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Restorative yoga and metabolic risk factors: The Practicing Restorative Yoga vs. Stretching for the Metabolic Syndrome (PRYSMS) randomized trial☆,☆☆,★

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ABSTRACT

Aims: Intensive lifestyle change prevents type 2 diabetes but is difficult to sustain. Preliminary evidence suggests that yoga may improve metabolic factors. We tested a restorative yoga intervention vs. active stretching for metabolic outcomes.
Methods: In 2009–2012, we conducted a 48-week randomized trial comparing restorative yoga vs. stretching among underactive adults with the metabolic syndrome at the Universities of California, San Francisco and San Diego. We provided lifestyle counseling and a tapering series of 90-min group classes in the 24-week intervention period and 24-week maintenance period. Fasting and 2-h glucose, HbA_{1c}, triglycerides, HDL-cholesterol, insulin, systolic blood pressure, visceral fat, and quality of life were assessed at baseline, 6- and 12-months.
Results: 180 participants were randomized and 135 (75%) completed the trial. At 12 months, fasting glucose decreased more in the yoga group than in the stretching group (−0.35 mmol/L vs. −0.03 mmol/L; p = 0.002); there were no other significant differences between groups. At 6 months favorable changes within the yoga group included reductions in fasting glucose, insulin, and HbA1c and an increase in HDL-cholesterol that were not sustained at 1 year except changes in fasting glucose. The stretching group had a significant reduction in triglycerides at 6 months which was not sustained at 1 year but had improved quality of life at both time-points.
Conclusions: Restorative yoga was marginally better than stretching for improving fasting glucose but not other metabolic factors.

1. Introduction

Approximately 35% of the U.S. adult population is obese (Flegal, Carroll, Kit, & Ogden, 2012), half of whom fulfill criteria for the metabolic syndrome which substantially increases risk of type 2 diabetes (Laaksonen et al., 2002). Intensive lifestyle interventions have been shown to prevent or delay the incidence of type 2 diabetes (Knowler et al., 2002; Ramachandran et al., 2006; Tuomilehto et al., 2001), but achieving and maintaining weight loss with lifestyle changes can be challenging (Wing & Phelan, 2005). Alternative methods of preventing diabetes are urgently needed.

Small clinical trials have shown benefits of yoga in patients with diabetes (Cohen et al., 2011; Jain, Uppal, Bhatnagar, & Talukdar, 1993), hypertension (Patel, 1975), dyslipidemia (Mahajan, Reddy, & Sachdeva, 1999), and atherosclerosis (Manchanda et al., 2000), and a systematic review found that yoga improved metabolic risk factors (Innes, Bourguignon, & Taylor, 2005). Yoga generally includes both a physically active component and a relaxation component. Restorative yoga is a specialized form of yoga that focuses on maximizing the restful components. Restorative yoga consists of prolonged periods of rest in supported poses using props to remove all muscular effort, reduce stress, and induce deep relaxation by triggering quieting reflexes with inverted postures, sustained, mild, passive stretching and neural reactions to covering of the eyes (Iyengar, 2001; Khattab, Khattab, Ortak, Richardt, &

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Bonnemeier, 2007). We previously tested a restorative yoga intervention in a small pilot trial and found it to be a feasible and acceptable intervention in obese individuals with beneficial changes in blood pressure and weight maintenance (Cohen, Chang, Grady, & Kanaya, 2008).

In this randomized clinical trial, we tested the effects of restorative yoga vs. a control intervention carefully constructed to retain certain key aspects of yoga—active stretching, range of motion, and healthy body alignment. We compared the effects of restorative yoga vs. active stretching on metabolic outcomes among underactive overweight adults with the metabolic syndrome. We hypothesized that restorative yoga would achieve significant improvements in metabolic factors (fasting and 2-h glucose, HbA_{1c}, triglycerides, HDL-cholesterol, fasting insulin, systolic blood pressure and visceral fat area) compared to the stretching group.

1.1. Subjects

The Practicing Restorative Yoga or Stretching for the Metabolic Syndrome (PRYSMS) randomized trial was conducted at two clinical sites, the University of California, San Francisco and the University of California, San Diego, between November 2009 and June 2012. Each institution obtained Institutional Review Board approval and all participants provided written informed consent.

2. Material and methods

Eligible participants were 21 to 65 years old; met metabolic syndrome International Diabetes Federation (Anon, 2006) criteria (a large waist circumference and two of the following criteria: fasting glucose $\geq$100 mg/dl; triglycerides $\geq$150 mg/dl, HDL-cholesterol < 50 mg/dl for women or <40 mg/dl for men, and blood pressure $\geq$130/$\geq$85 or use of anti-hypertensive medication); had an underactive lifestyle (<150 min/week of moderate intensity activity), and agreed not to use other treatments for weight reduction during the study. Exclusion criteria were fasting glucose $\geq$126 mg/dl, HbA_{1c} $\geq$7.0%, fasting triglycerides $\geq$300 mg/dl, weight $\geq$400 lb (due to CT scanner weight limits), chronic conditions that may affect metabolic factors, neurological conditions limiting mobility, hospitalization for coronary heart disease in past 6 months, current pregnancy or lactation, history of bariatric surgery, substance abuse, or use of medications affecting metabolic factors. We also excluded persons currently practicing either yoga or stretching, enrolled in other behavioral or pharmacologic intervention trials, or unable to commit to the length of the study due to limited life expectancy or expected living changes. We also excluded individuals who were unable to speak or read English, had uncontrolled psychiatric problems, or cognitive impairment.

2.1. Recruitment methods

Both sites advertised the study by posting flyers in community and clinical settings, newspaper advertisements, direct mailings, email lists, web-based advertisements, and community outreach. To keep the class sizes relatively small, we conducted recruitment and randomization for the study in four waves enrolling approximately 40–50 people per wave. The overall study goal was to randomize approximately 180 participants with each site randomizing approximately 20–25 participants for each wave.

At telephone screening, participants who were potentially eligible were scheduled for a clinical screening visit. For the screening visit, potential participants were requested to fast for at least 10 h before their visit and to bring all current medications and supplements. Height, weight, waist circumference and seated blood pressure were measured using standard protocols. Fasting blood samples were obtained for glucose, lipid panel, and HbA_{1c}. Final study eligibility was determined by fulfillment of metabolic syndrome criteria.

2.2. Baseline clinical examination

At the baseline clinical examination, fasting plasma glucose was measured using an automated analyzer with an immobilized enzyme biosensor (YSI 2300 STAT Plus, YSI Life Sciences, Yellow Sprints, OH). Total cholesterol, triglycerides and HDL-cholesterol were measured by enzymatic calorimetric methods (Quest Diagnostics, San Jose, CA), and LDL-cholesterol was calculated (Friedewald & Fredrickson, 1972). Participants were given a 75-g oral glucose load with blood samples taken after 120 min. We evaluated two surrogate measures of insulin resistance, fasting insulin (RIA, Millipore, St. Charles, MO) and the HOMA-IR (Matthews et al., 1985).

Staff obtained a brief medical history, smoking and alcohol use, and recorded all current medications. Total caloric intake was estimated using the 2005 Block Food Frequency questionnaire and physical activity using the Typical Week's Activity Survey (Ainsworth, Irwin, Addy, Whitt, & Stolarczyk, 1999). Quality of life was measured by the mental and physical health subscales from the SF-12 instrument (McHorney, Ware, & Raczek, 1993). Participant weight was measured on a standard balance beam scale and height using a stadiometer. Waist circumference was measured using a Gullick II tape spring-tension measure at the site of maximum circumference midway between the lower ribs and the anterior superior iliac spine. The mean of two waist circumference measurements was calculated. Three seated blood pressure measurements were conducted five minutes apart with an automated blood pressure monitor and mean systolic and diastolic blood pressures were calculated.

Abdominal CT scans were performed using a 16-detector helical CT scanner. A trained radiology technician used a lateral scout image of the spine to establish the correct position (between the L4 and L5 vertebrae) for the abdominal CT using standardized protocols. All CT scans were digitally recorded for batched readings at the CT reading center at UCSD.

2.3. Randomization

Randomization was stratified by sex and race/ethnicity (white or ethnic minority group). Stratum-specific sequential ID numbers were generated and pre-assigned to the two groups. Randomization was accomplished through a tamper-proof web-based system in randomly permuted blocks of 2 and 4. Study coordinators told the participant the result of the randomization at the end of the baseline clinic visit.

2.4. Study Interventions

The restorative yoga intervention was created by an expert yoga panel employing Iyengar poses (Iyengar, 2001) and Iyengar influenced poses (Lasater, 2011). The poses consisted of five main resting poses with several modifications to each pose. These included forward and backward bending, twisting, inverted and reclining positions, and most poses were held for 10–15 min at a time with eyes covered with a towel or an eye pillow. The stretching intervention was created by a physical therapist and a yoga expert and consisted of 27 seated or standing stretches that involved all parts of the body. Stretching was designed to promote flexibility, range of motion, and postural alignment without strong exertion or relaxation. The yoga poses and stretches were photographed and recorded on DVD for the participants to use for their home intervention. (See online supplements for the restorative yoga and stretch participant manuals.) Each intervention was delivered in a group setting twice-weekly for the first 12 weeks, then weekly for the next 12 weeks and then monthly for the subsequent 24 weeks. Participants were asked to practice yoga or stretching at home for at least 30 min three times per week. All group class instructors were trained by the same yoga expert and physical therapist.

All participants received a structured 30-min didactic presentation on healthy lifestyle including nutrition and physical activity information with printed materials at their first group class session.

2.5. Outcomes and Follow-up

Metabolic outcomes included changes in fasting and 2-h glucose, HbA_{1c}, triglycerides, HDL-cholesterol, fasting insulin, systolic blood pressure and visceral fat area. We also measured participant quality of life. Outcomes were determined after the active intervention period at 6-months and after the maintenance phase at 12-months.

Participants were scheduled to return for a brief clinical examination at the 3-month and 9-month time-points to measure their weight, waist circumference, seated blood pressure, and fasting blood tests. Changes in medications and any adverse events were recorded at each examination.

Class attendance was recorded and participants recorded minutes/day of home practice. Adherence was defined as completing 80% of required classes and 80% of requested home practice.

2.6. Sample Size

We calculated the estimated sample size based on the between-group differences in change in waist circumference of 1.0 to 2.0 cm observed in our pilot trial.(Cohen et al., 2008) After accounting for an estimated loss of 20% of subjects, randomizing a total of 160 subjects would provide at least 80% power in a two-sided t-test with type-I error rate of 5% to detect a between-group difference in the average decrease of 1.5 cm or higher of the change in waist circumference. We also calculated power for our other outcomes using available data from prior yoga trials with >80% power for detecting changes in insulin, systolic blood pressure and triglycerides. Since our attrition rate was higher than 20% after our first wave of the study, we increased our sample size goal to 180 participants.

2.7. Statistical Analysis

We compared baseline characteristics of participants by randomized assignment using chi-square and *t*-tests. The analysis was by intention-to-treat, without regard to adherence to the intervention; missing outcomes at follow-up were not imputed. We used linear mixed models to compare changes since baseline at each follow-up visit, adjusting for the baseline value, and using random subject-specific intercepts to account for within-subject correlation of the outcomes. Mixed models provide consistent estimates in the presence of missing data due to dropout, provided the data are missing at random, given the observed outcomes, and the model is correctly specified (Laird, 1988). Available data from all study visits were included in each model and treatment effects were summarized by adjusted between-group differences and within-group differences at 6 and 12 months.

We used a Hochberg procedure (Hochberg, 1988) for testing the level of significance of multiple outcomes for our between-group comparisons. This procedure controls the type-I error rate with less loss of power than the Bonferroni correction. For example, the Hochberg procedure rejects the null hypothesis for all k outcomes considered if the largest p-value is <0.05; rejects for all but one with p-value ≥ 0.05 if the rest have p-values $<0.05/2$; and rejects for all but two with p-values $\geq 0.05/2$ if the rest have p-values $< 0.05/3$. All analyses were conducted in SAS version 9.2 (SAS Institute, Cary, NC).

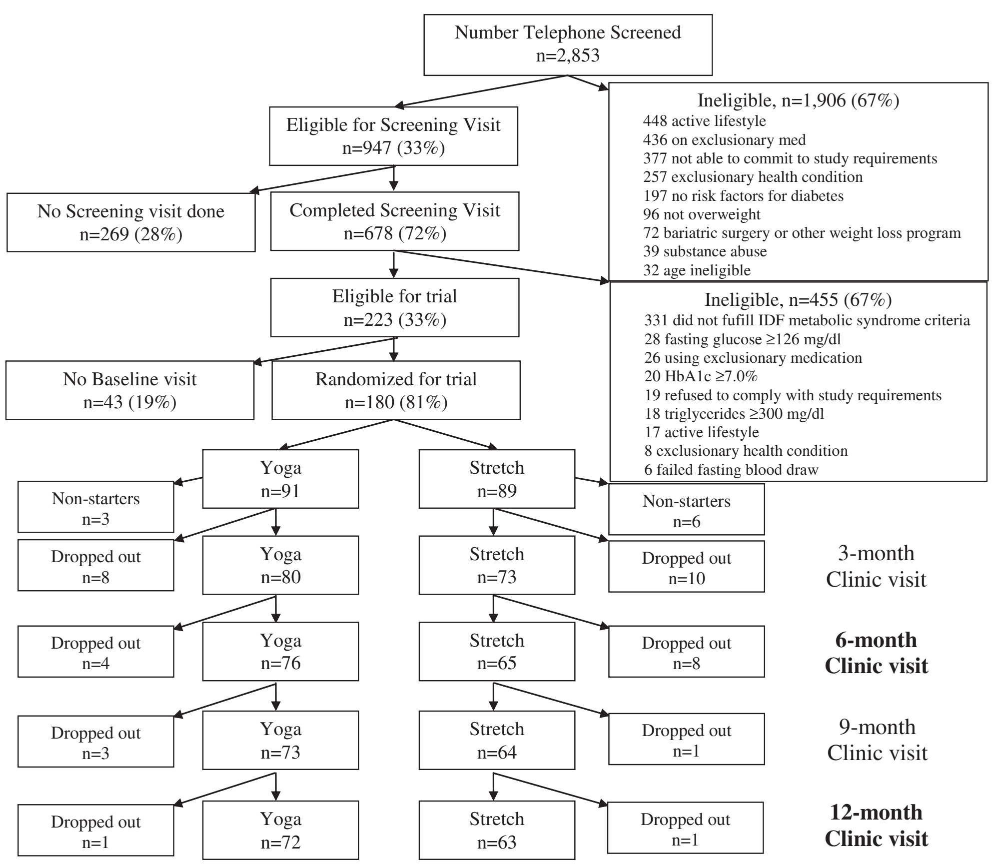

Fig. 1. Flow Diagram for PRYSMS.

3. Results

Fig. 1 shows participant flow at each of the screening and clinical visits. We randomized 180 participants; 9 people who were randomized failed to initiate the study intervention. Of the 171 persons who were enrolled in the trial and initiated the interventions, mean age was 55 ± 7 years, 72% were women and 35% were from ethnic minority groups (Table 1). The randomized groups were well-balanced at baseline except that BMI and waist circumference were higher among the yoga group and there were more married participants in the stretching group. CT measured visceral fat did not differ between groups.

Table 1
Baseline characteristics of the PRYSMS trial participants who initiated the intervention.

	Restorative Yoga n = 88	Stretching n = 83	p-value
Demographic variables:			
Age, years	55 ± 7	54 ± 7	0.42
Female sex	65 (74%)	59 (71%)	0.68
Race			
White	56 (64)	56 (67)	0.60
Black	5 (6)	5 (6)	0.92
Latino	14 (16)	14 (17)	0.87
Asian	12 (14)	10 (12)	0.76
Other	3 (3)	3 (4)	0.94
Relationship			
Married	42 (48)	56 (67)	0.03
Divorced/separated	11 (12)	11 (13)	
Single	29 (33)	13 (16)	
In significant relationship	6 (7)	3 (4)	
Education			
<High school	7 (8)	2 (2)	0.26
Some college	24 (26)	23 (28)	
≥Bachelor's degree	57 (65)	58 (70)	
Clinical site			
UCSD	48 (54)	41 (49)	0.50
UCSF	40 (45)	42 (51)	
Clinical Measurements:			
BMI, kg/m^2	36.0 ± 7.3	32.5 ± 5.9	<0.001
BMI categories			
<25 kg/m^2	0	6 (7)	0.32
25–29.9	18 (20)	25 (30)	
30.0–34.9	28 (32)	28 (34)	
35.0–39.9	22 (25)	15 (18)	
40.0–44.9	12 (14)	5 (6)	
≥45.0	8 (9)	4 (5)	
Waist circumference cm			
women	110 ± 14	103 ± 13	0.005
men	112 ± 10	112 ± 12	0.86
Visceral fat area, cm^2	192 ±68	178 ± 74	0.23
Systolic blood pressure, mmHg	124 ± 14	124 ± 14	0.95
Diastolic blood pressure, mmHg	72 ± 9	73 ± 9	0.41
Behavioral measures:			
Current smoker	5 (6)	5 (6)	0.92
Alcohol use			
none in past 30 days	23 (26)	22 (26)	0.57
Up to 2 drinks/week	54 (62)	46 (55)	
>2 drinks/week	11 (12)	15 (18)	
Exercise, median MET-min/week	315 (0–4567)	307 (90–2940)	0.12
Total caloric intake, kcal/day	1 838 ± 719	1 790 ± 653	0.69
Laboratory values:			
Fasting glucose, mmol/L	5.8 ± 0.7	5.7 ± 0.6	0.40
2-h post-challenge glucose, mmol/L	7.4 ± 2.7	7.0 ± 2 · 7	0.47
HbA1c, %	5.9 ± 0.4	5.9 ± 0 · 4	0.93
Fasting insulin, μU/ml	27 ± 12	28 ± 22	0.75
Total cholesterol, mmol/L	5.3 ± 1.0	5.4 ± 1.0	0.34
HDL-cholesterol, mmol/L			
women	1.3 ± 0.3	1.3 ± 0.3	0.64
men	1.0 ± 0.2	1.2 ± 0.3	0.07
Triglycerides, mmol/L	1.8 ± 0.6	1.9 ± 0.9	0.31
LDL-cholesterol, mmol/L	3.2 ± 0.9	3.3 ± 0.9	0.61
Medical History:			
Hypertension (on meds and/or >140/90 mmHg)	58 (66)	45 (54)	0.12
Number of Metabolic Syndrome criteria (not including waist circumference)	2.5 ± 0.6	2.6 ± 0.7	0.42
Medication use:			
Aspirin use	25 (28)	20 (24)	0.52
Statin use	21 (24)	20 (24)	0.97
Any hypertension medication use	50 (57)	42 (51)	0.41

Table 2 shows all outcomes. Among 10 outcomes considered at 6 and 12 months of follow-up, the only two significant between-group differences occurred at 12-months, with a −0.33 mmol/L (−5.9 mg/dl) greater reduction of fasting glucose in the yoga group compared to the stretching group ($p = 0.002$), and a 2.9 point greater improvement in the SF-12 mental health subscale in the stretching group compared to the yoga group ($p = 0.01$). Only the effect on fasting glucose met the Hochberg criterion of $p < 0.05/20 = 0.0025$.

There were multiple significant improvements from baseline within both groups (Table 2). There was significant reduction of waist circumference and weight at 6- and 12-months for the yoga group and at 6-months for weight and 12-months for waist circumference in the stretching group. Favorable metabolic changes observed in the yoga group included reductions in fasting insulin, fasting glucose, and HbA_{1c} and an increase in HDL-cholesterol. Favorable changes in the stretching group were a reduction in triglyceride levels at 6-months and improved mental health scores at both time points. These changes persisted after adjusting for baseline BMI and after excluding the women in the highest BMI categories.

Both intervention groups significantly improved their physical activity and caloric intake. At 6-months, both groups had increased physical activity by approximately 700–800 MET-min/week ($p < 0.001$) and decreased total caloric intake by 200–250 kcal/day ($p < 0.001$). At the 12-month visit these effects were somewhat attenuated but remained significantly improved from baseline for both groups (500–600 MET-min/week, $p < 0.001$ for physical activity and −140 to −180 kcal/day, $p \leq 0.01$ for total caloric intake).

Overall, 75% of participants completed the study. Of the 171 who initiated the study intervention, 16 (18%) in the yoga group and 20 (24%) in stretching dropped out ($p = 0.34$). We checked if any of the baseline factors were imbalanced among the 36 people who dropped out and those who remained in the study. There were two significant differences: those who dropped out were younger (52 ± 9 years vs. 56 ± 6 years, $p = 0.02$) and men who dropped out had a smaller waist circumference than the men who remained in the study (105 ± 8 cm vs 114 ± 11 cm, $p = 0.02$). However, controlling for the lower age and waist circumference of the participants who dropped out had no impact on the outcomes.

Table 3 shows adherence to the group classes and home practice. There were higher group class attendance and home practice in the yoga group during the active intervention period, but adherence was similar in the two groups during the maintenance period. There were few adverse events, the most frequent being minor musculoskeletal problems (23.9%), flu-like symptoms (23.3%), and gastrointestinal symptoms (14.4%) which did not differ by intervention assignment.

We determined whether the significant between-group results on fasting glucose varied by clinical site, sex, or intervention adherence and found no evidence of effect modification. Sensitivity analyses excluding those using medications that might confound the results did not change the findings. Finally, we determined whether favorable changes in physical activity and caloric intake and better intervention adherence explained improvement in fasting glucose in the yoga group. After adjusting for these lifestyle factors and adherence in mixed models, fasting glucose was still significantly lower in the yoga compared to the stretching group (−0.25 mmol/L vs. −0.03 mmol/L, $p = 0.02$) at the 12-month examination.

Table 2
Effect of the yoga and stretch interventions on change in each outcome at 6-months and 12-months, PRYSMS study.

Outcomes	Baseline mean (SD)		Change at 6 months (95% CI)			Change at 12 months (95% CI)		
	Yoga	Stretch	Yoga	Stretch	Difference b/w groups	Yoga	Stretch	Difference b/w groups
Fasting glucose, mmol/L	5.8 ± 0.7	5.7 ± 0.6	−0.02 (−0.14, 0.11)	0.07 (−0.06, 0.21)	−0.09 (−0.28, 0.09)	−0.35 (−0.49, −0.21)**	−0.03 (−0.19, 0.13)	−0.33 (−0.54, −0.12)†‡
2-h glucose, mmol/L	7.4 ± 2.7	7.0 ± 2.7	−0.06 (−0.45, 0.33)	−0.15 (−0.60, 0.29)	0.09 (−0.49, 0.68)	−0.34 (−0.75, 0.08)	−0.35 (−0.83, 0.13)	0.01 (−0.61, 0.63)
HbA_{1c}, %	5.9 ± 0.4	5.9 ± 0.4	−0.07 (−0.13, −0.01)*	−0.05 (−0.12, 0.01)	−0.01 (−0.09,0.06)	−0.05 (−0.11, 0.00)	−0.04 (−0.1, 0.02)	−0.01 (−0.09,0.06)
Triglycerides, mmol/L	1.8 ± 0.6	1.9 ± 0.9	−0.07 (−0.19, 0.07)	−0.18 (−0.32, −0.05)**	0.11 (−0.07, 0.31)	−0.03 (−0.19, 0.12)	−0.10 (−0.18, 0.16)	−0.02 (−0.26, 0.21)
HDL-cholesterol, mmol/L	1.3 ± 0.3	1.3 ± 0.3	0.05 (0.01, 0.08)**	0.03 (−0.003, 0.07)	0.02 (−0.04, 0.06)	0.02 (−0.02, 0.06)	0.04 (−0.008, 0.08)	−0.02 (−0.07, 0.04)
Fasting insulin, μU/ml	27 ± 12	28 ± 22	−0.01 (−2.2, 2.2)	0.06 (−2.3, 2.4)	−0.06 (−3.0, 2.9)	−2.4 (−4.5, −0.3)*	−1.2 (−3.5, 1.0)	−1.2 (−4.2, 1.9)
HOMA-IR	7.2 ± 3.8	7.2 ± 6.2	−0.1 (−0.7, 0.5)	−0.2 (−0.8, 0.5)	0.1 (−0.8, 1.0)	−0.9 (−1.5, −0.3)*	−0.4 (−1.1, 0.2)	−0.5 (−1.4, 0.4)
Systolic blood pressure, mmHg	124 ± 14	124 ± 14	1 (−2, 3)	−1 (−3, 2)	1 (−2, 5)	1 (−1, 4)	−1 (−4, 2)	2 (−2, 7)
Visceral fat area, cm^2	192 ± 68	178 ± 74	−2 (−10, 5)	−3 (−11, 4)	1 (−10, 11)	−1 (−9, 7)	−4 (−12, 4)	3 (−9, 14)
Waist circumference, cm	110.6 ± 12.8	105.4 ± 13.5	−1.7 (−2.6, −0.7)**	−0.8 (−1.9, 0.2)	−0.8 (−2.2, 0.6)	−2.1 (−3.1, −1.0)**	−1.1 (−2.2, −0.1)*	−1.0 (−2.5, 0.6)
Weight, kg	97.2 ± 19.1	90.3 ± 19.1	−1.3 (−1.9, −0.7)**	−0.7 (−1.4, −0.1)*	−0.6 (−1.5, 0.4)	−1.7 (−2.6, 0.7)**	−0.7 (−1.7, 0.3)	−0.9 (−2.3, 0.4)
Quality of Life, SF-12:								
mental health component	44.4 ± 7.8	44.3 ± 7.7	−0.9 (−2.3, 0.6)	1.5 (−0.1, 3.1)*	−2.4(−4.5, −0.3)†	−0.3 (−1.7, 1.2)	2.6 (1.1, 4.2)**	−2.9 (−5.0, −0.8)†
physical health component	38.6 ± 5.8	38.7 ± 6.0	0.5 (−0.8, 1.7)	−0.7 (−2.1, 0.7)	1.2 (−0.7, 3.0)	0.4 (−0.9, 1.8)	−1.2 (−2.6, 0.3)	1.6 (−0.4, 3.6)

* Within-group change $p<0.05$ compared to baseline value.
** Within-group change $p<0.01$ compared to baseline value.
† Between-group difference, $p<0.05$.
‡ Between-group difference $p = 0.002$ after adjusting for multiple comparisons testing with the Hochberg procedure.

Table 3
Adherence to intervention with group class attendance and home practice.

	Restorative yoga	Stretch	p-value
Group Classes attended total, mean ± SD (total 30 possible)	22·9 ± 9·1	19·8 ± 10·2	0.04
Group classes attended in intervention period, 0–6 months (of 24 possible)	67%	52%	0.04
Group classes attended in maintenance period, 6–12 months (of 6 possible)	72%	73%	0.85
Adherent to group classes during entire study period, >80% attendance	68%	55%	0.08
Home practice completed throughout study period, mean min ± SD	4508 ± 2651	3546 ± 2541	0.02
Home practice completed in intervention period (of 2160 min)	85%	67%	0.005
Home practice completed in maintenance period (of 2160 min)	72%	63%	0.26
Adherent to home practice during entire study period, >80% practice	78%	60%	0.01
Adherent (>80%) to both group classes and home practice, 0–6 months	63%	47%	0.04
Adherent (>80%) to both group classes and home practice, 6–12 months	61%	55%	0.51
Adherent (>80%) to both group classes and home practice, entire study	62%	46%	0.04

4. Discussion

In this first large randomized trial of restorative yoga compared to an active stretching control group, we did not find strong evidence for a benefit of yoga compared to stretching for most metabolic outcomes. There was one significant outcome with the yoga group experiencing a greater reduction in fasting glucose after 1 year which was not explained by favorable lifestyle changes or intervention adherence. However, both groups made significant lifestyle changes with increased physical activity and decreased caloric intake, and achieved meaningful improvements in several metabolic risk factors.

Other than our prior pilot study (Cohen et al., 2008), restorative yoga has not been tested in randomized controlled trials for effects on metabolic outcomes. A systematic review found that Hatha yoga, which usually includes much more physical activity and a relaxation component, improved metabolic risk factors (Innes et al., 2005). Another 12-week feasibility study of 23 patients at risk for diabetes found that those randomized to a Vinyasa style yoga had trends towards improvements in weight, systolic blood pressure, fasting insulin, and triglycerides compared to an education control (Yang et al., 2011). Two randomized controlled trials of yoga compared to conventional risk factor control found a significant weight reduction in the yoga group compared to controls (Manchanda et al., 2000). Other small uncontrolled trials have also found a benefit of yoga in diabetes management (Malhotra et al., 2002; Sahay, 1986) and for hypertension (Patel, 1975) and dyslipidemia (Mahajan et al., 1999).

The mechanism whereby restorative yoga might reduce fasting glucose levels is not clear. Yoga was still associated with significant reductions in fasting glucose after controlling for favorable changes in physical activity and caloric intake, suggesting that there may be other factors, such as relaxation or stress reduction, that explain this effect. There were greater reductions in waist circumference and body weight in the yoga group than in the stretching group, but this did not explain the effect on fasting glucose levels. Moreover, controlling for the baseline imbalance in BMI between groups did not change these findings. Additionally, the yoga group did have several other consistent within-group changes including reductions in fasting insulin at 12 months and HbA_{1c} and an increase in HDL-cholesterol at 6 months. However, we did not see similar improvements in 2-h glucose at any time-point or on HbA_{1c} levels in the yoga group at 12 months. The 2-h glucose value has higher variability and poorer reproducibility than fasting glucose (Ko et al., 1998; Mooy et al., 1996) and may miss small changes in glucose tolerance. The HbA_{1c} test integrates serum glucose values over a 3-month period but the relative contribution of fasting and post-prandial glucose is variable and has limited correlation with fasting glucose (Bonora & Tuomilehto, 2011; Monnier, Lapinski, & Colette, 2003). Since all of the measures of glucose homeostasis did not show consistent effects, we cautiously conclude this favorable fasting glucose outcome and urge future studies to confirm our findings.

Our goal was to test a relaxing non-exercise form of yoga with an active stretching comparison group to determine whether inducing the relaxation response by restorative yoga would be associated with metabolic improvements. The healthful active comparison group focused on postural correction and static stretching without aerobic activity or inducing a relaxation response, and provided similar group and home practice time as the yoga group—a methodologically better comparison than a usual care group. While the drop-out rate was similar in both intervention groups, the participants assigned to yoga were more adherent to the group classes and home practice than the stretching group. However, the stretching group had significant improvements in the mental health measure that we hypothesize may be due to social group bonding effects with verbal interactions during classes, while the restorative yoga classes were mostly silent and student's eyes were covered with eye pillows restricting group social interactions. However, this improvement in the SF-12 mental health measure in the stretch group was not statistically significant after controlling for multiple outcomes testing and an increase of 2.6 points is not considered clinically significant.

We hypothesized that between-group changes would be greatest after the first six-month active intervention period and would be attenuated in the following six month maintenance phase as has been observed in other weight loss and diabetes prevention trials. Yet we found that the only significant between-group difference occurred at the 12 month time-point and many of the beneficial effects within the yoga group emerged at 12-months rather than at 6-months. We may have been underpowered to see smaller between-group differences earlier in the study, or metabolic changes due to yoga practice may take up to a year or longer to manifest. These findings suggest that future yoga interventions for metabolic outcomes may need bigger sample sizes and longer than one year follow-up time to find clinically meaningful effects. Since we purposefully designed this study with an active comparison group, we did not have a usual care control group that would resemble the standard behavior change counseling that a patient with the metabolic syndrome may receive from his/her healthcare provider. Future studies should test a yoga intervention vs. an active control group vs. a usual care control group to definitively test whether the yoga group had significant improvements compared to usual clinical care. Finally, both the restorative yoga program and the stretching program were created specifically for this study with expert panel input and may not be similar to restorative yoga or stretch classes that are available in community settings.

In conclusion, we found that restorative yoga was not significantly better than active stretching for most metabolic factors among underactive and overweight adults with the metabolic syndrome. Only fasting glucose improved significantly more in the yoga group vs. stretching after 12 months. Several metabolic factors improved within both groups, suggesting that both restorative yoga and stretching may be better than usual care, although our trial could not test this hypothesis. Restorative yoga and active stretching warrant further study as possible alternative or adjunctive methods to promote and sustain healthy lifestyle change among individuals at risk for type 2 diabetes.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at http://dx.doi.org/10.1016/j.jdiacomp.2013.12.001.

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