


RESEARCH ARTICLE

Mindfulness effects on lifestyle behavior and blood pressure: A randomized controlled trial

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Abstract

Background and aims: HTN affects nearly 50% of U.S. adults and is the leading modifiable cardiovascular risk factor. A healthy diet and exercise can improve BP control, but adherence to these interventions is low. We tested whether a multimodal mind-body program, Mindful Awareness Practices (MAP) could improve BP and lifestyle behaviors associated with HTN when compared to a Health Promotion Program (HPP).

Methods: Adults with BP >120/80 were randomized to MAP or HPP. Outcome measurements of BP, self-reported diet, and exercise were analyzed with intent-to-treat group comparisons using repeated measures linear mixed models.

Results: There was an MAP-HPP between-group difference in interactions of time-by-systolic BP ($P = 0.005$) and time-by-diastolic BP ($P = .003$). The mean drops in SBP from baseline to week 13 for the MAP group was 19 mm Hg (138 ± 15 mm Hg- 119 ± 6 mm Hg) compared to 7 mm Hg (134 ± 18 mm Hg- 127 ± 22 mm Hg) in the HPP group. Similarly, a greater reduction in DBP was observed in the MAP group compared to the HPP group, 12 mm Hg (89 mm Hg ± 11 - 77 ± 7 mm Hg) and 1 mm Hg (81 ± 16 mm Hg- 80 ± 18 mm Hg), respectively. Mediation analysis of the MAP group showed the total effect of mindfulness practice minutes on SBP with indirect effect (ab) of $-.057$ was significant, resulting in a 40% lower SBP for total effect (c) compared to direct (c') effect alone. The mediational model suggests MAP has a modest positive influence on participants initiating lifestyle behavior change, which partially explains the greater reduction in BP by the MAP group.

Conclusion: Our findings suggest a multimodal mind-body program involving mindfulness practice may improve BP control in adults with HTN.

KEYWORDS

blood pressure, diet, exercise, hypertension, lifestyle behavior, meditation, mindfulness

1 | INTRODUCTION

Hypertension (HTN) is considered the leading modifiable risk factor for cardiovascular (CV) complications, including myocardial infarction

and stroke.¹ Unfortunately, nearly half of adults with HTN report inadequate blood pressure (BP) control.^{1,2} HTN treatment guidelines emphasize the importance of lifestyle behaviors, such as a healthy diet and regular physical activity.³ However, many individuals find

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modifying lifestyle behaviors difficult and even harder to maintain.³ For example, fewer than 10% of individuals with HTN adhere to the Dietary Approaches to Stop Hypertension guidance and close to a third report no regular physical activity, suggesting that health information and education by itself may be insufficient for many individuals to make enduring changes.³⁻⁶

People may find other methods, in addition to health information, more helpful in facilitating lifestyle behavior modifications. Meditation approaches, which teach mindfulness practices, may potentially offer that support for lowering BP through lifestyle behavior modification. A systematic review by the American Heart Association (AHA) found various meditation approaches including mindful meditation help lower CV risks, including BP.⁷ The potential role of meditation practices and its effect on lifestyle behavior modification, however, was not discussed in the AHA's review. Therefore, the purpose of this study is to evaluate mindful meditation and its effect on lifestyle behaviors among individuals with HTN.⁸

Various forms of meditation practices have been utilized in the United States in clinical and secular settings in the last three decades. Meditation practices have been used widely for the treatment of numerous physical and mental disorders.^{7,9} Our study focuses on CV risk reduction, specifically HTN. The AHA review found that meditation approaches offer a low-cost therapeutic solution for overall CV health.⁷ We build on AHA's systematic review and evaluate whether there is any effect on lifestyle behavior modification through the use of a mindful meditation approach.¹⁰

We briefly describe the most widely used meditation approaches for lowering BP.⁷ First, we offer a brief description of the types of meditative practices. Meditation could be classified into two broad categories. One is mindful/mindfulness meditation (open-monitoring meditation) and the other is concentrative meditation (focused attention).¹¹ Focused attention is attained through a mantra (repeating a word or phrase) or fixed attention by staring at an inanimate object, and this type of meditative practices emphasizes a more stricter attitude toward the mind-wandering.¹¹ Conversely, mindful meditation approaches take a more open attitude and nonjudgment toward the mind-wandering.^{11,12} Regardless of the nuances between these types of modalities, typical outcomes for most meditative practices are mental calmness and focus.¹¹ Of note, the terms mindfulness meditation and mindful meditation are used interchangeably in many published works.⁷ For clarity and consistency, the term mindful meditation will be used going forward.

Transcendental meditation (TM: a mantra-based meditation) was one of the early concentrative meditation approaches brought to the U.S. from India in the early 1970s. Since then, this approach has shown numerous physiological benefits, including lower BP, heart rate, and respiration rate.⁷ This form of meditation takes years to master, involving some aspects of spirituality, and, therefore, may not be an ideal meditation approach for novice practitioners or a healthcare setting. The details of the TM practice are described elsewhere.¹³

Applying TM's techniques without the spiritual context, Benson Herbert discovered what he termed the relaxation response (RR), which has shown physiological changes similar to those of TM.¹⁴

Herbert's RR is a 10-to-20-minute session where the practitioner deliberately takes slow breaths while relaxing their muscles. Herbert hypothesized that slow breathing, the initial step in RR, brings a sense of calm to the practitioner.¹⁴ Eliciting the RR has been shown to reduce BP in pre-HTN and HTN.⁷ A recent study suggests that eliciting the RR influences BP through a set of biological transcription actions, particularly the nuclear factor NF- κ B, a protein complex that controls transcription associated with inflammation and stress.¹⁵

Whereas TM and RR are different meditation methods, mindful meditation is a broader category of meditation technique that encompasses such practices as Mindfulness-Based Stress Reduction (MBSR) and a Mindful Awareness Practice (MAP).⁷ A popular form of mindful meditation is Jon Kabat-Zinn's MBSR.^{7,16} The MBSR program has been widely applied in various clinical settings and helped popularized the term "mindfulness," a mental state centered and grounded in one's bodily sensations and thoughts with openness and no judgment.¹² Of note, while MBSR is similar to other contemplative practices, the MBSR includes Hatha yoga as part of its program. The MBSR has also shown numerous health benefits, including lower BP.^{7,9}

Like MBSR, MAP is considered a mindful meditation practice with a wide range of health benefits.¹⁷⁻²¹ The MAP program is offered through the University of California, Los Angeles (UCLA), and has been widely disseminated over the last decade with teaching in person, on-line, and delivery via the app, UCLA Mindful.

2 | METHODS

2.1 | Study design and recruitment

This study was a single-site two-arm clinical trial designed primarily to establish feasibility and effect size and, secondarily, for testing effectiveness in behavior change and BP reduction. It was conducted at UCLA from 1 August 2017, through 1 August 2018. We recruited participants from the UCLA campus, medical center, and surrounding communities through flyers and online postings. Recruitment was conducted in blocks (cap of 15 participants) with participants assigned in sequence to the next upcoming MAP program and Health Promotion Program (HPP). Hence, the group assignments were dependent on the class schedules. Inclusion criteria included persons with elevated BP, with or without prescribed antihypertensive medications. Exclusion criteria were current pregnancy or lactation, substance abuse, and chemotherapy. Other exclusions included individuals currently practicing meditation or yoga, enrolled in weight loss programs or other behavioral interventions, or unable to commit to the length of the study, as well as uncontrolled psychiatric problems and an inability to speak or read English.

The UCLA Institutional Review Board approved the study protocol. The study was carried out per the approved guidelines and was registered on ClinicalTrials.gov protocol record of NCT03924531. All participants were informed of study's purpose and potential risks.

All participants provided written informed consent before enrollment in the study.

Based on a sample size calculation ($f = 0.30$, effect size at alpha of 0.05, power of 0.80) and differences in medication adherence, diet, and exercise between baseline, 6-, and 12-week follow-up, a sample size of 52 participants was determined. A moderate effect size was based on a meta-analysis of the effectiveness of mindful meditation practices on various disorders.²²

2.2 | Intervention: UCLA Mindful Awareness Program

The MAP is offered through the Mindful (also known as mindfulness) Awareness Research Center (MARC) at UCLA. The MARC was founded over a decade ago with the delivery of MAPs in diverse communities throughout Southern California, as well as online training to over 20 000 adults. Research-based evidence of its efficacy to improve stress, perceived stress, sleep, depression, and anxiety, as well as to promote altruism, and alter biologic outcomes such as inflammation has been previously reported.^{17-21,23}

The MARC defines mindfulness as “the moment-by-moment process of actively and openly observing one’s physical, mental, and emotional experiences.” The MAP classes are taught by MARC-certified instructors and are offered year-round, onsite at MARC or in other locations in the greater Los Angeles area. The 6-week, 2-hour weekly series provides fundamentals of mindfulness practice, including developing a personal practice and applying it during daily activities. Each session is a combination of lecture, practice, group feedback, and class discussion, facilitated by the MAP instructor (Table 1). The MAP includes mindful walking and mindful eating, so there is minimal physical activity involved.

All MAP participants received a book on mindfulness practice. They also received audio recordings containing guided mindfulness practices, ranging from 5 to 20 minutes, for use at home. The MAP instructor encouraged a daily practice of mindfulness, starting with 5 minutes and increasing to 20 minutes by week 5. Marvin Belzer,

who was the primary instructor for the study participants, also completed training in MBSR and has over two decades of meditation and mindfulness training experience. The MAP group received the same health information that was part of the HPP program.

2.3 | Attention-control: Health Promotion Program

The HPP program is held for 1 hour per week for 6 weeks, consisting of health educational sessions that are publicly available through the Office of Disease Prevention and Health Promotion ([url: https://health.gov/](https://health.gov/)). The sessions are called “Eat Healthy, Be Active Community Workshops” (Table 1). These educational materials follow the Dietary Guidelines for Americans and the Physical Activity Guidelines for Americans published by the U.S. Department of Health and Human Services. The 1-hour class includes lectures, group feedback, and discussion as well as food tasting demonstrations. A registered nurse provided the weekly educational sessions.

2.4 | Study measures

Health behavior measurements included diet, exercise, and antihypertensive medication adherence. All three measurements were self-reports submitted by the participants weekly. For dietary intake, we used the Rapid Eating and Activity Assessment for Patients (REAP). The REAP is a 30-item questionnaire designed to quickly assess nutritional intake quickly and requires only 10 minutes to complete.^{24,25} REAP has been used in various settings across a diverse population.²⁴⁻²⁷ The 6-item Exercise Behaviors (EB) questionnaire, developed and available to the public from the Stanford Self-management Chronic Disease center, was utilized to capture physical activity. We used the Brief Medication Questionnaire 1 (BMQ), designed specifically for collecting antihypertensive medication adherence.²⁸

Participants were provided with a BP monitor (Omron 3 series) for measuring BP at home. We used the AHA’s standard BP measuring guidelines. These guidelines were also taught and demonstrated during the enrollment process. Participants were instructed to take their BP measurements daily, at or around the same time of day, to minimize temporal variations. Mindfulness practice minutes and BP measurements were recorded by the participants using a booklet provided by this study, which were collected weekly in-person during the 6 weeks training sessions and then online for the 6-week follow-up. Likewise, the self-reported questionnaires were collected during the training sessions in person and then online thereafter.

2.5 | Statistical analysis

We analyzed the data with the Statistical Package for the Social Sciences (SPSS), version 25, and SAS. Effect sizes were calculated from results of a mixed model with the group as a between-group factor and week (1–13) as a repeated factor with ARMA (1) covariance

TABLE 1 Weekly topics in the MAP and the HPP programs

Week	Mindful Awareness Program (MAP)	Health Promotion Program (HPP)
1	Introduction to Mindfulness	Enjoy Healthy Food Choices that Taste Great
2	Listening, Embodiment, and Obstacles	Quick, Healthy Meals and Snacks
3	Working with Pain	Eating Healthy on a Budget
4	Difficult Emotions/ Positive Emotions	Tips for Losing Weight and Keeping It Off
5	Thoughtful and Mindful Interactions	Making Healthy Eating Part of Your Lifestyle
6	Loving Kindness	Physical Activity is Key to Living Well

pattern over time, using SAS Proc Mixed, following the procedure outlined by Selya et al.²⁹ The Cohen's f^2 sizes were translated into the d metric for easier interpretation using procedure previously described in Calculation of Effect Sizes.³⁰ Additionally, a detailed examination of patterns across time within each group was examined for systolic BP and diastolic BP. Simple mediation models were tested using Model 4 of the regression-based approach available in the PROCESS macro developed by Hayes.³¹ The PROCESS macro was installed to SPSS. The statistical threshold for effectiveness testing was set at 0.05 and bootstrapping method, with 5000 samples, were used in all analyses.

3 | RESULTS

3.1 | Participation flow and characteristics

There were four groups in total: two groups received the MAP and the other two groups received the HPP training. Effect sizes for this calculation were based on differences in diet, exercise, meditation intake between baseline, at week 6, at week 12 follow-up, and covariate age. We were conservative in determining power based on the number of participants after attrition, utilizing an intent-to-treat analysis. Of the 82 people assessed for eligibility, 20 participants were randomized to the intervention (MAP) and 17 to attention control (HPP). The remaining 45 did not meet the inclusion criteria (Figure 1). One HPP participant was removed from the final analysis after being placed on two new antihypertensive medications. Participants allocated to the HPP were given the option of enrolling in an MAP class of their choosing at the conclusion of the study.

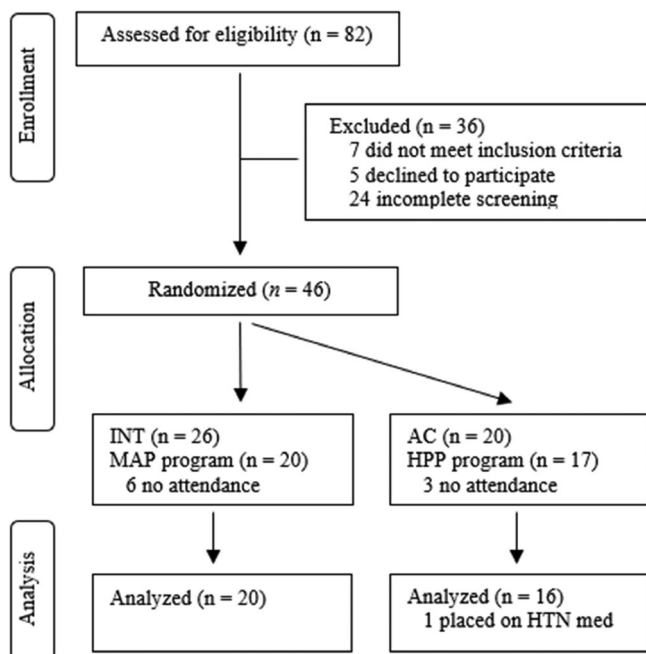


FIGURE 1 Study flow diagram. AC, attention-control; HTN, hypertension; INT, intervention

Baseline characteristics of groups MAP and HPP are shown in Table 2. The HPP group had a higher mean BMI and a wider SD of 6.4 kg/m^2 , the only significant group difference. Over 60% of study participants reported having an HTN diagnosis and reported being prescribed at least one antihypertensive medication. Health status at baseline was collected. We asked participants the following question: *In general, would you say your health is* Excellent, Very good, Good, Fair, or Poor. Majority of the subjects reported their health status as good or better. As with other similar studies, female (75%) participants outnumbered male participants.^{10,32}

3.2 | Between group: health behaviors and effect sizes

The health behavior outcomes (diet, exercise, and medication adherence) are listed in Table 3 with P -values for the interaction between time (13 weekly time points) and group. All three health behavior

TABLE 2 Baseline demographic characteristics of participants

Characteristics	MAP (n = 20)	HPP (n = 16)	P value
Age, y	58 ± 12.6	64 ± 9.0	.17
Female, n (%)	14 (70)	13 (81)	-
BMI (weight (kg)/ [height (m)] ²)	26 ± 3.7	30 ± 6.4	.01*
Blood pressure at baseline, mm Hg			
Systolic	138 ± 14.6	133.7 ± 17.9	.50
Diastolic	89 ± 11.2	81 ± 16.3	.10
Hx of HTN Dx (on at least 1 antihypertensive), n (%)	15 (75)	13 (81)	
Health status: In general, would you say your health is: n (%)			-
Excellent	2 (10)	1 (6)	
Very good	5 (25)	4 (25)	
Good	13 (65)	9 (25)	
Fair	-	2 (13)	
Poor	-	-	
Ethnicity/race, n (%)			-
Asian or Pacific Islander	7 (35)	1 (6)	
Black not Hispanic	4 (20)	9 (56)	
Hispanic	2 (10)	-	
White not Hispanic	7 (35)	6 (38)	

Note: Values are mean ± SD or no. (%) of subjects.

Abbreviations: BMI, Body Mass Index calculated as weight in kilograms divided by height in meters squared); Dx, diagnosis; HPP, Health Promotion Program; Hx, history; MAP, Mindful Awareness Program.

* $p \leq 0.05$, 2-tailed T-test.

outcomes are modifiable risk factors for maintaining a healthy BP level.³ There were no statistical differences between the groups except for these two diet behavior questions, “Choose higher fat red meats like prime rib, T-bone steak, hamburger, ribs, etc. instead of lean red meats” and “Eat regular ice cream instead of sherbet, sorbet, low fat or fat-free ice cream, frozen yogurt, etc.” For physical activity, there was no significant difference ($P = .09$) between the groups. The interaction between time and group was not significant for the outcome of antihypertensive medication adherence.

3.3 | Between group: blood pressure outcomes

A total of 13 weekly data points were analyzed. Intent-to-treat analysis was performed. There was a significant interaction of systolic BP (SBP, $P = .005$) and diastolic BP (DBP, $P = .003$) and time difference between the MAP and HPP (Table 4). The mean drop in SBP from baseline to week 13 for the MAP group was 19 mm Hg (138 ± 15 mm

TABLE 3 Health behavior outcomes and effect sizes comparison of MAP and HPP groups

Health behavior outcomes	Interaction between time and group P-value	Standardized effect size [Cohen's f^2], [Cohen's d]
Blood pressure medication adherence		
Missed medication days	.912	-
Diet behavior		
Eat high sodium processed foods	.914	-
Add salt to foods during cooking	.104	-
Eat less than 2-3 servings of fruit/day	.511	-
Eat less than 3-4 servings of veg/day	.351	-
Eat beef, dark meat chicken >2/wk	.480	-
*Choose higher fat red meats	.015	[.094], [.61]
Eat regular sweets instead of low fat	.209	
*Eat regular ice cream instead of	.013	[.097], [.62]
Physical activity level	.091	[.268], [.538]

* $P < .05$.

TABLE 4 Systolic blood pressure and diastolic blood pressure differences and effect sizes

Secondary outcome	Interaction between Time and Group P-value	Standardized effect size [Cohen's f^2], [Cohen's d]	MAP Group SBP mean [95% CI] DBP mean [95% CI] Baseline - wk 12	HPP Group SBP mean [95% CI] DBP mean [95% CI] Baseline - wk 12
*SBP	.005	[.096], [.620]	138 [131,145] - 119 [115,123]	134 [124,143] - 127 [114,140]
*DBP	.003	[.102], [.638]	89 [84,95] - 77 [72,81]	81 [72,90] - 80 [69,91]

* $P < .05$.

Hg- 119 ± 6 mm Hg) compared to 7 mm Hg (134 ± 18 mm Hg- 127 ± 22 mm Hg) in the HPP group. Similarly, a greater reduction in DBP was observed in the MAP group compared to the HPP group, 12 mm Hg (89 mm Hg \pm 11 - 77 ± 7 mm Hg) and 1 mm Hg (81 ± 16 mm Hg- 80 ± 18 mm Hg), respectively. The SBP on average was lower each week for the MAP group compared to the HPP group despite two subjects in the MAP group having discontinued their antihypertensive medications (Figure 2). This trend was also observed for the DBP, but the difference was smaller between the two groups (Figure 3).

The pattern across time within each group was examined for SBP and DBP. For SBP, there is a significant time effect for the MAP group ($F(12,145)=7.44$, $P < .001$), with post hoc tests showing that baseline is significantly different from each of the other time points (weeks 2-13). However, the time effect was not significant for the HPP group ($F(12,137)=1.30$, $P = .225$), even though the baseline value was significantly different from weeks 7 to 13. For DBP, there was a significant time effect for the MAP group ($F(12,145)=5.51$, $P < .001$), with post hoc tests showing baseline significantly different from each of the other time points. The time effect is not significant for the HPP group ($F(12,137)=1.37$, $P = .190$). Overall, the MAP group showed a lower BP trend than the HPP group, particularly in SBP (Figures 2 and 3).

3.4 | Within group: dose (mindfulness practice minutes) on health behaviors mediators

There was a reduction in BP for both groups at the end of the study. However, on average, the MAP group had a lower BP consistently

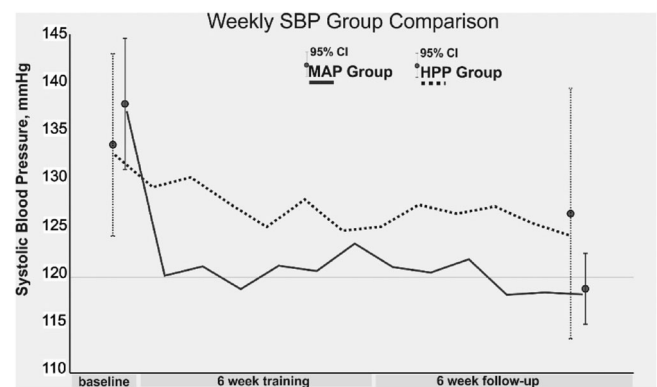


FIGURE 2 Weekly comparison of SBP between groups from baseline to week 13

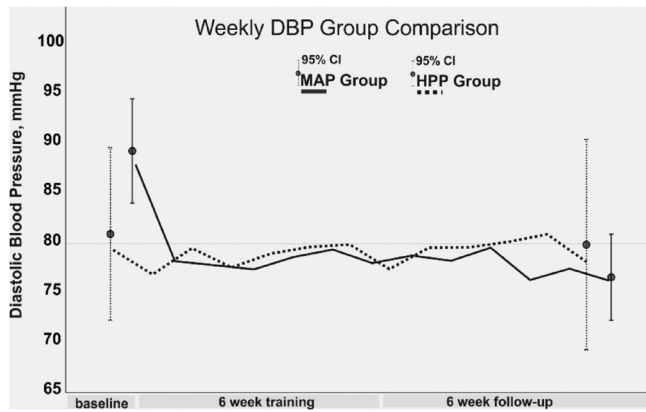


FIGURE 3 Weekly comparison of DBP between groups from baseline to week 13

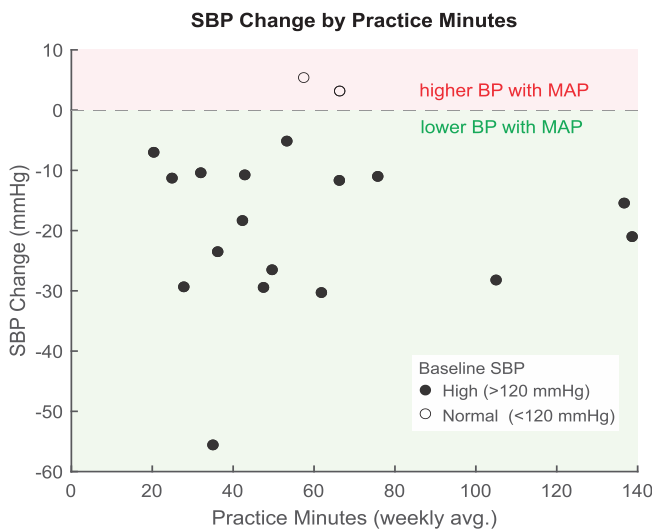


FIGURE 4 SBP change with mindfulness practice minutes in MAP (n = 20) group

TABLE 5 Diet questions: mediators on blood pressure by mindfulness practice minutes

Variables	Diet Questions
DietQ4	Eat less than 2–3 servings of fruit a day?
DietQ5	Eat less than 3–5 servings of vegetables/potatoes a day?
DietQ9	Eat beef, pork, or dark meat chicken more than two times a week?
DietQ11	Choose higher fat red meats like prime rib, T-bone steak, hamburger, ribs, etc., instead of lean red meats?
DietQ19	Eat regular sweets like cake, cookies, pastries, donuts, muffins, and chocolate instead of low-fat or fat-free sweets?
DietQ20	Eat regular ice cream instead of sherbet, sorbet, low fat or fat-free ice cream, frozen yogurt, etc.?
DietQ23	Eat high-sodium processed foods like canned soup or pasta, frozen/packaged meals (TV dinners, etc.), chips?
DietQ24	Add salt to foods during cooking or at the table?

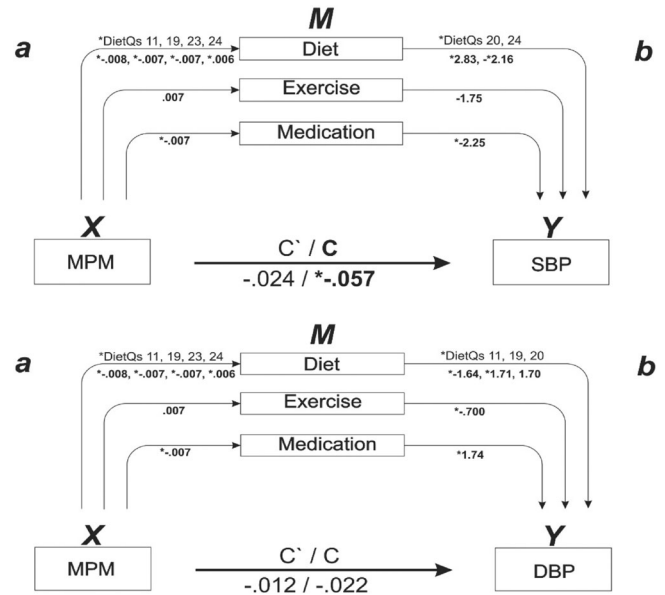


FIGURE 5 Simple mediation model of SBP/DBP mediated by lifestyle behaviors by mindfulness practice. “*” indicate significant ($P \leq .05$) effects. Included significant a and b paths, and direct/indirect effects; X independent variable; Y dependent variable; C' direct effect, C total effect. MPM (mindfulness practice minutes)

TABLE 6 The 95% confidence intervals for the path (a) and path (b) in the simple mediational analysis

SBP Mediators	a 95% [CI]	b 95% [CI]
DietQ4	[−.022, .004]	[−.952, 2.28]
DietQ5	[−.007, .008]	[−.843, 3.87]
DietQ9	[−.015, .001]	[−1.77, 1.59]
DietQ11	*[−.015, −.002]	[−3.47, .913]
DietQ19	*[−.014, −.000]	[−2.65, 2.18]
DietQ20	[−.011, .001]	*[.101, 5.57]
DietQ23	*[.000, .013]	[−3.16, 2.99]
DietQ24	*[.000, .013]	*[−4.17, −.155]
PAMin	[−.009, .022]	[−.968, .619]
MissMedDays	*[−.013, −.000]	*[.630, 3.86]
DBP Mediators	a 95% [CI]	b 95% [CI]
DietQ4	[−.012, .004]	[−.562, 1.44]
DietQ5	[−.007, .008]	[−1.41, 1.51]
DietQ9	[−.015, .001]	[−1.65, .438]
DietQ11	*[−.015, −.002]	[−3.00, −.284]
DietQ19	*[−.014, −.000]	[−.217, 3.21]
DietQ20	[−.011, .001]	*[.009, 3.39]
DietQ23	*[.002, .011]	[−3.00, .815]
DietQ24	*[.000, .013]	*[−2.14, −.351]
PAMin	[−.009, .223]	[−1.19, .207]
MissMedDays	*[−.013, −.000]	*[.739, 2.74]

* indicates significant ($P \leq 0.05$, 2-tailed) mediational effects.

throughout the study period (baseline to week 13). There was a small difference in behavior change between two groups (only two diet questions showed a statistically significant difference between groups), suggesting that behavior change differences between the groups did not correlate with the greater reduction of BP observed in the MAP group (Table 4). Therefore, we evaluated the MAP group further by using a mediation model to better understand whether mindfulness practice (dose effect) mediated the BP reduction through lifestyle behavior change.

Of note, Figure 4 illustrates the relationship between practice minutes and SBP reduction. Participants who practiced more did not have a larger reduction in SBP. Therefore, the more substantial reduction in SBP and DBP, as seen in the MAP group, could not be attributed to just mindfulness practice time. It could be that any amount of practice may provide some beneficial outcome to the practitioner.

As suggested in the previous paragraph, if the amount of mindfulness practice minutes did not explain the greater BP reduction in the MAP group than the HPP group, then possibly, the lifestyle behavior change in the MAP group may have impacted the BP difference. A simple mediation analysis was conducted in the MAP group to evaluate whether mindfulness practice minutes had a positive impact on health behaviors associated with greater BP reduction observed in the MAP group. Ten mediators were included in the mediation analysis, eight of which are diet-related questions (Table 5).

The other mediators are PAMin (physical activity minutes) and MissMedDays (antihypertensive medication missed days). In Figure 5, the coefficients of the various paths are shown. Paths that are significant are noted with an asterisk. For example, for every one unit in mindfulness practice minutes, a decrease in MissMedDays of -0.007 was seen, and for every one-unit increase of MissMedDays, an increase in systolic blood pressure (SBP) of 2.25 was seen. The direct effect of mindfulness practice minutes on SBP (-0.024) was not significant; however, the total effect of mindfulness practice minutes on SBP with indirect effect (ab) of (-0.057) was significant, resulting in a 40% increase in SBP reduction in total effect (c) compared to direct effect (c') alone. The direct effect and total effect of MPM on DBP were not significant, 0.012 and -0.022 , respectively. The 95% confidence intervals for the path (a) and path (b) are listed in Table 6.

4 | DISCUSSION

These findings suggest that MAP had a modest impact on lifestyle behaviors but lowered BP in adults with HTN. The MAP group's BP decreased at baseline from 138/89 to 119/77 mm Hg at week 13. In contrast, the HPP group's BP decreased from 134/81 to 127/80 mm Hg. The more significant drop in BP observed in the MAP group may be partially explained by MAP's positive influence on lifestyle behaviors, as demonstrated in the mediational analysis results. We hypothesize that the addition of a mindful meditation approach with health education provides the most robust strategy for individuals wanting to better self-manage their BP.

The more significant drop in BP observed in the MAP group given the relatively small sample size could have occurred for several reasons. The small sample size may have afforded more attention to both groups, but more so for the MAP group as MAP classes are 2-hour weekly sessions compared to the HPP group's 1-hour sessions. Weekly communications regarding reminders for class attendance and requests to fill out the questionnaires may have added another layer of attention to both groups. Selection bias may also have contributed to the impressive reduction in BP observed in both groups. Participants may have been more inclined or motivated to take better control of their BP or were possibly more encouraged by the MAP class offering. Surprisingly, antihypertensive medication adherence was high for both groups, a possible explanation for the impressive BP drop observed. Overall, although not conclusive, these possible reasons may have contributed to a more favorable environment where participants were more willing and motivated to take better care of their health and BP.

The method used to measure BP is another important consideration. The 2017 guidelines for prevention, detection, evaluation, and management of BP in adults take into account self-monitoring of BP in an out-of-office setting as the best evidence for BP measurements.³ Ambulatory blood pressure monitoring (ABPM) is viewed as the best out-of-office BP measuring protocol, although the ABPM comes with its set of challenges.³² Case in point, the Hypertension Analysis of Stress Reduction Using Mindfulness Meditation and Yoga (HARMONY) study, evaluated MBSR's effect on BP at week 12 and week 24 from baseline and found no significant BP reduction of the MBSR group compared to the waitlist control group.³² The HARMONY study authors used the ABPM method where BP measurements were taken at 15 minute intervals between 7:00 AM and 11:00 AM during the day and at 30-minute intervals at night between 11:00 PM and 7:00 AM. The frequency in BP measurements may have contributed to higher BP readings.³² We chose the out-of-office home BP monitoring for participants' convenience and comfort and believe that it provides a more realistic BP reading.

Meditation approaches have shown, to varying degrees, lower BP among individuals with pre-HTN and HTN.⁷ Transcendental meditation was one of the first meditation methods that made its way to the mainstream of complementary therapies in the United States. It was one of the first meditation approaches that demonstrated beneficial BP changes.³³ Likewise, the RR and Herbert Benson's research prompted other investigators to utilize meditation approaches for improving CV health. While these two contemplative approaches have shown to lower BP, the mindful meditation-based approaches have appealed to a larger audience.⁹

Because of its popularity and appeal, mindful meditation approaches have adapted the techniques found in MBSR for different health disorders. For example, Loucks and associates developed the Mindfulness-Based Blood Pressure Reduction (MB-BP) for pre-HTN and HTN.¹⁰ Their MB-BP study showed that baseline SBP lowered from 139.3 to 133.2 mm Hg at one-year follow-up compared to the waitlist control. The MB-BP was adapted from MBSR, hence the instructors for the MB-BP were certified in MBSR. The MB-BP

training consists of eight 2.5-hour weekly sessions and a 7.5-hour 1-day session, similar to MBSR's time commitment. Because MB-BP is specific to individuals with HTN, the education component included information on lifestyle behavior changes (physical activity, the Dietary Approaches to Stop Hypertension plan, as well as lowering alcohol and salt intake) known to lower BP.¹⁰

Health education, especially in BP management, is essential for individuals struggling to keep their BP under control. However, health education alone is not enough for drastic lifestyle behavior changes. For example, Lynch and colleagues found that even a comprehensive self-management approach did not yield the desired health outcomes among adults with co-morbid diabetes type II and HTN.³⁴ Their results showed no significant changes in HbA1c (commonly known as glycated hemoglobin, indicator for diabetes control) and weight, suggesting that physical activity and diet changes were not followed through by the study participants.³⁴ Our study results suggest that adding a mindful meditation approach with health education improves lifestyle behavior changes among adults with HTN, albeit the small sample size.

Although we have made significant strides in studying the benefits of mindful meditation, we are still far from fully understanding the mechanisms of mindful meditation. Some theorists suggest that mindful meditation approaches promote a state of acute awareness, particularly self-awareness, which potentially could lead to better self-regulation.^{35,36} Colloquially, the act of self-regulation is known as willpower or self-control. Those with "stronger" willpower tend to foster healthier behaviors.^{37,38} Studies have shown that self-regulation is an essential component of the self-management process, which is particularly important in adopting and maintaining positive health behaviors.³⁹⁻⁴³

Our study suggests that a mindful meditation approach is a technique that may influence lifestyle behavior change. However, without comprehending the mechanistic pathways related to the positive health outcomes, we may not fully grasp the potential benefits of mindful meditation approaches. As with Louke and colleagues' study, it is prudent for future studies to include a theoretical framework to support mindful meditation approaches for CV risk reduction.^{10,44}

5 | LIMITATIONS

Two subjects in the MAP group discontinued antihypertensive medications, which might mean that the actual mindfulness effect was larger than measured. The self-reported surveys may be biased, which may lead to more variability, or if the bias is toward more socially favorable responses, the reported health behaviors and practice minutes may be more likely to be overestimated. Some of the short-term impacts of mindfulness practice on directly lowering BP may be attributed to its calming effect. We were not able to disentangle the calming effect that mindfulness has on BP in our analysis. Our relatively small sample size may have limited our ability to identify some possible positive effects of MAP on health behavior change between the groups. Nonetheless, this is one of the first studies to demonstrate

HTN self-management improvements using a mindful meditation approach. Lastly, we did our best to schedule the MAP and HPP at the same 6-week cycle, but in some instances, the timing of classes and participants' availability did not align; therefore, pseudo-randomization was used.

6 | CONCLUSION

These findings show that the MAP intervention reduces BP in participants with HTN, consistent with other mindful meditation approaches.⁷ In terms of the feasibility and effect size calculation goals, there was good retention during the 6 weeks of training that continued in the 6 weeks of follow-up. The effect sizes on BP reductions were substantial. However, at least using the measures here, the influence of lifestyle behaviors may result in more moderate effect sizes. Despite minimal differences in lifestyle behavior change between the two groups, the more significant BP reduction observed in the MAP group supports evidence that a mindful meditation approach is a low-risk method for lowering BP in adults with HTN.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

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Eunjoo An had full access to all of the data in this study and takes complete responsibility for the integrity of the data and the accuracy of the data analysis.

TRANSPARENCY STATEMENT

The lead author affirms that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are openly available in Ann Arbor, MI: Inter-university Consortium for Political and Social Research at <https://www.icpsr.umich.edu/web/pages/ICPSR/index.html>.

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