ICCR Rotation IRB Protocol
Maria E. Hamm PGY2
14 November 2007

Sustainable Weight Loss with Nutrition and Exercise Education for an Urban, Hispanic Population

I. Intro:

A. Rationale: The problem of obesity is growing nationally, and disproportionately among Hispanics. In 2000 in Washington Heights, 18% of people were obese and 30% report having no physical activity.[1] From 2001-2002, Latinos in NYC had a rate of obesity of 24.2%, compared to 18% in the general population in NYC.[2] The WH community also poses unique challenges for education and behavior, as our patients are largely Hispanic (71%) and foreign born (51%), with low educational attainment (44% with less than a high school education) and high levels of poverty (31% below poverty level).[3]

As primary care providers to the Washington Heights community, internists at CUMC have very little appropriate educational material available to help patients learn about nutrition and exercise for sustainable weight loss and health benefits. At AIM clinic, a large percentage of clinic visits relate to obesity. Health problems such as back pain, arthritis, diabetes, hypertension, hyperlipidemia, and depression are all related to overweight and obesity, yet our interventions for weight loss are minimal, consisting of written hand-outs in English or Spanish.

Therefore, in order to reach our population in a meaningful way which can produce lasting changes in behavior, education on diet an exercise must be understandable and motivational to our patients. Specifically, the information should be in Spanish, at grade school level of health literacy, in a visual format, with economically and practically considered interventions, and capitalizing on the strengths of the community's culture.

The intervention I plan to design for this study is an educational video on nutrition and exercise to help patients from AIM clinic lose weight. I plan to do the background research for this video by identifying 5 female patients from my regular clinic patients who are interested in participating. First I will spend some time interviewing these women on their thoughts about food, body image, barriers to losing weight, barriers to exercising, providing food for their families, etc. I will then film these women making typical Dominican meals in their homes. After some basic nutritional education, we will together think of specific substitutions in the typical Dominican diet to improve its nutritional content but maintain its uniqueness (such as brown rice for white rice or skim milk for whole milk), as well as model portion control. The education will entail physically going to grocery stores and bodegas in the neighborhood to find the foods we discuss, compare prices, and prepare the new meals with the participants. I would also like to discuss exercise and film the women walking in the neighborhood and doing basic exercises at home. Finally, I would like to film them doing some behavioral

modifications, such as meal planning and recording weights. All of these things will be done in participants' homes and surrounding neighborhood, capturing their thoughts and reactions so that other patients can identify with the concepts and envision themselves making these changes.

B. Review of the Literature: The benefits of weight loss are extensive, specifically in improving and preventing diabetes, lowering BP, lowering LDL and raising HDL, and decreasing the risk of OA. [4],[5],[6]. How much weight loss is necessary to have clinical benefit? The benefits of weight loss are seen with even very modest changes in weight. NIH guidelines for the treatment of obesity suggest that a reasonable goal suggest that patients should lose 10% of their body weight over 6 months, with subsequent effort to maintain body weight at that level.[7] Two studies have shown that loss of about 5 kg from initial body weight can reduce the risk of developing diabetes by about 50%.[8], [9], which argues that even a 5kg weight loss can improve fasting glucose significantly. Other large scale studies show that weight loss of 5-15% reduces risks of most disorders associated with obesity such as hyperlipidemia, hypertension and DM. [10]

One of these studies, known as the Finnish Diabetes Prevention Study, showed that with a reasonable amount of individualized education on nutrition and exercise, patients who are overweight could lose an average of 4.5 kg over 1 year and reduce the incidence of diabetes by 58%. In this study, 522 subjects were randomized to 2 groups, a control group who received a 2-page nutrition and exercise leaflet, and an intervention group who received individualized counseling on reducing weight, decreasing fat and calorie intake, increasing fiber intake and physical activity over 7 group sessions. After 1 year, the intervention group had average weight loss of 4.5 +/- 5.1 kg and 11% incidence of diabetes, compared with the control group's weight loss of 0.8+/- 3.7kg and 23% incidence of diabetes. ($p < 0.001$ for both groups). The risk of diabetes was reduced by 58%.

Similar amounts of weight loss over one year were reported in meta-analysis comparing RCT's which randomized patients to receive education on diet alone or diet plus exercise.[11] Weight loss was achieved in both groups, but was more effective with diet and exercise. Diet and exercise showed weight loss of -6.7kg with SD of 8.3 after 1 year, while diet alone with a loss of -4.5 kg and SD of 11.3. Interventions included regular visits in small groups throughout the course of the studies.

It is suggested that racial/ethnic minorities have a higher prevalence of overweight and obesity and therefore a greater risk of diabetes in the US.[12] Although immigrants to the US usually have lower rates of obesity than Americans when they immigrate, their rates of obesity at least match those of Americans by about 15 years.[13] There is some literature addressing culturally appropriate nutrition and exercise information that has been specifically developed to match the Mexican American culture. No such literature exists for a predominantly urban, Caribbean or Dominican population.

Literature on specific nutritional, exercise and behavioral content will not be reviewed here. However, the development of an educational video will involve evidence-based weight loss methods in these areas. For example, increasing dietary fiber,

vegetables and protein, decreasing saturated fats, and portion control through the use of portion-control plates have been proven to decrease caloric intake and lead to weight loss.[14], [15] Likewise, achieving a goal of 30 minutes of cardiovascular activity daily has been shown to augment weight loss and glycemic control.[16] Finally, behavior modification techniques such as meal planning, impulse control and involving friends and family also improve weight loss results. [17], [18]

II. Hypothesis: An educational tool in the form of a video which is tailored to the Washington Heights community can help patients from AIM clinic lose at least 5kg over one year. This tool will be effective because it will teach patients about lasting behavior change in a way that builds on the strengths of the culture, taking into consideration environmental and socioeconomic limitations, and presented in a visual format which is relational and at an attainable level of health literacy.

III. Methods

A. Conceptual and Operational Definitions: The health benefits of weight loss have been confirmed in many previous studies. This study will focus specifically on the efficacy of the educational video to promote behavior change for weight loss.
The primary outcome in this study will be weight lost in kilograms. Patients enrolled in the study will be weighed on a study scale at the time of admission to the study, at 6 months and at 1 year. A secondary outcome will also be the prescribed diabetes medications that the patient is taking and how these medications change in relation to weight loss. At the time of admission to the study the PMD will note which diabetes medications the patient is taking at the time, if any. At the 6 month and 1 year weigh-in, the patient will be asked to bring any diabetic medications she is taking, if any.

B. Study Design: This will be a longitudinal, prospective, interventional study. It will be randomized and parallel arm, with the intervention group receiving the educational video with supplemental paper materials and the control group receiving the current educational handouts available at AIM. The study will only be partially blinded, as the provider and study coordinators will be blinded but it will be impossible to blind the patients to the intervention.

C. Statistical Analysis: As the primary outcome will be a parametric (continuous) variable (weight lost), I will use an t-test analysis. As I am comparing an intervention group to a control group in parallel arms, it will be an unpaired t-test. A regression analysis can be used to evaluate for confounding factors such as new onset of diabetes medications.

D. Sample Size: The sample size is determined by the need for adequate power, and the power calculation in an unpaired t test is dependent on the amount of effect which can be considered both reasonable to attain and clinically meaningful, as well as a standard deviation which is realistic. Based on my review of the literature, a 5kg weight loss (11 lbs.) is considered clinically meaningful, and a standard deviation of 10kg is conservative. With these values, for an alpha of 0.05 and power of 80%, the study size would be 64 in each group. If an even more minor change in weight of 3 kg is to be

detected, a sample size of 176 in each group should be used (total 354). Since the mantainence of any weight loss should be considered a significant achievement, I will use a larger sample size to detect a smaller difference. This will also be an intention to treat model in order to most accurately and realistically capture the effect of this kind of educational tool in the community.

IV. Subjects Selection: Subjects will be AIM patients of residents with a BMI of greater than or equal to 25 who are interested in losing weight. For this intervention the patients will be women who are of Hispanic ethnicity (self-reported) who understand Spanish and/or read English (as the video will be in Spanish with English subtitles). Only the patients of residents will be included since it is known that the outcomes of attending and resident patients differ. Exclusion criteria consist of co-morbidities which could significantly affect weight loss/gain such as Class III or IV heart failure, cirrhosis, thyroid disease, pregnancy, malignancy, AIDS (but not HIV). Patients with diabetes can be included, but information on current diabetes medications, as well as when these medications were started will be collected as the initiation of treatment for diabetes can lead to a confounding weight gain. Patients who have brittle diabetes and who have had clinically significant episodes of hypoglycemia should not be included. Patients should not be taking any oral weight loss medications or be referred to other formal weight loss programs which could alter the interpretation of the video's efficacy. If patients seek out other means of weight loss on their on after randomization this will not be controlled for.

V. Miscellaneous

A. Description of Study Procedures: First I will identify one or two areas in AIM which has a regular group of residents, estimating that each resident could refer about 20 patients each, this would require 18 residents for a total sample size of 358. I would identify 2 nurses who could be educated on how to enroll people in the study. I would educate the 18 residents about the study and inclusion criteria.
The involvement needed from the residents will be:

- Identify Hispanic women with a BMI greater than or equal to 25 who are interested in losing weight.
- Rule out exclusion criteria (Class III or IV heart failure, cirrhosis, thyroid disease, pregnancy, malignancy, AIDS (but not HIV).
- Determine if they understand Spanish or read English
- Determine if they are they taking any oral weight loss medications or currently involved in any formal weight loss programs.

If these criteria are met, then they will:

- Record if they are taking diabetes medications and if so for how long?
- Explain that the study will consist of a program of nutrition and exercise education and that their weight will be checked at 6mo and 1 year.
- if patient is on diabetes medications the resident should counsel them to take
- schedule follow up in one

month to monitor for hypoglycemia and adjust medications as needed.

If eligible, the resident marks the chart for nurse to weigh and enter in study. After finishing with the provider, the patient will be weighed and her weight in kg and height in cm and record on entrance sheet, as well as up to date contact information. The patient will then be given an opaque envelope with either control or intervention materials in it. The envelopes will be numbered, the number recorded on entrance sheet. The numbers of envelopes and correlation with what materials they contain will be assigned by a person independent from the study in a random manner.

The enrollment period will be three months. The patients will be grouped into one month groups. Each group of patients will then be called one group at a time to come in to be weighed at 6 months after randomization, and asked to bring in diabetes medications if they are taking any. Patients are weighed by the nurses at the same area in AIM with the same scale and medications recorded. The same procedure is performed at 1 year.

B. Confidentiality of Study Data: Patient name, MRN, contact information, weights and diabetes medications will be collected by one or two nurses at AIM in folders kept in a secure location. Data collected and analyzed on secure hospital computers. No disclosure of protected health information to any other sources is necessary.

C. Risks and Benefits: The risks of this study are minimal. Change in diet to include lower glycemic index foods may result in hypoglycemia for patients on oral diabetes medications or insulin. Patient on these medications should be educated to monitor their blood sugar more carefully during this period and to hold diabetes medications if blood sugars are low. Patients should have follow-up with a primary care provider shortly after entering the study to adjust medications as needed. The benefits of this study are all of the benefits of weight loss if patients are able to make the necessary changes. Having a control group who receive the currently used information on diet and nutrition is not unethical or withholding treatment.

D. Alternative Therapies: Current alternative therapies for overweight and obesity include weight loss drugs and bariatric surgery. These treatments have some efficacy but significant risk and cost. An initial trial of diet and exercise for weight loss is always recommended.

E. Compensation and Costs to subjects: The cost of this study to patients is minimal, consisting of transportation to clinic 3 times in one year. Patients will need access to a DVD player in order to watch the nutritional video, which are very prevalent even in the context of a lower socio-economic community. The nutritional and exercise advice of the video will be specifically designed to match the income level of the community. For example, the food substitutions will be comparable to the cost of the average diet and not require excessive time or travel to be purchased. The exercise suggestions will not involve expense, will be safe to perform and in the patient's neighborhood.

F. Cost of the study: Copying of 178 videos, copying of printed materials, envelopes, a standardized scale, transportation compensation for patients for 2 additional clinic visits for weigh-ins.

---

[1] Karpati A, Lu X, Mostashari F, Thorpe L, Frieden TR. The Health of Inwood and Washington Heights. NYC Community Health Profiles 2003;1(24):1–12.

[2] Liao, Y. REACH 2010 Surveillance for Health Status in Minority Communities- US 2001-2002. MMWR, August 2004; 53(SS06);1-36.

[3] Ibid, Karpati.

[4] Wadden, T. "The Practical Guide Identification, Evaluation, and Treatment of Overweight and Obesity in Adults." NIH National Heart, Lung, and Blood Institute, October 2000.

[5] Delahanty, L. "Evidence-Based Trends for Achieving Weight Loss and Increased Physical Activity: Applications for Diabetes Prevention and Treatment". *Diabetes Spectrum*. (2002); 15 (3), 183-189.

[6] Curioni, CC. "Long term weight loss after diet and exercise: a systematic review." *International Journal of Obesity*. 2005; 29, 1168-1174.

[7] Ibid, Curioni.

[8] Colditz, G. "Weight Gain as a Risk Factor for Clinical Diabetes Mellitus in Women". *Annals of Internal Medicine*, 1995; 122(7). 481-486.

[9] Tuomilehto, J. "Prevention of type 2 Diabetes Mellitus by Changes in Lifestyle Among Subjects with Impaired Glucose Tolerance." *NEJM* (2001); Vol 344 (18). 1343-1350.

[10] Goldstein, DJ. "Beneficial Health Effects of Modest Weight Loss." *International Journal of Obesity*. 1992; 16: 397.

[11] Curioni,.

[12] Curioni,.

[13] Sanghavi Goel, M. "Obesity Among US Immigrant Subgroups by Duration of Residence". *JAMA. 2004;292:2860-2867*

[14]Pedersen. S. “Portion Control Plate for Weight Loss in Patients with Type 2 Diabetes Mellitus.” *Archive of Internal Medicine*. 2005: 167, pg 1277-1283.

[15] Kromhout, D. “Physical Activity and Dietary Fiber Determine Population Body Fat Levels: the Seven Countries Study.” International Journal of Obesity. 2001; 25, pg 301-306.

[16] Curoni.

[17] Shaw K, O’Rourke P, Del Mar C, Kenardy J. “Psychological interventions for overweight or obesity”. *Cochrane Database of Systematic Reviews* 2005, Issue 2.

[18] McLean, N. “Family involvement in weight control, weight maintenance and weight-loss interventions: a systematic review of randomised trials.” *International Journal of Obesity* (2003) 27, 987–1005.