Central Pennsylvania Women's Health Study *(CePAWHS):* *Strong Healthy Women* Intervention

Cynthia H. Chuang, MD, MSc
Carol S. Weisman, PhD
Marianne M. Hillemeier, PhD
Sara A. Baker, MSW

Penn State College of Medicine
Hershey, PA

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Strong Healthy Women is…

- An evidence-based behavioral intervention for improving the health of pre- and interconceptional women
- Designed to be administered in small groups with lay facilitators

What we will cover…

- Development of *Strong Healthy Women*
  - Assessment of target population
  - Content and format issues
- Testing of *Strong Healthy Women*
  - Evidence of effectiveness
  - Implementation issues
- Modifications to *Strong Healthy Women* and next steps

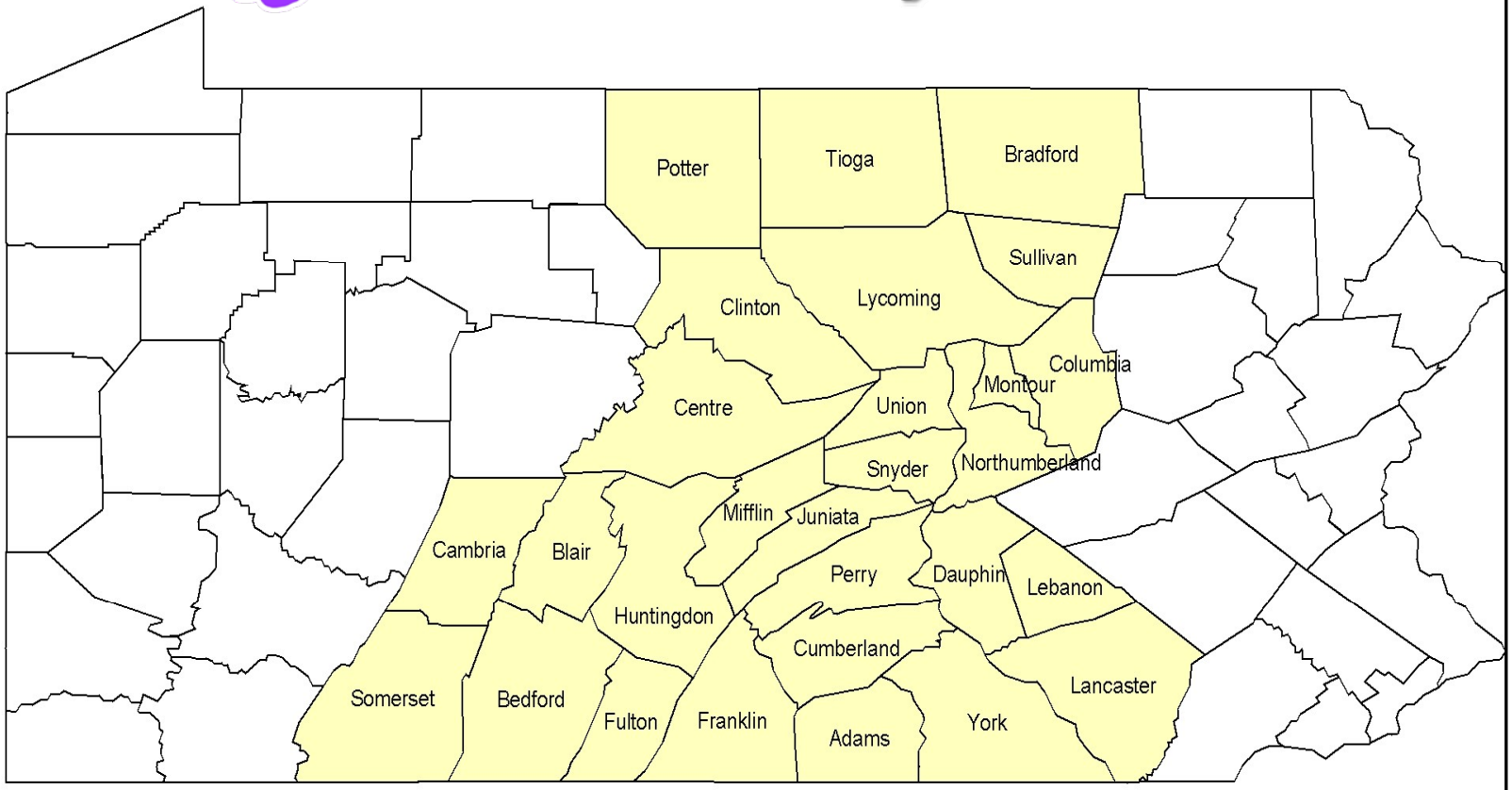
The Central Pennsylvania Women's Health Study (CePAWHS)

An ongoing program of research
to improve women's health
and pregnancy outcomes,
focusing on *pre- and interconceptional women*
in low-income rural and urban communities

Research Objectives

- To identify the key *risks* for adverse pregnancy experiences and outcomes in the population of women of reproductive age in Central Pennsylvania
- To design and test an intervention to reduce these risks in *pre- and interconceptional* women

Central Pennsylvania



28-county region with 3 mid-sized cities (Harrisburg, York, Lancaster) and a large rural population including from small towns and isolated rural areas

CePAWHS Phase I

Population-based surveys of reproductive-age women in Central PA

- *General population* (ages 18-45) *n = 2,002*
- *Amish population* (ages 18-45) *n = 288*

Objectives:

- To establish *prevalence* of multiple risk factors for adverse pregnancy outcomes
- To identify *subpopulations* at greatest risk

Survey Content

- Health status indicators (physical and mental health)
- Pregnancy history
- Health-related behaviors
- Psychosocial stress and exposures
- Health care access and patterns of care
- Sociodemographics

Preterm Birth, LBW, and Macrosomia

(CePAWHS general population sample, n = 2,002)

Among those who ever had a live birth (73%):

Ever had preterm birth (< 37 weeks gestation)	16%
Ever had LBW birth (<2,500 grams)	14%
First singleton birth preterm	9%
First singleton birth LBW	8%
First singleton birth macrosomic*:	
Grade 1: 4000-4499 g (labor and newborn complications)	12%
Grade 2: 4500-4999 g (neonatal morbidity)	3%
Grade 3: > 5000 g (infant mortality)	<1%

* Definitions from SL Boulet et al., *AJOG*, 2003

Prevalent Risk Factors in Central PA, Compared with PA and U.S.*

(women ages 18-45, weighted data)

	CePAWHS Sample	PA	U.S.
Obesity (BMI = 30+)	**23%**	18%	19%
Depression/anxiety diagnosis	**29%**	--	16%
Depressive symptoms (high)	**22%**	--	21%
Nutritional deficits:			
fruit < daily	**68%**	57%	60%
vegetables < daily	**56%**	31%	34%
Alcohol use (any)	**48%**	--	32%
Binge drinking (among drinkers)	**34%**	29%	23%
Cigarette smoking	**28%**	32%	23%
Folic acid supplementation	**38%**	53%	50%

* Comparison data sets include BRFSS 2003, Commonwealth Fund Survey of Women's Health 1998, National Health Interview Survey 2003

Other Prevalent Risk Factors*

(CePAWHS general population sample, unadjusted data)

	CePAWHS Sample
Physical inactivity (< 30 min/day on most days of week, past month)	75%
1+ gynecologic infections, past 5 yrs	38%
Stress (moderate/severe), past 12 mos:	
Money worries	26%
Feeling overloaded	25%
Illness of family member/friend	19%
Work or job problems	16%

* Comparison data are not available

Subgroups at Risk

- Reproductive life stage: *pre*conceptional women often were at greater risk than *inter*conceptional women
- Socioeconomic level: poor/low-income and less well-educated women were at higher risk
- Geography: rural women were *not* at lower risk than urban women

CePAWHS Phase II

- Developed a behavioral intervention, *Strong Healthy Women,* targeting prevalent modifiable risk factors identified in Phase I
- Tested the intervention in a randomized controlled trial (RCT) with pre- and interconceptional women in *low-income rural* communities

Strong Healthy Women
Intervention

- Behavioral intervention for small groups of pre- and interconceptional women
- Designed to be implemented in community settings by lay facilitators
- Targets multiple risk factors simultaneously
- Based on theories of behavior change (Social Cognitive Approach)

Intervention:

Education,
Behavior change skills,
Self-enhancement tools

Knowledge,

Self-efficacy,

Intention

Health behavior change

Health status improvement

Improved pregnancy experiences and outcomes

Curriculum developed by team led by Drs.
Danielle Symons Downs,
Department of Kinesiology,
and
Mark Feinberg,
Prevention Research Center,
Penn State

Strong Healthy Women: Intervention Content

Behavioral objectives for:

- Stress management
- Nutrition
- Physical activity
- Tobacco, alcohol use/exposure
- Gynecologic infections
- Preparing for pregnancy

Intervention Framework and Outcomes

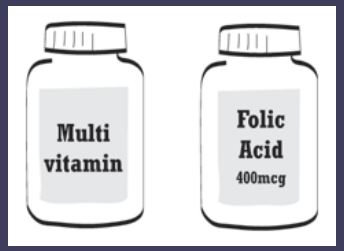
Risk Dimension	Behavior Change Goals	Learning Objective (Example)	Behavioral Outcome (Example)
Stress	Decrease psychosocial stress	Understand causes of stress and behavioral responses	Practice relaxation techniques
Nutrition	Increase healthy food choices	Understand nutrition and identify barriers to healthy eating	Eat healthier foods
Physical Activity	Achieve exercise recommendations	Understand guidelines and practice exercises	Exercise regularly per guidelines
Tobacco/ Alcohol	Decrease tobacco & alcohol use and exposure	Understand impact on pregnancy, triggers, and alternatives	Decrease smoking/drinking and exposures
Infections	Decrease gynecologic infections	Understand causes of infection	Decrease risk behaviors and seek care
Preparing for pregnancy	Strategize for pregnancy planning	Understand maternal health and contraception	Discuss plan with provider; use folic acid supplement

Intervention Process

- Six 2-hour group sessions over 12-weeks
  - Mix of topics covered at each session
  - Active learning, including discussions, problem-solving exercises, physical activity, food preparation
- Groups facilitated by 2 lay personnel
  - College graduates
  - Trained in content and group dynamics

Intervention Process

- Motivational strategies
  - Goal-setting (“baby steps”)
  - Behavior tracking tools
  - Social support (buddy system; facilitator phone calls)
  - Incentives (supplies, gift cards)



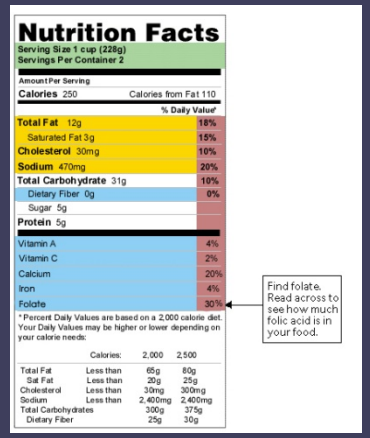
A group using core balls*

** They sat still for this picture!*

Images from Workbook and Handouts

Alcohol-free drinks

Food portions

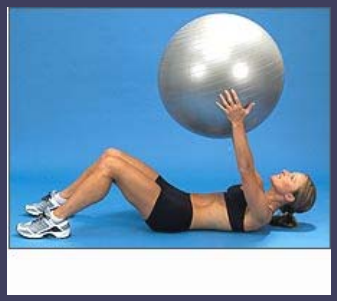


Nutrition labels

Birth control

Stress management

Tobacco avoidance



Physical activity

Testing whether

Strong Healthy Women

works

Hypotheses

H_1: Women who participate in the intervention will demonstrate significant improvements in behavioral intent, self-efficacy, health behaviors, and health status, compared to women in the control group.

H_2: More intensive participation in the intervention will be associated with better outcomes.

Research Design

Recruitment *(n =692)*

↓

Baseline Risk Assessment

↓

Random Assignment

Intervention (12 weeks) | **Control**

↓

Follow-up Risk Assessment

↓

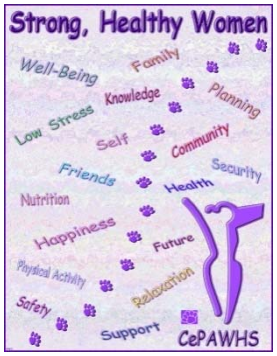
Follow-up telephone surveys at 6 and 12 months

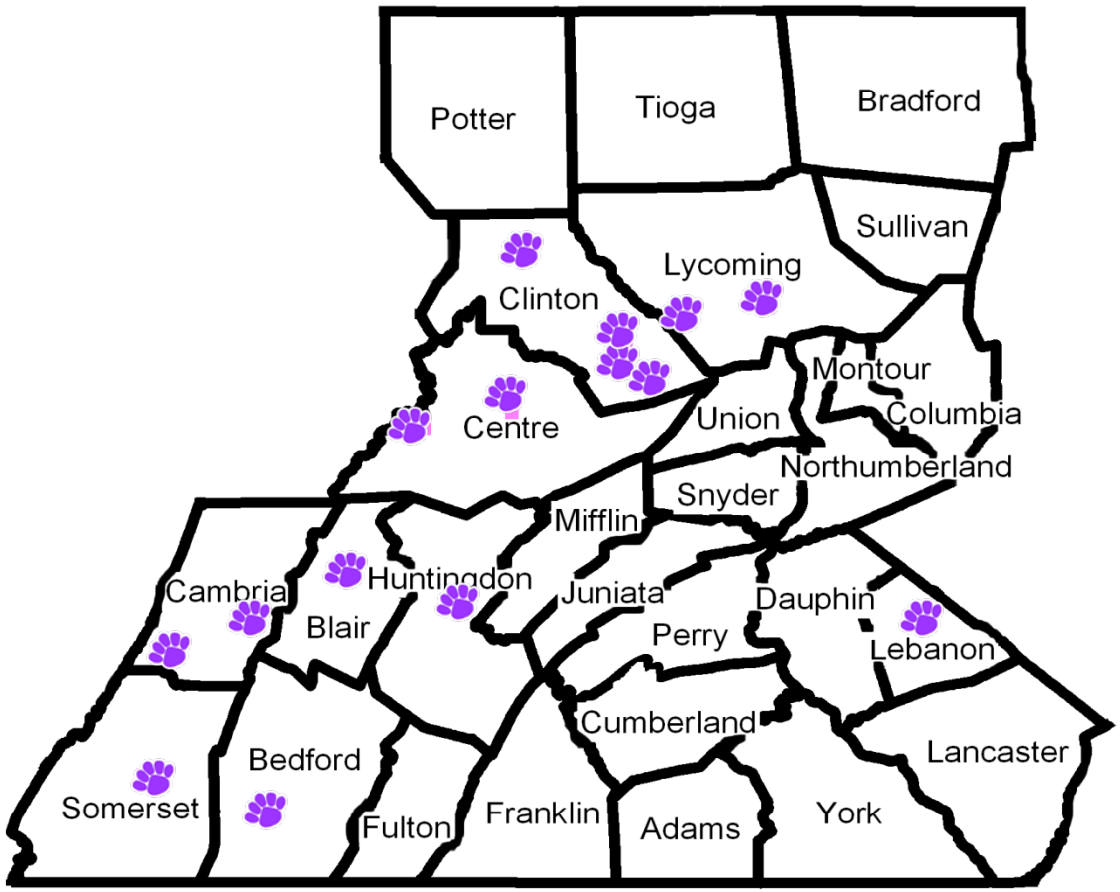
Recruitment Considerations

- Whom to recruit: Only high-risk women? Only patients in clinical settings?
- How to frame the program: Women's health? Reproductive health?
- Methods of recruitment: Active, passive, or some combination?

Whom to recruit?

- For this RCT, we recruited women in *low-income rural communities*
- We recruited from the community, rather than from clinical settings
  - *This approach includes women who do not have access to health care (e.g., no regular provider)*
  - *An alternative approach would be to recruit women in clinical settings (primary care or reproductive health services)*





Intervention Communities (n = 15)

Participants

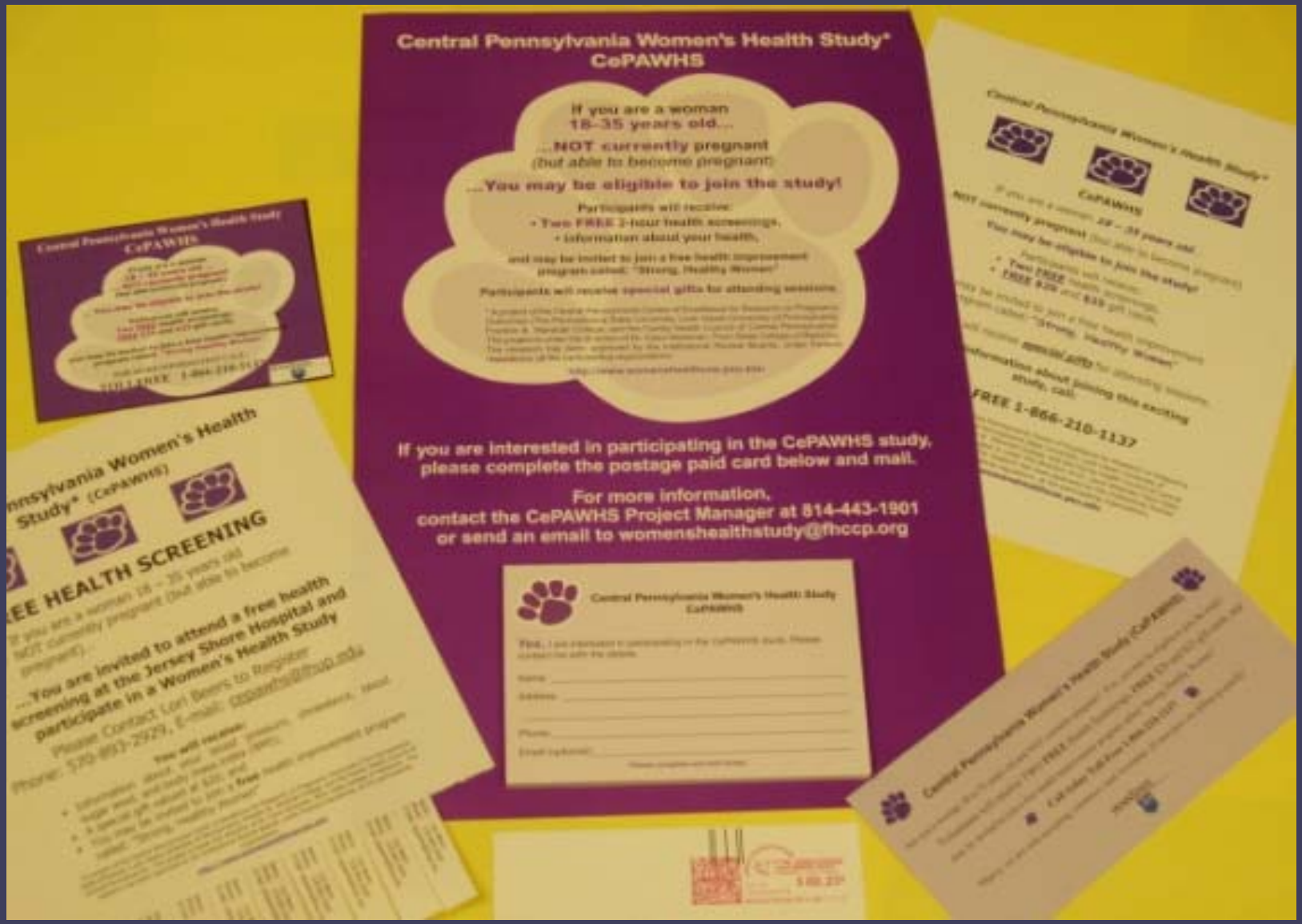
Eligibility

- Ages 18-35 at enrollment*
- Resides in target area
- Not pregnant at enrollment (either pre- or interconceptional)
- Capable of becoming pregnant (no hysterectomy or tubal ligation)
- *Exclusions:* non-English speaking

***** This age group accounts for >85% of pregnancies in Central PA

Recruitment Materials

Program framed as "women's health"



Recruitment Methods

Tailored to communities with help of local Steering Committee members; Organizational partner identified in each community

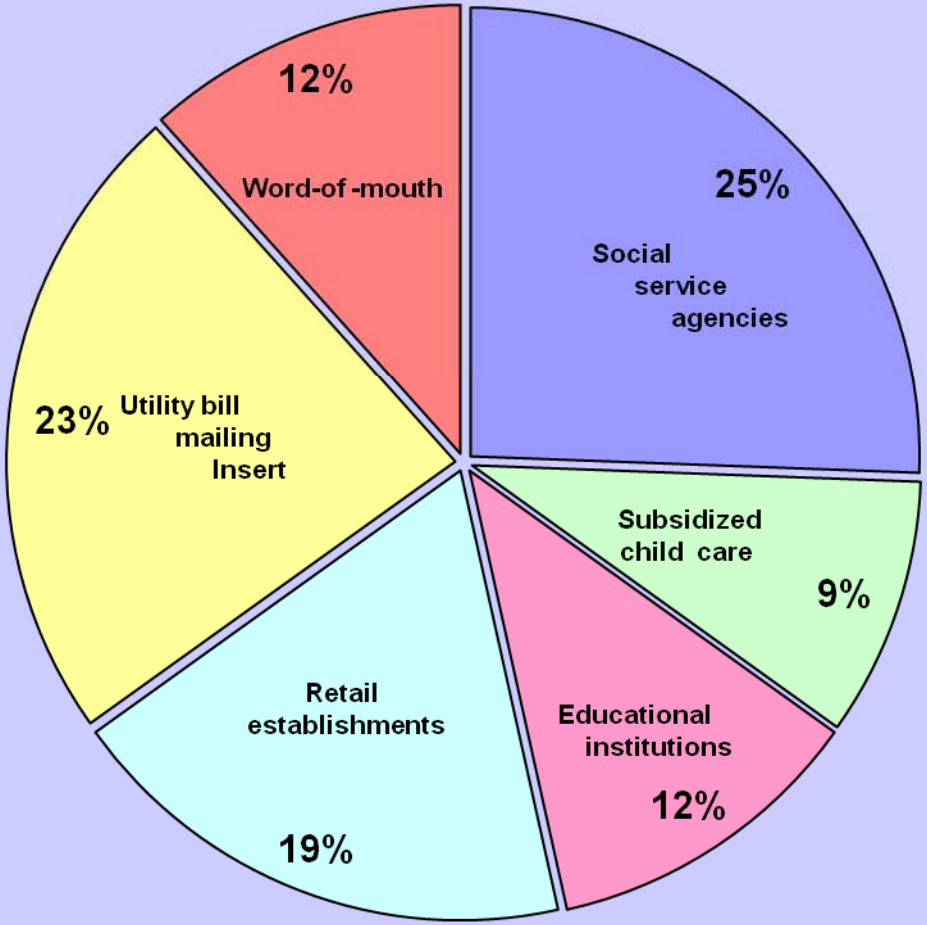
Active Methods

- One-on-one recruitment at social service agencies (e.g., WIC programs), schools, daycare, shops

Passive Methods

- Presentations in social service agencies, schools
- Posters and tear-off flyers in supermarkets, churches, community centers
- Kiosks at local health fairs, farm shows
- Inserts in utility bills
- Postcards to parents of subsidized child care

Participant Recruitment Sources for One Community



RCT Enrollees Compared with Pre- and Interconceptional Women Ages 18-35 in Target Counties

Recruitment methods succeeded in enrolling low-SES, minority, and rural women

	Counties (n = 257)	Enrollees (n = 692)	p-value
Poor or near poor *	34%	63%	<.0001
Education < college	35%	41%	ns
Non-white	3%	9%	.003
Unmarried	28%	49%	<.0001
No usual source of care	7%	24%	<.0001
No health insurance	20%	29%	.004
Rural	33%	51%	<.0001

* Based on federal poverty level

Risk Assessment:
Behavioral and Biological Markers

- Questionnaire (health status, health behaviors, psychosocial stress, access to health care, etc.)
- Anthropometric measurements (height, weight, BMI, waist circumference)
- Blood pressure
- Non-fasting blood glucose and lipid panel using fingerstick blood and CardioCheck analyzer

Total Enrollees
n = 692

Intervention
473 (68%)

Control
219 (32%)

Did not complete FURA
221 (47%)

Completed FURA
252 (53%)

Completed FURA
110 (50%)

Did not Complete FURA
109 (50%)

Telephone interviews

Base n for pre-post change in biomarkers = 362

Telephone interviews

Mean number of sessions attended = 3.9
0 (14%) 1 – 2 (11%) 3 – 4 (21%) 5 – 6 (54%)

Retention Issues

Those who dropped out of the study tended to be younger and to have lower educational levels than those who were retained.

Problem	Solution
Forgetting sessions	*Increase inter-session contacts by group facilitators; use email and telephone contacts*
Lack of childcare	*Provide on-site childcare*

What is the evidence that

Strong Healthy Women

works?

Statistical Analyses

- Intent-to-treat analyses conducted with analysis of variance
- Baseline measure (pre-test) included as covariate to adjust for differences in baseline measures; follow-up (post-test) measure is the dependent variable
- Used GLM, ordinal logistic regression, or ordinary logistic regression (depending on dependent variable)
- Age and educational attainment controlled to account for potential confounding

Strong Healthy Women:
Significant Pre-Post Intervention Effects

	Intervention Effect	p-value
Self-Efficacy		
For eating healthy food	GLM coefficient=1.109	0.018
Internal control of birth outcomes	OR=1.916	0.031
Behavioral Intent		
To eat healthier foods	OR=1.757	0.008
To be more physically active	OR=2.185	0.000
Behavior Change		
Reads food labels for nutritional values	OR=2.264	0.001
Daily use of multivitamin with folic acid	OR=6.595	0.000
Meets recommended exercise guidelines	OR=1.867	0.019

NOTE: GLM and logistic regression models also included pre-intervention level on outcome variable, age, and educational attainment

Strong Healthy Women:
Pre-Post Biomarker Assessments

No significant differences found

	Intervention Effect (GLM coefficients)	p-value
Weight (lbs)	-0.219	0.806
Systolic blood pressure (mm Hg)	-0.865	0.465
Diastolic blood pressure (mm Hg)	-0.014	0.990
Serum glucose (mg/dL)	0.849	0.798
HDL cholesterol (mg/dL)	-2.270	0.246
Total cholesterol (mg/dL)	-3.119	0.532

NOTE: GLM models also include pre-intervention value on outcome variable, age, and educational attainment

Strong Healthy Women:
Significant Dose-Response Effects Among Intervention Participants

	Effect per additional intervention session attended	p-value
Self-Efficacy		
Internal control of birth outcomes	OR=1.309	0.002
Behavior Change		
Reads food labels for nutritional values	OR=1.161	0.015
Uses relaxation exercise or meditation to manage stress	OR=1.236	0.009
Uses daily multivitamin with folic acid	OR=1.448	0.000

NOTE: Logistic regression models also included pre-intervention value on outcome variable, age, and educational attainment.

Additional Analyses

- Moderation effects: intervention did not appear to work better for certain subgroups of women
- Maintenance: intervention effect on folic acid use was maintained over the 12-month follow-up period, and intervention participants had lower BMI at 12-month followup compared with controls
- Pregnancy-related outcomes *(n=54 births)*: no intervention effect on preterm birth or LBW, but women in intervention group had *lower pregnancy weight gain* than women in control group

Summary of Evidence

Strong Healthy Women

significantly improved attitudes and behaviors related to *nutrition, folic acid supplementation, physical activity, and stress management,* increased *internal control of birth outcomes,* and lowered *BMI*

CePAWHS Phase III

Modified *Strong Healthy Women* based on participant feedback, focus groups with low-income urban women, and new information

- cut some uncomfortable role-play exercises
- added physical activity strategies for urban areas
- added chicken recipes as alternatives to fried chicken
- emphasized tobacco *exposure* rather than use
- increased content on IPV as a stressor
- included IOM *Weight Gain During Pregnancy* guidelines (2009)

Next Steps

- RCT focused on *low-income urban* women in safety-net clinics *(CDC approved for funding but did not fund)*
- RCT focused on *overweight and obese* women *(NIH grant pending review)*
- Replications in other communities

Replications

- *Strong Healthy Women* is now available to other sites *for purposes of research,* with a users' agreement from Penn State
- Users agree to acknowledge CePAWHS, follow the *Strong Healthy Women* protocol, evaluate its effectiveness, and share results with Penn State investigators

What do you need to implement *Strong Healthy Women*?

- Permission to use the *Strong Healthy Women* protocol
- Capacity to train group facilitators in use of *Strong Healthy Women* protocol
- A convenient site with free parking, space for childcare, and kitchen facilities
- Capacity to conduct pre-post evaluation (with usual care control group if possible)

What we can provide

- Protocol manual for *Strong Healthy Women,* including list of materials and handouts
- Evaluation instruments for pre-post assessment of attitudes and behaviors
- Consultation on facilitator training, recruitment, implementation, evaluation, and/or data analysis if funding is available

Contact CePAWHS

http://www.womenshealthcoe.psu.edu

Carol S. Weisman, PhD
cweisman@psu.edu

CePAWHS Publications

(selected)

- Weisman CS, Hillemeier MM, Chase GA, Dyer AM, Baker SA, Feinberg M, Downs DS, Parrott RL, Cecil HK, Botti JJ, MacNeill C, Chuang CH, Yost B. Preconception Health: Risks of Adverse Pregnancy outcomes by Reproductive Life Stage in the CePAWHS. *Women's Health Issues* 16:216-224, 2006.

- Weisman CS, Hillemeier MM, Chase GA, Misra DP, Chuang CH, Parrott R, Dyer AM. Women's Perceived Control of Their Birth Outcomes in the Central Pennsylvania Women's Health Study. *Women's Health Issues* 18:17-25, 2008.

- Downs DS, Feinberg M, Hillemeier MM, Weisman CS, Chase GA, Chuang CH, Parrott R, Francis LA. Design of the CePAWHS *Strong Healthy Women* Intervention: Improving Preconception Health. *Maternal and Child Health Journal* 13:18-28, 2009.

- Velott DL, Baker SA, Hillemeier MM, Weisman CS. Participant Recruitment to a Randomized Trial of a Community-based Behavioral Intervention for Pre- and Interconceptional Women: Findings from the CePAWHS. *Women's Health Issues* 18:217-224, 2008.

- Hillemeier MM, Downs DS, Feinberg ME, Weisman CS, Chuang CH Parrott R, Velott D, Francis LA, Baker SA. Improving Women's Preconception Health: Findings from a Randomized Trial of the *Strong Healthy Women* Intervention in the CePAWHS. *Women's Health Issues* 18:S87-S96, 2008.

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Franklin & Marshall College

Lock Haven University of Pennsylvania

CePAWHS Steering Committee

(community representatives)

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- Highmark

Questions & Answer Period

Please complete the evaluation following this webcast