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Trials of Maharishi Ayurveda for cardiovascular disease: A pooled analysis of outcome studies with carotid intima-media thickness

Kenneth G. Walton, PhD^{*}, Brian Olshansky, MD[†], Erika Helene, ND, PhD[‡], Robert H. Schneider, MD, FACC[§]

^{*}Department of Physiology and Health, Maharishi University of Management, Fairfield, IA 52557, United States; Institute for Natural Medicine and Prevention, Maharishi Vedic City, IA 52556, United States

[†]Department of Internal Medicine, University of Iowa School of Medicine, Iowa City, IA 52242, United States

[‡]Private Practice, Ayurvedic & Naturopathic Medicine, Bad Neuenahr 53474, Germany

[§]Institute for Natural Medicine and Prevention, Maharishi Vedic City, IA 52556, United States; Department of Physiology and Health, Maharishi University of Management, Fairfield, IA 52557, United States

Abstract

Objective: To investigate a multimodality, natural medicine systems approach—Maharishi Ayurveda (MAV)—for prevention or reversal of atherosclerotic cardiovascular disease (ASCVD).

Design: Pooled analysis of data from existing trials that used MAV to reduce carotid artery intima-media thickness (CIMT).

Settings: Two large medical centers in the U.S. Midwest.

Subjects: Thirty-four elderly patients with or at high risk for ASCVD.

Interventions: Four components of MAV: Transcendental Meditation[™], Ayurvedic diet, Ayurvedic exercise, and Ayurvedic herbal food supplements.

Primary outcome measure: CIMT, a surrogate measure of ASCVD, was determined by B-mode ultrasonography.

Results: After 9–12 months of intervention, CIMT declined in the MAV group (change in CIMT = -0.15 ± 0.22 mm; 95% CI = -0.22 to 0.01 mm) and increased in the usual care group (change in CIMT = $+0.02 \pm 0.06$ mm; 95% CI = -0.02 to 0.04). This difference between groups of -0.17 mm was significant [$F(1,29) = 14.1$, $p < .01$]. In the MAV group, those individuals showing the largest reductions in CIMT with treatment also had the highest risk factor levels at the start. Baseline data from this subgroup indicated the presence of hypertension, (systolic blood pressure (SBP) = 141 ± 11 mmHg, diastolic blood pressure (DBP) = 80 ± 12 mmHg, means \pm SD).

Address for correspondence: Dr. Kenneth G. Walton: kw Walton@natel.net.

They also had elevated waist circumference (91 ± 8 cm), and dyslipidemia (triglyceride-to-HDL-cholesterol ratio = 4.8 ± 2.9). Each individual in this “high-CIMT-change” group, 80% of whom were women, improved notably in one or more risk factors with the MAV intervention.

Conclusions: The pooled results of these two trials suggest that MAV multimodality intervention programs, including the Transcendental Meditation technique and heart-healthy Ayurvedic diet, exercise, and herbal food supplements, may be effective in the regression of ASCVD, especially in patients at high risk for cardiovascular disease.

Keywords

Ayurveda; Maharishi Ayurveda; Transcendental Meditation; Meditation; Natural medicine; Herbal supplements; Carotid IMT; Cardiovascular disease; Atherosclerosis; Hypertension; Dyslipidemia

Introduction

Maharishi Ayurveda (MAV) is a modern restoration of Ayurveda, reported to be the world’s oldest system of natural medicine.^{1,2} This restoration of Ayurveda was introduced by Maharishi Mahesh Yogi, who brought together leading Ayurvedic experts and Vedic scholars to examine and revise current practices in the light of the ancient texts and modern scientific principles.³⁻⁵ The therapeutic, diagnostic, and preventive modalities of MAV are drawn from the broad range of Vedic literature and are said to holistically enhance the body’s innate self-repair and homeostatic mechanisms.⁶⁻⁸

The Ayurvedic texts place high importance on meditation and the role of development of consciousness in gaining optimum health. The Transcendental Meditation™ technique is a basic modality of MAV. Research has determined that this technique has beneficial effects in the prevention and treatment of cardiovascular diseases and their risk factors.^{4-6,9} A recent scientific statement from the American Heart Association recommends this meditation technique for consideration in clinical practice to lower blood pressure while other meditation techniques did not receive this level of recommendation.¹⁰ Further, randomized controlled trials have reported the effectiveness of the Transcendental Meditation program in reducing cardiovascular events.^{11,12} Other commonly used modalities of MAV are Ayurvedic diet, Ayurvedic exercise, and Ayurvedic herbal nutritional supplements. Ayurvedic diet and exercise recommendations, including personalized recommendations, are based on different principles than conventional lifestyle modification approaches, and may provide additional benefits.^{3-5,7} Moreover, the herbal dietary supplements recommended by MAV may provide clinical benefits unavailable in conventional care, including pharmaceutical therapy.⁵

Little controlled research has been published on the effects of multiple components of MAV on ASCVD. Here we report a quantitative analysis of the pooled results of previous trials of MAV on CIMT, a common surrogate measure of coronary atherosclerosis.

Methods

Selection of clinical trials

Two controlled trials of MAV on CIMT were identified for the present analysis.^{13,14} A literature search of Medline and Dissertation Abstracts from 1984 to January 2013 yielded no other trials on this topic. Searches employed the different expressions that have been used to denote MAV (Maharishi Ayur-Veda, Maharishi Ayurveda, MAV, Maharishi Vedic Approach to Health, Maharishi Vedic Medicine, Maharishi Consciousness-Based Health Care) combined with carotid atherosclerosis, coronary artery disease, cardiovascular disease, or carotid intima media thickness.

The four basic components of MAV employed in each trial are: 1. The Transcendental Meditation technique, 2. Maharishi Ayurveda approach to exercise, 3. Maharishi Ayurveda approach to diet, and 4. Maharishi Ayurveda approach to herbal dietary supplementation. The seven-step course of instruction in the Transcendental Meditation technique, which totals 8–10 hours over a 6-day period, and the process of training teachers of the Maharishi Transcendental Meditation technique, are standard worldwide.¹⁵ The recommendation for a continuing home practice of 15–20 min twice a day is also standard. Other distinctive features of the technique are described elsewhere.^{15,16} The additional three components of MAV employed in the studies are described separately in the following sub-sections.

Description of Study 1

Design and Subjects—Study 1 was a single-blinded, randomized trial of subjects over 65 years of age.¹³ The 43 participants in that study (40% women; mean age 74 years) were normal volunteers recruited from the area surrounding Saint Joseph Hospital in Chicago, Illinois. The primary outcome for this trial was CIMT, and the intervention period was 12 months. Subjects were randomized to one of three groups: usual care alone, usual care plus MAV, and usual care plus a conventional health education intervention with four components (a didactic stress reduction seminar, a modern exercise program, vitamin supplements, and modern diet recommendations). This program was a modern control condition chosen to parallel the four components of the MAV intervention. Because most of the subjects in Study 1 were normal with regard to cardiovascular health, the current analysis used only the subgroup identified in Study 1 as being at high-risk for cardiovascular disease.

MAV Interventions—The MAV intervention for Study 1 consisted of the Transcendental Meditation technique and the three other components mentioned. The Ayurvedic exercises used in Study 1 were a set of gentle yoga postures (asanas), a gentle yoga breathing exercise (pranayam), and a brisk 30 min walk daily. The herbal dietary supplement used was Maharishi Amrit Kalash, a commercially available set of products considered as a general “tonic” or “adaptogen” suitable for everyone. Previous research has found this two-part, herbal formula to be beneficial for reducing circulating free-radical levels, enhancing immune function, and normalizing endocrine functions.¹⁷ It also has been reported to reduce angina pectoris.¹⁸ The Ayurvedic dietary recommendations in Study 1 were based on general factors common to all participants, such as food variations according to season of the year. The diet emphasized fresh vegetables, fruits, grains, nuts, and high fiber, with

moderate to low fat levels. Digestion was enhanced by taking the main meal in the middle of the day.

Compliance with the MAV Intervention—Home practice adherence to the recommended MAV interventions was determined using daily log methods. Adherence to each of the four components was marked on a data sheet each day. Adherence rates were calculated as a percentage of the recommended rates per week, and these were averaged to get one number for percentage adherence for each subject for the entire study duration.

Outcome Assessments—B-mode ultrasonography measurements were obtained by an experienced, registered vascular technician using a high definition Ultramark 9 imager (Advanced Technologies Inc., Bothel, Washington). The CIMT protocol for Study 1 was the same as that used in the Asymptomatic Carotid Artery Plaque Study.¹⁹ The method recorded measurements from the near and far walls at 6 anatomic sites—the common carotid, the internal carotid, and the bifurcation (bulb), each on the left and right sides. Measurements of the common carotid and the internal carotid covered a 1 cm range centered 1 cm from the bifurcation. These CIMT measurements were first averaged for the near and far walls at each of the sites, and then these 6 numbers were averaged to obtain a single CIMT score.

Description of Study 2

Design and Subjects—Study 2 was a prospective, single-blinded, nonrandomized trial with control participants matched to experimental participants on age, gender, and severity of CVD.¹⁴ The primary outcome measure was CIMT, and the intervention time was 9 months. The 22 participants (9% women, mean age 72 years) were patients with ASCVD recruited through the Cardiovascular Health Assessment, Management, and Prevention Service (CHAMPS) of the University of Iowa Heart Care Center. ASCVD was defined as having had a previous myocardial infarction, coronary revascularization, or positive coronary angiography. All subjects had graduated from a 4–6 week cardiac risk reduction program given at CHAMPS. This program included conventional exercise and dietary recommendations, stress management, and smoking cessation. All patients were encouraged to continue standard medical therapy throughout the trial.

MAV Interventions—Participants in Study 2 received standardized instruction in the Transcendental Meditation technique, including the recommendation of 20 min twice daily practice sessions at home, recommended Ayurvedic exercises (gentle yoga postures, a traditional breathing exercise, and a daily 30 min walk), personalized Ayurvedic herbal dietary supplements aimed at imbalances associated with CVD, as diagnosed in each patient by a professional trained in MAV [EH], and other personalized dietary recommendations that included, in addition to the general guidelines used in Study 1, specific guidelines based on the imbalances detected in each individual by the trained MAV professional using Ayurvedic pulse diagnosis, questionnaires, and clinical interview. MAV diagnosis of imbalances is based in large part on the patient's Ayurvedic body/mind constitution at the time of diagnosis, i.e., the particular balance of the *doshic* qualities (*Vata*, *Pitta*, and *Kapha*). In addition to the patient's imbalances, the MAV clinician used Ayurvedic formulae for determining disease strength and patient strength to help choose the appropriate dietary

and supplement recommendation. Further details of these methods are given in the original study.¹⁴ Note that the 30 min walk recommendation was also given to both the MAV and control group as part of the CHAMPS risk reduction program.

Compliance with the MAV Interventions—Home practice adherence to the recommended MAV interventions was determined using daily log methods that were similar to those used for Study 1 described earlier.

Outcome Assessment—The B-mode ultrasonography measurement protocol was modeled after The Los Angeles Atherosclerosis Study.²⁰ The approach used a high resolution ATL 5000 system and TOMTEC image analysis. Eight images of the far walls of the left and right common carotid arteries 1 cm from the bifurcation were recorded. Duplicate CIMT images were taken in two positions for left and right carotid arteries. The 8 images were digitized and then CIMT was measured in blinded fashion using a fully automated, digitized, edge-detection tracking method and the Prosound analytical software system. Each individual subject's CIMT score for baseline and post-test thus represented the mean of 8 distinct measurements. The same reader evaluated both the baseline and the follow-up scans.

Data analysis

Statistical analyses used the method of meta-analysis of individual patient data.²¹ Because Study 2 participants were ASCVD patients, to achieve the closest match of subjects from the two studies, only the subgroup of “high-risk” participants from Study 1 was included. High-risk subjects were defined as those with three or more standard CVD risk factors (i.e., hypertension, smoking, obesity, and blood level of triglycerides, HDL-cholesterol, or glucose in the range commonly recognized as high-risk). Statistical comparisons were made between two intervention categories: 1) Usual care alone, and 2) Usual care plus the multimodality MAV program. The ANCOVA comparisons of the two intervention categories included two independent variables—Treatment Group and Study—and one covariate—the baseline or entry level of the outcome variable being analyzed. Because the total *N* of 34 participants is small, special care was taken to evaluate whether the assumptions for ANCOVA were met. The Kolmogorov-Smirnov test was used to confirm that the data did not differ significantly from a normal distribution. Levene's test was used to assure homogeneity of variances. Between-group and within-group analyses of risk factor data were examined using ANCOVA and *t*-test methods. Two-sided *p* values ≤ 0.05 were considered statistically significant.

Results

Comparison of the means of demographic and outcome variables for the treatment and control groups in each separate study is shown in Table 1. Two variables were modified to make the comparisons consistent, i.e., education was scored at two levels: those with no college (assigned 0) and those with some college (assigned 1), and income was scored at four levels: $< \$10,000/\text{yr}$, $\$10,000$ to $20,000/\text{yr}$, $\$20,000$ to $\$50,000/\text{yr}$, $> \$50,000/\text{yr}$, matching the scheme used in Study 1. The experimental and control groups in Study

1 did not differ significantly on any variables measured. Study 2 participants in the experimental and control groups were statistically different on two risk factors (systolic blood pressure and triglycerides) and three demographic variables (income, marital status, and beta-adrenergic blocker dosage). Differences also were found between the two studies. Study 1 participants were older (trend, $p < .08$), had lower income, more women, and higher LDL-cholesterol ($p < .01$, see Table 1). Baseline CIMT also was higher in Study 1 participants than in Study 2 ($p < .01$), likely due to partially different sites used for CIMT measurement (see Discussion).

In the analysis of pooled data, the reduction of CIMT was found to be significantly greater for the MAV group than for the usual care group (see Figure 1 and Table 2). The MAV group showed a large reduction in CIMT (0.17 mm) relative to the control group. For the MAV group, change in CIMT was -0.15 ± 0.22 mm (95% CI = -0.22 to 0.01 mm) and for the usual care group it was 0.02 ± 0.06 mm (95% CI = -0.02 to 0.04), a significant difference [$F(1,29) = 14.1$, $p < .0008$]. Raw CIMT data for the total sample of $N = 34$ did not deviate significantly from a normal distribution. Although the dependent variable variances were significantly different for the treatment groups, a problem not corrected by using common data transformations (e.g., log to base 10, square root, reciprocal), dropping the two CIMT values qualifying as statistical outliers (> 3 SD from the mean) allowed the homogeneity of variances criterion for CIMT to be met while causing only a slight change in the p value (from $p < .0008$ to $p < .002$). In addition to the main effect, there was a significant interaction between the independent variables “Treatment Group” and “Study,” with the larger responses to the MAV treatment occurring in Study 1. Inclusion of the second independent variable “Study” controlled for an inhomogeneity of regression slopes, i.e., a difference of slopes of the regression of change in CIMT on pretest IMT for the two treatment groups.

Risk factor differences at baseline and changes from study entry to study exit were analyzed in two ways. First they were analyzed for the same participant groupings as the primary CIMT analysis. In this analysis, blood pressures were found to decrease significantly in both the MAV group and the usual care control group (Table 2). No other risk factor changed significantly within-group nor were there any significant differences between-group in the entry to exit changes for any risk factor.

The second approach to analysis of risk factor levels and changes was based on the observation that a small number of participants in the MAV group showed large decreases in CIMT that dominated the statistical outcome (see Figure 1). For purposes of this analysis, these “high-CIMT-change” participants formed one group while the remaining “low-CIMT-change” participants formed the comparison group. Baseline comparisons are shown in Table 3. Risk factor levels for these high-change individuals were found to be exceptional at baseline (study entry), with notably higher blood pressures, triglycerides, triglyceride-to-HDL-cholesterol ratio, waist circumference, and LDL-cholesterol than the low-CIMT-change group (see Table 3). Table 3 also shows the within-group changes in risk factors from study entry to study exit in these two groups. Notable decreases occurred in the high-CIMT-change MAV group as well as in the low-change group. However, due to the high variability and the small number of participants in the high-CIMT-change category,

within-group changes in this group did not reach significance nor were the between-group differences in risk factor change statistically significant (not shown).

Although the mean changes in risk factors were not different between the MAV and control groups, each of the individuals in the high-CIMT-change category was found to exhibit a notable reduction in one or more risk factors. Also note that the top four individuals with regard to CIMT declines were female, and all of these high-CIMT-regression subjects were from Study 1.

Discussion

Few studies have investigated natural medicine approaches for preventing or treating ASCVD, and those that have tend to be small.¹⁰ The present study pools the data from two trials with similar natural medicine interventions, similar outcomes, and similar subject samples. Each of the individual trials produced evidence of MAV effectiveness, but we hypothesized that a quantitative analysis of pooled data would give more representative mean changes.

The analysis of pooled data conducted here appears to confirm an effect that is both statistically and clinically significant. The relative mean CIMT decrease of 0.17 mm (15%) in the MAV group compared with the usual care group is noticeably larger than the effects found with other interventions.^{22,23} However, this outcome is similar to that obtained in a prior randomized trial using the Transcendental Meditation technique alone in which the mean CIMT reduction was slightly smaller than in the present comparison (i.e., -0.15 vs. -0.17 mm).²⁴

Confidence in the correctness of CIMT data obtained in the present study is increased by comparing the pooled data from the usual care controls with similar data on CIMT progression from other studies. The weighted rate of progression in “mean common” CIMT, based on data from the pooled control groups of 13 studies, is reported as 0.0147 mm/yr (95% CI, 0.0122 to 0.0173).²⁵ (“Mean common” CIMT is the ultrasonography measure used in Study 2 of the present analysis, while “mean maximum” CIMT refers to the method used in Study 1—see Methods.) The rate of progression in mean maximum CIMT, based on data from 7 studies, is slightly larger than for mean common CIMT, 0.0176 mm/yr (95% CI, 0.0149 to 0.0203).²⁵ Estimates of progression based only on patients with coronary heart disease are somewhat more pronounced, being 0.0170 mm/yr for mean common CIMT and 0.0258 mm/yr for mean maximum CIMT, on the basis of data from 6 and 3 studies, respectively.²⁵ Adjusting for the fact that the CIMT of one-third of the subjects in the present study was measured by the mean maximum method and two-thirds by the mean common method, the mean rate of progression in the usual care group (i.e., 0.02 ± 0.06 mm per 9–12 months) agrees well with the estimated progression rates from these meta-analyses. However, the negative rate of CIMT progression (i.e., a regression) in the MAV group, -0.15 ± 0.22 mm for 9–12 months, is an order of magnitude greater, in the opposite direction, than the usual progression rates—a large difference.

If this large mean reduction of CIMT is representative of the effects of MAV generally, then the clinical significance of these reductions can be estimated based on prior studies of CIMT. Studies have been conducted on subjects with^{26,27} and without^{28–30} prior CVD. The benefit of reducing CIMT has been quantitatively estimated based on results of a meta-analysis of data from 37,197 subjects followed for a mean of 5.5 years.³¹ That study related CIMT measured by a variety of methods, including the mean maximum and mean common methods used in the studies reviewed here, to the future incidence of myocardial infarction (MI) and stroke. It was estimated that a CIMT difference of 0.1 mm in the general population corresponds to a 10–15% difference in risk of MI and a 13–18% difference in risk of stroke. Based on these estimates, the addition of the MAV modalities for 9–12 months appears to have reduced the risk of MI by an estimated 22% and the risk of stroke by as much as 27%.

The present pooled analysis has limitations that may influence interpretation of results. One possible limitation is the comparability of CIMT measurements when somewhat different combinations of anatomic sites were used for the ultrasonic measurement of CIMT in the two studies. As mentioned before, the “mean maximum” method of measurement includes the carotid bulb as one of three sites. The bulb, being distal to the bifurcation, is known generally to be a site of higher plaque deposition than are the common carotids used in the “mean common” measurement, a difference that may affect CIMT. An argument favoring the meaningfulness of our results, however, comes from the direct demonstration that CIMT at each of the individual anatomic sites and the combinations of sites used in these two studies has a similar ability to predict future MI.³² The larger meta-analyses referenced earlier also combined results from trials using both these types of CIMT measurements. Furthermore, although Study 2 used only the far wall readings, and Study 1 used both near and far wall readings, cross-sectional data have shown that the association between near wall CIMT and prevalent CVD is as strong and precise as is the association between far wall CIMT and prevalent CVD.³³

Another possible limitation of this pooled analysis is that not all the assumptions for ANCOVA were fully met. ANOVA and ANCOVA require first of all a random sample of the population in question. If the population of interest is “all those with or at high risk for ASCVD,” then the studies reviewed fell short of that requirement. Study 1, like most randomized clinical trials, drew its sample from those who were willing to participate in the study, a select subset of the entire population of interest. For Study 2, however, the self-selection went farther in that the control subjects were those who were willing to participate in the study, but were unwilling to be randomized to the MAV intervention.

Moreover, as described in Results, the assumption of homogeneity of variances was not met for the change in CIMT data unless two extreme cases were dropped from the analysis. Doing so satisfied the assumption and had only a small effect on the p value, favoring the significance of the statistical outcome. A third assumption, that of homogeneity of slopes of the regression of change in CIMT against the baseline CIMT covariate, was met by the inclusion of Study as a second two-level independent variable. In light of these considerations, while the statistical significance of the primary outcome is upheld, the exact p value is taken to be only approximate. The changes in CIMT found, however, are the raw

means and can be taken as fairly representative of the population with or at high risk for ASCVD who are willing to participate in a study of this sort.

If the observed CIMT reduction in the MAV group is real, it seems likely that risk factors known to relate to CIMT would also show a marked reduction, compared to that in the usual care control group. However, when only the mean changes in these risk factors were observed, such differential changes were not found. On the other hand, among the small number of MAV subjects that showed large reductions in CIMT, termed the “high-CIMT-change” subgroup, some individuals showed large reductions in one or another risk factor with little or no change in the others, while other individuals showed moderate reductions in several risk factors. This non-uniformity in risk factor changes across individuals, though potentially adequate to account for the observed decrease in CIMT, prevented any changes in the risk factors from reaching statistical significance.

It is notable that these high-CIMT-change participants were substantially higher at baseline in several risk factors than were the remaining participants. The mean blood pressures for these participants were in the hypertensive range, and indicators of dyslipidemia also were in the abnormal range. The ratio of triglyceride to HDL-cholesterol, e.g., is an accurate indicator of the dyslipidemia associated with the metabolic syndrome and is a powerful, independent predictor of all-cause mortality and cardiovascular events.^{34,35} The mean ratio at baseline in this subgroup exceeded the value of 3.5, an optimal predictor of dyslipidemia and risk for cardiovascular events.³⁴ The mean blood pressures declined from the hypertensive range to the normal range following MAV treatment in this high-CIMT-change group, and the triglyceride-to-HDL ratio declined toward the normal range, an observation consistent with a separate study³⁶ in which other indicators of the metabolic syndrome were reduced by the Transcendental Meditation program alone.

The fact that most members of the high-CIMT-change subgroup were women may be important. Women show unique vulnerabilities to depression and to factors related to CIMT, inflammation, and serotonin metabolism.^{37,38} The four individuals in the present study who showed the greatest regression in CIMT were women.

Whatever the mechanism(s) involved in the regression of CIMT found in the present analysis, the expected result of such a reduction would be improved cardiovascular health and reduced clinical events in the MAV subjects. Published studies on health insurance claims and mortality may confirm this expectation. One retrospective study analyzed the medical insurance utilization of 2000 practitioners of the Transcendental Meditation technique over a 5-year period.³⁹ Hospital admission rate for heart disease was 7.9 times higher in the control group than in the Transcendental Meditation practitioners. Admission rates for other disease categories were also significantly reduced in the meditation practitioners, but generally at lower percentages than for heart disease.³⁹ In a similar study of Transcendental Meditation technique practitioners who had used one or more additional components of MAV, hospital admission rate for cardiovascular disease was 11.4 times higher in the control group than in the MAV group⁴⁰, possibly reflecting an added benefit of the other MAV modalities.

Further results consistent with these observations come from a follow-up study of mortality rates in subjects who had participated in randomized controlled trials of the Transcendental Meditation technique for hypertension.¹¹ This study found a 30% decrease in the rate of CVD-related mortality in the Transcendental Meditation group compared with controls. A more recent randomized trial of this technique for secondary prevention of CVD over an average 5.4-year period found a 48% risk reduction in the primary end point of all-cause mortality, myocardial infarction, and stroke.¹²

Conclusions

Two prior studies of the effects of MAV on CIMT were found. The present analysis of pooled data from these prior studies gave results consistent with a substantial effect of this natural medicine approach on ASCVD in high-risk or known CVD subjects. These and other data support the use of this approach for the prevention and treatment of CVD generally. Larger randomized trials of this approach to prevention and treatment of ASCVD appear warranted.

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Table 1: Demographic and baseline characteristics for subjects from Study 1 and Study 2

Variables	Study 1		Study 2	
	MAV (n = 6)	Usual Care (n = 6)	MAV (n = 10)	Usual Care (n = 12)
Age (years)	74 ± 6	77 ± 7	70 ± 9	69 ± 10
Education	1.0 ± 0	0.83 ± .41	0.90 ± 0.32	0.83 ± 0.39
Income	2.8 ± 0.8	2.5 ± 1.2	3.5 ± 1.0	4.3 ± 1.0 ^a
Married	–	–	0.70 ± 0.48	1.00 ± 0.00 ^a
Male	33%	50%	80%	100%
Smoking (cigarettes/d)	0.0	0.0	0.0	0.0
Alcohol (drinks/week)	1.8 ± 2.7	1.0 ± 2.2	6.1 ± 4.5	7.2 ± 10.2
Beta-blocker dosage	–	–	48.1 ± 34.1	11.9 ± 16.1 ^a
CIMT (mm)	1.64 ± 0.57	1.30 ± 0.34	0.95 ± 0.13	0.88 ± 0.13
Systolic BP (mm Hg)	142 ± 10	137 ± 20	137 ± 18	121 ± 16 ^a
Diastolic BP (mm Hg)	81 ± 11	74 ± 12	78 ± 8	74 ± 10
Pulse (beats per min)	72 ± 7	71 ± 7	58 ± 9	66 ± 16
Weight (kg)	76 ± 11	72 ± 18	91 ± 13	81 ± 14
Body mass index (kg/m ²)	27 ± 5	27 ± 3	31 ± 5	27 ± 5
Triglycerides (mg/dL)	188 ± 96	147 ± 42	189 ± 90	97 ± 33 ^a
HDL-cholesterol (mg/dL)	45 ± 12	47 ± 16	41 ± 9	50 ± 15
LDL-cholesterol (mg/dL)	151 ± 37	131 ± 34	88 ± 33	93 ± 20
Total cholesterol (mg/dL)	233 ± 50	207 ± 34	166 ± 34	162 ± 30

Abbreviations: MAV (Mahanishi Ayurveda), BP (blood pressure), HDL (high density lipoprotein, LDL (low density lipoprotein)

Data for variables are either percentages or means ± SD.

^ap 0.05, within-study comparison of MAV and Usual Care groups

Table 2:

Baseline comparisons and study entry-exit changes for the pooled raw data

Variables	MAV (n = 16)			Usual Care (n = 18)		
	Entry	Exit	Change	Entry	Exit	Change
Carotid-IMT, mm	1.29 ± .49	1.14 ± .40	-1.50	1.09 ± .28	1.11 ± .28	+ .015 ^d
SBP, mm Hg	139.6 ± 15.2	133.3 ± 13.9	-6.3	128.5 ± 18.2	120.0 ± 20.2 ^b	-8.5
DBP, mm Hg	79.2 ± 8.9	70.8 ± 8.7	-8.4 ^c	73.6 ± 10.6	65.5 ± 9.1 ^c	-8.1
MAP, mm Hg	108.9 ± 10.5	101.5 ± 10.0	-7.4 ^c	99.7 ± 13.3	90.8 ± 13.7 ^c	-8.9
Pulse, bpm	63.3 ± 10.4	63.1 ± 8.1	-1.6	67.6 ± 14.1	67.1 ± 10.8	-50
BMI, kg/m ²	29.0 ± 5.5	29.7 ± 6.0	+7	26.9 ± 4.6	26.6 ± 4.5	-3
TG, mg/dL	188.8 ± 88.9 ^a	189.0 ± 77.3	+19	113.7 ± 42.8	111.4 ± 46.7	-2.3
HDL-C, mg/dL	41.1 ± 9.6	39.9 ± 8.1	-1.2	51.9 ± 14.2	46.4 ± 16.3	-5.5
TG/HDL-C, ratio	5.07 ± 3.04 ^a	5.54 ± 3.39	+47	2.22 ± 1.02	2.66 ± 1.77	+44
LDL-C, mg/dL	104.9 ± 41.8	107.1 ± 39.4	+2.2	103.0 ± 23.2	98.1 ± 30.8	-4.9
Total-C, mg/dL	183.4 ± 41.4	185.8 ± 42.4	+2.4	172.4 ± 33.3	165.1 ± 38.4	-7.3

^a $P < .05$, comparing MAV entry with Usual Care entry;^b $P < .05$;^c $P < .01$, for entry-exit changes within-group;^d $P < .01$, for between-group difference in entry-exit change

Table 3: Risk-factor baseline and change in the high- and low-CIMT-change groups

Variables	High-change		Low-change	
	Study entry (Mean ± SD)	Study exit (Mean ± SD)	Study entry (Mean ± SD)	Study exit (Mean ± SD)
SBP, mm Hg	141.0 ± 10.8	135.0 ± 6.6	130.5 ± 18.5	122.6 ± 19.9 ^a
DBP, mm Hg	80.0 ± 12.1	72.2 ± 4.4	75.3 ± 9.7	66.4 ± 9.6 ^b
MAP, mm Hg	110.5 ± 8.9	103.6 ± 3.4	102.9 ± 13.1	94.5 ± 13.7 ^b
Waist, cm*	91.1 ± 7.9	91.6 ± 8.3	78.3 ± 4.9	77.8 ± 5.0
BMI, kg/m ²	28.4 ± 4.7	28.9 ± 4.2	27.9 ± 5.3	25.8 ± 4.2
TG, mg/dL	205.0 ± 97.0	164.4 ± 71.2	139.4 ± 71.1	145.1 ± 74.6
HDL-C, mg/dL	45.2 ± 12.7	41.3 ± 6.2	46.9 ± 13.4	44.5 ± 14.5
TG/HDL-C, ratio	4.83 ± 3.3	4.42 ± 2.3	3.36 ± 2.49	3.94 ± 3.11
LDL-C, mg/dL	158.8 ± 34.8 ^c	150.0 ± 17.1	96.8 ± 28.0	94.8 ± 30.7

^a $P < 0.05$;

^b $P < 0.01$, for within-group change;

^c $P < 0.01$, for baseline (study entry) difference

BP = blood pressure; MAP = mean arterial pressure

* Data available from Study 1 only