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IMPROVING WOMEN'S PRECONCEPTIONAL HEALTH
Findings from a Randomized Trial of the *Strong Healthy Women* Intervention in the Central Pennsylvania Women's Health Study

Marianne M. Hillemeier, PhD[a,*], Danielle Symons Downs, PhD[a], Mark E. Feinberg, PhD[a], Carol S. Weisman, PhD[b], Cynthia H. Chuang, MD[b], Roxanne Parrott, PhD[c], Diana Velott, MPA[b], Lori A. Francis, PhD[a], Sara A. Baker, MSW[b], Anne-Marie Dyer, MS[b], and Vernon M. Chinchilli, PhD[b]

[a]*Pennsylvania State University, College of Health and Human Development, University Park, Pennsylvania*
[b]*Pennsylvania State University, College of Medicine, Hershey, Pennsylvania*
[c]*Pennsylvania State University, College of Liberal Arts, University Park, Pennsylvania*

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Purpose. **Improving the health of women before pregnancy is an important strategy for reducing adverse pregnancy outcomes for mother and child. This paper reports the first pretest–posttest results from a randomized trial of a unique, multidimensional, small group format intervention, *Strong Healthy Women,* designed to improve the health behaviors and health status of preconceptional and interconceptional women.**

Methods. **Nonpregnant pre- and interconceptional women ages 18–35 were recruited in 15 low-income rural communities in Central Pennsylvania ($n = 692$). Women were randomized in a ratio of 2-to-1 to intervention and control groups; participants received a baseline and follow-up health risk assessment at 14 weeks and completed questionnaires to assess behavioral variables. The analytic sample for this report consists of 362 women who completed both risk assessments. Outcomes include measures of attitudinal and health-related behavior change.**

Main Findings. **Women in the intervention group were significantly more likely than controls to report higher self-efficacy for eating healthy food and to perceive higher preconceptional control of birth outcomes; greater intent to eat healthy foods and be more physically active; and greater frequency of reading food labels, physical activity consistent with recommended levels, and daily use of a multivitamin with folic acid. Significant dose effects were found: Each additional intervention session attended was associated with higher perceived internal preconceptional control of birth outcomes, reading food labels, engaging in relaxation exercise or meditation for stress management, and daily use of a multivitamin with folic acid.**

Conclusions. **The attitudinal and behavior changes attributable to the intervention were related primarily to nutrition and physical activity. These results show that these topics can be successfully addressed with pre- and interconceptional women outside the clinical setting in community-based interventions.**

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* Correspondence to: Marianne M. Hillemeier, PhD, Department of Health Policy and Administration, Pennsylvania State University, 604 Ford Building, University Park, PA 16802.

E-mail: mmh18@psu.edu.

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Recent recommendations to improve preconception health and health care in the United States have inspired calls for innovative approaches to reduce adverse pregnancy outcomes, including strategies for improving women's health before they become pregnant (Haas et al., 2005; Korenbrot, Steinberg, Bender, & Newberry, 2002; Moos, 2004). The Centers for Disease Control and Prevention (CDC, 2006) recommends

a multipronged strategy for improving women's health before pregnancy through greater access to clinical care, community-based health promotion programs, and a focus on individuals' health-related behavior. Addressing the latter 2 points, we developed the *Strong Healthy Women* intervention to improve health-related behaviors, attitudes, and health status among pre- and interconceptional women recruited in community settings (Downs et al., 2008). This paper reports the pretest–posttest results of a randomized trial of this unique multidimensional behavior change intervention.

Adverse pregnancy outcomes including preterm birth and low birthweight remain high-priority public health problems (Hamilton, Martin, & Ventura, 2007a; Institute of Medicine [IOM], 2006), and are linked with infant mortality and neurodevelopmental morbidity that can impair health and functioning throughout childhood and beyond (Anderson & Doyle, 2003; Bhutta, Cleves, Casey, Cradock, & Anand, 2002; IOM, 2006; Singh & Yu 1995). According to recent IOM estimates, the annual societal economic burden associated with preterm birth in 2005 was $51,600 per infant, totaling at least $26.2 billion for the United States as a whole (IOM, 2006). Moreover, the economic and health-related costs of preterm and low birthweight are like to fall disproportionately on low-income and minority families (Gilbert, Nesbitt, & Danielsen, 2003; IOM, 2006; Petrou, 2003; RAND, 1998).

Despite increasing rates of prenatal care utilization, rates of adverse pregnancy outcomes have risen substantially during the past 2 decades. The preterm birth rate increased from 9.6% in 1983 to 12.8% by 2006, and the low birthweight rate increased from 6.8% to 8.3% during the same time period (Hamilton et al., 2007a). Multiple gestations do not account for this upswing (Hamilton et al., 2007b). The combination of increased prenatal care and deterioration in these benchmarks have stimulated a paradigm shift in strategies to improve women's health and pregnancy outcomes from a focus on the prenatal period to the preconceptional period (Moos, 2004).

This shift in focus is also prompted by the recognition of several factors. First, multiple risk factors for adverse pregnancy outcomes have been identified in the literature (e.g., obesity, chronic disease, nutritional deficiencies, and behavior patterns including physical inactivity, smoking, and alcohol use), and large percentages of women enter pregnancy with $\geq$1 of these risk factors (Anderson, Ebrahim, Floyd, & Atrash, 2006; CDC, 2006). Second, increasing numbers of women are delaying childbearing (Martin et al., 2006), with the result that more women have a chronic health condition (e.g., overweight, hypertension) when they become pregnant for the first time. Third, the articulation of a lifespan perspective on women's health—in which health-related issues at 1 life stage affect health at later life stages—suggests that early intervention in women's health can reduce cumulative risks and impact pregnancy outcomes at later stages of life (Misra, Guyer, & Allston, 2003). To date, however, little research addresses the effectiveness of approaches to reduce adverse pregnancy outcomes by improving the physical and psychological health of women before pregnancy.

The Central Pennsylvania Women's Health Study

The *Strong Healthy Women* intervention was developed as part of the Central Pennsylvania Women's Health Study (CePAWHS), funded by the Pennsylvania Department of Public Health (Miller et al., 2007; Weisman et al., 2006). CePAWHS consisted of 2 phases. In the first phase, population-based survey data were collected for women of reproductive age to ascertain the prevalence of multiple risk factors for adverse pregnancy outcomes in a 28-county region of Central Pennsylvania. This region was chosen because it is diverse with respect to socioeconomic status and includes urban as well as rural and semirural locations. Survey participants reported high levels of multiple risk factors for adverse pregnancy outcomes compared with both the US and Pennsylvania female populations of comparable age. The risk factors that were relatively high in Central Pennsylvania included obesity measured by body mass index (BMI $\geq$30), depressive symptoms, low fruit and vegetable consumption ($<$1/day), alcohol use, binge drinking (defined as $\geq$5 drinks on 1 occasion in the past month), cigarette smoking, and nonuse of folic acid supplementation. Respondents also reported lack of regular physical activity (less than one third of women engaged in $\geq$30 minutes of moderate strenuous exercise on most days of the week), high rates of gynecologic infections, and high levels of psychosocial stress from multiple sources, including job and financial issues and unfair treatment owing either to race/ethnicity/culture or gender (Weisman et al., 2006). Most of these risk factors have been linked in prior research with elevated risk for preterm birth and low birthweight outcomes (Hillemeier, Weisman, Chase, & Romer, 2006; IOM, 2006; Misra et al., 2003).

In the second phase of CePAWHS, the population-based information from Phase I was used to develop a multidimensional behavioral intervention, *Strong Healthy Women*, to address the prevalent modifiable risk factors identified in Phase I. Detailed description of the development of this intervention is available elsewhere (Downs et al., 2008). Briefly, the rationale for the targets and approach of the group format, multisession intervention was based on 3 primary considerations: 1) the risk factors identified in CePAWHS Phase I; 2) prior successful behavior change interventions such as the Diabetes Prevention Program (Diabetes Prevention Research Group, 2002) and WISEWOMAN (Viadro,

Farris, & Will, 2004; Will, Farris, Sanders, Stockmyer, & Finkelstein, 2004; Will et al., 2001); and 3) the social cognitive approach to behavior change.

Our social cognitive approach to behavior change is based partly on Social Cognitive Theory (Bandura, 1986), which 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. In addition to self-efficacy, motivation and intention to change are important determinants of behavior change (Ajzen, 1991). Thus, the intervention content was designed to strengthen women's level of motivation and intention to make behavioral changes. For example, motivation was addressed through education about the link between current health-related behaviors and the future health of the woman, her child, and family generally. The intervention content also aimed to enhance participants' perceived ability to perform the new behavioral changes (i.e., self-efficacy). We chose a group format approach in part because social support is recognized as an important element in facilitating behavior change (Ajzen, 1991).

The content areas addressed in the *Strong Healthy Women* intervention included pregnancy and conception, managing stress, physical activity, nutrition (including folic acid supplementation), preventing gynecologic infection, tobacco exposure, and alcohol use. This content was integrated across six 2-hour sessions over a 12-week period. The 6 sessions were organized as follows: Session 1 introduced the content areas, set expectations, and established the buddy system (dyadic mutual support phone calls) and homework assignments. Session 2 provided information on stress and problem solving, smoking, physical activity, and gynecologic infections in relation to pregnancy, with time set aside for guided physical activity and relaxation modules. Sessions 3 and 4 focused on preconception health, stress and social support, physical activity, avoiding second-hand smoke, and nutrition, with time set aside for physical activity (e.g., guided aerobics, walking) and in healthy eating demonstrations (e.g., reading food labels, grocery shopping trip). Session 5 focused mainly on preconception health services, alcohol use, physical activity, and healthy eating. Session 6 addressed relaxation techniques, contraception, physical activity, and healthy eating.

In a randomized trial, we tested the effectiveness of the *Strong Healthy Women* intervention in improving self-efficacy for behavior change, behavioral intent, and behavior change in the topic areas addressed by the program. This trial represents an initial assessment of whether such an approach can enhance women's health and reduce the risks of adverse pregnancy outcomes among pre- and interconceptional women. In this report, we present results at posttest.

Methods

Overall study design

A randomized controlled trial of the *Strong Healthy Women* intervention was conducted in 15 low-income rural communities within the 28-county Central Pennsylvania region. Low-income rural communities were targeted because women in these communities were shown to have high rates of risk factors for adverse pregnancy outcomes in the Phase I CePAWHS population-based surveys.

The randomized trial study design is shown in Figure 1. The study was approved by the Penn State College of Medicine Institutional Review Board. Women recruited to the study provided written informed consent administered by trained study facilitators and completed a baseline risk assessment that included a self-administered 20-minute questionnaire prepared at the 7th-grade reading level. In addition to survey measures, several clinical assessments were collected, including anthropometric measurements (height, weight, waist circumference, and calculated BMI); and biomarkers (blood pressure, non-fasting blood glucose, total and high-density lipoprotein [HDL] cholesterol). All participants were given a printed report of their anthropometric and biomarker readings at the conclusion of each risk assessment, and individuals whose biomarker values fell outside the normal range were referred to a health care provider. After the baseline risk assessment, participants were randomized using a 2-to-1 ratio to either the intervention or control group. Because the study was conducted at 15 different sites, stratified randomization was performed according to site. Data checks were performed during the course of the study to ensure that women were randomized according to protocol.

Women in the intervention group were invited to participate in 6 biweekly small group sessions of the *Strong Healthy Women* intervention, beginning approximately 2 weeks after the baseline risk assessment. These group sessions were led by group facilitators who were trained for this project by the study investigators; training included grounding in the content of the intervention as well as techniques for group facilitation and successful group dynamics. Fidelity monitoring was conducted using videotapes of a sample of group sessions (2 videotaped sessions per group of women) that were rated systematically for adherence to the study protocol and for completion of content for each session. Each session was coded for the percentage of content delivered; across all sessions and groups, an average of 77% of the content was delivered, with some variation across topic areas. Participants who were unable to attend a session were provided with session materials and given the opportunity for a short make-up session before the next group meeting. Very few women took advantage of

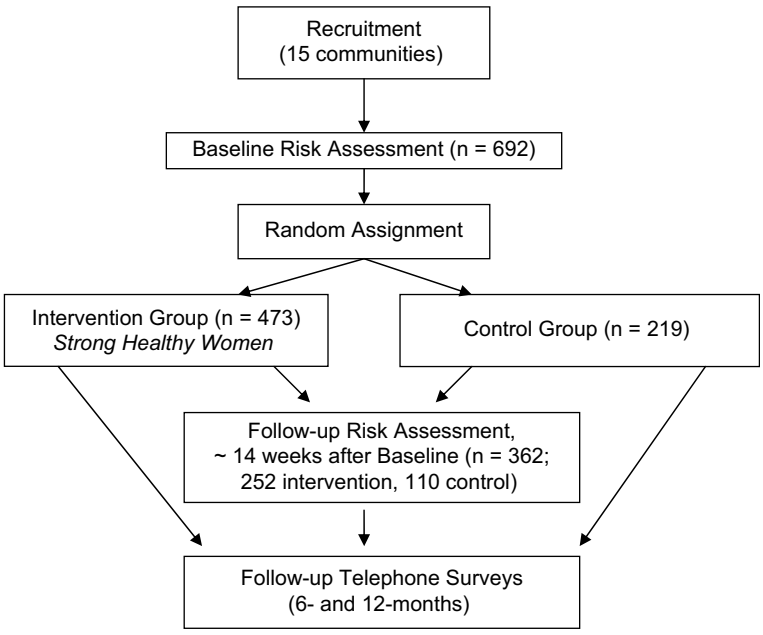

Figure 1. Randomized trial design.

the make-up sessions, and the make-up sessions are not counted in the dose–response analyses.

Women in both the intervention and control groups were invited back for a follow-up risk assessment, scheduled approximately 14 weeks after the initial baseline assessment, to obtain repeated measurement of the questionnaire, anthropometric measures, and biomarkers. Data collected over the study period from the baseline risk assessment through the follow-up risk assessment are presented in this manuscript. Long-term follow-up of all women in both conditions (by telephone interviews at 6 and 12 months after the follow-up risk assessment) to assess maintenance of behavior change is currently ongoing, and results are not yet available. Study participants received gift card incentives (e.g., $20 from local grocery stores) for attendance at each study session, including the risk assessments, the intervention sessions, and the follow-up telephone interviews.

Recruitment

Nonpregnant women ages 18–35 who were capable of pregnancy ($n = 692$) were recruited in 15 low-income, rural communities using a triangular community-based approach which has been described elsewhere (Velott, Baker, Hillemeier, & Weisman, 2008). Briefly, this approach combined partnering with a local community organization—a public service, not-for-profit agency, health care facility, or educational group—with the use of both active and passive recruitment methods tailored to the local community. Active methods involved direct communication between a study recruiter and potential participants at a community location; passive methods included use of the media, mailings, and posters/flyers. Recruitment materials designed specifically for CePAWHS were an essential ingredient of both the active and passive recruitment methods. Although recruitment targeted low-income rural communities, some of the women recruited in these communities resided in adjacent areas that were not predominantly low income or rural. Nevertheless, our recruitment approach yielded a sample of women of lower socioeconomic status and from more rural locales than women of comparable reproductive life stage, age, and county of residence in the general Central Pennsylvania population (Velott et al., 2008).

Sample

Eligibility criteria for inclusion in the study included residence within the 28-county target study region; ages 18–35; not pregnant at the time of enrollment; and capable of becoming pregnant in the future (i.e., no history of tubal ligation, hysterectomy, or other known cause of infertility). Exclusion criteria included non-English speaking. The 18–35 age range was chosen because women ages 18–35 account for >85% of live births in Central Pennsylvania and are therefore the appropriate target audience for a study focusing on pregnancy and birth-related risk factors.

The original sample size calculation was based on randomizing 500 women (in a 2-to-1 ratio of intervention to control) to achieve 80% statistical power for each primary outcome variable with a 2-sided, 0.05 significance level test, while allowing for a 30% dropout rate. Thus, the target of 80% statistical power would be met if 350 women completed the study. In actuality, 692 women were randomized, 362 of whom completed

the study. Therefore, the target of 350 completers was met.

The analytic sample for the pretest–posttest findings presented here ($n = 362$) includes those women who attended both the baseline and follow-up risk assessments. Women who did not attend the follow-up risk assessment were excluded because posttest data were not available; 47% of participants in the intervention group and 50% of the women in the control group did not attend the follow-up risk assessment.

Measures

Dependent variables. Consistent with the social cognitive model, dependent variables included self-report measures of self-efficacy, behavioral intent, and behavior associated with the specific content areas addressed in the intervention: pregnancy and conception, stress management, physical activity, nutrition (including folic acid supplementation), gynecologic infection, tobacco exposure, and alcohol use. All measures were designed to apply to all participants, regardless of their baseline value on the risk factor.

The measures of self-efficacy assessed the individual's level of self-confidence that she could engage in the desired behavior, on a 4-point scale ranging from "not at all confident" to "completely confident," when confronted with specific barriers. For example, for physical activity, the question read, "How confident are you that you could get enough physical activity even if…," and a list of 13 common barriers to physical activity followed (e.g., "The weather was very bad," "I was pregnant"). In addition, internal control of birth outcomes was measured using a single item assessing perceived Preconceptional Control (Weisman et al., 2008). Because the intervention focused on improving women's health to reduce adverse pregnancy outcomes, the hypothesis was that the intervention would increase perceived preconceptional control of birth outcomes related to the baby's health.

The measures of behavioral intent assessed the individual's intent of engaging in healthy behaviors "over the next 4 months," using a 7-point scale ranging from strongly disagree to strongly agree. For example, for physical activity, the question read, "On a scale of 1 to 7, how much do you agree or disagree with the following statement: I intend to be more physically active over the next 4 months?" For analysis, responses in the upper end of the scale were collapsed for some variables due to infrequent number of responses.

Specific behaviors were measured by self-report. For example, for physical activity, questions assessed how many days per week the woman engaged in moderate or vigorous physical activity and how many minutes per day she engaged in moderate or vigorous physical activity; these questions were combined to assess whether the woman was meeting current exercise recommendations of $\geq$30 minutes of moderate to strenuous physical activity on most, if not all, days of the week (American College of Sports Medicine, 2000; Pate et al. 1995). Using questions adapted from the Behavioral Risk Factor Surveillance Survey and other sources, nutritional intake was measured by asking women how often in a typical week they consumed fruit (not counting fruit juice), green salad, vegetables (not counting carrots, potatoes, or salad), snack foods (such as chips, cookies, ice cream, frozen yogurt, and candy), dairy foods (such as milk, cheese, and yogurt other than frozen yogurt), and whole grains (such as whole wheat bread, brown rice, and cereal with fiber). We also assessed other nutrition-related behaviors, including how often they read labels on foods to compare products' nutritional value, and whether or not they use a daily multivitamin that contains folic acid. Additional health-related behaviors measured included frequency and quantity of alcohol use; any use of tobacco products including cigarettes; vaginal douching; receiving preventive gynecologic examinations; sleep patterns; and use of specific stress management techniques.

Anthropometric and biomarker indicators of health status were measured using standardized equipment and measurement techniques across sites, including digital scales for measuring weight and height; plastic measuring tapes for measuring waist circumference; and blood pressure monitors with appropriate cuff sizes. Anthropometric indicators included weight (pounds and fractions of pounds), height (inches), BMI (calculated from weight and height and analyzed as a continuous variable), and waist circumference (inches). Finger-stick blood samples were used to measure non-fasting glucose, HDL and total cholesterol, using the CardioChek P•A analyzer (Polymer Technology Systems, Inc., Indianapolis, IN). Additional health status indicators included systolic and diastolic blood pressure (mmHg), non-fasting serum glucose (mg/dL), HDL cholesterol (mg/dL), and total cholesterol (mg/dL). Anthropometric and biomarker measurements were taken by the trained facilitators, who were blinded to treatment condition (intervention or control group) when taking baseline measurements but not when taking follow-up measurements.

Independent variables. The main independent variable is treatment condition (either intervention or control group) for the pre–post analyses and the number of sessions attended (range, 0–6; mean, 4) for the dose–response analyses. In addition, age (18–35 years) and educational level (dichotomized as high school or less versus some college or more) at baseline were utilized as covariates.

Analyses

Intent-to-treat pre–post analyses were done with analysis of covariance. For this approach, the baseline

measure (or pretest) is included as a covariate to adjust for any differences in baseline measures, and the follow-up measure (or posttest) is the response. Analysis was performed using a general linear model, ordinal logistic regression, or ordinary logistic regression, depending on the response variable being analyzed. A test of the proportional odds assumption was run and satisfied for all ordinal logistic regression models. In addition to treatment condition and baseline measure, age and educational level at baseline were included in each model. Their inclusion resulted from a separate analysis, which showed that age and education were predictive of attendance at the follow-up risk assessment: older women within the 18–35 age range and more highly educated women (women with some college or more) were more likely to attend the follow-up risk assessment. Accordingly, age and educational level were controlled. We included site as a blocking factor in secondary statistical analyses even though we do not report these results in the summary tables. In every circumstance, the inclusion of site does not alter the interpretation of the significance of the intervention, although the tendency was for the inclusion of site to render a slightly more conservative result for the statistical significance of the intervention.

Dose–response analyses were performed in a manner similar to the pre–post analyses, with 2 differences. First, the sample was restricted to women randomized to the intervention group. Second, the number of sessions attended, a continuous variable ranging from 0 to 6, replaced treatment group as the independent variable of interest.

Results

For descriptive purposes, the sociodemographic characteristics of the analytic sample are shown in Table 1. The sample is quite diverse with respect to all sociodemographic variables except for race/ethnicity (reflecting the demographics of the population in the targeted low-income rural communities) and with respect to health care access (i.e., having a regular source of health care and health insurance status). No statistically significant differences in the sociodemographic characteristics of the intervention and control groups were found, with the exception of age: Women in the intervention group were 1.78 years older than women in the control group, on average. As noted, age is controlled for in pre–post analyses.

Pre–post changes (over the 14-week interval between the baseline and follow-up risk assessments) were analyzed for self-efficacy for behavior change, behavioral intent, self-reported behaviors, and both anthropometric and biomarker indicators of health status. Table 2 shows the statistically significant ($p <$ 05) pre–post changes for self-efficacy, behavioral intent, and behavior change related primarily to nutrition and physical activity. Women in the intervention group were significantly more likely than controls to report higher self-efficacy for eating healthy food. They were also more likely to perceive higher preconceptional control. Participation in the intervention was also associated with greater intent to eat healthier foods and to be more physically active. Statistically significant behavior changes included greater likelihood of reading food labels to identify nutritional values, using a daily multivitamin that contains folic acid, and meeting recommended levels of physical activity. Results for pre–post analyses of anthropometric and biomarker measures from the baseline and follow-up risk assessments are shown in Table 3. No statistically significant effects of the intervention were seen in these measures.

Because there was variation in the number of group sessions attended among the intervention participants,

Table 1. Baseline Sociodemographic Characteristics and Health Care Access, by Study Group (percentages and *n*)

Sociodemographic Variables	Intervention ($n = 252$)	Control ($n = 110$)	*p*-Value*
Marital status			
Married or living with a partner	59% (148)	48% (53)	
Never or formerly married	41% (103)	52% (57)	.058
Mean age in years (standard deviation)	26.52 (5.02)	24.74 (4.64)	.002
Educational level			
High school graduate or less	36% (91)	31% (34)	
Some college	33% (83)	32% (35)	
College graduate or more	31% (78)	37% (41)	.220
Race/ethnicity			
White, non-Hispanic	92% (231)	91% (100)	
Other (African American, Hispanic, Asian)	8% (19)	9% (10)	.424
Rural–urban residence†			
Urban-focused RUCA code	47% (118)	54% (59)	
Rural RUCA code	53% (134)	46% (51)	.645
Poverty status‡			
Poor	27% (58)	29% (24)	
Near poor	33% (70)	30% (25)	
Not poor	40% (85)	42% (35)	.968
Health care access			
Usual source of health care			
Yes	75% (189)	78% (86)	
No	25% (62)	22% (24)	.554
Health insurance			
Private	57% (144)	62% (68)	
Public (largely Medicaid)	25% (64)	19% (21)	
None	17% (44)	19% (21)	.428

* Tests of statistical significance are the χ^2 test, the Mantzel-Haenszel χ^2 test, or the *t*-test, as appropriate.

† Based on ZIP code approximation of Rural–Urban Commuting Area Codes. For more information, see http://depts.washington.edu/uwruca/new.html.

‡ US Census definitions based on household income and composition.

Table 2. Statistically Significant Pre–Post Intervention Effects

	Intervention Effect	*p*
Self-efficacy		
For eating healthy food†	GLM coefficient = 1.109*	.018
Preconceptional Control‡	Odds ratio = 1.916	.031
Behavioral intent§		
To eat healthier foods	Odds ratio = 1.757	.008
To be more physically active	Odds ratio = 2.185	.000
Behavior change		
Reads food labels for nutritional values‖	Odds ratio = 2.264	.001
Uses daily multivitamin with folic acid¶	Odds ratio = 6.595	.000
Meets recommended physical activity level#	Odds ratio = 1.867	.019

* GLM (Generalized Linear Models) or logistic regression models with dichotomous or ordinal responses were used, depending on the format of the dependent variable. All models were adjusted for preintervention level on the dependent variable, baseline age, and educational level (see text).
† Based on 8-item summated scale.
‡ Based on single-item measure of preconceptional control of birth outcomes (Weisman et al. 2008).
§ Based on a single-item 7-point scale (categorized).
‖ Based on a single-item 4-point scale (dichotomized).
¶ Recode of 2 questions; indicates whether or not woman uses daily multivitamin that contains folic acid.
# Recode of 2 questions; indicates whether or not woman meets recommendations for ≥30 minutes of moderate or vigorous physical activity on ≥4 days per week.

we examined the effect of number of sessions attended on all study outcomes among those women randomized to the intervention (Table 4). Significant dose effects were found for 1 measure of self-efficacy—Preconceptional Control of birth outcomes—indicating significant improvement with each additional session attended. Significant dose effects were also seen for several behaviors, including reading food labels, engaging in relaxation exercise or meditation for stress management, and daily use of a multivitamin with folic acid.

Discussion

This is the first report of findings from the CePAWHS randomized, controlled trial assessing the effectiveness of a behavior change intervention designed to improve the health of preconceptional and interconceptional women. The *Strong Healthy Women* intervention is a unique group format program targeting multiple health-related behaviors that are related to pregnancy outcomes. This initial randomized trial with pre- and interconceptional women recruited in low-income rural communities demonstrated a number of positive effects. The findings suggest that participation in the *Strong Healthy Women* intervention can significantly improve self-efficacy and behavioral intentions related to several risk factors for adverse pregnancy outcomes, as well as induce actual behavior change. Key attitudinal and behavior changes achieved were related to nutrition (including reading nutritional food labels and using folic acid supplementation, but not nutritional intake related to specific food groups) and physical activity levels. These are important findings; folic acid intake is associated with reduction in certain birth defects, and nutrition and physical activity are related to important areas of health risk, including overweight and obesity, diabetes, and cardiovascular health.

In addition, evidence was found for a dose–response effect in that the number of intervention sessions attended was linked with the strength of the intervention impact. Additional dose–response analyses were performed categorizing the number of sessions attended (data not shown). For several outcomes, intervention

Table 3. Pre–Post Analyses of Anthropometric and Biomarker Measures

Measurements	Intervention Effect (GLM coefficients)*	*p*-Value
BMI (kg/m^2)†	−0.036	.809
Weight (lbs)	−0.219	.806
Waist circumference (inches)	−0.112	.752
Blood pressure (mm Hg)		
Systolic	−0.856	.465
Diastolic	−0.014	.990
Blood tests (nonfasting)		
Serum glucose (mg/dL)	0.849	.798
HDL cholesterol (mg/dL)	−2.270	.246
Total cholesterol (mg/dL)	−3.119	.532

* GLM (Generalized Linear Models) coefficients are shown. All models were adjusted for preintervention level on the dependent variable, baseline age, and educational level (see text).
† Calculated based on height and weight and analyzed as a continuous variable.

Table 4. Statistically Significant Dose–Response Effects*

	Effect Per Each Additional Intervention Session Attended	
	Odds Ratio	*p*
Self-efficacy		
Preconceptional Control†	1.309	.002
Behavior change		
Reads food labels for nutritional values‡	1.161	.015
Does relaxation exercise or meditation to relax§	1.236	.009
Uses daily multivitamin with folic acid‖	1.448	.000

* Logistic regression models were estimated, and odds ratios are shown. All models were adjusted for preintervention level on the dependent variable, baseline age, and educational level (see text).
† Based on a single item measure of preconceptional control of birth outcomes (Weisman et al., 2008).
‡ Based on a single-item 4-point scale (dichotomized).
§ Based on 2 items indicating whether or not woman used each of these techniques for stress management in the past 2 weeks.
‖ Recode of 2 questions; indicates whether or not woman uses daily multivitamin that contains folic acid.

effects among those attending 3 sessions were significantly better than for those attending ≤2; also, the effects among those attending 3 sessions were not significantly different than for those attending ≥4 sessions. Hence, 3 sessions seems to be the optimum number of sessions. Feedback from the group facilitators and a sample of participants as part of a process evaluation provided some information about which modules were perceived as most interesting and effective, but there was no evidence that specific 2-hour sessions were less important than others. To assess this further, our future research will develop and test a 3-session version of the *Strong Healthy Women* intervention that covers the same topic areas but in a more compact format.

No significant differences in changes in anthropometric and biomarker measures were identified. We attribute these null findings to the relatively short interval of time between pre- and posttest (i.e., 14 weeks between baseline and follow-up risk assessments). Although it is possible to see changes in anthropometric and biomarker measures over this time period, such change would require relatively rapid and substantial change in behavior, rather than a gradual change, which is more realistic and attainable. In fact, the program content explicitly fostered gradual change by introducing potential behavior change in stages and providing support for the frequently tentative nature of initial change attempts. It is more likely that assessment after a longer follow-up period would allow detection of changes in these biomarkers. In future studies, we intend to conduct biomarker assessments over a 6-month follow-up period.

Other null findings are worth noting. The intervention had no significant effects on self-efficacy, behavioral intention, or behavior change in the areas of tobacco exposure (cigarette smoking and exposure to tobacco smoke in the home) and alcohol use. These are notoriously difficult behaviors to change, and it could be that the relatively brief attention to these topics within the context of the 6-session intervention was not sufficient to produce desired changes. In addition, we found no significant effects for use of stress management techniques, perhaps because the intervention could not address the underlying levels of stress experienced by participants. Finally, the intervention did not impact the prevention of gynecologic infections through reducing the use of vaginal douching or obtaining more preventive gynecologic health care; the latter might not be expected over a 14-week study period, because research shows that women seek preventive gynecologic health care approximately every 1–2 years (Salganicoff, Ranji, & Wyn, 2005). Our longer-term survey follow-up may show an impact on use of preventive health care. With modifications in the intervention, some of these topic areas could be addressed more effectively in future research.

The results of this randomized trial are promising for specific outcomes variables. However, although the sample was diverse with respect to socioeconomic status and rural–urban residence, the sample was racially homogenous (predominantly non-Hispanic white) owing to the demographic characteristics of the underlying rural Central Pennsylvania population. A goal of future research is to test the *Strong Healthy Women* intervention, after it has been modified based on our experience in this trial, in a more racial/ethnically and geographically diverse population.

The public health and policy implications of this study are noteworthy. The promising results of this initial field trial suggest that the health-related behaviors and health risks of pre- and interconceptional women can be addressed outside of the clinical setting in community-based behavior change programs. This is an important insight because effective behavior change programs are likely to be too time consuming and labor intensive for most clinical settings in which women receive routine health services before becoming pregnant. Furthermore, because this field trial recruited women in high-risk and geographically dispersed low-income rural communities, the findings also provide evidence that the behavior change intervention approach can be successful in challenging populations. Although policy and financing discussions about preconception health tend to focus on expanding access to clinical services, the public policy agenda could be broadened to include increasing the availability and financing of community-based approaches to preconception health promotion, particularly in underserved communities.

It is also noteworthy that women in the intervention group seem to have gained increased control over their own health. For example, the ability to read food labels was enhanced. This skill, which may be taken for granted, should be promoted at the community and population levels to increase the response efficacy associated with policies behind labeling. The findings can inform potential interventions related to enhanced health literacy in the nutritional domain.

The need to develop evidence-based programs to improve preconception health has been highlighted by the CDC (2006). This test of the *Strong Healthy Women* intervention provides initial evidence of the effectiveness of a unique program for reducing risks of adverse pregnancy outcomes among pre- and interconceptional women in high-risk communities. The results reported here provide the basis for further refinements to the *Strong Healthy Women* intervention as well as a model for future preconception health interventions.

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Author Descriptions

Marianne M. Hillemeier, PhD, is a sociologist/demographer with research interests in maternal and child health disparities.

Danielle Symons Downs, PhD, is an exercise psychology researcher whose interests include understanding the psychosocial and behavioral correlates of exercise in women and children.

Mark E. Feinberg, PhD, is a psychologist whose research focuses on family and community preventive programs.

Carol S. Weisman, PhD, is a sociologist and health services researcher with a principal interest in women's health care

Cynthia H. Chuang, MD, is a general internist with research interests in reproductive health care for women with chronic medical conditions.

Roxanne Parrott, PhD, is a health communication researcher with specific interests in women's health.

Diana Velott, MPA, is an instructor in health services research and project coordinator for a multisite study of fertility patterns following cesarean section delivery.

Lori A. Francis, PhD, is a developmental psychologist with research interests in eating behaviors and the family environment.

Sara A. Baker, PhD, is project director for the Central Pennsylvania Women's Health Study.

Anne-Marie Dyer, MS, is the data manager and chief data analyst for the Central Pennsylvania Women's Health Study.

Vernon M. Chinchilli, PhD, is a biostatistician with interests in clinical trails research.