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ORIGINAL ARTICLE

Improvements and Maintenance of Clinical and Functional Measures Among Rural Women: Strong Hearts, Healthy Communities-2.0 Cluster Randomized Trial

Rebecca A. Seguin-Fowler, PhD; Galen D. Eldridge, MS; Chad D. Rethorst, PhD; Meredith L. Graham, MS; Margaret Demment, PhD; David Strogatz, PhD; Sara C. Folta, PhD; Jay E. Maddock, PhD; Miriam E. Nelson, PhD; Seungyeon Ha, PhD

BACKGROUND: Cardiovascular disease is the leading cause of death in the United States; however, women and rural residents face notable health disparities compared with male and urban counterparts. Community-engaged programs hold promise to help address disparities through health behavior change and maintenance, the latter of which is critical to achieving clinical improvements and public health impact.

METHODS: A cluster-randomized controlled trial of Strong Hearts, Healthy Communities-2.0 conducted in medically underserved rural communities examined health outcomes and maintenance among women aged ≥40 years, who had a body mass index >30 or body mass index 25 to 30 and also sedentary. The multilevel intervention provided 24 weeks of twice-weekly classes with strength training, aerobic exercise, and skill-based nutrition education (individual and social levels), and civic engagement components related to healthy food and physical activity environments (community, environment, and policy levels). The primary outcome was change in weight; additional clinical and functional fitness measures were secondary outcomes. Mixed linear models were used to compare between-group changes at intervention end (24 weeks); subgroup analyses among women aged ≥60 years were also conducted. Following a 24-week no-contact period, data were collected among intervention participants only to evaluate maintenance.

RESULTS: Five communities were randomized to the intervention and 6 to the control (87 and 95 women, respectively). Significant improvements were observed for intervention versus controls in body weight (mean difference: −3.15 kg [95% CI, −4.98 to −1.32]; P=0.008) and several secondary clinical (eg, waist circumference: −3.02 cm [−5.31 to −0.73], P=0.010; systolic blood pressure: −6.64 mmHg [−12.67 to −0.62], P=0.031; percent body fat: −2.32% [−3.40 to −1.24]; P<0.001) and functional fitness outcomes; results were similar for women aged ≥60 years. The within-group analysis strongly suggests maintenance or further improvement in outcomes at 48 weeks.

CONCLUSIONS: This cardiovascular disease prevention intervention demonstrated significant, clinically meaningful improvements and maintenance among rural, at-risk older women.

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Key Words: cardiovascular disease ■ intervention ■ multilevel ■ prevention ■ rural

Correspondence to: Rebecca A. Seguin-Fowler 1500 Research Parkway, Ste B270 College Station, TX 77845. Email r.seguin-fowler@ag.tamu.edu
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For Sources of Funding and Disclosures, see page 911.

WHAT IS KNOWN

- Cardiovascular disease risk among rural women is notably higher compared with urban counterparts and exacerbated by geographic challenges including living in medically underserved areas due to limited access to care (particularly specialty care) and barriers to active living and healthy food access.
- Community-engaged multilevel interventions have demonstrated promise in other settings, but there is a dearth of evidence rigorously evaluating these approaches in rural areas with limited resources and an at-risk population.

WHAT THE STUDY ADDS

- Implementation and evaluation of this community-engaged multilevel intervention were both feasible and acceptable to community members and partners, using a community-randomized design that required relatively limited resources to conduct the intervention.
- Participants in the active intervention improved in numerous cardiovascular disease risk factors including body weight and other clinical and functional fitness outcomes.
- Many of these improvements were maintained for 6 months after the active intervention concluded, indicating strong durability of the behavior changes adopted.

Nonstandard Abbreviations and Acronyms

BMI	body mass index
CVD	cardiovascular disease
MI	multiple imputation
SHHC	Strong Hearts, Healthy Communities

Cardiovascular disease (CVD) is the leading cause of death in the United States,[1] and mortality rates are notably higher for women living in rural areas.[2] Compared with men, women are less likely to receive preventive guidance[3] and more likely to die from a heart attack.[4] Compared with urban women, rural women have a higher prevalence of obesity; are less active; tend to be older, poorer, and less educated; and are more likely to be uninsured.[5,6] Additionally, rural adults tend to access health care services, including preventive services, less frequently than urban adults.[7]

As noted in the American Heart Association's recent Call to Action for Cardiovascular Disease in Women,[4] a key component of addressing health equity in this area is to engage communities to optimize cardiovascular health. Community-based research may actively involve community members and partners, which helps allow for adaptations in program "fit" for communities and increases the likelihood that programs will continue beyond research funding.[8] According to Israel et al,[8] key principles of community-based research include building on resources within the community, promoting an empowering process, and addressing health from an ecological perspective. Incorporating civic engagement activities, in which participants work to understand and improve aspects of their food or physical activity environment, is a viable strategy to address community participation and multiple levels of influence.

Evidence-based programs that employ a community-engaged approach and address multiple levels of influence can play an important role in helping to address rural health disparities in particular. Social determinants of health for women in rural areas are multifaceted, including access to resources for physical activity and healthy food, food insecurity, educational opportunities, health literacy, and health care access. A growing body of literature demonstrates that providing individuals with information and skills to change and maintain health behaviors may be less effective if social, community, and/or environmental factors are not considered.[9,10] Prior work also indicates that midlife and older women may feel less comfortable using traditional and/or co-ed exercise facilities and that sex- and age-specific classes with social support components are an important facilitator of behavior change and maintenance.[10–15] However, to date, there is a dearth of such evidence-based CVD prevention programs for rural populations.[16,17]

Strong Hearts, Healthy Communities (SHHC) was designed to address this gap. It is a multilevel, multicomponent community-engaged intervention program specifically for women in rural areas. The formative development of SHHC involved working with residents, health care practitioners, health educators, local leadership, and other stakeholders in medically underserved rural towns to develop a program aiming to: (1) improve diet and physical activity behaviors; (2) promote built environment resources; and (3) shift social norms about active living and healthy eating through civic engagement, capacity building, and community-based programming.[11,15] SHHC was designed to be implemented in relatively isolated and low-resource rural communities with limited equipment in settings such as church basements and meeting rooms at community centers.[11] An initial randomized clinical trial (SHHC-1.0) was conducted in Montana and New York, followed by in-depth process evaluation (surveys, interviews, and focus groups) that resulted in adaptations to the original program;[18,19] a second randomized trial (SHHC-2.0), presented herein, was conducted in new communities in

rural New York. To our knowledge, there are no other multilevel intervention trials besides SHHC-1.0 and SHHC-2.0 that have included a combination of individually tailored activities in experiential, skill-based group classes; social network involvement; and civic engagement activities.

This article reports on the intervention effects on the primary outcome, body weight, as well as other clinical and functional fitness outcomes between intervention and control groups. In addition, outcomes are examined within the intervention group participants following a no-contact period at the 48-week time point to examine maintenance. This is a critical need because the majority of participants in weight loss programs lose weight initially and then regain the weight they lost; very few studies report maintenance follow-up measures.[20] Because more than half of CVD cases occur in older adults and the proportion of the US population over age 60 is increasing, CVD-related societal and health care burdens are important public health issues. Women tend to live longer than men and experience more years with disabilities[21]; maintaining physical function in older adulthood can extend functionally independent and disability-free years.[22] Older women may also be impacted differentially by intervention programs due to individual, household, familial, social, employment, and other factors.[23] Therefore, outcomes were examined separately among women 60 years or older.

METHODS

Study Design

The SHHC-2.0 study was a community-randomized, 2-group (intervention and control/delayed-intervention group) trial conducted with midlife and older women in rural communities in upstate New York. Details of the design, protocol, sample, and recruitment were published previously[18] and are described briefly herein.

SHHC-2.0 was implemented January 2017 to August 2018. Cornell University and Bassett Medical Center Institutional Review Boards approved the study. The data that support the findings of this study are available from the corresponding author upon reasonable request. Participants provided written, informed consent at baseline assessments; health care provider approval was obtained prior to enrollment.

Community Setting

Study locations were rural, medically underserved communities.[24] Medically underserved areas or populations are designated by the Health Resources and Services Administration as "having too few primary care providers, high infant mortality, high poverty, and/or a high elderly population."[24] Rural-Urban Commuting Area codes[25] of 4 or higher (micropolitan or rural) were used for rural designation. Community sites were matched into pairs for randomization based upon population size (394–8836) and Rural-Urban Commuting Area codes (4.1–10.2). All communities involved in this trial were geographically distinct and were not involved in the original SHHC trial (SHHC-1.0).[26,27] Median household income averaged $22 446; an average of 28% of the adult population had an undergraduate degree or higher.[28]

Intervention

The SHHC-1.0 program was informed by extensive community input including focus groups, surveys, and community audits.[11,15] Information was gathered about economic and social/cultural topics, built environment, food access, health care, and related issues.[11,15] Results from that trial[26] as well as from in-depth process evaluation of SHHC-1.0[29] led to the creation and testing of the refined SHHC-2.0 intervention presented herein. The SHHC-2.0 intervention includes 24 weeks of twice-weekly, 60-minute experiential group classes; details on the program have been published previously.[18,26,27] Briefly, at the individual level, areas of focus included healthy eating, physical activity (aerobic exercise, strength training), and other heart healthy information and behavioral strategies. Social components included peer discussions and involvement of friends and family members in out of class activities (eg, community walk; physical activity and food environment audits). The civic engagement component used a stepwise process to identify and address a physical activity or food environment issue in the community and involved assessing community resources and needs through a community audit; identifying a specific community change objective, such as improving park or trail access or features or serving healthy snacks at local community events such as student athletic games; identifying potential partners and stakeholders; mapping assets; establishing and implementing action steps; monitoring progress; and overcoming emergent challenges.[30,31]

Classes were led by local health educators (eg, Cooperative Extension agents/educators), herein "leaders," with experience delivering health education programs. Classes and data collection sessions were held at community locations such as churches, town halls, and annex buildings; the research project provided dumbbells, exercise mats, and aerobic exercise videos as well as a leader toolkit and participant guides. Leaders attended a comprehensive full-day program and implementation training and weekly support calls. Program fidelity questionnaires were completed by leaders after each class; site visits were conducted at class 40 by trained research staff. The control (delayed intervention) group did not receive any intervention or materials other than the delayed SHHC-2.0 intervention.

Randomization

Following baseline assessments, 11 communities were randomly assigned in pairs to intervention and control (delayed intervention) groups using JMP software by a consulting statistician who had no subsequent role in the study. Communities were paired by population and Rural-Urban Commuting Area codes; one of the paired communities was randomly assigned to the intervention group and the other to the control (delayed intervention) group. In one case, 3 communities were matched; one of the 3 communities was assigned to the intervention group and 2 were assigned to the control group.

Sample

Study participants were recruited by local leaders using flyers, radio announcements, newspaper articles, social media, and word of mouth. Eligible participants were female, aged 40 years and older, and were either: (1) overweight (body mass index [BMI]=25–30) and currently sedentary (no more than 1 bout of >30 minutes of leisure physical activity per week on average, during the past 3 months) or (2) obese (BMI>30). Women were ineligible if they did not provide informed consent or permission from a health care provider, had systolic blood pressure >160 mmHg or diastolic blood pressure >100 mmHg, had a resting heart rate <60 or >100 bpm, had a cognitive impairment,[32] were participating or planning to participate in another health behavior change program in the next 12 months, or were unwilling to be randomized to either group. Potential participants were informed that they would either receive the intervention immediately or in 6 months, depending upon which group their community was assigned (intervention or delayed intervention).

Sample Size

The SHHC-2.0 cluster randomized trial was powered for the primary outcome, mean change in weight from baseline to 24 weeks. Sample size estimates were based on the currently-named Strong People Living Well program, in which intervention participants lost 2.1 (SD=2.5) kg compared with control participants.[33] An intra-class correlation of 0.15 (with 11 clusters of 12 people each) and 15% attrition rate were estimated, yielding a design effect of 2.65. The sample size ensured at least 80% power to detect an effect size of 0.75 with a 2-sided alpha and 2.6 kg SD. This would allow detection of difference in weight change between groups of 1.95 kg.

Outcomes and Measurement

Measurements were completed at 0, 24, and 48 weeks. From 0 to 24 weeks, intervention group participants were exposed to the intervention, while control participants were not. Intervention participants had no contact with the study team during the 24 to 48 week time period, during which controls received the intervention; the 48-week timepoint was the intervention group's follow-up measure to evaluate maintenance. Due to study funding and timing, the final measure for controls was at 48 weeks, directly following the end of their participation in the program; thus, data are only available for within-group comparison among the intervention group participants for the evaluation of maintenance.

All data collection was conducted in community-based settings by research team staff who were trained by the Principal Investigator. At baseline, participants self-reported demographic information (eg, age, ethnicity/race) via questionnaire using Qualtrics.

Clinical Measures

The primary outcome was change in body weight; additional measurements included BMI, percent body fat, waist circumference, hip circumference, heart rate, and blood pressure. Equipment used included free-standing Seca stadiometers for height; Omron scales for weight and body composition; Omron automated devices for blood pressure and heart rate; and retractable Gulick tape measures for waist and hip circumferences. Fasting blood specimens were collected by phlebotomists and registered nurses to measure total cholesterol, HDL (high-density lipoprotein) cholesterol, LDL (low-density lipoprotein) cholesterol, triglycerides, glucose, and hemoglobin A1c.

Functional Fitness Measures

The functional fitness test protocol[34] included tests of upper and lower body strength, aerobic fitness, and agility as follows: arm curl (number of arm curls with a 5-pound weight in 30 seconds), chair stand (number of stands in 30 seconds), 2-minute step test (number of mid-thigh height steps in 2 minutes), and 8-foot up and go (seconds to stand, walk 8 feet, walk back, and sit), respectively.

Adverse Events

Study participants were instructed to report any adverse events to leaders and/or the research team at any time. Survey questions about adverse events were included at 24 and 48 weeks.

Statistical Analyses

Normality was checked by visual examination of Q-Q plots and plausibility of outliers was examined. The same analyses were conducted on the transformed data and consistent conclusions were drawn; results from raw data are presented. For the primary outcome, difference in change from 0 to 24 weeks between groups was analyzed using linear mixed-effects multilevel models. These models included random cluster (community) effects to account for the community-level randomization and correlation between participants in the same community. Covariates in the models, determined a priori, included age and education. Intention-to-treat analyses that included all participants as randomized were conducted, regardless of the number of assessments obtained or intervention attendance. For complete case analysis we used restricted maximum likelihood and incorporated all available data. For maintenance of outcomes at 48 weeks, change in outcomes from 0 to 24 weeks, 24 to 48 weeks, and 0 to 48 weeks within-person within-intervention group was examined using linear mixed-effects multilevel models. These models included random cluster (community) effects and time as fixed effects. The abovementioned analyses were both conducted among participants aged >60 years as well.

Missing Data

At baseline, only 2% of data was missing for any of the outcome variables. At 24 weeks, 50 participants (27%) withdrew or did not complete the data collection visit. The primary concern was that data may not be missing at random and that participants with worse health might be more likely to drop out or not report. To explore this potential bias, baseline characteristics of respondents and non-respondents were compared at 24 and 48 weeks. No significant differences were observed for age, income, education, race, BMI, weight, meeting physical activity guidelines, or self-reported perceived overall health (Table S1). These findings do not indicate systemic bias resulting from missing data.

Multiple Imputation

Multiple imputation (MI) was used to estimate missing data and standard errors. Imputations (n=50) followed hierarchical, standardized, rigorous procedures, and included auxiliary variables: random assignment group, community site, age, education, and BMI. Fraction of missing information was used to measure the level of uncertainty about the values imputed for missing values

Table 1. Strong Hearts, Healthy Communities-2.0 Participant Characteristics at Baseline

		Participants by group		Participants 60 years and older	
	All participants	Control	Intervention	Control	Intervention
Participants n (%)	182 (100)	95 (52.2)	87 (47.8)	35 (50.0)	35 (50.0)
Age (n=182) y±SD	57.2±9.0	55.9±8.5	58.5±9.3	64.3±5.2	67.7±6.1
Race/ethnicity (n=168), n (%)					
White non-Hispanic	164 (97.6)	84 (97.7)	80 (97.6)	30 (96.8)	31 (96.9)
Non-White or Hispanic	4 (2.4)	2 (2.3)	2 (2.4)	1 (3.2)	1 (3.1)
Annual income (n=162), n (%)					
<$25 000	29 (17.9)	17 (20.0)	12 (15.6)	10 (33.3)	7 (25.0)
$25 000-50 000	37 (22.8)	15 (17.6)	22 (28.6)	7 (23.3)	10 (35.7)
>$50 000	96 (59.3)	53 (62.4)	43 (55.8)	13 (43.3)	11 (39.3)
Relationship status (n=171), n (%)					
In a relationship	116 (67.8)	62 (71.3)	54 (64.3)	18 (58.1)	16 (48.5)
Not in a relationship	55 (32.2)	25 (28.7)	30 (35.7)	13 (41.9)	17 (51.5)
Educational attainment (n=172), n (%)					
High school or less	26 (15.1)	14 (16.1)	12 (14.1)	7 (22.6)	6 (17.7)
Some college/technical or vocational school	35 (20.3)	17 (19.5)	18 (21.2)	6 (19.4)	7 (20.6)
College graduate	63 (36.6)	33 (37.9)	30 (35.3)	10 (32.3)	10 (29.4)
Postgrad/professional	48 (27.9)	23 (26.4)	25 (29.4)	8 (25.8)	11 (32.4)
Smoking status (n=171), n (%)					
Never	100 (58.5)	49 (56.3)	51 (60.7)	15 (48.4)	18 (54.5)
Former	69 (40.4)	37 (42.5)	32 (38.1)	16 (51.6)	14 (42.4)
Current	2 (1.2)	1 (1.2)	1 (1.2)	0 (0)	1 (3.1)
Self-report overall health (n=175), n (%)					
Excellent/very good	46 (26.3)	20 (22.5)	26 (30.3)	13 (40.6)	14 (40.0)
Good	99 (56.6)	50 (56.2)	49 (57.0)	11 (34.4)	18 (51.4)
Fair/poor	30 (17.1)	19 (21.3)	11 (12.7)	8 (25.0)	3 (8.6)
Self-report condition/disease (n=170), n (%)					
High blood cholesterol	71 (41.8)	33 (38.4)	38 (45.2)	18 (60.0)	20 (60.6)
Hypertension	71 (41.8)	41 (47.7)	30 (35.7)	15 (48.4)	16 (48.5)
Arthritis	70 (41.2)	39 (44.8)	31 (37.3)	18 (58.1)	17 (53.1)
High blood sugar	37 (21.8)	16 (19.3)	21 (24.1)	8 (25.8)	8 (25.0)
Diabetes	25 (14.7)	17 (19.5)	8 (9.6)	8 (25.8)	5 (15.6)
Cancer	12 (7.1)	5 (5.7)	7 (8.4)	3 (9.7)	3 (9.4)
Heart disease	10 (5.9)	5 (5.7)	5 (6.0)	2 (6.5)	2 (6.3)
Kidney disease	3 (1.8)	1 (1.1)	2 (2.4)	1 (3.2)	1 (3.1)
Clinical measures (n=178–182), mean±SD					
Weight, kg	96.7±21.1	100.3±22.6	92.7±18.6	97.1±20.5	88.8±17.9
BMI, kg/m^2	36.7±7.8	37.9±8.5	35.4±6.8	37.1±8.6	33.9±6.4
Waist circumference, cm	108.9±14.3	111.5±14.6	106.1±13.4	111.5±13.3	103.9±13.5
Hip circumference, cm	122.8±15.5	125.3±17.1	120.0±13.1	124.9±17.4	117.7±12.0
WHR, ratio	0.89±0.07	0.89±0.07	0.89±0.07	0.90±0.07	0.89±0.06
DBP mmHg	85.5±9.6	86.4±9.3	84.4±9.8	86.0±8.0	83.2±10.6
SBP, mmHg	132.6±15.8	131.8±16.3	133.5±15.3	136.1±14.1	137.1±16.4
Heart rate, bpm	74.4±9.9	75.5±9.9	73.1±9.9	75.1±9.9	70.9±10.3
Body fat, %*	48.7±5.0	48.6±5.2	48.8±4.8	48.2±5.2	47.4±4.5
Total cholesterol, mg/dL	185.3±35.0	179.9±37.7	191.4±30.7	185.9±44.4	191.1±30.1
HDL cholesterol, mg/dL	57.2±16.2	55.1±16.0	59.4±16.2	54.4±15.9	59.4±17.6
LDL cholesterol, mg/dL	128.0±31.8	124.8±33.8	131.7±29.1	131.4±38.4	131.7±27.3

(*Continued*)

Table 1. Continued

	All participants	Participants by group		Participants 60 years and older	
		Control	Intervention	Control	Intervention
Triglycerides, mg/dL	126.9±62.4	131.4±62.0	121.8±62.9	152.2±70.6	139.5±85.0
Glucose, mg/dL	109.3±29.7	114.5±37.6	103.5±15.1	121.3±47.6	104.4±14.5
Hemoglobin A1c, %	5.85±0.82	5.95±1.00	5.74±0.56	6.08±1.08	5.76±0.39
Functional measures (n=182, mean±SD)					
Chair stand, # of stands	13.2±3.3	13.0±3.4	13.5±3.2	11.8±3.6	12.5±3.5
8-foot up and go, seconds	6.5±2.0	6.7±2.4	6.3±1.4	7.9±3.5	6.9±1.7
Arm curl, # of curls	18.6±4.9	18.6±5.2	18.5±4.7	17.3±4.7	17.9±4.5
2-minute step test, # of steps	85.3±22.5	85.5±21.7	85.1±23.5	76.0±25.8	77.1±25.0

BMI indicates body mass index; DBP, diastolic blood pressure; HDL, high-density lipoprotein; LDL, low-density lipoprotein; SBP, systolic blood pressure; and WHR, waist-to-hip ratio.

*For body fat % n=160. For participants who weighed over 300 pounds, a Weight Watchers scale was used and body composition was not collected.

(median fraction of missing information for outcomes was 0.07 [range: <0.0001 to 0.29]). The analysis with 50 imputations satisfies the recommendations to have the number of imputations (at least) equal the highest fraction of missing information percentage.[35] Based on the recommendations of the National Research Council,[36] tipping point analysis was conducted to test the point at which adjusting imputed values in missing data reversed the main findings. The tipping point helps determine the plausibility of erroneous conclusions based on data not missing at random and MI modeling.[37]

All analysis were conducted in 2022 using SAS, version 9.4. Dr. Seguin-Fowler, as study Principal Investigator, had full access to all study data and takes responsibility for its integrity and the data analysis.

RESULTS

From January 2, 2017 to June 30, 2017, 316 participants were screened and 182 were enrolled. The 182 enrolled women included 70 women aged 60 years or older. Baseline characteristics are displayed in Table 1 for intervention and control participants, as well as for the subgroup of women aged >60 years of age. Five communities were randomized to the intervention group (n=87 participants) and 6 communities to the delayed intervention/control group (n=95 participants) (Figure 1). Sixty-nine percent of participants attended >50% of classes; 38% of participants attended >75% of classes; class sizes ranged from 7 to 17 women per class.

Primary Outcome Analyses

Change in outcomes from baseline to end of intervention are displayed in Table 2. The results from complete case and MI were similar; MI estimates are described herein. Intervention participants lost more weight (change in weight, −3.96 kg) than controls (change in weight, −0.81 kg); mean between group difference was 3.15 kg (P=0.008). Intervention participants improved compared with controls in several clinical measures (all P<0.05) including BMI (−1.22 BMI units), waist circumference (−3.02 cm), hip circumference (−2.81 cm), systolic blood pressure (−6.64 mmHg), and percent body fat (−2.32%) as well as in all functional fitness measures: chair stand (3.55 stands), 8-foot up and go (−0.61 seconds), arm curl (4.20 curls), and 2-minute step test (14.70 steps).

Subgroup Analysis: Participants 60 Years and Older

Overall, results from the subgroup analysis with participants 60 years and older were similar to the total sample findings. Table S2 shows the change in clinical measures from baseline to end of intervention (24 weeks) with complete case and multiple MI models for participants 60 years and older. The results from complete case and MI were similar; MI estimates are described herein. Intervention participants improved compared with controls in several clinical measures (all P<0.05): weight (mean difference −3.97 kg), BMI (−1.51 BMI units), waist circumference (−4.10 cm), percent body fat (−3.52%), and functional fitness measures: chair stand (3.48 stands), arm curl (3.98 curls), and 2-minute step test (19.17 steps).

Additional Analyses

Maintenance Analysis

Table 3 shows the estimated change in clinical and functional measures in the intervention group only from baseline to follow-up (0–48 weeks) and the subgroup analysis within participants 60 years and older. For reference, the intervention group changes for all time periods are shown in Table S3 (0–24, 24–48, and 0–48 weeks). The following improvements from 0 to 48 weeks (all P<0.05) were observed within the full sample of intervention participants: weight (−4.44 kg), BMI (−1.84 BMI units), waist circumference (−3.40 cm), hip circumference (−4.54 cm), systolic blood pressure (−6.01 mmHg), percent body fat (−2.34%), triglycerides (−15.31 mg/dL), hemoglobin A1c (−0.17%), and all functional fitness

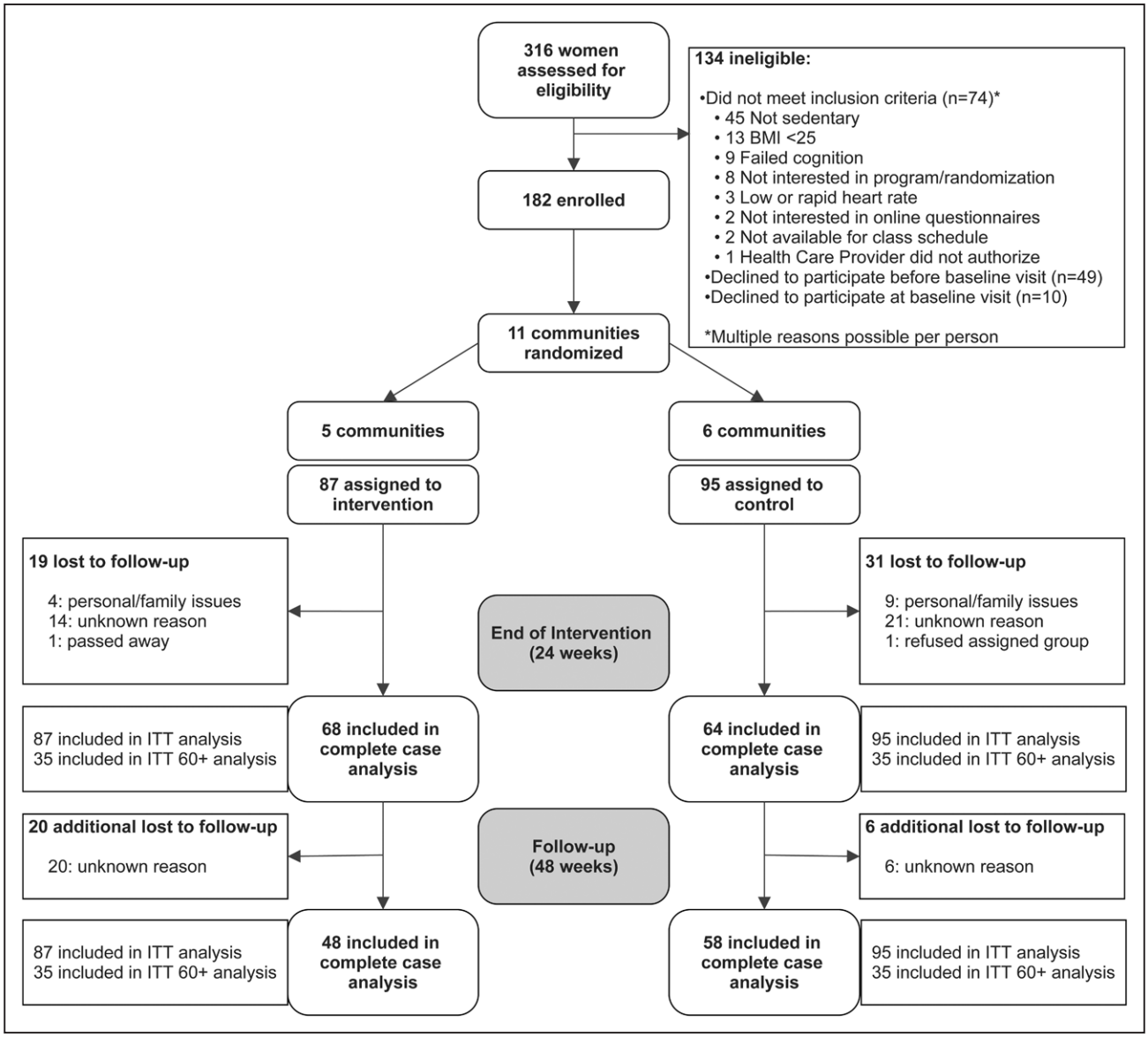

Figure 1. Profile for Strong Hearts, Healthy Communities-2.0 Randomized Trial.
"60+ analysis" refers to analysis of participants 60 years old or older. BMI indicates body mass index; and ITT, intention to treat

measures: chair stand (6.30 stands), 8-foot up and go (−0.92 seconds), arm curls (7.54 curls), and 2-minute step test (26.76 steps). From 24 to 48 weeks (Table S3), additional improvement in chair stands (1.83 stands, P=0.016) was observed. Figure 2 shows mean change at intervention end (24 weeks) and follow-up (48 weeks) as the evaluation of maintenance.

Maintenance Subgroup Analysis: Participants 60 Years and Older

In the 60 years and older sample, the following improvements (all P<0.05) from 0 to 48 weeks were observed: BMI (−1.54 BMI units), percent body fat (−2.24%), and all functional fitness measures: chair stand (4.20 stands), 8-foot up and go (−1.03 seconds), arm curls (7.18 curls), and 2-minute step test (30.07 steps; Table 3).

Sensitivity Analysis

Three sensitivity analyses were conducted: (1) controlling for baseline BMI; (2) controlling for baseline and end of intervention medication (self-report medications for hypertension, insulin, diabetes, and lipids) in blood pressure and blood draw outcomes and (3) excluding all outliers from the analysis (1.5 interquartile range above the third quartile or below the first quartile). The results for controlling for baseline BMI are the same as the analyses above at 24 weeks (Table S4) with one additional outcome improving in the participants aged ≥60 years sample: 8-foot up and go (mean difference −0.83, P=0.012). The findings are also maintained in the 48-weeks analysis (Table S5), with one additional outcome improving in the participants aged ≥60 years sample: weight (mean change −2.04, P=0.010) and one outcome no longer

Table 2. Within-Group Change and Between-Group Change in Clinical and Functional Measures From Baseline to Intervention End Point (24 Weeks)

	Multiple imputation model within group (pre-post) change		Complete case model between groups (intervention versus control)		Multiple imputation between groups (intervention versus control)	
	Control	Intervention	Differencee (95% CI)	*P* value	Difference (95% CI)	*P* value
Clinical measures						
Weight, kg †	−0.81	−3.96	−3.35 (−5.17 to −1.53)	<0.001	−3.15 (−4.98 to to−1.32)	0.008
BMI, kg/m^2 †	−0.30	−1.52	−1.28 (−1.95 to −0.60)	<0.001	−1.22 (−1.90 to −0.54)	<0.001
Waist circumference, cm ‡	0.22	−2.80	−2.57 (−4.77 to −0.37)	0.024	−3.02 (−5.31 to −0.73)	0.010
Hip circumference, cm ‡	−0.37	−3.18	−3.27 (−5.51 to −1.03)	0.0050	−2.81 (−5.00 to −0.61)	0.012
WHR, ratio‡	0.00	0.00	−0.00 (−0.02 to 0.02)	0.799	−0.00 (−0.02 to 0.01)	0.619
DBP, mmHg§	−1.55	−2.94	−1.35 (−4.46 to 1.76)	0.396	−1.39 (−4.89 to 2.11)	0.437
SBP, mmHg §	2.35	−4.29	−6.27 (−11.75 to −0.79)	0.027	−6.64 (−12.67, −0.62)	0.031
Heart rate, bpm §	−2.98	−2.76	0.26 (−2.61 to 3.13)	0.860	0.22 (−2.80 to 3.24)	0.886
Body fat, % ‖	0.69	−1.63	−2.03 (−3.09 to −0.96)	<0.001	−2.32 (−3.40 to −1.24)	<0.001
Total cholesterol, mg/dL ‡	−5.56	−2.36	0.58 (−7.00 to 8.16)	0.881	3.20 (−4.72 to 11.12)	0.428
HDL, mg/dL‡	−0.10	−1.04	−0.33 (−3.41 to 2.74)	0.832	−0.94 (−4.16 to 2.28)	0.567
LDL, mg/dL ‡	−5.47	−1.33	3.36 (−2.96 to 9.68)	0.299	4.14 (−2.83 to 11.11)	0.245
Triglycerides, mg/dL ‡	−0.73	−6.39	−7.93 (−22.96 to 7.10)	0.303	−5.66 (−22.78 to 11.45)	0.517
Glucose, mg/dL ‡	−0.77	−1.87	−1.11 (−5.51 to 3.28)	0.620	−1.10 (−5.87 to 3.67)	0.651
Hemoglobin A1c, % ‡	−0.10	−0.10	−0.02 (−0.14 to 0.10)	0.779	0.00 (−0.12 to 0.12)	0.960
Functional measures						
Chair stand, # of stands §	1.20	4.75	3.52 (2.34 to 4.69)	<0.001	3.55 (2.36 to 4.75)	<0.001
8–foot up and go, seconds †	−0.45	−1.06	−0.42 (−0.78 to −0.07)	0.020	−0.61 (−0.98, −0.24)	0.001
Arm curl, # of curls †	2.52	6.72	4.53 (2.83 to 6.22)	<0.001	4.20 (2.63 to 5.78)	<0.001
2-minute step test, # of steps ‡	9.72	24.42	14.28 (6.79 to 21.76)	<0.001	14.70 (7.56 to 21.84)	<0.001

All estimates adjusted for random cluster (community) effects, random assignment group, age, and education. Weight was the pre-specified primary outcome. All other outcomes in the table were pre-specified secondary outcomes. BMI indicates body mass index; DBP, diastolic blood pressure; HDL, high-density lipoprotein; LDL, low-density lipoprotein; SBP, systolic blood pressure; and WHR, waist-to-hip ratio.

†Data available for 131 or 182 total.

‡Data available for 129 or 182 total.

§Data available for 130 or 182 total.

‖Data available for 126 or 182 total.

showing improvement in the total sample: triglycerides (mean change −13.48 mg/dL, *P*=0.132). The results for the 2 other sensitivity analyses are similar to the main analysis (Table S6), with one additional outcome improving, diastolic blood pressure. The intervention group decreased relative to the control group (mean difference of -2.64 mmHg, *P*=0.046).

Adverse Events

No adverse events related to the study intervention were reported.

DISCUSSION

In this multilevel, multicomponent intervention trial with rural women, intervention participants improved significantly compared with control participants in body weight, BMI, body fat, waist and hip circumference, blood pressure and functional fitness, and results were maintained during a no-contact 6-month follow-up period. The findings add critical and new understanding to the body of literature examining the effectiveness of a community-engaged, multilevel, multicomponent intervention for improving health outcomes, including maintenance, among an at-risk underserved group—rural women with overweight/obesity and sedentary lifestyle.[38–39] Recent systematic reviews that included multilevel interventions have found promising results in workplaces[16] and churches,[17] but the authors noted that it was difficult to draw conclusions due to the small number of multilevel studies and variable quality of the studies.

The original SHHC-1.0 program was developed with Cooperative Extension and extensive community input, and SHHC-2.0 refinements were based upon in-depth process evaluation with leaders and participants from SHHC-1.0. Findings from the current analyses suggest that SHHC-2.0 was more effective at improving outcomes among a similar population of rural women. For example, the between group difference (improvement) was greater among SHHC-2.0 participants for weight,

Table 3. Change in Clinical and Functional Measures Within Intervention Group From Baseline to Follow-Up (48 Weeks): Intervention Participants and 60 Years and Older Intervention Participants

	Intervention participants (all, n=87)		Intervention participants (60 years and older, n=35)	
	Mean change (95% CI)	*P* value	Mean change (95% CI)	*P* value
Clinical				
Weight, kg	−4.44 (−6.87 to −2.02)	<0.001	−3.46 (−7.12 to 0.20)	0.064
BMI, kg/m^2	−1.84 (−2.76 to −0.91)	<0.001	−1.54 (−2.95 to −0.12)	0.034
Waist circumference, cm	−3.40 (−5.98 to −0.83)	0.010	−1.24 (−5.51 to 3.02)	0.568
Hip circumference, cm	−4.54 (−6.77 to −2.31)	<0.001	−2.44 (−6.21 to 1.34)	0.206
WHR, ratio	0.00 (−0.01 to 0.02)	0.600	0.01 (−0.02 to 0.04)	0.542
DBP, mmHg	−2.18 (−4.76 to 0.40)	0.100	−1.18 (−5.14 to 2.78)	0.560
SBP, mmHg	−6.01 (−10.91 to −1.11)	0.017	−1.68 (−8.89 to 5.53)	0.648
Heart rate, bpm	−0.50 (−3.83 to 2.84)	0.771	0.02 (−5.22 to 5.26)	0.995
Body fat, %	−2.34 (−3.86 to −0.81)	0.003	−2.24 (−4.42 to −0.07)	0.044
Total cholesterol, mg/dL	2.08 (−6.81 to 10.98)	0.647	10.16 (−4.36 to 24.68)	0.172
HDL, mg/dL	1.36 (−1.28 to 4.00)	0.313	3.18 (−1.26 to 7.62)	0.161
LDL, mg/dL	0.72 (−7.49 to 8.93)	0.863	6.98 (−6.52 to 20.48)	0.312
Triglycerides, mg/dL	−15.31 (−28.89 to −1.73)	0.028	−14.32 (−38.33 to 9.69)	0.244
Glucose, mg/dL	−1.58 (−6.09 to 2.92)	0.492	−3.64 (−10.72 to 3.43)	0.315
Hemoglobin A1c, %	−0.17 (−0.30 to −0.042)	0.011	−0.10 (−0.32 to 0.12)	0.382
Functional				
Chair stand, # of stands	6.30 (4.63 to 7.97)	<0.001	4.20 (1.75 to 6.64)	<0.001
8-foot up and go, seconds	−0.92 (−1.21 to −0.63)	<0.001	−1.03 (−1.49 to −0.56)	<0.001
Arm curl, # of curls	7.54 (5.88 to 9.21)	<0.001	7.18 (4.82 to 9.55)	<0.001
2-minute step test, # of steps	26.76 (15.12 to 38.39)	<0.001	30.07 (13.07 to 47.06)	<0.001

All estimates are from multiple imputation models and adjusted for random cluster (community) effects. Weight was the pre-specified primary outcome. All other outcomes in the table were pre-specified secondary outcomes. BMI indicates body mass index; DBP, diastolic blood pressure; HDL, high-density lipoprotein; LDL, low-density lipoprotein; SBP, systolic blood pressure; and WHR, waist-to-hip ratio.

BMI, and percent body fat, suggesting the revised program effects were impactful and sustained.[26]

Critically, participants maintained improvements, and in some cases, possibly further improved, during the no-contact 6-month period. For instance, although only within-group analyses were conducted for maintenance outcomes, there was a strong signal that hemoglobin A1c, a CVD risk factor, improved during the 24- to 48-week period; further studies with larger sample sizes are needed to corroborate this finding. SHHC-2.0 demonstrated maintenance outcomes that were similar to or greater than those observed in other studies. For example, SHHC-2.0 intervention group weight loss from 0 to 12 months was −4.44 kg; Flore and colleagues reported that in 4 of 8 studies with intensive maintenance weight loss protocols (e.g., group sessions), participants had gained weight by the 12-month timepoint.[40]

The observed improvements among SHHC-2.0 intervention participants in multiple CVD risk factors are statistically significant and also clinically important. For example, a waist circumference decrease of 3 cm is considered clinically significant.[41] SHHC-2.0 intervention participants averaged a decrease of 3.40 cm by 48 weeks. Likewise, a decrease of 2 mmHg in systolic blood pressure is considered clinically significant.[42] SHHC-2.0 intervention participants averaged a decrease of 6.01 mmHg by 48 weeks. These improvements in CVD risk can result in health care cost savings. One study found that over the course of 10 years, the difference between CVD-related health care costs for women with low versus high risk was more than $30 000/person.[43] Considering the prevalence of CVD risk factors and the number of years individuals live with these risk factors, improvement in CVD risk similar to what was observed in SHHC 2.0 would result in major cost savings.

The improvements in clinical measures and physical function in the SHHC-2.0 participants aged ≥60 years also warrant specific attention. More than 40% of older women have at least one disability[44] and maintaining functional fitness can add years of independence.[22] Physical disabilities may begin in midlife, but increasing physical activity can prevent or reduce declines.[45] Health care spending for those aged >65 years and older is almost 3 times the spending per person for working-age adults;[46] programs that prevent or improve symptoms of

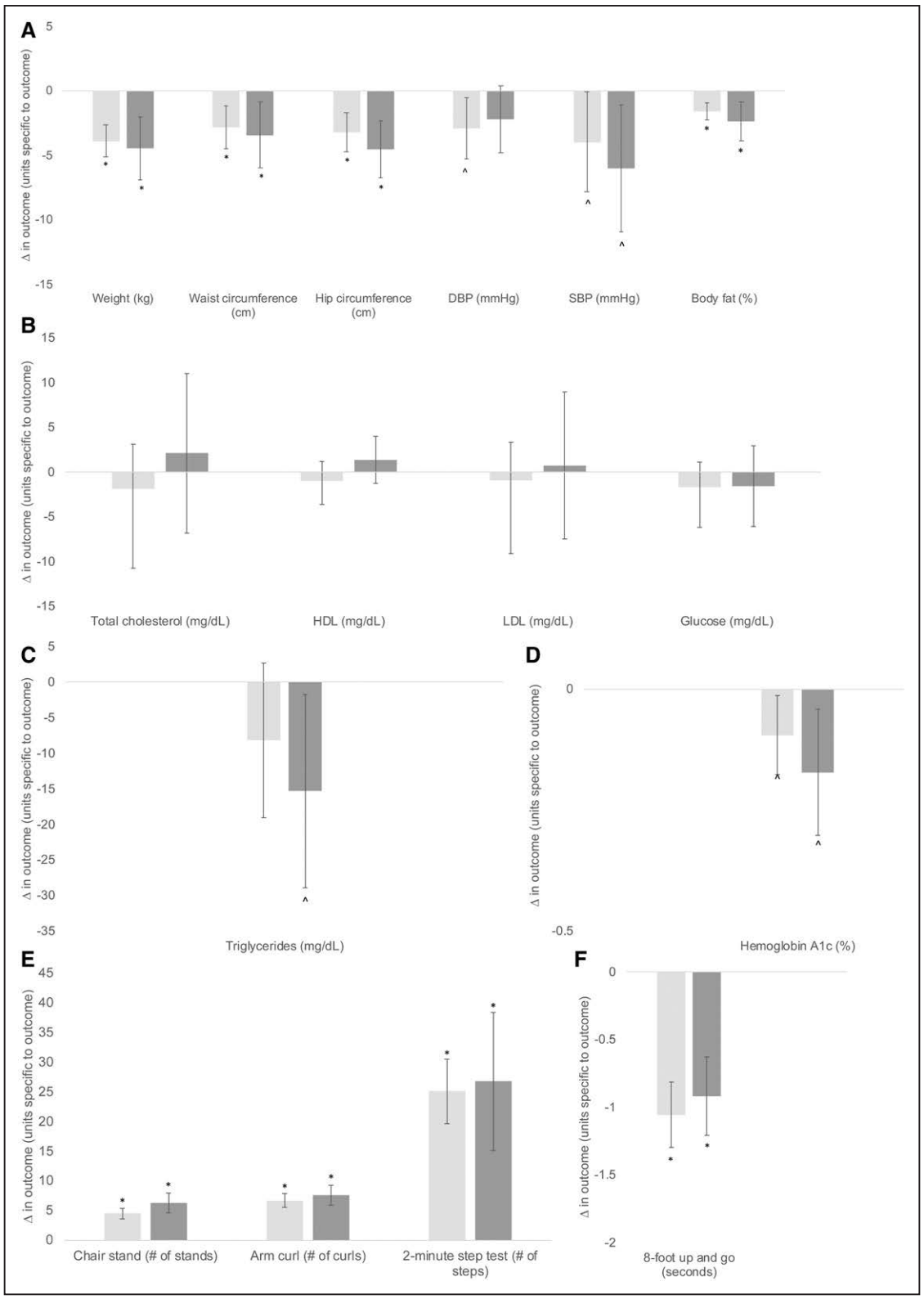

Figure 2. Change in clinical (A–D) and functional (E and F) measures from baseline to intervention end point (24 weeks) and follow-up (48 weeks): intervention participants only.

0 to 24 weeks=light gray bars; 0 to 48 weeks=dark gray bars *P<0.01 and ^P<0.05. Estimates are shown with 95% CIs bars and significance testing comes from within-person changes from the 0 to 24 week model and the 0 to 48 week linear mixed models adjusted for random cluster (community) effects. DBP indicates diastolic blood pressure; HDL, high-density lipoprotein; LDL, low-density lipoprotein; and SBP, systolic blood pressure.

chronic disease for older adults have strong potential to yield healthcare cost savings.

The study setting and population are of particular importance in considering future implications. Noting disparities in health outcomes, groups such as the American Heart Association have called for prioritizing both women and rural populations in research and programming for cardiovascular health improvement.[4,47] Likewise, considering the shortage of medical providers in rural settings and the lower utilization of medical services for people living in rural settings,[7] community-engaged interventions that can reduce burdens on resource-limited health care services in rural settings must be prioritized.

Many Cooperative Extension agencies and public health departments offer community-based health behavior change programs, but not all are evidence-based and/or community-engaged, which are increasingly recognized as key factors for success. Because SHHC-2.0 requires only modest resources (eg, mats, dumbbells), classes can be conducted in community spaces, and training modules for community-based leaders/educators are readily available, there is strong potential to scale up the program in medically underserved rural areas given that programs tailored to that setting are greatly needed. It is of further benefit that the civic engagement lessons and activities are intentionally designed to be tailored to local needs and capacity.[30]

Finally, to explore the minimally effective dose for attendance, we used a data-driven approach to explore different cut-off points for attendance on weight, from attendance at 5% to 95% increasing in 5% increments. At 50% to 60%, attendance becomes a significant predictor of a decrease in weight, BMI, and triglycerides (Figure S1). Using 60% as a cutoff point, we then tested whether the outcomes differed by intervention participant's attendance rate at a 60% threshold and used a 1-sided t test, significance level of $P<0.10$. We found that those who participated at 60% or greater saw a greater reduction in: weight (−2.13 kg, $P=0.055$), BMI (−0.77 BMI units, $P=0.064$), and triglycerides (−22.73 mg/dL, $P=0.043$; Table S7).

Limitations

Due to the racial composition of the communities in SHHC-2.0, there was a lack of representation of women of color (Black, Latina, etc) in the study enrollment; it is critical that next steps in the research adapt and evaluate SHHC-2.0 within an ethnically diverse sample of rural (and urban) women. These steps are underway by members of the research team.

In addition, the attrition rate of 27.4% was higher than the 15.1% rate estimated in the protocol. This was likely due to a move toward centralized study management for cost efficiencies of SHHC-2.0 for data collection reminders and scheduling; in SHHC-1.0, the local leaders managed these activities. For both SHHC-1.0 and SHHC-2.0 data collection reminders included scheduling the data collection in person or via email or phone, a save-the-date email 2 weeks before the data collection date, an email 1 week before the data collection date (which included the questionnaire links), and a phone reminder the night before the data collection date. Additionally, for those who did not complete the questionnaire by the data collection date, reminders were sent 3 days after (email), 10 days after (phone), 17 days after (email), and 24 days after (phone). While attrition was underestimated, selection bias was not apparent in this study. The "tipping point" sensitivity analysis that found that those lost to follow-up in the intervention group would have to gain 6 to 7 kg more than the control group during the 24-week intervention period to reverse the findings. In future studies, programs of similar intensity should estimate a higher attrition rate and include additional strategies to minimize attrition,[48] and study timelines and budgets should prioritize the opportunity for between-group analyses for maintenance evaluation.

An additional limitation of this study is that it was not designed to examine how much the civic engagement component of the intervention added to the effectiveness of SHHC-2.0. Future research would be well served to pursue that question. Additionally, cost-effectiveness analysis of interventions such as SHHC-2.0 are critical and that is planned for this study as well; however, it was beyond the scope of this current report.

CONCLUSIONS

The SHHC-2.0 intervention demonstrated significant, clinically meaningful improvements in multiple CVD risk factors among at-risk rural midlife and older women; improvements were sustained or further improved 6 months beyond the end of the intervention. The maintenance of clinical and functional measures among this population, who would likely be trending in a worsening direction in terms of clinical and functional outcomes, demonstrates strong potential for impact in helping to address rural health disparities among aging women. Future studies with larger, more diverse samples of both men and women as well as the ability to rigorously evaluate long-term program impacts are important next steps.

ARTICLE INFORMATION

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Affiliations

Institute for Advancing Health through Agriculture, Texas A&M AgriLife, College Station (R.A.S-F.). Texas A&M AgriLife Research and Extension Center, Dallas (G.D.E., C.D.R., M.L.G., M.D.). Bassett Research Institute, Cooperstown, NY (D.S.). Friedman School of Nutrition Science and Policy, Tufts University, Boston (S.C.F., M.E.N.). Texas A&M University, College Station (S.C.F., M.E.N.). Statistical Collaboration Center, Texas A&M University, College Station (J.E.M., S.H.).

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Disclosures

Drs Seguin-Fowler and Nelson are co-founders of strongpeopleprogram.org. The other authors report no conflicts.

Supplemental Material

Figure S1
Tables S1–S7

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