

# Design of the Central Pennsylvania Women's Health Study (CePAWHS) Strong Healthy Women Intervention: Improving Preconceptional Health

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**Abstract** Considerable evidence suggests that modifiable risk factors for adverse pregnancy outcomes such as preterm birth and low birthweight include obesity, sedentary behavior, and infections. There is a growing consensus that the preconceptional and interconceptional periods may be an ideal time for preventive intervention targeting these risk factors; enhancing health before pregnancy would subsequently reduce the risk for poor pregnancy outcomes. This paper provides an overview of the development of a health behavior intervention, *Strong Healthy Women*, that aims to improve women's preconceptional and interconceptional health. We describe the rationale, delivery, and targeted outcomes of the program, as well as the design of

an ongoing trial currently testing program efficacy. The content areas are also discussed and include pregnancy-conception, stress, physical activity, nutrition, infection, sources of smoke in the home, and substance use. This intervention protocol may offer researchers and healthcare professionals a framework for designing other programs aiming to improve women's preconceptional health.

**Keywords** Interconception · Physical activity · Nutrition · Stress · Infection · Alcohol · Sources of smoke in home

## Introduction

Despite medical and technological efforts to advance prenatal care, maternal and infant health in the United States over the past few decades has demonstrated little improvement [1]. Adverse pregnancy outcomes, including preterm birth and low birthweight, are high-priority public health problems [2, 3] and incidence rates are continuing to rise [4]. While trends such as increasing birth rates at older maternal ages and greater numbers of multiple births from assisted reproductive technologies are thought to contribute to poor birth outcomes, these trends do not completely explain escalating preterm birth and low birthweight rates [2]. In 2005, 13.5% of U.S. births occurred prior to 37 weeks of gestation, representing an increase of more than 30% since 1981. The current low birthweight rate of approximately 8% is the highest reported since 1968 [4]. These trends persist despite improved access to prenatal services [5], leading many to conclude that intervention during pregnancy are, by themselves, insufficient [6–10]. Consensus among women's health experts is emerging that a stronger emphasis should be given to women's health

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status and risk behavior patterns before they become pregnant [11–15], particularly among underserved populations such as rural women.

A recent report by the Centers for Disease Control and Prevention (CDCP) [16] recommended a comprehensive strategy for improving women's preconceptional health including greater access to clinical care, community-based health promotion programs, and a focus on individual health-related behavior. Specifically, four distinct goals were set to improve health and pregnancy outcomes in the United States. These goals are to: (1) improve the knowledge, attitudes, and behaviors of men and women related to preconception health; (2) ensure that all U.S. women of childbearing age receive preconception care services screening, health promotion, and interventions that will enable them to enter pregnancy in optimal health; (3) to reduce risks indicated by a prior adverse pregnancy outcome through interventions in the interconception period that can prevent or minimize health problems for a woman and her offspring; and (4) to reduce disparities in adverse pregnancy outcomes.

These issues are especially important to address among women living in rural areas, particularly because they are both underserved and under-researched. While the research examining negative pregnancy outcomes among rural women is relatively scant, there is evidence to suggest that these women have less overall access to prenatal care [7]. Also, many rural women enter into prenatal care later in their pregnancy than their non-rural counterparts [17]. Furthermore, there is evidence that women living in rural areas are at elevated risk of delivery complications [18] and adverse pregnancy outcomes such as low birthweight [19] and preterm delivery [19, 20], and thus, warrant the target of intervention.

#### Need for the Intervention

Because of the need for research in this area and consistent with the emerging consensus from researchers and the CDCP that preconceptional interventions are warranted, we developed a theoretically based behavior change intervention designed to promote women's preconceptional health. This program specifically targets risk factors such as sedentary behavior, poor nutrition, and stress associated with adverse pregnancy outcomes. This approach to improving women's health and preventing adverse pregnancy outcomes is innovative and different from prior research in several important ways. First, prior research on the prevention of preterm birth has focused almost exclusively on high-risk pregnant women [21] rather than targeting high-risk women before they become pregnant. Second, previous attempts to improve preconceptional health have used a clinical care model, focusing on services

to individual patients in the context of healthcare visits (e.g., obesity, cardiovascular disease, diabetes, etc.) despite the fact that most women do not receive preconceptional healthcare. Furthermore, if preconceptional healthcare is offered, it is frequently delivered in a single office visit which may have little impact on a woman's health-related behaviors [7]. The proposed intervention targets women outside of the clinical setting for health education and behavior change within the context of a novel intervention program with repeated contact to improve their preconceptional health. Third, existing preconceptional clinical and behavioral interventions have been effective for women who are seeking family planning and nutritional services for specific conditions such as diabetes [11]; however, little to no intervention research has targeted a wider-range of women in a universal approach (i.e., recruiting all eligible women in a high-risk community). Finally, as noted above, no similar interventions in this area have focused on low-income rural women, a high-risk group that has received little research attention.

Whereas preventing adverse pregnancy outcomes for every woman is unrealistic, it is nonetheless important to identify strategies that can improve preconceptional health and thus reduce the frequency and severity of such outcomes in a large range of women. For this reason, the Central Pennsylvania Women's Health Study (CePAWHS) *Strong Healthy Women* health behavior intervention was developed.

#### Objective of the Strong Healthy Women Intervention

The present article reports on the development and content of the *Strong Healthy Women* intervention. This intervention is now being tested in a randomized trial of women ages 18–35 in 15 low-income rural communities in Central Pennsylvania. The results of this trial will be reported separately when data are available. This article addresses how the intervention was developed and its evidence base. There are important benefits for the research community in publishing the rationale and design of a randomized control trial (RCT) before the findings are available [22, 23]. For example, because most research articles on RCT's are primarily focused on the study findings, a comprehensive description of the rationale behind and design of the intervention is often omitted. Thus, other researchers are not able to replicate and further test a particular intervention despite the fact that this process is crucial for scientific progress, as well as recommended in the translation and dissemination of public health innovations. Also, publishing the intervention design and protocol before the findings are revealed allows for a comparison between what was originally intended and what was actually done.

The overall objective of this innovative intervention is to improve the physical and psychological health of pre- and interconceptional women by: (1) providing education about health-related factors associated with poor pregnancy outcomes, (2) facilitating behavior change through increasing physical activity, improving nutrition, reducing risk behaviors (e.g., smoking, drinking), and improving self-management and regulatory skills (e.g., problem-solving, stress reduction, and time management), and (3) encouraging self-efficacy for personal healthcare by providing information about and addressing barriers to obtaining healthcare services.

## Two Phases of CePAWHS

The CePAWHS is a novel two-phase research project funded by the Pennsylvania Department of Health and focused on women's preconceptional health. Phase 1 included a population-based survey of reproductive-aged women in Central Pennsylvania to estimate the prevalence of multiple risk factors for preterm birth and low birthweight. Phase 2 is a randomized trial of the *Strong Healthy Women* behavior change intervention to improve women's preconceptional health and reduce risk factors for adverse pregnancy outcomes. The intervention content was based on the risk factors identified in the Phase 1 survey and in prior research [2, 24, 25].

### Phase 1 CePAWHS Survey: Reproductive Risks Among Preconceptional and Interconceptional Women in Central Pennsylvania

The Phase 1 CePAWHS survey included a random digit dial (RDD) telephone survey, with oversampling in rural counties and in areas where minority residents comprised 30% or more of the total population. Inclusion criteria were female gender, age 18–45 years, residence in the 28 county target region of Central Pennsylvania, and English or Spanish speaking. Details of the survey design have been published previously [26]. The procedure yielded 2,002 completed interviews. A response rate of 52% was obtained, calculated using an estimated proportion eligible among households for which eligibility could not be determined. The cooperation rate among eligible households contacted was 63%. Comparisons of sample demographics with data from the US Census published previously indicate that the sample is highly representative of the target population [26]. Prevalence rates for key risk factors for adverse birth outcomes are shown in Table 1. Data presented in the table are from a subset of women in the full RDD sample ( $N = 1,325$  out of 2,002) who did not

report being incapable of reproduction secondary to hysterectomy, tubal ligation, menopause, or other factors. The results are displayed separately for women who are preconceptional (never having been pregnant) and interconceptional (having had at least one pregnancy; see Table 1).

Preconceptional women were younger on average, with a mean age of 27.1 years as compared to 33.5 years for interconceptional women. There were, however, both preconceptional and interconceptional participants as young as 18 and as old as 45. Both groups were predominantly white non-Hispanic (92.5% of preconceptional women, 88.5% of interconceptional women), with a slightly higher proportion of interconceptional women self-identifying as African American (5.8% vs. 3.4%), Hispanic (3.9% vs. 2.9%), or some other race (1.8% vs. 1.3%). Multiple stressors were prevalent among both pre- and interconceptional women in the sample. Less than one-third of women in the sample engaged in regular physical activity (i.e., at least 30 min of moderate-strenuous exercise on most, if not all days, of the week; American College of Sports Medicine [27]), and less than half reported recommended nutritional intake of vegetables (i.e., five servings per day) and a vitamin containing folic acid. Close to half the women were classified as overweight or obese, using body mass index (BMI) cutoffs of  $\geq 25$  and  $\geq 30$ , respectively. Gynecological infections were reported among 32% of preconceptional and 43% of interconceptional women. Substance use was common; one in five women reported current tobacco use, and binge drinking was particularly high among preconceptional women at 27%. The experience of unfair treatment due to race, ethnicity or culture was reported by over 10% in both groups, and unfair treatment due to gender was even more common, especially among preconceptional women. Intimate partner violence in the past 12 months was reported by 5–8% of the women.

### Phase 2: CePAWHS Randomized Behavioral Intervention Strong Healthy Women

#### Study Design

The CePAWHS Phase 2 study is an innovative randomized intervention trial, *Strong Healthy Women*, aimed at evaluating the effectiveness of a behavior change intervention to improve women's preconceptional health. The main focus of the intervention is on risk factors for adverse pregnancy outcomes prevalent in Central Pennsylvania. Risk factors identified in the Phase 1 population-based survey became the basis of the content areas for the intervention, namely, pregnancy and conception, psychosocial stress, physical activity, nutrition, gynecologic infection, smoking, and

**Table 1** Sociodemographics and reproductive health-related risks among preconceptional<sup>a</sup> and interconceptional<sup>b</sup> women ages 18–45 in Central Pennsylvania

	Preconceptional ( <i>N</i> = 385)	Interconceptional ( <i>N</i> = 950)
Sociodemographics		
Age ( <i>M</i> , <i>SD</i> )	27.1 (7.5)	33.5 (7.0)
Age Range	18–45	18–45
Race/Ethnicity		
White (%)	92.5	88.5
African American (%)	3.4	5.8
Hispanic (%)	2.9	3.9
Other (%)	1.3	1.8
Risk factors		
Stressors		
Unfair treatment due to race, ethnicity, culture past 12 months (%)	10.7	12.0
Unfair treatment due to gender, past 12 months (%)	27.0	16.4
Intimate partner violence, past 12 months (%)	5.5	6.4
Psychological Hassles Scale ( <i>M</i> , <i>SD</i> )	18.1 (4.19)	16.7 (3.95)
Substance use		
Cigarette smoking (%)	18.2	20.6
Binge drinking (%) <sup>c</sup>	42.6	22.3
Physical activity		
Moderate or strenuous exercise (%)		
Never	19.0	36.5
1–3 days/week	50.5	39.7
4–7 days/week	30.5	23.8
Body Mass Index		
Underweight (<18.5)	3.2	1.6
Normal (18.5–24.9)	54.9	47.4
Overweight (25.0–29.9)	22.6	28.6
Obese (≥30.0)	19.4	22.5
Nutrition		
Servings of vegetables (%)		
Twice/week or less	19.0	15.3
3–6 times/week	43.1	39.0
Once a day	24.2	30.8
More than once a day	13.8	15.0
Uses vitamin with folic acid (%)	43.4	47.7
Infection		
Any gynecological infection (%) <sup>d</sup>	31.7	42.7

Note: *M* = mean,  
*SD* = standard deviation

<sup>a</sup> Preconceptional women are defined as having never been pregnant

<sup>b</sup> Interconceptional women are defined as having had one or more pregnancies, regardless of pregnancy outcome

<sup>c</sup> Defined as ≥5 drinks on 1 occasion in past month, among those who use alcohol

<sup>d</sup> A history of urinary tract infection, Chlamydia, herpes, gonorrhea, syphilis, pelvic inflammatory disease, bacterial vaginosis, vaginal yeast infection, HIV/AIDS, and hepatitis B

alcohol. These risk factors are also prevalent in other populations based on national CDCP data. The Institutional Review Board of the Pennsylvania State University Hershey Medical Center approved the study design, protocols, and informed consent procedures. Eligible women are randomized to either the intervention or control group, participate in biobehavioral assessments at baseline and again 14 weeks later, and are followed by telephone surveys at 6 and 12 months after the follow-up assessment (described further below).

### Test Setting

The *Strong Healthy Women* intervention is currently being tested among women residing in low-income rural communities in Central Pennsylvania. The targeted counties are within the Pennsylvania Department of Health North Central and South Central health districts and the counties served by the Family Health Council of Central Pennsylvania. This region of Pennsylvania accounted for 24% of all Pennsylvania births in 2001. In addition, all of the

counties had higher rates of low birth weight and nearly all of the counties had higher preterm birth rates than the goals outlined in Healthy People 2010 [24]. This region is also diverse in terms of socioeconomic status, race/ethnicity, and population density. The majority of the counties in this region have fewer college graduates than the state average, a mean household income below the state average of approximately US \$40,000, and county populations ranging from 2 to 24% non-White.

### Test Population

The intervention is currently being tested among women in the targeted communities of Central Pennsylvania, ages 18–35 years, English speaking, and who are not pregnant at the time of study enrollment, but are capable of becoming pregnant in the future (i.e., have not had a tubal ligation or hysterectomy and have no other known cause of infertility). We targeted the age group of 18–35 in the intervention study, rather than 18–45 age group targeted in the Phase I population-based survey, because women ages 18–35 account for more than 85% of live births in Central Pennsylvania. Also, we targeted only English-speaking participants for the intervention based on intervention resources. Moreover, we wanted to increase the probability that the women in the study would eventually become pregnant. Maximizing the number of births is important for determining the impact of the intervention on birth outcomes during long-term follow-up.

Women are recruited for the intervention through in-person or mailed initial contact from clinical and non-clinical sites available through our collaborative university-community network in Central Pennsylvania (e.g., family planning and WIC sites administered by the Family Health Council of Central Pennsylvania, community organizations, churches, and neighborhood groups). Because a high proportion of low-income, rural women do not have regular health care providers, the collaboration with community-based partners is an important element facilitating recruitment in diverse settings.

### Rationale for the Intervention

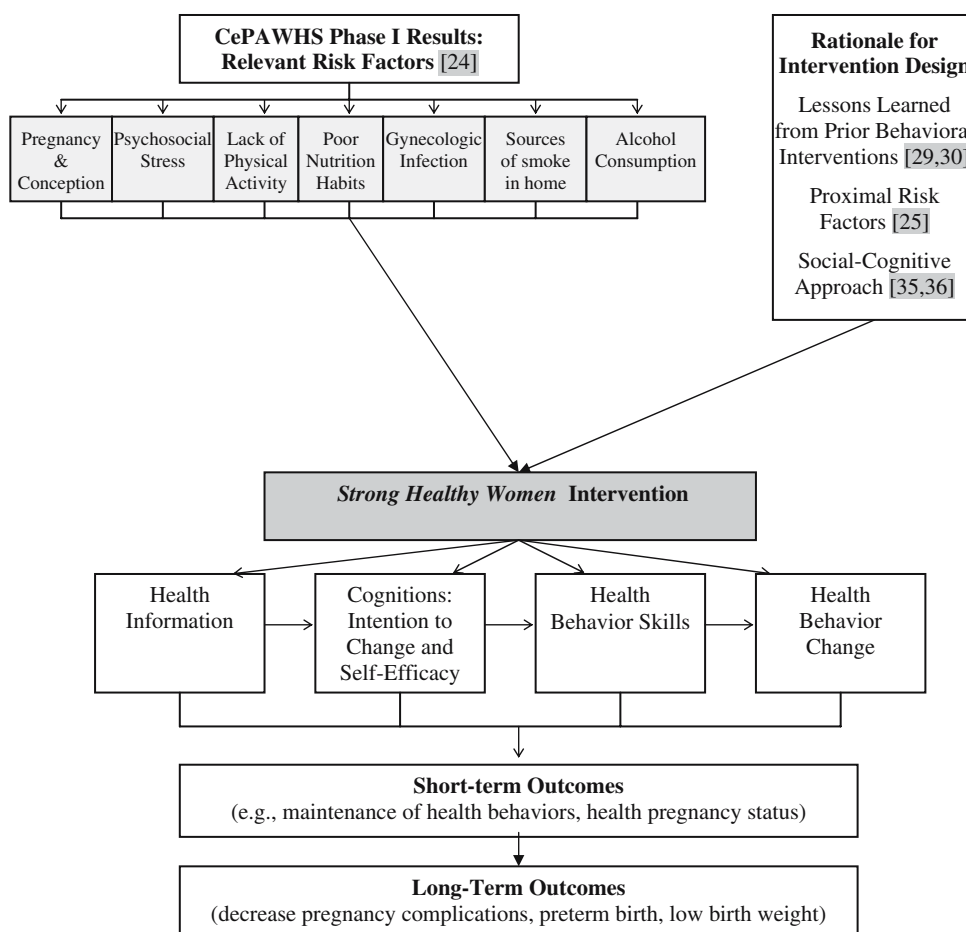
The intervention is a multidimensional program to improve women's preconceptional health. This is an innovative approach to preventing adverse pregnancy outcomes such as preterm birth and low birthweight. The rationale for the intervention is based on three primary components: (1) proximal determinants of health, (2) prior successful behavior change interventions, and (3) the social cognitive approach (see Fig. 1). First, the decision to develop a

preconceptional as opposed to prenatal intervention program is based on the “integrated perinatal health framework” by Misra and her colleagues [25]. This framework incorporates a lifespan perspective on reproductive health and classifies risk factors for adverse pregnancy outcomes based on the Evans and Stoddart [28] model of health determinants. This classification distinguishes between “distal” (e.g., family context, genetic factors) and “proximal” (e.g., psychosocial stress, chronic conditions, etc.) determinants of health. The proximal factors are those that appear to be modifiable within the context of a health behavior change intervention and in turn, may improve birth outcomes.

Second, model intervention programs such as the Diabetes Prevention Program [29] and WISEWOMAN [30] have established that a health behavior change approach is a potentially effective means of promoting behavior change and improved health. Research on behavior change interventions related to risk behaviors (e.g., smoking cessation, nutrition, physical activity, and stress reduction) provides evidence of the effectiveness of multi-session group approaches for diverse female participants. For example, the WISEWOMAN project, in its enhanced intervention component, used group-based activities to reduce cardiovascular risks (poor nutrition and physical inactivity) in low-income women [31]; psychoeducational support groups were used to help reduce stress in African American working women [32]; and group sessions over a 12-month period were used to influence dietary and activity patterns in low-income postpartum women [33].

Third, interventions to promote health behavior change must be based on a theoretical understanding of the psychosocial constructs to best guide hypotheses testing and prediction [34]. That is, to intervene effectively, we need to understand what facilitates and inhibits behavior change. The social-cognitive approach, which has guided the development of several effective education and health behavior change interventions, is used as the theoretical framework for the behavior change strategy employed in the intervention. Social Cognitive Theory [35] assumes that behavior is goal-directed and people are capable of self-regulation. Self-efficacy, the belief in one's ability to attain a goal, is the primary mediator of behavior change [35]. In addition to self-efficacy, one's motivation for changing behavior (i.e., level of intention) is an important determinant of behavior [36]. Thus, the intervention content of *Strong Healthy Women* was tailored to strengthen women's level of motivation (i.e., intention) to make behavioral changes and to increase their perceived ability to perform the new behavioral changes (i.e., self-efficacy). Furthermore, the role of social support for facilitating behavior change is recognized as an important element in most cognitive behavioral interventions [36]. *Strong Healthy Women* is delivered to women in small groups and a

**Fig. 1** Conceptual framework guiding rationale for strong healthy women intervention



“buddy system” is employed such that women are paired up with another person in their group to receive weekly phone calls for support and encouragement. Through increased health-related knowledge, motivation, social support for change, and self-regulation skills, the intervention aims to help women gain a sense of personal control, and in turn, increase their self-efficacy to perform healthy behavior changes (e.g., increase physical activity, healthy eating, decrease sources of smoke in the home, etc.). Collectively, these three components (i.e., proximal determinants, prior model intervention programs, Social-Cognitive Theory) along with the results from the Phase 1 population-based study (identifying the relevant risk factors for poor pregnancy outcomes in the test population) influenced the development of the content areas of the *Strong Healthy Women* intervention.

**Key Attributes of the Intervention**

This innovative intervention targets health behavior changes in the preconceptional and interconceptional period. Some key attributes of this approach include:

- Population-based (i.e., it is based on population-level data and is implemented with women recruited in clinical and community settings in Central Pennsylvania).
- Multidimensional (i.e., addresses multiple biopsychosocial risks for preterm birth and low birthweight and targets multiple health-related outcomes such as self-efficacy, health behavior change, access to healthcare, and health status).
- Offered in group settings rather than one-on-one clinical encounters.
- Delivered to women in Central Pennsylvania residing in low-income rural communities.

**Intervention Content**

Overview

The intervention content of *Strong Healthy Women* was developed by a multidisciplinary team of co-investigators led by the first two authors. The content was assessed by

members of the CePAWHS Executive Committee and modifications were made as needed. A set of behavioral objectives guide each of the content areas and these are discussed below. The end result was content addressing the following topics: pregnancy and conception, stress, physical activity, nutrition, infection, sources of smoke in the home, and substance use/abuse (i.e., tobacco and alcohol use).

The specific content and style of presentation to address each topic was developed with general communication guidelines in mind. For instance, we considered the issue of a *persuasion dilemma* [37]. In view of the reality that the ultimate goal in the intervention is to improve preconceptional health to ultimately enhance pregnancy outcomes, communication may arouse anxieties or fears; and/or distort or manipulate information to achieve these aims. It is assumed that each one has the right to make decisions for herself on any matter affecting her so far as it does not harm others (i.e., the principle of autonomy). This principle suggests interventions should avoid “scaring” people into action. That is, we did not distort or manipulate the information through strategies such as selective information dissemination. We were also careful to avoid a *coercion dilemma*. That is, we did not employ approaches within the intervention that coerced women into making changes (e.g., need to quit smoking or leave the intervention); rather, the intervention content was informative and provided helpful suggestions for making behavior changes regardless of women’s choices to engage in unhealthy behaviors. We were careful to consider these communication issues in the development of the intervention content and delivery.

We organized the intervention content across the six sessions based on two major considerations. First, improving health-related behaviors in some areas is difficult as such behaviors (e.g., stress management, diet, and physical activity) are entrenched in longtime habits, preferences, and lifestyles. For such topics, we attempted to facilitate incremental change in attitudes and behaviors across several sessions [38]. Content in later sessions reinforced the earlier material, allowed for participants to discuss problems and receive supportive feedback. For other topics, health-related behavior is not as pervasive but rather enacted in a more limited sphere. For these areas (i.e., preconceptional healthcare), we addressed topics in only one or two sessions. Second, evidence from the Phase I population survey indicated that some risk factors (e.g., stress, physical inactivity, and poor nutrition) are more prevalent than other risk factors (e.g., alcohol, infection) in our target population. Thus, we dedicated more time for these higher prevalence risk factors across sessions.

In Session 1, we introduced each of the seven content areas and discussed their association with elevated disease risk including cardiovascular disease, stroke, diabetes,

cholesterol, hypertension, and immune disorders. Session 2 is comprised of information on pregnancy/conception, stress, physical activity, nutrition, and smoking, with time set aside for guided physical activity and relaxation sessions. The third and fourth sessions are focused on pregnancy/conception, stress, physical activity, and nutrition with time set aside for physical activity (e.g., guided aerobics, walking) and healthy eating demonstrations (e.g., reading food labels, grocery shopping trip). Session 5 is focused mainly on overcoming barriers to stress, physical inactivity, and poor eating habits. Session 6 was primarily dedicated to physical activity. The rationale for the order and sequence of the content is based on: (1) basic flow of content from other model interventions (e.g., DPP [29] and WISEWOMAN [30]); (2) pairing content based on topic area (e.g., having information about an exercise buddy paired with information about social support for overcoming barriers to stress within the same session); and (3) the goal of keeping the sessions interesting and engaging for the participants (e.g., a nearly 2-h session of just education is not as appealing as a 2-h session filled with interactive talk, physical activity, healthy eating demonstrations, etc). The seven content areas are presented below.

#### Content Area #1: Pregnancy and Conception

The three behavior change objectives of the pregnancy and conception content are: (1) taking a daily multivitamin with folic acid (0.4 mg); (2) planning the timing of the next pregnancy by (a) selecting an optimal spacing between pregnancies, (b) considering lifecourse development (e.g. education, employment, relationship quality and status), and (c) developing and utilizing planning, preparation, and organizational skills; and (3) accessing preconception care and addressing individual risk factors for poor pregnancy outcomes. The content thus includes: the benefits of good preconceptional health and folic acid for infant health and reduction of neural tube defects, identification of modifiable risk factors for adverse pregnancy outcomes and the importance of optimizing general maternal health. Regarding pregnancy planning, the intervention content focuses on the effects of increasing age on conception and pregnancy, the benefits of optimal pregnancy spacing, the potential consequences of an unplanned pregnancy, lifecourse factors related to pregnancy timing (e.g., health status, financial circumstances, career/school goals, etc.), and available family planning methods (e.g., contraception, natural family planning, abstinence, etc.). In addition, the content focuses on the essentials of genetic screening and vaccinations (e.g., hep-B, rubella, varicella) to identify individuals risks for adverse pregnancy outcomes. With

each issue, emphasis on the actions that women might take to enhance their control over their health and possible future pregnancy outcomes is addressed.

#### Content Area #2: Stress

The three behavior change goals of the stress content are: (1) decreased overall physical and psychological stress, (2) increased problem solving and coping skills, and (3) increased amount of sleep. The content includes information about stress and the role that unhealthy behaviors play in increasing daily stress; identifying personal sources of stress; physiological stress responses; the connection between stress, emotions, and psychological health; strategies for coping with stress and ways to solve problems; and the benefits of and strategies for promoting increased relaxation and sleep in daily life. Again, the aim is to include strategies that any woman might adopt to enhance her motivation, self-efficacy, and well-being while reducing and coping with daily stressors.

#### Content Area #3: Physical Activity

The three behavior change objectives of the physical activity content are: (1) meet physical activity guidelines during the intervention and follow-up (i.e., at least 30 min of moderate to strenuous physical activity on most, if not all, days of the week; ACSM [27]), (2) achieve personal exercise goals, and (3) improve psychosocial determinants (i.e., exercise beliefs and attitudes, social support, and self-efficacy) and barriers of physical activity participation. The content includes the benefits of regular exercise behavior and the importance of meeting the current exercise guidelines; basic principles of goal setting, exercise training, and general adaptations to walking and jogging; importance of social support for exercise and sources of support for exercise in one's personal environment; and helpful tips for overcoming exercise barriers and staying motivated for life-long exercise behavior. Women are encouraged to engage in regular exercise behavior (i.e., meet the guidelines for exercise behavior) in their own environment. Support for these recommendations included: (1) women are given a pedometer and tracking log to self-monitor their daily activity steps, (2) each woman uses an individual goal-setting and tracking sheet and the intervention leaders provide tailored feedback on strategies to increase daily physical activity (e.g., park farther away from the store, use the steps instead of the elevator, etc.); and (3) women are encouraged to find an exercise buddy at home (e.g., family member, friend, etc.) to exercise with on days that the intervention does not meet. The objective is to

expose women to guided physical activity and increase women's physical activity motivation and self-efficacy to engage in more free-living physical activity that is done in their own environment (e.g., home, work, and leisure).

#### Content Area #4: Nutrition

The two behavior change goals of the nutrition content are: (1) increasing healthy food choices, and (2) increasing consumer food knowledge. The content includes discussion of personal barriers (e.g., no time to make a healthy meal); factors that promote healthy eating (e.g., self-recognition of success in packing a healthy lunch versus going out to a fast food restaurant); tips on storing fruits and vegetables to maximize freshness; understanding food labels and ingredients lists, sources of calcium, iron, folate, and protein in foods; and recognition of appropriate portion sizes for common foods. The integrative nature of lesson content is well illustrated in this lesson. An emphasis on folic acid is linked to efforts to understand and comprehend the sources of food folate. Efforts to integrate the program into women's lives is emphasized via links to the likelihood that women would dine at fast food restaurants, do the grocery shopping, and prepare foods in the home.

#### Content Area #5: Infection

The two behavioral objectives of the infection content are: (1) decreasing behaviors that increase vaginal infections (e.g., inappropriate antibiotics, douching), and (2) seeking medical attention when necessary. The content includes description of common causes of vaginal infections; the importance of healthy bacteria in the vagina for preventing bacterial vaginosis, which is related to preterm labor; activities that reduce "good" bacteria in the vagina (e.g., douching, multiple sexual partners, etc.); and seeking medical attention when a woman is experiencing symptoms of vaginal infection. The behavioral objectives of the infection content thus emphasize improving health for both the woman and a future pregnancy as is also the case in other areas of the intervention (e.g., optimizing management of chronic medical conditions).

#### Content Area #6: Sources of Smoke in the Home

The two behavioral goals of the smoking content are: (1) examining the home for sources of smoke, and (2) removing sources of smoke from the home. Because the personal habit of smoking is one that is hard to change, the planned intervention sought to introduce novel content

associated with the benefit of others in addition to the individual woman. As a result, we connect to information about a growing incidence of asthma and sources of environmental smoke. In view of the geographical location of the intervention, many homes are heated with sources that may introduce smoke into the home. The content thus includes understanding the relation of indoor air quality and smoke-free homes to good preconceptional and prenatal health and identifying factors that facilitate (e.g., supports) and inhibit (e.g., barriers) change to the home environment.

#### Content Area #7: Substance Use

The two behavioral objectives of the substance use content are: (1) decreasing alcohol and tobacco use, and (2) increasing positive beliefs and attitudes toward healthy alternatives. The content includes health risks of alcohol and tobacco use for both women and their families; the impact of alcohol and tobacco use on preconceptional and prenatal health; barriers and supports for reducing/stopping alcohol and tobacco use; recommendations for alcohol and tobacco use in pregnancy; reasons for alcohol and tobacco use or nonuse; and healthy alternative options to integrate into daily living.

#### Intervention Delivery

The content of the *Strong Healthy Women* program is currently being delivered to women randomized to the intervention condition in small group settings (e.g., 10–12 women) occurring biweekly over a period totaling 12 weeks. The group sessions are led by a pair of trained group leaders. Group leaders participate in a comprehensive two-day training session that included the following components: (1) overview of the CePAWHS project; (2) recruitment strategies and procedures; (3) informed consent procedures; (4) risk assessment protocol (e.g., psychological and biological measures such as height, weight, blood glucose, lipids; will be reported separately when the intervention results are available); (5) training in group facilitation techniques; and (6) in-depth discussion of the content of the intervention sessions. The intervention sessions are conducted with women in a variety of community settings, including WIC facilities, church buildings, and community centers. During the weeks in between the biweekly group meetings, participants receive a phone call from their group leader reinforcing the behavioral and learning objectives and addressing questions and concerns.

#### Primary Outcomes

The intervention is designed to enable women to improve their health by providing them with information and behavior change skills. The primary outcomes of interest will be quantified through comparison of the baseline and follow-up risk assessment information, and include:

1. Improved health literacy regarding healthy dietary intake and physical activity levels, multivitamin use, stress reduction, reproductive health, and reliable sources of health information.
2. Improved behavior change skills in relation to physical activity levels, dietary intake, maintaining a smoke free home, alcohol use, multivitamin use, and stress reduction.
3. Increased self-efficacy for health behaviors.
4. Actual behavior change as evidenced by more optimal self-reported physical activity patterns, dietary intake, maintaining a smoke free home, alcohol use, multivitamin use, reported stress reduction, and improved anthropomorphic and biophysical measurements.

Short- and medium-term outcomes of interest include maintenance of health behaviors, healthy pregnancy status, and in longer-term follow-up, reduction of adverse pregnancy outcome risks (e.g., complications, low birth weight, and preterm delivery).

#### Program Fidelity

To assess the fidelity of the intervention as delivered, we videotaped one or two sessions for each group, and are rating these sessions on a number of dimensions. Aspects of group leader competence and style are rated such as time management, confidence, friendliness, and clarity of presentation. In addition, for each segment of the intervention, we are coding the percentage of content that was delivered. These measures will be useful in diagnosing strengths and weaknesses of intervention delivery, as well as exploring whether intervention fidelity is related to outcomes. After the intervention is completed, a small sample of women who completed the intervention (i.e., completed all sessions) and those who did not (e.g., dropped out, left early, only complete some of the sessions) will be contacted via phone to complete a formal evaluation of the program.

#### Incentives

Incentives are provided to the participants for completing segments of this study. Participants receive gift cards to local grocery stores, gas stations, retail stores, and

restaurants in the amount of US \$20 for the baseline risk assessment and each intervention session, US \$25 for the follow-up risk assessment, and US \$20 for each follow-up telephone call at 6 and 12 months after the intervention.

## Discussion

The *Strong Healthy Women* intervention is the first program of its kind designed to improve health behaviors among women specifically in the preconceptional and interconceptional periods. The development and implementation of this intervention has important implications given the 2006 CDCP report [16] emphasizing preconceptional health. The *Strong Healthy Women* intervention has direct relevance to one of the goals of this report (i.e., ensure that all U.S. women of childbearing age receive preconception care services screening, health promotion, and interventions that will enable them to enter pregnancy in optimal health) and it may provide researchers and healthcare professionals with a model for developing ideal interventions for women during this time.

The results of the current randomized intervention trial will provide insight on the impact of health behavior change modifications among preconceptional and interconceptional women. In addition, the study findings will inform the use of a multidimensional intervention for improving women's immediate health and their future pregnancy and postpartum health status. These findings will be reported separately when all follow-ups are completed. Whether or not the *Strong Healthy Women* intervention program proves to be effective at improving women's health and reducing adverse pregnancy outcomes, this intervention protocol offers researchers and healthcare professionals a tool for initiating preconceptional health programs. It may also inform clinical practice by illustrating the types of health behaviors (i.e., the content areas of the intervention) that should receive focus in standard clinical care.

The next steps of our work include: (1) utilizing the formal evaluations from the participant and leader feedback, as well as outcome results, to determine if adjustments, modifications, and/or changes to the intervention content and delivery should be made; (2) determine whether the content of this behavioral intervention can be translated for use in preconception and interconception clinical care, employed in other community settings, or applied to other populations; (3) explore alternative delivery mechanisms (e.g., one-on-one consultation, Internet, etc). It is important to note that this intervention has been designed specifically to target risk factors that are problematic in rural communities in Central Pennsylvania. Although we suspect the risk factors targeted in this

intervention are common risk factors across the country, the translation and dissemination to other communities will be essential for determining the broad public health impact this intervention may have on women's preconceptional and interconceptional health.

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