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# Mindfulness-Based College: A Stage 1 Randomized Controlled Trial for University Student Well-Being

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## ABSTRACT

**Objective:** To evaluate effects of a mindfulness-based program, adapted to the young adult life course stage (age, 18–29 years), named Mindfulness-Based College (MB-College). The primary outcome was a young adult health summary score, composed of key health risk factors: body mass index, physical activity, fruit and vegetable intake, alcohol consumption, stress, loneliness, and sleep duration. Secondary outcomes were hypothesized self-regulation mechanisms, including attention control, interoceptive awareness, and emotion regulation.

**Methods:** This was a stage 1 randomized controlled trial of the 9-week MB-College program ( $n = 47$ ) versus enhanced usual care control ( $n = 49$ ) including students from three universities. Assessments were at baseline, during the beginning of the college term when stress is typically lower, and at MB-College completion (3-month follow-up), when term-related stress is typically higher. Intention-to-treat, linear regression analyses estimated the marginal effects of MB-College versus control on the outcomes.

**Results:** MB-College participants (mean age = 20 years, 68% female, 37% racial minorities) demonstrated improved health summary scores at follow-up compared with control participants whose health summary scores worsened (marginal effect for MB-College versus control = 0.23;  $p = .004$ ). Effects on loneliness were pronounced (marginal effect =  $-3.11$  for the Revised University of Los Angeles Loneliness Scale score;  $p = .03$ ). Secondary analyses showed significant impacts of MB-College on hypothesized self-regulation mechanisms (e.g., Sustained Attention to Response Task correct no-go percent,  $p = .0008$ ; Multidimensional Assessment of Interoceptive Awareness,  $p < .0001$ ; Center for Epidemiologic Studies—Depression scale,  $p = .03$ ).

**Conclusions:** Findings of this early stage clinical trial suggest that MB-College may foster well-being in young adults.

**Trial Registration:** NCT03124446

**Key words:** mindfulness, meditation, clinical trial, college, young adult, behavioral medicine.

## INTRODUCTION

Over the last 50 years, there have been many shifts in young adults. They spend more time in higher education (1). They also marry and have children later (1). The young adult stage, sometimes referred to as “emerging adulthood,” which spans 18 to 29 years of age, has higher risk-taking behavior, exploration, psychiatric disorders, and adverse health behaviors than did prior generations (1,2). Indeed, young adults’ mental illnesses increased in recent decades, including anxiety and depression (3). For physical health, obesity recently doubled (4), and half of young adults exercise below national recommendations (5). Furthermore, one-third of college students binge drink (6). Sleep difficulties considered “traumatic” or “very difficult to handle” rose by 30% between 2009 and 2017 (7). In addition, many young adults have often

recently left home and do not yet have long-term romantic relationships or children; consequently, loneliness is high: up to 71% feel lonely “sometimes” or “often” (2,8). Sadly, mortality rates climbed 38% in American young adults from 2011 to 2017 (9).

**AE** = adverse events, **BAI** = Beck Anxiety Inventory, **CESD-R** = Revised Centers for Epidemiologic Studies—Depression scale, **CONSORT** = Consolidated Standards of Reporting Trials, **MAAS** = Mindful Attention Awareness Scale, **MAIA** = Multidimensional Assessment of Interoceptive Awareness, **MB-College** = Mindfulness-Based College, **MBSR** = Mindfulness-Based Stress Reduction, **MET** = metabolic equivalent, **PSQI** = Pittsburgh Sleep Quality Index, **PSS-10** = 10-item Perceived Stress Scale, **RCT** = randomized controlled trial, **R-UCLA** = revised University of California, Los Angeles scale, **SAE** = serious adverse events, **SART** = Sustained Attention to Response Task

## SDC Supplemental Digital Content

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Overall, many young adults are struggling with numerous health issues that are on the rise. Much of this takes place on college campuses.

Young adulthood is a unique time in the life course to intervene with behavioral interventions, because the prefrontal cortex is still developing and habits are being formed. For example, Gogtay et al. (10) demonstrated that cortical development of gray matter density continued into early adulthood, using prospective serial dynamic anatomic magnetic resonance imaging sequencing. Brain regions involved in executive function, attention, and motor coordination are some of the last to mature and are also engaged by mindfulness interventions (10,11). Furthermore, young adults are often leaving their parental home and identifying their life's path, creating opportunities to establish healthy developmental trajectories (4). Support from health care systems and interventions is limited, as many have not yet adapted to the differences between people aged 18 and 29 years compared with adolescents and mature adults (1,4). This is particularly true for care relevant to the risk-related behaviors and psychiatric disorders described previously (1,4).

Evidence is growing that mindfulness programs hold promise as behavioral interventions during young adulthood (12). Mindfulness has been defined as involving a) "... the self-regulation of attention so that it is maintained on immediate experience..." and b) "...adopting a particular orientation toward one's experiences in the present moment... characterized by curiosity, openness, and acceptance" (13). Numerous randomized controlled trials, summarized in a recent systematic review and meta-analysis of 51 randomized controlled trials, suggest that mindfulness programs delivered to college students significantly improve outcomes such as distress, depression, and state anxiety symptoms, compared with inactive controls (12). Effect of mindfulness programs compared with active controls (e.g., relaxation and self-awareness strategies including guided imagery, restful breathing, and muscle relaxation; restructuring thinking patterns; or health education programs) are typically less strong than inactive controls (12). A major gap identified in the systemic review was methodological quality, including lack of adverse event (AE) monitoring (73% of studies), random sequence generation (55% of studies), and allocation concealment (77% of studies) (12). Furthermore, many studies had incomplete outcome data (47% of studies) and selective reporting (88% of studies) (12). Mechanisms have been minimally explored (12). Finally, most mindfulness research in young adults has focused on mental health, whereas little is known about impacts on health behaviors (e.g., diet and sleep), social health (e.g., loneliness), or physical health (e.g., body mass index) (12,14,15). The current study aimed to fill these gaps by rigorously evaluating a mindfulness-based program adapted to young adults, called Mindfulness-Based College (MB-College), using a young adult health summary score composed of physical, mental, behavioral, and social health outcomes.

As we developed the MB-College curriculum, research has shown that young adults focus strongly on their peers, so having more opportunities for partner and small-group sharing was important (16). Identity formation is a major feature of this life phase, experimenting with possibilities of what type of person to be and what kind of life to live, including the areas of intimate relationships, career, and ideology (1,16). Mindfulness programs offer a supportive container to explore identity formation. Young adulthood involves a strong self-focus that relates to their stress and social relationships (16). This age group is experimenting with health

behaviors that could last a lifetime (16,17). As a result, we adapted the evidence-based Mindfulness-Based Stress Reduction (MBSR) program (18,19) to the young adult life stage. In doing so, we hypothesized that a program adapted to young adults would be successful through a) training mindfulness skills such as attention control, self-awareness, and emotion regulation using the MBSR curriculum, and b) applying these skills to the health behaviors and priorities most relevant to young adults. Specifically, the behaviors and priorities targeted were the following: social relationships, sleep, stress, diet, physical activity, obesity, alcohol consumption, substance use, and performance (e.g., athletic, artistic, and academic). Our approach met young adults where they are developmentally, using approaches such as peer group and partner sharing, digital access to mindfulness practices, direct experiential learning such as for physical activity and diet, and teachers who directly relate to and are accessible by young adults. Figure 1 shows the theoretical framework of MB-College and is based on a consensus theoretical framework described elsewhere (20).

The primary objective of this stage 1 randomized controlled trial was to evaluate effects of MB-College on young adult health. The primary outcome, registered a priori on ClinicalTrials.gov (Registration No. NCT03124446), was a young adult health summary score composed of mean standardized scores of key health risk factors that predict mortality, cardiovascular disease, and depression (21): health behaviors (physical activity using International Physical Activity Questionnaire—assessed total metabolic equivalent (MET)-minutes per week (22), diet using fruit and vegetable intake from Harvard 80-item food frequency questionnaire (23), alcohol consumption using the Behavioral Risk Factor Surveillance Survey questionnaire (24), sleep duration using the Pittsburgh Sleep Quality Index [PSQI] (25)), mental health (distress, using the Perceived Stress Scale-10 [PSS-10] score) (26), social health (loneliness assessed using the revised University of California, Los Angeles [R-UCLA] Loneliness Scale) (27), and physical health (directly-assessed body mass index). Secondary analyses evaluated the impacts of MB-College on each individual validated young adult health summary score subcomponent measure. We hypothesized that MB-College would improve the young adulthood health score at 3-month follow-up assessment compared with an enhanced usual care control group. Secondary mechanistic outcomes were attention control, self-awareness, and emotion regulation, described in the theoretical framework shown in Figure 1.

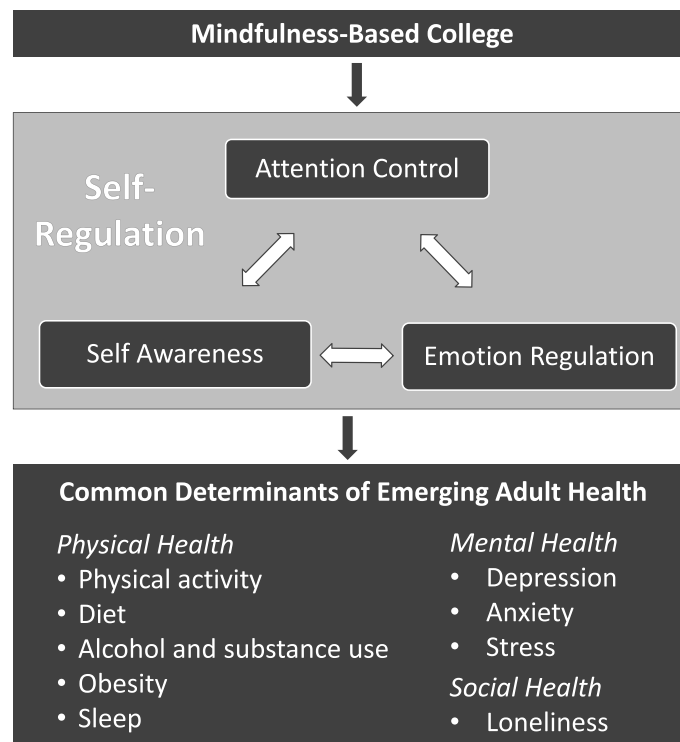
## METHODS

This was a randomized controlled trial of MB-College versus enhanced usual care control ( $n = 96$ ). Assessments were performed at baseline, during the beginning of the college term when stress is typically lower, and within 3 weeks after MB-College completion (on average, 3 months after baseline assessment) when stress is typically higher, nearing the end of term when final examinations are approaching, and term papers are due.

## Study Sample Description

Participant recruitment occurred from 2016 to 2018. Follow-up assessments were completed in June 2018. Recruitment sources were e-mail and digital listservs (45% of participants); referral from friends, classmates, or other person (21% of participants); study flyers (18%); social media (e.g., Facebook and Twitter; 12%); and other (4%).

Participants were included if they were a) 18 to 28 years of age; b) currently matriculated undergraduate students at any university; and c) able to read, write, and speak in English. Exclusion criteria were the following: a)



**FIGURE 1.** Theoretical framework of mechanisms through which Mindfulness-Based College influences young adult health behaviors.

current regular meditation practice (>once/week); b) serious medical illness precluding regular class attendance; c) current substance abuse, suicidal ideation, or eating disorder; and d) history of bipolar or psychotic disorders or self-injurious behaviors. These participants were excluded following standard guidelines because of risk for disrupting group participation, requiring additional or specialized treatment beyond the capacity of this study, or already participating in practices similar to the intervention. The study protocol was approved by the institutional review board of the Office of Research Integrity at Brown University (Protocol No. 1608001570). Participants provided written informed consent.

Participation rates are shown using a Consolidated Standards of Reporting Trials (CONSORT) diagram in Figure 2. After notification that participants were included in the study and baseline assessments, participants were randomized within sex and racial strata to MB-College versus control, using the computer software Research Randomizer (Version 4.0), performed by a researcher blinded to participant identification. The study protocol was designed to adhere to the CONSORT statement extended to randomized trials of nonpharmacologic treatment (28) and to minimize risk of bias based on the Cochrane Risk of Bias Tool Version 2 (29).

### Intervention Description and Theoretical Framework

This study adapted MBSR for young adults. It emphasized well-being priorities for this demographic. Specifically, MB-College is based on, and classroom time-matched to, the standardized MBSR intervention described elsewhere (30). The unique areas of MB-College are education and bio-feedback on determinants of young adult well-being, including human flourishing, and specific mindfulness modules focused on awareness of diet, physical activity, alcohol use, stress, sleep, social relationships, social support, and performance. MB-College builds a foundation of mindfulness skills (e.g., meditation, yoga, self-awareness, attention control, and emotion regulation) through the MBSR curriculum and directs those skills toward participants' relationship with a number of health-related factors relevant in young adulthood as shown in the theoretical framework (Figure 1) (20). Although MBSR recommends listening to 45 minutes of formal mindfulness practice recordings at least 6 days a week, MB-College

provides 10-, 20-, 30-, and 45-minute recordings and encourages the students to decide each day what length would be best for them. Details on how MB-College is customized to young adults are shown in Supplemental Digital Contents 1 and 2, <http://links.lww.com/PSYMED/A666>, <http://links.lww.com/PSYMED/A667>. The curriculum guide and MB-College instructor certification program can be accessed by contacting the lead author. Classes were at Brown University in Providence, Rhode Island.

### Control Group Description

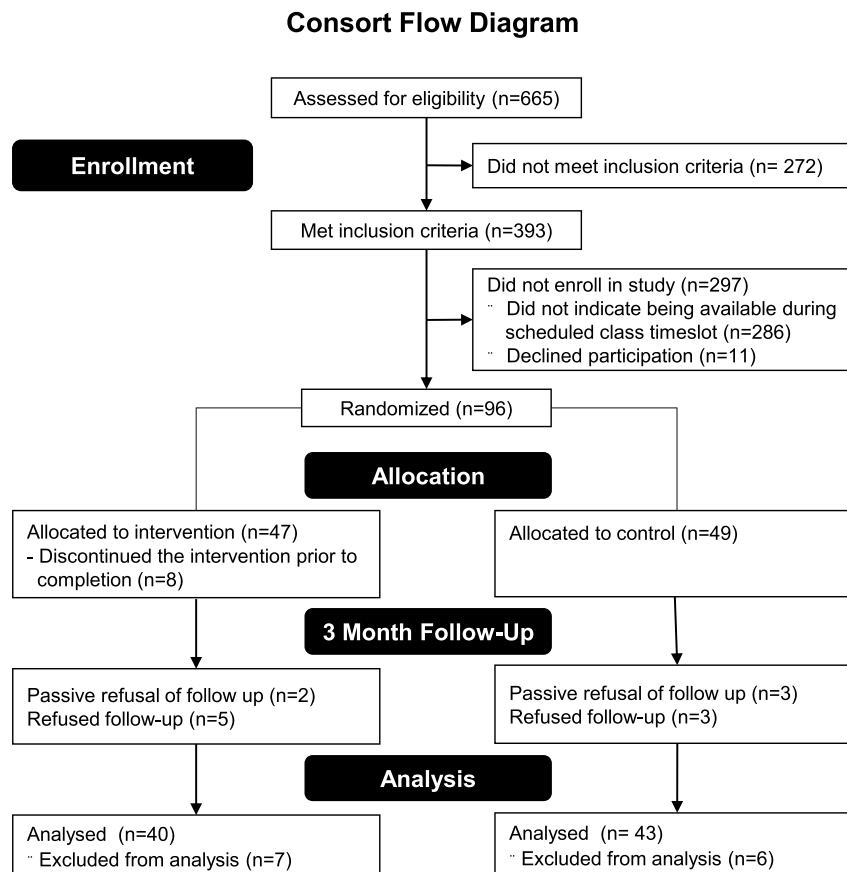
Participants in the enhanced usual care control group were spoken with by trained study staff, and as part of the enhanced usual care, they were offered a referral to the study's psychiatrist and university counseling resources, if anxiety, depression, or suicidal ideation levels at baseline or follow-up reached clinical levels on the Beck Anxiety Inventory (BAI) or the Revised Centers for Epidemiologic Studies—Depression (CESD-R) scale. These services were also provided if students requested them, regardless of mental health scale levels. Of the 49 participants in the control group, 4 were referred to these resources. These same resources were provided to the MB-College group, of which two were referred. Participants in the control group were eligible to take the MB-College program during the following term.

### Measures

All assessments were performed by trained research assistants, instructed in demonstrating equipoise. Regular quality control and assurance evaluations were performed on research assistants via direct observation of assessment accuracy, protocol adherence, and equipoise. Equipment (e.g., weighing scale and stadiometer) accuracy was evaluated at the beginning of every intervention cycle. Most self-report questionnaires were administered via Qualtrics, accessible by participants in their home or school environment through computer or smartphone. In-person measurements were in assessment rooms at Brown University.

### Treatment Fidelity Methods

Treatment fidelity strategies were performed in accordance with recommendations of the National Institutes of Health Behavior Change consortium,



**FIGURE 2.** CONSORT flow diagram for the MB-College study participation. CONSORT = Consolidated Standards of Reporting Trials; MB-College = Mindfulness-Based College.

ensuring treatment fidelity in the following five areas: study design, provider training, treatment delivery, receipt of treatment, and enactment of treatment skills (31). Specifically, the study provided the same treatment dose for each participant enrolled in the MB-College intervention, including fixed length and number of contact sessions for all MB-College sessions. We ensured equivalent classroom dose among participants including meditation, yoga, and stress reduction training, by allocating time recommendations in the MB-College Curriculum Guide for each module and observing 100% of audio/video recordings during instructor training sessions, with the senior investigator and developer of MB-College (E.L.) providing feedback on curriculum adherence. MB-College instruction was performed by qualified MBSR instructors, further certified in MB-College. An MB-College Curriculum Guide was created and followed by the instructors. MB-College instructor certification methods were developed through this intervention and are now available (contact the lead author for more information). Receipt of treatment and enactment of treatment skills were assessed by course discontinuation rates, mindfulness levels as measured by the Mindful Attention Awareness Scale (MAAS), and frequency with which participants engaged in evidence-based behaviors that foster well-being. Specifically, these behaviors included physical activity, fruit and vegetable intake, alcohol consumption, sleep quantity/quality, loneliness, and stress management (21).

### **Primary Outcome: Young Adult Health Summary Score**

The primary outcome was registered a priori on ClinicalTrials.gov (Identifier No. NCT03124446) and was assessed by calculating the mean  $z$  scores of the following seven outcome variables, each demonstrated to predict major health outcomes such as mortality, cardiovascular disease, and

depression (21). We then calculated an overall mean of all the mean scores of each component. The variables were as follows: mental health (distress, using the PSS-10 score) (26), social health (loneliness assessed using the R-UCLA loneliness scale) (27), health behaviors (physical activity using International Physical Activities Questionnaire—assessed total MET-minutes per week (22), diet using fruit and vegetable intake from the Harvard 80-item food frequency questionnaire (23), alcohol consumption using the Behavioral Risk Factor Surveillance Survey questionnaire (24), sleep duration using the PSQI (25)), and physical health (directly-assessed body mass index). Reverse scoring of the PSS-10, R-UCLA loneliness scale, alcohol consumption, and body mass index were done so that a positive health summary score represented healthier levels of all score components. When interpreting findings, it should be noted that, although the overall summary score has not gone through a validation process, each of the component measures has (described hereinafter), suggesting that each individual driver of the summary score is important for health (22–27). This measure was selected as the primary outcome to provide an overall measure of young adult health while having validated individual measures within it to identify which young adult-relevant health factors are most impacted by MB-College. Although other well-being measures, such as the Patient Reported Outcome Measurement Information System-29 and the Short Form-36, are validated for health-related quality of life, we are not aware of a global measure of physical, mental, and social well-being that includes health behaviors, specific for a general population of young adult university students. The primary benefit of the current measure is that it includes validated measures of well-being relevant to young adults and a university student population, including body mass index, physical activity, fruit and vegetable intake, alcohol consumption, stress, loneliness, and sleep duration.

### **Mental Health Outcomes**

Depressive symptoms were evaluated using the validated CESD-R (32). Anxiety symptoms were assessed using the BAI, with substantial validation described elsewhere (33). Distress was assessed using the 10-item PSS-10 with established validity and reliability (26).

### **Social Health Outcome**

Loneliness was assessed using the validated R-UCLA loneliness scale (27).

### **Health Behavior Outcomes**

Physical activity during the previous week was measured using the International Physical Activity Questionnaire as total MET-minutes per week of physical activity and time spent in sedentary sitting activities, with validation described elsewhere (22). Diet was measured as mean fruit and vegetable serving consumption, assessed using the 18 fruit and vegetable consumption questions from the Harvard 80-item food frequency questionnaire (23). Alcohol consumption was assessed via a modified Centers for Disease Control and Prevention Behavioral Factor Surveillance System Questionnaire, which has demonstrated concurrent validity with other nationally representative survey measures (e.g., National Health Interview Survey and National Health and Nutrition Examination Surveys) in multiple studies evaluating alcohol consumption (24). Current smoking was assessed via self-report. Sleep duration and quality were measured using the validated PSQI (25).

### **Physical Health Outcome**

Body mass index (in kilograms per meter squared) was calculated by weight and height measures obtained from participants wearing light clothing without shoes, using a calibrated stadiometer (SECA, Hamburg, Germany) and weighing scale (Model 22089; SECA) operated by trained technicians. Heads were positioned in the Frankfurt plane.

### **Self-Regulation Outcomes**

Attention control was evaluated using the Sustained Attention to Response Task (SART), which is a computerized go/no-go task that evaluates sustained attention, response inhibition, and self-regulation, with good validity and reliability detailed elsewhere (34). Interoceptive awareness was measured using the validated Multidimensional Assessment of Interoceptive Awareness (MAIA). The MAIA is a measure of self-awareness with a particular focus on body awareness (35). Self-compassion was assessed using the Self-Compassion Scale, with validity and reliability described elsewhere (36). Centering was evaluated with the validated Experiences Questionnaire (37).

### **Feasibility and Acceptability**

Participation rates and follow-up rates served as quantitative measures of feasibility and acceptability. Furthermore, after MB-College completion, participants were invited to participate in focus group discussions to assess the acceptability and feasibility of the intervention (Supplemental Digital Content 3, <http://links.lww.com/PSYMED/A702>).

### **Adverse Events**

AEs and serious AEs (SAE) were monitored. Participants were evaluated for psychological distress (i.e., anxiety, depression, and suicidal ideation) using the BAI and the CESD-R. These self-report questionnaires were administered at each in-person assessment. Participants whose BAI and/or CESD-R scores fell outside of the predetermined “acceptable” range outlined in the study’s safety protocol required the research assistant to first check in with the student to rule out any immediate risk of self-harm, find out if the student has resources available, and then contact either the study psychiatrist or appropriate emergency medical assistance for possible follow-up. Students flagged for anxiety, depression, or suicidal ideation were given referrals to university counseling services and to the study clinician (if preferred).

AE data on all SAEs were reported immediately to the study principal investigator. Passive monitoring was implemented, where the study interventionist and research staff were trained on how to document and report all AEs and SAEs as observed or reported during the course of in-person interaction with study participants (e.g., during the study intervention, in-person assessments, or study communications).

### **Analytic Approach**

Analyses were performed as intention to treat. We analyzed all participants with data regardless of whether they completed the MB-College program or not. These included three participants who were randomized to receive MB-College and completed their follow-up assessment, but either did not attend the program at all ( $n = 2$ ) or attended less than half the program ( $n = 1$ ). This complete case analysis is the main outcome analysis. The analytic approach included unpaired  $t$  tests and Fisher exact tests to evaluate group differences at baseline. Paired  $t$  tests assessed within-group differences at follow-up versus baseline. Linear regression models were used to estimate the marginal effects of MB-College versus control on the outcomes at 3-month follow-up while adjusting for baseline levels of the outcome in each model. To address the possibility that missing follow-up assessments is differentiable across arms, a sensitivity analysis was performed. The sensitivity analyses imputed missing data either as null or as 20% in the opposite direction as observed for the intervention or control group.

To reduce investigator biases, the principal investigator (E.L.) did not have access to the master data set. The data analyst (Y.L.) performed all statistical analyses, blinded to group allocation. All analyses were performed using Stata statistical software, version 14.0 (StataCorp LLC, College Station, Texas).

## **RESULTS**

Of the 393 participants who met the inclusion criteria, 286 were not available for the course time slot. A further 11 declined participation after learning about the study (Figure 2). This left 96 participants available, of which racial/ethnic composition was 62.5% White, 14.6% Asian, 8.3% Black, and 14.6% other (Table 1). Sixty-eight percent were female, and 2% were nonbinary. Mean age was 20.0 years (range, 18–26 years). For childhood socioeconomic status, 65% had at least one parent with greater than a college undergraduate education. There were no significant differences between the intervention and control groups for demographic variables (Table 1).

At baseline, participants were, on average, feeling high levels of stress (38) and reported lower fruit and vegetable consumption (four per day) than American Heart Association–recommended levels (8–10 servings per day; Table 2) (21). Participants were within healthy guidelines for daily alcohol consumption, body mass index, sleep duration, and anxiety symptoms (Table 2) (21,33,39). Participants had sitting time and loneliness levels similar to the general US population (Table 2) (40,41).

Eight of the 47 participants allocated to MB-College discontinued the intervention before completion (17%). Three of them completed follow-up assessments. At the 3-month follow-up, 83 (86%) of 96 participants completed assessments, which suggests good acceptability and feasibility using these measures. Qualitative findings using focus group discussions investigating acceptability and feasibility in a subset of 16 MB-College group participants are summarized in Supplemental Digital Content 3, <http://links.lww.com/PSYMED/A668>, with details in Supplemental Digital Contents 4–8, <http://links.lww.com/PSYMED/A669>, <http://links.lww.com/PSYMED/A670>, <http://links.lww.com/PSYMED/A671>, <http://links.lww.com/PSYMED/A672>, <http://links.lww.com/PSYMED/A673>.

**TABLE 1.** Baseline Levels of Demographic Variables in the MB-College Study, Stratified by MB-College Intervention Versus Control Group

Demographics	<i>n</i>	Point Estimate	<i>p</i>
Age, y	96	20.0	.94
Control	49	20.0	
MB-College	47	20.0	
Race	96		.80
Asian			
Control	6	42.9	
MB-College	8	57.1	
African American/Black			
Control	4	50.0	
MB-College	4	50.0	
White			
Control	30	50.0	
MB-College	30	50.0	
Other			
Control	8	61.5	
MB-College	5	38.5	
Sex	96		.46
Female			
Control	33	50.8	
MB-College	32	49.2	
Male			
Control	16	55.2	
MB-College	13	44.8	
Other			
Control	0	0.0	
MB-College	2	100.0	
Parental education	96		.33
≤ High school			
Control	3	33.3	
MB-College	6	66.7	
College or professional school			
Control	11	45.8	
MB-College	13	54.2	
≥1 y postcollege			
Control	35	57.4	
MB-College	26	42.6	

MB-College = Mindfulness-Based College.

Parental education was coded as the parent with the highest level of education. *p* values calculated using unpaired *t* test for age, and Fisher exact test for race, sex, and parental education

The young adult health summary score (primary outcome) significantly improved over the course of the college term for participants randomized to MB-College, compared with the control group where the health summary score worsened over the school term, by the time 3-month follow-up assessments were performed shortly before the final examination period. The marginal effect on the health summary score was 0.23 ( $p = .004$ ;  $n = 83$ ; Figure 3) for MB-College versus control. This effect size translated into a Cohen's *d* of 0.48, which suggested a medium-sized effect.

Several sensitivity analyses tested how robust the finding was. Complete case analyses for participants with data on all seven summary score components showed a stronger 0.25 ( $p = .001$ ;  $n = 61$ ) marginal effect. Effects were less but still strong (marginal effect = 0.17;  $p = .012$ ;  $n = 96$ ), when we imputed null values for missing summary score components. When we imputed mean health summary scores in participants lost to follow-up as 20% in the opposite direction as actually observed for participants with follow-up data that received the same intervention or control condition, marginal effects were 0.19 ( $p = .004$ ;  $n = 96$ ). Overall, the primary outcome findings were robust to sensitivity analyses.

Although all components of the health summary score moved in hypothesized directions, effects were particularly pronounced for loneliness (marginal effect for MB-College versus control =  $-3.11$  R-UCLA score;  $p = .03$ ; Table 3, Figure 4). Findings on further secondary outcomes in mental health/emotion regulation demonstrated strong effects on depressive symptoms (marginal effect for MB-College versus control =  $-2.83$  CESD score;  $p = .03$ ; Figure 5). Other findings for secondary mental health/emotion regulation outcomes (anxiety symptoms,  $p = .15$ ) and health behaviors (total PSQI score,  $p = .04$ ; average sitting minutes per day,  $p = .006$ ) are shown in Table 3. Please see Table 3 for Cohen's *d* values, suggesting small- to medium-sized effects for loneliness, sleep quality, depressive symptoms, and anxiety symptoms, and medium effect size for sedentary activity.

In terms of more proximal mechanisms consistent with the theoretical framework shown in Figure 1, a number of self-regulation outcomes significantly improved including the SART correct no-go percent ( $p = .0008$ ), the MAIA ( $p < .0001$ ), and decentering ( $p = .006$ ), shown in Table 3. Self-compassion marginally improved in MB-College versus control ( $p = .11$ ; Table 3). Mindfulness measured via the MAAS improved in both groups, and although improvements were greater in the MB-College group, it was not statistically significant at the 0.05 nominal value ( $p = .19$ ). Additional analyses on all measured SART and MAIA outcomes are shown in Supplemental Digital Contents 9 and 10, <http://links.lww.com/PSYMED/A674>, <http://links.lww.com/PSYMED/A675>. Overall, mechanistic evidence was generally consistent with the theoretical framework in Figure 1, suggesting improvements in attention control (SART), emotion regulation (loneliness, depressive symptoms), and self-awareness (MAIA). Cohen's *d* values in Table 3 show a large effect size for MAIA, a small effect size for MAAS, and a medium effect size for SART and decentering.

There were four participants with AEs detected through the 3-month follow-up and no students with SAEs. AEs were found in three control group participants and one MB-College participant. The three control group participants were flagged for clinical anxiety levels (two participants), depression (one participant), and suicidal ideation (one participant); one participant presented with both anxiety and depression. The MB-College participant presented with both depression and anxiety, which this participant attributed to a major leg injury, compounded emotionally by being a college athlete. Overall, evidence suggested potentially promising effects of MB-College on well-being, with no evidence of AEs attributed to MB-College.

## DISCUSSION

Overall, findings suggest that the MB-College program improved overall health of young adults during the college school term; in

**TABLE 2.** Baseline and Three-Month Follow-Up Levels of Variables in the MB-College Study, Stratified by MB-College Intervention Versus Control Group

	n	Baseline			3-mo Follow-Up		
		Point Estimate	SD	p (Baseline Group Difference)	Point Estimate	SD	p (Change From Baseline)
<b>Primary outcome</b>							
Emerging adult health summary score	83	0.00		.099	-0.05		
Control	43	0.09	0.50		-0.10	0.55	.09
MB-College	40	-0.09	0.46		0.00	0.41	.36
<b>Mental health</b>							
Depressive symptoms, CESD score	80	28.3		.30	29.9		
Control	40	27.6	5.4		31.0	8.2	.033
MB-College	40	29.0	6.7		28.8	6.5	.91
Anxiety symptoms, BAI score	80	8.36		.99	7.8		
Control	40	8.35	8.2		8.6	8.4	.89
MB-College	40	8.38	7.8		7.1	7.6	.45
Perceived stress, PSS score	77	29.0		.004	28.9		
Control	40	27.0	6.5		28.8	7.0	.23
MB-College	37	31.2	6.0		29.1	6.1	.14
<b>Social health</b>							
Loneliness, R-UCLA score	77	41.7		.25	39.8		
Control	40	40.6	9.0		40.3	10.2	.91
MB-College	37	43.0	9.6		39.2	10.4	.11
<b>Health behaviors</b>							
<b>Physical Activity</b>							
Total physical activity, MET-min/wk	78	5368		.048	4907		
Control	40	6161	4290		5091	3768	.24
MB-College	38	4534	2600		4713	4356	.83
Average sitting, min/d	78	461		.37	421		
Control	40	427	174		461	176	.40
MB-College	38	496	446		380	137	.13
<b>Diet</b>							
Mean fruit and vegetable consumption per day	81	4.0		.94	3.6		
Control	41	4.0	2.6		3.5	2.5	.33
MB-College	40	4.0	2.7		3.7	2.5	.61

Drinks per day	74	0.56					.14	0.54		
Control	38	0.68	0.75					0.72	1.00	.83
MB-College	36	0.44	0.66					0.34	0.42	.45
Sleep										
Total PSQI score	78	5.15					.085			
Control	40	4.63	2.43					5.40	2.78	.19
MB-College	38	5.71	3.05					4.97	2.50	.25
Smoking										
Current smoker, %	94	0.0						0.0		
Control	48	0.0						0.0		
MB-College	46	0.0						0.0		
Mean sleep hours per night, h	78	8.11					.74			
Control	40	8.15	1.08					7.86	1.06	.23
MB-College	38	8.07	1.07					7.55	1.94	.15
Physical health										
BMI, kg/m <sup>2</sup>	80	23.2					.52	23.4		
Control	40	22.9	3.00					23.2	3.03	.66
MB-College	40	23.4	4.30					23.7	4.73	.78
Self-regulation										
SART CorrNoGoPercent	59	51.9					.98	58.1		
Control	29	51.9	19.4					52.3	21.0	.94
MB-College	30	52.0	16.3					63.7	23.6	.029
MAIA, mean score of all scales	77	21.1					0.73	23.5		
Control	40	21.4	5.5					20.6	5.2	.53
MB-College	37	20.9	5.4					26.7	4.9	<.0001
Self-compassion, score	78	34.4					.81	20.7		
Control	40	34.2	8.3					20.0	3.1	<.0001
MB-College	38	34.6	6.7					21.3	5.7	<.0001
Decentering, score	83	38.1					.19	37.5		
Control	43	39.3	8.5					34.7	11.6	.038

*Continued on next page*



TABLE 2. (Continued)

	Baseline			3-mo Follow-Up			
	<i>n</i>	Point Estimate	SD	<i>p</i> (Baseline Group Difference)	Point Estimate	SD	<i>p</i> (Change From Baseline)
MB-College	40	36.8	8.9		40.5	13.8	.17
Mindfulness							
MAAS score	77	48.4		.60	52.8		
Control	40	49.1	12.1		52.6	10.5	.17
MB-College	37	47.7	10.3		53.0	11.5	.040

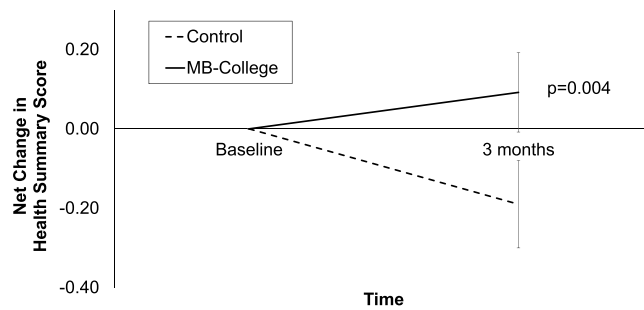
MB-College = Mindfulness-Based College; SD = standard deviation; CESD = Centers for Epidemiologic Studies—Depression; BAI = Beck Anxiety Inventory; PSS = Perceived Stress Scale; R-UCLA = revised University of California, Los Angeles scale; MET = metabolic equivalent; PSQI = Pittsburgh Sleep Quality Index; BMI = body mass index; SART = Sustained Attention to Response Task; MAIA = Multidimensional Assessment of Interoceptive Awareness; MAAS = Mindful Attention Awareness Scale.

Statistical analyses were unpaired *t* test for baseline difference and paired *t* test for 3-month follow-up versus baseline differences.

fact, evidence suggested that MB-College may provide resilience in the face of mounting stressors, as final examinations approached and term papers become due toward the end of the term. The primary outcome (young adult health summary score) was significantly improved in MB-College participants compared with the control group where it worsened. All seven components of the health summary score (i.e., perceived stress, loneliness, physical activity, diet, alcohol consumption, sleep duration, and body mass index) moved in expected directions. Findings were particularly strong for loneliness. Mechanistically, MB-College improved the self-regulation pathways including attention control, interoceptive awareness, and emotion regulation, compared with control. Overall, the findings are promising and support continued investigation of MB-College using replication studies, longer-term follow-up, and diverse participant samples.

Evidence in the literature on impacts of mindfulness interventions in young adults is relatively strong for mental health outcomes such as distress and depressive symptoms. A systematic review on mindfulness interventions in youth (ages 12–25 years) showed significant impacts on depression (42), confirmed by a systematic review and meta-analysis in college students, which showed stronger findings for mindfulness interventions among inactive than among active controls (12). The latter systematic review showed significant effects on distress outcomes for both inactive and active group comparisons (12). Health behaviors, social health, and physical health outcome are studied less often for mindfulness programs in young adults (12,14,15). The data produced from this study provide both novel and significant findings to show the impact of MB-College on the health summary score among young adults and, more specifically, how acquiring and implementing mindfulness skills into daily lives can positively affect loneliness, depressive symptoms, sedentariness, and sleep quality. In addition, although some outcomes were not statistically significant, they all trended in hypothesized and favorable directions (i.e., alcohol consumption [*p* = .07] and perceived stress [*p* = .09]), which may be promising in studies with larger sample sizes or meta-analyses of this study combined with others. With regard to the significant effects on loneliness, although few studies have investigated impacts of mindfulness on loneliness, the evidence to date is quite consistently supportive (43,44). For group-based mindfulness programs, effects on loneliness may, in part, be due to improved abilities of participants to find meaning in life when alone and due to fostering prosocial skills that make participants more effective and amicable in relationships (44,45). However, it may also be that the group process itself is important for loneliness, as participants are forming relationships with each other in class and having conversations about meaningful experiences in their lives (46). This can extend beyond the class into friendships. MB-College creates a supportive framework for positive relationships between the teacher and students, and between the students themselves who are together exploring ways to improve their well-being. However, it should be noted that an app-delivered mindfulness program investigated by Lindsay et al. (44) recently showed reductions in loneliness and increased social contact as a result of training in both monitoring and acceptance, without a group process as part of the app. Overall, it may be that both the group process and the mindfulness training itself impact loneliness and other outcomes.

With regard to mechanisms, these data support the theoretical framework presented in this article, which suggests that self-regulatory



**FIGURE 3.** Changes in the net health summary score from baseline through 3-month follow-up for MB-College versus control. Statistical analyses were marginal effects linear regression, adjusted for baseline values of outcome. *p* Values represent marginal effects of MB-College versus control on the net health summary score at 3-month follow-up. Error bars are standard errors of the mean. MB-College = Mindfulness-Based College.

mechanisms of attention control, interoceptive awareness, and emotion regulation may be influenced by mindfulness-based programs. Future work with adequately powered samples should

perform mediation analyses to evaluate if mindfulness-based program-induced changes in these mechanisms translate into improved health outcomes. Furthermore, decentering, the ability to

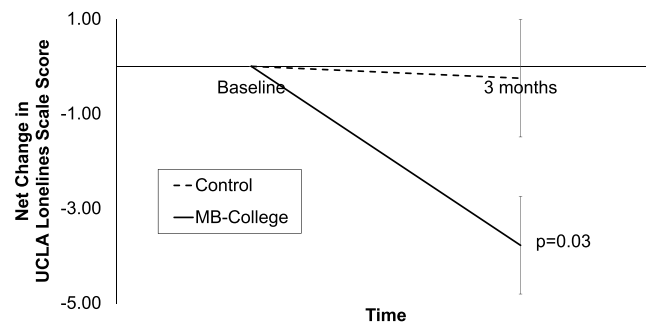
**TABLE 3.** Marginal Effects of MB-College Versus Control on 3-Month Outcomes

	<i>n</i>	Marginal Effect	SE	Cohen's <i>d</i>	SE	<i>p</i>
Primary outcome						
Emerging adult health summary score	83	0.23	0.08	0.48	0.22	<b>.004</b>
Mental health						
Depressive symptoms, CESD score	80	-2.83	1.53	-0.37	0.23	<b>.035</b>
Anxiety symptoms, BAI score	80	-1.54	1.45	-0.19	0.22	.15
Perceived stress, PSS score	77	-1.88	1.40	-0.28	0.23	.093
Social health						
Loneliness, R-UCLA score	77	-3.11	1.61	-0.30	0.23	<b>.03</b>
Health behaviors						
Physical activity						
Total physical activity, MET-min/wk	78	302.2	884.9	0.07	0.23	.37
Average sitting, min/d	78	-90.1	34.8	-0.53	0.23	<b>.006</b>
Diet						
Mean fruit and vegetable consumption per day	81	0.23	0.36	0.09	0.22	.26
Alcohol						
Drinks per day	74	-0.21	0.14	-0.27	0.23	.066
Sleep						
Total PSQI score	78	-0.96	0.5	-0.36	0.23	<b>.037</b>
Mean sleep hours per night, h	78	-0.30	0.35	-0.19	0.23	.20
Physical health						
BMI, kg/m <sup>2</sup>	80	-0.04	0.18	-0.01	0.22	.41
Self-regulation						
SART CorrNoGoPercent	59	11.3	4.5	0.51	0.26	<b>.008</b>
MAIA, mean score of all scales	77	6.30	0.94	1.27	0.25	<b>&lt;.0001</b>
Self-compassion, score	78	1.25	1.02	0.28	0.23	.11
Decentering, score	83	6.92	2.68	0.55	0.22	<b>.006</b>
Mindfulness						
MAAS score	77	1.45	1.64	0.13	0.23	.19

MB-College = Mindfulness-Based College; SE = standard error; CESD = Centers for Epidemiologic Studies—Depression; BAI = Beck Anxiety Inventory; PSS = Perceived Stress Scale; R-UCLA = Revised University of California Los Angeles Loneliness Scale; MET = metabolic equivalent; PSQI = Pittsburgh Sleep Quality Index; BMI = body mass index; SART = Sustained Attention to Response Task; MAIA = Multidimensional Assessment of Interoceptive Awareness; MAAS = Mindful Attention Awareness Scale.

Effect sizes and direction of effect are for 3-month change in MB-College intervention versus control. Statistical analyses were marginal effects linear regression, with corresponding Cohen's *d*, adjusted for baseline values of outcome.

Statistically significant values ( $p < .05$ ) are shown in boldface.

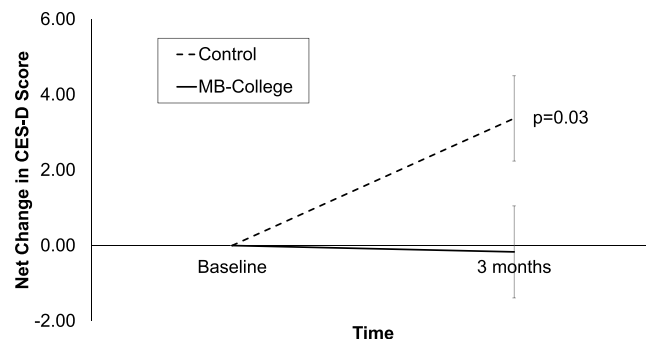


**FIGURE 4.** Changes in the R-UCLA Loneliness Scale from baseline through 3-month follow-up for MB-College versus Control. Statistical analyses were marginal effects linear regression, adjusted for baseline values of outcome. *p* Values represent marginal effects of MB-College versus control on loneliness at 3-month follow-up. Error bars are standard errors of the mean. R-UCLA = Revised University of California, Los Angeles; MB-College = Mindfulness-Based College.

take a step back from one's thoughts, emotions, and physical sensations, significantly improved. It is a mechanism frequently described as being important in mindfulness-based programs, and evidence here suggests it was engaged well by MB-College (20,47). A recent systematic review and meta-analysis of mediation analysis suggested that the following mechanisms are important: mindfulness, repetitive negative thinking, and emotional/cognitive reactivity (47). Findings in the current study are supportive of these findings. Although the Mindfulness Attention Awareness Scale score significantly increased in the MB-College group compared with baseline and increased 1.5 units more than the waitlist control ( $p = .19$ ), it was not statistically significant but may have been with a larger sample size. Many plausible mechanisms have yet to be tested in formal mediation analyses, and this remains a research priority in the coming years to understand how mindfulness-based programs could influence health.

Strengths of the study include the randomized controlled trial design and the theoretical innovations to adapt MBSR to young adults. Furthermore, the principal investigator, who developed MB-College, did not have access to the data file, and the data analyst was blinded to group allocation. Intention-to-treat analyses were performed. Dropout rates from the MB-College group during the intervention were acceptable (17%), and follow-up rates at 3-month follow-up assessments were quite good (86%). Limitations include the 3-month follow-up from baseline assessment. Longer-term follow-up is needed to evaluate lasting effects. Furthermore, although fairly racially diverse for a mindfulness study, the

sample was still 63% White, and participants' parents were typically well educated. Finally, the enhanced usual care control comparison group was chosen to provide an implementation science-informed, pragmatic answer to college administrators, health insurers, and young adults themselves, about if this program would be effective on well-being compared with if they did not take it. However, non-specific usual care controls make it impossible to determine whether any effects were due to nonspecific factors, such as support from the clinician or the group. As we have described elsewhere, Mindfulness-Based Programs are indeed multimodal interventions, and we hypothesize that effects are likely in part due to group and teacher (46). MBSR was originally designed to be integrative to medical care and includes recognized approaches, such as participatory medicine and elements of motivational interviewing (18). These could represent part of the power of Mindfulness-Based Programs, and we do not hypothesize that only mindfulness is driving the effects, similarly to other third-wave therapies like Acceptance and Commitment Therapy (48). Despite this, mediation analyses suggest that mindfulness is indeed a mediator (likely one of several) for Mindfulness-Based Programs (47). The field is at a stage where sometimes specific active controls are emphasized to be used in research studies, but unless done as a comparative effectiveness study with another clinically valid comparator (e.g., cognitive behavioral therapy), this can leave end-users confused. For example, university administrators or clinicians would typically avoid referring young adults to a specific active control unless it was evidence based, so the research comparison loses its meaning.



**FIGURE 5.** Changes in the CESD scale from baseline through 3-month follow-up for MB-College versus Control. Statistical analyses were marginal effects linear regression, adjusted for baseline values of outcome. *p* Values represent marginal effects of MB-College versus control on depressive symptoms at 3-month follow-up. Error bars are standard errors of the mean. CESD Centers for Epidemiologic Studies—Depression; MB-College = Mindfulness-Based College.

Furthermore, specific active controls need content to engage participants, and the active elements of that content are often underappreciated, underreported, and poorly understood. Research on creating an extensive, consensually agreed hierarchically structured taxonomy of behavior change techniques used in behavior change interventions showed that the interventions are typically complex. They identified 93 different behavior change techniques commonly used, and that most behavior interventions and active control groups contain many behavior change techniques within each program (49). The CONSORT statement for randomized trials of “nonpharmacological” interventions recommends precise specification of trial processes, including “description of the different components of the interventions” (28). This is rarely done, especially for active control groups (49). Future work clearly stating active elements of both intervention and active control groups is needed to avoid confusing pragmatic end-users about if programs work for their clients. Freedland et al. [50] and Michie et al. [49] write clearly on this issue, and Freedland et al. [50] emphasize the importance selecting the control group that best answers the research question. The primary research question in this study was to determine whether MB-College affects a young adult health summary score, composed of body mass index, physical activity, fruit and vegetable intake, alcohol consumption, stress, loneliness, and sleep duration. Future work on dismantling studies can further evaluate how MB-College works and if effects are independent of factors such as instructor attention, expectancy, and group effects. However, we felt that at this stage it was important to evaluate *if* it works, and then move further to *how* it works in future dismantling studies. Replication of the study in more racially and socioeconomically diverse samples will, along with longer-term follow-up, provide more robust information to college administrators, health insurers, and young adults about if and how this program would be effective.

In conclusion, the study suggests that at this time in history when many young adults have high levels of distress, depressive symptoms, loneliness, body mass index, and sedentary activities (3–7), MB-College may serve to foster positive health. Although all of the subcomponents of the young adult health summary score improved in healthy directions, evidence suggested particularly strong effects for loneliness. We are at a time in human development where many adults are delaying marriage and emphasizing education, often relying for companionship on social relationships with peers, which may be more fragile or transitory. Developmentally, this young adult life course stage is characterized by more time spent alone and a focus on exploring life’s potential pathways. Evidence suggests that mindfulness programs, such as MB-College, could support the health of young adults, who are destined to be the future of our societies.

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