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Strong Hearts for New York: a multilevel community-based randomized cardiovascular disease risk reduction intervention for rural women

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Abstract

Background: Rural midlife and older women have high rates of cardiovascular disease (CVD) risk factors and lower access to healthy living resources. The Strong Hearts, Healthy Communities (SHHC) intervention, tailored to the needs of rural women, demonstrated effectiveness on many outcomes. The purpose of the Strong Hearts for New York (SHNY) study is to evaluate the efficacy of an enhanced version of the curriculum (SHHC-2.0).

Methods: SHNY is a randomized controlled efficacy intervention, comparing participants receiving the SHHC-2.0 curriculum with a delayed intervention control group. SHHC, informed by formative research, includes core elements from three evidence-based programs. Changes based on extensive outcome and process evaluation data were made to create SHHC-2.0. Classes will meet twice weekly for 24 weeks and include individual, social, and environmental components. Overweight women age 40 and over will be recruited from 11 rural, medically underserved communities in New York; data will be collected at baseline and 12, 24, 36, and 48 weeks across individual, social, and environmental levels. Primary outcome is body weight. Secondary outcomes include Simple 7 (composite CVD risk score), anthropometric, physiologic, biochemical, physical activity, and dietary intake measures; healthy eating and exercise self-efficacy and attitudes; and self-efficacy of the social network of participants.

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Competing interests: The authors declare that they have no competing interests.

Discussion: The aims of this study are to evaluate the efficacy of the enhanced SHHC-2.0 program for participants, changes among participants' social networks, and the difference in outcomes when participants are and are not provided with technological tools (Fitbit and body composition scale).

Keywords

Physical activity; Nutrition; Social network; Civic engagement; Rural; Cardiovascular disease

INTRODUCTION

Cardiovascular disease (CVD) is the leading cause of mortality in the United States, accounting for one out of every three deaths [1]. People in rural areas have higher rates of risk factors for CVD, including obesity [2, 3], high blood pressure [4], diabetes [5], smoking [4], and poor diet [6], as well as lower access to physical activity [7] and healthy eating [8] resources.

Physical activity and diet improvements can reduce risk for CVD for all individuals, including midlife and older adults [9]. Recognizing the influence of social and environmental variables on health, the Centers for Disease Control and Prevention [10] recommends multilevel programs with individual, interpersonal, and environmental elements.

In the interpersonal sphere, people tend to exhibit concordance with their social network in health risk factors, including diet, physical activity, and obesity [11]. Most studies examining the effect of healthy behavior interventions on changes in family members find that overweight spouses lose weight [12–18], but few studies have looked at intervention effects on a larger social network. If interventions extend benefits to participants' social networks, the reach and cost-effectiveness of interventions could be greater than previously measured.

In the environmental sphere, evidence suggests that built environment features are linked to chronic disease risk; changes in policies and the built environment have shown potential in improving health behaviors, including physical activity and diet [19–26]. There is little known about the effect of intervening at the environmental level in rural, medically underserved areas within the context of a multilevel intervention.

Within the individual sphere, self-monitoring is an important aspect of changing diet and physical activity patterns [27] and weight loss or maintenance [28], and recent technology adds greatly to the ease and precision of self-monitoring. The use of technology for self-monitoring results in improvements in health behaviors [29, 30], but little is known about the effect of the addition of this technology to a multilevel intervention.

The Strong Hearts, Healthy Communities (SHHC) program includes activities aimed at the individual, social, and environmental levels of health behaviors. For instance, SHHC includes aerobic and strength training (individual level), class discussions about strategies building social support for exercising outside of class (social level), and grocery store and

town walking audits (environmental level). SHHC includes key elements of three previous StrongWomen curricula: strength training [31–33], aerobic exercise [34, 35], nutrition education and behavioral strategies [34, 35], and civic and social engagement strategies [36–38]. SHHC included formative research to gather information about barriers and facilitators to healthy living, particularly within the rural context. SHHC was tested in a 24-week community-based randomized controlled trial with overweight, sedentary midlife and older women in sixteen rural, medically underserved communities in Montana and New York. Compared to participants in a minimal intervention control group, intervention participants improved diet, physical activity, strength, BMI/weight, C-reactive protein, and CVD risk scores [39–41]. Outcome and process evaluations from SHHC were used to improve the curriculum [42]. The next iteration of this curriculum, Strong Hearts, Healthy Communities, version 2 (SHHC-2.0), will be tested in this study.

METHODS/DESIGN

The overall objective of SHNY is to create an effective, comprehensive, multilevel CVD prevention program to improve diet and physical activity behaviors.

Aims

Aim 1. Evaluate the efficacy of the SHHC-2.0 intervention to change CVD-related biometric, diet, and physical activity parameters in participants and perceived and objective built environment measures; conduct process evaluation, including cost-effectiveness.

Aim 2. Evaluate changes in biometric, diet, and physical activity behavior, attitudes, and knowledge among participants' social networks.

Aim 3. Evaluate differences in outcomes when participants are and are not provided with activity trackers and Bluetooth-enabled body weight/composition scales.

Participants

Towns/communities.—Rural-Urban Commuting Area codes [43] of 4 or higher (micropolitan or rural) and Primary Care Health Professional Shortage Areas [44] were used to define rural, medically underserved communities. Five rural, medically underserved communities in upstate New York will be randomized to the intervention and six additional communities will be randomized to the delayed intervention, which will begin 24 weeks after baseline.

Professionals.—Classes will be taught by extension educators or health educators with experience as coaches or personal trainers.

Recruitment.—Program leaders will use a variety of methods to recruit participants including flyers, community bulletin boards, social media, radio, newspapers, direct mail post cards, and 'word of mouth.' Snowball sampling will also be done; participants will be given a $20 Amazon gift card for each eligible participant that is referred.

Retaining participants.—We successfully retained participants in the SHHC study and will use similar effective retention and attendance strategies for SHNY. Leaders will use team-building strategies, establish an accepting environment, and provide informational and emotional support to participants. If a participant misses a class, the leader will call her, acknowledge she was missed, ask about the reason she missed class, and assist her in developing a plan to overcome attendance barriers. To minimize attrition of the delayed intervention group, we will contact participants via email, postal mail, and phone calls at regular intervals, including email and phone notifications for data collection sessions. If participants drop out of the intervention, attempts will be made to have them continue to participate in data collection sessions.

Screening and eligibility.—Potential participants will be screened to ensure they meet the inclusion criteria. Women who meet the initial screening criteria will be required to obtain authorization to participate from a healthcare provider, indicating that it is safe for the individual to participate in SHNY. If a participant's health changes in such a way that the program becomes unsafe, the participant will be asked to discontinue the program.

Inclusion criteria.: Participants must be female, age 40 or older, and live in one of the participating communities. Participants must either be 1) obese (BMI >30) or 2) overweight (BMI 25 to 30) and currently sedentary (participating in no more than one bout of 30+ minutes of physical activity per week on average, over the past three months).

Exclusion criteria.: Potential participants will be ineligible if they do not provide informed consent or permission from their healthcare provider, have systolic blood pressure higher than 160 or diastolic blood pressure higher than 100, have a heart rate <60 or >100, have cognitive impairment, are unable or unwilling to complete online questionnaires, are currently participating or planning to participate in another health behavior change program in the next six months, or are unwilling to be randomized to immediate or delayed intervention.

SHHC-2.0 enhanced curriculum

The curriculum was enhanced based on outcome and process evaluations from the SHHC trial [42]. SHHC leaders completed an online survey after each class and participants completed a survey after the program ended. Additionally, focus groups were conducted with participants via telephone, and semi-structured interviews were conducted with leaders after completion of the program. Focus groups and interviews were designed to assess satisfaction with the program and suggestions for improving the program. Overall response to the program was positive, and analysis of quantitative and qualitative data revealed common suggestions for improvement. In response to these suggestions, a number of revisions were made to the SHHC curriculum. In adaptation of the curriculum, we also considered the efficacy of the program among the measured variables.

Below we list changes to the SHHC curriculum as it was transformed into SHHC-2.0.

1. *Inclusion of a Fitbit and WiFi scale for Group 1 participants.* Based on the positive feedback received from participants and leaders about the use of Fitbits

during SHHC, we offered this element plus an additional technology element and guidance in the participant handbook on how to use both. Given the additional cost of these materials, we intentionally did not include them in the program for the control arm. Thus, since Group 1 (immediate program) will be provided with Withings weight and body composition scales and Fitbit activity trackers, both of which connect to the Fitabase data management platform, and Group 2 will not be provided with scales or activity trackers. We will compare the effect of the intervention with and without technology.

2. *Timing of nutrition education and HEART Club materials.* Participants response to the civic engagement component of the SHHC curriculum indicated they wanted to focus primarily on individual level change at the beginning of the program and conduct HEART Club activities later. They also requested nutrition education be introduced earlier [42]. In response to this feedback, class order was changed; nutrition topics were moved to the beginning of the program and HEART Club topics are not introduced until nearly halfway through the program.

3. *Inclusion of a greater variety of aerobic exercise DVDs.* Also in response to participant feedback [42], additional options were added for the aerobic exercise DVDs. In SHHC, one main DVD developed by the study team was used, plus one additional appropriate commercial DVD. For SHHC-2.0, three additional commercial DVDs were added.

4. *More consistency for strength training in class.* Participants requested more consistency of strength training exercises [42]; this aspect of the curriculum was addressed in SHHC-2.0 by ensuring that exercises were varied and repeated equally throughout the program.

5. *All HEART Club content included in class.* In SHHC, HEART Club activities were conducted in additional monthly meetings (beyond the twice-weekly classes). In SHHC-2.0, HEART Club activities are included in the twice-weekly classes to accommodate the logistic challenges for participants and leaders. The civic engagement process remained the same.

6. *Fewer snacks/participants will bring snacks.* SHHC required leaders to prepare prescribed healthy recipes for most of the twice-weekly classes; this posed a logistical challenge for leaders [42]. In order to decrease time and financial costs for organizations offering the program in the future, SHHC-2.0 includes fewer snacks and requests that participants volunteer to prepare and bring the prescribed snacks. Most SHHC participants indicated a willingness to prepare and bring snacks [42].

7. *Health journal.* SHHC included one-page participant logs for exercise that were collected once a week and entered by the educators into Qualtrics. The data entry burden for leaders was substantial and the participants did not find the logs particularly helpful. For SHHC-2.0, we created a detailed health journal for participants to record diet and exercise goals and progress.

8. *Additional curriculum content in the participant guide.* The SHHC leader guide included information beyond that in the participant guide. Based on participant and leader feedback [42], we included some of this additional content in the SHHC-2.0 participant guide. For example, the revised participant guide includes new introductory sections on the overall SHHC program, as well as on exercise, including instructions for each strength training exercise, and nutrition, including sample healthy meal plans. In addition to the new introductory sections, additional handouts were developed for each class, and the following additional sections were added for most classes: 1) Takeaway Messages, 2) Things to Try at Home, 3) Suggested Resources, 4) Homework.

9. *Added nutrition guidance from Strong Women Stay Slim* [45]. In order to not only improve dietary quality, but also provide more specific guidance for weight loss, and in response to leader and participant feedback [42], a detailed dietary plan is included in SHHC-2.0. Strong Women Stay Slim provides a Daily Food Plan with a calorie goal, plus daily food group portions [45].

10. *More frequent goal-setting reminders.* Because goal-setting is such an important component of behavior change and leaders recommended increasing goal-setting guidance and regularly monitoring progress during class [42], additional check ins about goals were added to the curriculum.

11. *Added homework.* In order to encourage participants to engage in program-related activities (particularly strength training and aerobic exercise), outside of class, homework was added to the curriculum.

12. *Additional content related to social support and sabotage.* Recognizing the importance of social level factors [46], we added additional content relating to support from friends and family members for increasing physical activity and improving diet, as well as dealing with difficulty in this area [42].

Staff training

Leaders will attend a one-day training on the SHHC-2.0 intervention and a half-day training on research methods, and weekly support calls will be held for leaders during active program implementation. Leaders will complete questionnaires after each class related to program fidelity, and trained research staff will conduct site visits at Class 40 and complete fidelity checklists.

Data collection and outcomes

Data will be collected at six time points: screening, baseline, 12 weeks, 24 weeks, 36 weeks, and 48 weeks. (See Table 1.) The primary timepoint for comparison is change from baseline to 24 weeks. We will collect individual and social network level data across biometric, behavioral, and psychosocial measures, and physical activity and nutrition environment level data. Leaders will report individual participant attendance for each class.

Additions to Measures from SHHC.—SHNY will include the following data which was not measured in SHHC: nutrition and physical activity built environment direct

observation measures (described below); perceived food environment measures; additional data related to gastric bypass, having a scale at home, and participation in other programs; additional Fitabase Fitbit and scale data; additional friends and family data, particularly related to impact of the intervention; and site visit fidelity checklists.

Individual level measures.: Research staff and programs leaders will explain the study and obtain written informed consent from participants; consent forms will be approved by the Cornell University and Bassett Research Institute Institutional Review Boards (IRBs).

Demographic information.: Participants will answer questions about demographics (e.g. age, race/ethnicity, education, income).

Biometric.: We will measure objective waist and hip circumferences, weight, height, body fat, bone density, body composition, blood pressure, and fasting blood draws of participants. Family and friends will self-report height and weight. We will use free-standing stadiometers for height, and Omron HBF-510W scales will be used for weight and body composition measures. For Group 1, the Fitabase program will also be used to collect weight, at any time during the study at which the participant weighs herself. Retractable Gulick tape measures will be used for waist and hip circumferences. Height, weight, and hip and waist circumferences will be measured two times, unless specified criteria are not met. In that case, a third measurement will be taken. Blood draws will be used to measure hemoglobin A1c, C-reactive protein, total cholesterol, LDL cholesterol, HDL cholesterol, and triglycerides.

Diet/eating.: For an objective, reliable, non-invasive measure of fruit and vegetable intake, a dermal scan will be performed, using a Pharmanex BioPhotonic Scanner, which measures carotenoid levels using Raman Spectroscopy [47]. Self-report measures of diet intake, behavior, and other nutrition-related variables will include five days of automated self-administered 24-hour dietary recalls (ASA-24 [48]), eating habits (Rapid Eating and Activity Assessment for Participants-Short Version (REAP-S [49]), Three Factor Eating Questionnaire; (TFEQ [50]), fruit and vegetable intake (National Cancer Institute Fruit and Vegetable Screener; NCI FV [51]), Simple 7 fruit and vegetable questions (S7 FV [52]), healthy eating attitudes (Healthy Eating Attitudes Scale; HEAS [53]), and self-efficacy for healthy eating (Self Efficacy for Diet Behaviors[54]).

Physical activity/sedentary behavior.: Objective physical activity measurements will be obtained by Actigraph GT3XE accelerometers worn for seven days at baseline, and 12, 24, 36, and 48 weeks. For Group 1, the Fitabase program will also be used to collect any recorded Fitbit data. The following physical activity and sedentary-related measures will be collected via self-report: physical activity (International Physical Activity Questionnaire; IPAQ [55]), sedentary behavior (Sedentary Behavior Questionnaire; SBQ [56]), walking activity (Health Behavior and Environment Questionnaire; HBEQ [57]), self-efficacy for physical activity (Self Efficacy for Exercise Behaviors[54]), and attitudes toward exercise (American Association of Retired People Exercise Attitudes and Behaviors Survey; AARP [58]).

Psychosocial variables.: Psychosocial measurements will include depression (Patient Health Questionnaire-8; PHQ-8 [59]), anxiety (Generalized Anxiety Disorder-7; GAD-7 [60]), stress (Perceived Stress Scale; PSS [61]), and resilience (Brief Resilience Scale; BRS [62]).

Program satisfaction.: Each group will complete program satisfaction surveys at the middle and end of their respective active 24-week program.

Social level measures.: Social network members identified by participants will be invited to complete questionnaires about their health, diet, and physical activity.

General.: Social network members will sign an informed consent form approved by the Cornell University and Bassett Research IRBs and respond to questions about demographics and general health.

Biometric.: Social network members will self-report their height (baseline only) and weight.

Diet/eating.: Social network members will answer questions about their eating habits (REAP-S), fruit and vegetable intake (NCI FV, S7 FV), and healthy eating attitudes (HEAS).

Physical activity/sedentary behavior.: Physical activity and sedentary behavior-related information of social network members will be via self-report and include physical activity (IPAQ), sedentary behavior (SBQ), walking (HBEQ), self-efficacy for physical activity (Self Efficacy for Exercise Behaviors), and attitudes toward exercise (AARP).

Built environment level measures.

Nutrition environment.: There will be two objective measures of the nutrition environment: at baseline and 48 weeks, research staff will conduct the Nutrition Environment Measures Survey in Stores (NEMS-S [63]); at 24 weeks (participants) and 48 weeks (research staff) a walking tour with photos and audio recordings will be completed. Perceived measures of the nutrition environment will be collected from participants and social network members via the following questionnaires: Perceptions of Neighborhood Food Environment Questionnaire [64], Self-Reported Neighborhood Characteristics Questionnaire [65], and the Perceived Nutrition Environment Measures Survey-Short [66].

Physical activity environment.: Similar to objective measurements of the nutrition environment, there will be two objective measures of the physical activity environment: at baseline and 48 weeks, research staff will conduct a community audit inventory (Inventories for Community Health Assessment in Rural Towns; iCHART [67]), and the walking tour with photos and audio recordings conducted at 24 weeks (participants) and 48 weeks (research staff) will also capture physical activity environment information. Perceived physical activity environment will be collected from participants and social network members via the Perceived Physical Activity Environment Scale [68] and reported changes in the physical activity environment.

Outcomes: The primary outcome is body weight change from baseline to 24 weeks, which will be collected immediately following the six-month intervention. Secondary outcomes are

Simple 7 composite CVD risk score, blood pressure, blood lipids, C-reactive protein, hemoglobin A1c, waist and hip circumferences, 7-day accelerometry, 5-day dietary recall, healthy eating and exercise self-efficacy, and healthy eating and exercise attitudes and self-efficacy of the social network of participants.

Additional measures.

Cost effectiveness.: From program leaders, we will collect information on wages and benefits, cost of facilities, equipment/supplies, travel, and staff training, and from participants, we will collect information on time costs (participants' time at hourly wage rate), travel costs, and time spent exercising and preparing meals.

Randomization

Randomization will be done at the town level. Towns are paired within counties such that one town's participants will receive the intervention and the other town's participants will receive the delayed intervention. Following completion of participants' baseline assessments in each county, the statistician will randomly assign one town from each pair of towns in a county to receive the intervention. Note that with one county that has three towns, they will have one town participating in the intervention and two towns participating in the delayed intervention. After baseline assessments, randomization assignments will be revealed to leaders and participants.

Power

The trial has been powered to compare the intervention arm to the delayed intervention arm on changes in weight from baseline to post-intervention (24 weeks). The sample size calculation is based on a similar behavior change study in midlife and older women, the StrongWomen-Healthy Hearts study, in which intervention arm participants lost 2.1 kg (SD = 2.6) over twelve weeks compared to controls [34]. In this SHNY study, participants are clustered within 11 towns and we assumed an intra-class correlation of 0.15 (with clusters of 12 people per town) and 15% attrition, which yields a design effect of 2.65. Therefore, a sample size of 29 people per arm will ensure at least 80% power to detect an effect size of 0.75 with a 2-sided alpha and 2.6kg standard deviation, which means that we will be able to detect a difference in weight change between arms of 1.95kg.

Statistical analysis

Univariate descriptive statistics will be calculated for all variables, and outliers will be identified, investigated, and possibly rectified. We will compile and tabulate descriptive statistics by treatment group. We will compare the groups using chi-square test (binary and categorial variables), *t*-test (continuous variables), or non-parametric Wilcoxon signed rank test (continuous variables unsuitable for *t*-test). To account for the clustering of participants in communities, we will use mixed effect regression models with town included as a random effect.

We will analyze following Intention-to-Treat principles and will use multiple imputation to handle missing data. Multiple imputation will be conducted in SAS (PROC MI) for both

missing baseline and outcome variables. SAS PROC MIANALYZE will be used to combine the model results from within each imputed data set in the standard way.

To evaluate the primary outcome model, we will run a PROC MIXED MODEL predicating change in weight from baseline to post-intervention (24 weeks) with the following covariates: intervention assignment, town random effect, age, and education. We will run the same model for evaluating changes in secondary outcomes including Simple 7 composite CVD risk score, dietary outcomes, physical activity outcomes, and psychosocial outcomes. To account for multiple comparisons of the secondary outcomes, we will report the critical p-value using a Bonferroni correction at alpha=0.05 in addition to the unadjusted for multiple comparisons p-value. Analysis will be conducted using SAS v9.4.

Economic analysis.—We will calculate cost analysis and cost effectiveness from the payer, societal, and healthcare sector perspectives. For the payer cost analysis, we will identify resources directly used in administration and implementation and identify costs of these resources (e.g. facilities, labor) to calculate the total and per participant costs. For the societal perspective, we will measure the direct program costs as well as opportunity costs, including participant time, based on relevant wage rates. We will calculate the incremental cost-effectiveness ratios (for the payer and societal perspectives) as the ratio of incremental cost over incremental effectiveness, based on change in weight, BMI, C-reactive protein, and Simple 7. For the healthcare perspective, we will use estimates of the medical costs of cardiovascular disease to estimate the quality adjusted life years saved based on cardiovascular events prevented, comparing SHNY to status quo (no intervention).

Process evaluation.—Aforementioned, we will compile process evaluation data including outcome effectiveness, leader and participant feedback and satisfaction, attendance, and fidelity.

Dissemination of results and access to data

We will share our results with diverse audiences through a variety of methods. We will publish our results in peer-reviewed journals and deliver presentations at scientific meetings. For community members, we will publish articles in lay press (e.g. newspapers) and include results on the study website, after acceptance of the main findings for publication. The Principal Investigator and her research team will have access to the final dataset and the dataset will be shared with other researchers who request access, via data sharing agreements, after acceptance of the main findings for publication. The International Committee of Medical Journal Editors guidelines will be used for authorship eligibility.

DISCUSSION

Because midlife and older women in rural areas face health disparities in terms of risk factors for CVD, and multilevel programs are recommended for CVD interventions, we aim to improve a previously effective multilevel curriculum designed for this population. Programs that include individual, social, and environmental components have the potential to improve diet and exercise behaviors for participants, friends and family members, and community members. If effective and cost-effective, SHHC-2.0 could be disseminated

nationally, providing a practical, feasible format for reducing CVD risk factors and improving health in underserved rural areas.

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List of Abbreviations

AARP	American Association of Retired People Exercise Attitudes and Behaviors Survey
ASA-24	Automated Self-Administered 24-h Recall
BMI	Body Mass Index
BRS	Brief Resilience Scale
CRP	C-reactive protein
CVD	Cardiovascular disease
GAD-7	Generalized Anxiety Disorder-7
HBEQ	Health Behavior and Environment Questionnaire
HEAS	Healthy Eating Attitudes Scale
IPAQ	International Physical Activity Questionnaire
NCI FV	National Cancer Institute Fruit and Vegetable Screene
NEMS-S	Nutrition Environment Measures Survey in Stores
PHQ-8	Patient Health Questionnaire-8
PSS	Perceived Stress Scale
REAP-S	Rapid Eating and Activity Assessment for Participants-Short Version
S7 FV	Simple 7 Fruit and Vegetable Questions
SBQ	Sedentary Behavior Questionnaire
SHHC	Strong Hearts, Healthy Communities
SHHC-2.0	Strong Hearts, Healthy Communities curriculum, version 2

SHNY	Strong Hearts for New York
TFEQ	Three Factor Eating Questionnaire

References

1. Benjamin EJ, Blaha MJ, Chiuve SE, Cushman M, Das SR, Deo R, et al. Heart disease and stroke statistics—2017 update: a report from the American Heart Association. Circulation 2017;135(10):e146–e603. [PubMed: 28122885]
2. Hales C, Fryar C, Carroll M, Freedman D, Aoki Y, Ogden C. Differences in obesity prevalence by demographic characteristics and urbanization level among adults in the United States, 2013–2016. JAMA 2018;319(23):2419–29. [PubMed: 29922829]
3. Meit M, Knudson A, Gilbert T, Yu AT-C, Tanenbaum E, Ormson E, et al. The 2014 Update of the Rural-Urban Chartbook Bethesda, MD: Rural Health Reform Policy Research Center 2014.
4. United Health Foundation. America's Health Rankings: 2017 Annual Report. www.americashealthrankings.org. (Accessed 27 December 2018.)
5. O'Connor A, Wellenius G. Rural-urban disparities in the prevalence of diabetes and coronary heart disease. Public Health 2012;126(10):813–20. [PubMed: 22922043]
6. Trivedi T, Liu J, Probst J, Merchant A, Jones S, Martin AB. Obesity and obesity-related behaviors among rural and urban adults in the USA. Rural Remote Health 2015;15(4).
7. Roubal AM, Jovaag A, Park H, Gennuso KP. Development of a nationally representative built environment measure of access to exercise opportunities. Prev Chronic Dis 2015;12:E09. [PubMed: 25611798]
8. Larson NI, Story MT, Nelson MC. Neighborhood environments: disparities in access to healthy foods in the US. Am J Prev Med 2009;36(1):74–81. e10. [PubMed: 18977112]
9. Mozaffarian D, Fried LP, Burke GL, Fitzpatrick A, Siscovick DS. Lifestyles of older adults: can we influence cardiovascular risk in older adults? Am J Geriatr Cardiol 2004;13(3):153–60. [PubMed: 15133418]
10. Centers for Disease Control and Prevention. Strategies to Prevent Obesity and Other Chronic Diseases: The CDC Guide to Strategies to Increase Physical Activity in the Community Atlanta: U.S. Department of Health and Human Services; 2011.
11. Cunningham SA, Vaquera E, Maturo CC, Narayan KMV. Is there evidence that friends influence body weight? A systematic review of empirical research. Soc Sci Med 2012;75(7):1175–83. [PubMed: 22749656]
12. Gorin AA, Wing RR, Fava JL, Jakicic JM, Jeffery R, West DS, et al. Weight loss treatment influences untreated spouses and the home environment: evidence of a ripple effect. Int J Obesity 2008;32(11):1678–84.
13. Matsuo T, Kim MK, Murotake Y, Numao S, Kim MJ, Ohkubo H, et al. Indirect lifestyle intervention through wives improves metabolic syndrome components in men. Int J Obesity 2010;34(1):136–45.
14. Gorin AA, Lenz EM, Cornelius T, Huedo-Medina T, Wojtanowski AC, Foster GD. Randomized controlled trial examining the ripple effect of a nationally available weight management program on untreated spouses. Obesity 2018;26(3):499–504. [PubMed: 29388385]
15. Golan R, Schwarzfuchs D, Stampfer MJ, Shai I, Grp D. Halo effect of a weight-loss trial on spouses: the DIRECT-Spouse study. Public Health Nutr 2010;13(4):544–9. [PubMed: 19706214]
16. White E, Hurlich M, Thompson RS, Woods MN, Henderson MM, Urban N, et al. Dietary-changes among husbands of participants in a low-fat dietary intervention. Am J Prev Med 1991;7(5):319–25. [PubMed: 1790038]
17. Schierberl Scherr AE, McClure Brenchley KJ, Gorin AA. Examining a ripple effect: do spouses' behavior changes predict each other's weight loss? J Obesity 2013;2013.
18. Rossini R, Moscatiello S, Tarrini G, Di Domizio S, Soverini V, Romano A, et al. Effects of cognitive-behavioral treatment for weight loss in family members. J Am Diet Assoc 2011;111(11):1712–9. [PubMed: 22027054]

19. 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(3):167–93. [PubMed: 15693346]
20. Audrey S, Batista-Ferrer H. Healthy urban environments for children and young people: a systematic review of intervention studies. Health Place 2015;36:97–117. [PubMed: 26457624]
21. MacMillan F, George ES, Feng XQ, Merom D, Bennie A, Cook A, et al. Do natural experiments of changes in neighborhood built environment impact physical activity and diet? A systematic review. Int J Environ Res Public Health 2018;15(2).
22. Smith M, Hosking J, Woodward A, Witten K, MacMillan A, Field A, et al. Systematic literature review of built environment effects on physical activity and active transport - an update and new findings on health equity. Int J Behav Nutr Phys 2017;14.
23. Karmeniemi M, Lankila T, Ikaheimo T, Koivumaa-Honkanen H, Korpelainen R. The built environment as a determinant of physical activity: a systematic review of longitudinal studies and natural experiments. Ann Behav Med 2018;52(3):239–51. [PubMed: 29538664]
24. Hunter RF, Christian H, Veitch J, Astell-Burt T, Hipp JA, Schipperijn J. The impact of interventions to promote physical activity in urban green space: a systematic review and recommendations for future research. Soc Sci Med 2015;124:246–56. [PubMed: 25462429]
25. de Nazelle A, Nieuwenhuijsen MJ, Anto JM, Brauer M, Briggs D, Braun-Fahrlander C, et al. Improving health through policies that promote active travel: a review of evidence to support integrated health impact assessment. Environ Int 2011;37(4):766–77. [PubMed: 21419493]
26. Crawford P, Dunning L, Kappagoda M, O'Connor J. The Role of Law and Policy in Achieving the Healthy People 2020 Nutrition and Weight Status Goals of Increased Fruit and Vegetable Intake in the United States Department of Health and Human Services, Office of Disease Prevention and Health Promotion Rockville, MD 9 13, 2018.
27. Greaves CJ, Sheppard KE, Abraham C, Hardeman W, Roden M, Evans PH, et al. Systematic review of reviews of intervention components associated with increased effectiveness in dietary and physical activity interventions. BMC Public Health 2011;11.
28. Burke LE, Wang J, Sevick MA. Self-monitoring in weight loss: a systematic review of the literature. J Am Diet Assoc 2011;111(1):92–102. [PubMed: 21185970]
29. Hermsen S, Frost J, Renes RJ, Kerkhof P. Using feedback through digital technology to disrupt and change habitual behavior: a critical review of current literature. Comput Human Behav 2016;57:61–74.
30. Lewis ZH, Lyons EJ, Jarvis JM, Baillargeon J. Using an electronic activity monitor system as an intervention modality: a systematic review. BMC Public Health 2015;15.
31. Seguin R, Economos C, Nelson M, Hyatt R, Palombo R, Reed P. Design and national dissemination of the StrongWomen Community Strength Training Program. Prev Chron Dis 2008;5(1).
32. 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(2):183–90. [PubMed: 22234966]
33. Seguin RA, Eldridge G, Lynch W, Paul LC. Strength training improves body image and physical activity behaviors among midlife and older rural women. J Ext 2013;51(4).
34. 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(7):1271–7. [PubMed: 19443826]
35. Folta SC, Seguin RA, Chui KK, Clark V, Corbin MA, Goldberg JP, et al. National dissemination of StrongWomen–Healthy Hearts: a community-based program to reduce risk of cardiovascular disease among midlife and older women. Am J Public Health 2015;105(12):2578–85. [PubMed: 26469644]
36. Seguin R, Heidkamp-Young E, Juno B, Knott A, Fenton M, Folta S, et al. Community-based participatory research pilot initiative to catalyze positive change in local food and physical activity environments. I Int J Behav Nutr Phys Act 2012;Annual Meeting Oral Presentation.

37. Seguin RA, Sriram U, Connor LM, Silver AE, Niu B, Bartholomew AN. A civic engagement approach to encourage healthy eating and active living in rural towns: the HEART Club pilot project. Am J Health Promot 2018; 32(7):1591–1601. [PubMed: 29390863]
38. Seguin RA, Folta SC, Sehlke M, Nelson ME, Heidkamp-Young E, Fenton 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.
39. Seguin RA, Paul L, Folta SC, Nelson ME, Strogatz D, Graham ML, et al. Strong Hearts, Healthy Communities: a community-based randomized trial for rural women. Obesity 2018;26(5):845–53. [PubMed: 29634086]
40. Pullyblank K, Strogatz D, Folta S, Paul L, Nelson M, Graham M, et al. Effects of the Strong Hearts, Healthy Communities intervention on functional fitness of rural women. J Rural Health In press.
41. Folta S, Paul L, Nelson M, Strogatz D, Graham M, Eldridge G, et al. Changes in diet and physical activity resulting from the Strong Hearts, Healthy Communities randomized cardiovascular disease risk reduction multilevel intervention trial. Int J Behav Nutr Phys In press.
42. Sriram U, Sandreuter K, Graham M, Folta S, Pullyblank K, Paul L, et al. Process evaluation of Strong Hearts, Healthy Communities: a rural community-based cardiovascular disease prevention program. J Nutr Educ Behav 2019;51(2):138–149. [PubMed: 30738562]
43. United States Department of Agriculture Economic Research Service. Rural-Urban Community Area (RUCA) Codes. 2010. https://www.ers.usda.gov/data-products/rural-urban-commuting-area-codes/documentation/. (Accessed 27 December 2018.)
44. US Department of Health and Human Services. Health Resources & Services Administration. HPSA Find. https://datawarehouse.hrsa.gov/tools/analyzers/hpsafind.aspx. (Accessed 27 December 2018.)
45. Nelson ME. Strong Women Stay Slim United States: Random House, Inc; 1998 317 p.
46. Sriram U, Morgan EH, Graham M, Folta S, Seguin R Support and sabotage:a qualitative study of social influences on health behaviors among rural adults. J Rural Health 2018 12;34(1):88–97. [PubMed: 28045193]
47. Mayne ST, Cartmel B, Scarmo S, Jahns L, Ermakov IV, Gellermann W. Resonance Raman spectroscopic evaluation of skin carotenoids as a biomarker of carotenoid status for human studies. Arch Biochem Biophys 2013;539(2):163–70. [PubMed: 23823930]
48. National Cancer Institute. Automated Self-Administered 24-Hour Recall (ASA-24) Bethesda, MD 2014.
49. Segal-Isaacson CJ, Wylie-Rosett J, Gans KM. Validation of a short dietary assessment questionnaire: the Rapid Eating and Activity Assessment for Participants Short Version (REAP-S). Diabetes Educ 2004;30(5):774–81. [PubMed: 15510530]
50. Cappelleri JC, Bushmakin AG, Gerber RA, Leidy NK, Sexton CC, Lowe MR, et al. Psychometric analysis of the Three-Factor Eating Questionnaire-R21: results from a large diverse sample of obese and non-obese participants. Int J Obesity 2009;33(6):611–20.
51. Thompson F, Kipnis V, Subar A, Krebs-Smith S, Kahle L, Midthune D, et al. Evaluation of 2 brief instruments and a food-frequency questionnaire to estimate daily number of servings of fruit and vegetables. Am J Clin Nutr 2000;71(6):1503–10. [PubMed: 10837291]
52. American Heart Association. Life's Simple 7. http://www.heart.org/en/healthy-living/healthy-lifestyle/my-life-check--lifes-simple-7. (Accessed 27 December 2018.)
53. Naughton P, McCarthy S, McCarthy M. Healthy eating attitudes and healthy living: an examination of the relationship between attitudes, food choices and lifestyle behaviours in a representative sample of Irish adults. Proc Nutr Soc 2013;72(OCE4):E221-E.
54. Sallis JF, Pinski RB, Grossman RM, Patterson TL, Nader PR. The development of self-efficacy scales for health-related diet and exercise behaviors. Health Educ Res 1988;3(3):283–92.
55. Craig C, Marshall A, Sjostrom M, Bauman A, Booth M, Ainsworth B, et al. International physical activity questionnaire: 12-country reliability and validity. Med Sci Sports Exerc 2003;35(8):1381–95. [PubMed: 12900694]

56. Rosenberg DE, Norman GJ, Wagner N, Patrick K, Calfas KJ, Sallis JF. Reliability and validity of the Sedentary Behavior Questionnaire (SBQ) for adults. J Phys Act Health 2010;7(6):697–705. [PubMed: 21088299]
57. Boehmer TK, Lovegreen SL, Haire-Joshu D, Brownson RC. What constitutes an obesogenic environment in rural communities? Am J Health Promot 2006;20(6):411–21. [PubMed: 16871821]
58. Roper A Exercise attitudes and behaviors: a survey of adults age 50–79 AARP, Washington, DC, USA 2002.
59. Kroenke K, Strine TW, Spitzer RL, Williams JBW, Berry JT, Mokdad AH. The PHQ-8 as a measure of current depression in the general population. J Affect Disord 2009;114(1–3):163–73. [PubMed: 18752852]
60. Spitzer RL, Kroenke K, Williams JBW, Lowe B. A brief measure for assessing generalized anxiety disorder: the GAD-7. Arch Intern Med 2006;166(10):1092–7. [PubMed: 16717171]
61. Cohen S, Williamson GM. Perceived stress in a probability sample of the United-States. Social Psychology of Health 1988:31–67.
62. Smith B, Dalen J, Wiggins K, Tooley E, Christopher P, Bernard J. The brief resilience scale: assessing the ability to bounce back. I Int J Behav Med 2008;15(3):194–200. [PubMed: 18696313]
63. Glanz K, Sallis JF, Saelens BE, Frank LD. Nutrition Environment Measures Survey in Stores (NEMS-S) - development and evaluation. Am J Prev Med 2007;32(4):282–9. [PubMed: 17383559]
64. Ma XG, Barnes TL, Freedman DA, Bell BA, Colabianchi N, Liese AD. Test-retest reliability of a questionnaire measuring perceptions of neighborhood food environment. Health Place 2013;21:65–9. [PubMed: 23434497]
65. Echeverria SE, Diez-Roux AV, Link BG. Reliability of self-reported neighborhood characteristics. J Urban Health 2004;81(4):682–701. [PubMed: 15466849]
66. Green SH, Glanz K. Development of the Perceived Nutrition Environment Measures Survey. Am J Prev Med 2015;49(1):50–61. [PubMed: 26094227]
67. Seguin RA, Lo BK, Sriram U, Connor LM, Totta A. Development and testing of a community audit tool to assess rural built environments: Inventories for Community Health Assessment in Rural Towns. Prev Med Rep 2017;7:169–75. [PubMed: 28702314]
68. Hume C, Ball K, Salmon J. Development and reliability of a self-report questionnaire to examine children's perceptions of the physical activity environment at home and in the neighbourhood. Int J Behav Nutr Phys Act 2006;3.

Table 1.

Data collection schedule

Assessment	Screening	Baseline	12 weeks	24 weeks	36 weeks	48 weeks
INDIVIDUAL LEVEL MEASURES						
General						
Informed consent form	X	X				
Demographics	X	X				
Adverse event form			X	X	X	X
General Health: physical health, health history/status, preventive care		X	X	X	X	X
Biometric measures						
Waist and hip circumferences, weight, height (baseline only), body fat, bone density, body composition, blood pressure, blood draw for lipids, hemoglobin A1c, and C-reactive protein		X	X[c,a]	X	X[c,b]	X
Diet/Eating Measures						
Objective: -Carotenoid skin scan		X	X[a]	X	X[b]	X
Self-report: -24 h recalls -Eating habits -Factors affecting healthy eating -Fruit and vegetable intake -Self-efficacy -Attitudes		X	X	X	X	X
Physical Activity/Sedentary Measures						
Objective: Accelerometry		X	X	X	X	X
Objective: Fitabase*§						
Self-report: -Physical activity -Sedentary behavior -Walking -Self-efficacy -Attitudes		X	X	X	X	X
Psychosocial Measures						
-Depression -Anxiety -Stress -Resilience		X	X	X	X	X
Cost Effectiveness						
Time and money spent on food and physical activity		X	X	X	X	X
Program Satisfaction						
Satisfaction survey			X[a]	X[a]	X[b]	X[b]
SOCIAL LEVEL MEASURES – completed by Social Network Members						
General						
Informed consent		X				
Demographics		X				
Biometric						

Assessment	Screening	Baseline	12 weeks	24 weeks	36 weeks	48 weeks
Self-report: height (baseline only) and weight		X		X		X
Diet/Eating Measures						
Self-report: -Eating habits -Factors affecting healthy eating -Fruit and vegetable intake -Attitudes		X		X		X
Physical Activity/Sedentary Measures						
Self-report: -Physical activity -Sedentary behavior -Walking -Self-efficacy -Attitudes		X		X		X
BUILT ENVIRONMENT LEVEL MEASURES						
Nutrition Environment						
Objective: Nutrition environment in stores		X				X
Objective: Walking tour photos and audio				X[g]		X
Perceived:[f] -Neighborhood food environment -Neighborhood characteristics		X		X		X
Physical Activity Environment						
Objective: Community audit inventory		X				X
Objective: Walking tour photos and audio				X[g]		X
Perceived:[f] -Physical activity environment -Changes in physical activity environment		X		X		X

[a] Group 1 only.

[b] Group 2 only.

[c] Only waist and hip circumferences and weight.

[d] Data collected throughout program.

[e] Health Behaviors and Environment Questionnaire only.

[f] Completed by participants and social network members.

[g] Walking tour photos and audio completed by participants.