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A randomized controlled trial comparing the effects of yoga to an active control on ambulatory blood pressure in individuals with Pre- and Stage 1 Hypertension

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Abstract

The purpose of this study was to compare the effects of yoga to an active control (non-aerobic exercise) in individuals with pre- and Stage 1 hypertension. A randomized clinical trial was performed using two arms: 1) yoga and 2) active control. Primary outcomes were 24-hour, day and night ambulatory systolic and diastolic blood pressures. Within-group and between-group analyses were performed using paired t-tests and repeated measures ANOVAs (time x group), respectively. Eighty-four participants enrolled with 68 participants completing the trial. Within-group analyses found 24-hour diastolic, night diastolic, and mean arterial pressure all significantly reduced in the yoga group (−3.93, −4.7, −4.23 mmHg, respectively) but no significant within-group changes in the active control group. Direct comparisons of the yoga intervention to the control group found a single blood pressure variable (diastolic night) to be significantly different (p =.038). This study has demonstrated that a yoga intervention can lower blood pressure in patients with mild hypertension. Although this study was not adequately powered to show between-group differences, the size of the yoga-induced blood pressure reduction we observed appears to justify performing a definitive trial of this intervention to test whether it can provide meaningful therapeutic value for the management of hypertension.

Keywords

yoga; blood pressure; hypertension; complementary; lifestyle changes

Introduction

Currently, almost 80 million US adults have high blood pressure [1] with less than half of those with hypertension having their blood pressure controlled.[2] Uncontrolled hypertension is thought to be responsible for 62% of cerebrovascular disease and 49% of ischemic heart disease events [3] and estimated to cost the United States $93.5 billion in health care services,

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medications, and missed days of work in 2010.[4] The cost of drugs, drug interactions, and non-adherence with prescribed drug regimens all contribute to the high rates of uncontrolled hypertension. Alternative, less expensive methods to reduce blood pressure with lower risk of drug interactions, which may convey the benefit of long-term adherence, are much needed. Yoga is an alternative health care practice that might improve blood pressure control.[5,6] The number of persons who practice yoga continues to rise, with current estimates indicating at least 10.4 million people in the United States (5.1%) practice yoga. [7]

Blood pressure control is one of the most studied outcomes for yoga with several reviews [5,8–12] and one meta-analysis [13] suggesting yoga is generally effective with effect sizes equivalent to other types of lifestyle interventions. Importantly however, these reviews also uniformly suggest that current studies of yoga are of poor quality with methodological limitations. In fact, a recent American Heart Association review [14] classified the existing evidence for the effects of yoga on blood pressure in the lowest possible category for estimates of certainty of treatment effect (Class C). Many of the studies examining the effects of yoga on blood pressure are uncontrolled or use non-hypertensive participants [8]. Very few studies have controlled for important confounding factors and only two used ambulatory blood pressure measures which are known to give a more accurate estimate of treatment effects than office measurements.[13] Therefore, the purpose of the current study was to conduct and evaluate a well-controlled randomized trial comparing the effects of yoga to an active control group on ambulatory blood pressure in individuals with pre- and Stage 1 hypertension.

Methods

A randomized clinical trial of pre- and Stage I hypertensive participants was performed using two arms: 1) yoga, and 2) active control (non-aerobic exercise). Our hypothesis was that yoga practice would provide significantly better blood pressure reduction than the active control. Prior to recruitment the study was approved by the Long Island University (LIU) Institutional Review Board and was registered with Clinicaltrials.gov (NCTO1542359). We estimated the study would need 90 participants (20% expected drop out rate) to achieve 85% power to observe a 5 mmHg change in SBP between the two groups [15].

Participants were recruited through flyers, advertisements, and email distribution to the local community. The study was described as a “stress reduction” program for hypertension. Inclusion criteria were: 21–70 years of age; Pre- or Stage I hypertension as determined by a 24-hour ambulatory blood pressure (ABP) reading with systolic between 120 and 159 mmHg or diastolic between 80 and 99 mmHg [3]; medically stable on any current medications; BMI (kg/m2) between 18.5 – 40; and English speaking. In addition, participants were required to be available during the expected class time periods (both interventions). Exclusion criteria were: current use of insulin or oral hypoglycemic agents; previous cardiovascular event (prior myocardial infarction, stroke, or angina pectoris); current or previous cancer diagnosis; congestive heart failure; history of kidney disease; signs or symptoms of significant peripheral vascular disease; significant co-morbidities that preclude successful completion of the study (e.g., current fractures, Parkinson’s disease, vertigo); current/regular yoga practitioner (participated in more than 3 yoga sessions within the last year).

Participants were told that the study was comparing two potentially beneficial stress reducing interventions. Participants in both groups were asked to attend two 55 minute classes per week for 12 weeks and to perform three sessions of home practice for 20 minutes each week as described in detail below. Participants received $100 for completion of all phases of the study including: pre- and post-test measures, attendance of 75% or greater of the intervention sessions (18 out of 24 classes), and completion of homework logs.

Potential participants who met initial criteria (e.g., age, medical history, activity levels) via a phone screening and agreed to the requirements/expectations of the study were invited to a blood pressure screening within the Physical Therapy Department at Long Island University (LIU) where clinical measures of blood pressure (e.g., aneroid sphygmomanometer) were used to determine if the participant's blood pressure was in the range of the inclusion criteria. If the clinical measures were within the criterion range the participant was asked to wear an ABP device for 24 hours. After the 24-hour data were evaluated, if either or both the mean 24 hour systolic or diastolic blood pressure were within the inclusion range participants were invited to participate in the study. Measurements were implemented such that no longer than one month occurred between the measures and the start of the intervention. Five cohorts of approximately 18 participants each were enrolled across the study period.

Measures

Primary outcomes were systolic and diastolic blood pressure and heart rate (HR). Twenty-four hour ABP monitoring was performed at pre- and post-test ("Oscar2," Suntech Medical, Morrisville, NC). This device has been validated as per internationally recognized standards. [16,17] Twenty-four hour ABP values were further categorized as day or night value using each participant's reported awake and sleep times. A minimum of 14 daytime values and 7 nighttime values were required for the data to be considered valid.

Demographic data on race, age, sex, as well as height and weight were collected at pre-test (Table 1). Diet and physical activity were assessed pre- and post-intervention using the Block 100-Item Food Frequency Questionnaire (FFQ) [18,19] and the Baecke Questionnaire of Physical Activity [20], respectively. Participants were encouraged to not change their diets, levels of physical activity, or medications during the course of the study unless advised to do so by their physician. At post-test participants were asked if they had changed medications during the course of the study. Participants were given access to both internet-based and paper methods of self-report for homework compliance. Efficacy expectations of participants for their assigned intervention were obtained after attendance of the first treatment session using the Credibility Expectancy Questionnaire (CEQ) [21,22]. Self-report psychosocial measures were obtained at pre- and post-test but will be reported elsewhere.

Randomization

Coin tosses performed by the primary investigator (MH) were used for sequence generation for treatment group assignment. Sequential results (e.g., Participant 1 = yoga) were placed inside ninety opaque sealed envelopes numbered in advance (e.g. 1–90). Once each participant completed pre-test measures (with the exception of the survey regarding expectations of treatment efficacy) he/she took the next numbered concealed envelope from within a box located with the measurement lab. All outcome assessors remained blinded to assignment of intervention throughout the study. By necessity for an active intervention, participants were not blinded to intervention assignment.

Interventions

The arms of the study were explicitly designed for equivalence of subject effort and time investment, investigator and instructor interaction and attention, social interaction, and expectations of efficacy. Consequently, classes and homework requirements were identical in terms of length, frequency and duration. All participants were provided with printed text and photos describing the intervention, a video of the respective intervention on DVD and procedures for recording homework compliance. Classes had similar opportunities before, during, and after class for social interaction. Instructors for both arms completed separate two hour-long workshop sessions defining goals, approach to participants, administrative duties, and specific structure and physical requirement of each class. Instructors were provided with a standardized teacher's manual and a video (DVD) of the practice. Instructors for both arms were trained to provide positive expectations to participants regarding the potential for the class to lower blood pressure.

In addition, the two interventions of the study were designed to be equivalent in terms of metabolic output. Our previous estimates of the metabolic output of the yoga exercises [23] was used to design the level of physical intensity of the exercises used for the active control group. The targeted average intensity across the 55 minute class was 3 metabolic equivalents (METs) (approximately equal to a brisk pace of walking)—a level considered non-aerobic. The validity of this metabolic equivalence across groups during the study was experimentally tested. A subset of participants from each arm (yoga = 9, active control = 8) volunteered to perform his/her respective intervention within the regular class period while wearing a portable indirect calorimeter ($K4b^2$, Cosmed, USA, Inc., Chicago Il.)[24] Estimates of metabolic output (METs) were obtained from the calorimeter through measures of oxygen and carbon dioxide flow through the face mask worn by participants. Measures for both intervention arms were taken during weeks 6–8 of the intervention.

Yoga arm—Yoga is generally described as a practice which incorporates three elements: postures, breath control, and meditation [25,26]. The specific yoga intervention incorporated all three of these elements and was based on the primary (beginner) series of Ashtanga yoga originally developed by Pattabhi Jois [27] and as specifically designed for this study by a long-term student of Jois: Eddie Stern (Director of *Ashtanga Yoga New York*). The program was explicitly designed to allow adaptation of poses as needed for individual participants who were expected to be sedentary, older, and with somewhat larger body mass. Please see the Appendix (part A) for a complete description of the yoga program. All yoga instructors had a minimum 200-hour training (Registered Yoga Teacher 200 ®, *Yoga Alliance*).

Active control arm—The active control exercise class was non-aerobic, and consisted of a warm up, exercises (e.g., "step-touch", squats, upper extremity resistive band work, abdominal strengthening) and stretching/cool down. It was designed by Tracey Rawls Martin (Assistant Professor, Athletic Training and Exercise Sciences Department, LIU). Details of the active control group can be seen in the Appendix (part B). All active control group instructors had at least two years of experience in leading fitness classes.

Statistical Analysis

Analytic Strategy—Means and standard deviations for all demographic and primary outcomes were calculated. The primary outcomes of interest were means of systolic and diastolic values (24-hour, day, night, mean arterial pressure (MAP), and "dipping" status defined as mean day less mean night values), and heart rate. ANOVAs and chi-square analyses were used for retention analysis to determine systematic variation in the factors characterizing (a) persons who completed one or more classes but were lost to follow up from (b) persons who participated fully. Separate repeated measures ANOVAs (time x group) were performed on physical activity and diet variables to determine if these factors varied across groups during the trial. Independent t-tests were performed on expectation of efficacy to determine if this factor varied across groups at baseline and on measures of adherence at post-test (number of classes attended and homework performed). Equivalency of the interventions relative to metabolic output was determined by independent t-tests of the mean MET values obtained with indirect calorimetry.

Primary analyses—Paired t-tests were used to assess changes within group pre- to post-intervention. Separate repeated measures ANOVAs (time x group) were used to determine significant differences relative to the intervention.

Results

Recruitment occurred from January, 2010 to March 2012, with interventions occurring from March, 2010 to June, 2012. A large number of potential participants were screened (n = 459; see Figure 1) to achieve 84 participants enrolled. Sixteen (19%) were lost to follow up after completing one or more classes, leaving 68 participants who completed the trial: 1) Baseline demographic characteristics were similar in the randomized groups (Table 1.) No adverse events were reported. No participants reported changing blood pressure medications during the trial.

Retention analysis

Completion did not vary by group χ^2 (1) = 0.81, p = 1.00 and there were no differences between completers and non-completers as a function of sex, χ^2 (1) = 0.32, p = .45, race, χ^2 (3) = 2.51, p = .47, age, F (1, 82) = 0.38, p = .54, BMI, F (1, 82) = 0.12, p = .73, expectation scores from the CEQ (all p values ≥ 0.12), physical activity, F (1, 77) = 0.49, p = .49, heart rate (p = .31) or baseline 24-hour systolic pressure (p = .20); completers did, however, have lower diastolic BP at baseline than those lost to follow up, F (1, 82) = 6.56, p < .05. As might be expected, those who were lost to follow up after one or more classes attended fewer sessions, F (1, 82) = 292.83, p < .01. Mean number of classes attended across groups by completers was 21.91 (±3.02).

Repeated measures ANOVAs (time x group) found no significant differences in physical activity (p = .174) or diet variables (all p values ≥ .05) across the groups during the trial. Independent t-tests found no significant differences in expectation of efficacy measures from the CEQ obtained at pre-test (all p ≥ .183). Independent t-tests found no significant differences between groups in number of classes attended (mean = 21.91 (±3.02); p = .749) or in minutes of homework performed (mean = 675.45 (±464.39); (p = .506).

Independent t-tests comparing the metabolic requirements of the two arms found that the yoga arm required significantly more energy to complete (2.79, ±0.59 METS) than the active control group (2.36, ±0.49 METS) (p < 0.001). Figure 2 displays the mean metabolic requirements of both arms of the trial across a single session.

Primary analyses

Within group—Results of paired t-tests assessing within group pre- to post-intervention changes are described in Table 2. Twenty-four hour diastolic, night diastolic, and mean arterial pressure were all significantly reduced in the yoga group (−3.93, −4.7, −4.23 mmHg, respectively). Similarly, trends (p <0.10) for the yoga group to reduce blood pressure were seen in 24-hour systolic, day diastolic, and night systolic blood pressure. However, unlike the yoga group, the active control group did not demonstrate any significant within group changes or trends.

Between group—Repeated measures ANOVAs (time x group) demonstrated a significant difference between groups in pre-to-post intervention changes in diastolic night time pressures (p = .038) and a trend in diastolic 24-hour pressures (p = .081). There were no significant differences or trends in any other variables (Table 2). See Figure 3 for a display of blood pressure change values from pre- to post-test.

Discussion

This study has shown that yoga decreases blood pressure in patients with very mild hypertension while the active control intervention (non-aerobic exercise) used in this study does not reduce blood pressure. However, in direct comparisons of the yoga intervention to the control group only a single blood pressure change variable (diastolic night) was found to be significantly different. Although recruitment goals for this study were essentially met (n= 84 vs. goal of n = 90), and effect size and drop-out rates were accurately estimated, the expected variability in blood pressure measurements was underestimated. Standard deviations are displayed in Table 2 and range from approximately 9–16 mmHg. These values are similar to some previous studies using ambulatory blood pressure monitoring [28,29] but are greater than in others [30]. Future research will require larger sample sizes to achieve sufficient power for comparisons with control groups.

The current study found that yoga decreased 24-hour mean systolic and diastolic blood pressure by approximately 5 and 4 mmHg, respectively. These blood pressure reductions are consistent with the values found in a recent meta-analysis of controlled studies examining the effect of yoga on individuals with hypertension (systolic 4 and; diastolic 4 mmHg). [13] The differences in blood pressure reported in the present study are comparable to those reported for other non-pharmacologic strategies such as the DASH diet, physical exercise and salt reduction. Apart from their value in all patients with hypertension, these interventions have been recommended for people with pre-hypertension by the national hypertension guidelines [3], and it may now be appropriate to consider yoga programs, which have no known adverse effects for participants, as an additional strategy to be considered in delaying or even preventing the onset of hypertension in patients at risk of this condition.

The mechanisms by which yoga may influence blood pressure are not well understood. Figure 4 presents a previously suggested model of hypothesized pathways.[6] Yoga may reduce feelings of stress and increase a sense of well-being, reducing activation of the sympathetic nervous system and positively altering neuroendocrine status and inflammatory responses (See pathway 1 in Figure 4). The physical practices of yoga may directly stimulate the vagus nerve increasing parasympathetic output (See pathway 2 in Figure 4).

To our knowledge, there are only three controlled trials that adequately reported blood pressure data and have examined the effects of yoga on individuals with hypertension using exercise comparison groups.[13] In all three studies [31–33] there were no significant effects of yoga when compared to exercise. In the current study the use of a non-aerobic exercise arm was designed primarily as an active control with no expectation of improvement in blood pressure outcome; this was confirmed with the observation of no significant within-group changes or trends. Although the intent of the design was to have the active control match the yoga arm in metabolic output, the mean METs of the yoga arm required more energy than that of the active control group. The mean difference between treatment arms was small and unlikely to be clinically meaningful, but it did achieve statistical significance. Future studies attempting to balance treatment arms relative to metabolic output would benefit from additional efforts to develop an active control arm with practices more precisely aligned with the energy requirements of the yoga practice under study.

Although this study is one of many that have examined the effects of yoga on blood pressure, it is among the first to use rigorous methods in a randomized trial on individuals with pre- or stage 1 hypertension. There were no significant differences between groups on measures of physical activity, food, expectation of efficacy, or adherence minimizing these potential sources of bias. Additionally, control of potential sources of bias related to selection, detection, attrition, and reporting [34], the successful balancing of treatment arms

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relative to duration, frequency, and social interaction, and the use of state of the art ambulatory blood pressure monitoring give confidence that this type of research can be conducted in compliance with highly credible clinical trial methodology.

Given the variability found in this study, future research will require larger sample sizes to achieve sufficient power for comparisons with control groups. Future research might also benefit from techniques to predict which patients are most likely to positively engage in yoga, thus making more targeted interventions possible.

This study has demonstrated that a yoga intervention in patients with mild hypertension can significantly reduce blood pressure. Although this study was not adequately powered to test this effect against a control group, the size of the yoga-induced blood pressure reduction we observed appears to justify performing a definitive trial of this intervention to test whether it can provide meaningful therapeutic value for the management of pre- and stage 1 hypertension.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

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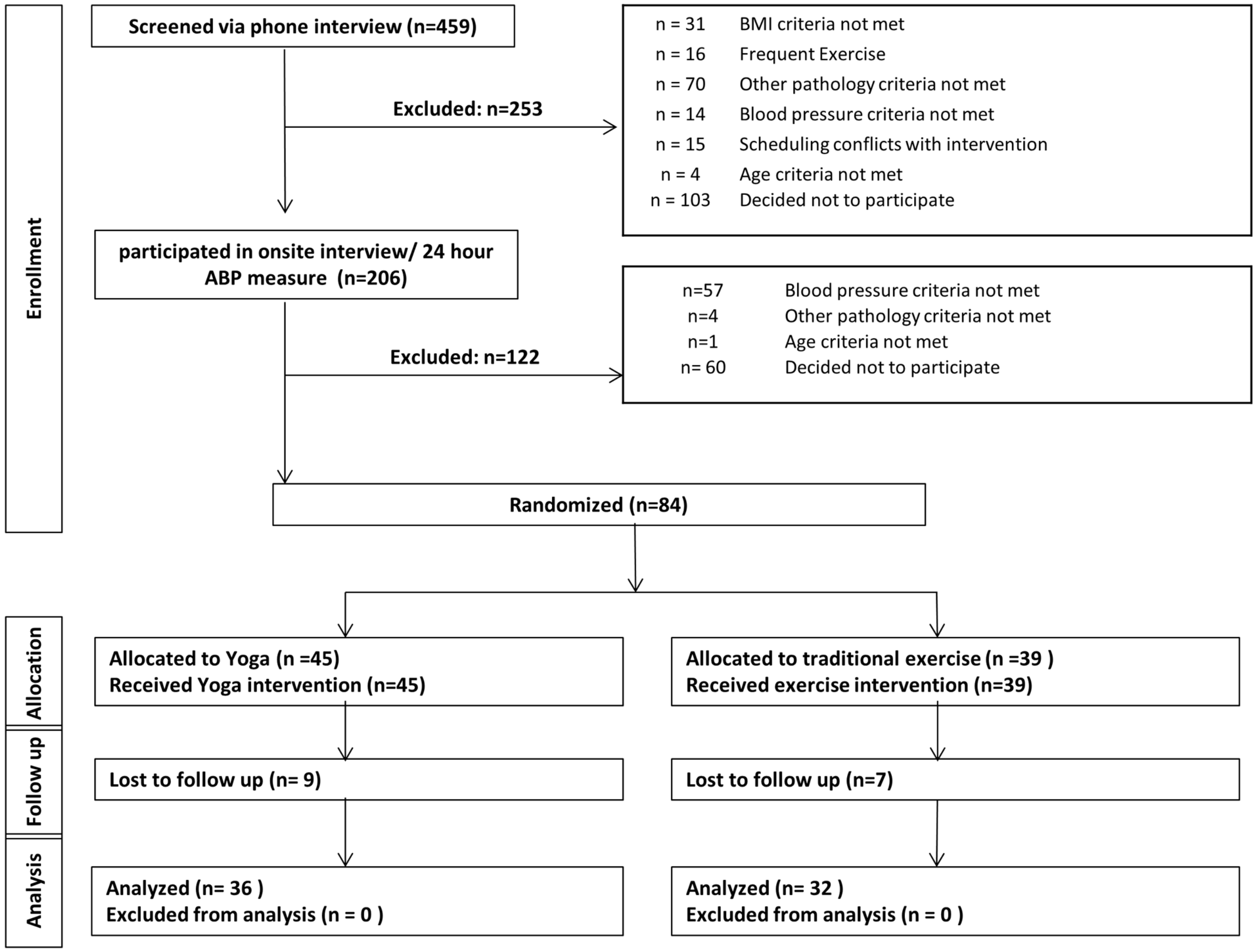

Figure 1.
Recruitment flow diagram

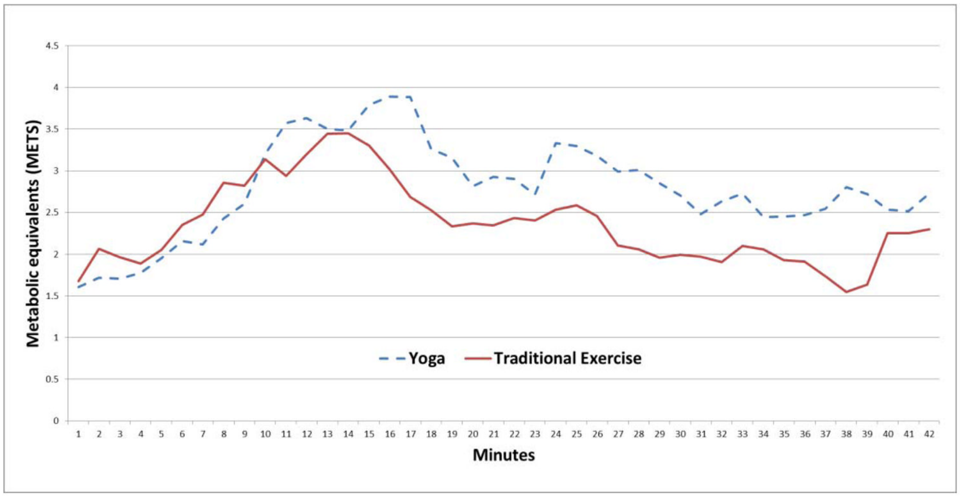

Figure 2.
Metabolic requirements for each intervention

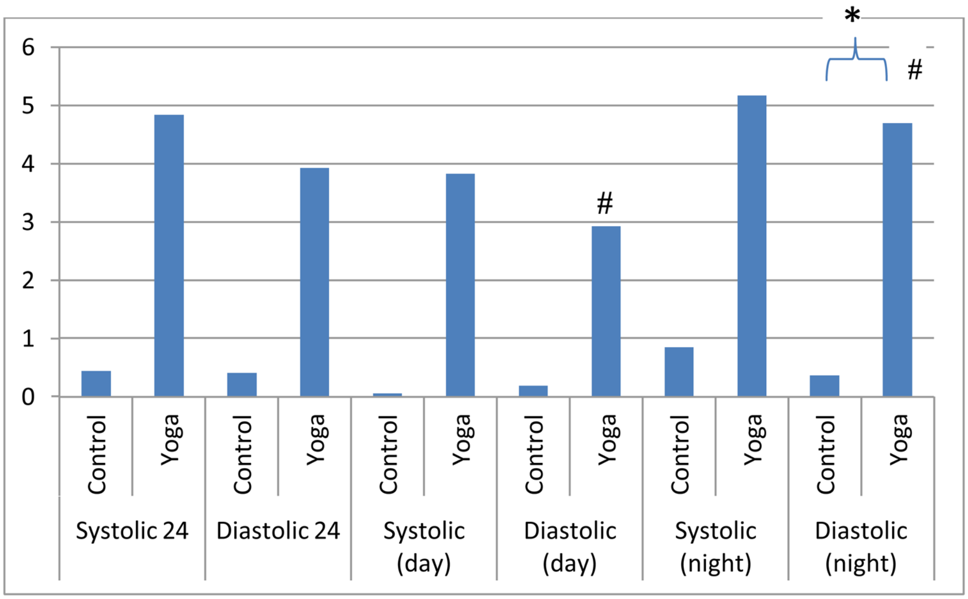

Figure 3.
Change value (*decrease* in mmHg) from pre- to post test
* = significant between-group difference using repeated measures ANOVA (time x group); $p < 0.05$;
# = significant within group difference using paired t-tests; $p < 0.05$

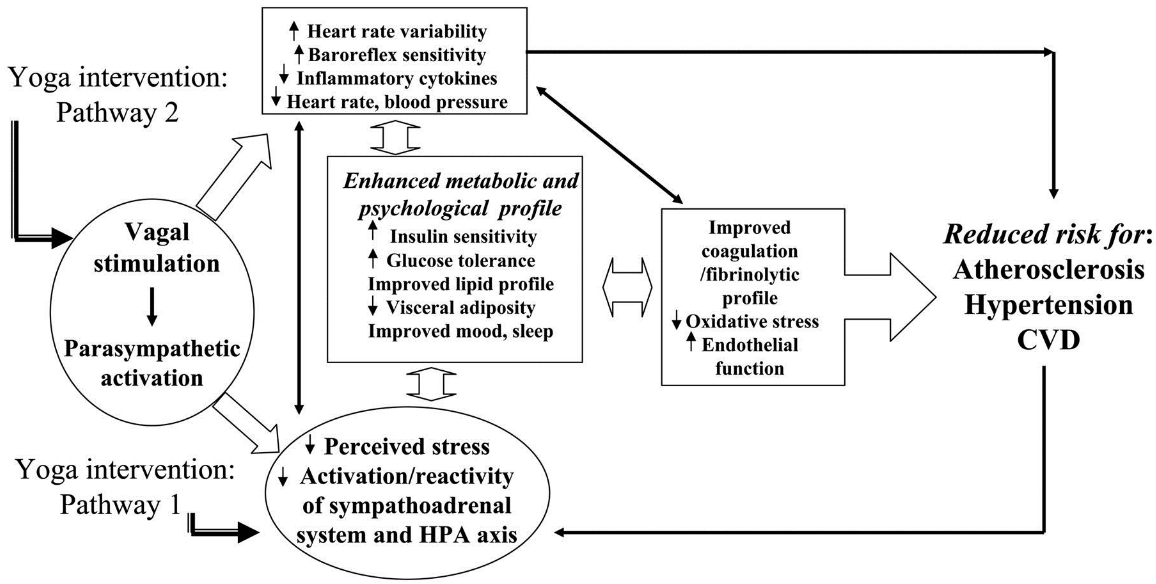

Figure 4.

Hypothesized pathways by which yoga may influence hypertension and cardiovascular risk profiles

Table 1

Baseline Characteristics by Randomized Group

	Yoga	Control
Age, mean (SD) years	56.4 (9.78)	52.45 (12.19)
Female	33 (91.6)	25 (80.6)
BMI, mean (SD)	30.27 (.94)	29.75 (.93)
* **Physical Activity,** mean (SD)	6.61 (2.51)	6.97 (2.25)
Pre-hypertensive (SBP 120–139 mmHg.)	23 (71.9)	25 (69.4)
Hypertensive (SBP >140 mmHg.)	9 (28.1)	11 (31.0)
Race or ethnicity		
African American	31 (86.2)	27 (84.4)
Non-Hispanic White	1 (2.7)	1 (3.1)
All others	4 (11.1)	4 (12.5)

* Baecke Physical Activity Survey, total of work, leisure, and sport scores

Data are presented as No. (%) unless otherwise indicated

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Table 2

Means (standard deviations) and results of within-group and between-group analysis of systolic, diastolic, HR, mean arterial pressure (MAP), and dipping status

		Time 1		Time 2		Change Value Time1-Time2		Within Group p value	Between Group p value
		M	SD	M	SD	M	SD		
Systolic 24	Control	133.80	9.86	133.36	18.29	−.44	15.00	.868	
	Yoga	135.53	9.79	130.68	14.99	−4.84	14.54	.053	.224
Diastolic 24	Control	80.17	7.49	79.76	11.11	−.41	8.19	.778	
	Yoga	80.82	7.33	76.89	8.61	−3.93	8.14	.006*	.081
HR 24	Control	77.58	10.63	75.75	9.72	1.83	8.98	.258	.999
	Yoga	72.34	8.25	70.5	7.04	1.83	6.79	.114	
Systolic (day)	Control	138.63	10.39	138.68	17.87	.052	16.18	.986	
	Yoga	139.64	10.72	135.81	16.55	−3.83	16.13	.163	.326
Diastolic (day)	Control	84.62	7.52	84.42	11.48	−.19	9.90	.913	
	Yoga	84.31	8.63	81.38	10.19	−2.93	9.81	.081	.256
HR (day)	Control	80.39	11.10	79.08	10.38	1.3	9.75	.454	.905
	Yoga	75.18	9.45	73.61	7.59	1.56	8.01	.248	
Systolic (night)	Control	122.61	12.72	121.76	19.97	−.85	15.80	.764	
	Yoga	125.14	12.06	119.96	15.05	−5.17	15.70	.056	.262
Diastolic (night)	Control	69.95	10.55	69.59	12.23	−.36	8.26	.807	
	Yoga	72.07	7.97	67.36	7.97	−4.70	8.60	.002*	.038*
HR (night)	Control	70.35	10.96	68.71	9.69	1.63	8.88	.306	.880
	Yoga	65.59	8.29	63.65	7.07	1.93	7.63	.137	
MAP 24 hour	Control	98.13	7.71	97.62	13.17	.51	10.23	.781	.134
	Yoga	99.05	7.36	84.82	9.89	4.23	10.01	.016*	

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		Time 1		Time 2		Change Value Time1-Time2		Within Group p value	Between Group p value
		M	SD	M	SD	M	SD		
Systolic (dip)	Control	−13.78	10.18	−14.77	8.35	−.98	11.09	.620	.890
	Yoga	−12.29	10.84	−13.66	9.72	−1.37	12.08	.500	
Diastolic (dip)	Control	−22.80	16.46	−22.86	14.66	.06	15.5	.981	.370
	Yoga	−18.01	15.1	−21.43	13.00	3.42	15.1	.183	

Within group = results of paired t-tests of within group change scores Time 1 vs. Time 2; Between group = results of repeated measures ANOVA (time x group);

* $p < 0.05$;

M = mean; SD = standard deviation; MAP = mean arterial pressure = Diastolic + [0.33333 X (Systolic -Diastolic)]]