muscle relaxation (PMR) techniques. Exercise recommendations were similar across arms in amount of activity prescribed, but the active control condition received instruction in strength training with exercise bands rather than mindful walking practices. Didactic material such as discussion of societal issues concerning weight loss matched the time spent in each session with the mindfulness intervention arm. Active control participants also received home activities using course content to control for home practices in the mindfulness intervention arm. Active control participants received handouts and audio recordings with PMR instruction for optional home practice. Registered dietitians led the active control intervention group sessions.

Measures

All participants completed two sets of questionnaires at each timepoint. A questionnaire completed during a clinic visit included measures of mindfulness, positive emotions, perceived stress, anxiety symptoms, and depressive symptoms, and a questionnaire completed at home using Survey Monkey contained psychological flexibility, reflection, rumination, meditation practice and mindful eating measures. As some participants did not complete all questionnaires at a particular time point, the number of participants in each group for whom a self-report measure was available for analysis is specified in Tables 2 and

3. If a time period was specified for a measure (e.g., past two weeks) this is described for the measure

Demographic Variables.

Participants self-reported their age, biological sex, race/ethnicity, and level of education at baseline.

Mindfulness.

The 39-item Five Facet Mindfulness Questionnaire (FFMQ; Baer et al., 2006) measured overall trait mindfulness, and the five statistically established factors over the prior three months. This measure assesses the following facets: (1) Observing Sensations, Perceptions, Thoughts; (2) Describing with Words; (3) Acting with Awareness; (4) Nonjudging of Inner Experience; and (5) Nonreactivity to Inner Experience. Participants responded on a 5-point Likert scale (1 = *never or very rarely true*; 5 = *very often or always true*) and we summed items to create an overall score (as recommended by Baer et al., 2006) and five subscale scores, with higher values indicating higher levels of mindfulness. The FFMQ showed excellent internal consistency at each time point in the present sample (α = .91-.95, ω = .91-.94).

Positive emotions.

The 10-item positive emotions subscale of the Differential Emotions Scale (DES; Izard et al., 1991) assessed the extent to which a participant experienced positive emotions in the prior week. Participants responded on a five-point scale (0 = *not at all*, 4 = *extremely*) and we summed items to create a total score, with higher scores indicating more positive emotions. This scale showed excellent internal consistency in this sample (α = .86-.90, ω = .86-.91).

Psychological flexibility.

The 16-item Acceptance and Action Questionnaire (AAQ-II; Bond et al., 2011) measured psychological flexibility. This scale assesses an individual's capacity to change perspective and adapt to changing situational demands. Participants responded on a seven-point scale (1 = *never true*, 7 = *always true*) and we reverse-scored and summed items to create a total score where lower scores indicated greater psychological flexibility. This questionnaire showed adequate internal consistency across timepoints (α = .75-.80, ω = .75-.81).

Reflection.

The 12-item subscale of the Rumination-Reflection Questionnaire (RRQ; Trapnell & Campbell, 1999) assessed the extent to which a respondent had introspective, self-attentive thought patterns. This subscale measures self-attentiveness motivated by curiosity or interest in the self. Participants responded on a five-point scale (1 = *strongly disagree*, 5 = *strongly agree*) and we summed items to create a total score, with higher scores indicating greater levels of reflection. This scale showed excellent internal consistency in this sample (α = .91-.93, ω = .91-.94).

Perceived stress.

The 10-item version of the Perceived Stress Scale (PSS; Cohen et al., 1983) assessed the extent to which situations in one's life during the prior month are appraised as stressful. Participants responded on a five-point scale (0 = *never*, 4 = *very often*) and we summed items to create a total score, with higher levels indicating greater perceived stress. This scale showed acceptable internal consistency across timepoints (α = .84-.88, ω = .85-.88). Mean scores on the PSS in a general population are 12.1 (SD = 5.9) for men and (13.7 SD = 6.6) for women (Cohen & Janicki-Deverts, 2012).

Anxiety symptoms.

The 20-item State subscale from the State-Trait Anxiety Inventory (STAI; Spielberger et al., 1970) measured anxiety symptomology, fear, and worry. Participants responded on a four-point scale (1 = *almost never*, 4 = *almost always*) and items were summed to create a total score, with higher levels indicating greater levels of anxiety. This scale showed excellent internal consistency in this sample (α = .92-.95, ω = .92-.94).

Depressive symptoms.

The 9-item Patient Health Questionnaire (PHQ-9; Kroenke, 2001) assessed depressive symptoms within the prior two weeks using a four-point scale (0 = *not at all*, 3 = *nearly every day*). Items were summed to create a total score, with higher scores indicating greater severity of depressive symptoms. This scale showed acceptable internal consistency in this sample (α = .79-.86, ω = .86-.95). A 5-point change on the PHQ-9 is considered clinically significant (Kroenke, 2012). The cut off for mild depression is a score of 5 and for severe depression is a score of 10 (Kroenke et al., 2001).

Rumination.

The 12-item rumination subscale of the Rumination-Reflection Questionnaire (RRQ; Trapnell & Campbell., 1999) assessed the extent to which a respondent had repetitive, negative, and self-attentive thought patterns. This subscale measures self-attentiveness motivated by perceived threats, losses, or injustices to the self. Participants responded on a five-point scale (1 = *strongly disagree*, 5 = *strongly agree*) and items were summed to create a total score, with higher scores indicating greater levels of rumination. This scale showed excellent internal consistency in this sample (α = .92-.94, ω = .93-.94).

Data Analyses

Intention-to-treat analysis using observed data from all randomized participants examined between- and within-group changes from baseline to follow-up time points both during the intervention (3 months, mid-intervention) and post-intervention (6-, 12-, and 18-months post-baseline) for all psychological measures. The detailed protocol and primary outcomes have been reported elsewhere (Daubenmier et al., 2016). Linear mixed effects models in STATA v16.1 predicted change in each measure from baseline to 3, 6, 12, and 18 months in separate models. Unadjusted linear mixed effects models included intervention group, time, and their interaction as fixed effects, and person nested within cohort as random effects to account for clustering in this independently randomized group treatment trial. Adjusted

models additionally included sex, race/ethnicity, and education as fixed effects. A decision was made a priori to adjust for biological sex, race/ethnicity, and level of education. This approach was further warranted as a separate analysis evidenced subgroup differences in the primary outcome of the trial (weight loss) based on race/ethnicity and education level (Daubenmier et al., 2020). Adjusted models were compared with unadjusted models to ensure findings are not merely a consequence of covariate inclusion (Simmons et al., 2011). Effect sizes were quantified as Cohen's *d* using standard deviations derived from our mixed model output (Hedges, 2007).

Last, the PROCESS macro for R version 4.0.1 (Model 4; Hayes, 2018) explored whether changes in mindfulness from baseline to post-intervention (6 months; M) mediated the effects of intervention arm (X) on psychological outcomes (Y) at post-intervention (6 months) and the final follow-up timepoint (18 months), residualizing for baseline values, simultaneously (Hayes, 2018). The intervention arm was coded as 0 (active control intervention arm) and 1 (mindfulness intervention arm). As described elsewhere (Hayes, 2018), this study reports the (1) indirect effect of intervention arm (X) on each outcome (Y) through the mediator (M) assessed at 6 months, after including baseline values of M and Y in the model; (2) direct effect of X on Y after including the M and Y assessed at baseline and M at 6 months; and the (3) total effects of X on Y after including M and Y assessed at baseline. PROCESS yields bias-corrected 95% confidence intervals (CIs) using 5000 bootstrapped samples for unstandardized estimates of the indirect and direct effects. Where bootstrapped confidence intervals excluded zero, effects are interpreted as statistically significant.

Results

Between- and Within-Group Changes in Mindfulness

Between-group analyses showed that participants randomized to the mindfulness intervention arm had statistically significantly greater increases in overall mindfulness at 6 and 12 months compared to control participants (Table 2) and significantly greater scores on the *observe* facet at 3, 6, and 12 months and greater scores on the *describe* facet at 12 months. Unadjusted models yielded a greater increase in overall mindfulness and the awareness facet at 3 months in the mindfulness intervention arm compared to the control arm (Table S1). Within-group analyses showed that participants in the mindfulness intervention arm had a statistically significant increase in overall mindfulness at 3, 6, 12, and 18 months relative to baseline (Table 2). These improvements in overall mindfulness were driven primarily by increases in two of the five mindfulness facets: *observe* and *nonjudge*. Active control participants had a statistically significant increase in *observe* from baseline to 18 months and also showed statistically significant increases at each timepoint in *nonjudgement* of inner experience.

Changes in Positive Emotions, Psychological Flexibility, and Reflection

Participants in the mindfulness intervention arm had statistically significantly greater increases in positive emotions at each time point compared to control participants (Table 3 and Figure 2). Mindfulness participants also had statistically significantly greater increases

in psychological flexibility at 3, 12, and 18 months compared to control participants. Similarly, mindfulness participants had greater increases in reflection at 12 and 18 months compared to control participants. Unadjusted models yielded very similar results (Tables S3).

For within-group analyses, mindfulness participants had statistically significant increases in positive emotions at 6, 12, and 18 months and in psychological flexibility at each time point (Table 3 and Figure 2). Control participants reported significantly lower positive emotions at 3 and 12 months, greater psychological flexibility at all time points, and significantly lower reflection at 12 and 18 months. Unadjusted models and follow-up analyses yielded generally similar patterns of results (Tables S3).

Between- and Within-Group Changes in Perceived Stress, Anxiety and Depressive Symptoms, and Rumination

Mindfulness participants had significantly greater decreases in anxiety symptoms at 12 months and point estimates showing similar differences were non-significant at 18 months compared to control participants (Table 3 and Figure 3). Mindfulness participants had greater reductions in depressive symptoms compared to control participants at 12 months. Notably, both sets of PHQ-9 score averages were well below the cutoff score for high risk for major depressive disorder (Table 1; Kroenke et al., 2001).

For within-group analyses, participants in the mindfulness intervention arm had significant decreases in perceived stress at 6 months, and significant decreases in anxiety and depressive symptoms, as well as rumination at each time point (Table 3 and Figure 3). Control participants had significant decreases in anxiety symptoms at 3, 6, and 18 months, decreases in depressive symptoms at 3 and 6 months, and rumination at each follow-up time point. Unadjusted models and sensitivity analyses demonstrated similar patterns of significance (Tables S3).

Changes in Mindfulness as Potential Mediators of the Effect of Intervention on Psychological Outcomes at 6 and 18 Months

Changes in overall mindfulness from baseline to 6 months mediated the effects of intervention group such that participants randomized to the mindfulness intervention group reported increases in mindfulness that were in turn associated with improvements in several psychological outcomes at 6 months (see indirect effects for each outcome in Table 4). Specifically, greater increases in mindfulness were associated with decreases in perceived stress, decreases in depressive symptoms, increases in reflection, and increases in positive emotions, decreases in anxiety symptoms, decreases in rumination, and increases psychological flexibility at 6 months.

Changes in mindfulness from baseline to 6 months also mediated the effects of intervention group at 18 months such that participants randomized to the mindfulness intervention group experienced increases in mindfulness that were in turn associated with improvements in all psychological outcomes (Table S4).

Discussion

This study examined the long-term impact of adding mindfulness meditation and mindful eating training to a diet-exercise weight loss program on self-reported mindfulness and aspects of positive and negative psychological well-being among adults with obesity compared to a diet-exercise active control intervention. Participants in the mindfulness intervention arm reported statistically significantly greater increases in mindfulness, positive emotions, psychological flexibility, and reflection post-intervention compared to participants in the active control intervention arm at multiple time points. Most of these differences between intervention arms remained statistically significant out to 1 year after the end of the intervention period, suggesting these benefits were durable. In contrast, there were fewer statistically significant between-group differences in indicators of negative psychological well-being (i.e., perceived stress, and rumination). However, there were statistically significant reductions at 12 months for anxiety and depressive symptoms in the mindfulness intervention arm compared with the control intervention arm.

As hypothesized, participants in the mindfulness intervention arm had greater increases in overall mindfulness at 6 and 12-months post-baseline compared to control participants. This is consistent with prior research on changes in self-report measures of mindfulness in MBIs (Keng et al., 2011). These differences were driven primarily by the *observe* and *describe* facets, especially at the 12-month time point; however, by 18 months, the effects were diminished. These facets assess how we see, feel, and perceive the internal and external world and the way we label our experiences and express them in words (Baer et al., 2006). Components of the MB-EAT program included in mindfulness intervention arm specifically focused on cultivating attention toward sensory information related to food, eating-related sensations, and emotions. For example, participants were encouraged to notice physical hunger, taste satisfaction, cravings, fullness sensations, thoughts and feelings while eating, and observe flavor and texture preferences. Participants also discussed their experiences in a group context to describe and express their experiences (Kristeller & Wolever, 2011). Thus, the mindfulness facets of *observe* and *describe* were expected to increase compared to the active control intervention.

Although participants in the mindfulness intervention arm had greater increases in the summed mindfulness facets during the intervention period as well as at 12 months, this was not statistically significant at 18 months. This appeared to be driven by an increase in the mindfulness measure from 12 to 18 months in the control intervention arm. Participants in the active control were given a mind-body practice of progressive muscle relaxation training, which was related to improvements in sleep quality (Adler et al., 2017). It is possible that elements of the active control intervention might account for some increases in mindfulness on our self-report measure.

As hypothesized, the mindfulness intervention arm reported greater increases than the control intervention arm in psychological flexibility at 3, 12 and 18 months, as well as in positive emotions at every time point. Prior work examining the theoretical foundations of mindfulness suggests that the present moment awareness and approach-oriented attentional focus fostered by mindfulness interrupts automatic reactions and facilitates the flexible

generation of novel situational appraisals (Farb et al., 2014). Considering this mechanistic framework, it is plausible that our mindfulness-based intervention could have strengthened flexible responses toward changing environmental demands, a fundamental aspect of psychological well-being (Kashdan & Rottenberg, 2010).

The improvements observed in positive emotions have potential implications for health and well-being (Fredrickson, 2004; Pressman et al., 2019). Although a meta-analysis did not find statistically significant evidence for the beneficial effect of meditation programs on positive mood (Goyal et al., 2014), other research suggests that mindfulness training may stimulate an upward spiral of positive affect (Garland et al., 2015) with long-term increases in positive affectivity (Garland et al., 2017) and increased subjective well-being up to 6 years post-intervention (de Vibe et al., 2018). A limitation of the meta-analysis is that it included a range of meditation-based interventions, some of which were mindfulness-based and some of which were mantra-based. Given the greater emphasis on emotion regulation skills in most mindfulness-based programs, this may have diluted the ability to observe benefits in positive emotion in the meta-analysis (Guendelman et al., 2017). Recent randomized controlled trials also provide experimental evidence that positive emotions may increase following mindfulness training and posit that this effect is the result of developing acceptance toward present-moment experiences (Lindsay et al., 2018). Our findings support prior research suggesting that mindfulness training promotes adaptive emotion regulation and positive psychological processes integral to health (Farb et al., 2014; Garland et al., 2015). A recent analysis of stress reactivity from the SHINE trial (Daubenmier et al., 2019) found that the mindfulness intervention arm increased adaptive psychological and cardiovascular stress responsiveness.

As noted, the mindfulness participants experienced decreases in depressive symptoms and anxiety at 12 months, but these differences were not statistically significant at 18 months. The mindfulness intervention components in this study targeted stress management, healthy eating, and exercise, and did not specifically focus on anxiety and depression, nor did the study specifically recruit participants selected to be high in depression or anxiety symptoms. This likely led to some floor effects, in which there was limited room for improvement for some participants. For example, although obesity is generally associated with higher risk of psychological distress, this sample had, on average, lower PSS scores than national averages (Cohen & Janicki-Deverts, 2012), and average PHQ-9 scores comparable to those of the general population (Kocalevent et al., 2013). Further research might better assess the issue of whether incorporating mindfulness training into diet-exercise weight loss programs for individuals with obesity improves anxiety and depression by focusing on participants who have been diagnosed with or are at high risk for anxiety and depression.

Limitations and Future Research

Despite many strengths in this study, including its size, rigorous active control condition, and long duration of follow-up with good participant retention, our study has several methodological limitations. First, participants completed self-report measures to assess all psychological well-being outcomes. Participants completed batteries of self-report measures at each assessment period, and this may have introduced common method bias (Podsakoff

et al., 2012). Of particular relevance for these analyses, self-report measures are known to introduce biases such as social desirability (Arnold & Feldman, 1981), and it is possible that participants responded in ways that they believed the investigators wanted them to respond.

Second, participants were masked to the content of arm they were not randomized to, which was aimed at minimizing bias due to participant perception of whether they were in a less desirable intervention arm. Future studies may benefit from clinician and community observer ratings of participant psychological functioning.

Third, this was primarily a weight-loss, not a psychological well-being, intervention. A mindfulness-based intervention aimed more specifically at improving psychological well-being in a clinical population may have shown stronger effects on psychological outcomes. Although the study included a relatively large sample size, it may not have been large enough to detect benefits that would have health and quality of life implications with statistically significant results. This is particularly true with outcomes such as stress, depression, and anxiety, where there were likely floor effects from studying a population with limited psychological distress.

Statistical testing did not include adjustment for multiple tests (e.g., Bonferroni adjustments), in part because the outcomes examined were pre-specified hypotheses. Approaches such as Bonferroni corrections, particularly with pre-specified hypotheses, have been shown to increase the risk of type II error (concluding that there is not benefit when there truly is benefit; see Perneger, 1998). The overall pattern of results with multiple outcomes is important to assess, as has been advocated by many methodological experts (Bacchetti, 2002). In this case, the consistent direction of findings using various measures of positive and negative psychological outcomes helps to reinforce confidence in the findings, rather increasing the likelihood of chance as explanation. However, the conclusions should still be viewed with caution until there is further replication from other studies.

There is support for our hypothesis that participants in a mindfulness-based diet and exercise weight loss intervention would increase in mindfulness and positive psychological well-being such as positive emotions compared to an active control arm. Data demonstrated limited evidence that the mindfulness intervention improved measures of negative psychological well-being. Finally, results suggested relatively durable effects on positive psychological well-being out to 18 months after intervention initiation.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Data Availability Statement

All data are available at the Open Science Framework (https://osf.io/yh4cb/).

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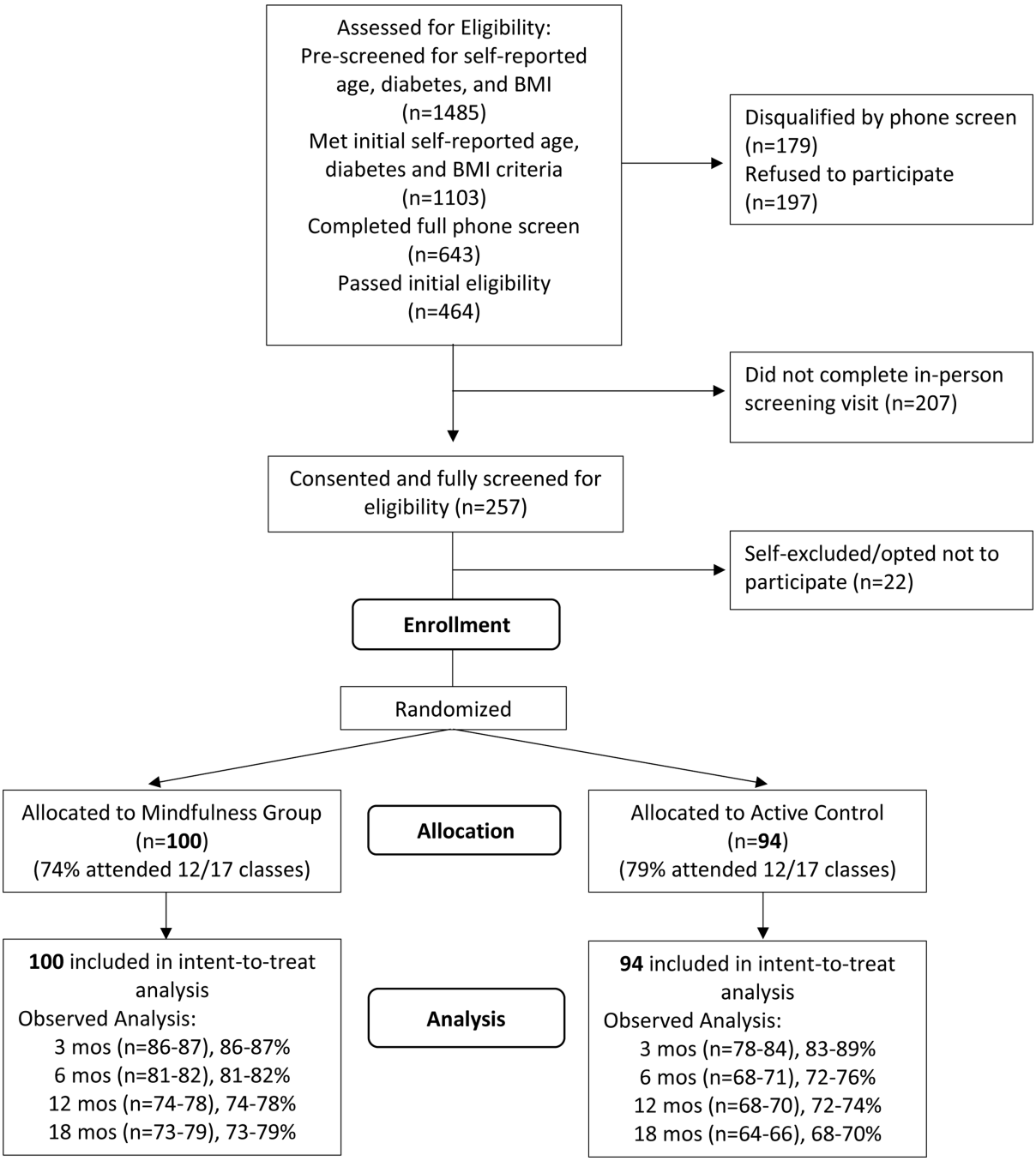

Figure 1.
Participant Recruitment, Randomization, and Follow-up

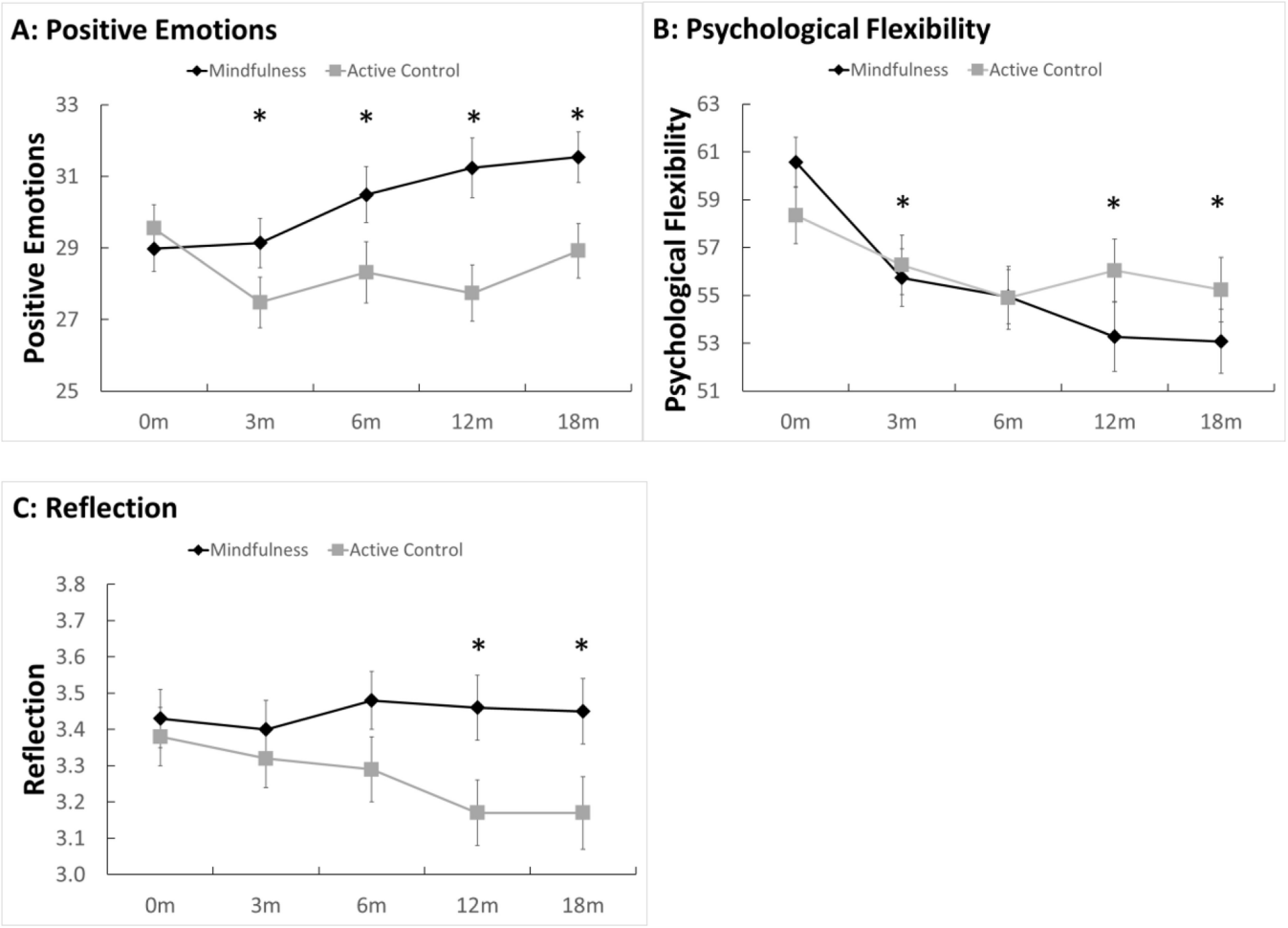

Figure 2.

Changes in Positive Psychological Well-being Over Time

Note. Each panel shows changes from trial initiation in positive psychological well-being measures, with the control group in gray lines and the mindfulness group in black lines. Standard error bars are shown. Panel A shows changes in positive emotions, panel B shows changes in psychological flexibility, and panel C shows changes in reflection. See Table 3 for statistical tests at different time points. m=months.

*p<0.05 for between-group difference in mindfulness and control participants

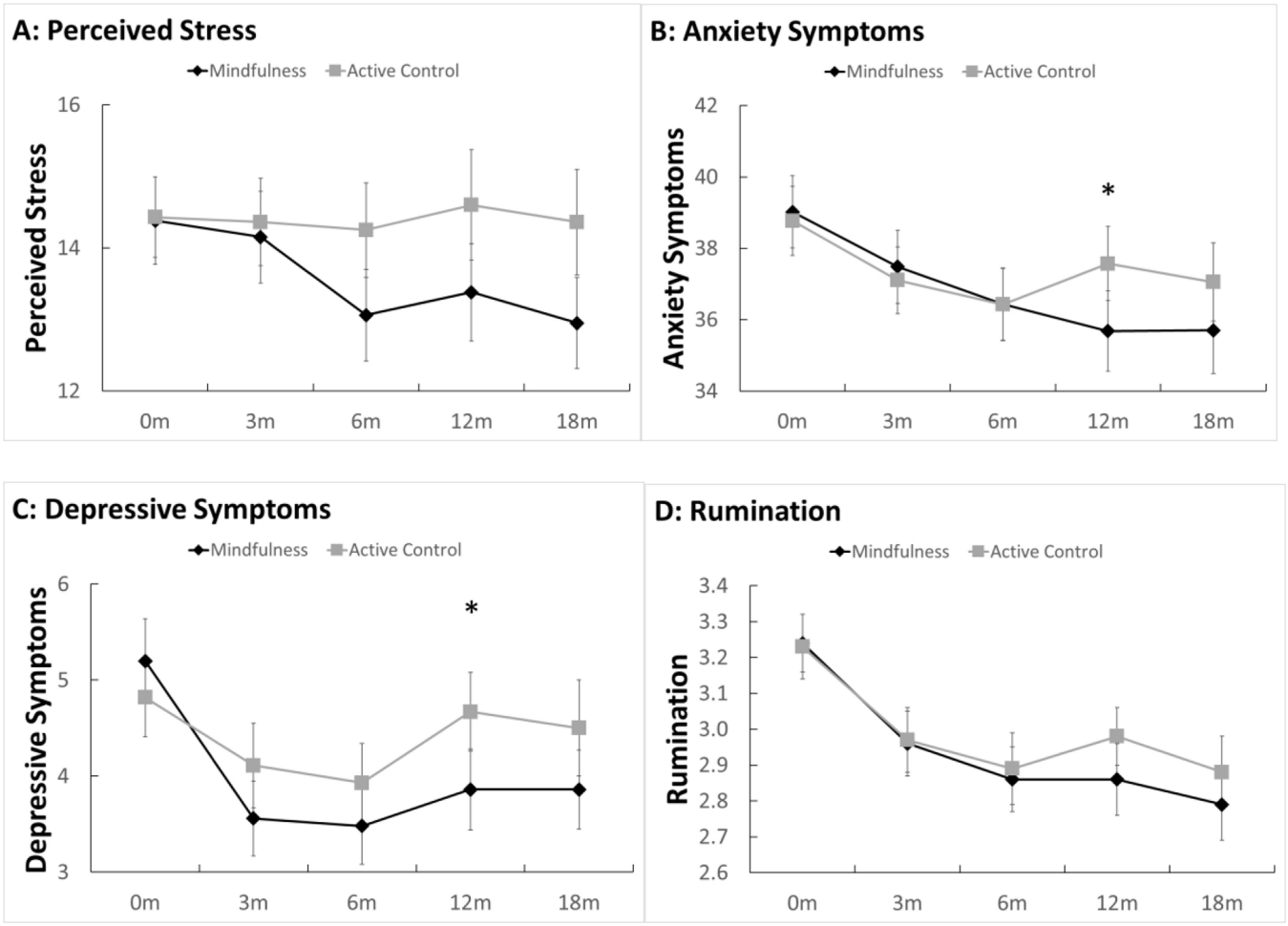

Figure 3.

Changes in Negative Psychological Well-being Over Time

Note. Each panel shows changes from trial initiation in negative psychological well-being measures, with the control group in gray lines and the mindfulness group in black lines. Standard error bars are shown. Panel A shows changes in perceived stress, panel B shows changes in anxiety symptoms, panel C shows changes in depressive symptoms, panel D shows changes in rumination (m=months). See Table 3 for statistical tests at different time points.

*p<0.05 for between-group difference in mindfulness and control participants

Table 1

Baseline Characteristics of Study Participants

Characteristic	Mindfulness (*n*=100)	Active Control (*n*=94)
	Mean (SD) or % (*n*)	
Demographic Characteristics		
Age, years	47 (13)	47 (12)
Female	79% (79)	81% (76)
Ethnicity		
White	65% (65)	53% (50)
Black	13% (13)	13% (12)
Latina/o	7% (7)	17% (16)
Asian/Pacific Islander	8% (8)	12% (11)
Native American	0% (0)	2% (2)
Other	7% (7)	3% (3)
Education attained		
Bachelor's degree or higher[a]	70% (69)	60% (56)
Body mass index	35.4 (3.5)	35.6 (3.8)
Prior meditation practice[b]	9% (9)	4% (4)
Anti-depressant medication use	17% (17)	17% (16)
Mindfulness		
Mindfulness, Overall	137.6 (17.5)	138.7 (19.7)
Observe	27.7 (4.8)	26.7 (5.6)
Awareness	28.0 (5.6)	27.8 (6.5)
Describe	29.3 (5.4)	30.4 (5.9)
Nonjudge	30.1 (6.7)	30.8 (6.3)
Nonreactivity	22.6 (4.5)	22.9 (4.6)
Positive Psychological Well-Being		
Positive emotions	29.0 (6.4)	29.5 (6.4)
Psychological flexibility	60.6 (10.5)	58.4 (11.5)
Reflection	3.4 (0.8)	3.4 (0.7)
Negative Psychological Well-Being		
Perceived stress	14.4 (6.1)	14.4 (5.5)
Anxiety symptoms	39.0 (10.0)	38.8 (9.4)
Depressive symptoms	5.2 (4.3)	4.8 (4.0)
Rumination	3.2 (0.8)	3.2 (0.8)

Note.

[a]One participant in the mindfulness intervention arm was missing education data. This same participant was also missing baseline data for mindfulness, perceived stress, anxiety and depressive symptoms, and negative and positive emotions.

[b]Responded affirmatively to the question "*In the past month, have you practiced meditation?*". SD=Standard deviation.

Table 2

Between- and Within-Group Changes in Mindfulness Measures from Baseline to Follow-Up

	N	Mean (SE) change				
Measure	**M, C**	**Mindfulness**	**Active Control**	**Difference (M-C), mean (95% CI)**	***P* value**	**Effect size**
Mindfulness (Overall)						
3m	88, 84	4.58 (1.30)*	0.98 (1.33)	3.60 [−0.07, 7.27]	.06	0.19
6m	82, 71	6.04 (1.33)*	1.72 (1.41)	4.32 [0.50, 8.13]	.03	0.23
12m	79, 70	7.06 (1.36)*	1.13 (1.42)	5.93 [2.07, 9.79]	.003	0.32
18m	81, 66	6.36 (1.34)*	3.72 (1.45)*	2.64 [−1.26, 6.53]	.18	0.14
Observe						
3m	88, 84	2.40 (0.42)*	0.37 (0.43)	2.03 [0.84, 3.23]	.001	0.39
6m	82, 71	1.97 (0.43)*	0.44 (0.46)	1.53 [0.29, 2.77]	.02	0.29
12m	79, 70	1.87 (0.44)*	0.27 (0.46)	1.60 [0.34, 2.85]	.01	0.30
18m	81, 66	1.72 (0.44)*	1.00 (0.47)*	0.73 [−0.54, 1.99]	.26	0.14
Describe						
3m	88, 84	−0.28 (0.41)	−0.62 (0.41)	0.34 [−0.79, 1.47]	.55	0.06
6m	82, 71	0.42 (0.42)	−0.54 (0.43)	0.96 [−0.22, 2.14]	.10	0.17
12m	79, 70	1.06 (0.42)*	−0.56 (0.44)	1.62 [0.43, 2.81]	.01	0.29
18m	81, 66	0.93 (0.41)*	0.15 (0.45)	0.78 [−0.42, 1.98]	.20	0.14
Awareness						
3m	88, 84	0.43 (0.44)	−0.55 (0.45)	0.97 [−0.28, 2.22]	.13	0.17
6m	82, 71	0.52 (0.45)	0.28 (0.48)	0.24 [−1.06, 1.54]	.72	0.04
12m	79, 70	0.58 (0.46)	0.07 (0.48)	0.51 [−0.80, 1.82]	.44	0.09
18m	81, 66	0.34 (0.46)	0.20 (0.49)	0.13 [−1.19, 1.46]	.84	0.02
Nonjudge						
3m	88, 84	1.86 (0.49)*	1.68 (0.50)*	0.19 [−1.19, 1.56]	.79	0.03
6m	82, 71	2.80 (0.50)*	1.82 (0.53)*	0.97 [−0.46, 2.40]	.18	0.16
12m	79, 70	3.02 (0.51)*	1.60 (0.53)*	1.41 [−0.04, 2.86]	.06	0.24
18m	81, 66	2.54 (0.50)*	1.85 (0.54)*	0.69 [−0.77, 2.16]	.35	0.12
Nonreactivity						
3m	88, 84	0.21 (0.38)	0.08 (0.39)	0.13 [−0.94, 1.20]	.82	0.03
6m	82, 71	0.42 (0.39)	−0.31 (0.41)	0.73 [−0.39, 1.84]	.20	0.16
12m	79, 70	0.63 (0.40)	−0.29 (0.41)	0.93 [−0.20, 2.05]	.11	0.21
18m	81, 66	0.93 (0.39)*	0.48 (0.42)	0.44 [−0.69, 1.58]	.44	0.10

Note. Mindfulness was measured with the FFMQ. Intent-to-treat analysis using adjusted linear mixed effects models, which included intervention group, time, their interaction, and covariates (education, race/ethnicity, and gender variables) as fixed effects, and person and a person-cohort round

interaction term as random effects to adjust for clustering. M=mindfulness, C= control, SE=Standard Error, CI = Confidence Interval, Effect size= Calculated Cohen's *d*.

* $p<0.05$ for within-group change in Mindfulness and Control participants

Table 3

Between- and Within-Group Changes in Psychological Well-Being from Baseline to Follow-Up

	N	Mean (SE) change				
Measure	**M, C**	**Mindfulness**	**Active Control**	**Difference (M-C), mean (95% CI)**	***P* value**	**Effect Size**
Positive Psychological Well-Being						
Positive emotions						
3m	88, 84	0.35 (0.63)	−2.03 (0.64)*	2.38 [0.61, 4.15]	.01	0.37
6m	82, 71	1.31 (0.64)*	−1.04 (0.68)	2.35 [0.51, 4.19]	.01	0.36
12m	79, 70	2.41 (0.65)*	−1.52 (0.68)*	3.93 [2.08, 5.79]	<.001	0.61
18m	81, 66	2.39 (0.65)*	−0.29 (0.70)	2.68 [0.80, 4.55]	.01	0.42
Psychological flexibility						
3m	87, 78	−4.55 (0.86)*	−2.00 (0.91)*	−2.55 [−5.02, −0.08]	.04	−0.23
6m	82, 68	−5.02 (0.88)*	−4.13 (0.95)*	−0.89 [−3.44, 1.66	.49	−0.08
12m	73, 68	−6.69 (0.92)*	−3.07 (0.95)*	−3.62 [−6.23, −1.01]	<.01	−0.33
18m	79, 66	−6.58 (0.90)*	−3.76 (0.96)*	−2.81 [−5.41, −0.22]	.03	−0.26
Reflection						
3m	87, 78	−0.002 (0.05)	−0.02 (0.05)	0.02 [−0.12, 0.16]	.77	0.03
6m	82, 68	0.05 (0.05)	−0.02 (0.05)	0.07 [−0.08, 0.21]	.37	0.09
12m	74, 68	0.03 (0.05)	−0.14 (0.05)*	0.16 [0.01, 0.31]	.03	0.21
18m	79, 66	0.01 (0.05)	−0.18 (0.06)*	0.19 [0.04, 0.34]	.01	0.25
Negative Psychological Well-Being						
Perceived stress						
3m	88, 84	−0.23 (0.54)	−0.14 (0.55)	−0.09 [−1.61, 1.43]	.91	−0.02
6m	82, 71	−1.09 (0.55)*	−0.22 (0.58)	−0.87 [−2.45, 0.71]	.28	−0.15
12m	79, 70	−0.77 (0.56)	0.12 (0.59)	−0.89 [−2.48, 0.71]	.28	−0.15
18m	81, 66	−0.99 (0.56)	−0.12 (0.60)	−0.87 [−2.48, 0.74]	.29	−0.15
Anxiety symptoms						
3m	88, 84	−1.47 (0.66)*	−1.54 (0.68)*	0.06 [−1.80, 1.93]	.95	0.01
6m	82, 71	−2.33 (0.68)*	−2.18 (0.72)*	−0.15 [−2.09, 1.79]	.88	−0.02
12m	79, 70	−3.38 (0.69)*	−1.28 (0.72)	−2.11 [−4.08, −0.15]	.04	−0.23
18m	81, 66	−3.16 (0.68)*	−1.56 (0.74)*	−1.60 [−3.58, 0.38]	.11	−0.17
Depressive symptoms						
3m	88, 84	−1.67 (0.37)*	−0.81 (0.38)*	−0.86 [−1.92, 0.20]	.11	−0.23
6m	82, 71	−1.78 (0.38)*	−0.95 (0.41)*	−0.83 [−1.93, 0.27]	.14	−0.22
12m	79, 70	−1.42 (0.39)*	−0.16 (0.41)	−1.26 [−2.37, −0.14]	.03	−0.33
18m	81, 66	−1.29 (0.39)*	−0.35 (0.42)	−0.94 [−2.07, 0.18]	.10	−0.25
Rumination						

	N	Mean (SE) change				
Measure	**M, C**	**Mindfulness**	**Active Control**	**Difference (M-C), mean (95% CI)**	***P* value**	**Effect Size**
3m	87, 78	−0.28 (0.06)*	−0.24 (0.07)*	−0.03 [−0.22, 0.15]	.74	−0.04
6m	82, 68	−0.40 (0.07)*	−0.33 (0.07)*	−0.06 [−0.26, 0.13]	.51	−0.08
12m	74, 68	−0.42 (0.07)*	−0.26 (0.07)*	−0.16 [−0.35, 0.04]	.11	−0.20
18m	79, 66	−0.44 (0.07)*	−0.36 (0.08)*	−0.08 [−0.27, 0.11]	.42	−0.10

Note. Adjusted linear mixed effects models included intervention group, time, their interaction, covariates (sex, race/ethnicity, education) as fixed effects, and person and a person-cohort interaction as random effects. See Table 2 note.

Table 4

Total, Direct, and Indirect Effects from Models Testing Changes in Mindfulness as a Mediator of the Effects of Intervention Arm on Psychological Outcomes Assessed at 6 Months

Outcome	Effect	Coefficient (b)	SE (b)	95% CI (lower, upper)
Psychological Stress (PSS)	Total	−1.19	0.72	−2.60, 0.23
	Direct	−0.51	0.68	−1.91, 0.83
	Indirect	−0.68	0.28	−1.29, −0.16
Depressive Symptoms (PHQ-9)	Total	−0.59	0.49	−1.55, 0.37
	Direct	−0.20	0.47	−1.17, 0.67
	Indirect	−0.39	0.18	−0.77, −0.08
Anxiety Symptoms (STAI)	Total	−0.35	0.96	−2.24, 1.54
	Direct	1.24	0.74	−0.20, 2.68
	Indirect	−1.59	0.61	−2.82, −0.38
Psychological Flexibility (AAQ-II)	Total	−0.68	1.18	−3.02, 1.65
	Direct	0.75	1.08	−1.30, 2.83
	Indirect	−1.43	0.57	−2.65, −0.42
Rumination (RRQ-Rumination)	Total	−0.06	0.10	−0.25, 0.14
	Direct	0.05	0.09	−0.14, 0.23
	Indirect	−0.10	0.05	−0.21, −0.03
Reflection (RRQ-Reflection)	Total	0.09	0.08	−0.07, 0.24
	Direct	0.06	0.08	−0.09, 0.21
	Indirect	0.03	0.02	0.00, 0.07
Positive Emotions (DES)	Total	2.34	0.97	0.43, 4.25
	Direct	1.36	0.91	−0.47, 3.15
	Indirect	0.98	0.39	0.24, 1.78

Note. We report unstandardized results of 5,000 bootstrapped samples to generate bias-corrected 95% asymmetrical confidence intervals around the indirect and direct effects (see Method); PROCESS outputs OLS standard errors and 95% CIs for the total effects. Total effects represent the effects of intervention arm on each outcome at 6 months when including the outcome assessed at baseline in the model. Direct effects represent the effects of intervention arm on the outcome at 6 months after including the outcome at baseline and the mediator assessed at baseline and at 6 months, in the model. Indirect effects represent the mediated effect of intervention arm on the outcome at 6 months, through the mediator assessed at 6 months, after including baseline values of the outcome and the mediator in the model. PROCESS does not output bootstrapped p-values; confidence intervals around the estimate that do not include 0 are statistically significant (p<.05).