Does a Program that Focuses on Lifestyle Changes Reduce Heart Disease Risk Factors in a Rural Community in Appalachian Kentucky?

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Abstract

Background: People who live in rural Appalachian Kentucky represent the top 1% for cardiovascular disease (CVD) risk, morbidity, and mortality in the United States. Despite the marked CVD disparities seen in this geographic area, efforts directed toward CVD risk reduction and prevention are limited.

Objective: To determine the effect of an individualized, culturally appropriate, self-care CVD risk reduction intervention (HeartHealth) compared with referral of patients to a primary care provider for usual care on the following CVD risk factors: tobacco use, blood pressure, lipid profile, body mass index, depressive symptoms, physical activity levels, and overall Framingham risk score.

Methods: We developed the study protocol and intervention in conjunction with a community advisory board that consisted of lay community members who were part of the targeted population, business owners, local government officials, church leaders, and health care providers. In this randomized trial, we enrolled 355 individuals living in Appalachia who were at high risk for CVD by virtue of having 2 or more CVD risk factors. The intervention was delivered in person to groups of 10 or fewer individuals over 12 weeks. We designed the HeartHealth intervention to provide participants with successful self-care skills appropriate to CVD risk reduction and to reduce barriers to risk reduction found in austere rural environments. We measured the targeted CVD risk factors at baseline, 4 months, and 12 months postintervention.

Results: More individuals in the intervention group compared with the control group met their lifestyle change goal (50% vs 16%; $p < 0.001$). HeartHealth produced a positive impact on systolic blood pressure, diastolic blood pressure, total cholesterol, high-density lipoprotein, body mass index, smoking status, and depressive symptoms; we saw improvement at 4 months in these risk factors, and positive changes were maintained through 12 months. We saw no differences across time by group in low-density lipoprotein or triglyceride levels, nor did we observe differences in either the mental health or the physical health component of the Short Form-12 Health Survey quality-of-life measure.

Conclusion: Interventions like HeartHealth—that focus on self-care of CVD risk factors

and that are driven by collaboration with the community of interest—are effective in medically underserved, socioeconomically distressed rural areas.

Limitations and Subpopulation Considerations: A potential limitation is lack of widespread generalizability, given that we conducted this study in southeastern Appalachian Kentucky; it may not be generalizable to the rest of Appalachia or to other rural areas. In heterogenity of treatment effect analyses, HeartHealth proved equally effective in men and women, in depressed and nondepressed individuals, and in those with high and low health literacy.

Background

In the United States, Appalachian Kentucky is in the highest percentile of cardiovascular disease (CVD) morbidity and mortality and has among the worst CVD health disparities in the United States.[1-7] Residents in the area also have the highest rates of multiple CVD risk factors in the nation.[8] Life in a persistently socioeconomically distressed environment only amplifies this problem.[9] There is a critical need to test CVD risk reduction interventions appropriate for such socioeconomically distressed rural areas; in the absence of such interventions, the dramatic CVD disparities present in these areas will continue.[7]

Modifying CVD risk factors by promoting lifestyle change reduces CVD risk by 44%.[10-12] Modifiable factors account for 90% of risk for myocardial infarction.[13,14] Multiple modifiable CVD risk factors in an individual are common; however, interventions designed to modify multiple CVD risk factors are not widely used in clinical practice, and their use in distressed environments is extremely rare.[15] Delivery of care by primary care providers to reduce CVD risk—particularly in the setting of multiple risk factors—has been found to be only marginally effective in the long term.[16] Given the dearth of providers and the lack of emphasis on prevention in medically underserved areas, CVD health disparities are increasing in rural underserved areas.[17-20] Residents in these areas need other choices for addressing their CVD risk factors.

Interventions promoting self-care of multiple CVD risk factors are highly relevant to distressed, medically underserved environments because of the lack of sustained preventive services and because successful long-term management of chronic conditions requires engagement in self-care. Yet, few such interventions have been tested in rural areas. We and others have demonstrated that lifestyle change is most effective when patients are given the tools to engage in self-care and that individualized, patient-centered interventions are more effective than generalized approaches.[21-24] Therefore, we hypothesized that to be successful in socioeconomically distressed environments, CVD risk factor reduction interventions must focus on lifestyle change that is driven by individuals' abilities to engage in self-care, must be culturally appropriate, and must have components that overcome barriers in such

environments. We further postulated that to be effective, design of such an intervention and of the research testing the intervention needed to be community based.

Our specific aims were to compare the 4-month (short-term) and 1-year (long-term) impact of a self-care CVD risk reduction intervention for multiple CVD risk factors (HeartHealth) vs usual care on (1) a CVD risk factor target (ie, tobacco use, blood pressure, lipid profile, HgA1c for diabetics, body mass index, depressive symptoms, or physical activity level) selected by patients; (2) all CVD risk factors for each patient; (3) quality of life; (4) patient satisfaction; and (5) desirability and adoptability by assessing adherence to recommended CVD risk reduction protocols, and retention of recruited individuals. Specific aims 1 and 2 were our primary aims; aims 3 to 5 were secondary.

To examine any heterogeneity of treatment effect, we also compared the impact of the intervention on Framingham risk score between genders, between those with and without depressive symptoms at baseline, and between those with and without adequate health literacy. We compared the intervention effect between genders, given the large body of knowledge demonstrating gender differences in CVD risk and outcomes from cardiovascular interventions such as lifestyle interventions.[25-32] We compared HeartHealth effects based on depressive symptoms because depression is known to negatively affect multiple aspects of self-care, including adherence to lifestyle recommendations.[33-37] We designed HeartHealth to accommodate individuals with lower levels of health literacy, which can reduce understanding of lifestyle interventions.[38-41] Thus, we sought to determine if there were differences in degree of risk factor modification based on baseline health literacy.

Patient and Stakeholder Engagement

Individuals with known CVD risk factors and known CVD were important stakeholders. Other stakeholders included the following members of the University of Kentucky Center for Excellence in Rural Health and its subsidiary service, HomePlace: (1) the director and associate director; (2) HomePlace lay community health workers; (3) HomePlace regional directors; (4) nurses, social workers, and educators who worked in the center and in HomePlace; (5)

pharmacists; and (6) physicians. It was also vital to include physicians, nurses, pharmacists, social workers, and an administrator from local medical offices and hospitals who were not affiliated with the center or HomePlace. Other stakeholders we identified included the director of the Perry County senior center; chiefs of the local fire and police departments (stakeholders as potential users of the intervention, responders to cardiac emergencies and educators); directors of the local health departments; and agricultural extension agents. Churches are influential agents of health change, and pastors or lay directors of churches were vital stakeholders. Other important stakeholders were policymakers, who included the mayors or city managers of local towns. Local business groups can be influential in changing policies in small towns, so we included the Lions and Kiwanis Clubs as well as the directors of the local chambers of commerce.

Our community advisory board consisted of the director of HomePlace, 5 community health workers who represented the regions from which we recruited, 1 layperson from the community who used HomePlace for health care services, 1 layperson from the community who participated in the study, 1 director of a senior center, 1 director of the local chamber of commerce, 1 local business owner; and 1 physician.

By holding several focus groups across Appalachian Kentucky, we engaged key stakeholders—a local patient, a health care provider, and a policymaker—during the planning stages for the grant and the study (once funded). We sought to determine how cardiovascular health was viewed, what barriers to attaining cardiovascular health were seen by community members, what strengths in the community promoted health, and what an intervention to improve cardiovascular health should look like. Stakeholders assisted in the development of the design of the study; they chose the strategies for recruitment and retention, and they selected the outcomes.

During the study we met monthly with the community advisory board. We elicited their advice about recruitment, retention, any problems with study implementation, and how best to get the widest possible dissemination and uptake of our results. Prior to initiation of the study, the board approved the study design, helped design the recruitment and retention plan, and assisted in the selection of outcomes to ensure that they were those of interest to community

members as well as researchers and clinicians.

Methods

Study Overview

In collaboration with the local community, we tested a self-care CVD risk reduction intervention that was culturally appropriate for individuals who live in rural Appalachia. We developed HeartHealth with community members, who recommended many of the important features during focus groups or community advisory board meetings. We followed study participants for 1 year to compare the impact of the intervention with usual care.

Study Design

This was a community-based study guided and facilitated by a community advisory board. We based our intervention on their input and on pilot work in the community.[42] Community health workers—who were registered nurses—recruited, followed, and retained participants for the project; collected all data; and delivered the intervention.

We used a 2-arm randomized controlled trial to compare the effect of (1) the standard of care alone, which is referral to a health care provider for management of CVD risk factors, with (2) HeartHealth, a patient-centered, culturally appropriate, self-care CVD risk reduction intervention designed to improve multiple CVD risk factors and to overcome barriers to success. This study was registered with ClinicalTrials.gov in June 2013 (NCT01884246). We enrolled individuals who at time of recruitment lacked a primary care provider and who were at risk for CVD. Participants were randomly assigned to 1 of the 2 groups once signed, informed consent was granted. The study biostatistician, who had no contact with participants, completed randomization using a computerized schedule created with 15 blocks of 20. The randomization scheme was kept in a locked cabinet, and assignments in sealed envelopes were opened only after baseline data had been collected.

Study Setting

This study was open to residents of eastern Appalachian Kentucky. This 54-county region of eastern Kentucky is noted for extreme CVD health disparities. The study's main site

was HomePlace, in Hazard, in the heart of Appalachian Kentucky; although the main office is in Hazard, additional satellite offices are in most of the counties in Appalachian Kentucky. HomePlace is funded by the state to connect community members with needed health care services that they have difficulty accessing on their own or can't afford. Community health workers are trained at HomePlace to seek out, recruit, and welcome individuals to HomePlace for basic services. These culturally competent workers are employed from the affected areas and train to act as liaisons for the underserved individuals in their communities.

Participants

We obtained Institutional Review Board (IRB) approval from the University of Kentucky; this IRB also provides approval for research conducted at HomePlace. Community health workers employed at HomePlace recruited participants, and we trained these workers on how best recruit and retain research participants. These community health workers continued to interact with participants throughout the study as data collectors, and because they conducted both the intervention and the follow-up sessions, they maintained the trust they had initially developed with patients.

Community health workers used a number of methods to find and recruit people. As longtime members of the communities, they knew many of the individuals in need of health care. They presented the study at a variety of sites, including health fairs, agricultural extension offices, community centers, senior centers, local businesses, and churches. In addition, we recruited individuals to the study by (1) advertising in local newspapers; (2) placing notices in local churches, community centers, agricultural extension offices, senior centers, local business organizations, public health departments, public fairs of all types, county courthouses, beauty shops and barbers, convenience stores, gas stations, and drug stores; (3) advertising on the local radio and television stations that have a specific time set aside for announcing local happenings; and (4) word of mouth.

The participant yields from these various recruitment methods was approximately 50% by self-referral after the participant had heard about the study from someone in it or had seen or heard an advertisement. About 30% were recruited by the community health workers after presentations at health fairs, agricultural extension offices, community centers, senior centers,

local businesses, and churches; the remaining 20% were recruited directly by community health workers. All data collection procedures and the intervention were conducted at 1 of the HomePlace sites convenient to participants.

We enrolled 355 individuals who did not have a regular primary care provider; who were aged 21 or older and of either gender or any ethnicity; and who were at risk for CVD, as reflected by having 2 or more of the following modifiable risk factors: (1) clinical diagnosis of hypertension, taking medications diagnosed for hypertension, or found to be hypertensive during screening[43]; (2) diagnosis of hyperlipidemia, taking medication for dyslipidemias, or lipid abnormality found on our screening that indicates hyperlipidemia based on Adult Treatment Panel III guidelines[44]; (3) diagnosis of type 2 diabetes; (4) overweight or obese (BMI ≥ 25 kg/m^2); (5) clinical diagnosis of depression, on medication for depression, or found to have depressive symptoms (score of >9 on the Patient Health Questionnaire-9) by our baseline screening; and (6) sedentary lifestyle, meaning the individual does not engage in at least 30 minutes of moderate activity for at least 4 days per week.

Because the study focus was primary prevention, we excluded individuals if they had known coronary artery disease, cerebrovascular disease, and history of acute coronary syndrome or peripheral arterial disease. Although CVD risk reduction is vitally important in this population, the presence of existing CVD—in which CVD risk factors are treated more aggressively with medications—may introduce a confounding influence. We also excluded individuals for any of the following reasons: (1) taking medications (eg, protease inhibitors) that interfere with lipid metabolism; (2) cognitive impairment that precludes understanding the consent process, answering questionnaires, or participating in the intervention; (3) chronic drug abuse; (4) end-stage renal, liver, or pulmonary disease; (5) current active cancer (ie, undergoing active treatment for cancer) other than isolated skin cancer treatable by simple excision; and (6) gastrointestinal disease that requires special diets (eg, Crohn's disease, celiac disease).

Once potential participants were recruited, community health workers obtained signed, informed consent. Once consent was obtained, participants completed the baseline study instruments (with the assistance, if needed, of the community health workers) and had physical assessments performed. After baseline data collection, participants were randomized to either

HeartHealth or usual care. Community health workers arranged either the next data collection date—for those in the usual care group—or the intervention dates—for those randomized to HeartHealth. Data collected at baseline were repeated at the 4-month and 1-year time points.

Sample size and power considerations. With at least 135 patients per group and an alpha level of .05, the power of the analysis of variance *F* test (a component of the mixed model, with tests for the fixed effects of time, group, and time by group) to detect a medium effect is at least 95% for each of the 2 main effects (ie, group and time) and the interaction effect (group x time). A medium effect is defined as one in which the ratio of the standard deviation of the group means to the standard deviation of the observations within the populations is at least 0.25.[45] Even if the ratio is as small as 0.15, the power of the *F* test is at least 80% to detect significant main effects for group and time or the interaction of group x time.

Analysis of our pilot study data, preliminary to this study, demonstrated that for the outcomes of low-density lipoprotein, high-density lipoprotein, total cholesterol, body mass index, and depression, the improvements in each of these outcomes demonstrated a medium or smaller effect size. Given that the effect size of 0.15 in this context was only slightly larger than the ratio designated as a small effect size by Cohen (namely, 0.1), there was a high level of power to detect a significant change over time within the intervention group, with 135 per group and an alpha level of .01. While it is not possible to estimate the power associated with the GEE model directly, the power of the chi-square test of proportions is considered a close alternative. With 135 patients per group and a significance level of 0.01, the power of the chi-square test to detect an odds ratio as small as 2.3 is approximately 80%.

Because we included all subjects with at least 1 follow-up measure in the mixed and GEE models, we anticipated the sample size to be larger than 135 per group, thereby increasing the statistical power beyond the estimates above. The data analysis protocol we specified was purposely conservative to allow the detection of even relatively subtle, yet meaningful, clinical differences. Examples of this purposeful conservatism included use of the intent-to-treat model as well as specification of 2-sided tests even though we anticipated the direction of the intervention a priori. Further, we based the power analysis on the conservative alpha level of

.01 throughout to control overall type 1 error. In addition to the conservative conventions chosen, the proposed sample size per group allowed for comparisons by gender or by depression and health literacy category. With an alpha level of .01 and approximately 68 people in each group, the power of the 2-sample *t* test was at least 80% to detect a group difference if the ratio of the difference in means to the standard deviation was at least 0.6. We obtained power estimates using nQuery Advisor Version 6.02.

Interventions

Usual care. The HomePlace program referred all individuals enrolled in the study to a primary care provider, who would manage the CVD risk factors identified in our screening. HomePlace also arranged for the care to be free or at a low cost, depending on the patient's resources. We did not otherwise influence the delivery of care. Because we did not want to influence the delivery of usual care, there was no follow-up about the number of visits to the provider or the therapy provided. The standard of care in this area is to address CVD risk factor reduction with advice about lifestyle change and/or a prescription of medications in the 10- to 15-minute appointment, with follow-up typically 3 to 12 months later.

HeartHealth*.* We developed the HeartHealth intervention using community engagement methods and with the assistance of community stakeholders and the community advisory board. Prior to this randomized trial we designed and tested the feasibility and effectiveness of the HeartHealth intervention based on extensive input from laypeople and health care providers in the community; the severity of the prevalence of multiple CVD risk factors; the distressed nature of the environment; the barriers to CVD risk reduction; and the strengths inherent in the Appalachian community (Table 1).[42]

We considered HomePlace community health workers research staff and part of the research team; our research team attended to all aspects of the protocol together. Members trained together in all aspects of measurement, protocol maintenance, and fidelity to the protocol; all staff performing data collection were trained and certified by the principal investigator and other expert clinician-researcher team members. We ensured fidelity by oversight, review, and remediation of each staff member's recruitment, data collection, and intervention activities.

Although Appalachian Kentucky is commonly portrayed very negatively, people living there have several strengths that position them well to undertake the changes needed to improve their health. Such strengths include a strong tradition of community mobilization when awareness of a local problem occurs as well as the potential for "home-grown change."[46] People who live Appalachia are noted for their sense of helpfulness and concern for neighbors, friends, family, and community. Other cultural strengths include honesty, sense of family, a strong work ethic, self-reliance, and pride in community.[46,47]

Table 1. HeartHealth Intervention Component Principles and Relationship to Appalachian Kentucky

Intervention Component Principles	**Addresses CVD Disparities in Appalachia**	**Culturally Appropriate**	**Reduces Barriers to CVD Risk Reduction**	**Builds on Strengths in Appalachia**
Recruitment to study by lay community workers Intervention done by lay community health workers	Promotes recruitment, retention, and engagement in project of those with most severe health disparities	Increases recruitment, retention, and commitment to the intervention based on the relationship between participant and local community workers; shows respect for community	Promote recruitment and retention of those most in need who often do not respond to appeals from "outside" health care providers or researchers	Respect for lay local community workers who understand the region
Individualized Promotes self-care[122] within the context of the distressed environment[123,124]	Directly addresses each participant's unique needs and goals; self-care fundamental to effective lifestyle change in people with multiple morbidities	Shows respect and engagement at personal level; participant not just seen as "Appalachian problem"; provides self-care unique skills applicable to the environment	Provides participants with the skills and knowledge they need to overcome their specific and unique barriers	Promotes independence and self-reliance

Motivational interviewing techniques[125-127]	Highly effective for promoting behavior change	Nonjudgmental approach driven by participant goals; demonstrates respect for participants and their prior experiences	Breaks down fatalism, denial, and lack of interest in prevention	Shows respect for patients and gives them confidence to make change
Group setting for intervention	Increased effectiveness for behavior change in this population	Provides social support, neighborliness, and opportunity to help others	Participants learn from each other how to overcome barriers	Supports sense of neighborliness
Addresses multiple risk factors	Major source of health disparities	Addresses issues of direct concern to people of this culture	Provides solutions to barriers to reducing multiple risk factors	People in the community recognize this problem and want to work on it
Depression management	Major source of health disparities	Addresses issues of direct concern to people of this culture	Depression a major barrier to successful risk reduction	Reduction of poor mental health is a major focus of the community
Interactive	Increased adoption of behavior change	Shows respect for contributions of participants and for their existing knowledge	Solutions to barriers are often offered by participants if their views are solicited and respected, which they are with this method	Participants have much to offer to improve sessions
Gas cards for travel to sessions; meals served at sessions Times for sessions chosen by participants	Increases retention and engagement in the intervention	Demonstrates respect for participants' time and financial situation while promoting sense of community	Reduces barriers to coming to intervention	Willingness to make change if given the resources

In our focus groups, community members talked about their concern for the heart health of their community and their willingness to promote lifestyle change in themselves, and in their family, friends, and community if necessary resources were available. Their sense of community-mindedness was evident, as was the potential to produce positive change with the help of others—the value of the social support of the community for successful outcomes. In addition, they identified heart disease as a very important issue to tackle. A similar theme was identified in a study of Appalachia in which groups of women (traditional health gatekeepers in Appalachia) were interviewed to determine their health concerns in their communities.[46] With HeartHealth, we developed components to address the barriers to CVD risk reduction and to take advantage of the strengths in the region; they are outlined in Tables 1 and 2.

HeartHealth consisted of the following 6 interactive modules, all of which promote self-care: (1) principles of self-care and CVD risk reduction; (2) nutrition (controlling portions, eating a diet high in fruits and vegetable and whole grains, reducing saturated and trans fats, reducing sodium intake, reducing total fat intake, clearing up the "good fat vs bad fat" issue); (3) physical activity; (4) depression management and stress reduction; (5) managing multiple comorbid risk factors; and (6) medication adherence and smoking cessation, if appropriate.

Table 2. Barriers to Successful CVD Risk Reduction in Appalachian Kentucky and How the Interventions Addresses Them

Barriers to CVD Risk Reduction	Standard of Care	HeartHealth
Poverty	Provided free or at reduced cost through HomePlace	Program provided free through HomePlace
Poor access to health care and lack of health insurance	Provided free or at reduced cost through HomePlace	Program provided free; all materials and demonstrations, including meals, are free; teaching how to engage in self-care reduces need for health care service use
Low levels of education	Does not address	All materials and delivery methods adapted to address low health literacy;

		materials available for those at all levels of literacy
Lack of easy access to healthy, affordable foods and safe places to exercise	Does not address	Walking maps or activity plans developed for each participant to accommodate environment; eating heart healthy diet by modifying usual diet shown
Lack of trust in researchers and health care providers who are not from local community	Does not address	Researchers form a team with local providers from HomePlace, a trusted service; lay community workers recruit, collect data, and provide the backbone for intervention
Overwhelming nature of CVD health disparities	Does not address	Self-care intervention focuses on a "whole health" approach to CVD health, which reduces confusion and overwhelming nature of CVD; education about high effectiveness of lifestyle change

Community health workers—who had been trained extensively by our research nurse interventionist—delivered these modules via a group format every 2 weeks over a 12-week period. The groups had no more than 10 people, and each module was delivered over a 2-hour period using the principles of cultural sensitivity, community engagement, self-care, and behavior change. If an individual had to miss a meeting, the module content was delivered to him or her at another group meeting; thus all who completed the intervention completed all modules.

The intervention takes a "whole health" approach to improving participants' CVD risk factor profiles by promoting self-care of multiple CVD risk factors, underpinned by the Theory of Planned Behavior (TPB).[48-54] The approach involves adoption of basic healthy lifestyle choices, using self-care to influence many negative health behaviors. In contrast to most approaches, in which a single risk factor is targeted, we targeted multiple CVD risk factors. This way, the confusion faced by individuals attempting lifestyle change is reduced, as the same whole health approach is advocated for management of multiple CVD risk factors. Such an

approach is advocated for lifelong health and reduction of risk from all chronic diseases.[55] We created the modules to accommodate participants with low health literacy. Each module includes skill building and knowledge provision. Because of the importance of depression management and prevention and of nutrition, content from both modules was integrated throughout each session.

The TPB is often successfully used to organize lifestyle modification interventions that require behavior change.[48-54] We have developed and tested 3 (in addition to this one) successful self-care interventions using the TPB as the foundation.[21-23] The TPB states that determinants of behavior change are attitudes, subjective norm, and perceived behavioral control. Attitudes are determined by the individual's beliefs about outcomes of performing the behavior. An individual will have a positive attitude toward that behavior if he or she strongly believes that positively valued outcomes will result from it. The intervention encourages positive attitudes and behavioral beliefs by explaining, simplistically, the pathophysiology of CVD and the significance of CVD risk factors to the development and progression of CVD. A clear relationship between risk factors and outcomes is established. The benefits of reducing risk factors are emphasized. An individual's subjective norm is determined by his or her normative beliefs—whether significant others approve or disapprove of the behavior. Someone who believes strongly that certain significant others think she or he should perform a behavior, and who is motivated to meet the expectation of those referents, will hold a positive subjective norm. The program was supported by community health workers, who act as positive role models and subjective norm referents. In addition, the TPB is family centered, and all family members and significant others are encouraged to participate. Perceived behavioral control is the third independent element of the TPB. The ease or difficulty of behavioral performance affects behavioral change. Perceived control is determined by beliefs about the presence or absence of resources for and impediments to behavioral performance. Resources and impediments to lifestyle change were identified in the HeartHealth intervention, and we worked with participants to reduce them and increase a sense of control. Participants were taught skills needed to feel empowered to enact change.

Examples of how we achieved the principles of individualization, self-care, and reducing barriers to adhering to CVD risk reduction practices are as follows.

Individualization. The research team attended each intervention session, and time was set aside for individual counseling sessions in private (although most people opted to share their "numbers" and their problems with lifestyle change, it was possible for participants to keep their values private). At the first session, we discussed all results from the baseline data collection individually with each person, indicated what these data meant for him or her, and worked collaboratively with him or her to set up his or her goal for CVD risk reduction based on individual risk factors, desires, and values. We also discussed individual barriers to risk reduction and used motivational interviewing techniques to begin to reduce some of these barriers.

Self-care. We concentrated in each module on teaching and demonstrating skills (eg, using exercise bands and a pedometer, which we gave to participants, to increase and monitor activity; healthy cooking). We incorporated self-care principles into each module.

Reducing barriers. We interviewed each participant and then discussed as a group any personal and environmental barriers to risk reduction. All sessions included barrier-reducing skills and problem solving. For example, we provided a meal at each session that we prepared using locally bought groceries, demonstrating how to use what is readily available to cook a heart-healthy meal. We mapped for each community and each individual a walking route that was accessible to them. We provided information on eating out and on increasing the heart health of homecooked foods. In one session, we took a participant's recipe and modified it using heart-healthy principles.

Choice of comparators. We specifically designed HeartHealth to be patient centered and culturally appropriate and to address the barriers to CVD risk reduction in Appalachia. Therefore, we hypothesized that it would have successful outcomes. We included the standard of care (referral to a primary care provider for management of risk factors) in this intervention because it is potentially unethical not to offer the standard of care to individuals once CVD risk factors have been identified. We chose to compare HeartHealth plus standard of care with the standard of care alone because most people in Appalachia have not had the opportunity to

receive the standard of care, and one could argue that the effectiveness of standard of care has not been tested in Appalachia.

Study Outcomes

Screening. We used the Mini-Cog[56-60] to screen individuals for any cognitive impairment that would preclude their giving informed consent or participating in the intervention. This 3-minute screening instrument consists of drawing a clock and recalling 3 words. It is sensitive, reliable, and valid in individuals with low literacy and low socioeconomic status.[56-60] A score of 0 is positive for cognitive impairment, as is a score of 1 to 2 with an abnormal clock drawing test. We excluded from the study individuals with any of these scores (n = 3).

Outcomes

Specific aims 1 and 2. To compare the 4-month (short-term) and 1-year (long-term) impact of a self-care CVD risk reduction intervention for multiple CVD risk factors (HeartHealth) with usual care on (1) a CVD risk factor target selected by patients (ie, tobacco use, blood pressure, lipid profile, HgA1c for diabetics, body mass index, depressive symptoms, or physical activity level); and (2) all CVD risk factors for each patient.

Each participant selected a single goal from among the following: (1) cessation of tobacco smoking, as determined by urinary cotinine levels; (2) reduction of body weight by 5%; (3) reduction of blood pressure by 10%; (4) reduction of a component of lipid level by 10% or an increase in HDL by 10%; (5) reduction in HgA1c by 1%; (6) reduction in depressive symptoms below the cut point for mild depressive symptoms; or (7) increase in steps taken by 2000 to 3000 steps per day.

Tobacco use. We measured tobacco use using NicAlert (Encino, CA: Jant Corp), a valid and cost-effective commercial urine assay that uses cutoff limits of urine cotinine levels to validate smoking status in adults.[61] NicAlert measurement correlates well with more complex laboratory tests using high-performance liquid chromatography, as used in the Center for Disease Control laboratory.[62] We defined nonsmokers by urine cotinine ≤ 99 ng/mL (levels 0, 1, and 2). We defined current smokers by urine cotinine > 100 ng/mL (levels 3, 4, 5, and 6). Classification sensitivity and specificity were 88% and 92%, respectively, for cotinine measured

by NicAlert. NicAlert cutoffs for smoking validation are consistent with previous reported urine cotinine ranges.[63]

Blood pressure. We measured blood pressure according to American Heart Association standards.[64] We used a calibrated aneroid sphygmomanometer to obtain systolic and diastolic blood pressure. Data collectors were trained in proper technique and inter-rater reliability was assessed as >0.89.

Lipid profile. We analyzed lipid profile (ie, total cholesterol, high- and low-density lipoprotein, and triglycerides) using the Cholestech® (Hayward, CA: Cholestech), a small, lightweight analyzer for point-of-care (POC) testing using blood from a fingerstick. Accuracy and reproducibility of the Cholestech LDX has been certified by the Cholesterol Reference Method Laboratory Network, demonstrating that this POC method is comparable to centralized laboratory testing.[65-68]

Body mass index. We calculated body mass index from height and weight that had been measured with a professional grade stadiometer and a professional-grade digital body weight scale. Measurements were taken without shoes and with all overgarments (eg, jackets, sweaters, vests) removed.[69] We calculated body mass index as body weight in kilograms divided by height in m^2.

Depressive symptoms. We assessed depressive symptoms using the Patient Health Questionnaire-9 (PHQ-9), which consists of 9 items.[70-72] Each item corresponds to 1 of the 9 symptoms of the major depressive disorder criteria of the *Diagnostic and Statistical Manual of Mental Disorders-IV*. According to how often they experience these symptoms, patients rate items on a 4-point Likert scale ranging from 0 (not at all) to 3 (nearly every day). The summed scores can range from 0 to 27, with higher scores indicating greater levels of depression. The reliability and validity of the PHQ-9 has been demonstrated extensively in a number of populations as a measure of depressive symptoms; among those at risk for or with cardiac disease, the PHQ-9 has high specificity and predictive value for clinical measures of depression.[73]

Physical activity. We measured physical activity using the Fitbit One®. Participants wore the this device for 7 days. Data from Fitbit One® were downloaded and stored for use. The

Fitbit One® is simple to use, does not need to be removed during the 7-day period, and can be fitted for appropriate wear by each participant. The Fitbit One® has been demonstrated to be valid for measuring general levels of physical activity[74-76] and is able to track non-level-ground activity.[77] The Fitbit One® is a relatively inexpensive and calculates steps and distances walked.

Specific aim 3. To compare the 4-month (short-term) and 1-year (long-term) impact of a self-care CVD risk reduction intervention for multiple CVD risk factors (HeartHealth) with usual care on quality of life.

Quality of life. We measured quality of life using the Medical Outcomes Trust Short Form-12 Health Survey (SF-12).[78-81] The SF-12 was developed to measure quality of life in different illnesses or conditions.[78, 82-86] It has been reported in more than 1000 publications.[78] This 12-item questionnaire produces 2 summary scores that represent physical and emotional components of quality of life across 8 health concepts. Reliability of the 2 summary measures is excellent, as internal consistency and test–retest methods attest.[80,81,87,88] Criteria, content, and construct validity of the SF-12 also are supported by many studies.[80,81,87,88] Higher scores indicate better quality of life.

Specific aim 4. To compare the 4-month (short-term) and 1-year (long-term) impact of a self-care CVD risk reduction intervention for multiple CVD risk factors (HeartHealth) with usual care on patient satisfaction.

Participant satisfaction. We measured participant satisfaction using the RAND instrument, Patient Satisfaction Questionnaire (PSQ)-III.[89] This instrument has been tested extensively for validity and reliability. These qualities have been demonstrated in a variety of situations, with the instrument updated periodically to reflect current health care practice. PSQ-III's 50 items assess global satisfaction with health care as well as satisfaction with 6 aspects of care: technical quality, interpersonal manner, communication, financial aspects of care, time spent with health care provider, and accessibility of care. Each item is accompanied by response categories rated from 1 (strongly disagree) to 5 (strongly agree). Higher scores indicate greater satisfaction with care.

Specific aim 5. To compare the 4-month (short-term) and 1-year (long-term) impact of a self-care CVD risk reduction intervention for multiple CVD risk factors (HeartHealth) with usual

care on desirability and adoptability of the intervention, by assessing adherence to recommended CVD risk reduction protocols and retention of recruited individuals.

Adherence to the intervention. We assessed adherence to recommended CVD risk reduction measures and retention of recruited individuals using the self-report instrument the Medical Outcomes Study Specific Adherence Scale.[90-93] This instrument is a self-report questionnaire modified[92] to assess the following adherence behaviors relevant for individuals with or at risk for CVD: (1) following a low-sodium diet, (2) following a low-fat diet, (3) taking medications as prescribed, (4) exercising regularly (at least 30 minutes per day, most days of the week), (5) reducing stress, (6) eating 5 or more servings of fruits and vegetables per day, (7) following a diabetic diet (for patients with diabetes), (8) eating a diet high in whole grains, (9) stopping smoking (for current smokers), (10) reasonable weight loss diet (for overweight patients), and (11) eating a diet low in saturated/trans fats. Patients were asked to rate how often in the past 4 weeks they had performed, as recommended, the behaviors assessed by the scale, from 0 (none of the time) to 5 (all of the time). The instrument has reliability and validity in a variety of populations.[91-95] We measured retention of recruited individuals by assessment of dropout rates and time of dropout for all recruited individuals.

Descriptive and intervening variables. Using a standardized instrument developed for and used extensively in this population, we gathered data on participants' age, gender, education level, race/ethnicity, marital status, financial status, length of residence in Kentucky, number of people residing in the household, and medications prescribed.

We used the interview format Charlson Comorbidity Index to measure comorbidity burden.[96] This instrument is the most widely used scoring system to capture comorbidity burden. Scores range from 0 to 34 and are based on the number of conditions, weighted for severity of conditions. The reliability and validity have been demonstrated in several populations.

We used the Newest Vital Sign to measure health literacy.[97,98] Health literacy is defined as the degree to which individuals can obtain, process, and understand basic health information and services needed to make appropriate health decisions.[99] Given the low educational attainment of the target population, we assessed health literacy as a potentially intervening

variable. This instrument is sensitive, reliable, and valid for the assessment of health literacy; further, it is well accepted by individuals being screened—even when they have a low educational level.[97,98,100] The instrument's questions are structured for the participant to read, and they are based on a nutrition label on a container of ice cream. Scores range from a low of 0 (no answers correct) to 6 (all answers correct), and the cut point of 3 divides the score into inadequate and adequate health literacy categories.

Outcome for Heterogeneity of Treatment Effect

Framingham risk score. The Framingham risk score is a gender-specific score in which multiple individual risk factors are used to calculate the 10-year risk that a given individual will develop coronary heart disease. The risk score is calculated from known risk factors including age, HDL cholesterol, total cholesterol, smoking status, systolic blood pressure, and diabetes.[101]

Time Frame for the Study

The HeartHealth intervention is 3 months in length. We collected data at baseline and then obtained short-term follow-up data at 4 months postbaseline and long-term follow-up data at 12-months postbaseline.

HeartHealth was delivered in a group format (no more than 10 people per group), given the cultural norm of preferring group activities and social support for challenging activities. Despite delivery of the HeartHealth intervention in a group format, the intervention was individualized to account for each participant's risk factors, goals, and barriers.

Analytical and Statistical Approach

We based all group comparisons on the intent-to-treat convention, with patients retained in the group of assignment regardless of their completion of intervention elements. We compared baseline characteristics using independent *t* tests or chi-square, as appropriate. Between-study arm differences in the proportions between the groups by each of the lifestyle change goals were determined using chi-square stratified by specific goal. We compared outcomes from baseline to 4 months and from baseline to 12 months in the intervention vs usual care groups using mixed models for repeated measures; the fixed effects included time and intervention group and the time x group interaction. We compared rates of cigarette smoking from baseline to 4 months and from baseline to 12 months using a McNemar chi-

square, which is appropriate for repeated measures from the same individual. Given no differences in baseline characteristics, with the exception of ethnicity, or in baseline outcome measures, we included no covariates in the analysis. We did not use ethnicity as a covariate because of the small number of minorities.

To test potential heterogeneity of treatment effects based on gender, presence of depressive symptoms, or inadequate health literacy, we conducted 3 separate analyses, adding gender, depressive symptoms, or health literacy as an additional fixed factor in mixed modeling, with Framingham risk score as the outcome.

Results

Baseline Characteristics

A total of 355 rural Kentucky adults completed baseline questionnaires and physical assessments (see Figure 1). Dropout rates were equivalent at each of the follow-up time points, with a final retention rate of 82 for the full 12 months of the study. We observed no differences in reasons for dropping from the study between the groups.

Figure 1. Participant Flow Through the Study

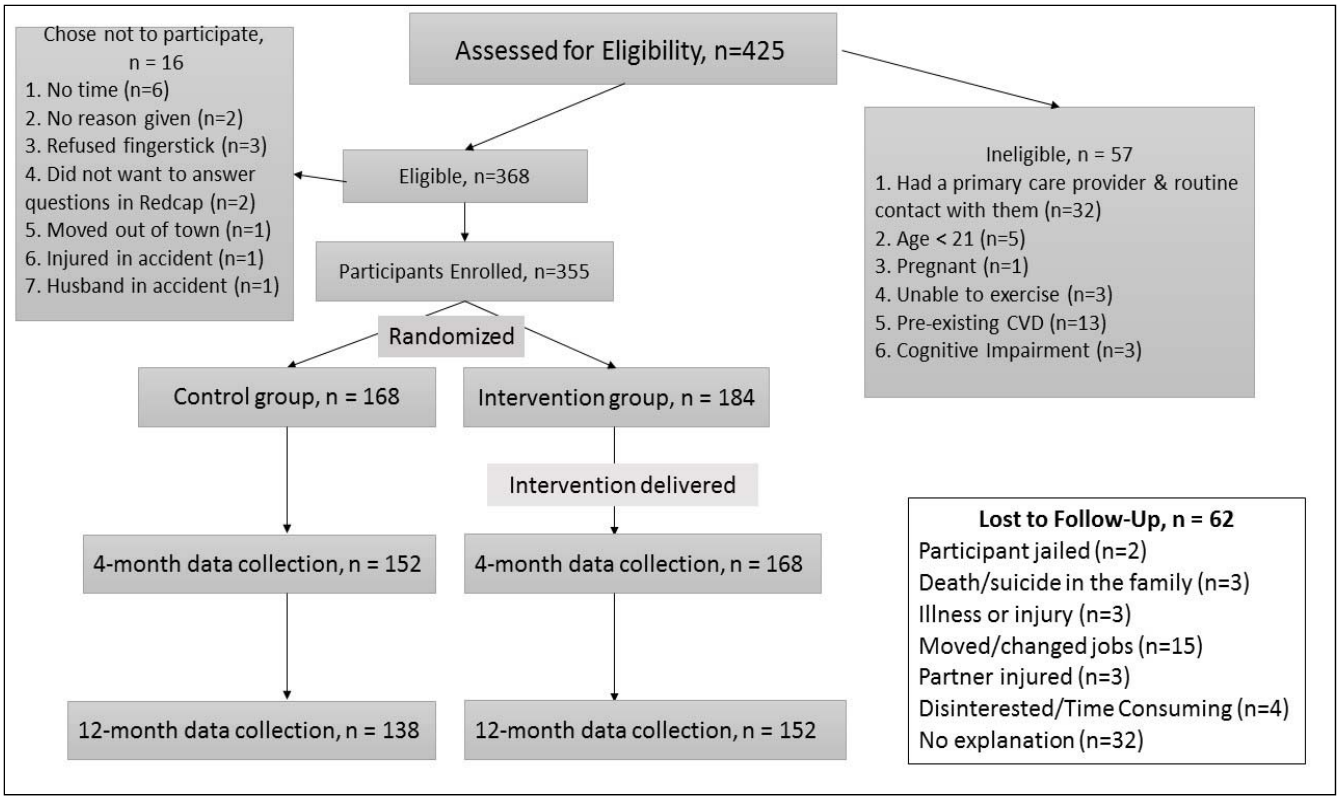


Table 3. Baseline Participant Characteristics, N = 355

	Total Sample (N = 355) N (%) or Mean ± SD	Control (n = 168) N (%) or Mean ± SD	Intervention (n = 184) N (%) or Mean ± SD	*P*
Age, years	42.8 ± 12.8	43.1 ± 12.2	42.6 ± 13.4	.727
Female gender	273 (76.9)	126 (74.1)	147 (79.5)	.258
Caucasian ethnicity	342 (96.9)	160 (94.7)	182 (98.9)	.030
Education, years	13.6 ± 2.9	13.5 ± 2.9	13.7 ± 2.9	.478
Married or cohabitating	212 (60.1)	103 (60.9)	109 (59.2)	.746
Years lived in Kentucky	39.0 ± 14.1	39.1 ± 14.1	39.1 ± 14.2	.992
Number of people in the home	2.9 ± 1.3	2.9 ± 1.3	2.9 ± 1.3	.953
Financial stability				.185
Comfortable	45 (12.9)	21 (12.6)	24 (13.2)	
Enough to make ends meet	213 (61.0)	95 (56.9)	118 (64.8)	

Table 3. Baseline Participant Characteristics, N = 355				
	Total Sample (N = 355) N (%) or Mean ± SD	Control (n = 168) N (%) or Mean ± SD	Intervention (n = 184) N (%) or Mean ± SD	*P*
Not enough to make ends meet	91 (26.1)	51 (30.5)	40 (22.0)	
Charlson comorbidity score	0.42 ± 0.88	0.36 ± 0.73	0.47 ± 0.99	.247
Adequate health literacy	270 (78%)	125 (76.2)	145 (79.7)	.439
Smoker (based on urinary cotinine category)	147 (41.8)	76 (45.2)	71 (38.6)	.206
Body mass index, kg/m^2	31.9 ± 7.6	31 ± 7	32 ± 8	.192
Systolic blood pressure, mmHg	137.9 ± 19.9	137.8 ± 21.3	138.1 ± 18.7	.899
Diastolic blood pressure, mmHg	88.7 ± 13.8	88.7 ± 13.8	88.7 ± 13.8	.997
Total cholesterol, mg/dL	188.5 ± 43.2	185.6 ± 41.0	191.2 ± 45.0	.229
Low-density lipoprotein, mg/dL	106.7 ± 34.3	103.4 ± 32.4	109.5 ± 33.8	.105
High-density lipoprotein, mg/dL	46.2 ± 14.3	46.2 ± 14.8	46.1 ± 13.9	.944
Triglycerides, mg/dL	187.6 ± 121.1	184 ± 121	191 ± 122	.603
Depression score	5.5 ± 5.5	5.5 ± 5.2	5.5 ± 5.8	.966
SF-12 Physical component score	46.6 ± 9.2	46.8 ± 9.2	46.5 ± 9.2	.697
SF-12 Mental component score	48.4 ± 10.8	47.3 ± 11.0	49.3 ± 10.6	.107
Framingham risk score, %	9.5 ± 8.7	9.5 ± 8.8	9.5 ± 8.8	.997
[a]We used Pearson chi-square test to determine differences between groups for categorical variables, and independent samples *t* test to determine differences between groups for continuous variables.				

The mean age of participants was 43 years (SD = 13, 21-79; Table 3). Participants were predominantly white (97%), female (77%), and married or cohabitating (60.1%). The mean years of education was 13.6 years (SD = 2.9). Participants had lived in Kentucky an average of 39 years (SD = 14, median = 38 years, <1-79 years). On average, 3 family members, including the participant, lived in participants' homes (SD = 1, 1-6). Only 12% reported financial status as "comfortable," 61% reported "enough to make ends meet," and 26% reported "not enough to

make ends meet." Most (75.6%) had no comorbidities, and 15% had 1 comorbidity. The mean Charlson comorbidity score was 0.42 (SD = 0.9, 0-6).

Of the 355 participants, 168 participants were randomly assigned to the control group and 184 were assigned to the HeartHealth. Comparison of sociodemographic characteristics (Table 3) revealed equality of the groups, with no differences on any characteristic except ethnicity. The HeartHealth group had more white participants than did the control group (98.9% vs 94.7%; p = .030).

Baseline Values on Outcome Variables

The mean BMI of participants at baseline was 31.9 (SD = 7.6, 19-60.2); 56.4% of participants were obese, 25.4% were overweight, and 18.2% were normal weight. Scores on the PHQ-9 ranged from 0 to 25, with a mean score of 5.5 (SD = 5.5, median = 4.0). Among the participants, 67 (19.2%) scored 10 or higher on the PHQ-9, indicating presence of depressive symptoms. Regarding blood pressure, 41% of participants had a systolic blood pressure of greater than 140 mmHg, and 39.2% had a diastolic blood pressure greater than 90 mmHg. Regarding lipid profile, 34.8% of participants had a total cholesterol greater than 200 mg/dL, 63.8% had a high-density lipoprotein less than 50 mg/dL, 53.6% had a low-density lipoprotein greater than 100 mg/dL, and 36.6% had a triglyceride level higher than 200 mg/dL. Based on urinary cotinine, 41.8% of participants smoked at baseline. The mean Framingham 10-year risk for developing coronary heart disease score was 9.5% (SD = 8.7, 0-30; Table 3). There was no difference in outcome measures at baseline between the intervention and control groups (Table 3).

Impact of the Intervention: Specific Aims 1 and 2 (Primary Outcomes)

More participants in the HeartHealth group than in the usual care group met the lifestyle change goal that they had set at baseline (50% vs 16%; $p < 0.001$). Of the goals, reducing body weight was the most commonly chosen goal, picked by 192 (54%) individuals, followed by increasing physical activity, which was chosen by 81 (23%). Of participants, 29 (8%) chose the goal of reducing their blood pressure, 27 (7.6%) chose reducing HgA1c, 19 (5.4%) chose improving some component of their lipid profile, 5 (1.4%) chose smoking cessation, and 2 (0.6%) chose reducing their depression level. Examination of differences between intervention and usual care for each goal revealed significant differences in those who met the goals of

reducing a lipid component (83% vs 10%; $p = 0.008$), HgA1c (67% vs 18%; $p = 0.014$), blood pressure (88% vs 18%; $p = 0.002$), and body weight (36% vs 9%; $p < 0.001$), and increasing steps walked (65% vs 35%; $p = 0.023$). Too few individuals chose smoking cessation (n = 5) or depression reduction (n = 4) for statistical analysis.

Examination of the differences between groups across time, using repeated measures of modeling revealed significant improvements in the following CVD risk factors in the intervention compared with the usual care group: systolic blood pressure, diastolic blood pressure, total cholesterol, high-density lipoprotein, body mass index, depressive symptoms, number of steps walked per day, and Framingham risk score (Table 4). In all of these risk factors, the groups were similar at baseline but diverged at the second time point, with improvement seen in the intervention but not in the usual care group. The degree of improvement in risk factors seen in the HeartHealth group was maintained at 12 months.

We used a McNemar chi-square to determine differences in smoking status across time. Smoking status, as assessed using cotinine levels, was significantly different across time in the intervention arm but not the control arm. From baseline to 4 months, smoking rates dropped from 38.6% in the HeartHealth group to 23.5% and from 45.2% in the control group to 38.8% ($p < 0.01$). At 12 months, smoking rates were 17.4% in the intervention group and 33.1% in the control group ($p < 0.01$). We saw no differences across time by group in low-density lipoprotein or triglyceride levels.

We examined potential heterogeneity of treatment effect for gender (female compared with male), depressive symptoms (no depressive symptoms compared with presence of depressive symptoms), and health literacy (inadequate health literacy compared with adequate health literacy) for the outcome of Framingham risk score. Neither gender (Figure 2), depressive symptoms (Figure 3), nor health literacy (Figure 4) interacted with treatment group to produce an effect on the outcome. We saw equal effectiveness of the intervention on the outcome in men and women, those with and without depressive symptoms, and those with adequate compared with inadequate health literacy.

Table 4. Comparison of Outcomes Across Time Between Intervention and Usual Care Groups

Outcomes	Groups	Baseline	4 Months	12 Months	*P*

					TimeXGroup Interaction
Body mass index	Intervention	32.6 ± 7.8	32.3 ± 7.9	32.2 ± 7.9	0.017
	Control	31.4 ± 7.4	31.7 ± 7.4	31.9 ± 7.4	
Systolic blood pressure, mmHg	Intervention	137.5 ± 18.8	136.6 ± 19.6	128.4 ± 17.2	0.002
	Control	138.3 ± 21.2	131.8 ± 19.2	136.9 ± 22.0	
Diastolic blood pressure, mmHg	Intervention	88.3 ± 13.4	83.3 ± 11.3	80.0 ± 10.5	0.001
	Control	89.3 ± 14.0	87.7 ± 12.5	87.1 ± 13.9	
Total cholesterol, mg/dL	Intervention	191.4 ± 45.1	184.5 ± 44.6	177.9 ± 39.8	0.026
	Control	189.9 ± 42.3	184.9 ± 41.3	186.5 ± 40.1	
Low-density lipoprotein, mg/dL	Intervention	109.1 ± 35.6	111.0 ± 118.6	106.1 ± 87.6	0.29
	Control	106.4 ± 31.9	99.9 ± 30.1	93.2±28.7	
High-density lipoprotein, mg/dL	Intervention	47.2± 14.0	46.8 ± 13.7	50.2 ± 15.2	0.022
	Control	48.0 ±14.9	46.9 ± 15.5	47.3 ±16.3	
Triglycerides, mg/dL	Intervention	193.7 ± 124.0	182.1 ± 99.9	184.9 ± 130.7	0.477
	Control	189.2 ± 120.8	193.1 ± 118.6	191.4 ± 123.6	
Depression scores	Intervention	5.4 ± 5.0	4.2 ± 4.4	4.2 ± 5.5	0.010
	Control	5.1 ± 5.4	4.8 ± 4.8	5.5 ± 6.1	
SF-12 Physical component score	Intervention	46.7 ± 9.6	47.2 ± 9.5	47.6 ±9.8	0.775
	Control	47.3 ± 8.6	47.3 ±9.2	47.5 ± 9.2	
SF-12 Mental component score	Intervention	49.8 ± 10.2	49.9 ± 10.0	50.1 ± 10.3	0.87
	Control	48.5 ± 10.0	49.1 ± 10.0	49.5 ± 9.6	
Framingham risk score, %	Intervention	9.4 ± 8.7	8.3 ± 8.2	7.7 ± 7.4	0.001
	Control	9.8 ± 8.5	10.2 ± 9.3	10.8 ± 9.3	
Steps taken per day	Intervention	6035 ± 4464	7837 ± 4005	8167 ± 3751	0.001
	Control	6110 ± 3777	5997 ± 3758	6255 ± 4510	

Figure 2. Framingham Risk Score over time stratified by gender

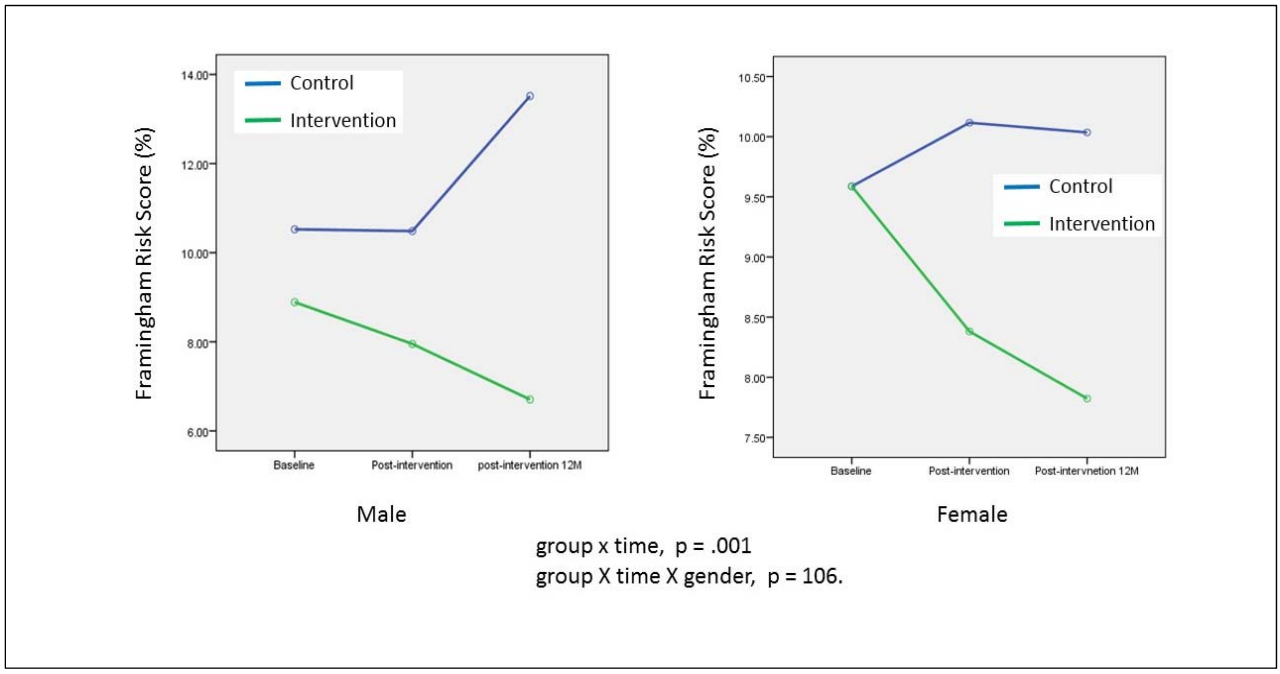


Figure 3. Framingham Risk Score over time stratified by depressive symptoms

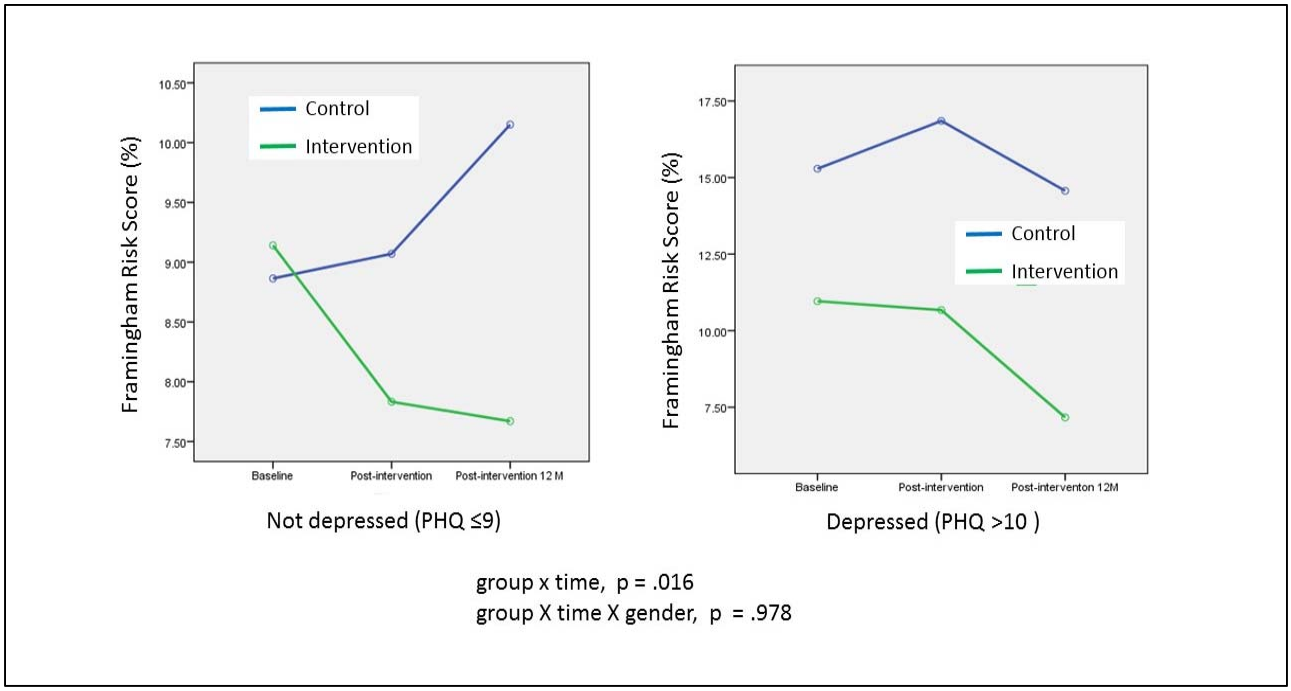
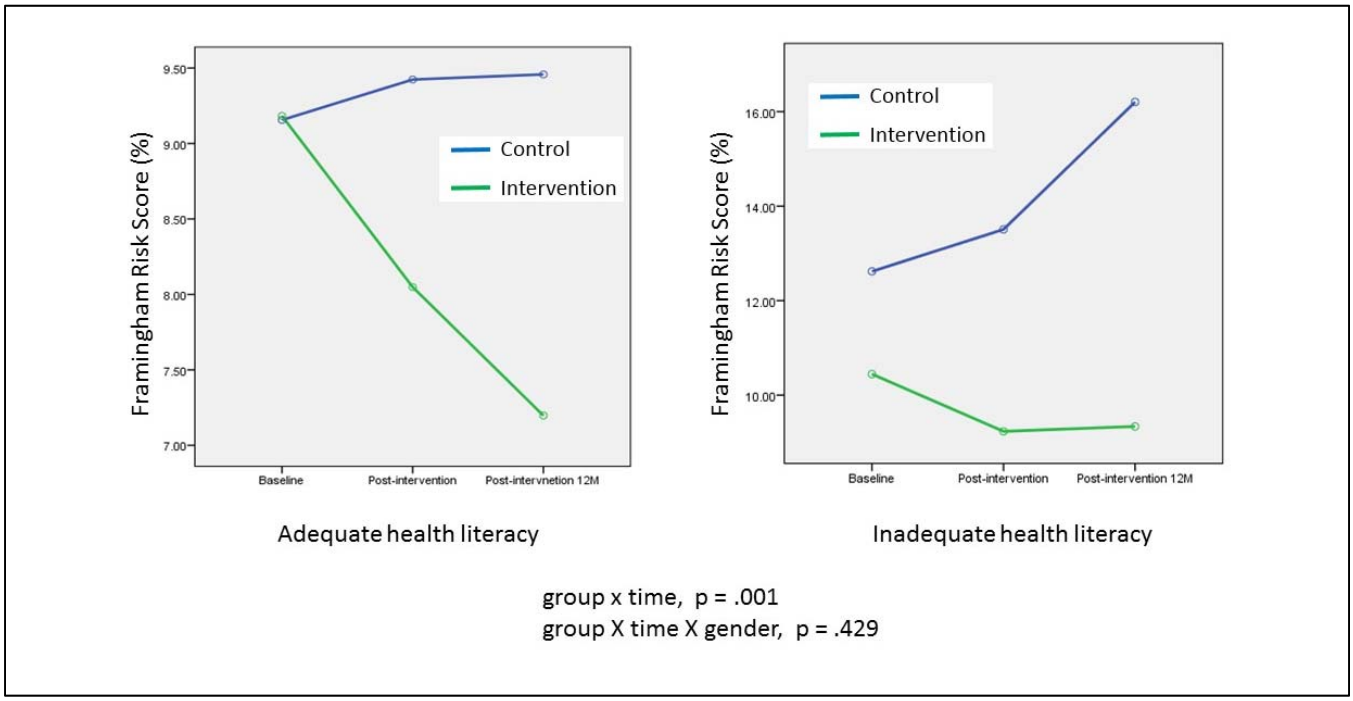


Figure 4. Framingham Risk Score over time stratified by health literacy



Impact of the Intervention on Quality of Life: Specific Aim 3 (Secondary Aim)

We observed no differences between the groups in either the mental health or the physical health component of the SF-12 quality of life measure.

Impact of the Intervention on Patient Satisfaction: Specific Aim 4 (Secondary Aim)

Regarding patient satisfaction with health care and providers, there was no time by group effect ($p = 0.815$), but there was a time main effect ($p < 0.001$). In both groups, satisfaction with health care increased at the second time point, and this increase was maintained at 12 months.

Acceptabililty of the Study and Adoption of Risk Factor Behaviors: Specific Aim 5 (Secondary Aim)

We assessed dropout rates between the groups as a proxy measure for the acceptability of the study design and intervention to participants. Dropout rates were equal between the groups at each of the follow-up time points, with a final retention rate of 82% for the full 12 months of the study. We further assessed participants' adoption of risk factor reduction

behaviors using a self-report adherence instrument. Scores on the Medical Outcomes Study Specific Adherence Scale improved in both groups, but they improved to a greater degree in the HeartHealth group ($p < 0.001$ for group x time interaction). Medical Outcomes Study Specific Adherence Scale scores of the control and intervention arms were not significantly different at baseline (25.4 ± 11.1 vs 27.0 ± 11.1; $p = 0.817$) but differed at 4 months (28.1 ± 11.8 vs 32.6 ± 12; $p = 0.002$) and 12 months (25.9 ± 11.1 vs 34.1 ± 12; $p = 0.001$).

Discussion

Study results in context

We tested the impact of a culturally appropriate CVD risk reduction intervention that focused on promoting self-care to improve cardiovascular health, and we demonstrated that the self-care intervention was superior to usual care for reducing most CVD risk factors. In addition, participants reported satisfaction with health care and providers who delivered the intervention and did not feel burdened by the demands of self-care. We completed recruitment and follow-up for the study ahead of schedule, and our retention rate compares favorably with those seen in other studies of rural individuals who live in austere environments.[102,103]

Together, these findings provide evidence for the use of community-based programs in which individuals collaborate with clinicians and researchers to define best practices for addressing problems in a given community.[104] Prior to and during the current study, community members gave us essential information about community strengths, needs, and desires for CVD risk reduction interventions in Appalachian communities.[42] We also used community health workers, based on prior evidence of their effectiveness in disadvantaged communities.[105] Community health workers who were trusted members of the community provided us with access to previously unreachable participants, were highly effective recruiters, and made excellent interventionists. We credit the collaboration for producing benefit from the tested intervention.

Generalizability

One potential limitation of this study is lack of widespread generalizability, given that it was conducted in southeastern Appalachian Kentucky; it may not be generalizable to the rest of Appalachia or to other rural areas. Limited generalizability, however, is highly unlikely, given the

widespread problems across most rural areas of the United States and the world of low income, poor access to health care, low education level, and poor access to healthy eating options and safe physical activity venues. Our findings suggest that developing culturally sensitive interventions that target specific barriers to CVD risk reduction inherent in the environment will be successful—regardless of the region.

Appalachian residents face enormous health challenges. Life in this area—one of the most health care–underserved and economically distressed environments in the United States—contributes to the worst CVD health disparities seen in the country.[106] Many of the same health and health care disparities seen in Appalachia are evident throughout rural America. Given the distressed economies and limited number of providers in rural America, preventive cardiovascular care has not been a priority. Reduction of CVD risk factors, however, is possible in rural areas, particularly in places such as Appalachian Kentucky with such marked disparities. Interventions like HeartHealth that focus on self-care of CVD risk factors are highly appropriate in these underserved areas.

Subpopulation considerations

The intervention was effective in both genders, in individuals with and without depressive symptoms, and in those with inadequate and adequate health literacy. In developing the intervention, we determined major impediments to successful CVD risk reduction in the region. High rates of depression and of low health literacy, common in the area, were essential to address. Our findings demonstrate that interventions designed with attention to health literacy can promote effective self-care and positively influence outcomes.

We did not find an effect of the intervention on either mental or physical quality of life. We did, nonetheless, demonstrate that the intervention effectively reduced depressive symptoms. Further evidence of the effectiveness of the intervention on depressive symptoms was the lack of effect of baseline depression level on the intervention outcomes.

Depressive symptoms are not a typical target of CVD risk reduction interventions, despite the abundant evidence demonstrating the strong association of depressive symptoms with CVD morbidity and mortality. A particularly striking barrier to CVD risk reduction in Appalachian Kentucky is the high rate of poor mental health—specifically, depressive

symptoms. Based on Behavioral Risk Factor Surveillance System data, Appalachian Kentucky has the highest rate of "mentally unhealthy days" in the United States,[107] and this region has a deteriorating level of mental health.[107] This is an important observation, because depressive symptoms, responsible for most mentally unhealthy days, (1) negatively impact behavior change,[108] and (2) promote the development of CVD risk factors, CVD, and CVD mortality.[109] Thus, the ability to reduce depressive symptoms with a CVD risk reduction intervention and the effectiveness of the intervention in the face of existing depression are important findings.

Implementation of study results

We committed substantial efforts in preparation for this study to determining barriers not only to CVD risk reduction, but to dissemination and use of evidence-based information about CVD risk reduction. Focus groups provided important information about the need to use local people to disseminate information in local outlets. Although researchers outside the community are respected, they felt it was important for local champions who supported the efforts to be fundamental to the dissemination process. Local champions are also respected and are viewed as better at speaking to the people who need the information most. It was viewed as essential to provide information not only to health care providers and to policymakers but also to patients who ultimately must use the innovations. Local community members viewed dissemination as a multipronged approach. They felt it was vital to get information out about important new innovations via local radio, television, and newspapers as well as at local fairs, churches, health departments, agricultural extension offices, schools, and businesses.

Our findings (along with previous data about the importance of self-care) strongly suggest that clinicians taking care of rural patients become proficient in promoting self-care of CVD risk factors among their patients, refer their patients to individuals or groups who promote self-care of CVD risk factors, or develop self-care expertise (possibly a nurse practitioner) in their setting. Our findings further demonstrate that people with multiple CVD risk factors can effectively reduce their risk by engaging in appropriate self-care with education and counseling from community health workers. This approach is clearly superior to referral to a health care practitioner in a standard care setting.

We know that implementation of specific lifestyle CVD risk factor reduction interventions is effective in reducing CVD risk.[55,110-118] Disparities in smoking, hypertension, body mass index, and hyperglycemia explain much of the CVD disparity in mortality seen in different areas of the United States, specifically Appalachia.[118] Reductions in these risk factors could reduce the probability of dying from cardiovascular causes by 69% to 80%.[118] In an international study, the INTERHEART investigators demonstrated that 9 preventable risk factors explained 90% and 94% of the incidence of myocardial infarction in men and women, respectively, independent of age or culture.[115] Simply improving 3 risk factors led to an 80% reduction in risk of a cardiac event. These results were similar to those from the Nurses' Health Study, which demonstrated in a prospective cohort study that 75% of the risk for myocardial infarction or stroke would be removed by adherence to lifestyle guidelines.[116] Other investigators have shown that lifestyle management of CVD risk factors before an event can prevent or postpone 33% of cardiac deaths, compared with prevention of only 8% of deaths if "perfect care" were used during an acute event. These data offer strong support for the importance of lifestyle change (ie, CVD risk factor management) in preventing CVD and further events[55] and for eliminating the marked CVD disparities seen in America.

Despite this evidence, however, lifestyle interventions are not widely used in clinical practice, and their use is extremely rare in distressed, underserved areas such as the region targeted in this project. Moreover, we[21-23,119] and others[120,121] have shown that lifestyle interventions must take into account individuals' unique cultural and societal needs to be effective. We developed our HeartHealth intervention to consider these needs and to focus specifically on promotion of self-care to avoid dependence on the health care system and to promote action to address CVD risk factors. Our findings provide evidence about effective methods to be used to promote lifestyle change in order to reduce CVD risk factors.

Limitations

A limitation of this study is the lack of long-term follow-up (longer than 1 year), which would allow us to assess the degree to which CVD risk factor reduction resulted in delay or prevention of CVD. Further research is needed to test such long-term outcomes. Another limitation is lack of data from this study about how usual care was enacted in referred

participants. Randomization should result in equalization of variability in usual care for CVD risk factor reduction, but these data are unavailable because we did not want to influence the delivery of usual care by collecting data from providers.

Conclusion

Our community-based approach to developing and testing the intervention can serve as an example for others working to reduce health disparities. The success of the intervention, ease of recruitment, high retention in the face of traditional obstacles to retention often seen in austere rural communities, and participant satisfaction with the intervention suggest that community-based approaches should be used to develop, refine, and test other needed interventions in rural, distressed areas.

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