Abstract:
Cardiovascular disease (CVD) is the leading cause of death for women in the United States and disproportionately affects underserved populations. The StrongWomen – Healthy Hearts Program has the potential for positive impact on this public health issue. The 12-week intervention has demonstrated effectiveness in increasing physical activity, improving diet quality, and decreasing body weight in a controlled, randomized trial in two states.

This proposal seeks to evaluate the dissemination of the StrongWoman - Healthy Hearts Program through two approaches in partnership with the Cooperative State Research, Education, and Extension Service (CSREES), our partner in the effectiveness trial. The proposed dissemination plan leverages a successful five-year collaboration between Tufts University and CSREES, which has an extensive network of 2,900 county and regional offices nationwide. First, we will work with Pennsylvania State Cooperative Extension to conduct an in-depth evaluation in Pennsylvania according to the RE-AIM (Reach, Effectiveness, Adoption, Implementation, and Maintenance) framework using quantitative and qualitative methods. Second, in partnership with the National Extension Association of Family and Consumer Sciences, we will evaluate the first wave of national dissemination with a larger number of CSREES educators to quantitatively assess the RE-AIM components.

The central objective of this proposal is to rigorously evaluate dissemination of the StrongWomen – Healthy Hearts Program using the RE-AIM framework in order to achieve maximal public health impact. The results will help to reach Healthy People 2010 Goal 1, Objectives 12, 19, and 22. This study is also designed to provide data on best practices for reaching priority subpopulations, especially low-income and rural women. In this way it will contribute to Healthy People 2010 Goal 2, the reduction of health disparities.
A. SPECIFIC AIMS

Cardiovascular disease (CVD) is the leading cause of death for women in the United States [1]. CVD disproportionately affects underserved populations, specifically low-income, minority, and rural women who have higher obesity rates and experience other health disparities [2-4]. There is a need for replicable, evidence-based programs that target women, particularly midlife and older women who represent an increasing proportion of the U.S. population, to reduce their CVD risk [5]. StrongWomen – Healthy Hearts is a 12-week, community-based program that has demonstrated effectiveness at improving CVD risk factors, including body weight, diet quality, and physical activity in a controlled, randomized trial conducted with midlife and older overweight and obese subjects in Arkansas and Kansas [6].

The central objective of this proposal is to rigorously evaluate dissemination of the StrongWomen – Healthy Hearts Program using the RE-AIM framework to achieve maximal public health impact. Expanded dissemination will occur through the Cooperative State Research, Education and Extension Service (CSREES), which is under the direction of the United States Department of Agriculture and has an extensive network of 2,900 regional and county extension offices in every U.S. state and territory. This partnership will leverage a long and successful collaboration between Tufts University and CSREES that provides strength training programs to older women in 41 states.

We will achieve this objective by using the RE-AIM framework [7] through two approaches. For the first component, we will partner with CSREES in Pennsylvania, a state with a diversity of community sites that mirror the demographics of the United States. We will work with Pennsylvania State University Cooperative Extension to conduct an in-depth evaluation of dissemination using quantitative and qualitative methods. For the second component, we will partner with the National Extension Association of Family and Consumer Sciences to evaluate the first wave of national dissemination. This will provide a larger number of CSREES educators and sites to quantitatively assess the components of the RE-AIM framework. We expect the results to confirm and augment those found in Pennsylvania.

AIM 1: To conduct an in-depth quantitative and qualitative evaluation of the dissemination of the StrongWomen – Healthy Hearts Program using the RE-AIM (Reach, Effectiveness, Adoption, Implementation, and Maintenance) framework in Pennsylvania. To achieve this goal, we will collect data from a number of sources to address the following questions:

• Reach:
  ▪ What is the participation rate?
  ▪ How representative are participants?
  ▪ What key factors determined who in the target audience were reached successfully and who were not?

• Effectiveness:
  ▪ Is the program effective in a variety of settings?

• Adoption:
  ▪ What percentage of extension educators begin a program within one year?
  ▪ What key factors determined adoption?

• Implementation:
  ▪ What is the CSREES educators’ fidelity to the various elements of the Program curriculum?
  ▪ Were key components of the intervention modified? How were they modified?
  ▪ Was the Program modified specifically to meet the needs of a particular audience? How was it modified?
  ▪ Did modifications alter effectiveness?

• Maintenance:
  ▪ How sustainable is the program at the setting level?

AIM 2: To conduct an evaluation of the first wave of national dissemination using the RE-AIM framework. To achieve this goal, we will partner with the National Extension Association of Family and Consumer Sciences to conduct a training of 100 CSREES educators at their annual meeting in Fall 2010. Data will be collected from several sources to address RE-AIM questions.
**B.1. SIGNIFICANCE**

Cardiovascular disease (CVD) is the leading cause of death and disability for women in the U.S., claiming approximately 500,000 female lives a year [1]. The direct and indirect costs of CVD were estimated to be over $450 billion in 2008 [1]. As the American population ages, the burden of CVD will continue to increase. Although CVD develops over decades and prevention is important early in life, lifestyle modifications reduce risk at any age, even in older adults [8]. It is important to focus efforts on midlife and older women, whose numbers are increasing in the overall U.S. population [5]. It is also important to target priority subpopulations, where CVD and associated lifestyle risks are higher, in an effort to reduce health disparities [1, 9, 10]. One strategic prevention tactic is the development and evaluation of educational and behavioral programs tailored to this population that can be implemented widely by community organizations where many higher risk women can be reached. Few such programs currently exist.

The StrongWomen - Healthy Hearts Program, conducted through a collaboration between the Friedman School of Nutrition Science and Policy at Tufts University and USDA’s Cooperative State Research, Education, and Extension Service (CSREES), addresses this need. Through this collaboration, the infrastructure, support, and desire to implement and evaluate the StrongWomen - Healthy Hearts Program are already in place. We have demonstrated the feasibility and effectiveness of the program in a randomized, controlled trial in Arkansas and Kansas. In the proposed study, we expect to gain an understanding of all aspects of program dissemination to midlife and older women in a wide variety of community settings. *This contribution is significant because it will provide the knowledge needed to further disseminate the program to all women across the U.S. in a way that is maximally effective.* It will help reduce health disparities because it *will provide the specific knowledge needed to effectively reach priority subpopulations.* There is the potential to thereby reduce risk of CVD in this population on a national scale. In the randomized, controlled trial, the intervention group saw an average weight loss of over four pounds, a decrease in overall caloric intake, saturated fat and cholesterol intake, and an increase of over 1600 steps per day. all significant compared to the control group. There are nearly 64 million women age 40 and over in U.S. who could potentially be reached through this moderately-intensive intervention conducted by local CSREES educators.

**B.2. BACKGROUND – REVIEW OF RELEVANT LITERATURE**

**B.2.a. Women, Heart Disease, Body Weight, Lifestyle and the Healthy People 2010 Goals**

Goal 1 of Healthy People 2010 (HP 2010) is to help people of all ages increase life expectancy and improve quality of life [11]. Objective 12 under this goal is to improve cardiovascular health and quality of life through the prevention, detection, and treatment of risk factors; early identification and treatment of heart attacks and strokes; and prevention of recurrent cardiovascular events [11]. Although death rates have declined in recent years, the overall burden of CVD remains high [1]. It remains the leading cause of death and disability for women in the United States and costs are estimated to be over $450 billion in 2008 [1].

Weight control is an important component of CVD risk reduction [12]. HP 2010 objective 19 is to promote health and reduce chronic disease associated with diet and weight [11]. Current trends indicate that in women, BMI increases over the decades of adult life and typically peaks at 40-59 years, at which point almost 70% are overweight or obese [2]. A dietary pattern that focuses on vegetables, fruits, low and nonfat dairy foods, whole grains, legumes, fish, and lean meats helps to reduce low-density lipoprotein concentrations and lower blood pressure, which can lead to an overall reduction in CVD risk [12-15]. According to 1999-2000 National Health and Nutrition Examination Survey data, half of women ages 51-70 years fail to eat at least five servings of fruits and vegetables per day [16]. Increasing physical activity also independently reduces risk of developing CVD in women; furthermore, physical activity and healthy eating improve energy balance and weight control [17]. Several studies show a strong negative correlation between fitness level and CVD-related morbidity and mortality in women [18-21]. HP 2010 objective 22 aims to improve health, fitness, and quality of life through daily physical activity [11]. Currently nearly 40% of women ages 45-54 years do not engage in any type of leisure-time physical activity, and it worsens as they get older [22]. Furthermore, less than 5% of adult women meet public health recommendations for physical activity [23].

**B.2.b. The Target Population – Midlife and Older Women**

As the American population ages, the burden of CVD will continue to increase. Although it develops over decades and prevention is important early in life, lifestyle modifications at any age reduce risk, even in
older adults [8]. It is important to focus efforts on midlife and older women whose numbers are increasing in the overall U.S. population [5]. For adult women, risk factors for cardiovascular disease, such as high obesity rates, poor dietary habits, and low levels of physical activity are highest among low-income women, racial/ethnic minorities, and rural women [1-4, 24, 25]. Dissemination research that provides answers on how to best reach these subpopulations, who carry a disproportionate morbidity burden in the U.S., can contribute to Goal 2 of HP 2010, reduction of health disparities.

Our study team has extensive experience with this population through the StrongWomen strength training program [26]. In addition, we have conducted thorough formative research to develop the StrongWomen – Healthy Hearts Program [27]. Qualitative methods helped us to better understand the attitudes, perceptions, and beliefs that shape current habits related to cardiovascular disease risk in midlife and older women; intervention strategies that are likely to be feasible and effective; and opportunities in the environment that support a heart-healthy lifestyle. We conducted four focus groups with 38 rural women ages 40 years and over and 25 interviews with CSREES educators in Kansas and Arkansas, as well as environmental audits in three communities. Results indicate that most women were aware of the modifiable risk factors for cardiovascular disease. Common themes for barriers to a healthy diet included lack of time and concern about wasting food. Most women had a positive attitude toward exercise and had exercised in the past, but found it difficult to resume when their routine was disrupted. The environmental audits suggested that healthful foods are readily available, except for fresh fish in Kansas, and there are opportunities to be physically active. Our findings indicated that it is especially important to offer programs, since women respond to national awareness campaigns and seek opportunities to build skills to change behavior.

B.2.c. Review of Other Relevant Programs

Few community-based programs are tailored to midlife and older rural women. Perry et al. recently conducted a 12-week intervention, Heart-to-Heart, with rural women [28] that included both individual and group-based components to promote goal-setting, self-monitoring, social support, and self-efficacy. As in our StrongWomen – Healthy Hearts effectiveness study, women in the intervention group improved cardiorespiratory fitness compared to a control group, although this was not statistically significant [28]. Unlike our program, no change in exercise self-efficacy was observed in either study group. Dietary outcomes were not assessed.

The WISEWOMAN programs, which specifically target under or uninsured midlife women, also attempt to reduce risk of developing CVD. Outcome evaluations for the WISEWOMAN programs have been published for three states: North Carolina [29], Massachusetts [30], and Arizona [31]. All three compared some type of minimal intervention, typically standard care, with at least one enhanced, theory-based intervention [32]. None of the studies observed a statistically significant change in blood pressure, serum cholesterol, or BMI in enhanced intervention groups compared to minimal intervention groups. However, pre-post change was evident in the minimal intervention groups, so the lack of difference between groups may have been because the minimal intervention was fairly robust. Similar to our study, the Massachusetts study observed a significant increase in physical activity levels, and the Arizona study observed an increase in fruit and vegetable consumption. The results of these studies, including our intervention study, suggest that it is possible to facilitate some behavior change in community settings, even in financially disadvantaged and rural women.


Most studies report on effectiveness of interventions, using an experimental design to determine whether or not it had an impact on outcomes of interest. This is critical for determining whether it is worthwhile to invest in replication, but it is essentially an individual-level consideration. To have a true sense of how to maximize public health impact, it is important to examine factors at a broader level. The RE-AIM framework, a five-factor analysis tool, was developed by NIH researchers as a way to do this [7] (see also www.re-aim.org).

One such factor is reach, which refers to the absolute number, proportion, and representativeness of those in the target population who participate in the intervention [7]. Participation rate, which is often reported, is important, but it does not answer two critical and related questions: Why didn’t other eligible subjects participate? Were they different than those who did? If non-participants are different, then recruitment and/or intervention strategies may need to be modified to be maximally relevant to the entire target population. It is also important to understand the factors that determined who in the target audience was successfully reached.
by recruitment, so that recruitment strategies can be modified if necessary to include a broader range and number in the target population.

Adoption refers to the intervention setting, and is defined as the absolute number, proportion, and representativeness of settings and intervention agents willing to initiate a program [7]. As with reach at the individual level, at the setting level if those who adopt are different than those who do not, the intervention may require modification. Factors such as facility size and equipment, resources available and ability to meet real or perceived costs, leader background, experience, leadership style, and expertise may affect adoption.

A second setting-level factor is implementation, which refers to how closely staff members follow the program provided [7]. Aspects of an intervention that are perceived to take too much time or that do not feel comfortable to leaders, for example, may not be fully implemented. If this is documented, then modifications can be made. An intervention may be effective even if not fully implemented, but it is important to know which components are responsible for producing the outcomes, and which may be superfluous. As a program is disseminated to a variety of subpopulations, it is also important to consider how it may be adapted to meet specific needs based on culture, resources, setting size, and location. Is it relatively easy to adapt? Are components key to effectiveness left intact? These questions need to be evaluated to ensure usefulness of the program across a variety of settings.

The final setting-level factor is maintenance, the extent to which a program or policy becomes institutionalized or part of routine organizational practices and policies [7]. This can be assessed by follow-up with leaders to determine the percentage that continues to offer the program after the initial program has concluded. The extent to which a program becomes institutionalized can profoundly affect the number of people reached over time and therefore the potential public health impact.

There are several published reports of program evaluations using the RE-AIM framework, including a physical activity intervention in churches [33]; a diabetes self-management intervention [34]; and a smoking cessation intervention [35]. It was also used to evaluate the WISEWOMAN Program. This study demonstrated that it is feasible to use the RE-AIM framework to evaluate a heart health program for women and that doing so provided a richer understanding of program success [36].

B.2.e. Conclusion

There is a clear need for more community-based programming to improve heart health in women, particularly midlife and older women. There is emerging evidence that community-based programs can be effective in establishing heart-healthy behaviors, yet there is a need to better understand the dissemination process. Evidence shows that the RE-AIM framework is a feasible and appropriate approach for doing so.

Our central objective is to rigorously evaluate dissemination of the StrongWomen – Healthy Hearts Program using the RE-AIM framework in order to achieve maximal public health impact. By conducting this evaluation, we will advance the field of community prevention research and more clearly define best practices for widespread national dissemination of a program to reduce the burden of cardiovascular disease in midlife and older women.
C. PRELIMINARY STUDIES

C.1. Study Team

Our research team represents a multidisciplinary group who has worked together for many years. Combined, our research expertise includes nutrition, nutritional biochemistry, exercise physiology, obesity research, behavior, statistical analysis, community health, public policy, and health communications. Drs. Nelson and Seguin have worked together for eleven years developing and implementing evidence-based physical activity and nutrition programming for midlife and older women. Drs. Goldberg and Nelson have been collaborating on health communications, behavioral interventions, and public health for two decades, with Dr. Foltz’s involvement for the past several years. Along with Ms. Kuder, they have also worked together over the past five years on community-based programming to reduce obesity in children [37]. Dr. Lichtenstein has been conducting basic research on nutrition and heart disease for two decades and has been the lead author on many of the U.S. policy recommendations regarding heart disease [15, 38]. The Tufts team has been collaborating with Penn State Cooperative Extension and the National Extension Association of Family and Consumer Sciences for the past five years to disseminate the StrongWomen strength training program in communities across the U.S.

C.2. Documentation of Scientific Evaluation of the Intervention

The StrongWomen – Healthy Hearts Program has been rigorously evaluated in the community setting in a randomized, controlled trial. Below, we describe the Program itself and provide the details of that trial (outcome paper is also attached in appendix).

C.2.a. Description of the StrongWomen – Healthy Hearts Program Intervention. The StrongWomen – Healthy Hearts Program is designed to take place two days per week for 12 weeks. Thirty minutes of each class includes aerobic dancing to a DVD created for the project or walking outside if location and weather permit. During the 12 weeks, subjects progress from approximately 20 minutes of low-to-moderate intensity physical activity (plus 5 minutes of gentle stretching) to 25 minutes of moderate-to-vigorous intensity physical activity (plus stretching), which is safe and appropriate for this population [39]. The other thirty minutes includes leader-directed and hands-on discussion and activities to modify dietary intake patterns, as well as weight control strategies. The Program emphasizes an eating pattern that is rich in fruits, vegetables, low-fat or nonfat dairy, fish, whole grains, and legumes; it encourages leaner meats and poultry, and fewer refined carbohydrates and saturated and trans fats. The theoretical basis for the intervention is Social Cognitive Theory [40]. Behavioral strategies include self-monitoring of food intake and physical activity, goal-setting, and skill-building around food preparation, supermarket shopping, and restaurant eating. For example, hands-on skill-building activities include preparation of recipes in small groups. Thorough formative research helped inform development of the curriculum [27]. (The complete 576 page curriculum is posted for your review at: http://jhpcan.nutrition.tufts.edu/publications/StrongWomenHealthHeartsToolKit.html; the class-by-class guide begins on page154).

In addition to the curriculum, logo and identity package materials were designed and used in the study. A password-protected website was also created for CSREES educators that contained all forms and handouts, as well as links to additional information about the topics covered.


Methods: A randomized, controlled trial was conducted in 8 counties in Arkansas and Kansas in partnership with CSREES. The counties were either non-metropolitan with large rural areas or completely rural [41]. Counties were randomly assigned to the intervention or to a delayed intervention. Intervention subjects participated in a twice-weekly 12-week program that included walking or aerobic dance and behavioral strategies to increase physical activity and heart-healthy eating.

Participants: Approximately 240 potential subjects were initially screened by phone to determine eligibility. Of these, 136 met the criteria, and 110 completed baseline testing. Fourteen were subsequently disqualified at baseline testing. Therefore baseline data were obtained on 96 qualified subjects: 61 in
intervention communities (28 in Arkansas, 33 in Kansas) and 35 in control communities (14 in Arkansas and 21 in Kansas). Of these, 85 completed follow-up testing at 12 weeks; 55 in intervention communities and 30 in control communities, for an overall completion rate of 88.5%. Reasons for loss to follow-up included medical issues unrelated to the study (N=6); work or family conflicts (N=3); and unknown reasons (N=2). Subjects who were lost to follow-up did not differ significantly from those who completed the study in terms of demographic factors or baseline values for main outcome variables. At baseline, there were no significant differences between intervention and control groups on demographic and anthropometric characteristics, dietary intake, aerobic fitness, or steps per day. All women were white except one, who was Native American, which reflected the demographics of the rural communities.

Process Evaluation: The average attendance at all sites was approximately 80%. There was good fidelity to the intervention. Issues with the program as designed were minor and were addressed as they arose.

Intervention Effects: At baseline, mean age was 57.8±9.4 years and BMI was 32.7±5.6 kg/m². Post-intervention, women in the intervention group compared with those in the control group showed significant decreases in body weight (-2.1 kg; 95% CI -3.2 to -1.0) and BMI (-0.8 kg/m²; 95% CI -1.2 to -0.5). Waist circumference decreased significantly in intervention group subjects compared with controls (-2.3 inches; 95% CI -4.2 to -0.5). Compared to the control group, the intervention group reported significant decreases in intakes of energy (-390 kcals/day; 95% CI -598 to -183), carbohydrate (-56.6 g/day; 95% CI -75.7 to -37.5), fat (-15.7 g/day; 95% CI -28.3 to -3.2), and cholesterol (-60 mg/day; 95% CI -78 to -43). Changes in protein intake were not significantly different between the two groups. There was a significant decrease in total grams of saturated fat in the intervention group compared with the control group (-5.2 g/day; 95% CI -9.4 to -1.0), but the change in percent energy from saturated fat was not significantly different between the two groups. With respect to food groups, there was an intervention effect of 0.6 fewer sweet food and dessert servings (95% CI -1.1 to -0.1) in the intervention group compared to controls. There was a trend toward significance in fruit and vegetable servings (0.6 servings per day; 95% CI -0.2 to 1.3; P=0.11). No other food group changes were observed. The pre-post change in walk time was 1:13 (min:sec) faster in intervention group compared with controls, a trend toward significance (95% CI -3:03 to 0:37; P=0.16). The intervention group subjects significantly increased the number of steps taken per day compared with controls (1637 steps per day; 95% CI 712 to 2562). Subjects in the intervention group significantly increased their self-efficacy for all dietary factors and for physical activity compared to control group subjects.

Conclusions: These data suggest that a community-based program can increase physical activity and self-efficacy, change relevant dietary behaviors, and facilitate weight loss in at-risk women.

C.3. Related Studies by the Project Team

The proposed study builds upon research conducted on the initial StrongWomen Program curriculum over the past five years through collaboration between our team and CSREES educators in 41 states. This research demonstrates our ability to work with this national partner, which has a local presence in every state, around a public health problem. It also demonstrates our ability to execute and sustain programming in geographically diverse communities, and to conduct research related to dissemination in these communities.

C.3.a. The StrongWomen Program

Funded in part by: The Fannie E. Rippel Foundation, The Aging Blueprint, and the Charles H. Farnsworth Trust

The initial StrongWomen Program is a strength training program to help women maintain muscle mass, strength, and function as they age. It has been successfully disseminated throughout the United States. The StrongWomen – Healthy Hearts Program was designed to build on this success to provide programming focused on diet and aerobic activity. While we have been able to conduct some dissemination studies of the StrongWomen Program, they were retrospective. This project, if funded, will provide the opportunity to prospectively and systematically study dissemination of this new evidence-based program. This is particularly important because we will have the opportunity to adjust and adapt strategies for dissemination.

Collaborators: Miriam Nelson, Rebecca Seguin, Christina Economos, Raymond Hyatt, Ruth Palumbo, and Julia Kuder
**StrongWomen Community Strength Training Program: Design and National Dissemination [26]**

**Objective:** The StrongWomen Strength Training Program aimed to develop, disseminate, and evaluate an evidence-based strength training program to enable midlife and older women to maintain their strength, function, and independence.

**Design and Development:** The StrongWomen Tool Kit and StrongWomen Workshop are the implementation and training tools, along with professional support, provided to allied health professionals and community leaders who adopt the programs for midlife and older women.

**Dissemination:** Dissemination began in May 2003, employing a three-part approach: communication strategies; strategic collaborations; and establishing and supporting sustainability.

**Assessment:** Site visits conducted during the first year documented adherence to the curriculum; a phone survey conducted in September 2004 provided data about adoption rates, leader backgrounds, program participants, and program locations and logistics. A database is used to track workshop locations and attendees. As of July 2006, 881 leaders in forty-three states were trained, and leaders from thirty-four of those states adopted programs. (An additional 700 leaders have been trained since the publication of this paper.)

**Conclusion:** Evidence-based health and nutrition programs can be successful when dissemination occurs at the community-level using trained leaders. This research demonstrates that key components of dissemination include multi-level media support, strategic collaborations, written curriculum, hands-on training, and an ongoing support mechanism for leaders. Results provide a model that may aid successful dissemination of a wide range of public health programs.

**Leadership in Community-Based Exercise Programs: Factors Related to Program Adoption [42]**

**Objective:** To examine factors related to the adoption of the StrongWomen Program.

**Methods:** Eight-hundred and fifty-four trained program leaders in 43 states were invited to participate in a survey that could be completed online or by mail. The survey included questions in the following primary categories: professional, socioeconomic, personal/behavioral, and leadership characteristics. Those who adopted the program were also asked to answer questions about it. Corresponding community-level data were collected from publicly available sources. Descriptive analysis, Pearson Chi-Square, t-tests, and logistic regression techniques were utilized for analysis.

**Results:** Four-hundred and eighty-seven program leaders responded to the survey (response rate=57%). Of those, 270 adopted the program (55%). There were no differences among the collected variables between online (78%) and mail (22%) survey respondents. One or more factors from each of the primary categories—professional, socioeconomic, personal/behavioral, and leadership—were significantly different between trained leaders who adopted the program and those who did not (p<0.05). Logistic regression analysis revealed a positive association between adoption and fitness credentials/certification, program-specific self-efficacy, and support-focused leadership, and a negative association between adoption and educational attainment (p<0.05).

**Conclusion:** In this sample of community-based exercise program leaders, having fitness credentials, support-focused leadership style, and greater levels of program-related self-efficacy were positively associated with program adoption; higher levels of educational attainment were negatively associated with adoption. Future community-based disseminations may consider these areas for leader selection, training, and adoption strategies.

**C.4. Conclusions**

The StrongWomen – Healthy Hearts Program was developed using state-of-the-art evidence by a team that includes one of the nation’s top cardiovascular nutrition researchers and one of the top physical activity researchers. The Program has been rigorously tested in a controlled, randomized trial and is ready for national dissemination.

Our team has over 5 years of experience in providing evidence-based programming to the target population through Penn State Cooperative Extension and NEAFCS, our project partners. The StrongWomen strength training program has been extremely successful, reaching an estimated 7000 mid-life and older women in 38 states in its first 3 years [26]. We stand poised to begin dissemination of the StrongWomen – Healthy Hearts program through the same successful mechanisms. At this juncture, we have a unique opportunity to prospectively and systematically evaluate that dissemination. Doing so will allow us to
understand how to best reach the greatest number of women, with an emphasis on priority subpopulations to help reduce health disparities.
D. RESEARCH DESIGN AND METHODS

D.1. Specific Aim #1: To conduct an in-depth quantitative and qualitative evaluation of the dissemination of the StrongWomen – Healthy Hearts Program using the RE-AIM (Reach, Effectiveness, Adoption, Implementation, and Maintenance) framework in Pennsylvania.

D.1.a. Introduction to Specific Aim #1. To meet the need for community-based programming to reduce risk of CVD, we developed the StrongWomen – Healthy Hearts Program and tested it in a randomized, controlled trial in collaboration with Cooperative State Research, Education and Extension Service (CSREES) in two states, Kansas and Arkansas. Results indicate that the program and its implementation are feasible and fit well with the mission and abilities of CSREES (see Section C.2.b. for more details). It has the potential to successfully reach and help create behavior change in the nearly 64 million women age 40 years and over in the communities where they live.

The objective of this aim is to understand and evaluate factors related to dissemination of the StrongWomen – Healthy Hearts Program using the RE-AIM framework. To attain the objective of this aim, we will collect data on recruitment strategies and exposure to recruitment; demographics; leadership characteristics of CSREES educators; barriers at the participant and site levels; weight, fruit and vegetable intake, and physical activity levels of participants; number of CSREES educators trained, number that run a program (adoption), and number that maintain a program (maintenance); how the program was delivered; and perceived and actual costs to run the program. Successful completion of this research will provide detailed information on best practices for the Program’s national dissemination so that it will have maximal public health impact.

D.1.b. The Project Coalition. Tufts University is a leader in advancing the field of aging, nutrition, and exercise science through sound research. In 2002, Drs. Nelson and Seguin developed the StrongWomen Program to translate the research into a curriculum for use in community-based settings. The program, launched in 2003, has had enormous success—with over 1500 trained leaders in most states throughout the country [26]. During dissemination of the StrongWomen Program, relationships were established with community leaders, health professionals, and their organizations. A prominent partner has been CSREES. CSREES educators offer research-based health information and programs to their communities. A key focus area for CSREES is to increase reach into underserved and rural locations.

The focus of this partnership has been primarily on community-based strength training programs aimed at maintaining muscle mass, bone density, strength, and vitality in midlife and older women. The StrongWomen – Healthy Hearts Program, with input from Dr. Alice Lichtenstein, built on this foundation and expanded it to include nutrition and aerobic exercise. The randomized, controlled trial of the StrongWomen – Healthy Hearts Program was conducted through CSREES [6]. Dissemination of the StrongWomen – Healthy Hearts Program through CSREES ensures optimal efficiency due to our existing collaboration as well as CSREES’ credibility among community members, widespread access, sound infrastructure, and organizational support.

To take an in-depth look at dissemination, we will partner with Pennsylvania State Cooperative Extension. Pennsylvania was chosen for this project because it is demographically similar to the overall U.S. population. For example, there is no more than a 2% difference between Pennsylvania and the U.S. overall on any of racial categories [43]. Pennsylvania is also representative in terms of percentage of people with primary and secondary education, mean household income, and percent of the population over 40 years old. Pennsylvania is 28% rural compared to 20% of the United States overall. Drs. Nelson and Seguin from Tufts and Dr. Corbin and Ms. Wiker from Penn State Cooperative Extension have worked together over the previous 5 years to specifically target and engage underserved women extensively throughout the state to increase physical activity through the StrongWomen Program. To help reach these populations, CSREES educators have developed extensive partnerships at the local level with organizations that serve these groups such as the Area Office of Aging, Pennsylvania Housing Finance Authority, low-income senior residences, Crispus Attucks Centers, Spanish American Civic Association, Salvation Army, Salud Hispana, Community Action Programs, United Way, local community centers, and housing authorities.
**D.1.c. Overall Study Design.** To evaluate the translatable of the StrongWomen - Healthy Hearts Program, dissemination will occur under “natural” conditions. This means that CSREES as an organization and the CSREES educators who will lead the program will not receive any extra compensation from these grant funds for its dissemination. CSREES educators will receive funds only to attend the initial training, per usual practice, and for collecting and providing data related to the RE-AIM evaluation. The RE-AIM framework will be evaluated through a combination of quantitative and qualitative methods. Effectiveness will be evaluated using a quasi-experimental pre-post design. The anticipated flow of the study with sample sizes is described below (Figure 1).

![Figure 1: Specific Aim 1 anticipated sample sizes (Pennsylvania)](image)

- 26 CSREES educators
- 20 attend training
- 2 non-adopters
- 18 adopters
  - Average class size = 15
  - Total 270 participants
- 5 non-maintainers
- 13 maintainers

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**D.1.d. Participant Recruitment and Screening.** CSREES educators usually recruit subjects using flyers, community bulletin boards, and local newspapers. Flyers will be placed at local community centers, libraries, restaurants, grocery stores, laundromats, houses of worship, banks, and other places where midlife and older adults gather or visit frequently. All recruitment efforts and the approximate number exposed to them will be carefully documented (see section D.1.g on Reach).

Potential participants will be screened to ensure that they are in the target population using an adaptation of the form that was used in the controlled, randomized trial. Women who pass this screen will be required to obtain a signed permission letter from her healthcare provider that indicates that physical activity is safe and appropriate before she can begin the Program. Once enrolled, participants will discontinue the Program if there are any changes in their medical status that would make exercise unsafe. (For more details on safety, minimization of risk, and participation of human subjects in this research, please see Section E).

**D.1.e. CSREES Educator Training.** CSREES educators will attend a full-day training workshop (8 hours, including a working lunch) at Penn State University in University Park, Pennsylvania. Workshops will consist of a series of seminars on women and heart disease, leadership and motivation, and the components of the StrongWomen – Healthy Hearts Program; and hands-on sessions to practice the cooking skills and exercise portions of the curriculum. CSREES educators will also be trained on to take heights and weights. All CSREES educators will receive a copy of the printed curriculum which includes a detailed class-by-class guide.
### D.1.f. Summary of RE-AIM evaluation in Pennsylvania

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<th>Component</th>
<th>Key Questions</th>
<th>Measurements</th>
<th>Analysis</th>
</tr>
</thead>
</table>
| Reach       | • What is the participation rate?  
• How representative are participants?  
• What key factors determined who in the target audience were successfully or unsuccessfully reached? | • At state training, CSREES educators will complete:  
  o About You Questionnaire  
  o Leadership Questionnaire  
  o Site Questionnaire  
• CSREES educators will document:  
  o Recruitment strategies  
  o Approximate # exposed to recruitment  
  o # who respond to recruitment  
  o # eligible for Program  
  o # eligible who participate  
• Program participants will complete  
  Participant Questionnaire  
• Research personnel will obtain from the U.S. Census Bureau:  
  o Estimate total target population  
  o Demographic information on counties  | • Calculate % who responded to recruitment  
• Calculate Reach into population  
• Calculate % eligible  
• Calculate % participation among eligible  
• Compare demographic factors between participants and overall target population in county and state  
• Test for associations between site characteristics, CSREES educator characteristics, recruitment strategies and participation rate, reach, and representativeness  
• Determine qualitatively barriers to participation |
| Effectiveness | • Is the program effective in a variety of settings?                                                                                                                                                    | • CSREES educators will take the following measurements on Program participants:  
  o Weight, BMI, fruit and vegetable intake, physical activity level | • Determine overall pre-post effectiveness on outcomes  
• Test for association between site & CSREES educator characteristics and effectiveness |
| Adoption     | • What percentage of CSREES educators adopt the program?  
• What key factors determined adoption?                                                                                                           | • At state training, CSREES educators will also complete a Perceived Costs Questionnaire  
• Research personnel will document:  
  o # of eligible CSREES educators  
  o # trained  
• Research personnel will monitor adoption within one year  
• Research personnel will conduct key informant interviews with non-adopters  | • Calculate overall % adoption  
• Calculate % adoption among trained  
• Test for association between site & CSREES educator characteristics and adoption  
• Test for association between perceived costs, importance of cost and adoption rate  
• Determine qualitatively barriers to adoption |
| Implementation | • What was the intervention agents’ fidelity to the various elements of the Program curriculum?  
• Adaptability – What key components of the intervention were modified to increase adoptability or use?  
• Cultural context – did the adaptation of the intervention to make it more culturally relevant result in loss of fidelity? Effectiveness? | • CSREES educators will complete:  
  o Weekly survey on delivery of curriculum activities  
• Research personnel will conduct:  
  o Site visits  
  o In-depth interviews with CSREES educators on modifications | • Determine “fidelity” score  
• Test for association between fidelity score and effectiveness  
• Determine actual costs across sites  
• Qualitative analysis of how components modified |
| Maintenance  | • What is the extent to which a program or policy became institutionalized or part of the routine organizational practices and policies?                | • Research personnel will document # who re-run the Program within 1 year  
• Research personnel will conduct key informant interviews with non-maintainers  | • Calculate % Maintenance  
• Test for association between site and CSREES educator characteristics, perceived cost, and Maintenance  
• Determine qualitatively barriers to maintenance |

**NOTE:** *Italicized* text indicates measures and analyses taken only in Pennsylvania and not for national first wave dissemination.
**D.1.g. REACH detailed methods for Specific Aim #1.** To determine Reach, we will obtain data to answer three questions: What is the participation rate? How representative are participants? What were the key factors that determined who in the target audience were reached? These questions are critical to achieving full representation from priority subpopulations. By answering them, we will be able to determine which recruitment strategies, site characteristics, and CSREES educator characteristics are significantly associated with their full inclusion.

*Data Collection.* To answer Reach questions, the following data will be collected.

**About You Questionnaire.** This questionnaire is designed to determine the personal characteristics of CSREES educators that are associated with reach, adoption, and maintenance. CSREES educators will complete this questionnaire on-line at the state training. It will ask about basic demographic factors: age, sex, race/ethnicity, and educational attainment. These questions will be based on national surveys (U.S. Census and the Behavioral Risk Factor Surveillance System). They will also be asked to report the length of time that they have been at their current position. They will be asked two self-efficacy questions related to recruitment: How confident are you that you can recruit at least 15 women age 40 and over for a class about heart health? and How confident are you that you can recruit so that at least a few of those women are low-income and/or minority? For these two questions, responses will range from 1=not at all confident to 5= completely confident. This format has been used to assess self-efficacy in a number of valid, reliable scales [44-46]. We will pre-test the questions with our CSREES collaborators in Arkansas and/or Kansas for comprehension and reliability during the development phase of this project.

**Leadership Questionnaire.** Evidence from the dissemination of the StrongWomen strength training program indicates that there is an association between support-focused leadership and program adoption [42]. We will test for leadership factors associated with adoption of the StrongWomen – Healthy Hearts Program using the leadership questionnaire from that study. CSREES educators will be asked whether they self-identify as a leader and whether they are comfortable leading people in activities, with yes/no responses [47]. Four primary categories from well-established leadership inventories will be used to characterize leadership style: organization, support, communication, and conflict resolution [47]. Eight questions will be asked within the four categories.

**Site Questionnaire.** This questionnaire will be used to determine site characteristics associated with reach, effectiveness, adoption, and maintenance. CSREES educators will complete this questionnaire on-line at the state training. It will ask questions about the availability of resources (funds available for health programming; space; equipment) and accessibility (distance from main community commerce center; accessibility by different forms of transportation). We will construct and pre-test this questionnaire with our CSREES collaborators in Arkansas and/or Kansas during the development phase of this project.

**Recruitment Monitoring Form.** To determine recruitment strategies and to estimate the number exposed to recruitment, CSREES educators will be asked to complete an on-line form that documents all recruitment activities. CSREES educators will log the type of recruitment activity conducted (for example, fliers, newspaper ad, listserve announcement, etc.) and the approximate number exposed to each type (for example, 100 people on listserve; newspaper circulation of 5,000, and so forth). During the development phase of the project, the form will be pre-tested and adapted as necessary to ensure ease of use.

**Participant Questionnaire.** To determine representativeness, it is necessary to know the demographic characteristics of the Program participants. Participants will complete a paper questionnaire that asks for basic demographic information (age, race/ethnicity, educational attainment, income level, marital status, and work status) just prior to beginning the program. All questions will be based on those used in national surveys (U.S. Census and the Behavioral Risk Factor Surveillance System).

**U.S. Census Data.** Research personnel at Tufts will obtain demographic information (educational attainment, household income, race/ethnicity) on all counties in which a program is being implemented as well as Pennsylvania overall using the U.S. Census 2005-2007 American Community Survey [43].

**Key Informant Interviews with Non-Participants.** Structured 15-20 minute telephone interviews will be conducted with women who have responded to recruitment, are eligible for the Program, but who do not participate in it. A random sample of 10% of eligible non-participants, based on our experience in the StrongWomen – Healthy Hearts effectiveness study, should yield approximately 20 non-participants. We will ask about reasons for non-participation, and specifically about any barriers to participation. The Project Coordinator at Penn State will conduct the interviews after being trained by Dr. Folta, who has expertise and
experience in qualitative methods. Phone calls will be digitally recorded and then transcribed by the Project Coordinator. Dr. Folta will analyze the data using the NVivo program (QSR International, version 8.0). Data will be coded in a two-step process: key phrases will be coded into a framework that is based on the questioning structure; and additional themes that emerge from the data will be added to the framework and coded. Key themes will then be compiled and reported. Dr. Folta and the Penn State Project Coordinator will work together to ensure that the final results accurately reflect the content of the interviews.

**Statistical Analysis.** We will do the following calculations:

% who respond to recruitment = (# in target population that contact educator/# exposed to recruitment) x 100  
% Reach into target population = (# who begin program/# in target population) x 100  
% eligible = (# eligible/total # who contact CSREES educator) x 100  
% participation among eligible = (# who participate/# eligible) x 100

Representativeness will be determined at the county and state levels. At the county level, each group of participants (representing one class with one CSREES educator) will be compared with the overall county population of women age 40 and over based on education, income, race, marital status, and work status. At the state level, all participants will be similarly compared with the overall state population of women age 40 and over. A chi-square test will be used since demographic factors will be reported categorically.

To test for associations between site characteristics and participation rate (a continuous variable), Pearson correlations will be used for continuous site variables and t-tests will be used for dichotomous site variables. The same approach will be used to determine associations between site characteristics and reach. For representativeness, we will first compile a representativeness score. Each of the 5 demographic factors (education, income, race, marital status, and work status) will receive a score of 1 if there is no significant difference between participants and the overall target population in that county. Therefore the representativeness score will range from 0 to 5, with 0 indicating very little similarity between program participants and the overall population, and 5 representing high similarity. This score will then be dichotomized, with 0-3 represented by 0 (low representativeness) and 4-5 represented by 1 (high representativeness).

Associations between site characteristics and representativeness will be tested using t-tests for continuous site variables and chi-square tests for dichotomous site variables.

The same approach will be used to determine the association between CSREES educator characteristics and participation rate, reach, and representativeness.

**Sample Size.** Sample size calculations are based on data from the StrongWomen strength training program (Seguin 2008 [42] and unpublished data). We calculated sample size based on a representative site characteristic (equipment availability) for which we had data. Based on this, we will need 17 CSREES educators/sites to detect any associations between site characteristics and participation rate and 41 to determine the association between site characteristics and representativeness (based on race). We are assuming that % reach, which will have the same numerator as participation rate, will have a similar sample size. We expect an actual sample of approximately 18 sites (CSREES educators that run a program) (Figure 1). We will therefore have a large enough sample for participation rate at a power level of at least 0.8. However, we will have a power level of only approximately 0.5 for representativeness.

We used the same approach to determine sample size for the association between CSREES educator characteristics (using a representative characteristic) and participation rate/reach, and representativeness, which yielded samples sizes of 10 and 53, respectively. So we will similarly have a large enough sample for participation rate at a power level of 0.8, and only a power level of approximately 0.5 for representativeness.

While we will have insufficient power to test for associations between site and CSREES educator characteristics and representativeness, these calculations provide only an estimate and it still may be possible to detect true associations. If we find that we truly lack power, we will pool this data with national data from Specific Aim #2 (section D.2.g).

**Interpretation and Implications of Results.** Overall, these results will allow us to adapt recruitment strategies and CSREES educator training as necessary to achieve maximum reach. For example, if either the percent who respond to recruitment or the overall representativeness are low, this will indicate that recruitment strategies need to be modified to reach more of the overall target population and priority subpopulations. We
will have data on recruitment among sites to determine which strategies achieved the best responses and representativeness. In this way it will be possible to develop “recruitment best practices” that can be shared at the training as dissemination proceeds nationally.

Examination of the association between site and CSREES educator characteristics and participation rate will provide information on factors that serve as facilitators or barriers to participation. For example, if accessibility is associated with low participation rate, it may be necessary to emphasize the need to find central, readily accessible locations for classes at CSREES educator trainings. It may also be necessary to provide time during the training for brainstorming on how to overcome barriers such as issues of cost, as we did during the StrongWomen strength training program [26]. By knowing what the most salient barriers are, this time can be used most efficiently. The qualitative data from eligible non-participants will help extend and broaden our understanding of barriers to participation.

Results will also provide important information on site and CSREES educator characteristics that are associated with ability to reach the highest number in the target population. This information may be used to promote these characteristics in CSREES educators. For example, if recruitment self-efficacy is associated with reach, part of the training may be used to build educators’ confidence in their ability to recruit.

Finally, these results will provide information on site and CSREES educator characteristics and representativeness. These results, in combination with qualitative data, will provide information on the factors that are affecting the participation of priority subpopulations. For example, we may find that accessibility is a particular issue for low-income women and that classes should be held in a different location to be fully inclusive of them. We will also know whether CSREES educators are recruiting participants that are mainly quite similar to themselves (based on race and educational attainment, for example). If this is the case, it may be necessary to include a section in the training on how to reach out to other groups.

D.1.h. EFFECTIVENESS detailed methods for Specific Aim #1. A controlled, randomized trial has already demonstrated the effectiveness of the StrongWomen – Healthy Hearts Program. However, it will be important to continue to monitor effectiveness as the Program is more broadly disseminated. A significant impact on the cardiovascular disease burden will only be achieved if it remains effective in a wide variety of settings. We will evaluate the effectiveness of the Program on weight/BMI, fruit and vegetable intake, and physical activity using a quasi-experimental pre-post within-subjects design.

Data Collection. To answer Effectiveness questions, CSREES educators will measure the heights and weights of Program participants. They will be trained to do this during the state training. Program participants will be asked to complete the Fruit and Vegetable Brief FFQ and Physical Activity Questionnaire just prior to starting the Program and just after completing it. Although we are collecting this information to monitor Effectiveness, we have also found that pre-post measurements encourage goal-setting and self-monitoring among participants. For this reason, we expect that Program leaders in the future will continue to take these measurements even after dissemination has been formally evaluated.

Weight. Weight control is an important part of CVD risk reduction [12] and the Program contains a considerable weight control component. Weight will be measured, in triplicate, to the nearest 0.5 kg on a digital floor scale (Seca 880, self-calibrating with 200kg capacity).

Height. Height will also be measured so that BMI (kg/m²) can be calculated. Body Mass Index is a measure based on weight and height and is used to evaluate adult weight status [48]. Height will be measured, in triplicate, to the nearest 0.5 centimeter, using a portable stadiometer (Seca 214) according to the procedures of Lohman [49]. The Seca 214 has a flat vertical surface with an accurate measuring rule attached and measures up to 6'9".

Fruit and Vegetable Brief FFQ. The Program emphasizes an eating pattern that is rich in fruits, vegetables, low-fat or nonfat dairy, fish, whole grains, and legumes. We will use the 5 A Day for Better Health 7-item screener to determine if there is pre-post change in this dietary factor. This instrument is brief, self-administered, and has been validated in diverse populations [50] and used to evaluate interventions designed to increase fruit and vegetable consumption [51]. It asks about fruit and vegetable consumption in the past month. Servings per day can be calculated from this instrument and will be used as the outcome.

Physical Activity Questionnaire. Aerobic activity is a component of the Program itself, and is strongly encouraged outside of class as well. We will use the International Physical Activity Questionnaire (IPAQ) short
version (self-administered) to assess pre-post changes in physical activity. The IPAQ measures the last 7 days of activity and has been validated in a diversity of populations [52-54] and used to evaluate interventions [55, 56]. Metabolic-equivalent (MET) minutes per week will be used as the outcome and will be calculated by multiplying MET intensity for each activity by weekly duration [52].

**Statistical Analysis.** Pre-post data for the entire state will be analyzed using a paired samples t-test which adjusts for the clustering of participants within a county (site).

To test for an association between site characteristics and effectiveness (a continuous variable), Pearson correlations will be used for continuous site variables and t-tests will be used for dichotomous variables. The same approach will be used to determine the association between CSREES educator characteristics and effectiveness.

**Sample Size.** The sample size calculation for overall effectiveness uses data derived from the StrongWomen – Healthy Hearts effectiveness study, looking at the change in weight in the intervention group. After the 12-week program, the estimated mean change in weight in this group was -3.8 kg with a standard deviation of 5.3. The ICC observed in the effectiveness trial was 0.11, giving a cluster effect of 2.7, assuming an average cluster size of 15 subjects. The test of equality of means will be carried out at the 0.05 level of significance. A sample size of 33 participants accounts for the design effect and gives a probability of 0.8 of rejecting the null hypothesis. We expect 270 participants and will therefore have an adequate sample (see Figure 1). (Note that this is the only individual level analysis described in this proposal. Because all other analyses are at the site level, clustering is not explicitly accounted for).

We were not able to determine sample sizes to test for associations between site and CSREES educator characteristics and effectiveness. The StrongWomen studies did not evaluate pre-post changes in participants’ weight (or other outcomes of interest for this study), and we did not obtain site and CSREES educator characteristics in the StrongWomen – Healthy Hearts effectiveness trial. However, because the analyses are similar, we expect sample sizes to be within the same range as for other RE-AIM components.

**Interpretation and Implications of Results.** If the Program demonstrates effectiveness overall, it will provide assurance that it is adaptable to a broad range of settings and that it will have a significant public health impact. Even if it does not, we will have gained further knowledge on the factors that influence effectiveness. For example, we may find that sites with fewer resources are not effective. If this is the case, we will be able to use detailed information on resources to determine the minimum resource level needed for a program to be effective. We will be able to work with CSREES educators and leadership to help provide minimum resources to any site that does not have them. These results will also give us information on leader characteristics associated with effectiveness. If certain leadership factors are associated with effectiveness, the training can be adapted to include a component designed to foster those qualities.

**D.1.i. ADOPTION detailed methods for Specific Aim #1.** If the number of CSREES educators and type of site that adopts a program is limited, then the number of women that can be reached is also limited. It is important to ensure that a program will fit in a variety of sites. We will collect the data needed to determine the rate of adoption and the key factors that may have influenced adoption. Adoption will be defined as a CSREES educator beginning a StrongWomen – Healthy Hearts Program in her community within one year of being trained. This is based on our experience with the StrongWomen program.

**Data Collection.** Data will be collected so that adoption rate can be determined. Research personnel at Tufts and Penn State will document the total number of eligible CSREES educators in Pennsylvania (currently, there are 26) and the total number trained at the state training. The number who adopt will be monitored. Dr. Corbin, as Associate Director and State Program Leader of Children, Youth, and Families, is informed of and must approve all CSREES educator activity within the state, including the StrongWomen – Healthy Hearts Program. Dr. Folta, in collaboration with Dr. Corbin, will use a database to track adoption, similar to that used for the StrongWomen strength training program to track adoption [26].
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To determine CSREES educator and site characteristics that affect Adoption, CSREES educators will be asked to complete the About You Questionnaire, Leadership Questionnaire, and Site Questionnaire at the state training (see Reach, section D.1.g). They will also be asked to complete the following at that time:

Perceived Costs Questionnaire. Cost is thought to be a significant factor in whether a program is adopted, implemented with high fidelity, and maintained [57]. A Perceived Costs Questionnaire will be constructed in collaboration with Dr. Corbin and Ms. Wiker and pilot tested our CSREES collaborators in Arkansas and/or Kansas during the project development phase. It will include questions about fiscal costs and the importance of those costs in ability to adopt the program and implement as specified in the curriculum. For example, “To run the StrongWomen – Healthy Hearts Program and conduct the cooking exercises as intended, you would need to purchase a small number of groceries, such as those listed below, on a typical week. Looking at the list, what is your estimate of how much this will cost? Please rate your site’s ability to cover these costs. Please rate the likelihood that these costs would prevent you from doing the cooking exercises. Please rate the likelihood that these costs would prevent you from running the program at all.” Similar questions will be asked in relation to equipment, space, and other supplies. We will also develop questions related to opportunity costs. For example, “The Program will require approximately 5 hours of your time per week for preparation, planning, and running the classes. Please rate the likelihood that you will be able to devote this much time to the Program. Please rate the likelihood that time will prevent you from being able to run the Program at all. Please describe what you would most likely be doing with this time instead of running the Program.”

Key Informant Interviews with Non-Adopters. We will also collect qualitative data to determine detailed information about barriers to adoption. To do this, we will contact the trained CSREES educators (expected to be 2 of the 20, based on input from Dr. Corbin at Penn State – see Figure 1) who fail to adopt the Program within one year. The interviews, designed to take 15-30 minutes, will be conducted by the Project Coordinator at Penn State who will be trained on qualitative methods by Dr. Folta. We will ask about reasons for non-adoption and barriers to adoption. Depending on the location of the CSREES educators, the interviews will be conducted either in-person or by telephone. They will be digitally recorded and then transcribed by the Project Coordinator. Dr. Folta will analyze the data as described above for the non-participant key informant interviews (section D.1.g). However, the small number of interviews does not warrant use of NVivo software for analysis.

Statistical Analysis. We will do the following calculations:
Overall % adoption = # who adopt/# eligible in state
% adoption among trained = # who adopt/# trained

To test for associations between site characteristics and adoption among those trained (a dichotomous variable), t-tests will be used for continuous site variables and chi-square tests will be used for dichotomous site variables. The same approach will be used to test for associations between CSREES educator characteristics and adoption, and perceived costs, importance of cost and adoption.

Sample Size. Based on data from the StrongWomen strength training program (Seguin 2008 [42] and unpublished data), we will need 45 CSREES educators who do or do not adopt to detect any associations between site characteristics and adoption, should they actually exist, at a power level of 0.8. This would give us an actual power level of approximately 0.5. While this is our best estimate based on previous work, it still may be possible to detect true associations. Should we in actuality lack the power to do so, we will pool this data with national data from Specific Aim #2 (see section D.2.i).

We used the same approach to determine sample size for the association between CSREES educator characteristics and adoption, which yielded a sample size of 18 CSREES educators. We therefore expect a large enough sample (20, see Figure 1) to test for associations at a power level of 0.8.

Interpretation and Implications of Results. The adoption rate will be an indicator of Program “fit” within the CSREES organization. Because of our previous collaboration with CSREES, we expect overall rates to be high. However, detailed examination of factors related to adoption will allow us to adapt both the training and the program itself to improve fit and thereby achieve higher adoption levels. As for reach and effectiveness, we
may discover that site resources are a factor in adoption. If so, we will be able to adapt the curriculum so that it conforms to a minimum resource level met by most sites, and that we also know to be associated with effectiveness. We expect the qualitative information on barriers to inform the adaptation. Similarly, if perceived costs are associated with adoption, the curriculum can be modified to further reduce cost.

Results related to leader characteristics and adoption will allow us to adapt the training if necessary. In the StrongWomen strength training program, program-related self-efficacy was associated with adoption [42]. The training is designed to provide the vicarious and enactive mastery experiences that would lead to increased self-efficacy [58]. If self-efficacy proves to be a key factor related to adoption, we will be able to monitor change in it during training, and adapt the training to maximize it.

D.1.j. IMPLEMENTATION detailed methods for Specific Aim #1. As a program is widely disseminated, there is ongoing tension between fidelity and flexibility. Fidelity to key components is critical to maintaining effectiveness, yet flexibility is also essential to effective translation in the local setting. The goal in evaluating implementation is to help determine which components must be adhered to and which can, and should, be modified.

Data Collection.

Implementation Survey. Once they start the Program, CSREES educators will be asked to complete an on-line survey every week (which will take approximately 10 minutes). This survey, adapted from the one used in the effectiveness trial, will ask them to respond to the following questions: Did you run both classes this week? What was the attendance? For physical activity, did you walk or do the cardiovascular dance DVD? How long did participants exercise? Did you use the handouts included in the curriculum? Describe any changes you made to the class plans for this week and the reason for the change. Did participants seem engaged with and receptive to this week's classes? If not, please comment. CSREES educators will also be asked to estimate fiscal costs (for groceries, equipment, supplies, space rental, etc.) for the week and the extent to which these costs were offset, such as through a local grant or by charging those who could pay a small fee for participation. They will also be asked to estimate how much total time they spent running the program and to comment on what other activities were displaced as a result of taking this time.

Site Visits. The Penn State Project Coordinator will observe one class at each of the expected 18 sites that adopt a program. S/he will visit during weeks 4-8 of the 12 week program. This is feasible because we are expecting staggered starts to the program. During the observation, the Project Coordinator will rate the class using a 5-point scale (1=unacceptable 2=needs improvement; 3=fair; 4=good; and 5=excellent) [26] on each of the following characteristics: Was exercise conducted for the recommended duration? Was exercise conducted at the recommended intensity? Did all participants exercise? Are classes being conducted in order? Are classes being delivered independently (not combined with other classes)? Were cooking demonstrations and hands-on exercises conducted as intended? Was everything prepared in advance for cooking? Was the food item prepared according to instructions in the curriculum? Was the leader-directed learning conducted as laid out in the curriculum? Was time allowed for discussion? Were participants treated equally? Was the class leader prepared overall? Was the length of the class within the expected range (60 to 75 minutes)?

Fidelity Scoring. Fidelity scores will be calculated using data from the Implementation Survey and the Site Visits. Fidelity-specific questions from the Implementation Survey will be rated on a 1 to 5 scale (similar to that used for site visits) based on CSREES educator responses. The Project Managers (Dr. Folta and Ms. Wiker) will independently do this rating and inter-rater reliability will be determined using Cohen's kappa. Any item that fails to achieve a value of 0.8 or higher on this statistic will be discussed until consensus is reached. These ratings and those from the site visits will be used to create an overall fidelity score. They will also be categorized by component, such as physical activity, cooking exercise, preparedness, etc. Rating within each category will be averaged to achieve a fidelity score for each program component.

In-Depth Interviews. In-depth interviews will be scheduled with CSREES educators in conjunction with the site visits. The main purpose is to explore in depth any changes that were made to the curriculum; why those changes were made; and perceptions about whether they affected behavior change in participants. Specifically, CSREES educators will be asked to describe any changes that were made to increase feasibility for themselves; to increase feasibility for participants; and to meet the needs of their target population based on culture, resources available, or any other factors. This qualitative data will be transcribed, analyzed, and reported as described above for Reach (section D.1.g).
**Statistical Analysis.** We will test for an association between overall fidelity score and effectiveness at the site level (using mean change in weight for the site) using Pearson correlations, since both variables will be continuous.

We will determine the cost of the program by compiling CSREES educators’ weekly reports of cost, and adding up costs for the entire program. We will calculate summary statistics (mean and standard deviation) for costs per site.

**Sample Size.** Sample size was determined based on the StrongWomen – Healthy Hearts effectiveness study, for which an overall fidelity score was determined by the Project Manager based on weekly check-ins and site visits. Fidelity score was associated with change in weight in that study. Based on that data, we will need 20 CSREES educators/sites to detect any associations between fidelity and effectiveness, should they exist, at a power level of 0.8. The 18 CSREES educators/sites will provide nearly that (power of 0.78).

**Interpretation and Implications of Results.** These results will provide the quantitative and qualitative data needed to guide training on the curriculum and to adapt it so that it will be effective in a broad range of sites. By testing for an association between overall fidelity and effectiveness, we will be able to quantify the importance of fidelity. If it is not necessary, we will encourage CSREES educators to adapt as they see fit. If a high level of fidelity is needed, stricter adherence will be emphasized in the training. The qualitative data will provide information on types of changes that were made at different sites. We expect that this, along with the quantitative data, will inform development of versions of the curriculum that are adapted to specific settings and cultures.

Finally, information on cost across sites will help us provide realistic estimates to CSREES educators interested in running the program. It can also be used to increase feasibility. For example, we will be able to follow up at sites where costs were low and get input on how this was done. These “tips and tricks” can be incorporated into the training.

**D.1.k. MAINTENANCE detailed methods for Specific Aim #1.** The full public health impact of a program will be realized only if it is sustained within an organization, giving it the ability to reach significant numbers of people over time. The goal of the Maintenance evaluation is to determine the extent to which this happens within CSREES in Pennsylvania. Consistent with the organizational structure of CSREES, we will monitor individual sites to determine collective maintenance. We will also identify the factors that affect Maintenance so that this information can be used to adapt the program if necessary.

**Data Collection.** Data will be collected so that the % Maintenance can be determined. Research personnel will be responsible for monitoring Maintenance. Based on our experience with the StrongWomen strength training program, Maintenance will be defined as running the program again within one year after the completion of the initial adoption. Dr. Corbin will be aware of any CSREES educators who run the program again within one year, since she must approve the time spent to do so.

To determine barriers to Maintenance, we will conduct key informant interviews with CSREES educators who do not run the program again within one year. Based on the StrongWomen strength training program, we anticipate % maintenance to be approximately 70%, yielding approximately 5 non-maintainers who we will invite to be interviewed (see Figure 1). Interviews will take place either in person or by phone, depending on the location of the interviewees. They will be designed to take no more than 20 minutes and will be digitally recorded. We will ask about reasons for non-maintenance, and specifically about barriers to participation. The Project Coordinator at Penn State will conduct the interviews and transcribe them. Dr. Folta will analyze the data using a two-step process as described above for Reach (section D.1.g). Key themes will then be compiled and reported. Dr. Folta and the Project Coordinator will work together to ensure that the final results accurately reflect the content of the interviews.

**Statistical Analysis.** We will calculate % Maintenance as follows:
\[
\text{% Maintenance} = \frac{\# \text{ of educators who re-run the program}}{\# \text{ initial adopters}}
\]
To test for associations between site characteristics and maintenance (a dichotomous variable), t-tests will be used for continuous site variables and chi-square tests will be used for dichotomous site variables. The same approach will be used to test for associations between CSREES educator characteristics and maintenance, and perceived costs, importance of cost and maintenance.

Sample Size. Based on data from the StrongWomen strength training program (Seguin 2008 [42] and unpublished data), we will need 41 CSREES educators, including both those who do and do not maintain, to detect any associations between site characteristics and maintenance, should they actually exist, at a power level of 0.8. Based on this, we will only have approximately 50% power to detect any associations that actually exist, given the expected sample size of 18 (those who adopt who may or may not maintain, see Figure 1). Our actual power may be higher than this estimate, and we may still detect true associations. However, if we find we do not have sufficient power, we will pool this data with national data from Specific Aim #2 (see section D.2.k).

We used the same approach to determine sample size for the association between CSREES educator characteristics and maintenance, which yielded a sample size of 21 CSREES educators. We will therefore have close to 80% power (actual power = 76%) with 18 expected sites.

Interpretation and Implications of Results. Like adoption, maintenance rates will provide an indicator of the overall fit of the Program within the CSREES organization. Results from this analysis will allow us to adapt the curriculum to improve fit. For example, if site resource availability is associated with Maintenance, it will suggest that CSREES educators were able to stretch resources to run the program once, but that it is not feasible to continue. It would be another indication that the curriculum needs to be adapted so that fewer resources are needed. Qualitative data will enhance our understanding of barriers to maintenance and changes that need to be made.

D.2. Specific Aim #2: To conduct an evaluation of the first wave of national dissemination using the RE-AIM framework.

D.2.a. Introduction to Specific Aim #2. The objective of Specific Aim #2 is to evaluate the first wave of national dissemination of the StrongWomen – Healthy Hearts Program using the RE-AIM framework. The goal is to obtain additional quantitative data to confirm and augment the information provided by Specific Aim #1. We expect that together, results from both specific aims will provide robust and comprehensive information that will be used to improve recruitment strategies, CSREES educator training, and the curriculum itself. In this way we will maximize the ability to improve the health of midlife and older women, and specifically to reach priority subpopulations (low-income, rural) as the program is further disseminated across the United States through CSREES.

D.2.b. Project Partner: National Extension Association of Family and Consumer Scientists (NEAFCS). NEAFCS is the national professional organization for family and consumer science educators for extension. Extension Family and Consumer Sciences professionals provide education in areas important to the quality of life for children and adults, individuals and families including: food preparation, food safety, nutrition, and healthy lifestyles, and other high priority issues. NEAFCS aims to develop future leaders, endorse academic excellence and learning, promote professional growth, facilitate networking among educators, and uphold the values of the Land Grant University Extension System. Typically, nearly half of the 2,000 members of the Association attend the annual fall meeting. The meeting serves to promote knowledge sharing, leadership skills development, and community/campus partnerships, and to recognize individuals for excellence in programming. Drs. Nelson and Seguin have worked with NEAFCS for five years. In 2004, Drs. Nelson and Seguin conducted a StrongWomen Program workshop at the annual conference in Nashville, TN. This training helped to launch the initial StrongWomen strength training program, now being conducted in 41 states.

D.2.c. Overall Study Design. Just as for Specific Aim #1, the RE-AIM framework will be evaluated in the first wave of national dissemination using a quasi-experimental pre-post design. The expected flow and sample sizes for Specific Aim #2 are described below (Figure 2):
D.2.d. Participant Recruitment and Screening. Recruitment and screening will take place as described for Specific Aim #1 (section D.1.d).

D.2.e. CSREES Educator Training. CSREES educators will attend a full-day training workshop (8 hours, including a working lunch) in conjunction with the NEAFCS annual meeting in Portland, Maine in October 2010. The content of the workshop will be similar to the one described for Specific Aim #1 (see section D.1.e). Penn State Cooperative Extension and Tufts will collaborate to plan and deliver this training.
D.2.f. Summary of RE-AIM evaluation in national first wave dissemination

<table>
<thead>
<tr>
<th>Component</th>
<th>Key Questions</th>
<th>Measurements</th>
<th>Analysis</th>
</tr>
</thead>
</table>
| Reach     | • What is the participation rate?  
• How representative are participants?  
• What were the key factors that determined who in the target audience were successfully or unsuccessfully reached? | • At training, CSREES educators will complete:  
  o About You Questionnaire  
  o Leadership Questionnaire  
  o Site Questionnaire  
• CSREES educators will document:  
  o # who respond to recruitment  
  o # eligible who respond  
  o # eligible who participate  
• Program participants will complete Participant Questionnaire  
• Research personnel will obtain demographic information from U.S. Census Bureau | • Calculate % participation among eligible  
• Compare demographic factors between all participants and target population in U.S.  
• Test for association between site & CSREES educator characteristics and participation rate, reach, and representativeness |
| Effectiveness | • Is the program effective in a variety of settings? | • CSREES educators will take the following measurements on Program participants:  
  o Weight, BMI, fruit and vegetable intake, physical activity | • Determine pre-post effectiveness on all outcomes  
• Test for association between site & CSREES educator characteristics and effectiveness |
| Adoption | • What percentage of CSREES educators adopt the program?  
• What were the key factors that determined adoption? | • At training, CSREES educators will also complete a Perceived Costs Questionnaire  
• Research personnel will monitor adoption within one year | • Calculate % adoption  
• Test for association between site & CSREES educator characteristics and adoption  
• Test for association between perceived costs, importance of cost, and adoption |
| Implementation | • What was the intervention agents’ fidelity to the various elements of the Program curriculum?  
• Adaptable – What key components of the intervention were modified to increase adoptability or use? Can the intervention vary, as needed, depending on the audience?  
• Cultural context – did the adaptation of the intervention to make it more culturally relevant result in loss of fidelity? | • CSREES educators will complete:  
  o Monthly survey on delivery of curriculum activities | • Determine “fidelity” score  
• Test for association between fidelity score and effectiveness  
• Determine overall costs across sites |
| Maintenance | • What is the extent to which a program or policy became institutionalized or part of the routine organizational practices and policies? | • Research personnel will document # who re-run program within one year | • Calculate % Maintenance  
• Test for association between site and CSREES educator characteristics, perceived cost, and Maintenance |

NOTE: *Italicized* text indicates a more robust analysis (because of larger sample sizes) using the national first wave dissemination data compared to the Pennsylvania data

D.2.g. REACH detailed methods for Specific Aim #2. The larger number of CSREES educators/sites that we will have for Specific Aim #2 compared to Specific Aim #1 (approximately 100 compared to 20) will allow us to use a regression model, rather than bivariate statistics, to test for associations between site and leader characteristics and participation rate, reach, and representativeness. It will also ensure adequate power to test these associations. By including all variables and determining the best model, we will be able to determine more robustly the characteristics that are most important for participation rate, reach, and representativeness.

*Data Collection.* We will use the same data collection instruments as for Specific Aim #1 (see section D.1.g). At the national training, CSREES educators will complete the About You Questionnaire and the Site Questionnaire. Using the on-line tool, they will document the number of women who respond to recruitment.
Statistical Analysis. Percent eligible and % participation among eligible will be calculated as for Specific Aim #1. To determine representativeness, participants will be compared to the total target population in their state and within the United States, using a chi-square test since demographic data will be reported categorically.

To test for an association between site characteristics and participation rate, stepwise regression analysis will be used. The hypothesized model is specified as: % participation = site characteristic 1 + site characteristic 2 + site characteristic 3, etc. Site characteristics will include factors like resource level and accessibility as determined by the Site Questionnaire. A similar model will be set up for reach, with % reach as the dependent variable, and for representativeness, using the representativeness score (see section D.1.g, Statistical Analysis) as the dependent variable.

Similar regression models will be constructed to test for associations between CSREES educator characteristics and participation rate, reach, and representativeness. The hypothesized models will be specified as: [participation rate, reach, or representativeness] = age + sex + race + education.

**Sample Size.** Sample size is calculated similarly to Specific Aim #1 (section D.1.g), yielding initial sample sizes of 17 and 41 CSREES educators (county sites) for testing the association between site characteristics and participation rate/reach and representativeness, respectively. These sample sizes are increased by 10 for each predictor in the regression model [59]. Similarly, the sample sizes of 10 and 53 needed to test for associations between CSREES educator characteristics and participation rate/reach and representativeness will be increased by 10 for each covariate. We will add no more than 4 covariates to ensure that our sample is sufficient (80 sites that run programs, see Figure 2) to conduct the analysis at a power level of at least 0.8.

**D.2.h. EFFECTIVENESS detailed methods for Specific Aim #2.** Overall effectiveness results will confirm and augment those from Specific Aim #1. To test for associations, as with reach, the larger number of CSREES educators/sites compared to Specific Aim #1 will allow us to use a regression model, rather than bivariate statistics. It will also ensure adequate power to test these associations.

**Data Collection.** CSREES educators will measure heights and weights of Program participants as for Specific Aim #1. They will be trained to do this at the same time they are trained on the Program. However, they will not be provided with scales and stadiometers as the CSREES educators in Pennsylvania will be. Instead, they will receive recommendations for equipment that can be obtained inexpensively and tips on how to use equipment they may already have. They will also administer the Fruit and Vegetable Brief FFQ and Physical Activity Questionnaire (see section D.1.h) to program participants just prior to starting the program and just after concluding it.

**Statistical Analysis.** To test for overall effectiveness of the Program, paired t-tests will be used just as for Specific Aim #1 (see section D.1.h). To test for an association between site characteristics and effectiveness, regression analysis will be used. The hypothesized model is specified as: pre-post weight change (site mean) = site characteristic 1 + site characteristic 2 + site characteristic 3, etc. Site characteristics will include factors like resource level and accessibility (as determined by the Site Questionnaire). Similarly, regression models will be constructed to test for associations between CSREES educator characteristics and effectiveness. The hypothesized models will be specified as: pre-post weight change = age + sex + race + education.

**Sample Size.** Sample size calculation for overall effectiveness will be the same as for Specific Aim #1 (see section D.1.h). We were unable to determine a sample size for tests of associations between site and CSREES educator characteristics and effectiveness, but expect ranges similar to other RE-AIM components.

**D.2.i. ADOPTION detailed methods for Specific Aim #2.** The larger number of CSREES educators/sites that we will have for Specific Aim #2 compared to Specific Aim #1 (80 compared to 18, see Figure 2) will allow us to use a regression model, rather than bivariate statistics, to test for associations between site characteristics, leader characteristics, cost, and adoption. By including all variables and determining the best regression model, we will be able to determine more robustly the characteristics that are most important for adoption.
**Data Collection.** At the national training, CSREES educators will complete the Leadership Questionnaire and the Perceived Costs Questionnaire (see sections D.1.g and D.1.i for details on the questionnaires). To monitor adoption, CSREES educators will be required to notify the Project Manager at Tufts before running the Program and to provide the date that the Program will start.

**Statistical Analysis.** Percent adoption will be calculated as follows:

% adoption among trained = # who adopt/# trained

To test for an association between site characteristics and adoption, logistic regression analysis will be used. The hypothesized model is specified as: adoption (yes or no) = site characteristic 1 + site characteristic 2 + site characteristic 3, etc. Similar models will be set up to test the association between CSREES educator characteristics and adoption, and perceived cost and adoption.

**Sample Size.** As for Specific Aim #1 (section D.1.i), we will need 45 CSREES educators including those who do and those who do not adopt to detect any associations between site characteristics and adoption, should they exist, at a power level of 0.8. In addition we will need 10 CSREES educators/sites per covariate [59], with no more than 4 covariates anticipated. We will therefore have sufficient power (at least 0.8) with 100 CSREES educators.

We used the same approach to determine sample size for the association between CSREES educator characteristics and adoption, which yielded a sample size of 58 CSREES educators (accounting for the multiple covariates in the model). We will therefore have sufficient power to test these associations.

**D.2.j. IMPLEMENTATION detailed methods for Specific Aim #2.** The larger sample size will allow us to examine associations between each component of fidelity (physical activity, cooking exercise, preparedness, etc.) and effectiveness. This will help determine which specific components must be adhered to and which can, and should, be modified.

**Data Collection.** As for Specific Aim #1, once they adopt the Program, CSREES educators will be asked to complete the on-line Implementation Survey (see section D.1.j). However, they will complete it monthly, at 4, 8, and 12 weeks, rather than every week. Fidelity Scores for the different Program components will be calculated based on responses as for Specific Aim #1.

**Statistical Analysis.** Regression analysis will be used to test for associations between fidelity for the various curriculum components and effectiveness. The hypothesized model is specified as: pre-post weight change (mean for site) = fidelity_component 1 + fidelity_component 2 + fidelity_component 3 + fidelity_component 4.

We will determine the cost of the program by compiling CSREES educators’ monthly reports of cost, and adding up costs for the entire program. We will calculate summary statistics (mean and standard deviation) for costs per site.

**Sample Size.** Sample size calculations are the same as for Specific Aim #1 (section D.1.j), except that we must add 10 CSREES educators/sites for each covariate in the model [59], expected to be no more than 4. We will therefore need a sample size of 60, which we expect to achieve (see Figure 2).

**D.2.k. MAINTENANCE detailed methods for Specific Aim #2.** Similar to Adoption, the larger number of CSREES educators/sites that we will have for Specific Aim #2 compared to Specific Aim #1 (80 compared to 18) will allow us to use a regression model, rather than bivariate statistics, to test for associations between site characteristics, leader characteristics, cost, and maintenance. By including all variables and determining the best regression model, we will be able to determine more robustly the characteristics that are most important for maintenance.

**Data Collection.** Data will be collected so that the % Maintenance can be determined. Research personnel will be responsible for monitoring Maintenance, defined as running the program again within one year of
conclusion of the initial adoption. Any CSREES educator who intends to run the program again within one year will be required to notify the Project Manager at Tufts so that this can be tracked.

**Statistical Analysis.** We will calculate % Maintenance as follows:

\[
\% \text{ Maintenance} = \frac{\# \text{ of educators who re-run the program}}{\# \text{ initial adopters}}
\]

To test for an association between site characteristics and maintenance, logistic regression analysis will be used. The hypothesized model is specified as: maintenance (yes or no) = site characteristic 1 + site characteristic 2 + site characteristic 3, etc. Similar models will be set up to test the association between CSREES educator characteristics and maintenance, and perceived cost and maintenance.

**Sample Size.** Based on data from the StrongWomen strength training program (Seguin 2008 [42] and unpublished data), we will need 41 CSREES educators, including both those who do and those who do not maintain, to detect associations between site characteristics and maintenance, should they exist, at a power level of 0.8. We used the same approach to determine sample size for the association between CSREES educator characteristics and maintenance, which yielded a sample size of 21 CSREES educators. We must add 10 for each covariate in the model, for final sample sizes of 81 for site characteristics and 61 for CSREES educator characteristics. We expect a sample of 80 CSREES educators who do or do not maintain (see Figure 2), and therefore will have an adequate sample.

**D.3. POTENTIAL PROBLEMS AND ALTERNATIVE APPROACHES.** It is possible that adequate sample size will not be achieved in Pennsylvania for Specific Aim #1. This is a potential problem because as sample size declines, so does statistical power, already estimated to be low for some of the analyses. However, our sample size estimates are based on the long experience of Dr. Corbin and Ms. Wiker in that state. We believe the estimates are highly realistic. Furthermore, if there is a decrease in power on some of the quantitative measures, we are assured an adequate sample size in the national first wave of dissemination (Specific Aim #2). If this is the situation, the Pennsylvania study will provide preliminary results which we can confirm with national data. We will also have the option of pooling Pennsylvania and national data. We will still gain in-depth information from more extensive monitoring and the qualitative efforts in that state.

It is also possible that in the course of examining dissemination of the StrongWomen – Healthy Hearts Program using the RE-AIM framework, we will discover that modifications will be necessary in one or more aspects to maximize translatability. In other words, we could get caught in a “fidelity versus flexibility” bind. However, because the effectiveness study took place in a real-world community setting, the chances that this will occur are minimized. We are confident that we will be able to work with CSREES educators, many of whom have lived and worked in their communities for decades, to make the necessary adaptations in a way that will not endanger Program effectiveness. We expect that the data from both specific aims will allow us to adapt recruitment strategies, training, and the curriculum itself to so that an improved and realistic plan for further dissemination is achieved.

**D.4. OVERALL PROJECT DATA MANAGEMENT PLAN**

*Data Collected On-Line.* CSREES educators will fill out the About You Questionnaire, Leadership Questionnaire, Site Questionnaire, and Perceived Costs Questionnaire at the trainings. Time will be allotted for this purpose and study laptops will be available to CSREES educators so they can complete them on-line. They will also complete a weekly on-line survey while running the Program and an Actual Costs Questionnaire at its conclusion. To protect confidentiality and to ensure that integrity of the data is not compromised, an encrypted SSL protocol (the same most online merchants use to protect customers’ financial information) will be used. In addition, each CSREES educator will be given a study ID number and questionnaires will be identified only by this number. The master list of subjects and ID numbers will be kept in a password-protected computer file by Ms. Wiker at Penn State University and by Dr. Folta at Tufts University. Data from questionnaires completed on-line will be stored on a secure server at Tufts University. These servers, under the administration of University Information Technology (UIT), are backed up nightly. Once all data has been collected, the resulting data file (expected to be in the form of an Excel spreadsheet) will be downloaded to a password-protected file folder on a study computer by Dr. Folta.
Data Collected on Paper. Program participants will be asked to complete the Participant Questionnaire, the Fruit and Vegetable Brief FFQ, and Physical Activity Questionnaire on paper just before beginning the Program and again just after it has ended. CSREES educators will obtain heights on program participants before beginning the Program and weights immediately before and after the 12-week Program. Data will be recorded on a paper data collection form. To protect confidentiality, a study ID will be assigned to each Program participant. The Penn State Project Coordinator and Dr. Folta will have a master list of subjects and ID numbers and each CSREES educator will have a list for their site only. All lists will be kept in a password-protected computer file. After the questionnaires and data collection forms have been completed, CSREES educators will make copies, store them in a locked file cabinet to which they alone have access, and send the originals to the Project Coordinator by certified mail with restricted delivery. Once the Project Coordinator has received the data, CSREES educators will shred copies. The Project Coordinator will double-enter the data and transfer the file using the secure study wiki (see section D.6.c).

Digital Audio Data. The Project Coordinator and Research Assistant will conduct key informant interviews under the direction of Dr. Folta. Key informant interviews will be conducted by telephone or in-person and in-depth interviews will be conducted in-person during the site visits. All interviews will be recorded using a digital microphone. Telephone interviews will be conducted using a speaker phone with the microphone placed next to it, a method we have found in other studies to work reliably. Interviews will be transcribed, with the interviewee identified by study ID only, by the Project Coordinator and Research Assistant. Audio recordings will be erased within 1 year. Transcripts will be stored in a password-protected file folder on a study computer at Tufts University.

Additional Data. This project will involve extensive monitoring. On-line forms will be created for CSREES educators to track recruitment, screening, and participation. Research personnel will also use on-line forms to track adoption, implementation, and maintenance. This data will be shared among the research team using the data sharing tools described below (section D.6.c).

All data will be cleaned and examined for outliers and influential data points if appropriate. We will run analyses using SPSS version 16.0 and SAS 9.1 for quantitative data and NVivo 8.0 for qualitative data.

D.5. OVERALL PROJECT TIMETABLE
Prepare database
Prepare on-line communications tools

- In Pennsylvania:
  - Set up and prepare for statewide training
  - Conduct training
  - Begin monitoring Adoption
  - Begin to collect data to determine Reach
  - Begin monitoring Implementation
    - Weekly email check-ins will be conducted with any sites that begin the program
    - Site visits will be planned for any sites that begin the program
  - Begin pre-intervention assessments to determine Effectiveness
    - CSREES educators who choose to adopt the program will collect pre-intervention data on subjects

- Nationally:
  - Set up and prepare for training

**Year 2**

- In Pennsylvania:
  - Continue collecting data on Reach
  - Continue assessments to determine Effectiveness
  - Continue monitoring Adoption
  - Continue monitoring Implementation
  - Begin monitoring Maintenance at sites that have finished programs

- Nationally:
  - Conduct training of 100 CSREES educators at National Extension Association of Family and Consumer Sciences annual meeting
  - Begin to monitor RE-AIM nationally

- Begin data entry and analysis

**Year 3**

- Continue to monitor Maintenance in Pennsylvania
- Continue to monitor RE-AIM nationally
- Continue data entry and analysis
- Manuscript and abstract preparation

D.6. COMMUNITY ACTION PLAN

D.6.a. Organizational Capacity of the Project Partners. CSREES is an agency within the U.S. Department of Agriculture. Its unique mission is to advance knowledge for agriculture, the environment, human health and well-being, and communities by supporting research, education, and extension in the Land-Grant University System and other partner organizations. CSREES collaborates or has formal working partnerships with many institutions and individuals. Key partners are institutions of higher learning. CSREES and its partners focus on critical issues affecting both people's daily lives and the nation's future. The advanced research and educational technologies they support empower people and communities to solve problems and improve their lives on the local level. CSREES operates through an extensive network of state, regional, and county extension offices in every U.S. state and territory. These offices have educators and other staff who conduct programs, workshops and other educational events.

Penn State Cooperative extension is comprised of a network of educators at the local level who connect university research to the people and thereby translate “research into reality.” The existing infrastructure of county CSREES educators function as change agents in communities by engaging in active outreach to assess local family needs, identify community resources, and facilitate the implementation of programming responsive to community needs. With the support of experienced CSREES educators, community interventions are successfully implemented following prescribed applied research protocols. CSREES educators know their communities, the people in their communities, and know how to effectively
deliver community education to families and consumers. Educating the public about health-promoting behaviors has been woven throughout many of the educational programs conducted by Cooperative Extension.

NEAFCS is the national professional organization for family and consumer science educators for CSREES. NEAFCS aims to develop future leaders, endorse academic excellence and learning, promote professional growth, facilitate networking among educators, and uphold the values of the Land Grant University Extension System. Typically, close to half of the 2,000 members of the Association attend the annual meeting held every fall. The meeting serves to promote knowledge sharing, leadership skills development, and community/campus partnerships, and to recognize individuals for excellence in programming.

D.6.b. Project Involvement of the Partners. Penn State Cooperative Extension (Dr. Corbin, Ms. Wiker, and the Project Coordinator) will be involved with all aspects of the research. They will help develop and plan the statewide training. They will oversee data collection for the effectiveness component, and will be involved in monitoring for the other components. Tufts will drive the data analysis, but interpretation of the results will be done in collaboration with the Penn State Cooperative Extension team. They will also partner with Tufts to develop, plan, and conduct the training for the first wave of national dissemination. NEAFCS leadership will also help plan and develop the national training. CSREES educators who attend that training will be involved in some data collection.

D.6.c. Collaboration, Coordination, and Communications Strategies

Coordination. The Project Coordinator (Penn State) will be responsible for day-to-day logistics and coordination. The project will be managed mainly by the Project Manager at Tufts (Dr. Folta) and the Project Manager at Penn State (Ms. Wiker). During the development, training, recruitment, and program implementation periods, there will be weekly phone meetings between the two Project Managers and the Project Coordinator. In addition, they will have regular informal communications by telephone, email, and an online forum (see below). For the national training, Drs. Nelson and Folta will work with Ms. Dothage at NEAFCS to organize the training and to follow the CSREES educators as they implement the program in their respective communities.

Communications. Tufts University and Penn State University project teams have had a positive collaborative relationship for several years. This creates an environment conducive to informal communication needed for successful program implementation and assessment. Communications have and will continue to take place by phone and email. In addition, we will expand the nutrition.tufts.edu/strongwomen website for this research and dissemination effort. The website will be enhanced to create a user friendly electronic network to post notices, create message boards for transfer of best practices and problem solving, and posting of curriculum updates for use by all three study partners (Tufts, Penn State, and NEAFCS) and CSREES educators to facilitate program implementation and secure data transfer. A range of online networking tools (blogs, wikis, and forums) are all available at Tufts through the University Information Technology (UIT) office. A forum is an online tool that “hosts” discussions among a group of individuals through online posting. We expect the three study partners (Tufts, Penn State and NEAFCS) to make use of this communications tool for continuous updates on the study progress.

Document sharing. Documents will be edited and shared using online networking tools, primarily a wiki. The wiki allows members of the research team at both universities to add, revise, and edit content. This type of networking tool (an internet-accessible, secure communication network) will allow for uninterrupted viewing of common documents. Once all parties have approved a document, it can be easily transferred to traditional word processing formats. The wiki that is available through the Tufts UIT office is user-friendly and intuitive to use. Support is available from the UIT office both online and via telephone and email.

Data sharing. Data files will be shared with Penn State and NEAFCS collaborators by posting them to the wiki. Subject confidentiality will be ensured by taking the following precautions: 1) posted data will contain only study numbers and not subject names; 2) the wiki will be restricted so that only research group members have access; and 3) the wiki uses an encrypted SSL protocol (the same most online merchants use to protect customers’ financial information) to protect it from outside malicious parties.

D.7. FUTURE DIRECTIONS
At the conclusion of this 3-year period, we expect to have gained valuable information about the Reach, Effectiveness, Adoption, Implementation, and Maintenance of the StrongWomen – Healthy Hearts Program. Dissemination activities in Pennsylvania will provide us with in-depth qualitative and quantitative information. By examining the first wave of national dissemination through a partnership with CSREES, we will have robust quantitative information on factors associated with successful dissemination. We expect, through future waves, to be able to disseminate the program within the 41 states where we currently partner with CSREES. The information from this study will allow us to build on the Program’s strengths and to modify the training and curriculum as necessary, so that all future waves of nationwide dissemination will occur in a way that will have maximal impact on risk factors for heart disease in midlife and older women.
E. PROTECTION OF HUMAN SUBJECTS

E.1. Risk to the Subjects

E.1.a. Human Subject Involvement and Characteristics.

Program Participants. All program participants will be female and age 40 or over. They will be recruited through use of flyers, bulletin boards, and newspapers. They will take part in a 12-week program, in which thirty minutes of each class includes either aerobic dancing to a DVD created for this project or walking outside. During the 12 weeks, subjects will progress from approximately 20 minutes of low-to-moderate intensity physical activity (plus 5 minutes of gentle stretching) to 25 minutes of moderate-to-vigorous intensity physical activity (plus stretching), which is safe and appropriate for this population [39]. The other thirty minutes includes leader-directed and hands-on training to modify dietary intake patterns, as well as weight control strategies. The Program will take place at CSREES sites within each study county. These will have sufficient space to allow women to engage in physical activity in a safe environment. Program participants will be measured to determine BMI and usual fruit and vegetable intake and physical activity levels. They will be asked to provide basic demographic information. Some eligible non-participants will also participate in key informant interviews.

Assessments will occur at the CSREES sites, or a similar appropriate location, within each county. They will be conducted by CSREES educators, who will be trained appropriately for all measures. Measurements will be taken at 2 time points, just before and just after the 12-week program.

CSREES Educators. CSREES educators will be involved both as researchers and as subjects. As researchers, they will be responsible for collecting some of the data, screening, obtaining informed consent, and implementing the program. Human subjects research will be conducted in Pennsylvania and at other CSREES sites across the country. CSREES educators are associated with universities and all CSREES educators have or will have received human subjects training in compliance with the IRB at their institutions prior to the start of the program. IRB approval for all aspects of the study, including informed consent, will be obtained from Pennsylvania State University and Tufts University.

As subjects, CSREES educators will be asked to provide basic information (demographics) about themselves and about their leadership style. They will also provide information about the CSREES site. They will document various aspects of recruitment and participation. They will participate in key informant and in-depth interviews. CSREES educators are almost entirely female (over 90%). All are over the age of 21. CSREES educators will be recruited through mailings, listservs, and by word-of-mouth. All CSREES educators will be required to complete an informed consent statement prior to participation in the study.

E.1.b. Sources of Materials. Data will be obtained from a variety of sources for this study. CSREES educators, who will be trained on these procedures, will measure weight (digital scale) and height (stadiometer) of program participants. Measurements will take place just prior to and just following the 12-week program. Usual fruit and vegetable intake will be measured using the 5 A Day for Better Health 7-item screener (Fruit and Vegetable Brief FFQ) and usual physical activity level will be measured using the International Physical Activity Questionnaire (IPAQ). The Participant Questionnaire will be given to the subjects will determine basic demographics. CSREES educators will be specifically trained on sensitivity and privacy prior to conducting anthropometric measurements. Qualitative data will be collected from eligible non-participants to determine barriers to participation.

The About You Questionnaire will be administered to CSREES educators to obtain basic demographic information. The Leadership Questionnaire will be used to obtain data on leadership style. The Site Questionnaire will provide information about the various aspects of their sites, such as the availability of resources and the location within the community. While they are implementing the program, CSREES educators will complete weekly surveys. No personal data will be collected, but CSREES educators will provide information about how the program is going at that site. Qualitative data will also be obtained from CSREES educators to determine barriers to adoption and maintenance and types of modifications made to the curriculum.
E.1.c. Potential Risks. There is potential psychological risk for participants through unintentional disclosure of private personal and health-related information. As described in more detail below, this risk will be reduced by assigning each participant an identification number known only by research staff, and storing information in locked file cabinets and password-protected computer files once the data have been entered.

Exercise has some risks associated with it. There is a risk of injury, such as a sprained ankle or skinned knees, hands, or elbows, should a subject fall during exercise (by tripping, for example). The likelihood of this is small, would require minor first aid procedures, and subjects would be expected to recover completely within a few days. There is also some risk of muscle tenderness and soreness, which is fairly common at the beginning of a new exercise program. This would produce minor discomfort that would subside within 1-2 days. Rarely, but more seriously, intense exercise can cause sudden illnesses, such as stroke or heart attack.

According to a recent study, the risk of sudden death in women is extremely low with one death for every 36.5 million hours of moderate to vigorous exercise [60]. Efforts will be made to reduce this risk as described below.

The nutrition education portion of the intervention presents minimal, everyday risks, as the education is presented in lecture format. Cooking activities present risks such as knife cuts or kitchen burns. However, the cooking activities require a minimal amount of knife and stove use and the risks are minimal. CSREES sites usually contain a first aid kit to use for injuries that occur in this setting.

The StrongWomen – Healthy Hearts Program includes a weight control component and weight loss is an expected effectiveness outcome. Weight loss may pose some risk for older adults, as it has the potential to negatively affect muscle and bone mass. However, evidence suggests that weight loss confers the same benefits in elderly populations that it does in younger ones [61]. The position of the American Society for Nutrition and NAASO (The Obesity Society) is that “weight-loss therapy that minimizes muscle and bone losses is recommended for older persons who are obese and who have functional impairments or medical complications that can benefit from weight loss” [61]. Weight loss in this population can specifically improve the metabolic abnormalities associated with CVD risk in elderly populations. As in the effectiveness study, we anticipate that most subjects will be below the age of 75 (average age was 57.8).

E.2. Adequacy of Protection Against Risks

E.2.a. Recruitment and Informed Consent. CSREES educators will recruit subjects using flyers, community bulletin boards, and local newspapers. Flyers will be placed at local community centers, libraries, restaurants, grocery stores, houses of worship, and banks, and anywhere else that midlife and older adults gather or visit frequently.

Potential subjects will be initially screened by telephone for inclusion criteria (female and age 40 or over). All subjects will be required to obtain a signed permission letter from her healthcare provider that indicates that physical activity is safe and appropriate. Once enrolled, subjects will discontinue the Program if there are any changes in their medical status that would make exercise unsafe.

Once the screening process is complete, study subjects will be invited to an information session led by CSREES educators. After the informational meeting, participants will be given an Informed Consent Form, and the CSREES educators will emphasize that participation in the study is entirely voluntary. CSREES educators may answer questions about the study or may refer participants to research personnel at either Penn State or Tufts. Participants will have the option of taking the informed consent with them and returning it on the day that data is collected, to ensure that they have time to read and review it carefully before making a decision about participation in the study.

E.2.b. Protection Against Risk. All personal health and other information collected from participants and CSREES educators throughout this study will be kept confidential. Anthropometric measurements will be taken in a private area to maintain this confidentiality. In addition, each CSREES educator and program participant will be given a study ID number and questionnaires will be identified only by this number. The master list of subjects and ID numbers will be kept in a password-protected computer file by the Coordinator at Penn State University and by Dr. Folta at Tufts University. CSREES educators will have temporary access to this list so that they can collect data on program participants at their site, but they will destroy the list by shredding the document immediately after data collection has concluded. All data, including forms and questionnaires, will include only the study number as an identifier. After the questionnaires and data collection forms have been completed, CSREES educators will make copies, store the copies in a locked file cabinet to which they alone
have access, and then send the originals to the Project Coordinator by certified mail with restricted delivery. Once the Project Coordinator has received the data, CSREES educators will shred copies. To protect the confidentiality of on-line data collected from CSREES educators, an encrypted SSL protocol (the same most online merchants use to protect customers’ financial information) will be used.

All CSREES educators, as well as research personnel at Penn State and at Tufts, have or will have received human subjects training in compliance with the IRB at their institutions prior to the start of the program. This will help ensure adequate protection of human subjects related their role in recruitment, screening, obtaining informed consent, and data storage.

A number of measures will be taken to minimize risk associated with physical activity. Before they can participate in the program, potential subjects will be required to obtain a signed permission letter from their healthcare provider. This is also required for the StrongWomen strength training program and we do not anticipate that this will serve as a barrier to participation. In the effectiveness study, all subjects successfully obtained physician approval. The Program emphasizes the importance of warming up prior to and cooling down following exercise sessions and will be instructed to do so if they do the walk. The cardiovascular dance DVD includes warm-up and cool-down segments. Program participants will also be instructed to engage in gentle stretching exercises following exercise to avoid sore muscles. CSREES educators will lead these stretching exercises, and a poster depicting them is included in the curriculum. The aerobic component of the intervention is designed specifically to be safe and appropriate for women who are currently sedentary, starting with shorter bouts of low-to-moderate intensity aerobic exercise and progressing gradually to longer bouts of moderate-to-vigorous intensity exercise. CSREES educators are prepared to handle sudden illnesses, sprains, and injuries from falling. They are also required to have current CPR certification. Educators will never be more than one minute’s walk away from any subject, and they will have a phone available at all times. If exercise is conducted outdoors, they will be required to carry a working cell phone.

To reduce risk of adverse effects on muscle and bone status in older subjects caused by weight loss, the Program follows the recommendations of the American Society for Nutrition and NAASO (The Obesity Society) [61]. It includes regular physical activity, which can attenuate bone loss caused by weight loss. It is designed for gradual weight loss, with a modest reduction in energy intake and adequate amounts of all nutrients, including protein, which also helps to minimize muscle and bone loss.

CSREES educators will monitor the health status of program participants throughout the study. Any participant for whom exercise becomes unsafe will discontinue her participation.

### E.3. Potential Benefits and Importance of Knowledge to be Gained

The Program has the potential to greatly benefit its participants, as it provides education about nutrition, diet, aerobic fitness, and a heart-healthy lifestyle. There is a great potential for psychological benefits from physical activity, friendships, and from the enjoyment of class participation.

Heart disease is of utmost public health concern for women in the U.S. From this program, we expect to gain valuable information about the Reach, Effectiveness, Adoption, Implementation, and Maintenance of the StrongWomen – Healthy Hearts Program. This information will allow us to build on strengths and to modify as necessary for nationwide dissemination that will have maximal impact on risk factors for heart disease in midlife and older women. Furthermore, we expect this study to provide critical information about how to best reach priority subpopulations (low-income, rural) so that health disparities can be addressed. With this potential, the risks to subjects are reasonable in relation to the anticipated benefits of the program.

### E.4. Dissemination Plan for Study Results

The results of the study will be relevant to other researchers, health promotion practitioners, and CSREES educators and state leaders. We will communicate findings to other researchers by presenting the results at professional meetings (likely candidates include the annual meetings of the American Public Health Association, the Society for Nutrition Education, the International Society for Behavioral Nutrition and Physical Activity, The Obesity Society). The co-investigators collectively have memberships in these societies and a long history of presenting research results at these and other meetings. We also intend to reach other researchers and health promotion practitioners through publication of study findings in peer-reviewed journals. The co-investigators have a good track record of publication of research findings. We will disseminate findings to CSREES educators and state leaders throughout the country by presenting them at the annual meeting of
the NEAFCS, one of our partners for this study. We have a longstanding relationship with this association as a result of our StrongWomen strength training programs. As a result of presentations at national scientific meetings, publications of the results in top-tier peer-reviewed journals, and annual meetings of the NEAFCS, the study will be widely disseminated to researchers, public health practitioners, and CSREES educators and leaders.

E.6. Data and Safety Monitoring Plan

A Data and Safety Monitoring Plan will be implemented to ensure the safety of the participants, as well as the validity and the integrity of the data. Dr. Nelson (Principal Investigator), with the help of the Co-Investigators and Project Managers, will monitor all aspects of safety. All unexpected and adverse events will be reported to the Project Managers (Ms. Wiker if it is in Pennsylvania, or Dr. Folta if it is elsewhere) and Principal Investigator through the individual CSREES educators in a timely manner. All of the CSREES educators at each study site will be notified via either fax or phone of all serious adverse events. An event will be considered serious if it results in death, is life-threatening, requires inpatient hospitalization, or results in a persistent or significant disability/incapacity, or might require medical or surgical intervention to prevent one of these outcomes.

Non-serious adverse events will be monitored as well. These are defined as conditions that may be unpleasant to the participant, such as sore muscles, that do not require termination of participation. Should these occur, CSREES educators will immediately notify the Project Manager. This notification can occur at any time, as all CSREES educator will have access to the Project Manager’s cellular and land-line telephone numbers. The Project Manager will then immediately notify the Principal Investigator, who will then review study protocol to assess the event. Any subject who experiences an adverse event has the option to continue participation in the study, if she so chooses. Any problems will be reported immediately to the Tufts IRB and the Pennsylvania State University’s IRB if it occurs there. These events will be logged by the individual CSREES educator.
F. TARGETED PLANNED ENROLLMENT

To ensure that the study population is representative of the Pennsylvania and states that participate in the first wave of national dissemination with regard to race and ethnicity, we will provide CSREES educators with recruitment goals that reflect the racial/ethnic composition of their counties. The table below tabulates the total number of women age 40 and over and the percent by race for Pennsylvania and for the U.S. as a whole. U.S. Census 2000 data [43] were used to develop this table.

<table>
<thead>
<tr>
<th>Pennsylvania</th>
<th>Females 40 years and Over (total)</th>
<th>Number</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>American Indian/Alaska Native</td>
<td>3,605</td>
<td>0.12%</td>
<td></td>
</tr>
<tr>
<td>Asian</td>
<td>36,746</td>
<td>1.18%</td>
<td></td>
</tr>
<tr>
<td>Native Hawaiian or Other Pacific Islander</td>
<td>594</td>
<td>0.02%</td>
<td></td>
</tr>
<tr>
<td>Black or African American</td>
<td>255,555</td>
<td>8.20%</td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>2,781,629</td>
<td>89.29%</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>19,703</td>
<td>0.63%</td>
<td></td>
</tr>
<tr>
<td>Two or More Races</td>
<td>17,483</td>
<td>0.56%</td>
<td></td>
</tr>
<tr>
<td>Total*</td>
<td>3,115,315</td>
<td>100%</td>
<td></td>
</tr>
</tbody>
</table>

*1.52% of females 40 years and over are Hispanic or Latino (n = 47,371)

<table>
<thead>
<tr>
<th>United States</th>
<th>Females 40 years and Over (total)</th>
<th>Number</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>American Indian/Alaska Native</td>
<td>405028</td>
<td>0.64%</td>
<td></td>
</tr>
<tr>
<td>Asian</td>
<td>2,062,276</td>
<td>3.24%</td>
<td></td>
</tr>
<tr>
<td>Native Hawaiian or Other Pacific Islander</td>
<td>59010</td>
<td>.093%</td>
<td></td>
</tr>
<tr>
<td>Black or African American</td>
<td>6,688,419</td>
<td>10.50%</td>
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</tr>
<tr>
<td>White</td>
<td>51,940,179</td>
<td>81.53%</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>1,662,399</td>
<td>2.61%</td>
<td></td>
</tr>
<tr>
<td>Two or More Races</td>
<td>887,628</td>
<td>1.39%</td>
<td></td>
</tr>
<tr>
<td>Total*</td>
<td>63,704,939</td>
<td>100%</td>
<td></td>
</tr>
</tbody>
</table>

*7.26% of females 40 years and over are Hispanic or Latino (n = 4,624,359)
The following table tabulates overall enrollment goals based on ethnicity and race following the percents listed above. Research subjects will include both program participants (approximately 270 in Pennsylvania and 1200 U.S.) and CSREES educators (approximately 20 in Pennsylvania and 100 in the overall U.S.)

**Pennsylvania**

<table>
<thead>
<tr>
<th>Ethnic Category</th>
<th>Females</th>
<th>Males</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hispanic or Latino</td>
<td>4</td>
<td>0</td>
<td>4</td>
</tr>
<tr>
<td>Not Hispanic or Latino</td>
<td>286</td>
<td>0</td>
<td>286</td>
</tr>
<tr>
<td><strong>Ethnic Category: Total of All Subjects</strong></td>
<td>290</td>
<td>0</td>
<td>290</td>
</tr>
</tbody>
</table>

**Racial Categories**

<table>
<thead>
<tr>
<th>Racial Category</th>
<th>Females</th>
<th>Males</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>American Indian/Alaska Native</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Asian</td>
<td>4</td>
<td>0</td>
<td>4</td>
</tr>
<tr>
<td>Native Hawaiian or Other Pacific Islander</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Black or African American</td>
<td>24</td>
<td>0</td>
<td>24</td>
</tr>
<tr>
<td>White</td>
<td>262</td>
<td>0</td>
<td>262</td>
</tr>
<tr>
<td>Other</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Two or More Races</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td><strong>Racial Categories: Total of All Subjects</strong></td>
<td>290</td>
<td>0</td>
<td>290</td>
</tr>
</tbody>
</table>

*The "Ethnic Category: Total of All Subjects must be equal to the "Racial Categories: Total of All Subjects"*

**United States**

<table>
<thead>
<tr>
<th>Ethnic Category</th>
<th>Females</th>
<th>Males</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hispanic or Latino</td>
<td>95</td>
<td>0</td>
<td>95</td>
</tr>
<tr>
<td>Not Hispanic or Latino</td>
<td>1205</td>
<td>0</td>
<td>1205</td>
</tr>
<tr>
<td><strong>Ethnic Category: Total of All Subjects</strong></td>
<td>1300</td>
<td>0</td>
<td>1300</td>
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</table>

**Racial Categories**

<table>
<thead>
<tr>
<th>Racial Category</th>
<th>Females</th>
<th>Males</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>American Indian/Alaska Native</td>
<td>10</td>
<td>0</td>
<td>10</td>
</tr>
<tr>
<td>Asian</td>
<td>46</td>
<td>0</td>
<td>46</td>
</tr>
<tr>
<td>Native Hawaiian or Other Pacific Islander</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Black or African American</td>
<td>141</td>
<td>0</td>
<td>141</td>
</tr>
<tr>
<td>White</td>
<td>1103</td>
<td>0</td>
<td>1103</td>
</tr>
<tr>
<td>Other</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Two or More Races</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td><strong>Racial Categories: Total of All Subjects</strong></td>
<td>1300</td>
<td>0</td>
<td>1300</td>
</tr>
</tbody>
</table>

*The "Ethnic Category: Total of All Subjects must be equal to the "Racial Categories: Total of All Subjects"*
TARGETED PLANNED ENROLLMENT FOR ENTIRE STUDY: Number of Subjects

<table>
<thead>
<tr>
<th>Ethnic Category</th>
<th>Sex/Gender</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Females</td>
<td>Males</td>
<td>Total</td>
</tr>
<tr>
<td>Hispanic or Latino</td>
<td>99</td>
<td>0</td>
<td>99</td>
</tr>
<tr>
<td>Not Hispanic or Latino</td>
<td>1491</td>
<td>0</td>
<td>1491</td>
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<tr>
<td>Ethnic Category: Total of All Subjects*</td>
<td>1590</td>
<td>0</td>
<td>1590</td>
</tr>
</tbody>
</table>

Racial Categories

<table>
<thead>
<tr>
<th>Racial Category</th>
<th>Sex/Gender</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>American Indian/Alaska Native</td>
<td>10</td>
<td>0</td>
<td>10</td>
</tr>
<tr>
<td>Asian</td>
<td>50</td>
<td>0</td>
<td>50</td>
</tr>
<tr>
<td>Native Hawaiian or Other Pacific Islander</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Black or African American</td>
<td>165</td>
<td>0</td>
<td>165</td>
</tr>
<tr>
<td>White</td>
<td>1365</td>
<td>0</td>
<td>1365</td>
</tr>
<tr>
<td>Other</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Two or More Races</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

Racial Categories: Total of All Subjects* | 1590 | 0 | 1590 |

*The "Ethnic Category: Total of All Subjects must be equal to the "Racial Categories: Total of All Subjects"
INCLUSION OF WOMEN AND MINORITIES

Inclusion of Women
We propose to recruit 1590 women for our study. Men will be excluded from this study. Every year since 1984, more women than men have died from cardiovascular disease. Despite this, CVD has generally been understudied in women, although this is changing.

Inclusion of Minorities
No ethnic/racial minority groups or subgroups will be excluded from the study. It is especially important to reach these groups since health disparities exist, leading to higher rates of obesity and CVD. We expect this research, which will examine recruitment and participation, to help elucidate best practices for full inclusion of minorities.
JUSTIFICATION FOR EXCLUSION OF CHILDREN

Children will be excluded from this study. The behaviors that can lead to CVD have origins in childhood, and children are increasingly developing biological precursors to this disease, such as hypertension and dyslipidemia. However, the behavioral strategies used in this study are specific to and appropriate for adult mid-life and older women. An age-specific study is warranted in this case.
REFERENCES


5. Gerberding G. Healthy Aging: Preventing Disease and Improving Quality of Life Among Older Americans 2006: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, Coordinating Center for Health Promotion; 2006.


