Cristina Brickman June 12 2009 ICCR Research Proposal

Let's start Walking and Talking! A novel fitness program for Latino women.

STUDY PURPOSE

Hypothesis: Combining physical activity with social support will increase adherence to exercise programs among Latino women.

Background and Rationale:

The benefits of increased physical activity are well-established, and felt to play an important role in preventing cardiovascular disease in women¹⁻³. Despite this, the percentage of Americans who engage in regular physical activity is low. Women are generally less active than men and Hispanics are generally less active than whites⁴. In fact, in one large cross-sectional survey, 74% of Hispanic women reported no physical activity⁵.

In order to decrease this percentage, it is important to understand the factors that influence physical activity among Hispanic women. There is evidence to suggest that social support is especially relevant among Hispanic women compared to other ethnic groups, and that this corresponds to higher levels of physical activity⁶. For example, the US Women's Determinant Study surveyed more than 3000 women across the United States and found a strong correlation between high degree of social support and physical activity among Hispanic women⁷. Several subsequent surveys of urban Latino women found that women who exercised were more likely to attend religious services, and also to know more likely to know or see other people who exercised⁸.

Therefore, implementing an exercise program that emphasizes social support as well as community ties could greatly improve physical activity among Latino women. A walking group (which involves only organizing a group of people to walk together several times a week) is an easy and exciting potential means to accomplish this.

STUDY DESCRIPTION

Study Type: Randomized controlled trial

Study Design:

Study subjects will be randomized to two groups: women in group A will be enrolled in a gym-based exercise program whereas women in group B will be enrolled in a walking group.

Informed consent will be obtained – while subjects will be told that they will be enrolled in a fitness program that involves walking, details regarding the two available groups will not be made available.

This study will be conducted in mid-spring to minimize temperature differences between an outdoor and an indoor, climate-controlled setting.

Women in group A will receive a free membership to one of 5 nearby gyms (Planet fitness, Urban total fitness, Jay's big Gym, Crunch Gym, Total Body fitness). Different gyms are chosen to minimize interaction between study participants. These are upper scale gyms such that unpleasant work-out conditions do not detract from exercise adherence. The cost of a monthly membership and the size and number of treadmills available within each gym will be approximately equal. Group A will be provided with a stipend to cover taxi-cab transportation. They will be instructed to attend three times a week on Monday, Wednesday and Fridays at approximately 5:00pm. They will be asked to sign-in upon arrival. At the gym, they will be asked exercise on the treadmill for 30 minutes at a comfortable pace.

Women in group B will meet at the entrance of AIM clinic on Monday, Wednesday and Fridays at 5:00pm. They will be provided with "Let's get walking...and talking!" t-shirts. Attendance will be taken. Shuttle buses will transport the group to Riverbank State Park on 679 Riverside Drive where they will be asked to walk for 30 minutes at a comfortable pace.

At the end of twelve weeks, there will be a record of the total number of sessions of each participant.

Statistical Analysis:

I will use chi-square analysis to compare the proportion of women in group A attending > 50% of sessions to the proportion of women in group B attending > 50% of sessions.

The rate of newly enrolled gym members who attend the gym at least twice a week after twelve months is only $20\%^9$. This value can be used to estimate the number of gym sessions that women in group A will attend. 150 members per group would be necessary to detect an increase in exercise adherence from 0.2 to 0.3.

I will therefore enroll 300 participants with subsequent randomization to groups A or B.

A value of p < 0.05 will be considered statistically significant.

RECRUITMENT:

The Columbia University Associates in Internal Medicine (AIM) Clinic located on the 2nd floor of the Vanderbilt Building (622 W 168th Street) will serve as the primary recruitment site. Fliers will be placed within the elevators and stairs of the clinic. Furthermore, 2 medical students will help recruit subjects in the waiting area of the AIM Clinic.

STUDY SUBJECTS:

Inclusion Criteria:

*Latino women ages 25-65

*Sedentary lifestyle (within last month: walking 20 minutes < 3 times a week, no jogging/biking/swimming/dancing/floor exercises/weight lifting)

Exclusion Criteria:

*CHF, uncontrolled hypertension or CAD (including stable angina, unstable angina, recent MI).

*Tobacco use, current heavy alcohol consumption or illicit drug use.

*Asthma (except mild-intermittent) or severe pulmonary disease.

* Severe degenerative joint disease

* BMI < 19.0 or > 40

Furthermore, study subjects will undergo stratified sampling for: age, BMI, current employment and presence of children under 18.

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