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A Randomized Controlled Trial of Stress Reduction in African Americans Treated for Hypertension for Over One Year

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Abstract

Background— Psychosocial stress has been implicated in the disproportionately higher rates of hypertension among African Americans. This randomized controlled trial compared the effects of two stress reduction techniques and a health education control program on hypertension during a period of 1 year in African-American men and women (N = 150, mean age 49 ± 10 years, mean blood pressure (BP) = 142/95 mm Hg) at an urban community health center.

Methods— Interventions included 20 min twice a day of Transcendental Meditation (TM) or progressive muscle relaxation (PMR), or participation in conventional health education (HE) classes. All subjects continued usual medical care. Outcomes assessed were systolic BP and diastolic BP at 3, 6, 9, and 12 months after treatment, analyzed by repeated measures ANCOVA.

Results— The TM group showed decreases in systolic BP/diastolic BP of −3.1/−5.7 mm Hg compared to −0.5/−2.9 mm Hg for PMR or HE, (P = .12 to .17 for systolic BP, P = .01 for diastolic BP). In addition the TM group demonstrated reduced use of antihypertensive medication relative to increases for PMR (P = .001) and HE (P = .09) groups. Group analysis by gender showed that women practicing TM had decreased BP (−7.3/−6.9 mm Hg) significantly more than women practicing PMR (0.7/−2.7 mm Hg) or HE (−.07/−3.0 mm Hg) (P .01 to .03). The change in men praticing TM (0.2/−4.7 mm Hg) was greater than men practicing HE (−0.9/−2.0 mm Hg) for diastolic BP only (P = .09,) and not different from PMR men (−2.0/−3.1).

Conclusions— A selected stress reduction approach, the Transcendental Meditation program, may be useful as an adjunct in the long-term treatment of hypertension in African Americans.

Keywords

Hypertension; African Americans; stress reduction; clinical trial; lifestyle modification; transcendental meditation; progressive muscle relaxation

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Hypertension is a major cause of the disproportionately high rates of coronary heart disease (CHD), stroke, and renal disease in African Americans compared to whites.[1,2] African Americans suffer from a higher incidence, prevalence, and severity of hypertension than whites,[3] with increased end-organ damage[4] and lower treatment rates.[5] Cardiovascular disease (CVD) is a primary contributor to the disparities in health and health care between African Americans and white Americans.[6,7]

Pharmacologic therapy is widely recommended for treatment of hypertension, yet despite advances in conventional antihypertensive drug therapy, the age-adjusted prevalence of stroke has increased, the rate of decline of CHD has leveled off, and the rates of morbidity and mortality from end-stage renal disease and heart failure have risen in the past decade.[8,9] Moreover, the efficacy of drug therapy in preventing the most common complication of hypertension—CHD—is significantly lower than expected.[10,11] Limitations of conventional antihypertensive pharmacotherapy include adverse effects, low compliance, high cost, and restricted access.[12,13] The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC 7) recommends lifestyle modification for high BP, from prehypertension to hypertension.[14] Despite this national guideline, there is a paucity of data from randomized controlled trials on the long-term effects of nonpharmacologic therapies for hypertension.[15,16]

Among lifestyle factors, accumulating evidence indicates that psychosocial stress is an important contributor to hypertension,[17,18] especially in African-American populations.[19] Systematic reviews of the efficacy of stress reduction approaches for hypertension have shown either negative results or heterogeneity of effects on blood pressure (BP) depending on the experimental design and selection of specific technique.[16,20,21] However, meta-analyses and reviews of stress reduction approaches indicate that the Transcendental Meditation program may be distinctively effective in reducing high BP and related CVD outcomes,[22,23] and is associated with greater BP effects in both medicated and nonmedicated subjects.[22,24]

A previously published randomized clinical trial of older African Americans found that TM practice reduced systolic and diastolic BP significantly more than progressive muscle relaxation (PMR) or a health education control program (HE) during a 3-month period for both genders and for both high and low risk groups on six measures of hypertension risk: psychosocial stress, obesity, alcohol, physical inactivity, sodium/potassium, and all factors combined.[25,26] Modest reductions in clinic BP and home BP has been shown in African-American older subjects practicing PMR compared to HE.[26] Yet few studies have directly compared two different approaches to stress reduction, particularly TM and PMR, in the context of a randomized controlled trial and none have provided long-term follow-up of BP outcomes. Therefore, the current clinical trial was independently conducted to determine the effects of two different approaches to stress reduction (TM and PMR) compared to HE on long-term BP outcomes in African Americans with hypertension. On the basis of the short-term findings from the earlier study,[25] it was hypothesized that TM would have a greater effect followed by PMR and HE in decreasing BP in hypertensive African-American adults.

Methods

Study Population

Eligible subjects included those who: 1) were self-identified as African American; 2) were residents of West Oakland, California, or surrounding communities; and 3) had a systolic BP of 140 to 179 mm Hg or a diastolic BP of 90 to 109 mm Hg averaged over three successive BP measurements. Exclusion criteria included psychiatric disorder (psychosis, substance abuse disorder, dementia), and life-threatening medical illness. Participants were recruited

from the adult patient populations of local health centers, senior citizens' centers, churches, and the Department of Aging programs. Blood pressure levels outside the required range was the major cause for subject ineligibility. Subjects were reimbursed $10 per visit to the research clinic to cover transportation and other costs related to study participation. None of these recruited subjects had participated in the previous 3-month study on stress reduction and hypertension.[25,26] The experimental protocols and the process of obtaining informed consent from each subject were approved by the West Oakland Health Center, Maharishi University of Management institutional review committees.

A total of 234 subjects were pretested and randomized. Of these, 19 subjects were excluded because of confirmed diagnosis of substance abuse disorder and 18 subjects were excluded because they did not meet the original BP inclusion criteria. Of the remaining 197 randomized subjects, 150 completed post-testing at month 12. The final numbers for the groups were TM = 54, PMR = 52, and HE = 44. During the study period there was one death in the PMR group, which was non-CVD related. The most frequent cause of attrition was change of residence. There were no significant differences between treatment groups with regard to the numbers of subjects excluded or lost to attrition.

Design and Measurement

Blood pressure and heart rate measurements were performed by trained clinic staff who were blinded to treatment status of subjects using standard clinical trial technique recommended by the American Heart Association and used in the Multiple Risk Factor Intervention Trial.[27] Pretest BP was measured on five different baseline sessions during approximately 1 month. Three measurements were taken each session, spaced during approximately 1 h, and the mean of the three was used as the value for that session. After baseline measurements were completed, subjects were randomly allocated by computer program with stratification by age, gender, and antihypertensive medication status into one of the three treatment groups, TM, PMR, or HE. To minimize the effects of laboratory habituation and white coat effect,[28] the pretest scores used in the statistical analyses were the means of baseline visits 4 and 5. Subjects were post-tested at 3, 6, 9, and 12 months, with three measurements each session, except that the 12-month post-test score was the mean of four sessions at weeks 49 through 52 after randomization.

Change in BP Medication

A physician and co-author familiar with the antihypertensive medications but blinded to the subjects' treatment assignment coded changes in medication at each post-test as "1" if there was an increase from no medication to medication, an increase in dosage of the same medication, or a change to a stronger medication; coded a "−1" to indicate a decrease in medication, and a "0"code for no change. These codes were assigned for each post-test, and comprised the "Medch" variable.

Lifestyle Factors

Dietary intake patterns were assesses with the Block Dietary Food Consumption Questionnaire.[29] Exercise, alcohol use, and smoking were assessed by short questionnaires modeled after the Multiple Risk Factor Intervention Trial (MRFIT) instruments.[30]

Interventions

As previously described, the three interventions were matched on structure, contact time with the instructors, expectation of positive outcome, and other nonspecific factors.[25,26] Each of the three interventions was led by trained and experienced African-American instructors drawn from the local community.

TM Program—The TM technique is described as a simple, natural, and effortless procedure, practiced twice a day for 20 minutes while sitting comfortably with the eyes closed. It was introduced in the West by Maharishi Mahesh Yogi in 1959 and is the primary approach of consciousness of Maharishi Consciousness-Based Health Care.31–33 During the TM technique, it has been reported that the ordinary thinking process settles down and a distinctive "wakeful hypometabolic state" is gained.34,35 The general format of instruction in the standard TM course includes an introductory and preparatory lecture meeting to discuss the benefits and mechanics of the technique, a brief personal interview, a 1- to 1.5-h session of personal instruction, and three follow-up sessions taking place during 3 consecutive days, lasting about 1.5 h per day. After personal instruction, subjects practice on their own at home.

PMR Program—In the present study, PMR served as a standardized physical relaxation technique and also provided an active control for attention, expectancy, participation in a novel activity, and time spent with the eyes closed. The general format of instruction in PMR was modeled after the standard TM course. Subjects assigned to this group learned PMR according to the procedure of Bernstein and Borkovec, which is based on Wolpe and Lazarus' adaptation of Jacobsen's classic muscle relaxation program.36 The technique involves directing the participants' attention to tensing and relaxing the various muscle groups throughout the body systematically to achieve deep relaxation. Physical relaxation allows mental relaxation with this practice. Subjects practiced PMR at home for 15 to 20 min, twice a day.

HE Program—This control intervention represented lifestyle modification instructions for cardiovascular risk factors that hypertensive individuals might receive in community medical settings during the course of their usual medical care.14 This group received written materials, instruction in, and group support for modifying the major cardiovascular risk factors with conventional behavioral approaches. Subjects learned the importance of diet, salt restriction, weight reduction, regular aerobic exercise, smoking cessation, and the effects of these factors on controlling BP. The topic of stress was covered, but subjects did not learn a specific stress reduction or relaxation technique. Subjects were encouraged to practice class recommendations that included exercise, restful activities, and healthful cooking at home for about 20 min twice a day.

To control for attention and other nonspecific factors, all three groups had an equal number of follow-up meetings every month with individual attention from their respective African-American instructors on an as-needed basis. In addition, all subjects in the TM and the PMR groups received brief instructions and written educational materials on CVD risk factor reduction.

Compliance

Each month the treatment instructors gathered information on regularity of practice through personal interviews during the educational and follow-up meetings and through telephone interviews. This information was coded into a six-point compliance scale: 0 = missing data, 1 = stopped, 2 = every other day, 3 = 1/day, 4 = 1.5/day, and 5 = 2/day and was averaged for each post-testing session and for the study as a whole. For this study, compliance was defined as regularity of home practice of subjects' respective programs.

Analysis of Data

Baseline characteristics of the three treatment groups were compared by ANOVA using the Statistica software packages (Statsoft, Tulsa, OK), or by χ^2 test for comparisons of binary variables (eg, percentage married, percentage on BP medication). The effect of attrition

between pretest and the 12-month post-test on the composition of the groups was analyzed by two-way ANOVA of the baseline variables with treatment and attriter versus nonattriter as grouping variables. Change scores in systolic and diastolic BP from pretest during the 3, 6, 9, and 12-month post-tests were analyzed by repeated measures ANCOVA using SAS PROC MIXED, which handles missing data by fitting a statistical model over all available observations. Separate repeated measures analyses were performed for systolic and diastolic BP. Pretest levels of systolic or diastolic BP were used as covariates in their respective analyses. Planned contrasts allowed pairwise comparisons of the three treatment groups on BP outcomes. Planned contrasts were one-tailed based on directionality of hypotheses derived from previous studies with similar populations and interventions.[19,25,26,37] Intent-to-treat analyses were performed on the 197 subjects randomized to treatment who met the inclusion/exclusion criteria. In this analysis, missing data for subjects with no post-test data, the BP recorded at their last clinic visit was used to fill in subsequent missing data. All other missing data was handled by SAS PROC MIXED, as noted previously. Statistical analyses were conducted on the 150 subjects who completed the 12-month post-testing without regard to treatment compliance level. In addition, because a previous study suggested possible gender effects,[26] post hoc subgroup analyses were done comparing the treatment groups for each gender separately as well as comparing the genders pooled across groups. Repeated measures ANCO-VAs were also used to compare groups on change in BP medication and regularity of practice of the treatments.

Results

Baseline Characteristics

Among the 197 eligible subjects, attendance rates at the four post-testing sessions averaged 72% (75% for TM, 76% for PMR, and 65% for HE). Among the 150 subjects who completed the 12-month post-test, attendance rates at post-testing sessions averaged 87% (87% for TM, 91% for PMR, and 82% for HE). The numbers of dropouts by treatment group were: TM, 11; PMR, 16; and HE, 20. The rates of dropout were not statistically different between the groups ($P = .16$). There were no significant differences between attriters and nonattriters with regard to baseline levels of systolic and diastolic BP, and no significant interaction between treatment group and attriters versus nonattriters with regard to baseline BP. Thus, attrition did not alter the composition of the groups with regard to the primary outcome variable at baseline. Table 1 compares the groups (total $N = 150$) on demographic variables, physiologic and lifestyle factors at the preintervention baseline. The groups did not differ significantly on these variables.

BP

Figure 1 and Table 2 report the main effects of treatment averaged across the post-test periods during the 12-month follow-up period of subjects who completed follow-up.

Systolic BP—The TM group decreased systolic BP by −3.12 ± 1.52 mm Hg ($P = .02$) whereas PMR decreased by −0.54 ± 1.52 mm Hg (P = NS) and HE by −0.90 ± 1.71 mm Hg (P = NS). However, there were marginal differences between treatment groups regarding the magnitude of the systolic BP changes ($P = .12$ for TM *v* PMR and $P = .17$ for TM *v* HE). The pretest level of systolic BP was a significant covariate ($P = .0001$).

Intent-to-treat analysis of systolic BP found a change of −2.44 ± 1.41 mm Hg for TM compared to −1.29 ± 1.37 mm Hg for PMR and −0.43 ± 1.45 mm Hg for HE, with no significant between group differences (P = NS).

Diastolic BP—The mean changes for diastolic BP were −5.67 ± .89 mm Hg for TM, −2.90 ± 0.89 mm Hg for PMR, and −2.59 ± 1.00 mm Hg for HE. All groups decreased on diastolic BP significantly more than zero ($P < .01$). The TM group decreased diastolic BP more than either PMR ($P = .01$) or HE ($P = .01$), whereas PMR and HE did not differ ($P = .44$). Pretest diastolic BP was a significant covariate ($P = .0001$). There were no other significant covariates.

Intent-to-treat analysis of diastolic BP showed reductions of −4.81 ± 0.85 mm Hg for TM, −2.56 ± 0.83 mm Hg for PMR, and −2.61 ± 0.87 mm Hg for HE. These results were significant for TM versus PMR ($P = .025$) and for TM *v* HE ($P = .03$). There was no significant difference between PMR and HE (P = NS).

Table 3 reports the BP changed scores over 3, 6, 9, and 12 months for all study groups.

Change in BP Medication

A repeated measures ANCOVA on the change in medication variable during the post-test periods showed a significant group effect. The TM group decreased use of antihypertensive medication, compared to increases in PMR ($P = .015$) and HE groups ($P = .006$), but the PMR and HE groups did not differ significantly from each other (P = NS) (Fig. 2). Change in antihypertensive medication was not a significant covariate in the repeated measures ANCOVA on BP change.

Compliance

Across all post-test periods the TM group was significantly more regular (ie, at least once a day of home practice) (76%) compared to the PMR group (54%) ($P = .019$) and the HE group (57%) ($P = .051$). The PMR compliance was not significantly different in regularity than the HE group (P = not significant). Across treatments, there was no significant change in regularity over time or group by time interaction, indicating that similar levels of compliance were sustained during the 12-month follow-up period. There were no significant prepost changes in diet, exercise, or weight in any of the intervention groups.

Gender Subgroup Analyses

There were no differences between men and women on baseline BP and heart rate variables or demographics (age, education, income, marital status). However, pooling across groups, women smoked less than men (2.9 *v* 6.8 cigarettes/day, $P = .001$) and drank less alcohol (3.8 *v* 8.5 drinks/week, $P = .004$). Repeated measures ANCOVA indicated that the change in systolic BP in women (−2.64 mm Hg) was not significantly greater than in men (−0.34 mm Hg) (P = NS). There was no significant overall gender difference in diastolic BP change (−3.53 mm Hg for men *v* −4.02 for women). However, the TM group women decreased more on both systolic and diastolic BP than either of the other treatment groups of women. Change in systolic BP for TM women was −7.32 mm Hg compared to 0.68 mm Hg for PMR women and −0.72 mm Hg for HE women: TM *v* PMR ($P = .01$); TM *v* HE ($P = .03$); PMR *v* HE (P = NS). Change in diastolic BP for TM women was −6.85 mm Hg compared to −2.72 mm Hg for PMR women and −3.0 mm Hg for HE women: TM *v* PMR ($P = .01$); TM *v* HE ($P = .02$); PMR *v* HE (P = NS) (Table 4).

For men, no there were no significant differences between treatment groups on systolic BP. The changes on systolic BP for men were: TM = 0.22 mm Hg; PMR = −2.04 mm Hg; HE = −0.89 mm Hg. The mean changes in diastolic BP were −4.71 mm Hg for TM, −3.12 mm Hg for PMR, and −2.0 mm Hg for HE. The men TM participants showed a trend of diastolic BP reduction greater than HE ($P = 0.09$), with no other significant group differences (Table 4).

Adjusting for baseline levels, women decreased their alcohol intake by 3.9 drinks/week more that did the men ($P = .02$). In addition, women were more likely to be taking antihypertensive medication than men (73% *v* 59%) ($P = .07$). Among women, the ratio of sodium to potassium dietary intake decreased in the TM group from 1.23 at baseline to 0.94 at the 12-month post-test, whereas the PMR women increased from 1.08 to 1.14 and the HE women increased from 1.39 to 1.51. The differences between the women in TM and HE groups on sodium/potassium ratio were statistically significant ($P = .012$). Other group comparisons were marginal (TM *v* PMR ($P = .11$), PMR *v* HE ($P = .16$)). There were no significant differences between treatment groups among the men on change in sodium/potassium ratio. Self-reported compliance with study interventions did not differ between the genders.

Discussion

This randomized controlled trial conducted with 1 year of follow-up extended the results of a previous independently conducted short-term follow-up study that compared the effects of different approaches to stress reduction on hypertension in African Americans during 3 months.[25,26] The present trial evaluated a vital clinical question, that is, whether any of these lifestyle modification programs would remain effective in reducing BP during the relative long-term. The results of the present study support the feasibility and long-term efficacy of the use of a selected stress reduction approach in reducing BP in urban adult African Americans with stage 1 or 2 hypertension. During the 1-year duration of the study, the Transcendental Meditation program significantly decreased diastolic BP more than PMR or HE, and there was a trend for a greater reduction in systolic BP. Progressive muscle relaxation or HE did not differ from each other on any BP change comparison. Differences in compliance with treatment could not explain the results because when the BP results were adjusted for treatment compliance, the same pattern of results was found. In addition there was a significant reduction in antihypertensive medication use in the TM group compared to relaxation and education controls.

Although this study was not designed to evaluate gender differences in response to behavioral interventions, post hoc analysis of gender groups indicated that the TM group women had significantly greater reductions in both systolic and diastolic BP than women in both the relaxation and HE groups. These analyses showed that the women in the TM group had a significant reduction in systolic BP compared to both PMR and HE groups (−7.3 mm Hg *v* 0.7 mm Hg *v* −0.7 mm Hg, respectively). These changes in systolic BP were somewhat similar to the reductions in systolic BP with these interventions reported earlier in the short-term study.[25,26] The changes in diastolic BP in the three groups paralleled changes in the entire sample (−6.9 mm Hg *v* −2.7 mm Hg *v* −3.0 mm Hg for the TM, PMR, and HE women groups, respectively) with significant differences between TM and both PMR and HE. The greater reduction in systolic BP in the TM group women may have been related to lifestyle factors such as reductions in dietary sodium/potassium ratio or alcohol use. These effects remain to be confirmed and elucidated. The group of men in this study showed diastolic BP reductions of −4.7 mm Hg *v* −3.1 mm Hg *v* −2.0 mm Hg for TM, PMR, and HE, respectively, with a statistical trend for difference between TM and HE group men.

The magnitude of change for TM in diastolic BP within the overall sample group in the present study (−5.7 mm Hg) was similar to the previous short-term 3-month study (−5.7 mm Hg within group); however, there was a greater reduction in diastolic BP in the HE group in the present study compared to the previous trial (−2.6 mm Hg *v* −0.8 mm Hg).[25] Thus, the control-adjusted reduction in diastolic BP in the TM group was −3.1 mm Hg during 1 year of follow-up compared with control-adjusted change of −6.4 mm Hg after 3 months of follow-up in the previous study.[25] In the short-term trial,[25] TM decreased systolic BP more

(−10.9 mm Hg within-group and −10.7 mm Hg control-adjusted) than the present trial (−3.1 mm Hg within-group and −2.2 mm Hg control-adjusted). The differences in results of the two independently conducted studies may have been due to one or more factors. As noted, the HE group showed a larger decrease in BP, suggesting the possibility of a more active lifestyle modification intervention. There was greater compliance in the previous study, 97% compared to 76% of the subjects in the present study regularly practicing the TM program. Also, the subjects in the current study were younger (ie, mean age 48.6 years *v* 66.6 years in the earlier study) and more likely to be in the workforce, which may have influenced compliance levels.

During the 1-year follow-up, the PMR and HE groups increased their use of BP medication compared to the TM group, which showed decreased antihypertensive medication use. These findings suggest that the effects of the TM program on reducing BP were not due to increased use of antihypertensive medication. The TM intervention also decreased BP at an earlier time period in the study compared to the other groups, with apparent differences by months 3 and 6. In contrast PMR and HE tended to reduce BP toward the end of the year but that effect may have been due to their increases in the use of antihypertensive medication. The long-term cost savings as well as prevention of adverse effects from drug therapy of using an effective nonpharmacologic approach such as the TM program are likely to be substantial from a public health perspective.38,39

The design of the present study addresses several methodological weaknesses identified in the literature.20 These include: 1) lack of adequate number of baseline BP measurements to control for habituation and regression to the mean; 2) lack of rigor in designing control treatments, balance of baseline characteristics, randomization, and blind data collection; 3) lack of comparison among different stress reduction techniques in the same experiment; 4) inadequate sample size; 5) inadequate length of follow-up; 6) medication changes not controlled or not carefully monitored; and 7) inadequate selection of appropriate patients for likelihood of response.

The validity of these results is supported by a randomized, single-blind design and multiple BP measures that were taken during five baseline visits. Regression to the mean was also statistically controlled by using pretest baseline systolic and diastolic BP as covariates in their respective analyses. The use of two stress reduction approaches in the same experimental setting allowed control for nonspecific intervention effects, with both active control groups given similar expectancy of benefits, attention from trainers, and time allowed for daily practice. External validity was enhanced by conducting the trial in a primary care center in a large inner city African-American community. The results could not be attributed to any of the pretest and demographic variables because the groups did not significantly differ on any of these variables.

It is unlikely that the results of this study could be due to attrition, as the intent-to-treat analyses yielded similar conclusions as analyses based on subjects who completed follow-up. Also, the attrition rates in each treatment group were similar. The reduction in high BP observed in the current study with the TM program were consistent with findings reported in previous randomized controlled trials in older and younger subjects using clinic BP25,26,40 or ambulatory BP measurements.41,42

Previous studies in adults, older adults, and adolescents have reported that PMR practice is associated with modest reductions in BP.20,43,44 These findings are somewhat similar to reductions found with PMR, particularly for diastolic BP, in the current trial. The general approach of PMR is to reduce muscular tension and thereby induce psychophysiological relaxation.36,45 There is some evidence for acute reductions in salivary cortisol, heart rate,

and state anxiety with PMR practice.46 Meta-analyses have found evidence for the usefulness of PMR in insomnia and headache.47–49 However, a range of neurophysiologic stress changes reported for TM practice (eg, increased electroencephalographic coherence, cerebral blood flow, reductions in respiratory activity, alterations in a range of neuroendocrine stress markers, reductions in sympathetic nervous system tone, and increases in parasympathetic tone50,51 have generally not been reported for PMR practice. A meta-analysis, which directly compared effects of PMR to those of TM on anxiety reduction, found almost twice the effect size for TM.52 However, few studies have previously assessed the effects of both interventions in the same experimental setting.

A systematic review of meta-analyses of behavioral stress reduction approaches suggests that the TM technique may be distinctively effective in modifying several clinically relevant physiological and psychological outcomes.22 This is consistent with meta-analyses of the effects of behavioral stress reduction methods on BP, which indicate a heterogeneity of effects of various stress reduction techniques.20,21 These latter findings may contribute to an explanation of the differential effects on BP of TM and PMR behavioral interventions observed in the present study.53

Reductions in BP of the magnitude seen in the present study were similar to and sometimes greater than BP reductions reported in systematic reviews of other lifestyle modifications for hypertension. For example, the most recent review of clinical trials on long-term effects of dietary sodium intervention reported that the average reductions in systolic and diastolic BPs were −2.5 mm Hg and −1.2 mm Hg for intermediate-term follow-up of 6 to 12 months.54 For long-term follow-up of 13 to 30 months, the BP reductions were −1.1 mm Hg systolic and −0.6 mm Hg diastolic. Hooper et al54 concluded that intensive dietary sodium interventions were “unsuited to primary care or population prevention programs, provide only small reductions in BP and sodium excretion, and effects on deaths and cardiovascular events are unclear” (pg. 628). Meta-analysis of trials on aerobic exercise reported reductions in BP of −3.84 mm Hg systolic and −2.58 mm Hg diastolic during a median duration of 12 weeks.55 However, by 24 weeks or longer, the average systolic BP reduction was −2.0 mm Hg with no significant change in diastolic BP.55 Systematic review of randomized controlled trials (RCTs) with interventions lasting longer than 6 months in adults aged 45 years or more with hypertension found no significant changes in BP with aerobic exercise. 16 In terms of weight loss, a meta-analysis reported that when antihypertensive drug regimens did not vary, loss of approximately 5 kg of weight reduced BP by −3.0 mm Hg systolic and −2.9 mm Hg diastolic.56 Two subsequent RCTs reported that weight reduction of 2 to 4 kg reduced systolic BP by about −1 mm Hg during 1 to 3 years of follow-up.57,58 A systematic review on RCTs on effects of moderating alcohol consumption found reductions of −3.3 mm Hg systolic and −2.0 mm Hg diastolic among fairly heavy, predominately male alcohol drinkers (≥ 3 drinks/d) for a median of 8 weeks follow-up.

The results of change in BP in the present study are clinically significant. For example, even a 2 mm Hg reduction in diastolic BP would be associated with a 17% decrease in the prevalence of hypertension, 6% reduction in risk for CHD, and 15% reduction in risk for stroke and transient ischemic attack.59 Slightly larger CVD preventive effects have been calculated from antihypertensive clinical trials and major prospective observational studies. 10,60

Mechanisms through which TM practice reduces BP may be via reductions in acute and chronic sympathetic nervous system tone37,61,62 and possibly modification of other neuroendocrine and neurophysiologic mediators of stress.37,63 In addition, long-term practice of the TM program has been associated with reductions in other cardiovascular and behavioral risk factors (eg, oxidized lipids,64 smoking,65 alcohol abuse,65 anxiety,52 and

psychological well-being), which may contribute to hypertension and CVD risk.66 Studies on effects of the TM program on CVD surrogate end points, morbidity and mortality, have reported regression of carotid atherosclerosis,67 reduced myocardial ischemia,68 and lower mortality rates.

Particularly relevant to the mechanisms of effects of the TM program on hypertension are the results of studies suggesting restoration of adaptive mechanisms.37,63,70 Adaptive mechanisms involve the autonomic nervous system, neuroendocrine axes, and the cardiovascular system and result in physiological adaptability and stability during stressful events.71 These mechanisms are altered by chronic stress leading to physiologic disorder including CVD.71,72 Allostatic load is the term applied to the pathophysiologic set of alterations of these adaptive mechanisms.71,72 From the perspective of the traditional Vedic system of natural health care from which the TM program originates, this approach enhances an integrated set of endogenous homeostatic and self-repair biochemical and physiologic mechanisms traditionally called the body's inner intelligence.31,33,73 It has been proposed that the effects of the TM program on adaptive mechanisms are consistent with reduction of allostatic load.37,39

In conclusion, the present clinical trial suggests that a selected stress reduction approach, the TM program may be effective in reducing hypertension in African-Americans adults when used as an adjunct to usual care, at least during 1 year. Finally, the results of this trial suggest that all techniques of stress reduction do not have the same effects, consistent with the results of several meta-analyses and previous randomized trials.22,25,65,66,74 These data contribute to bridging the gap between biomedical and biobehavioral research and medical practice.75

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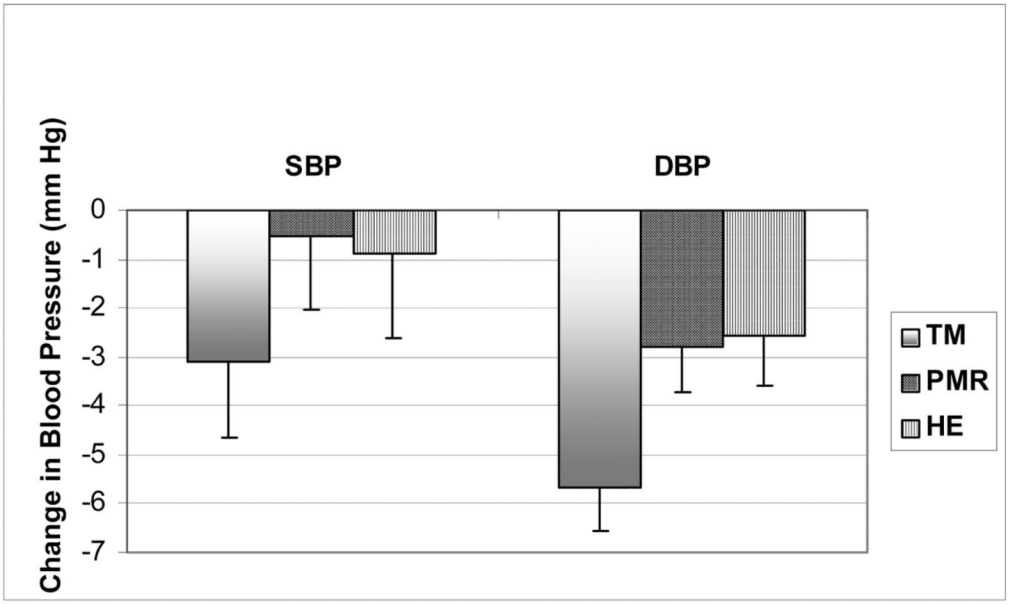

FIG. 1.

Change in BP by treatment group: comparison of the Transcendental Meditation (TM), progressive muscle relaxation (PMR), and health education (HE) groups on mean adjusted change scores in clinical systolic and diastolic BP during a 12-month period. TM decreased diastolic BP more than PMR (P = .03) or HE (P = .02), but PMR and HE did not differ (P = .44). There were trends of TM decreasing systolic BP more than PMR (P = .12) and HE (P = .17), and PMR and HE did not differ (P = .44).

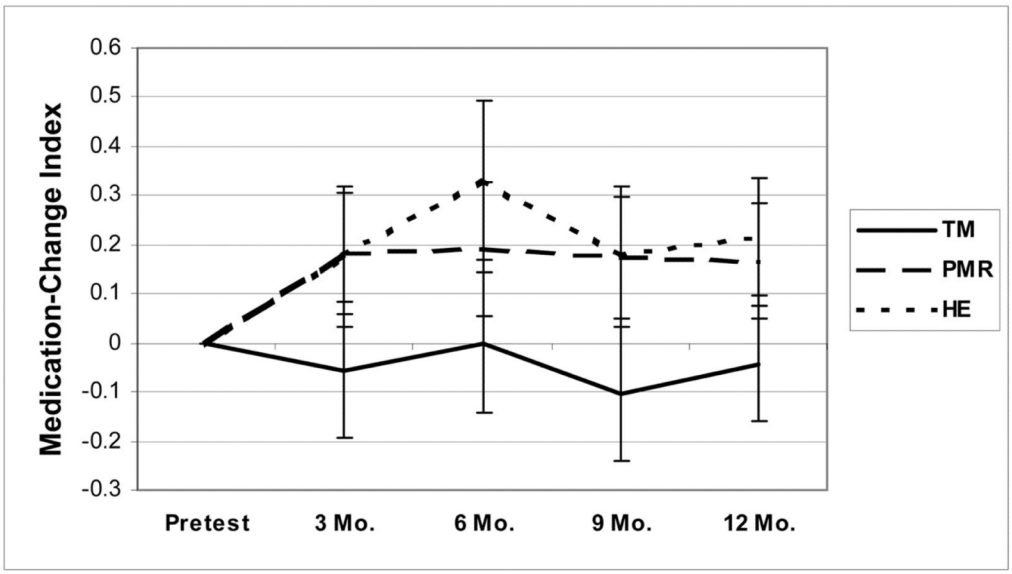

FIG. 2.

Change in antihypertension medication by group. Compared to the Transcendental Meditation group, the other groups significantly increased their use of BP medication: PMR (P = .015) and HE (P = .006) during the 12-month period.

Table 1

Baseline characteristics for study groups (mean ± standard deviation or percent)

	TM (*N* = 54)	PMR (*N* = 52)	HE (*N* = 44)	All Groups (*N* = 150)	*P**
Age (y)	49.3 ± 8.9	49.0 ± 10.4	47.1 ± 11.0	48.5 ± 10.1	.52
Gender (% female)	46.3%	55.8%	56.8%	52.7%	.50
Antihypertensive medication	70.4%	69.2%	59.1%	66.7%	.44
Education (some college)	73.1%	55.6%	55.0%	62.0%	.11
Income (<$10,000)	60.4%	61.4%	64.3%	61.9%	.92
Married (%)	17.3%	28.9%	22.0%	22.5%	.39
Weight (pounds)	188.5 ± 44.9	193.4 ± 39.1	193.8 ± 59.7	191.8 ± 47.7	.83
BMI (kg/m^2)	28.3 ± 6.5	28.7 ± 5.8	28.8 ± 7.8	28.6 ± 6.7	.92
SBP (mm Hg)	142.1 ± 13.5	141.7 ± 14.3	144.4 ± 17.2	142.7 ± 14.9	.64
DBP (mm Hg)	95.1 ± 4.0	94.8 ± 4.6	95.7 ± 3.6	95.2 ± 4.1	.56
Cigarettes/day	5.1 ± 7.6	4.4 ± 7.4	4.8 ± 6.9	4.8 ± 7.3	.91
Alcohol (drinks/wk)	7.1 ± 11.4	4.2 ± 6.8	6.8 ± 10.2	6.1 ± 9.8	.28
Physical activity (h/wk)	3.2 ± 3.9	3.1 ± 3.1	3.7 ± 3.8	3.4 ± 3.6	.68

*P values for the means are from ANCOVAs comparing groups at pretest and *P* values for percentages are for Pearson χ^2 on contingency tables of groups × variable categories.

Table 2

Mean change scores in blood pressure for study groups during 12 months*

Groups	Adjusted Change*	*P* Between Groups		
		TM versus PMR	TM versus HE	PMR versus HE
SBP (mm Hg)				
TM	−3.12 ± 1.52	.12	.17	.44
PMR	−.54 ± 1.52			
HE	−.90 ± 1.71			
DBP (mm Hg)				
TM	−5.67 ±.89	.013	.012	.44
PMR	−2.90 ±.89			
HE	−2.59 ± 1.00			

*Data are least square means of change scores ± standard error from repeated measures ANCOVA, Group Effect, adjusted for the covariate of pretest blood pressure for the 150 subjects who completed 12-month post-testing.

Table 3

Mean change scores in blood pressure by quarterly post-test periods for study groups*

Groups	3 mo	6 mo	9 mo	12 mo
SBP (mm Hg)				
TM	−1.57 ± 2.17	−4.60 ± 2.39	−4.17 ± 2.31	−2.13 ± 1.88
PMR	1.77 ± 2.13	−.10 ± 2.43	−.65 ± 2.22	−3.20 ± 1.92
HE	2.01 ± 2.40	−.40 ± 2.89	−4.16 ± 2.59	−1.08 ± 2.09
DBP (mm Hg)				
TM	−4.18 ± 1.41	−7.53 ± 1.37	−4.73 ± 1.43	−6.24 ± 1.29
PMR	−1.40 ± 1.39	−3.07 ± 1.40	−2.71 ± 1.37	−4.05 ± 1.31
HE	−.53 ± 1.56	−2.83 ± 1.67	−2.59 ± 1.58	−4.44 ± 1.43

*Data are least square means of change scores ± standard error from repeated measures ANCOVA, Group by Month effect, adjusted for the covariate (pretest blood pressure for 150 subjects who completed 12-month post-testing).

Table 4

Mean blood pressure change scores by gender for study groups*

Groups	Adjusted Change Women*	Adjusted Change Men*	*P* Between Groups		
			TM versus PMR	TM versus HE	PMR versus HE
SBP (mm Hg)			.01 (women)	.03 (women)	.34 (women)
TM	−7.32 ± 2.46	.22 ± 1.72	.09 (men)	.35 (men)	.35 (men)
PMR	.68 ± 2.24	−2.04 ± 1.91			
HE	−.72 ± 2.46	.89 ± 2.25			
DBP (mm Hg)			.01 (women)	.02 (women)	.44 (women)
TM	−6.85 ± 1.29	−4.71 ± 1.25	.20 (men)	.09 (men)	.30 (men)
PMR	−2.72 ± 1.16	−3.12 ± 1.39			
HE	−3.00 ± 1.28	−2.00 ± 1.62			

*Data are least square means of change scores ± standard error from repeated measures ANCOVA, Group Effect, adjusted for the covariate of pretest blood pressure for the 150 subjects who completed 12-month post-testing.