A Randomized Controlled Trial on Effects of the Transcendental Meditation Program on Blood Pressure, Psychological Distress, and Coping in Young Adults

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BACKGROUND

Psychological distress contributes to the development of hypertension in young adults. This trial assessed the effects of a mind-body intervention on blood pressure (BP), psychological distress, and coping in college students.

METHODS

This was a randomized controlled trial (RCT) of 298 university students randomly allocated to either the Transcendental Meditation (TM) program or wait-list control. At baseline and after 3 months, BP, psychological distress, and coping ability were assessed. A subgroup of 159 subjects at risk for hypertension was analyzed similarly.

RESULTS

Changes in systolic BP (SBP)/diastolic BP (DBP) for the overall sample were -2.0/-1.2 mm Hg for the TM group

compared to +0.4/+0.5 mm Hg for controls (P=0.15, P=0.15, respectively). Changes in SBP/DBP for the hypertension risk subgroup were -5.0/-2.8 mm Hg for the TM group compared to +1.3/+1.2 mm Hg for controls (P=0.014, P=0.028, respectively). Significant improvements were found in total psychological distress, anxiety, depression, anger/hostility, and coping (P values < 0.05). Changes in psychological distress and coping correlated with changes in SBP (P values < 0.05) and DBP (P values < 0.08).

CONCLUSIONS

This is the first RCT to demonstrate that a selected mind–body intervention, the TM program, decreased BP in association with decreased psychological distress, and increased coping in young adults at risk for hypertension. This mind–body program may reduce the risk for future development of hypertension in young adults.

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Hypertension affects ~33% of US adults.¹ College age individuals with mild blood pressure (BP) elevation are three times more likely to develop hypertension within 30 years than normotensives.²

Psychological distress such as anxiety, depression, and anger/hostility have been found to contribute to the development of hypertension.³ In young adults, affective distress was associated with the development of hypertension over 15 years.⁴ The risk for hypertension associated with anxiety, depression, and anger/hostility is similar to traditional predictors of hypertension such as obesity and physical inactivity.⁵ Studies also have indicated that positive coping strategies may moderate the

effect of stressful events on BP while negative coping may have a detrimental effect. $^{6,7}\,$

College students are particularly prone to psychological distress, ⁸ caused by interpersonal and social problems, pressures to succeed academically, financial strains, and uncertain futures. ^{9,10,11} Previous controlled studies on the Transcendental Meditation (TM) program, one of the most widely used mindbody approaches for reducing psychological distress, has shown significant reductions in BP, ^{12,13} anxiety, ^{14,15} depression, ¹⁵ and improved coping ability ¹⁶ in students and adults.

To further investigate the effectiveness of the TM program on BP, psychological distress, and coping, we conducted a randomized controlled trial (RCT) in college students. To our knowledge, this is the first RCT to evaluate the efficacy of a mind-body intervention on BP and psychological factors in young adults.

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METHODS

Study design. This was a single-blind RCT comparing stress reduction with the TM program to wait-list controls on change in BP, psychological distress, and coping in young adults.

The present study reports on both the overall sample and a subgroup at risk for hypertension. The field site was American University (Washington, DC). The administrative and datacoordinating center was the Center for Natural Medicine and Prevention at Maharishi University of Management Research Institute (Maharishi Vedic City, IA). The institutional review boards of both institutions approved the study. The trial was conducted from January 2006 to May 2007.

Study participants. The subjects were 298 students from American University and other surrounding colleges, including Georgetown and University of District of Columbia. Inclusion criteria included enrollment in an undergraduate or graduate program through August 2006. Students were excluded if they had a history of hypertension, hypoglycemia, chronic fainting, coronary heart disease, or current BP above 140/90 mm Hg or below 90/60 mm Hg.

Subjects were included in a high-risk subgroup if they had one or more of the following risk factors for hypertension: systolic BP (SBP) >130, diastolic BP (DBP) >85,¹⁷ family history of hypertension,¹⁸ overweight, or obesity defined as body mass index ≥25.^{19,20}

Study protocol. Interested participants were scheduled for small group informational sessions presented by the research staff and TM instructional staff. After providing written informed consent, students underwent baseline testing.

Students were then randomized to experimental or control groups, using the random blocks method²¹ stratifying on gender (male/female) and self-reported attention deficit hyperactivity disorder status (yes, no), to either (a) immediate instruction in the TM program or (b) wait list/delayed start condition. (The attention deficit hyperactivity disorder stratification was for the purpose of a separate substudy.)

The treatment group allocations were concealed by the study statistician, with individual treatment group assignments revealed to the project manager only when study participants completed baseline testing. Subjects were post-tested after ~3 months. All assessments were administered by research staff who were masked to treatment condition. Thus, this was a single-blind design. After post-test evaluation, wait-list participants were offered TM instruction.

Outcome measures. The primary outcome for the study was casual BP. Secondary outcomes were psychological distress (total mood disturbance, anxiety, depression, anger/hostility) and coping ability (global constructive thinking).

BP was measured in a seated position, with an automated BP monitor (model #UA-787; A&D Medical, Albany, GA) using standard clinical trial technique.²² Three readings were taken in both pre- and post-testing sessions. The first BP reading was taken after an adaptation period of 5 min in which subjects were seated comfortably not practicing any formal relaxation technique. Thereafter, a 1-min adaptation period was used between the first, second, and third readings. The last two were averaged for the study score.

Family history of hypertension was determined by self-report and body mass index by a ratio of weight and height (BMI = weight in kilograms/(height in meters × height in meters)).

Psychological distress was measured with the Profile of Mood States total mood disturbance main scale and tension/anxiety, depression/dejection, and anger/hostility subscales.²³ These scales were selected because of the association of these constructs with BP.⁵ Internal consistency coefficients range from 0.90 to 0.95.²³

Coping was measured using the Constructive Thinking Inventory global constructive thinking main scale, which measures constructive and destructive thinking patterns underlying coping ability. Previous research has shown that global constructive thinking is sensitive to mind-body intervention. He global constructive thinking scale includes emotional and behavioral coping items, with higher scores indicating more positive, healthy coping. Internal consistency is reported to be 0.90. Healthy coping.

Intervention. The TM technique is the principal mind-body modality of the Maharishi Vedic Approach to Health, a comprehensive traditional system of natural health care derived from the ancient Vedic tradition.²⁷ The TM technique is a simple, natural, and easy-to-learn procedure that allows the ordinary thinking process to become more quiescent and a unique psychophysiologic state of "restful alertness" to be gained.²⁸ This distinctive state of restful alertness,^{28,29} is characterized by decreased respiration rates, sympathetic tone and hypothalamic-pituitary-adrenal axis activity, 30,31 and high electroencephalography coherence.³² The program is practiced twice a day for 20 min while sitting comfortably with eyes closed.³³ Students who learned the TM technique were taught by certified instructors, according to the standardized format offered in the United States by Maharishi Vedic Education Development Corporation³³ and used in previous trials.^{34,35}

The TM technique was taught in a seven-step course³³ as follows: (i) group introductory lecture on potential benefits and previous research (90 min); (ii) group preparatory lecture, discussing the mechanics and origin of the TM technique (90 min); (iii) personal interview (10 min); (iv) personal instruction session (90 min); (v-vii) group "verification and validation of the practice" sessions on 3 consecutive days following personal instruction, verifying correctness of TM practice, and providing the understanding of the mechanics of the TM technique.

After the seven-step course, students were invited to attend individual meetings with the TM instructor to verify the mechanics of practice and maintain regularity. These meetings were held weekly for the first month, then monthly thereafter (30 min each). Weekly (group) knowledge meetings were also available.

Adherence. Adherence to the TM program was measured via self-report at post-testing among those who had received TM instruction. Participants were asked to describe the regularity

of their practice of the TM technique over the preceding week (not at all, less than once/day, once a day, or twice a day). Participants reporting having practiced at least once a day were considered adherent.

Power analysis. Based on previously published data,¹³ we estimated pre/post-test differences between TM and control groups of –4.4 (s.d. = 8.1) mm Hg for SBP and –3.9 (s.d. = 7.5) mm Hg for DBP. Calculations using SAS Proc Power (SAS, Cary, NC) indicated 90% power to detect significant differences in BP change at the 0.05 level between groups among the whole sample, and 80% power to detect significant differences between groups in the high-risk subsample.

Statistical methods. Differences between the treatment groups on demographic and baseline variables was examined using t-tests for continuous variables and χ^2 -tests for categorical variables, and by multivariate analysis of variance to assess multivariate differences across all variables. To investigate treatment effects on change in outcome variables from baseline and post-test, analysis of covariance (ANCOVA) was performed in the overall sample and in the hypertension risk subgroup on all eligible subjects with baseline and post-test data. In these analyses, the independent variable was TM program vs. the wait-list control condition. Baseline score of the dependent variable was a prespecified covariate; other baseline factors were not used in the primary analyses to statistically adjust estimated treatment effects. Additional ANCOVA were performed covarying also for baseline variables on which there were significant differences between the treatment groups, in order to assess the potential influence of such differences on the treatment outcomes. To investigate relationships in change among the outcome variables, partial correlations controlling for baseline scores for each pair of variables were calculated by multiple regression analysis. All analyses are reported as two-tailed.

RESULTS

Baseline variables

Of the 298 participants (average age = 25.5 years), 117 (40%) were men; 62% were Caucasian, 16% African American, 7% Asian American, 4% Hispanic, and 11% were of other ethnicities or declined to report race/ethnicity. Average SBP/DBP was 117/76 mm Hg.

Table 1 shows baseline data for the 207 students who completed both BP baseline and post-testing by group. Multivariate analysis of variance showed no significant differences between groups on baseline variables (F(17,173) = 0.78; P = 0.72).

Pre/post-test changes

ANCOVA, covarying for the baseline score of the dependent variable for the 207 subjects who completed baseline and post-test, indicated a mean reduction in SBP for the TM group of $-2.0 \,\mathrm{mm}\,\mathrm{Hg}$ compared to $+0.4 \,\mathrm{mm}\,\mathrm{Hg}$ for wait-list controls (P=0.15). DBP change was $-1.2 \,\mathrm{mm}\,\mathrm{Hg}$ for the meditation group compared to $+0.5 \,\mathrm{mm}\,\mathrm{Hg}$ for controls (P=0.15).

Table 1 | Baseline comparisons by treatment groups for students completing 3-month post-testing (N = 207)

	Mean \pm s.d.		
Variable	TM (n = 93)	Control (<i>n</i> = 114)	<i>P</i> value
Age	25.4 ± 9.2	26.2 ± 9.9	0.57
Gender, % male	38.7%	43.0%	0.54
Graduate students, %	33.3%	27.2%	0.34
Undergraduates, %	64.5%	71.1%	0.32
Weight, kg	68.0 ± 12.3	70.6 ± 16.1	0.21
BMI≥25	22.5%	31.5%	0.16
Current smoking, y/n	10.8%	12.3%	0.73
Family history of hypertension	26.9%	23.7%	0.60
Alcohol usage, drinks/week	4.3 ± 5.2	4.2 ± 6.4	0.91
SBP, mm Hg	116.7 ± 12.8	117.9 ± 13.7	0.50
DBP, mm Hg	74.7 ± 8.4	76.6 ± 8.7	0.12
SBP/DBP >130/85 mm Hg	23.7%	24.6%	0.88
Total psychological distress	45.2 ± 36.0	40.1 ± 33.2	0.30
Anxiety subscale	13.6 ± 6.8	12.1 ± 6.4	0.12
Depression subscale	13.7 ± 12.1	12.9 ± 11.2	0.64
Anger/hostility subscale	11.2 ± 9.0	9.9 ± 8.0	0.27
Coping ability	95.3 ± 17.5	101.5 ± 15.9	0.009

BMI, body mass index; DBP, diastolic blood pressure; SBP, systolic blood pressure; TM, Transcendental Meditation.

The TM group compared to controls showed improvement in total psychological distress (P = 0.004), anxiety (P = 0.003), depression (P = 0.012), and anger/hostility (P = 0.06), subscales, and coping ability (P = 0.003) (see **Table 2**).

Additional BP analysis, covarying for both baseline score of the dependent variable and baseline coping ability indicated a change in SBP for the TM group of -2.0 ± 1.2 mm Hg vs. $+0.4 \pm 1.1$ mm Hg for controls (P=0.14) and a change in DBP for the TM group of -1.4 ± 0.9 mm Hg vs. $+0.6 \pm 0.8$ mm Hg for controls (P=0.10).

Hypertension risk subgroup

Baseline variables. A total of 159 subjects met the inclusion criteria for this subgroup. Of these, 112 completed baseline and post-testing were included in these analyses. Average SBP/DBP was 122/79 mm Hg. In terms of inclusion criteria for this subgroup, 45% had BP >130/85, 46% had at least one family member with hypertension, and 50% had a body mass index \geq 25 (see **Table 3**). Multivariate analysis of variance showed no significant differences between groups on baseline variables (F(17,86) = 0.82; P = 0.67).

Pre/post-test changes. Findings indicated significant reductions for the TM group vs. controls in both SBP (-5.0 mm Hg vs. +1.3 mm Hg; P = 0.014) and DBP (-2.8 mm Hg vs. +1.2 mm Hg; P = 0.028).

Significant improvement was found in total psychological distress (P = 0.001) and anxiety (P = 0.001), depression (P = 0.013),

Table 2 | Pre/post-test changes in the Transcendental Meditation group compared to controls

	$ Adjusted\ mean\ change\ \pm \ s.e.m.$		
Variable	TM (n = 93)	Control (<i>n</i> = 114)	<i>P</i> value
SBP, mm Hg	-2.0 ± 1.2	0.4 ± 1.1	0.15
DBP, mm Hg	-1.2 ± 0.9	0.5 ± 0.8	0.15
Total psychological distress	-18.9 ± 3.2	-6.1 ± 2.9	0.004
Anxiety	-3.7 ± 0.7	-1.0 ± 0.6	0.003
Depression	-5.2 ± 1.0	-1.9 ± 0.9	0.012
Anger/hostility	-3.2 ± 0.8	-1.0 ± 0.8	0.06
Coping ability	6.0 ± 1.1	1.5 ± 1.0	0.003

Means are adjusted by covarying for the baseline score on each outcome variable. DBP, diastolic blood pressure; SBP, systolic blood pressure; TM, Transcendental Meditation.

Table 3 | Baseline comparisons of hypertension risk subgroup by treatment groups (N = 112)

Variable	Mean ± s.d.	Mean ± s.d.	P value
	TM (n = 48)	Control (<i>n</i> = 64)	
Age	27.7 ± 10.3	29.4 ± 11.2	0.42
Gender, % male	37.5%	40.6%	0.74
Graduate students, %	37.5%	29.7%	0.39
Undergraduates, %	58.3%	68.8%	0.26
Weight, kg	73.0 ± 13.6	75.5 ± 18.6	0.44
BMI≥25	42.6%	54.8%	0.21
Current smoking y/n	10.4%	10.9%	0.93
Family history of hypertension	52.1%	42.2%	0.30
Alcohol usage, drinks/week	4.1 ± 5.7	3.1 ± 4.6	0.30
SBP mm Hg	122.5 ± 13.4	121.2 ± 15.9	0.65
DBP mm Hg	78.3 ± 8.3	79.3 ± 9.4	0.56
SBP/DBP >130/85 mm Hg%	16.7%	28.1%	0.16
Total psychological distress	47.0 ± 38.7	39.0 ± 33.7	0.25
Anxiety	13.8 ± 7.1	12.4 ± 6.6	0.31
Depression	15.2 ± 12.8	12.1 ± 11.0	0.17
Anger/hostility	11.6 ± 9.4	9.4 ± 8.3	0.19
Coping ability	94.0 ± 17.8	100.8 ± 16.4	0.041

DBP, diastolic blood pressure; SBP, systolic blood pressure; TM, Transcendental Meditation.

and anger/hostility (P = 0.029) subscales, and coping ability (P = 0.002) (see **Table 4**). Changes in psychological distress and coping for both groups are shown in s.d. units in **Figure 1**.

Additional analyses for BP in the high-risk sample, covarying for both baseline score of the dependent variable and baseline coping ability, continued to indicate significant reductions for the TM group vs. controls in both SBP ($-5.3 \pm 2.0 \,\mathrm{mm}$ Hg vs. $+1.6. \pm 1.7 \,\mathrm{mm}$ Hg; P=0.01) and DBP ($-3.3 \pm 1.4 \,\mathrm{mm}$ Hg vs. $+1.4 \pm 1.2 \,\mathrm{mm}$ Hg; P=0.013). Two-factor ANCOVA on the entire sample, with treatment and level of BP

Table 4 | Pre/post-test changes comparing the Transcendental Meditation group to controls in the hypertension risk subgroup

	Adjusted mean		
Variable	TM (n = 48)	Control (<i>n</i> = 64)	P value
SBP (mm Hg)	-5.0 ± 1.9	1.3 ± 1.7	0.014
DBP (mm Hg)	-2.8 ± 1.4	1.2 ± 1.2	0.028
Total psychological distress	-21.8 ± 4.2	-1.6 ± 3.6	0.001
Anxiety	-4.7 ± 0.9	-0.2 ± 0.8	0.001
Depression	-5.4 ± 1.4	-0.7 ± 1.2	0.013
Anger/hostility	-3.8 ± 1.1	-0.5 ± 1.0	0.029
Coping ability	8.2 ± 1.5	1.9 ± 1.3	0.002

Means are adjusted by covarying for the baseline score on each outcome variable. DBP, diastolic blood pressure; SBP, systolic blood pressure; TM, Transcendental Meditation.

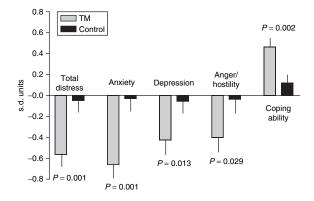


Figure 1 Three-month pre/post-test change in psychological distress and coping comparing the TM group to controls in the hypertension risk subgroup. TM, Transcendental Meditation.

risk (high vs. low) as grouping factors, covarying for baseline dependent variable and coping ability, showed significant interactions between treatment and level of BP risk for SBP (P = 0.01) and DBP (P = 0.018), indicating that BP treatment effects were specific to the high-risk subgroup.

Associations between outcome variables

Reduction in SBP was associated with change in total psychological distress (partial r = 0.19; P = 0.043), anxiety (r = 0.21; P = 0.029), depression (r = 0.21; P = 0.027), and coping ability (r = -0.21; P = 0.026). Reduction in DBP was associated with change in anxiety (partial r = 0.17; P = 0.08) and coping ability (r = -18; P = 0.06).

In addition, change in psychological distress scales and coping ability showed significant negative correlations with each other (partial r values range from -0.44 to -0.68; P values < 0.01).

Adherence to TM practice

Of the 93 participants who had received TM instruction and completed post-testing, 64% of the entire sample and 67% of the hypertension risk subgroup reported practicing the

TM technique regularly. There was no significant difference between the entire sample and high-risk subgroup with regard to the proportion of TM subjects who were regular in their practice ($\chi^2(1) = 0.365$; P = 0.55). An additional 15% in the entire sample and 13% in the subgroup reported some practice of the technique.

Comparison among completers and attriters at baseline

Across groups, there were no significant differences between subjects who completed post-testing (n = 207) and those who did not complete post-testing (n = 91) on any of the primary or secondary outcome variables at baseline, either in the whole sample or in the high-risk subgroup. Also no significant differences between the TM group and control group among subjects who did not complete post-testing were observed on any of the primary or secondary outcome variables at baseline, either in the entire sample or in the high-risk subsample.

DISCUSSION

Results of this RCT in a general population of college students indicated nonsignificant reductions of -2.0 mm Hg in SBP and –1.2 mm Hg in DBP in the TM group compared to increases of 0.4 mm Hg in SBP and 0.5 mm Hg in DBP in the control group. These BP reductions in the overall sample may have been limited by the relatively low baseline BP levels. However, findings in this sample showed significant improvement in psychological distress and coping ability. Analysis of the hypertension risk subgroup indicated significant reductions of -5.0 mm Hg in SBP and -2.8 mm Hg in DBP in the TM group compared to increases of 1.3 mm Hg in SBP and 1.2 mm Hg in DBP in the control group. Thus, net reductions of -6.3 mm Hg in SBP and -4.0 mm Hg in DBP for the TM group relative to the control group were observed. Decreased psychological distress and increased coping ability were also found for the TM group compared to controls in the high-risk sample. Reductions in BP were significantly correlated with reductions in psychological distress and increased coping.

Recent meta-analyses of RCTs in predominantly prehypertensive and hypertensive subjects showed that practice of the TM program produced an average SBP/DBP reduction of about $-5.0/-3.0\,\mathrm{mm\,Hg.^{12,13}}$ The net reductions $-6.3\,\mathrm{mm\,Hg}$ in SBP and -4.0 in DBP for the TM group relative to the control group in the high-risk subgroup in this study are consistent with previous findings in high-BP samples. Based upon a risk prediction scoring formula for the onset of hypertension from Framingham study data, the net reductions in BP for the TM group are associated with a 52% lower risk for onset of hypertension over a 4-year period. 20

Regression analyses further showed that the changes in SBP and DBP were significantly correlated with changes in psychological distress, including anxiety and depression, and coping ability. These findings are congruent with a biobehavioral model of high BP.³⁶ According to this model, psychological distress leads to hyperactivation of the sympathetic nervous system and hypothalamic–pituitary–adrenocortical axis.³⁷ This, in turn, leads to acute and chronic elevations in BP. Thus

the reductions in psychological distress factors may have contributed to lower BP. Reductions in sympathetic nervous system and hypothalamic–pituitary–adrenocortical activation with TM practice reported in previous studies suggest central nervous system and neuroendocrine pathways for the effects of the psychological distress changes on BP observed in the current trial.³⁸

Another element in this model is the buffering effect of coping mechanisms. According to the biobehavioral stress model, external stressors (such as financial concerns and work/school stress) induce negative affect (in the form of anxiety, depression, and anger), which in turn adversely impact BP.5,36,39,40 The influence of external stressors on negative affect and BP may be moderated by positive coping mechanisms (employed by constructive thinkers). Previous research has shown that high global constructive thinkers appraise external stressors as less threatening and produce less negative affective and cognitive responses to laboratory stressors, with lower levels of physiological arousal. In the present study, coping ability correlated with BP and psychological distress factors. Thus improved coping ability may have contributed to lower BP via its effects on moderating/reducing psychological distress factors.

Study strengths and limitations

There were several important methodological strengths, including the use of random assignment, the use of assessors masked to treatment condition to reduce demand characteristics, and a sizable racially diverse subject sample, which lends confidence in the generalizability of the findings to the college student population.

A limitation is that about 30% of the pretest sample was unavailable for post-testing. This concern is mitigated by the fact that across groups completers did not differ from non-completers on any baseline entry characteristics. Also there were no differences between groups on baseline primary and secondary outcomes in noncompleters.

It is unlikely that baseline differences between the treatment arms in the high-risk subsample could have contributed to the observed BP reduction. ANCOVA results for BP were very similar, regardless of whether baseline coping ability, which was significantly different between groups, was included as a covariate. Differences on other baseline variables were relatively small (~0.1 s.d. on BP and 0.2 s.d. on total psychological distress) and are therefore unlikely to have affected the results substantially.

Future randomized trials of the TM program in college students should evaluate longer-term intervention periods to assess long-term effects on BP and psychological distress.

In conclusion, this is the first RCT to demonstrate that a selected mind-body intervention, the TM program, significantly decreased BP in association with improved psychological distress and coping ability in young adults at risk for hypertension. In addition, there were improvements in mental health in the general student sample and trends toward reduction of BP. Practice of this mind-body intervention may be an effective method to reduce psychological distress, BP, and the

risk for prospective development of hypertension in high-risk young adults.

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