DGIM Project Summary

Name of Project: SHINE Study – Supporting Health by Integrating Nutrition and Exercise

Investigator(s). (Include phone numbers and email address, indicate PI and primary contact)
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Research question(s):
This randomized, controlled clinical trial will examine the effects of two different 6-month weight loss programs on weight, body fat, and psychological well-being. Key outcomes include weight loss and maintenance, body fat distribution, insulin sensitivity, psychological well-being, stress hormones, immune function, and cell aging.

Brief Background/Significance:
The high prevalence of obesity and its medical consequences make it one of the most important public health issues in the US. Few interventions have been consistently successful at reducing obesity. This trial will test an intervention program that lasts 22 weeks, with 15 evening sessions and 2 weekend days. Participants will be randomized to one of two arms; both will receive diet and exercise intervention elements. The study aims for gradual weight loss, with a calorie target that will maintain ideal body weight, rather than a more calorie restricted diet. The exercise component is based on increasing walking. The arms will compare methods for producing long-lasting behavior change.

Inclusion/exclusion criteria (list)

Inclusion Criteria: Age 18+ years old, BMI > 30-45, Waist circumference > 102 cm (men) or > 88 cm (women), Live in San Francisco Bay Area and able to attend more than 16 classes and up to 12 assessment visits in San Francisco over an 18 month period.

Exclusion Criteria: Inability to provide informed consent; Age < 18; A substance abuse, mental health, or medical condition that, in the opinion of investigators, will make it difficult for the potential participant to participate in the group intervention; Type I or II Diabetes or fasting glucose ≥ 126 mg/dl or hemoglobin A1c ≥ 6; Use of systemic (oral or IV) corticosteroids in the 6 months prior to enrollment or severe autoimmune disorders or other conditions (e.g. rheumatoid arthritis, lupus), that are likely to require these medications; Use of immunosuppressive or immunomodulating drugs or chronic or acute conditions that would require the use of such medications; A history of known coronary artery disease (CAD), or typical or atypical anginal chest pain requires a letter from the participant's physician that he or she has been adequately evaluated and that a moderate exercise program is appropriate; Non English speaker; Pregnant or planning to get pregnant in the next 12 months, breastfeeding or less than 6 months post-partum; Initiation of new class of psychiatric medications in past 2 months; Currently on a specific weight loss diet; Active bulimia or strong history of bulimia; Current use of weight loss medications or supplements such as amphetamine-based drugs that are believed to have some effect on weight; History of or planned weight loss surgery; Untreated hypothyroidism: TSH > 4mU/mL (or the upper limit of normal reference defined by the lab doing the assay)

Method of contact/recruitment (be specific)
The study will be advertised in the following ways; Interested potential participants will call the study line for more information and for screening:

1. Advertisements will be posted on craigslist.org. 2. Fliers describing the study and providing contact information will be posted on UCSF campuses and clinics, community bulletin boards (such as cafes, gyms), and relevant email groups by study staff. Fliers will be distributed at street or health fairs, seminars, etc. or other public and community events. 3. The study will be listed on clinicaltrials.gov and the Osher Center website. 4. Links to the flier and the consent on the Osher website will be
placed on other websites (e.g. UCSF COAST). 5. Paid advertisements will be placed in local newspapers and online (e.g. Examiner, Facebook and/or Google per-click advertisement).

We would like to post fliers with tear-away strips on designated bulletin boards or other approved areas in DGIM clinics, as well as possibly placing small cards advertising the study on designated side tables in the waiting area of the General Medicine clinics.

**Benefits/burden for participants (clearly identify potential for harm)**

Overall, the study presents very limited risks to participants, and all measures for protection against risks will be applied. Participants will be told that their participation is voluntary and they can choose to withdraw from the study at any time without any further obligation. Both interventions involve moderate modifications to diet and exercise and pose no major risks; these lifestyle modifications may have healthful benefits for obese individuals, including weight loss, reductions in risk factors for chronic diseases, such as reduced blood pressure and decreased fasting glucose, and decreased feelings of stress.

The assessment procedures involve primarily routine procedures with limited risks to participants, including venipuncture, OGTT, questionnaires, and waist/hip measurements taken while wearing a gown. A few of the procedures have slightly increased risks, and the risks will be moderated as follows:

Before administering the flu vaccine, we will be screening for severe allergic reaction to eggs or to a previous flu shot. The low dose dexamethasone pill taken up to 3 times during the study typically has no side effects or interactions with medications. Participants will do thinking and talking tasks at two visits that they might find stressful or uncomfortable, but will be able to stop the procedure at any time, and will be told the purpose and scientific basis for the study procedures at the second of these visits. The ANS monitoring utilizes non-invasive sensors that could cause discomfort or redness when removed (like a band-aid). The fat aspirate, which participants may opt out of, has some minor risks as follows: There is a very small (less than 1%) risk of infection any time the skin is broken; Sterile methods will be used to keep this risk very small. There is a small (1-2%) risk of getting scar tissue under the skin where the needle has passed. This would form a small firm area under the skin. Participants should not be left with a visible scar. This procedure will cause a bruise at the site of the biopsy. It can take as long as two to six weeks for the bruising to disappear. There may be some mild swelling under the skin along with the bruise and some discoloration at the site after the procedure. Participants will be told not to do vigorous physical activity involving abdominal muscles for at least a few hours after the procedure, as this may increase bruising. There is usually minimal discomfort, and a local anesthetic (Lidocaine) will be given to minimize discomfort. Participants will be asked to avoid taking any aspirin for one week, and any NSAIDS medications, such as Advil, Motrin, Naproxen at least 24 hours before the procedure, and will be screened for a clotting disorder or current use medications that affect the ability of blood to clot, including warfarin, aspirin, heparin, enoxaprin, etc. before the procedure is done. Abdominal MRI: Participants will be screened for MRI safety (metal objects in the body, pregnancy) before the MRI is done. Naltrexone: Taking naltrexone may cause side effects. Should any of these occur, they pass fairly quickly and will not cause any permanent problems. Participants will be given contact information to reach a study MD if they have side effects that concern them. Participants will be screened for medication interactions, opioid use and pregnancy before participating in the naltrexone procedure; this procedure is optional.

Any benefits or burden to DGIM practitioners? None anticipated.

**Timeline for recruitment (projected start and stop dates):** Now through the end of 2012.

**Funding source** NIH/NCCAM

**Potential for DGIM collaborators?** We would be happy to discuss the possibility of opportunities for residents or fellows to participate and learn the process of conducting an RCT or collaborate on secondary analyses when data collection is complete.

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

**Date form completed** 05.25.10