

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

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**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  $49 \pm 10$  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 practicing 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. Am J Hypertens 2005;18:88–98 © 2005 American Journal of Hypertension, Ltd.

**Key Words:** Hypertension, African Americans, stress reduction, clinical trial, lifestyle modification, transcendental meditation, progressive muscle relaxation.

**H**ypertension is a major cause of the disproportionately high rates of coronary heart disease (CHD), stroke, and renal disease in African Americans compared to whites.<sup>1,2</sup> African Americans suffer from a higher incidence, prevalence, and severity of hypertension

than whites,<sup>3</sup> with increased end-organ damage<sup>4</sup> and lower treatment rates.<sup>5</sup> Cardiovascular disease (CVD) is a primary contributor to the disparities in health and health care between African Americans and white Americans.<sup>6,7</sup>

Pharmacologic therapy is widely recommended for

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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.<sup>8,9</sup> Moreover, the efficacy of drug therapy in preventing the most common complication of hypertension—CHD—is significantly lower than expected.<sup>10,11</sup> Limitations of conventional antihypertensive pharmacotherapy include adverse effects, low compliance, high cost, and restricted access.<sup>12,13</sup> 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.<sup>14</sup> Despite this national guideline, there is a paucity of data from randomized controlled trials on the long-term effects of nonpharmacologic therapies for hypertension.<sup>15,16</sup>

Among lifestyle factors, accumulating evidence indicates that psychosocial stress is an important contributor to hypertension,<sup>17,18</sup> especially in African-American populations.<sup>19</sup> 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.<sup>16,20,21</sup> 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,<sup>22,23</sup> and is associated with greater BP effects in both medicated and nonmedicated subjects.<sup>22,24</sup>

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.<sup>25,26</sup> Modest reductions in clinic BP and home BP has been shown in African-American older subjects practicing PMR compared to HE.<sup>26</sup> 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,<sup>25</sup> 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.<sup>25,26</sup> 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.<sup>27</sup> 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,<sup>28</sup> 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,

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