

Strengthening Community-Clinical Linkages to Reduce Cardiovascular Disease Risk in Rural NC: Feasibility Phase of the CHANGE Study

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Abstract

Background Community Health Workers (CHW) are recommended for delivery of interventions to prevent cardiovascular disease, but there is insufficient evidence from interventions conducted in rural, medically underserved areas. Methods Using a hybrid implementation-effectiveness design, we evaluated the implementation and effectiveness of an adapted, evidence-based cardiovascular disease risk reduction intervention among rural high-risk adults. CHWs at a community health center and local health department recruited, enrolled and counseled participants during 4 monthly home visits and 3 brief phone contacts. Participant data collection included pre- and post-intervention measurements of blood pressure, weight, and dietary and physical activity behaviors. We evaluated implementation with measures of intervention reach and delivery fidelity. Statistical analyses included descriptive statistics and paired t-tests. Results Study participants ($n=105$) had a mean age of 62 years and included 88% Non-Hispanic Blacks and 82% females. Recruitment strategies resulted in the enrollment of 38% of interested and eligible participants who received 80% of the planned intervention visits and phone contacts. Mean differences in pre-/post-intervention measures showed significant mean reductions in blood pressure (-5.4 mm Hg systolic, $p=.006$; -2.3 mm Hg diastolic, $p=.04$) and body weight (-3.8 lb., $p=.02$). Self-reported dietary and physical activity behaviors also improved significantly. Conclusion This feasibility study demonstrated preliminary implementation and program effectiveness of a CHW-delivered intervention to reduce cardiovascular disease risk factors. Additionally, it identified areas for future refinements to strategies that strengthening community-clinical linkages with an integrated role of CHWs in rural health care delivery. If results from this feasibility study can be enhanced in a larger sample, there would be significant potential to positively impact the excess burden of chronic diseases that adversely impact rural, low-income, and medically underserved populations.

Background

The leading cause of death in the US is cardiovascular disease (CVD), with the greatest CVD burden concentrated in the southeastern states.(1-3) Within this geographic region, CVD rates are highest among African Americans,(4) Native Americans, those with lower socioeconomic status,(5) and those living in rural communities.(6) Factors that contribute to high CVD rates in these populations include consuming fewer fruits and vegetables,(7,8) engaging in less leisure-time physical activity,(9) and having more limited access to healthcare (10,11) compared to their higher income, non-minority, urban/suburban, and non-southeastern counterparts.

About 40 percent of North Carolinians or approximately 4 million people live in one of the state's 80 rural counties.(12) Despite increased risk for CVD in rural Americans, few CVD prevention interventions are available for rural populations.(13-15) To address this gap, we developed and tested the Carolina Heart Alliance Networking for Greater Equity (CHANGE) intervention which combines an evidence-based behavior change counseling intervention with strategies to link clinical and community services to prevent CVD in a rural county in the Southeastern US. The CHANGE intervention is designed to be delivered by Community Health Workers (CHWs), defined as frontline public health workers who are trusted members of and/or have an unusually close understanding of the community served.(16) Prior research has demonstrated the effectiveness of CHW-led interventions at reducing cardiovascular disease risk factors,(15) and CHWs are well suited to delivering interventions in rural settings.

This report describes the feasibility phase of a hybrid implementation-effectiveness (17) study designed to test the implementation and effectiveness of the CHANGE intervention in one predominantly African American, rural county's community health center and health department. In this report, program implementation and effectiveness outcomes are described along with implications for the follow-up phase, where the CHANGE strategy will be tested in a larger sample of predominantly African American, rural adults.

Methods

Using a hybrid implementation-effectiveness design for this feasibility study, we evaluated the implementation and effectiveness of the CHANGE program with a single arm, pre-/post-study design,(18) where participants were measured before and immediately after receiving the intervention. The University of North Carolina (UNC) Non-Biomedical Institutional Review Board (IRB) approved and monitored the study, beginning with approval in January 2016; direct interaction with study participants ended in September 2017. All participants provided written informed consent, and clinic patients consented to have study staff obtain CVD-related lab values from their medical record by signing a separate Health Insurance Portability and Accountability Act (HIPAA) consent form.

The CHANGE Intervention: Two CHWs delivered an adapted version of the evidence-based Heart-to-Health lifestyle intervention (19) and referred participants to community and clinical resources. Heart-to-Health is a low-intensity behavioral lifestyle intervention targeting CVD risk reduction through dietary and physical activity behavior changes, smoking cessation, and medication adherence. To support these behavioral changes, CHANGE also included a community 'heart healthy' resource guide and protocols for referring participants to and following up on their use of those resources. CHWs delivered the CHANGE intervention over 4 monthly, in-person counseling visits (45-60 minutes) in participants' homes or at local venues selected by the participant. Between these monthly counseling visits, the CHW made short 'booster calls' (about 15-20 minutes) to follow up with participants on the progress made with goals set and actions taken on referrals made at the last counseling visit. Each participant received a program manual with educational materials on healthy eating, taking medicine, physical activity, stopping smoking, and a community resources directory including resources in their community related to heart health, health care, and transportation services. To maximize the potential benefits of lifestyle changes, program topics were introduced to participants based first on the participant's selection of the behavior they most wanted to change, then on the potential CVD risk reduction expected by making the behavior change (ranked from highest to lowest). See Table 1 for more details on the CHANGE program content (4 main areas), listed in order of importance for CVD risk reduction. The total planned contact time (4 counseling visits + 3 booster calls) for this low-intensity intervention is estimated at 4 to 6 hours.

Site, CHW, and Participant Recruitment. The two sites selected for our feasibility study included a Federally Qualified Health Center (FQHC) and a local health department in Hertford, a rural NC county. We selected Hertford county because of its high rates of CVD risk factors and our prior relationships with FQHC leadership. Hertford county is located in the northeastern region of NC, with a population of about 24,000, poverty rate of 26%, and over 60% of the population self-identified as African American.(20) In 2016, Hertford County was ranked 89th for health outcomes and 93rd for health behaviors, among NC's 100 counties.(21) The research team created subcontracts with both sites to cover the costs of staff member participation on the community-engaged research team and the salary and benefits for a full-time CHW.

The CHANGE Study's enrollment goal for Hertford County was 150 participants. To be eligible, participants had to: live in or receive medical care in Hertford County, North Carolina; be 18-80 years of age; and speak English. Women who reported that they were pregnant were excluded or withdrawn, as pregnancy may account for observed changes in weight and blood pressure. The CHW at the health department recruited participants through community outreach, including strategies such as word-of-mouth, flyers, local newspaper or magazine advertisements, participation in health fairs and community events, and visits to churches, beauty salons, and senior centers. The CHW at the FQHC recruited through the electronic health record systems. Clinic nurses pre-screened existing patients for elevated risk of a cardiac event, and then created a list that the CHW used to recruit study participants, either at a clinic visit or via a phone call. Patients were eligible to participate if they were smokers or had uncontrolled diabetes (A1c greater than 8%), hypercholesterolemia (low density lipoprotein [LDL] greater than 130 mg/dL), or hypertension (systolic blood pressure >140 or diastolic >90 mm Hg). Patients who appeared in multiple risk categories were prioritized.

Staff Training for Intervention Delivery. Prior to patient recruitment, the research team conducted an intensive 6-day centralized study training with the staff responsible for participant recruitment and intervention delivery (site supervisors and CHWs). The training sessions included reviews of study protocols, informed consent and participant confidentiality,

participant recruitment and study site protocols, CHANGE intervention content, community referral resources, and data collection methods. Training also included opportunities for CHWs to practice motivational interviewing skills and to role-play enrolling, counseling, and referring study participants.

Data Collection: Data collection included measures of both implementation and effectiveness outcomes; methods for each type are detailed below.

Implementation Outcomes: Data were collected to assess reach and delivery fidelity. Data on reach were captured thorough tracking logs that CHWs maintained of the number of individuals they invited to participate, whether they agreed to participate, and reasons for declining. Data on fidelity were collected through an online system where CHWs documented delivery of the intervention including contact duration, content covered, goals set, referrals made to community resources, and disposition of referrals given (action taken and/or services received).

Effectiveness Outcomes: We collected blood pressure, weight, self-reported dietary and physical activity data to measure program effectiveness. CHWs collected outcome measures at the first and last intervention visits (Home visits 1 and 4). With this study's primary focus on the effective implementation of the CHANGE program, and a secondary focus on its effectiveness in reducing CVD risk, we intentionally limited our data collection to reduce the burden on both the CHW and participants. Data collection included physical measures of weight and blood pressure, brief validated surveys of dietary and physical activity behaviors, and general demographic and health information. Weight, as the average of two measures, was assessed in pounds to the nearest tenth, by an electronic scale (Seca 874, Seca, Hanover, MD). Blood pressure (BP) measurements were taken with an automated BP machine (Omron HEM-907XL, Omron Healthcare, Lake Forest, IL). Two BP measurements (reported as an average systolic and diastolic value) were taken at 1-minute intervals after the participant was seated for 5 minutes. Self-reported dietary behaviors were measured with items from two validated brief food frequency surveys (10 total items) measuring dietary fat quality (22) and estimated intake of fruits and vegetables. (23) A single item (adapted from the 2 items used in BRFSS)(24) was used to assess usual daily consumption of sugar-sweetened beverage consumption. We gathered self-reported data on physical activity behaviors with a validated adaptation of the RESIDE survey which focuses on walking.(25, 26)

Statistical Analysis: For this pilot feasibility study, baseline sample characteristics were summarized using descriptive statistics such as means, percentages, standard deviations etc. Analyses of primary and secondary outcomes and pre-post-changes at 4 months were conducted using paired t-tests. For 10 participants, weight and blood pressure values from their last visit after baseline served as their post-intervention values. All analyses were conducted using SAS Version 9.4 (SAS Institute, Cary, NC).

Results

Figure 1 shows the flow of participants through the CHANGE intervention. Although 131 participants consented to be in the study, only 105 (80%) completed the first intervention visit, which typically happened on the same day that informed consent was obtained and the baseline survey administered. Among the 105 participants who completed the first counseling visit, 82% completed the second visit, and 72% completed the third and fourth visits. The 29 participants lost to follow-up included 59% for whom we could not ascertain the reason for missing their follow-up visit, 6 participants (21%) who were affected by turnover of the CHWs and the subsequent delay in hiring new staff, 17% who could not be scheduled, and 1 withdrawal from the study (3%). The loss to follow-up was much higher among participants enrolled at the health center compared to the health department (22/62 (35%) vs. 5/43 (12%).

Study participants included 62 (59%) from the community health center and 43 (41%) from the local health department. Participant characteristics presented in Table 2 show most participants were Non-Hispanic Black (88%) and female (82%), with a mean age of 62 years. Over half reported having a high school diploma or less in educational attainment. In risk factors for CVD, 79% were diagnosed with hypertension, 32% with diabetes, 56% had hypercholesterolemia, and about 10%

were current smokers. The mean blood pressure values were 137 mm Hg systolic, and 82 mm Hg diastolic; mean weight was 216 lbs. Self-reported physical activity was 80 minutes per week and dietary behaviors included 3.7 daily servings of fruits and vegetables, 1.8 servings of nuts weekly, and 1.2 (12 oz) servings daily of sugar-sweetened beverages.

The primary focus of the CHANGE study was the effective *implementation* of an adapted evidence-based intervention. Table 3 includes selected implementation variables related to intervention reach and delivery fidelity. We employed many strategies to recruit patients and community members to the CHANGE program but did not begin collecting data on how participants heard about the study until the last six months of implementation. Our recruitment efforts yielded 346 persons who were interested and eligible and of these 131 (38%) enrolled in the program.

Implementation of the CHANGE program, as measured by delivery fidelity, showed the average counseling visit lasted 76 minutes and booster calls on average lasted 15 minutes. Participants (n=105) received 80% (590/735) of the planned visits and phone contacts (see Figure 1). The proportion of planned contacts completed by each site differed slightly, with the health department participants completing 86% of all planned visits, while the health center participants completed 74%. Overall, 82% (343/420) of home visits and 78% (247/315) of booster calls were completed.

Participants could select the topic (module) considered their top priority and most participants (72%) chose the "Healthy Eating" module, followed by Physical Activity (15%) and Medication Adherence (8%) modules. Each topic module included 1 to 4 sessions (sub-topics) and participants completed on average 1.6 sessions, set 2.2 goals, and received 0.7 referrals per visit. Referrals were made to a variety of community resources, with programs and activities at community-based centers and Cooperative Extension accounting for the largest proportion of referrals (42% combined). Participants given referrals attempted to follow-up on half of those referrals and successfully accessed services for 40% of referrals.

Table 3 also shows our effectiveness outcomes (mean changes between pre- and post-intervention measurement) for program completers. Program completers did not differ from those lost to follow-up in age, gender or, education. Non-completers, however, included a significantly larger proportion of participants with diagnosed diabetes and taking blood pressure medications ($p<.01$). For physiological outcomes, we observed significant mean reductions in both weight and blood pressure. Moreover, among participants with uncontrolled hypertension at baseline, at follow-up 22% had systolic pressure < 140 mm Hg, and 14% reduced their diastolic pressure to < 90 mm Hg.

Self-reported dietary and physical activity behaviors also improved significantly. On average, weekly servings of nuts increased by 0.41 servings, and fruits and vegetables by 0.86. Participants also reported lowering their intake of sugar-sweetened beverages by about half a serving daily. For physical activity, participants reported a mean increase of 40 minutes weekly.

Discussion

The feasibility phase of the CHANGE study was designed to refine strategies for implementing a CHW-delivered, evidence-based, CVD intervention that also strengthens clinical-community linkages. Our findings from this phase not only demonstrate effectiveness in both implementation and intervention outcomes, but also identify opportunities to improve implementation strategies.

Implementation effectiveness was our primary focus with the purpose of refining our plans for implementation with a larger study sample. Key lessons learned from this study include:

- Recruitment of community participants by the health department CHW was time-intensive. Better data about how participants heard about the program, would have allowed us to identify the most effective strategies. The potential for adding social media (e.g., Facebook and YouTube) to enhance recruitment efforts should be considered in the next phase to improve recruitment efforts (timeliness) and the program's reach.

- CHWs can be more effective at clinical-community linkages if they are well integrated as a valued member of the agency's health care delivery team. A streamlined system of provider referral of eligible patients to the CHW is critical to timely recruitment and enrollment in a clinical setting. Using the electronic health record (EHR) to facilitate this process is essential and CHWs will require training in using the EHR and interacting with providers to create a system of patient identification and program referrals.
- Staff turnovers should be anticipated, and contingency plans developed before program implementation. Both CHWs resigned and accepted new jobs shortly before their time with the project was to end. With no contingency plans in place, there was an extended period when participants did not receive program contacts and were eventually lost to follow-up.
- CHW supervision is a key component that involves ongoing training, problem-solving, and implementation monitoring. CHWs are often selected for their skills in program delivery and patient engagement but are asked to do other important tasks such as data collection and entry, following study protocols, and completing reports. The supervisor must be able to monitor and guide the CHW in all these areas, and the CHW selection process should include these skills.
- In a rural context where resources are limited and/or difficult to access, intervention delivery protocols should specify more than just referring participants to community resources; protocols also need to include potential means to access those services.

Effectiveness in program outcomes was a secondary aim of this study because of the adaptions made. With CHWs delivering an adapted evidence-based intervention we observed significant mean changes in our targeted CVD risk factors. Moreover, our mean reductions in blood pressure and weight were similar to those observed in the Heart-to-Health in-person counseling arm.(19) Compared to CHW interventions included in a recent systematic review(15) our findings are also encouraging for blood pressure outcomes. In this review, among studies with higher quality designs, the median decrease in systolic blood pressure was 6.0 to 2.2 mm Hg depending on the presence or absence of a team-based approach to patient clinical care; for diastolic pressure the median changes were 1.1 to 1.3 mm Hg.(15) In CHANGE where the CHWs did not work alongside physicians and nurses (e.g., team-based care), our median decrease in systolic and diastolic blood pressure was 3.5 and 3.0, respectively.

These findings cannot be fully interpreted without mentioning a few noteworthy limitations. First, our use of a single-arm, pre-post study design means we cannot distinguish between the intervention being responsible for the effect observed versus alternate explanations (e.g., a placebo effect or contributions from other community-level factors). Given that this intervention was already found to be effective in a comparative effectiveness study, we elected to focus this study on feasibility with the goal of obtaining preliminary evidence of effectiveness of the intervention when adapted for delivery by CHWs in a rural context. It should be noted that even though CHWs have been recommended for delivery of interventions to prevent CVD, the Community Preventive Services Task Force (15) identified a gap in the evidence for "interventions conducted in rural areas" and knowledge of "whether CHWs are effective in helping patients access care for their CVD risk factors, especially patients from medically underserved groups." This study helps to fill these evidence gaps. Second, we observed a high level of attrition, particularly in the clinic population. Despite these limitations, this feasibility study fulfilled our aims of identifying key refinements needed for more effective implementation of the CHANGE program in a larger study sample.

Conclusions

In summary, initial evidence for the implementation and program effectiveness of CHANGE provide preliminary support for CHW-delivery of the intervention to reduce CVD risk factors among a rural, predominantly African American population. If results from this feasibility study can be enhanced in a larger sample, there would be significant potential to positively

impact the excess burden of chronic disease that adversely impacts rural, low-income populations. Implications for refinements in the follow-up phase include: 1) pre-implementation planning for staff turnover at partnering health agencies; 2) improved training of CHWs and their supervisors; and 3) focus on integrating CHWs into the health care delivery team.

List Of Abbreviations

BP = Blood Pressure

CHW = Community Health Worker

CVD = Cardiovascular disease

CHANGE = Carolina Heart Alliance Networking for Greater Equity

EHR = Electronic Health Record

FQHC = Federally Qualified Health Center

HIPAA = Health Insurance Portability and Accountability Act

NC = North Carolina

UNC = University of North Carolina

Declarations

Ethics Approval and Consent to Participate – The UNC Non-Biomedical Institutional Review Board (IRB) approved and monitored the study. All participants provided written informed consent, and clinic patients consented to have study staff obtain CVD-related lab values from their medical record by signing a separate Health Insurance Portability and Accountability Act (HIPAA) consent form. [IRB #: 15-2822]

Consent for Publication – Not Applicable

Availability of Data and Materials – The deidentified datasets analyzed in the study reported are available from the corresponding author on reasonable request.

Competing Interest – The authors declare that they have no competing interests.

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Authors Contributions – Author contributions are as follows: conception and design of the study (JL, SC); data acquisition (AB, AE, SA); data analysis and interpretation (ZG, CS-H, SC); drafting or substantively revising text (CS-H, JL, SC). All authors read and approved the final manuscript.

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Tables

Table 1 CHANGE Program Content and Contacts*

Program Contacts	Program Content**
Counseling Visit 1 [45-60 minutes duration]	<ul style="list-style-type: none"> § Written informed consent (HIPAA consent if clinic patient) § Baseline study measurements (weight, blood pressure, survey) § CVD Risk Score calculation § Taking Medications Module <ul style="list-style-type: none"> o What you should know o Reasons for not taking medication and ways to address o Local pharmacies § Goal-setting and action planning § Referrals to community resources (as needed)
Counseling Visit 2 [45-60 minutes duration]	<ul style="list-style-type: none"> § Stopping Smoking Module <ul style="list-style-type: none"> o What Works (QuitlineNC, Asking for Support, Medicines) § Goal-setting and action planning § Referrals to community resources (as needed)
Counseling Visit 3 [45-60 minutes duration]	<ul style="list-style-type: none"> § Healthy Eating Module <ul style="list-style-type: none"> o Nuts, Oils, Dressings and Spreads o Vegetables, Fruits, Beans and Whole Grains o Drinks, Desserts, Snacks, and Eating Out o Fish, Meat, Dairy and Eggs § Goal-setting and action planning § Referrals to community resources (as needed)
Counseling Visit 4 [45-60 minutes duration]	<ul style="list-style-type: none"> § Physical Activity Module <ul style="list-style-type: none"> o Walking o Keep Walking and Moving More o Stay on Track o Add Muscle Strengthening § Follow-up measurements and survey administration
Booster Calls 1- 3 [15-20 minutes duration]	<ul style="list-style-type: none"> § Check-in on goal progress (successes and challenges related to the topic(s) covered) § Check-in on referrals (actions taken or barriers to following through) § Reminder for next counseling session

* Monthly counseling visits were designed as home visits or in-person visits at a community location selected by the participant. Booster calls were scheduled for 10-14 days after each of the first 3 counseling visits.

**Content modules are ordered by highest to lowest potential to reduce CVD risk. No more than 2 topics were covered at each counseling visit.

Table 2 Participant Characteristics

Characteristic (N=105)	N (%) or Mean (SD)
Race/ Ethnicity, %	
Non-Hispanic Black	92 (87.6)
Non-Hispanic White	12 (11.4)
Female, %	86 (81.9)
Age, y	61.9 (10.5)
Education, %	
High school diploma or less	56 (53.3)
Some college	26 (24.8)
College degree (2-year or higher)	23 (21.9)
Physiologic and Behavioral Characteristic, N (%) or Mean (SD)	
Current Smoker, %	11 (10.5)
Diagnosed hypercholesterolemia, %	59 (56.2)
Diagnosed hypertension, %	83 (79.0)
Systolic blood pressure, mm Hg (n=94)	136.6 (22.8)
Diastolic blood pressure, mm Hg (n=94)	81.7 (12.2)
Weight, lb. (n=93)	215.7 (60.7)
Physical activity, minutes/week (n=103)	80.0 (122.9)
Fruit & vegetable servings / d	3.7 (1.7)
Healthy fats, nuts servings / week	1.8 (0.8)
Sugar sweetened beverages / d	1.2 (0.8)

Table 3 Implementation and Program Effectiveness Outcomes

Implementation Variables	Mean (SD) or N (%)^a
Recruitment yield (reach) (Enrolled/Interested) (%)	131/346 (38)
Program Delivery	
Contact duration in minutes, mean (SD)	
Counseling visit	76(24)
Booster call	15(14)
Module selected as priority topic for first counseling visit, %	
Medication Adherence	
Smoking Cessation	8 (8)
Nutrition (Healthy Eating)	4 (4)
Physical Activity	76 (72)
None selected	16 (15)
	1 (1)
Mean modules completed / visit	1.6
Mean goals set / visit	2.2
Mean referrals /visit	0.7
Referral frequency by type	
Wellness center	42 (18)
Senior or Community center	41 (17)
Cooperative Extension programs	16 (7)
Medication assistance	10 (4)
Smoking cessation	7 (3)
Diabetes / other support groups	14 (6)
Farmers market / food resources	38 (16)
Parks / Walking or bike trail	26 (11)
Gym / Walking group	7 (3)
Other community resources	37 (16)
Referrals acted on / referrals given, mean	0.5
Referrals resulting in services received / referrals given, mean	0.4

Post-Intervention Outcomes

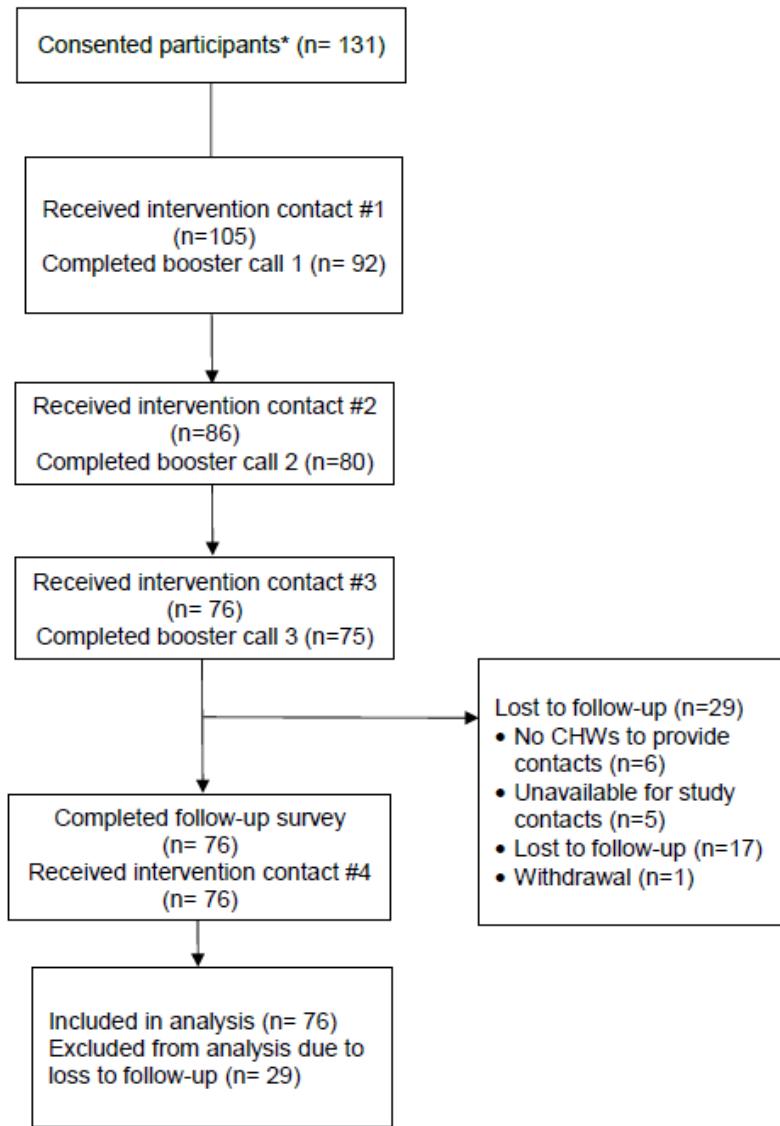
4-Month Outcomes	N^b	Mean Change (SD)	P-value
Weight, lb.	73	-3.8 (13.1)	0.02

Systolic blood pressure (SBP)	76	-5.4 (16.5)	0.006
Diastolic blood pressure (DBP)	76	-2.3 (9.6)	0.04
Proportion at goal	76	--	--
SBP (<140), % increase		22	
DBP (<90), % increase		14	
Nuts, healthy fats, servings weekly	76	0.41 (0.98)	0.0005
Fruit & vegetable servings, daily	76	0.86 (1.70)	<0.0001
Sugar-sweetened beverages, servings daily	76	-0.47 (0.79)	<0.0001
Physical activity, weekly minutes	71	40.4 (113.9)	0.004

^a Percentages may not add to 100 because of rounding.

^b Last visit values used as post-intervention values for participants (n=10) missing weight and blood pressure measures from the last intervention visit.

Figures



* There were 26 participants who consented to participate but did not receive the first intervention contact.

Figure 1

Participant Flow Diagram.