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PGY-1
CRC IRB Protocol

Title: Nutrition Facts: Education in Accurate Nutrition Label Reading and its Effects on Weight Loss in Hispanic/Latino Women

A. Study Purpose and Rationale

Cardiovascular disease and stroke are the leading causes of death among women in the United States. About 450,000 women die each year from heart disease, accounting for one third of all deaths in women[1]. Though death from coronary disease decreased during the 1970s and 1980s, more recently, the rate in decline has leveled off considerably, especially in women[2]. Women of color are at increased risk for heart disease and stroke.

Obesity is an independent risk factor for heart disease with estimates that overweight status places one at 45% increased risk of coronary heart disease due to its effects on cholesterol levels and blood pressure control[3]. Over the past three decades, obesity prevalence rates in the United States have more than doubled among adults aged 20 – 74 years of age[4]. According to the 2007 – 2008 National Health and Nutrition Examination Survey (NHANES), 34.2% of American adults are overweight (BMI 25.0 – 29.9), 33.8% are obese (BMI ≥ 30) and 5.7% are extremely obese (BMI ≥ 40)[5].

Groups at greater risk for obesity include minorities and persons of lower socioeconomic status (SES). Among women in the United States, almost half of Mexican-American and non-Hispanic black women are likely to be obese compared to one-third of non-Hispanic white women[4]. The Northern Manhattan area is an ideal region of focus for this project, as it represents a microcosm of issues, like poverty and poor education, which affect minority health. The population of Northern Manhattan is ethnically diverse, with the Washington Heights/Inwood area having a female population that is about 80% Hispanic/Latino and African American. Of this population, 40% of African-American women and 61% of Hispanic women live at or below the 200% poverty level. About 73% of the Washington Heights/Inwood community identify as Hispanic/Latino in origin, with about 84% reporting origins from Caribbean Latino nations (the Dominican Republic, Puerto Rico, and Cuba). The Caribbean Latino population represents a fast growing ethnic group, collectively making up 15.5% of the United States Hispanic/Latino population[6].

In 1990, the Nutrition Labeling and Education Act was passed, mandating that all pre-packaged foods carry nutrition labeling. In previous studies, the majority of consumers report reading nutrition labels. However, upon further investigation, many of these same consumers profess confusion when trying to interpret the data from the label to incorporate it into their diet

choices [7]. We propose that providing adult women participants with specific instruction in reading of nutrition labels and incorporating its use into their diets, adult women participants will experience a 3% reduction of total body weight within a 6 month interval in comparison to adult women participants receiving standard diet instruction. We would like to examine if among women in the Washington Heights/Inwood community, if a small intervention, such as nutrition label reading instruction, would result in weight loss.

Research has shown that modest clinical improvements in blood pressure, glycemic, and cholesterol level control begin to appear with relatively small amounts of weight loss (about 5% of total body weight)[8]. In 1998, the National Institute of Health (NIH) established its first guidelines regarding identification, evaluation, and treatment of overweight and obesity in adults, recommending weight loss for persons with BMI of 30 or more and for persons with BMI between 25 – 29.9 and at least two or more cardiovascular risk factors[9]. In the United States, nearly 50% of women report trying to lose weight; however, many have unrealistic weight loss goals, such as a 30% weight loss[10]. It has been demonstrated in the literature that with a diet program (usually a 1,200 kcal diet with 30% reduction in overall fat intake) over at least a six-month period of time, persons can lose a mean of 4.9 kg (5% of total body weight) of weight at 6 months[11].

B. Study Design and Statistical Analysis

There will be two study arms consisting of at least 6 - 10 subjects each, for a total of about 20 women. Sample size number was obtained using an unpaired t-test analysis to obtain a power of 80% with a type I error rate of 0.5 with an effect size of 3%. Standard deviation was estimated to be 3 kilograms. Exact sample size number using these parameters estimate a sample size of 8 subjects for each group. The first arm would consist of women randomly assigned to standard diet instruction. The second arm would consist of women randomly assigned to nutrition label reading instruction in addition to standard diet instruction. Each arm would be given a diary to record their diet choices over the course of a week, and would then meet individually each week with a dietician to review their food choices. To control for bias, each dietician would alternate between interviewing subjects from the control group versus the intervention group. The primary outcome will be measured weight loss within a 6 month interval. Statistical analysis would be done using an unpaired t-test analysis.

C. Study Procedure

Each study arm would participate in a ten week diet period instruction course given by a trained dietician. Women assigned to the control arm would receive standard diet instruction in accordance with standard weight loss guidelines proposed by the American Dietetic's Association Adult Weight Management Evidence-Based Nutrition Practice Guideline[12].

Women assigned to the intervention arm would receive standard diet instruction along with nutrition label reading instruction.

Demographic data about age, race/ethnicity, country of origin, and education, geographic area of residence, health insurance, income, and sources of information about nutrition, diet, and weight would be collected. Each study participant would be weighed by a trained research assistant using the same scale. Other variables that would be measured at study onset include height (to determine body mass index) and waist circumference. Participants would then be weighed again and have their waist circumference measured at the end of a three month interval and then a six month interval.

D. Study Drugs

N/A.

E. Medical Device

N/A.

F. Study Questionnaires

N/A.

G. Study Subjects

Inclusion criteria would be limited to women of Hispanic/Latino origin who are of childbearing age (21 years of age to 39 years of age) who are literate in English, have at least ten years of formal education or its equivalent (9^{th} grade or higher), and reside within the Washington Heights/Inwood area (loosely defined as north of 145^{th} Street to 220^{th} Street in the borough of Manhattan). Only women using these said contraceptive measures, an intrauterine device, oral contraceptive pills, hormonal patch or ring, or sterilization, will be allowed to participate. Participants must have stable weight over the preceding six months to enrollment (no variation greater or lesser than 5.0 kg (10.4 lbs). Participants must be overweight, which is defined as having body mass index of 25.0 – 29.9.

In regards to exclusion criteria, participants could not have been pregnant, recently given birth, or currently lactating over the preceding six months to enrollment. Participants cannot have hypertension, type 1 or type 2 diabetes mellitus, hyperthyroidism, hypothyroidism, substance abuse, or malignancy. Participants cannot be enrolled in another clinical trial at the same time. Participants cannot have a known history of coronary artery disease, cardiovascular disease procedure (angioplasty, bypass surgery, placement of stent), myocardial infarction, ischemic cardiac syndrome, stroke, or transient ischemic attack.

H. Recruitment of Subjects

Participants will be primarily recruited through the New York-Presbyterian/Columbia Ambulatory Care Network clinics, such as the Associates in Internal Medicine (AIM) Practice, the Washington Heights Family Health Center, and the Broadway Family Practice. Flyers will be placed in the waiting rooms of the clinics and all clinical staff will be asked to recruit suitable candidates. Once clinic staff ascertains patient's interest, patient would then be referred to research staff, who would explain the study in greater detail and obtain informed consent.

I. Confidentiality of Study Data

Participant data will be coded using a unique three digit identifier. All names and other identifying information will be stored separately from study data. Data will be stored in a locked file cabinet that is only accessible to research staff.

J. Potential Conflict of Interest

None of the investigators or research staff stands to benefit financially from study results.

K. Location of the Study

Instruction sessions will occur in the patient care rooms at New York-Presbyterian/Columbia Washington Heights Family Health Center.

L. Potential Risks

There are no foreseeable potential risks to participants.

N. Alternative Therapies

N/A.

O. Compensation to Subjects

Participant would be offered a nominal cash fee ($20.00) for attending each scheduled instruction session.

P. Costs to Subjects

Patient may incur nominal transportation cost (around $4.50 for round trip MTA fare).

Q. Minors as Research Subjects

N/A.

R. Radiation or Radioactive Substances

N/A.

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