Original Article
CLINICAL TRIALS AND INVESTIGATIONS

Obesity

Strong Hearts, Healthy Communities: A Community-Based Randomized Trial for Rural Women

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Objective: The aim of this study was to evaluate a multilevel cardiovascular disease (CVD) prevention program for rural women.

Methods: This 6-month, community-based, randomized trial enrolled 194 sedentary rural women aged 40 or older with BMI $\geq$ 25 kg/m^2. Intervention participants attended 6 months of twice-weekly exercise, nutrition, and heart health classes (48 total) that included individual-, social-, and environment-level components. An education-only control program included didactic healthy lifestyle classes once a month (six total). The primary outcome measures were change in BMI and weight.

Results: Within-group and between-group multivariate analyses revealed that only intervention participants decreased BMI (−0.85 units; 95% CI: −1.32 to −0.39; $P = 0.001$) and weight (−2.24 kg; 95% CI: −3.49 to −0.99; $P = 0.002$). Compared with controls, intervention participants decreased BMI (difference: −0.71 units; 95% CI: −1.35 to −0.08; $P = 0.03$) and weight (1.85 kg; 95% CI: −3.55 to −0.16; $P = 0.03$) and improved C-reactive protein (difference: −1.15 mg/L; 95% CI: −2.16 to −0.15; $P = 0.03$) and Simple 7, a composite CVD risk score (difference: 0.67; 95% CI: 0.14 to 1.21; $P = 0.01$). Cholesterol decreased among controls but increased in the intervention group (−7.85 vs. 3.92 mg/dL; difference: 11.77; 95% CI: 0.57 to 22.96; $P = 0.04$).

Conclusions: The multilevel intervention demonstrated modest but superior and meaningful improvements in BMI and other CVD risk factors compared with the control program.

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Introduction

Cardiovascular disease (CVD) is the leading cause of mortality in the United States, accounting for approximately one-quarter of all deaths (1). People living in rural areas are more likely than those in urban areas to be diagnosed with CVD and exhibit more CVD risk factors, including smoking, having type 2 diabetes, having a BMI in the overweight or obesity categories, and having a sedentary lifestyle (2,3). Rural women are also more likely to be uninsured, older, and less educated and to have lower income and higher rates of chronic health conditions—due, in part, to limited access to physical activity opportunities, healthy foods, and health care resources (4-7). Thus, women living in rural, medically underserved areas are a critical target population for CVD prevention efforts.

Didactic, education-only, individual-level approaches are common among weight management and healthy lifestyle programs despite the fact that experiential, hands-on learning techniques tend to result in superior outcomes (8). Although the socioecological model is often referenced in the context of health behavior change interventions and the Academy of Nutrition and Dietetics notes that "interventions incorporating more than one level of the

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socioecological model and addressing several key factors in each level may be more successful than interventions targeting any one level and factor alone" (9), few programs have actively engaged the individual, social, and environmental spheres of influence to help support behavior change. In addition, a 2014 review found that evidence-based interventions promoting physical activity and healthy eating for adults are limited by a lack of high-quality, multilevel intervention studies (10). This is likely due to the lack of clear, specific strategies for linking multiple socioecological levels (11).

The objective of Strong Hearts, Healthy Communities (SHHC) was to address these gaps by 1) developing an innovative intervention informed by the socioecological framework to target key behaviors related to CVD prevention and overweight/obesity, bolstering social and environmental support through civic engagement; 2) integrating an experiential learning approach including core concepts of experience, observation and reflection, analysis and generalizations, and application to future situations; and 3) conducting a pragmatic comparative effectiveness trial evaluating SHHC compared with an education-only, minimal intervention control program, Strong Hearts, Healthy Women (CON), on anthropometric and physiologic outcomes. We hypothesized that there would be superior improvement in the full intervention program, resulting in significant and clinically meaningful improvements in CVD risk factors.

Methods

Design

This randomized community intervention trial occurred in 2015 to 2016 in 16 towns in Montana and New York. All towns were rural (based on Rural-Urban Commuting Area designations) (12) and were designated as medically underserved areas or populations (13). Population per town ranged from 470 to 5,900, with an average of 2,200 residents. Randomization occurred at the town level, with half randomized to deliver the SHHC intervention program and half to deliver the CON program. The study protocol has been previously published (14). The study was approved by the Cornell University and Bassett Healthcare Institutional Review Boards.

Participants

Participants were recruited by local health educators through word of mouth, community advertising (e.g., posters/flyers at senior centers), recruitment events (e.g., tables at grocery stores), newspaper ads and articles, radio ads, Facebook, website posts, and targeted direct mailing. Eligible participants were female, 40 years or older, with BMI ≥ 25 kg/m^2, sedentary (not meeting the Physical Activity Guidelines for Americans (15) or having an estimated total energy expenditure below 34 kcal/kg per day, per the 7-Day Physical Activity Recall scale), and English-speaking, and they had their physician's approval to participate. Participants with blood pressure >100 (diastolic) or >160 (systolic), heart rates of <60 or >100, or cognitive impairments were excluded. All participants provided written informed consent.

Program educators

The 16 program educators who delivered the program were members of each local community, were affiliated with cooperative extension offices or a local rural health care system, and had experience delivering health education programs to adults. They also had cardiopulmonary resuscitation certification, training in human subject ethics, and extensive training in research methods related to the study and the curriculum to be delivered; trainings were conducted through in-person workshops, webinars, and weekly phone calls. Full details are described in the protocol manuscript (14).

Multilevel intervention program and minimal intervention control program

The multilevel SHHC intervention program integrated three evidence-based community programs—two targeting the individual and a third targeting positive change in social and built environments (16-18). SHHC focused on behavior change through experiential learning in the following areas: dietary improvement, physical activity and fitness, weight loss, and other relevant CVD-related prevention skills and strategies such as stress management. Grocery store audits and community food and physical activity environment assessments (e.g., local walking tour to identify barriers and facilitators to active living and healthy eating) included friends and family members, as part of the social environment and HEART Club civic engagement component. SHHC participants met twice weekly for 24 weeks (48 one-hour classes).

The diet component aimed to change dietary patterns through classroom skill-building activities (e.g., measuring true portion sizes, label reading) and field-based learning (e.g., grocery store audits, home food environment awareness activities); it was informed by DASH (Dietary Approaches to Stop Hypertension) diet principles (19), the Dietary Guidelines for Americans (20), and the Mediterranean dietary pattern (21). Nutrition behavioral aims included increasing fruits and vegetables, replacing refined grains with whole grains, and decreasing calories, desserts, processed foods, saturated and trans fats, sodium, and sugar-sweetened beverages.

SHHC physical activities included aerobic exercise (e.g., indoor and outdoor walking, aerobic dance), starting at low to moderate intensity with a transition to moderate to vigorous intensity; progressive strength training exercises for upper and lower body and core; and field-based learning with reflections (e.g., community walking tour). Goal setting, behavioral feedback and tracking, and motivational interviewing techniques were used. Progressive, moderate-intensity aerobic exercise (typically 20-30 minutes), such as walking DVDs and aerobic dance, was included in nearly all classes. Progressive strength training (typically 10-20 minutes; two sets of 10 repetitions) of major muscle groups, such as squats, lunges, bicep curls, and chest press, was included in about two-thirds of classes. Participants were encouraged to increase the intensity of both exercise components throughout the program.

Curriculum content addressed the social environment's influence on heart-healthy behavior related to diet and exercise, social support for heart-healthy behaviors, heart-healthy eating plans for friends and family, social influences on sugar-sweetened beverage consumption, and what to do when loved ones are unsupportive. Engagement and reinforcement of these concepts occurred within HEART Club activities, which also formalized knowledge/awareness of built environment change opportunities to support healthy lifestyles in rural towns, a novel feature of the intervention program. The HEART Club used a formal, stepwise process with groups identifying a food or physical activity environment issue they believed important and feasible to address in their community to support healthier lifestyles, followed by a system to articulate and evaluate action steps by the group (16). To facilitate HEART Club efforts and raise general awareness of local resources for healthy eating and active living, there were HEART Club community activities, designed by participants, based on the issue and action steps identified, with the goal of participants acting as positive change agents for their families, friends, and communities (22). As an additional component to support the multilevel approach of the intervention, Community Guides were developed for each SHHC community with lists of and basic information about local resources for healthy eating, physical activity, health care and wellness, and community change.

The Strong Hearts, Healthy Women control (CON) classes served as the reduced-dose, education-only, minimal intervention control program. The CON classes met for a 1-hour class once per month over 24 weeks (six classes total). Classes provided evidence-based healthy lifestyle information (e.g., current dietary and physical activity guidelines) presented didactically. Participants did not engage in physical activity, skill building, or other active learning elements (e.g., reflection, monitoring) or civic engagement during the class sessions.

Outcome assessments

Analysis for the current study includes baseline data and postintervention (outcome) data collected immediately after the 6-month intervention. Participants completed a demographic questionnaire at baseline only, unless they indicated a change (e.g., marital status). Demographic questions were derived from national surveys (e.g., US Census). Participants also completed behavioral and health-related questionnaires at baseline and postintervention, including data on relevant diagnoses and medications (e.g. hyperlipidemia, statin use). Qualtrics software (Provo, Utah) was used for questionnaire-based data collection.

Anthropometric measures included height, weight, BMI (kg/m^2), body composition, and hip and waist circumference, all measured in duplicate (only in triplicate if needed per study protocol). Freestanding Seca model 213 stadiometers (Seca GmbH, Hamburg, Germany) were used for height measurements; Omron HBF-510W scales (Omron Healthcare, Kyoto, Japan) were used for weight and body composition measures. A retractable Gulick tape measure (Country Technology Inc., Gays Mills, Wisconsin) was used for hip and waist circumferences. Physiologic measures included blood pressure, resting heart rate, and fasting (overnight, $\geq$12 hours) blood draws to assess glucose, hemoglobin A1c, C-reactive protein (CRP), and lipid panel with total cholesterol, LDL cholesterol, HDL cholesterol, and triglycerides. Anthropometric and physiologic measures were completed by independent, trained staff from Western Health Screening in Montana and Bassett Healthcare Network in New York.

Simple 7 is a cardiovascular health metric composed of four health behaviors (smoking, BMI, physical activity, healthy diet) and three health factors (total cholesterol, blood pressure, fasting glucose) (23). The classification scores determined by the American Heart Association are poor, intermediate, or ideal, which are correlated with prevalence of CVD events (24). The Simple 7 components for this study were derived from a combination of self-reported (smoking, physical activity by International Physical Activity Questionnaire (25), healthy diet (26)) and measured (BMI, total cholesterol, blood pressure, fasting serum glucose) data. To calculate the Simple 7 score, the number of ideal/intermediate/poor Simple 7 components for each participant was counted. Ideal cardiovascular health is defined as having all seven cardiovascular health metrics in the ideal range. Intermediate cardiovascular health is defined as having at least one intermediate metric and no poor metrics. Poor cardiovascular health is defined as having at least one poor health metric. Further details in Supporting Information Table S1 describe each characterization for the poor, intermediate, and ideal score as well as the data source for each measure included in the analysis for this study. In addition, 10-year risk for atherosclerotic cardiovascular disease (ASCVD) was calculated using the Pooled Cohort Equations (27).

Statistical analysis

Our sample size estimates were based on the StrongWomen—Healthy Hearts study (17) in which intervention participants lost an average of 2.1 kg (SD = 2.6) compared with controls. We determined that a sample size of 34 people per group would allow us to detect an effect size of 0.690 from a two-sided independent means test with 80% power and type 1 error of 5%. Given the data were clustered within towns, we assumed intraclass correlation of 0.025 (with clusters of 12 people) and 10% initial attrition, resulting in a design effect of 1.275, yielding a sample size requirement of 48 people per group (96 total). To ensure adequate power, taking into consideration the potential for additional attrition and possible subgroup analyses based on baseline characteristics, additional participants were recruited. For randomization, towns were paired based on the closest match to rural (RUCA 2.0) designation and population size (28). Following completion of participants' baseline assessments, the statistician randomly assigned one town from each pair to receive the intervention (SHHC) or control (CON) program.

Univariate descriptive statistics for the entire sample and by treatment group were compiled and tabulated. Comparison between baseline characteristics was completed using χ^2 (binary and categorical variables) and *t* tests (continuous variables). Because observations were clustered within towns, multilevel linear regression models were used (Model 1). Site was treated as a random effect to examine adjusted effects of the intervention on the primary outcomes (change in BMI and body weight) and key secondary outcomes (physiologic [e.g., blood pressure, lipids, CRP, hemoglobin A1c], anthropometric [e.g., waist circumference], and aggregate [e.g., Simple 7, ASCVD risk]) following a modified intent-to-treat analysis (29) wherein all participants who completed data collection were analyzed according to their randomized treatment assignment, regardless of their level of intervention adherence (complete case analysis). The a priori multivariate participant model (Model 2) controlled for baseline values of the outcome (30), age, marital status, and education as fixed effects in addition to the treatment variable. Table 2 displays Model 1 and Model 2 as within-group pre- to postintervention change values and significance of those changes within each treatment group (SHHC and CON). Table 3 displays Model 1 and Model 2 as the between-group comparison of the pre- to postintervention change values and significance of those change differences between the two treatment groups. Multilevel ordinal logistic regression models were used to assess the effect of the intervention on Simple 7. All tests were two-sided, and $P \leq 0.05$ was used as the cutoff for statistical significance. In addition, we conducted sensitivity analyses in which missing data were imputed and with the last observation carried forward (LOCF), which are included in Supporting Information Tables S2 and S3. Sample sizes for the complete case analysis and LOCF are noted in Figure 1 and in each of the tables. Analyses were conducted using the PROC MIXED command for multilevel analysis in SAS version 9.4 (SAS Institute, Cary, North Carolina).

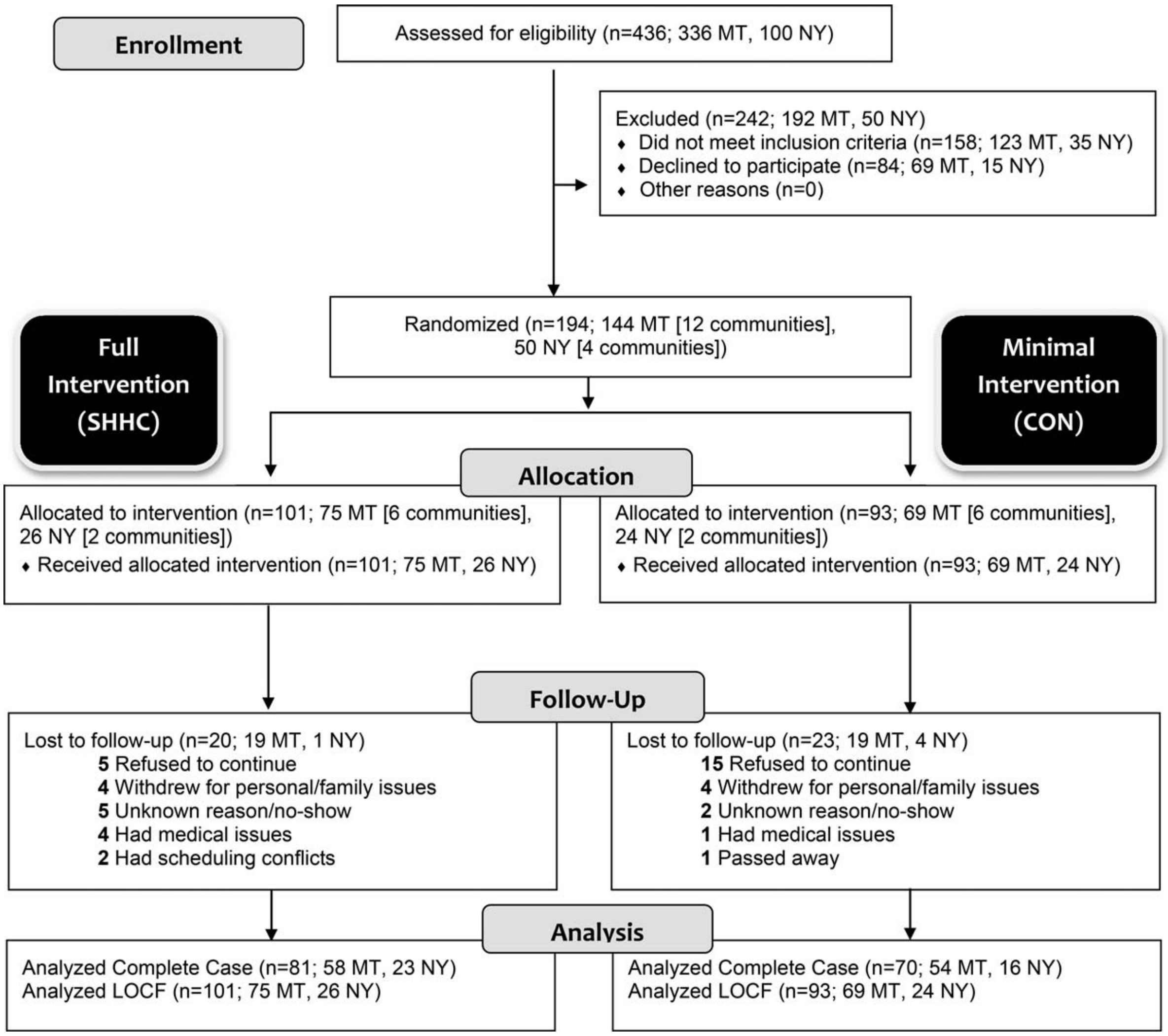

Figure 1 CONSORT flowchart describing progress of participants through the study. CON, Strong Hearts, Healthy Women–Control; LOCF, last observation carried forward; MT, Montana; NY, New York; SHHC, Strong Hearts, Healthy Communities-Intervention.

Results

A total of 194 participants consented to participate and were randomized; 151 (78%) completed both baseline and outcome assessments (Figure 1). There was a difference in two demographic characteristics between the intervention and control groups; intervention participants had a larger household size (mean [SD] household size 2.5 [1.4] people vs. 2.1 [0.9] people, respectively) and a greater number of children in the household (mean [SD] 1.4 [0.8] children vs. 1.1 [0.5] children, respectively). There were no differences in baseline health measures between the intervention and control group participants ($P \geq 0.05$; Table 1). Analysis revealed no differences in baseline characteristics among those for whom outcome data were or were not available, with the exception of an age interaction with Simple 7: the average age with a Simple 7 score was 59.8 years, while those for whom a Simple 7 score was not available because of loss to follow-up or missing data was 56.9 years ($P = 0.04$).

Primary outcomes (body weight and BMI)

In the pre-post within-group multivariate analysis, only intervention participants significantly decreased BMI (−0.85 units, 95% CI: −1.32 to −0.39; $P = 0.001$) and weight (−2.24 kg, 95% CI: −3.49 to −0.99; $P = 0.002$); there were no improvements among controls (Table 2, Model 2). In the between-group multivariate analysis, the intervention group lost significantly more weight (difference: −1.85 kg, 95% CI: −3.55 to −0.16; $P = 0.03$) compared with the control group (Table 3, Model 2). This equated to a significant BMI decrease among intervention participants compared with controls (−0.71 units, 95% CI: −1.35 to −0.08; $P = 0.03$).

Secondary outcomes

In the pre-post within-group multivariate analysis, only intervention participants had a significant decrease in CRP (−1.13 mg/L, 95% CI: −1.89 to −0.37; $P = 0.004$), Simple 7 (0.88, 95% CI: 0.48 to 1.28; $P < 0.001$), ASCVD risk (−0.96, 95% CI: −1.49 to −0.43,

TABLE 1 Baseline characteristics of participants by intervention condition

		Total, *N* (range = 174-194)	SHHC, *n* (range = 88-101)	CON, *n* (range = 86-93)
Age, mean (SD), y		58.9 (9.5)	59.0 (9.4)	58.7 (9.7)
Income, No. (%)				
<$25,000		37 (21)	24 (27)	13 (15)
$25,000-$50,000		53 (31)	23 (26)	30 (35)
>$50,000		84 (48)	41 (47)	43 (50)
Marital status, No. (%)				
In a relationship	Married	130 (70)	68 (72)	62 (69)
	Member of an unmarried couple	2 (1)	2 (2)	0 (0)
Not in a relationship	Divorced	20 (11)	9 (9)	11 (12)
	Widowed	22 (12)	14 (15)	8 (9)
	Separated	3 (2)	1 (1)	2 (2)
	Never been married	8 (4)	1 (1)	7 (8)
Educational level, No. (%)				
High school or less		42 (23)	22 (23)	20 (22)
Technical or vocational school/some college		55 (30)	30 (32)	25 (28)
College graduate		58 (32)	28 (30)	30 (33)
Postgrad/professional		29 (16)	14 (15)	15 (17)
Household size (total), mean (SD)		2.3 (1.2)	**2.5 (1.4)**	**2.1 (0.9)**
Number of adults in the household, mean (SD)		2.0 (0.7)	2.0 (0.7)	2.0 (0.7)
Number of children in the household, mean (SD)		1.3 (0.7)	**1.4 (0.8)**	**1.1 (0.5)**
Racial/ethnic minority, No. (%)		10 (5)	5 (5)	5 (6)
Employment status, No. (%)				
Employed for wages		110 (59)	50 (52)	60 (67)
Self-employed		20 (11)	11 (11)	9 (10)
Out of work for more than 1 year		1 (1)	1 (1)	0 (0)
Out of work for less than 1 year		0 (0)	0 (0)	0 (0)
Homemaker		9 (5)	6 (6)	3 (3)
Student		0 (0)	0 (0)	0 (0)
Retired		41 (22)	24 (25)	17 (19)
Unable to work		5 (3)	4 (4)	1 (1)
Smoking		9 (5)	5 (5)	4 (4)
BMI, mean (SD)[a]		35.2 (6.5)	34.9 (6.1)	35.5 (6.8)
Weight, mean (SD), kg		93.8 (18.1)	92.2 (16.8)	95.5 (19.5)
CRP, mean (SD), mg/L		4.9 (4.3)	4.8 (4.6)	5.0 (3.9)
Simple 7, mean (SD)		7.3 (1.9)	7.3 (1.9)	7.2 (1.9)
ASCVD risk, mean (SD)		7.2 (9.3)	8.0 (10.7)	6.3 (7.3)
Waist-to-hip ratio, mean (SD)		0.9 (0.1)	0.9 (0.1)	0.9 (0.1)
Body fat, mean (SD), %		48.4 (5.0)	48.2 (5.2)	48.7 (4.9)
Resting heart rate, mean (SD)		73.1 (9.2)	72.9 (8.8)	73.3 (9.7)
Diastolic blood pressure-automated, mean (SD), mmHg		87.5 (20.4)	87.9 (27.1)	87.1 (8.3)
Systolic blood pressure-automated, mean (SD), mmHg		134.4 (17.1)	134.7 (19.0)	134.0 (14.9)
Waist circumference, mean (SD), cm		105.8 (12.7)	104.9 (13.3)	106.7 (12.0)
Cholesterol (total), mean (SD), mg/dL		203.7 (41.3)	202.0 (44.2)	205.5 (38.0)
HDL cholesterol, mean (SD), mg/dL		56.5 (14.5)	57.6 (15.3)	55.3 (13.5)
LDL cholesterol, mean (SD), mg/dL		124.8 (35.5)	122.2 (37.4)	127.7 (33.3)
Triglycerides, mean (SD), mg/dL		144.2 (72.7)	145.9 (78.1)	142.3 (66.7)
Fasting glucose, mean (SD), mg/dL		98.7 (22.0)	98.4 (19.7)	99.0 (24.3)
Hemoglobin A1c, mean (SD)		6.1 (0.8)	6.1 (0.8)	6.1 (0.9)

Boldface indicates statistical significance ($P \leq 0.05$).
[a]Calculated as weight in kilograms divided by height in meters squared.
ASCVD, atherosclerotic cardiovascular disease; CON, Strong Hearts, Healthy Women-Control; CRP, C-reactive protein; HDL, high-density lipoprotein; LDL, low-density lipoprotein; SHHC, Strong Hearts, Healthy Communities-Intervention.

TABLE 2 Within-group changes in BMI, weight, and CVD risk factors

	Unadjusted Model 1,[b] *N* range = 129-151				Multivariate Model 2,[c] *N* range = 127-145			
	Within-group change (SHHC)		Within-group change (CON)		Within-group change (SHHC)		Within-group change (CON)	
	Mean change baseline to outcome (95% CI)	*P*	Mean change baseline to outcome (95% CI)	*P*	Mean change baseline to outcome (95% CI)	*P*	Mean change baseline to outcome (95% CI)	*P*
BMI[a]	**−0.80 (−1.18 to −0.43)**	**<0.001**	−0.10 (−0.49 to 0.29)	0.60	**−0.85 (−1.32 to −0.39)**	**0.001**	−0.14 (−0.62 to 0.33)	0.53
Weight, kg	**−2.09 (−3.10 to −1.08)**	**<0.001**	−0.23 (−1.28 to 0.83)	0.65	**−2.24 (−3.49 to −0.99)**	**0.002**	−0.38 (−1.65 to 0.88)	0.53
CRP, mg/L	**−1.31 (−2.06 to −0.55)**	**<0.001**	−0.02 (−0.84 to 0.80)	0.96	**−1.13 (−1.89 to −0.37)**	**0.004**	0.03 (−0.75 to 0.80)	0.95
Simple 7	**0.93 (0.53 to 1.33)**	**<0.001**	0.32 (−0.11 to 0.76)	0.14	**0.88 (0.48 to 1.28)**	**<0.001**	0.21 (0.21 to 0.63)	0.32
ASCVD risk	**−0.86 (−1.43 to −0.29)**	**0.004**	−0.32 (−0.94 to 0.29)	0.30	**−0.96 (−1.49 to −0.43)**	**<0.001**	−0.47 (−1.01 to 0.065)	0.09
Waist-to-hip ratio	−0.01 (−0.02 to 0.01)	0.36	−0.003 (−0.02 to 0.01)	0.64	−0.01 (−0.02 to 0.01)	0.24	−0.002 (−0.02 to 0.01)	0.80
Body fat, %	**−1.56 (−2.01 to −1.10)**	**<0.001**	**−1.71 (−2.21 to −1.20)**	**<0.001**	**−1.65 (−2.20 to −1.11)**	**<0.001**	**−1.87 (−2.44 to −1.30)**	**<0.001**
Resting heart rate	**−2.76 (−4.60 to −0.92)**	**0.004**	−1.17 (−3.18 to 0.83)	0.25	−1.88 (−3.85 to 0.08)	0.06	−1.15 (−3.16 to 0.86)	0.26
Diastolic blood pressure, mmHg	**−6.46 (−9.60 to −3.32)**	**<0.001**	**−4.53 (−7.73 to −1.32)**	**0.009**	**−6.45 (−9.63 to −3.28)**	**<0.001**	**−3.89 (−7.09 to −0.68)**	**0.02**
Systolic blood pressure, mmHg	**−6.57 (−10.51 to −2.64)**	**0.003**	**−4.14 (−8.21 to −0.07)**	**0.05**	**−5.91 (−10.35 to −1.46)**	**0.01**	−3.85 (−8.32 to 0.63)	0.09
Waist circumference, cm	**−3.39 (−6.10 to −0.68)**	**0.02**	−2.10 (−4.84 to 0.64)	0.12	**−3.23 (−5.78 to −0.68)**	**0.02**	−1.83 (−4.41 to 0.75)	0.15
Total cholesterol, mg/dL	2.68 (−5.43 to 10.79)	0.49	**−9.41 (−17.72 to −1.10)**	**0.03**	3.92 (−4.22 to 12.06)	0.32	−7.85 (−16.05 to 0.35)	0.06
HDL cholesterol, mg/dL	0.93 (−1.75 to 3.61)	0.47	0.55 (−2.21 to 3.32)	0.68	1.81 (−0.88 to 4.50)	0.17	0.54 (−2.18 to 3.26)	0.68
LDL cholesterol, mg/dL	0.08 (−5.47 to 5.63)	0.98	**−8.08 (−13.83 to −2.32)**	**0.009**	0.99 (−5.02 to 7.01)	0.73	**−6.55 (−12.60 to −0.51)**	**0.04**
Triglycerides, mg/dL	−5.28 (−20.49 to 9.94)	0.46	−9.45 (−25.14 to 6.24)	0.22	−3.39 (−16.97 to 10.18)	0.60	−6.79 (−20.46 to 6.89)	0.31
Fasting glucose, mg/dL	2.66 (−1.57 to 6.89)	0.22	**5.61 (1.00 to 10.22)**	**0.02**	3.42 (−1.08 to 7.92)	0.14	**5.06 (0.46 to 9.67)**	**0.03**
Hemoglobin A1c	**−0.28 (−0.40 to −0.16)**	**<0.001**	**−0.28 (−0.41 to −0.16)**	**<0.001**	**−0.26 (−0.38 to −0.14)**	**<0.001**	**−0.28 (−0.40 to −0.16)**	**<0.001**

Boldface indicates statistical significance ($P \leq 0.05$).
[a]Calculated as weight in kilograms divided by height in meters squared.
[b]Adjusted for site.
[c]Adjusted for site, education, age, marital status, and baseline value of the outcome.
ASCVD, atherosclerotic cardiovascular disease; CON, Strong Hearts, Healthy Women-Control; CRP, C-reactive protein; HDL, high-density lipoprotein; LDL, low-density lipoprotein; SHHC, Strong Hearts, Healthy Communities-Intervention.

TABLE 3 Between-group differences for changes in BMI, weight, and CVD risk factors

	Unadjusted Model 1,[b] *N* range = 129-151		Multivariate Model 2,[c] *N* range = 127-145	
	Difference in change between SHHC and CON		Difference in change between SHHC and CON	
	Mean change baseline to outcome (95% CI)	*P*	Mean change baseline to outcome (95% CI)	*P*
BMI[a]	**−0.71 (−1.25 to −0.17)**	**0.01**	**−0.71 (−1.35 to −0.08)**	**0.03**
Weight, kg	**−1.86 (−3.32 to −0.41)**	**0.02**	**−1.85 (−3.55 to −0.16)**	**0.03**
CRP, mg/L	**−1.29 (−2.40 to −0.17)**	**0.02**	**−1.15 (−2.16 to −0.15)**	**0.03**
Simple 7	**0.61 (0.02 to 1.20)**	**0.04**	**0.67 (0.14 to 1.21)**	**0.01**
ASCVD risk	−0.54 (−1.38 to 0.30)	0.21	−0.48 (−1.19 to 0.22)	0.18
Waist-to-hip ratio	−0.003 (−0.02 to 0.02)	0.76	−0.01 (−0.02 to 0.01)	0.49
Body fat, %	0.15 (−0.53 to 0.83)	0.67	0.22 (−0.50 to 0.94)	0.54
Resting heart rate	−1.58 (−4.30 to 1.13)	0.25	−0.73 (−3.33 to 1.87)	0.58
Diastolic blood pressure, mmHg	−1.94 (−6.43 to 2.56)	0.37	−2.57 (−6.95 to 1.82)	0.23
Systolic blood pressure, mmHg	−2.44 (−8.10 to 3.23)	0.37	−2.06 (−8.14 to 4.03)	0.48
Waist circumference, cm	−1.29 (−5.15 to 2.57)	0.49	−1.40 (−4.96 to 2.16)	0.41
Total cholesterol, mg/dL	**12.09 (0.49 to 23.70)**	**0.04**	**11.77 (0.57 to 22.96)**	**0.04**
HDL cholesterol, mg/dL	0.37 (−3.48 to 4.22)	0.84	1.27 (−2.39 to 4.94)	0.47
LDL cholesterol, mg/dL	**8.16 (0.17 to 16.15)**	**0.05**	7.55 (−0.62 to 15.71)	0.07
Triglycerides, mg/dL	4.18 (−17.66 to 26.01)	0.69	3.39 (−15.03 to 21.82)	0.69
Fasting glucose, mg/dL	−2.95 (−9.21 to 3.30)	0.35	−1.65 (−7.60 to 4.31)	0.59
Hemoglobin A1c	0.001 (−0.17 to 0.17)	0.99	0.02 (−0.14 to 0.19)	0.78

Boldface indicates statistical significance ($P \leq 0.05$).
[a]Calculated as weight in kilograms divided by height in meters squared.
[b]Adjusted for site.
[c]Adjusted for site, education, age, marital status, and baseline value of the outcome.
ASCVD, atherosclerotic cardiovascular disease; CON, Strong Hearts, Healthy Women-Control; CRP, C-reactive protein; HDL, high-density lipoprotein; LDL, low-density lipoprotein; SHHC, Strong Hearts, Healthy Communities-Intervention.

$P < 0.001$), systolic blood pressure (−5.91, 95% CI: −10.35 to −1.46; $P = 0.01$), and waist circumference (−3.23 cm, 95% CI: −5.78 to −0.68; $P = 0.02$); only the control group had a decrease in LDL cholesterol (−6.55, 95% CI: −12.60 to −0.51; $P = 0.04$) and increase in fasting glucose (5.06, 95% CI: 0.46 to 9.67; $P = 0.03$; Table 2, Model 2). Both groups had a decrease in body fat (intervention: −1.65, 95% CI: −2.20 to −1.11; $P < 0.001$; control: −1.87, 95% CI: −2.44 to −1.30; $P < 0.001$); diastolic blood pressure (intervention: −6.45, 95% CI: −9.63 to −3.28; $P < 0.001$; control: −3.89, 95% CI: −7.09 to −0.68; $P = 0.02$); and hemoglobin A1c (intervention: −0.26, 95% CI: −0.38 to −0.14; $P < 0.001$; control: −0.28, 95% CI: −0.40 to −0.16; $P < 0.001$; Table 2, Model 2).

In the between-group multivariate analysis, intervention participants had significant improvement in CRP and Simple 7 compared with controls (difference: −1.15, 95% CI: −2.16 to −0.15; $P = 0.03$ and 0.67, 95% CI: 0.14 to 1.21; $P = 0.01$, respectively; Table 3, Model 2). In addition, the odds of an improvement in Simple 7 were more than twice as likely in the intervention group compared with the control group (odds ratio 2.45; $P = 0.004$; not shown in table). Total cholesterols levels improved among controls compared with intervention (difference: 11.77, 95% CI: 0.57 to 22.96; $P = 0.04$; Table 3, Model 2). Primary and secondary outcome results were similar between the site-only adjusted (Model 1) and multivariate models (Model 2) as well as the LOCF models (Supporting Information Tables S2 and S3).

Class sessions and civic engagement

The average class size was 12 participants. Median class attendance was 77% in the intervention group and 83% in the control group; mean attendance was 74% and 68%, respectively. Analyses showed that among participants who attended at least 75% of their classes, intervention participants lost 1.01 more BMI units than controls (95% CI: −1.83 to −0.194; $P = 0.04$). Among participants attending less than 75% of classes, there was no difference in BMI change by group. For the HEART Club civic engagement, groups engaged in community change projects and activities that included creating and/or improving walking trails and park areas, organizing and implementing countywide health fairs, and helping local restaurants identify healthy food choices on their menus for customers.

Discussion

Rural women who participated in the multilevel, experiential, socioecological SHHC curriculum achieved greater weight loss and enhanced improvements in CVD risk factors compared with the control program.

The control group also benefited in several parameters, although to a lesser degree; compared with the intervention group, they had more improvement in terms of total cholesterol, but these changes lack explanation based on the data collected, such as changes in medication use.

Our findings are similar to other community-based lifestyle interventions targeting CVD risk reduction among underserved (e.g., rural, low-income) populations (31-34). For example, Devine and colleagues, using an experiential education approach aimed at fruit and vegetable intake in low-income women, found significant increases in intake in intervention versus control group participants (33). The South Asian Heart Lifestyle Intervention also used both community-engaged and experiential learning approaches; intervention participants had significant weight loss and improved hemoglobin A1c levels compared with controls at 6 months (34).

In the current study, the odds of improvement in Simple 7 were more than twice as high in the intervention group compared with the control group. In the Atherosclerosis Risk in Communities Study, with a mean follow-up of nearly 19 years, participants with an ideal Simple 7 score had no CVD events, while CVD incidence was 7.5 per 1,000 person-years for those with intermediate Simple 7 scores and 14.6 for those with a poor Simple 7 score (24).

Compared with other interventions of a similar length, weight loss was modest. However, the goal of SHHC was stepwise, progressive (e.g., increased duration and intensity of aerobic exercise) lifestyle improvements to improve body weight and other CVD risk factors. Results of the SHHC study are similar to comparable healthy lifestyle interventions. For example, at the midpoint of Arredondo and colleagues' 2-year physical activity intervention, the intervention group decreased their BMI significantly more than the comparison group (−0.43 units; $P = 0.04$), which is similar to the results of our 6-month study (−0.71 units; $P = 0.03$) (35). Furthermore, the focus on social and built environment knowledge and activities, such as in the HEART Club, do direct time away from individually focused in-class activities such as exercise. Revisions are being made to the intervention curriculum to supplement the program's classes with additional out-of-class support materials, tools, and "assignments" to keep individual-level progress on track.

Relevant to this study are minimal versus enhanced intervention studies and pragmatic comparative effectiveness studies. Some report no difference in BMI, blood pressure, or cholesterol between minimal interventions and enhanced interventions (36-38). However, similar to our findings, minimal interventions themselves may be robust enough to create change; other 6-month behavior change interventions observed decreased weight and blood pressure with monthly classes (39,40). Monthly contacts following a 6-month intervention can yield superior weight maintenance compared with those not receiving contact (self-directed) (41). Additionally, a recent systematic review of multicomponent behavioral weight management programs suggested that when researchers assume minimal intervention, control participants may lose up to a kilogram by the end of the first-year follow-up (42).

Beyond the HEART Club civic engagement, additional activities were directed at the social and built environment of participants. For example, the walking tour allowed participants to document environmental opportunities and barriers to healthy eating and physical activity in their community. Although independent effects of civic engagement and the social and built environment components cannot be independently assessed with this design, they likely contributed additional benefits. For example, civic engagement can increase social, physical, and cognitive activity among older adults (43). Volunteering is linked to lower hypertension risk and a higher probability of achieving physical activity recommendations in older adults (43).

The Centers for Disease Control and Prevention recognizes the impacts of built and social environments and recommends changing them to promote healthier living (44). Particularly important is the built environment, including food stores, sidewalks, streets, parks, and bike lanes. Growing evidence links built environment features to obesity and related health behaviors, including physical activity and eating patterns (45). Changes in the built environment show potential in improving obesity risk factors (46). It would be best to evaluate the effects of built environment change on community members—beyond the participants and their friends and family members—through community audits and sampling, particularly over the long term (e.g., 5 to 10 years).

Evaluation of SHHC, with its hands-on, experiential learning focus combined with the social, built environment and civic engagement components, makes a novel contribution to the field. Strengths of this study also include integration of three evidence-based programs, randomization of participants after recruitment and baseline measurements, and the inclusion of 16 rural, medically underserved communities with hard-to-reach populations. Use of existing infrastructure of cooperative extension and rural health care systems is another notable strength of this study, as these partnerships hold potential for national dissemination.

Given the focus on medically underserved rural populations, it is possible our findings would not generalize to urban populations, although certainly aspects of limited health care access have universal implications; thus, this program may indeed be appropriate and should be further evaluated in new settings. Another possible limitation is that the women in this study were more highly educated (48% with college education) than the average female residents in these rural towns (approximately 20%). Thus, the study population was not reflective of the overall town population in terms of education. However, 52% of the study population was of lower educational attainment, and sensitivity analyses found no differential intervention effects by education, which provides some assurance of the program's relevance to the general population. Although the SHHC intervention group addressed aspects of the social and community environment and HEART Clubs implemented changes through civic engagement initiatives, it was not the objective of this study to evaluate major built environment or policy changes. However, an important contribution to the field would be future studies specifically designed to evaluate civic engagement's independent and additive effects.

Conclusion

Rural woman face unique challenges to living healthy lifestyles and are at greater risk for obesity-related CVD than other populations. Designing and evaluating effective programs that incorporate community-informed civic engagement initiatives hold important potential for health promotion for the participants and the broader community, as participants potentially act as powerful role models and agents of change for their families, friends, and communities (22). The SHHC curriculum was designed to meet this need, informed by extensive, multilevel formative data and implemented in partnership with local health educators in consideration of future dissemination feasibility. These findings demonstrate a clear potential for a multilevel approach with an experiential learning foundation. Future studies should include rigorous dissemination evaluation in a range of settings and populations. Additionally, longer-term follow-up and postintervention studies are needed to understand the durability of observed benefits. O

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References

1. Heron M. Deaths: Leading causes for 2013. National vital statistics reports, vol. 65, no. 2. Hyattsville, MD: National Center for Health Statistics; 2016.
2. Cossman JS, James WL, Cosby AG, Cossman RE. Underlying causes of the emerging nonmetropolitan mortality penalty. *Am J Public Health* 2010;100:1417-1419.
3. O'Connor A, Wellenius G. Rural-urban disparities in the prevalence of diabetes and coronary heart disease. *Public Health* 2012;126:813-820.
4. Bennett KJ, Olatosi B, Probst JC. Health disparities: a rural-urban chartbook. Columbia, SC: South Carolina Rural Health Research Center; June 2008.
5. Thornton L, Crawford D, Cleland V, Timperio A, Abbott G, Ball K. Do food and physical activity environments vary between disadvantaged urban and rural areas? Findings from the READI Study. *Health Promot J Austr* 2012;23:153-156.
6. Michimi A, Wimberly MC. Natural environments, obesity, and physical activity in nonmetropolitan areas of the United States. *J Rural Health* 2012;28:398-407.
7. Olsen J. An integrative review of literature on the determinants of physical activity among rural women. *Public Health Nurs* 2013;30:288-311.
8. Warren K, Mitten D, Loeffler T. *Theory & Practice of Experiential Learning*. Boulder, CO: Association for Experiential Education; 2008.
9. Raynor HA, Champagne CM. Position of the Academy of Nutrition and Dietetics: interventions for the treatment of overweight and obesity in adults. *J Acad Nutr Diet* 2016;116:129-147.
10. Brand T, Pischke CR, Steenbock B, et al. What works in community-based interventions promoting physical activity and healthy eating? A review of reviews. *Int J Environ Res Public Health* 2014;11:5866-5888.
11. Sautkina E, Goodwin D, Jones A, et al. Lost in translation? Theory, policy and practice in systems-based environmental approaches to obesity prevention in the Healthy Towns programme in England. *Health Place* 2014;29:60-66.
12. United States Department of Agriculture website. Economic Research Service. Rural-Urban Continuum Codes. https://www.ers.usda.gov/data-products/rural-urban-continuum-codes. Updated October 12, 2016. Accessed December 22, 2017.
13. Health Resources & Services Administration website. Shortage Designation. Types of Designations. https://bhw.hrsa.gov/shortage-designation/types Updated October 2016. Accessed December 30, 2016.
14. Seguin RA, Eldridge G, Graham ML, Folta SC, Nelson ME, Strogatz D. Strong Hearts, healthy communities: a rural community-based cardiovascular disease prevention program. *BMC Public Health* 2016;16:86. doi:10.1186/s12889-016-2751-4
15. Physical Activity Guidelines Advisory Committee. *Physical Activity Guidelines Advisory Committee Report, 2008*. Washington, DC: U.S. Department of Health and Human Services; 2008.
16. Seguin RA, Folta SC, Sehlke M, et al. The StrongWomen Change Clubs: engaging residents to catalyze positive change in food and physical activity environments. *J Environ Public Health* 2014;2014:162403. doi:10.1155/2014/162403
17. Folta SC, Lichtenstein AH, Seguin RA, Goldberg JP, Kuder JF, Nelson ME. The StrongWomen-Healthy Hearts Program: reducing cardiovascular disease risk factors in rural sedentary, overweight, and obese midlife and older women. *Am J Public Health* 2009;99:1271-1277.
18. Seguin R, Heidkamp-Young E, Kuder J, Nelson M. Improved physical fitness among older female participants in a nationally disseminated, community-based exercise program. *Health Educ Behav* 2012;39:183-190.
19. Siervo M, Lara J, Chowdhury S, Ashor A, Oggioni C, Mathers JC. Effects of the Dietary Approach to Stop Hypertension (DASH) diet on cardiovascular risk factors: a systematic review and meta-analysis. *Br J Nutr* 2015;113:1-15.
20. US Department of Health and Human Services website. Dietary Guidelines for Americans, 2015-2020. 8th ed. http://health.gov/dietaryguidelines/2015/guidelines. Published December 2015. Accessed December 22, 2017.
21. Rees K, Hartley L, Flowers N, et al. 'Mediterranean' dietary pattern for the primary prevention of cardiovascular disease. *Cochrane Database Syst Rev* 2013:CD009825. doi:10.1002/14651858.CD009825.pub2
22. Powell K, Wilcox J, Clonan A, et al. The role of social networks in the development of overweight and obesity among adults: a scoping review. *BMC Public Health* 2015;15:996. doi:10.1186/s12889-s12889-015-2314-0.
23. Tomaselli GF, Harty M-B, Horton K, Schoeberl M. The American Heart Association and the Million Hearts Initiative: a presidential advisory from the American Heart Association. *Circulation* 2011;124:1795-1799.
24. Folsom AR, Yatsuya H, Nettleton JA, Lutsey PL, Cushman M, Rosamond WD. Community prevalence of ideal cardiovascular health, by the American Heart Association definition, and relationship with cardiovascular disease incidence. *J Am Coll Cardiol* 2011;57:1690-1696.
25. Craig CL, Marshall AL, Sjostrom M, et al. International physical activity questionnaire: 12-country reliability and validity. *Med Sci Sports Exerc* 2003;35:1381-1395.
26. Lloyd-Jones DM, Hong Y, Labarthe D, et al. Defining and setting national goals for cardiovascular health promotion and disease reduction: the American Heart Association's Strategic Impact Goal through 2020 and beyond. *Circulation* 2010;121:586-613.
27. Goff DC, Lloyd-Jones DM, Bennett G, et al. 2013 ACC/AHA guideline on the assessment of cardiovascular risk. *Circulation* 2014;129(25 suppl 2):S49-S73.
28. United States Department of Agriculture website. Rural Classifications. http://www.ers.usda.gov/topics/rural-economy-population/rural-classifications.aspx. Updated November 17, 2016. Accessed December 22, 2017.
29. Chakraborty H, Gu H. A mixed model approach for intent-to-treat analysis in longitudinal clinical trials with missing values. RTI Press publication No MR-0009-0903. Research Triangle Park, NC: RTI Press; 2009.
30. Liu GHF, Lu KF, Mogg R, Mallick M, Mehrotra DV. Should baseline be a covariate or dependent variable in analyses of change from baseline in clinical trials? *Stat Med* 2009;28:2509-2530.
31. Khare MM, Koch A, Zimmermann K, Moehring PA, Geller SE. Heart Smart for Women: a community-based lifestyle change intervention to reduce cardiovascular risk in rural women. *J Rural Health* 2014;30:359-368.
32. Gilstrap LG, Malhotra R, Peltier-Saxe D, et al. Community-based primary prevention programs decrease the rate of metabolic syndrome among socioeconomically disadvantaged women. *J Womens Health* 2013;22:322-329.
33. Devine CM, Farrell TJ, Hartman R. Sisters in health: experiential program emphasizing social interaction increases fruit and vegetable intake among low-income adults. *J Nutr Educ Behav* 2005;37:265-270.
34. Kandula NR, Dave S, De Chavez PJ, et al. Translating a heart disease lifestyle intervention into the community: the South Asian Heart Lifestyle Intervention (SAHELI) study; a randomized control trial. *BMC Public Health* 2015;15:1064. doi:10.1186/s12889-015-2401-2
35. Arredondo EM, Haughton J, Ayala GX, et al. Fe en Accion/Faith in Action: Design and implementation of a church-based randomized trial to promote physical activity and cancer screening among churchgoing Latinas. *Contemp Clin Trials* 2015;45(Pt B):404-415.
36. Rosamond WD, Ammerman AS, Holliday JL, et al. Cardiovascular disease risk factor intervention in low-income women: the North Carolina WISEWOMAN project. *Prev Med* 2000;31:370-379.
37. Perry CK, Rosenfeld AG, Bennett JA, Potempa K. Heart-to-Heart: promoting walking in rural women through motivational interviewing and group support. *J Cardiovasc Nurs* 2007;22:304-312.
38. Will JC, Massoudi B, Mokdad A, et al. Reducing risk for cardiovascular disease in uninsured women: combined results from two WISEWOMAN projects. *J Am Med Womens Assoc (1972)* 2000;56:161-165.
39. Martin PD, Rhode PC, Dutton GR, Redmann SM, Ryan DH, Brantley PJ. A primary care weight management intervention for low-income African-American women. *Obesity* 2006;14:1412-1420.
40. Duff EMW, Simpson SH, Whittle S, Bailey EY, Lopez SA, Wilks R. Impact on blood pressure control of a six-month intervention project. *West Indian Med J* 2000;49:307-311.
41. Svetkey LP, Stevens VJ, Brantley PJ, et al. Comparison of strategies for sustaining weight loss - the weight loss maintenance randomized controlled trial. *JAMA* 2008; 299:1139-1148.
42. Johns DJ, Hartmann-Boyce J, Jebb SA, Aveyard P, Behav Weight Management Review G. Weight change among people randomized to minimal intervention control groups in weight loss trials. *Obesity* 2016;24:772-780.
43. Anderson ND, Damianakis T, Kroeger E, et al. The benefits associated with volunteering among seniors: a critical review and recommendations for future research. *Psychol Bull* 2014;140:1505-1533.
44. Khan LK, Sobush K, Keener D, et al. Recommended community strategies and measurements to prevent obesity in the United States. *MMWR Recomm Rep* 2009; 58(RR7):1-26.
45. Renalds A, Smith TH, Hale PJ. A systematic review of built environment and health. *Fam Community Health* 2010;33:68-78.
46. Matson-Koffman DM, Brownstein JN, Neiner JA, Greaney ML. A site-specific literature review of policy and environmental interventions that promote physical activity and nutrition for cardiovascular health: what works? *Am J Health Promot* 2005;19:167-193.