DGIM Project Summary

Name of Project: Practicing Restorative Yoga or Stretching for the Metabolic Syndrome (PRYSMS study)

Investigator(s): PI: Alka Kanaya, MD
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Research question(s):
Among 142 underactive adults, with metabolic syndrome, aged 21-65 years old, the aims of the study are:

Aim 1: To test the hypothesis that Restorative yoga will decrease visceral adiposity and select components of the metabolic syndrome, including, systolic blood pressure, triglycerides, and fasting insulin levels (co-primary outcomes). We will measure:
1a: change in visceral adipose tissue area measured on abdominal CT scan, resting systolic blood pressure, triglycerides, and fasting insulin levels
1b: change in glucose tolerance, HbA1c levels, high density lipoprotein (HDL) cholesterol, and quality of life (secondary outcomes).

Aim 2: To test the hypothesis that Restorative yoga changes stress arousal that may result in decreased visceral adiposity and improvement of features of the metabolic syndrome. We will measure:
2.a change in stress arousal with diurnal salivary cortisol, a dexamethasone suppression test, and validated questionnaires.
2.b. change in sleep duration, quality and efficiency with 3-day actigraphy and validated questionnaires.

Brief Background/Significance:
Metabolic abnormalities, including visceral adiposity, insulin resistance, hyperglycemia, hypertension, and dyslipidemia, occur together and are associated with excess caloric intake and inadequate physical activity. Approximately 66% of American adults are overweight, and almost half of all obese persons meet criteria for the ‘metabolic syndrome’, which substantially increases risk of developing diabetes and cardiovascular disease. Lifestyle and behavioral interventions reduce these risks, but many individuals with increased metabolic risk find it difficult to achieve and maintain weight loss and increased physical activity.

Yoga is an ancient self-awareness system that combines the use of body postures, breathing, and mental focus. A recent review of the effect of yoga on cardiovascular risk factors found beneficial changes in metabolic risk factors. We have completed two pilot trials of Restorative yoga, a type of yoga that uses supported poses to induce a state of total relaxation without muscular strain. In a randomized controlled pilot trial of overweight and underactive individuals with the metabolic syndrome, we found that teaching Restorative yoga to persons with the metabolic syndrome is feasible, and adherence and retention were excellent. After 10 weeks of weekly yoga training, there were trends toward improvements in weight, waist circumference, and blood pressure in the yoga group compared to the wait-list control group.

We propose a rigorous randomized controlled trial coordinated by UCSF with two clinical sites, UCSF and UC San Diego, to determine whether Restorative yoga vs. a stretching control group improves visceral adiposity, insulin sensitivity, glucose tolerance, dyslipidemia, and hypertension among 142 underactive adults with the metabolic syndrome. Participants will be randomized in two waves of 36 participants at each site for a 48-week
trial. Participants in the yoga and control groups will participate in group classes twice per week for the first 6 weeks, once per week during weeks 7-12, and twice per month during weeks 13-24. After evaluation at 6 months, both groups will enter a 24-week maintenance phase and undergo a 12-month end-of-trial evaluation.

**Inclusion/exclusion criteria:**

**Eligible participants will:**
1) be between 21 to 65 years old
2) have waist circumference (per the International Diabetes Federation criteria)

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<thead>
<tr>
<th>Ethnicity</th>
<th>Sex</th>
<th>Waist Circumference (cm)</th>
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<tbody>
<tr>
<td>White/European,</td>
<td>M</td>
<td>&gt; 94</td>
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<tr>
<td>African</td>
<td>F</td>
<td>&gt; 80</td>
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<td>South Asians</td>
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<tr>
<td>Chinese</td>
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<td>Other Asian</td>
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<tr>
<td>Japanese</td>
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<td>&gt; 85</td>
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<tr>
<td></td>
<td>F</td>
<td>&gt; 90</td>
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</tbody>
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and have at least two of the following criteria of the metabolic syndrome, as defined by the International Diabetes Federation38:

- HDL-cholesterol < 40 mg/dL for men or < 50 mg/dL for women, and/or
- triglycerides ≥150 mg/dL, and/or
- fasting glucose ≥100 mg/dL, and/or
- high blood pressure ≥130/≥85 mmHg or use of antihypertensive medication, and
3) have an underactive lifestyle defined as <150 minutes of moderate intensity exercise per week..
4) agree not to initiate new treatment for weight reduction, including behavioral, pharmacological or surgical therapies, for the duration of the study.

**Exclusion criteria:**
1) Currently pregnant or attempting pregnancy
2) Coronary heart disease (myocardial infarction, percutaneous or surgical coronary revascularization) or hospitalization for a heart condition in the past 6 months
3) Chronic illnesses: cancer, kidney disease, cirrhosis, rheumatologic diseases, or chronic infections
4) HbA1c >6.5%
5) fasting glucose ≥126 mg/dl
6) fasting triglycerides ≥300 mg/dl
7) Weight ≥ 400 pounds, or capacity of CT scanner.
8) Regular yoga or stretching practice (≥1/month) within the past 6 months
9) Use of any of these medications currently or within the last 3 months: oral hypoglycemic medications, insulin, corticosteroids, oral contraceptives, hormone therapy, testosterone, fibrates, niacin, antiretrovirals, oral chemotherapy, rheumatologic treatments, weight loss medications or over-the-counter, supplements for weight loss, or medical marijuana.
10) History of bariatric surgery; or future plans for bariatric surgery in next 12 months.
Additional Exclusion criteria:
11) Not ambulatory or neurological condition causing impaired mobility.
12) Participating in another research study that involves investigational drugs, behavioral change, or other studies that may potentially confound the results of this trial per the clinical center Principal Investigator’s discretion.
13) Inability to speak and read English, due to limited resources for employing clinical staff and instructors for the interventions who are bilingual.
14) Reports conditions that, in the judgment of the clinical center Principal Investigator, render potential participants unlikely to follow the protocol for 12 months, including illness likely to be terminal within 2 years, substance abuse, significant psychiatric problems, cognitive impairment, plans to move, or travel for 3 consecutive weeks during the study.

Method of contact/recruitment (be specific):
1. Posting flyers with tear-away strips on designated bulletin boards in each clinic (GMA, GMB, GMZ, and SACC).
2. Placing small cards advertising the study on designated side tables in the waiting area of the Gen Medicine clinics.
3. We will be advertising the study on Craig’s list, with ads in the Bay Guardian and SF Chronicle, and posting flyers in local clinics, hospitals, businesses, and restaurants.

Benefits/burden for participants (clearly identify potential for harm):
Both interventions (yoga and stretching) are gentle, pose no major risk, and may have healthful benefits for someone with the metabolic syndrome. The clinical visits will require time to complete an oral glucose tolerance test and abdominal CT scans (3 times during the year-long study). These CT scans are non-contrast, and limited to 4 slices. We will be screening all reproductive aged women for possible pregnancy before they undergo these CT scans.

Any benefits or burden to DGIM practitioners?
None anticipated except for answering questions that their patients may have about the metabolic syndrome after seeing one of the flyers/cards. Their patients may ask about the safety and efficacy of the intervention. Both interventions are gentle, pose no major risk, and have healthful benefits for someone with the metabolic syndrome. In addition to the study intervention, all participants regardless of which group they are randomized to, will receive standard nutrition, physical activity, and metabolic syndrome counseling materials and advice.

Timeline for recruitment (projected start and stop dates):
There are 2 separate waves for this study:
Wave 1 begins recruitment from December 1st, 2010 through March 2011. The study intervention begins in mid April 2010 and lasts 48 weeks.
Wave 2 will begin recruitment in October 2010 through February 2011, and the study intervention will begin in late February 2011 and last another 48 weeks.
Our final recruitment effort for the study will end on February 15th, 2011.

Funding source: NIH/NCCAM grant

Potential for DGIM collaborators? (We encourage DGIM resident and fellow involvement in particular) We welcome residents or fellows to participate and learn the process of conducting an RCT in a clinical setting. We will have data from the study available in 2012.
and there will be many opportunities to collaborate on secondary data analyses.

**Do you agree to notify us when recruitment is completed?** Yes.

Date form complete: 11/11/2009