Rationale and design of a cluster-randomized controlled trial to evaluate the effects of a community health worker–based program for cardiovascular risk factor control in India

Aditya Khetan, MD,[a] Raghunandan Purushothaman, MD,[b] Melissa Zullo, PhD, MPH, MA,[c] Rishab Gupta, MD,[d] Vittal Hejjaji, MD,[a] Sushil Agarwal, MD,[e] Sri Krishna Madan Mohan, MD,[a,f] and Richard Josephson, MS, MD[a,f]
Cleveland, Kent, OH; Little Rock, AR; New Delhi, and Dalkhola, India

Background The increasing burden of cardiovascular disease (CVD) in low- and middle-income countries is largely driven by the increasing prevalence of hypertension, diabetes, and tobacco use. We hypothesize that the utilization of community health workers (CHWs) to screen for and manage these 3 determinants of CVD in an integrated manner would be an effective approach to favorably affecting public health.

Methods We have designed and set up the infrastructure to implement a 2-year community-based cluster randomized controlled trial in an underserved region of West Bengal, India. Participants include around 1200 adults, aged between 35 and 70 years, with ≥1 cardiovascular risk factor. They are recruited through home-based screening into a total of 12 clusters, which are randomized to either a control or intervention arm before screening. After the screening, CHWs follow up with participants enrolled in the intervention arm for a period of 2 years through home visits. The control arm receives usual care in the community. The CHW arm follows a behavioral strategy focused on modifying the individual's lifestyle, increasing knowledge of CVD, promoting smoking cessation, increasing physician-seeking behavior, and promoting medication adherence. The main project office is based in Cleveland, OH, at University Hospitals/CWRU, and the local site office is located in Dalkhola, West Bengal, at a local nonprofit set up for the study. Institutional review board approval was obtained both in Cleveland as well as in India.

Outcome evaluation The 2-year primary outcome of the study is the absolute reduction in systolic blood pressure among hypertensive participants, absolute reduction in fasting blood glucose among diabetic participants, and absolute reduction in average number of cigarettes smoked per day among smokers.

Discussion We believe that this study infrastructure serves as a useful model for international collaboration. It builds on unique local resources, attends to important domestic requirements, and will ultimately provide an evidence-based approach that will help manage the increasing burden of CVD worldwide. (Am Heart J 2017;185:161-72.)

The Global Burden of Diseases, Injuries, and Risk Factors Study 2010 estimates that global mortality due to noncommunicable diseases increased from 52% of total mortality in 1990 to 62% in 2010. Cardiovascular diseases account for the largest fraction of these deaths.[1] Moreover, nearly three-quarters of these deaths take place in low- and middle-income countries,[2] where health care systems are still struggling with endemic communicable diseases, in the face of inadequate funding and a shortage of health care personnel.[3] It is therefore clear that national health care systems in these countries will need innovative strengthening and that expensive, technology-intensive health care models of the high-income countries may not be sustainable in these places.

India is an example of such a country, with an estimated 2 million deaths from cardiovascular diseases in 2010. Moreover, 52% of all cardiovascular deaths in India occur below the age of 70 years, as opposed to 23% in countries with established market economies.[4] This is

From the [a]Harrington Heart & Vascular Institute, University Hospitals Case Medical Center, Cleveland, OH, [b]University of Arkansas for Medical Sciences, Little Rock, AR, [c]Kent State University, Kent, OH, [d]All India Institute of Medical Sciences, New Delhi, India, [e]SEHAT, Dalkhola, India, and [f]Case Western Reserve University School of Medicine, Cleveland, OH.
Submitted March 11, 2016; accepted October 1, 2016.
Reprint requests: Aditya Khetan, MD.
E-mail: aditya.khetan@uhhospitals.org
0002-8703

http://dx.doi.org/10.1016/j.ahj.2016.10.027

Figure 1

FUNCTIONS	CLEVELAND, OH AT CMC/CWRU	DALKHOLA, WEST BENGAL, INDIA
IRB approval	From UHCMC	From SPECT (New Delhi) with a local monitoring committee
Design of the study	Primarily at UHCMC	Input from local investigators
Funding	No role of UHCMC	Funded by a local non profit, funding managed by local investigators and personnel
Consent forms and study materials	Developed by both sites through extensive collaboration	Bengali translations done by local investigators and personnel
Data	Stored on a server in Cleveland and monitored in real time	Acquired by CHWs and local supervisors and entered into secured database
Intervention	Kept track of via data monitoring and communication with local investigators	Delivered via CHWs and monitored by supervisors and local investigators
Analysis and interpretation	Primarily at UHCMC	Additional input from local investigators

Functions at both sites.

accompanied by a high burden of cardiovascular risk factors, with prevalence of diabetes reaching 10% in some states in India. In 2011, for example, 62 million people were estimated to be living with diabetes in India.[5] Community health workers (CHWs) have been very effective in managing numerous health care conditions in India, ranging from tuberculosis[6] to immunizations[7] and to maternal and child disease.[8] It is therefore reasonable to investigate if they can provide similarly appropriate care for cardiovascular risk factors. Training and utilization of CHWs for the purposes of screening have been shown to be effective in many developing countries,[9,10] including studies that have shown that CHWs can be effectively used to target single cardiovascular risk factors such as hypertension,[11] diabetes,[12] and smoking[13] in isolation. However, their efficacy in providing integrated care for multiple cardiovascular risk factors has not been tested.

However, implementing vertical programs for each of these conditions individually is neither feasible nor advisable. A CHW-based program that successfully targets these 3 major determinants of cardiovascular risk in an integrated manner would likely result in a cost-effective program that may be appropriate for health care systems of low- and middle-income countries.

We therefore designed a cluster randomized controlled trial, Project SEHAT (Study to Expand Heart Associated Treatments), to test the hypothesis that utilization of CHWs to screen for and manage 3 principal cardiovascular risk factors—hypertension, diabetes, and smoking—in an integrated manner would result in improved control of these 3 conditions.

Methods/design

The design, implementation, and reporting of the study follow recommendations from the "Ottawa Statement on the Ethical Design and Conduct of Cluster Randomized Trials."[14] The study protocol received ethics approval from the institutional review board at University Hospitals/Case Western Reserve University, USA, and Society for the Promotion of Ethical Clinical Trials, an independent review committee in India. The trial was registered in the clinicaltrials.gov database on 4 April 2014, and the registration number is NCT02115711. All trial participants provided written informed consent. The functions of each study site are summarized in Figure 1.

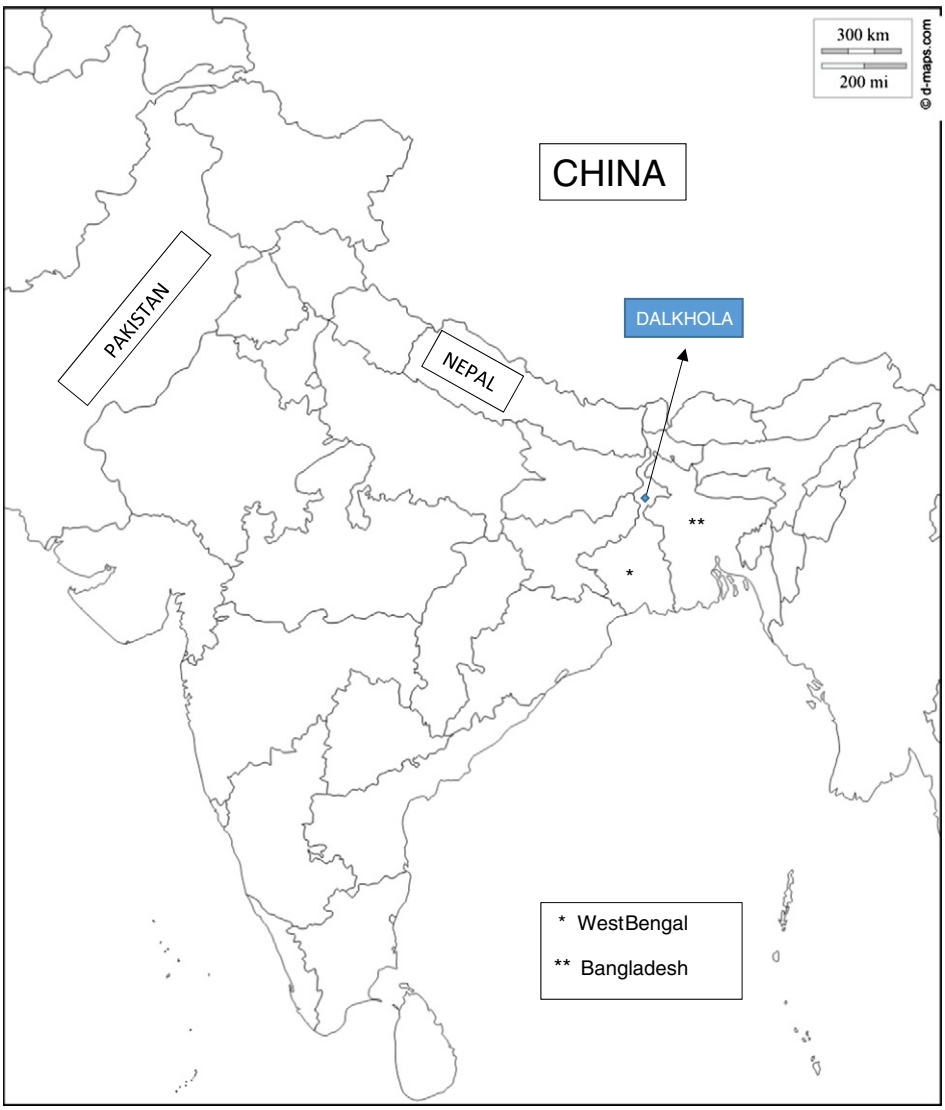
Study site

The study is being conducted in a single site, the town of Dalkhola in West Bengal, India. Dalkhola has an urban population of around 20,000 people, with the economy largely revolving around agriculture. The town is located in the Uttar Dinajpur district, which in the 2011 census had a literacy rate of 60%,[15] the lowest in the state and well below the national average of 74%.[16] The location of the study site is shown in Figure 2.

Study population

Participants between the ages of 35 and 70 years, residing in the geographical cluster allotted to the CHW, are offered home-based screening. Each CHW is provided with a voter roll of the assigned area, and she makes a door-to-door visit in serial order, starting from the first

Figure 2



Map of study site.

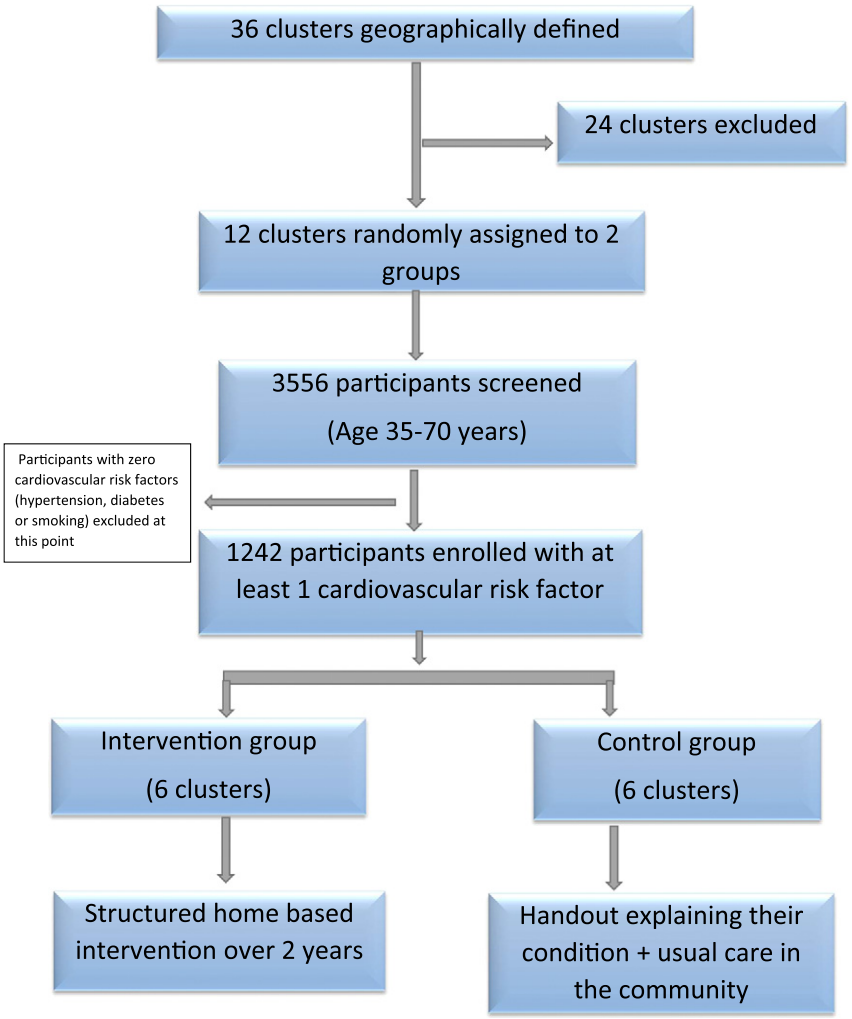
person listed in the voter roll from her cluster. Once she reaches her screening limit of 300 participants, she stops further visits. She makes 2 attempts to reach a household member before labeling them as "Not available to participate." Of the screened individuals, those with ≥1 cardiovascular risk factor (either one of hypertension [blood pressure {BP} ≥140 systolic and/or ≥90 mm Hg on 2 different days or on antihypertensive medications], diabetes [fasting blood glucose ≥126 mg/dL on 2 different days or on antidiabetic drugs], or current daily smoker [self-reported]) are enrolled in the study.

Exclusion criteria included individuals who are bed-bound and individuals who are deemed unable to participate in the intervention because of disabilities such as blindness, deafness, or intellectual disability. Individuals who are unlikely to be available for 2 years of follow-up are also excluded. These determinations are at the discretion of the CHW. For example, a 45-year-old male with hypertension and smoking who has advanced cancer and is mostly bed-bound would be excluded.

Randomization

The voter list is the reference document for our sampling frame. Dalkhola is divided into 14 wards. Each of these 14 wards is subdivided into 5-8 smaller areas, which were grouped into a total of 36 clusters so that each cluster had a uniform size of about 600 adults. We calculated that around 50% of the adults on the voter list

Figure 3



Study design.

would fall in our eligible age group, resulting in around 300 screening-eligible individuals per cluster.

We used a simple random sampling technique to select 12 of 36 clusters into either an intervention or control group. Sampling was done using computer-generated codes. To minimize contamination, adjacent control and intervention clusters were not allowed. We had to change 1 control cluster because it was adjacent to an intervention cluster. Once the clusters were finalized, the process of CHW recruitment from that cluster started. The study design is shown in Figure 3.

The CHW

CHWs are the backbone of the study, collecting data for the study and delivering the intervention. Because of the pragmatic design of the trial and logistics of the small-town setting, we decided that having a blinded observer for the data collection would not be feasible. The CHWs have been specifically recruited for the purpose of the project and are not a part of the public health system.

The CHWs are selected by a process that includes an application, a written test, and an interview. The recruiting committee consists of a study investigator, a local registered medical practitioner, and the elected ward councilor. The panel is trained through a 1-day workshop by the investigators. The workshop will focus on reviewing the interview guide, aiming to understand the thought behind each question. It will also include mock interviews with the study leader.

Essential qualifications for a CHW include female sex; age >18 years; and an ability to speak, read, and write Bengali, the local language. Female sex was an essential requirement as, historically, CHW programs in India have been female driven, mainly for cultural and social

reasons.[17] There was no strict cutoff for educational attainment to enable us to have access to a broad talent pool. Desired qualities included an interest in health care and community work, willingness to learn, leadership qualities, being bilingual (Bengali and Hindi), and previous health care or community work experience. Although previous community work experience was desirable, it was not mandatory.

The CHWs are paid a fixed monthly honorarium of ₹2000 (approximately $30 or €27), with an additional ₹100 as phone credit.

Study procedures

- Screening and recruitment

Each cluster has 1 CHW. The CHW visits every household in her geographical cluster and obtains consent for participation in the study.

At the first screening visit, she administers a questionnaire to each individual and takes 3 BP readings using an automated BP machine (Omron HEM-8711 BP monitor). The first reading is to be taken after 5 minutes of rest, followed by ≥2-minute intervals before the second and third reading. The average of the second and third readings is taken as the BP for that visit. If the patient's BP is >140/90 mm Hg or the patient reports having taken an antihypertensive in the last 2 weeks, he is offered a second screening visit. She also measures the fasting blood glucose using a glucometer (Accu-Chek Performa Nano), usually the next morning, and if the value is >126 mg/dL or the patient reports the use of an antidiabetic medication in the past 2 weeks, he is offered a second screening visit for diabetes.

Individuals with a possible diagnosis of hypertension or diabetes as described above and a self-reported history of daily smoking are offered a second screening visit at a minimum interval of 2 weeks after visit 1. At this visit, participants who have a repeat BP of >140/90 mm Hg or evidence of antihypertensive medication consumption in the past 2 weeks (upon review of blister pack by CHW) are classified as hypertensive. Participants are enrolled for diabetes in a similar manner (fasting blood glucose >126 mg/dL or medication use). All participants in the second screening visit will also have their weight measured with a digital machine and have their waist circumference recorded by a constant-tension tape.

All individuals classified as hypertensive, diabetic, or a daily smoker are enrolled in the trial.

- Intervention

a) Rationale and structure

The intervention arm follows a behavioral strategy focusing on modifying the individual's lifestyle, increasing knowledge of CVD, promoting smoking cessation, increasing physician-seeking behavior, and promoting medication adherence. Interventions for the 3 risk factors are staggered over time, with the hypertension intervention starting first followed by the diabetes intervention 6 months later and, finally, the smoking intervention 2 months after the start of the diabetes intervention. The principle behind staggering the interventions is to ensure a steady learning curve for the CHW instead of overburdening her with information and training upfront. Staggering a complex behavioral intervention to enhance uptake has been shown to be effective in decreasing catheter-related bloodstream infections in intensive care units,[18] although we are not aware of any such attempt in CHW-based literature. The different phases of the project are shown in Figure 4.

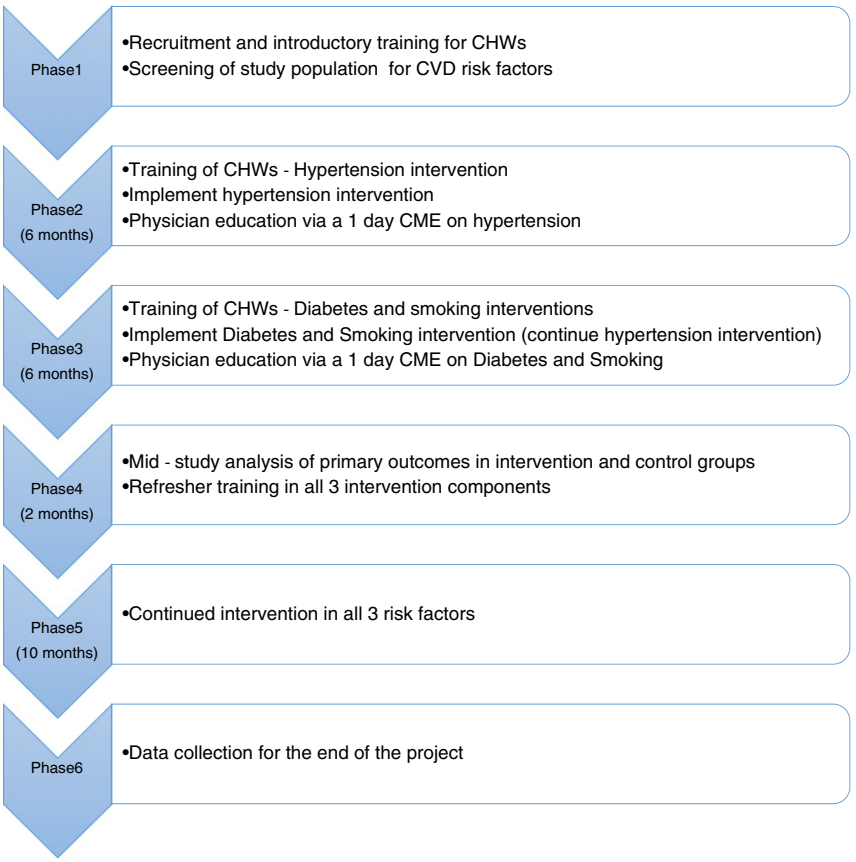
At the end of the second screening visit, the CHW provides brief advice to her diabetic patients to seek physician help and makes an unequivocal recommendation to her smoking patients to stop smoking. For her hypertensive patients, she schedules the first intervention visit within the next month. The structure of the visits for hypertension and diabetes is summarized in Table I, whereas the structure of the smoking intervention is summarized in Figure 5.

b) Hypertension

At the end of screening 2, the intervention CHWs are given a 1-week training session conducted by a study physician. This training includes (1) knowledge of basic human anatomy and physiology, and risk factors and complications of hypertension and other cardiovascular risk factors; (2) key hypertension management interventions including lifestyle interventions, increasing health care–seeking behavior, and measures to promote drug adherence; and (3) use of a 36-page flipbook to deliver hypertension education to patients. The flipbook has illustrations on the side facing the patient and text to guide the CHW on the other side. In addition to didactics, training includes focus on communication skills and motivational interviewing, role plays, case-based discussions, and use of video material.

The first intervention visit has a duration of ≥30 minutes, focusing on delivering hypertension education and understanding medication and lifestyle therapy. Leveraging her knowledge of the community, she adapts her advice to the socioeconomic condition of the family. The CHW encourages the patient to see a physician and tries to involve the family in the participant's care. All medicines are to be prescribed by community physicians, and the study physicians are only involved with training and supervising CHWs, not direct patient care. Similarly, the CHWs do not prescribe or titrate medications either.

Figure 4



Project phases.

For patients with low medication adherence, she tries to understand the barriers to medication adherence and address them. She then sets a follow up appointment for 2 months later but encourages patients to seek her out earlier if they want a repeat BP measurement or have any questions.

Because some hypertensive participants will also be diabetic, the CHW is given sufficient training to impart lifestyle advice that is appropriate for people with both hypertension and diabetes. She also encourages them to seek care for both hypertension and diabetes but does not provide comprehensive education for diabetes at this point. Similarly, for those with hypertension and tobacco use, she recommends quitting tobacco use, but no other education or intervention is carried out at this point.

Each subsequent visit focuses on (1) measuring BP and providing feedback to the patient on how their blood pressures have changed; (2) eliciting information on physician visits and/or medication adherence; (3) identifying barriers to physician visits and/or medication adherence, addressing knowledge deficits; and (4) trying to problem solve the barriers, including by eliciting help from other members of the family and community. The CHW also maintains a diary in which she records the names and doses of the BP medications the individual is on. Every visit, she also records details of the visit such as BP measurements and number of days in the past week that the individual (1) exercised 30 minutes a day, (2) consumed fruits or vegetables, and (3) took their BP medication. All hypertensive patients are given a patient card, and their BP is entered by the CHW in the card at every visit. The purpose of the card is to allow the patient to track their BP values.

c) Diabetes

At the end of 6 months of intervention, there is a 7-day training session focusing on diabetes, similar in structure and content to the hypertension training program. The first visit for diabetes lasts for 30 to 45 minutes, just like in hypertension, and focuses on basic knowledge regarding the disease process and consequences, lifestyle management, and the benefits from regular physician visits and medication adherence. This education is delivered via a 52-page flipbook.

Table I. Structure of the hypertension and diabetes intervention

Visit	Length	Interval	Intervention
1	1 h	–	• Education via flipbook: ✔ Hypertension and cardiovascular diseases ✔ Lifestyle changes ✔ Seeking physician assistance ✔ Importance of medication compliance • Customizing intervention: ✔ Discussion with family members ✔ Addressing financial barriers ✔ Teach back and setting up next appointment
2 and 3	15-30 min	2 m	• Continued hypertension intervention. Special focus on: ✔ Measurement of blood pressure ✔ Addressing barriers to seek physician assistance ✔ Medication compliance ✔ Lifestyle changes
4	1 h	At 6 m	• Education via flipbook for diabetes: ✔ Diabetes and its complications ✔ Lifestyle changes ✔ Seeking physician help ✔ Importance of being compliant with medications
5 and onward	15–30 min	2 m	• Measurement of BP (for hypertensive participants), blood sugar (for diabetic participants) at every visit • Addressing barriers to adequate hypertension and diabetes care

However, unlike hypertension, the education for diabetes is more tailored, and information regarding hypoglycemia and correct medication use is reserved for people on medications. Similarly, education regarding correct insulin use is reserved for people on insulin.

The CHW visits her diabetic patients every 2 months in a pattern similar to her hypertension patients. This continues until the end of the study. At every subsequent visit with a diabetic patient, the fasting blood glucose is checked. The participant will be reminded to fast the evening before the test either by a phone call or by a visit. In the morning, the CHWs will confirm with the participant if they are still in a fasting state before checking their blood sugar. They are also provided with education and support similar to the hypertension intervention. She also maintains a diary for her diabetic patients and records information as per the protocol listed in the hypertension intervention. All diabetic patients are also given a patient card.

d) Smoking

Two months after the start of the diabetic intervention, a 7-day training session is held on tobacco use, focusing on health effects, antitobacco laws, the transtheoretical model of change, the nature of nicotine addiction and withdrawal, second-hand smoke, and interventions to decrease tobacco use, including nicotine replacement therapy. The training does not include information on the use of bupropion or varenicline. The training modalities used are similar to hypertension and diabetes and are delivered by a study physician. Hand-rolled cigarettes (bidis), as opposed to manufactured cigarettes, are the most common form of smoking tobacco in India, and the intervention therefore targets all forms of smoking tobacco. Nonsmoking tobacco, which is also very commonly used in India, is tracked but not directly targeted by the intervention.

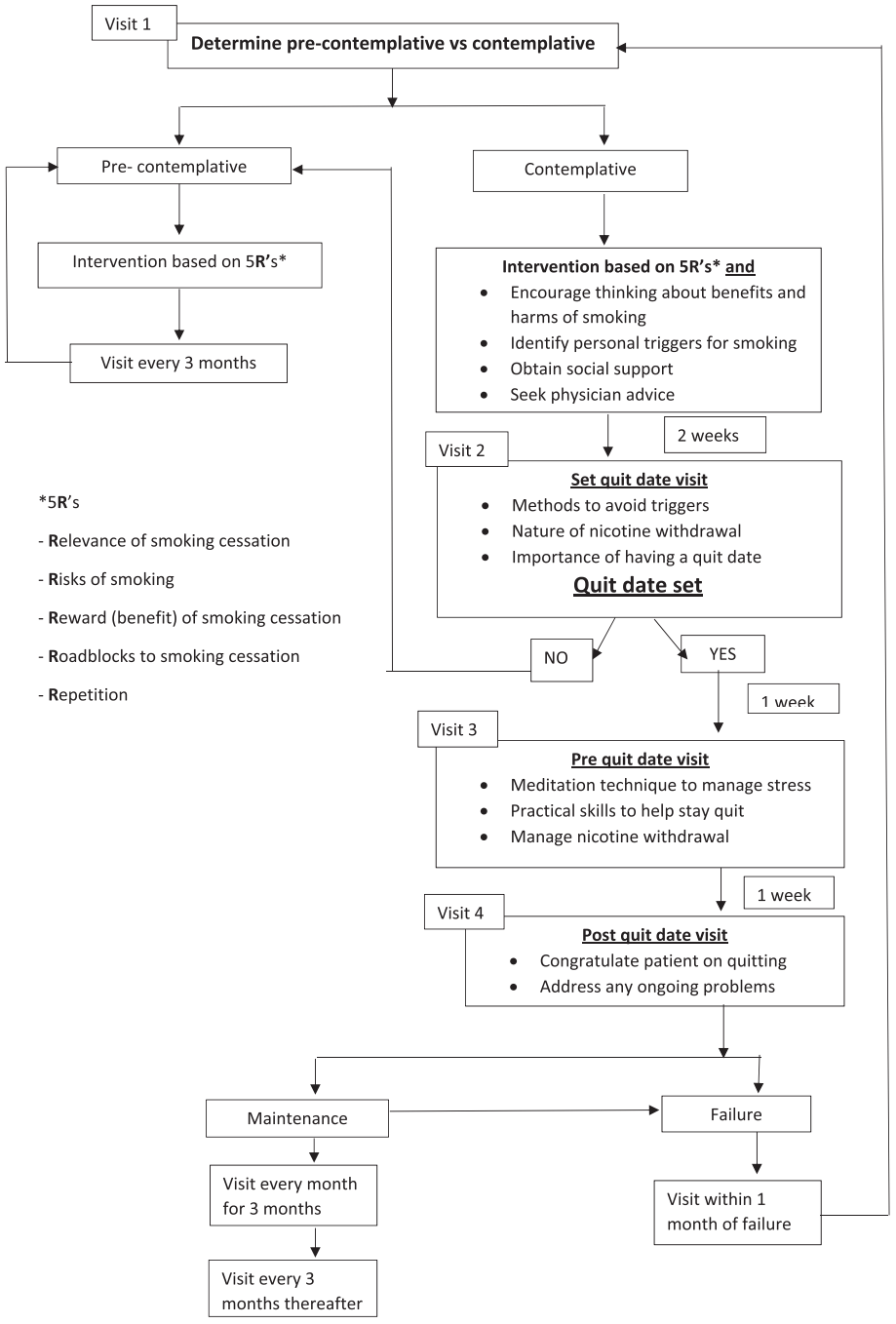
The structure of the visits is different from hypertension and diabetes and is summarized in Figure 4.

The CHW has a 42-page flipbook to assist her, with separate sections for the 4 different visits. The CHW also maintains a page in her diary for every smoker, recording the details of the smoker's habits at the first visit and entering the stage of change, current smoking frequency, and details of quit attempt at every subsequent visit.

- Refresher and ongoing training

Refresher training is provided at the end of the first year of the intervention, where key concepts are revised in a problem-solving format. CHWs are also encouraged to discuss patients who they find

Figure 5



Structure figure of the smoking intervention.

challenging, with the goal of using patient scenarios to practice and illustrate the general principles of the intervention.

CHWs also have continual access to a study physician via phone and can talk to him for any clarifications or help regarding patient care. The physician will not prescribe medications or otherwise engage directly in patient care. His role is only to serve as an educational resource for CHWs and assist in their training and development.

Table II. Planned secondary outcome measures

Absolute mean reduction in diastolic BP among hypertensive participants
Control rates of hypertension (*control* defined as BP <140/90 mm Hg)
Difference in the MMAS-8 score between the 2 arms among participants who have been prescribed an antihypertensive agent
Proportion of diabetic participants whose fasting blood sugars are *controlled* (defined as fasting blood glucose <126 mg/dL)
Difference in the MMAS-8 score between the 2 arms among participants who have been prescribed a hypoglycemic agent
Proportion of diabetes who have taken a statin on ≥5 of the last 7 d
Proportion of hypertensive smokers who have taken a statin on ≥5 of the last 7 d
Proportion of diabetic participants who have taken aspirin on ≥5 of the last 7 d
Proportion of smokers who have abstained from smoking at the end of 2 y
Absolute mean reduction in the weight and waist circumference, for those with increased waist size at baseline, hypertensive participants, and diabetic participants

MMAS-8, Morisky Medication Adherence Scale-8.

- Physician education

Physician education sessions are offered to all physicians in the town. These sessions are conducted by the study investigators. This component of the intervention package is nonrandomized due to logistic reasons because, being a small town, participants in both intervention and control clusters will likely seek care with the same set of physicians.

A 1-day session will be held separately for hypertension and diabetes where local qualified physicians will be invited. The session on diabetes will also include guidelines on promoting tobacco cessation.

- Control

The control group receives a 1-page written handout on their condition at the end of screening. For hypertension, the handout focuses on measures they should take for a healthy lifestyle and information on seeking care from local physicians. A similarly appropriate handout is given to smokers and diabetic participants. Illiterate participants are also provided brief verbal advice and encouraged to share the handout with literate family or friends.

At the end of year 1 visit for the control group, brief verbal advice is given by the field worker to seek care for hypertension and diabetes and to stop smoking. These field workers do not receive detailed training on hypertension, diabetes, and smoking care.

- Outcome evaluation

The primary outcome measures will be measured at the end of 2 years of intervention and will consist of an absolute reduction in systolic BP among hypertensive participants, absolute reduction in fasting blood glucose among diabetic participants, and absolute reduction in average number of cigarettes/bidis smoked per day among smokers. The planned secondary outcome measures are listed in Table II. Those who are diagnosed with more than 1 condition will be analyzed separately by hypertension, diabetes, or smoking. A person with all 3 risk factors will be counted under all 3 primary outcomes.

Sample size and statistical analysis

The sample size determinations, or power analysis, account for lack of independence in observations due to the clustered study design by multiplying the standard sample size calculation by the design effect, {1 + [(average cluster size − 1) × ICC]}, where the ICC is the intracluster correlation coefficient. In previous cluster randomized trials of hypertension control that used absolute reduction in systolic BP (SBP) as the primary outcome, the ICC has been reported to be ranging from 0.004 to 0.052.[11,19,20] There is a paucity of ICC estimates for blood glucose, but the CEART trial reported an ICC of 0.0156 (95% CI 0.012-0.019).[21] Based on other laboratory data like cholesterol, glycated hemoglobin, and triglycerides, we can safely assume an ICC ranging from 0.01 to 0.07 as an adequate range of ICC for fasting blood glucose. For the number of cigarettes/bidis smoked, we used an ICC estimate of 0.011 based on a study conducted in African American adolescents.[22] However, we decided to use more conservative ranges of ICC for both fasting blood glucose and smoking to ensure adequate power, as the study designs and settings of these studies were different from ours.

We then decided upon the minimum detectable difference (MDD) for each of these variables that we thought would be appropriate. We decided upon an MDD range of 7 ± 2 mm Hg for SBP, 15 ± 3 mg/dL for fasting blood glucose, and 5 ± 1 for number of cigarette/bidis smoked per day. Based on these ranges of ICCs and MDD, we calculated the range of sample sizes needed for a study with a power of 80%, α of .05, attrition of 30%, and number of clusters per group as 6. We fixed the number of cluster size for each group at 6 based on our financial and technical capabilities. Based on these

Table III. Sample size calculation

Variable	Assumed SD	ICC	MDD	Sample size	Adjusted sample size	Prevalence in population	Screening sample size
SBP	16	0.004	5	228	326	20%	3258
		0.052	9	126	180		1800
FBG	26	0.02	12	162	232	13%	3570
		0.07	18	96	138		2124
No. of smokes/d	10	0.01	4	150	215	15%	2858
		0.05	6	96	138		1828

assumptions, the sample sizes were calculated and are displayed in Table III. We used conservative estimates of the population prevalence of hypertension, diabetes, and smoking to determine the number of participants required.

We then verified that 6 was an adequate number of clusters based on the formula $k > N_i * \rho$, where k is the minimum number of clusters, N_i is the number of individuals required under individual randomization, and ρ is the ICC.[22]

Thus, we decided to use a screening sample size of 3,570, the largest required sample size for screening among all the possible combinations. We therefore expect to have more than adequate power for the other outcomes.

Data management

All data will be entered in the field office into Research Electronic Data Capture, which is a secure Web application for building and managing online databases. Only deidentified data will be accessed at University Hospitals of Cleveland, which is the coordinating center for the trial. All data will be analyzed in Cleveland using Stata. The investigators will meet regularly over video conference and in person to discuss the progress of the trial.

Quality control and trial monitoring

There is 1 supervisor assigned for every 3 CHWs. The supervisor is a woman with relevant prior experience and known to local investigators. She reviews 10% of all the screening data collected by the CHWs, including data collected in the control group. Once the intervention starts, she verifies 10% of the diary entries made by the CHWs during the course of the intervention. Every CHW is selected for review by the supervisors, and 10% of all the work that a CHW does is planned to be reviewed. The choice of which patients are to be selected is left to the supervisor and is often guided by any anomalies/patterns the supervisors sense. This review is also carried out by visiting the homes of the participants, and a fidelity checklist is used to evaluate adherence to the intervention protocol (reviewing attendance, length of sessions, and transfer of key concepts). The supervisors review the data collected with a study investigator and provide regular feedback to the CHWs, along with additional training as needed. The supervisors and CHWs interact at least monthly with a study investigator to identify and resolve any issues with the intervention. Fidelity of the intervention dose is also tracked by entering each CHW encounter with a patient into Research Electronic Data Capture. A formal process evaluation will be done at the end of the study primarily to check the actual dose of intervention delivered.

We will be measuring the knowledge levels of the CHWs 1 year after the start of the intervention and at the end of the study. This will be tested through a standard questionnaire by personal interview and will allow us to measure the effectiveness of training.

Limitations

Our study has a few limitations. The physician education sessions are open to all physicians in the town, which may minimize differences between the 2 groups. Also, we will not evaluate knowledge of the physicians either before or after training. For smoking status determination, our assessments are limited to self-report, and no biological verifications will be made. Moreover, we did not target smokeless tobacco use, which forms a large proportion of the tobacco burden in India.

Trial progress

Recruitment of the CHWs and other study personnel was completed in May 2014. Screening and enrollment were completed from June to September, 2014. A total of 3,556 adults were screened, and 1,242 individuals have been enrolled. The data collection for the study is expected to be completed by March 2017. At the end of the trial, we also plan to evaluate the cost-effectiveness of the intervention.

Baseline date

The baseline characteristics of the participants are summarized in Table IV. The characteristics are described for all screened participants and then those who were enrolled in the study compared with those who were not

Table IV. Baseline demographics of screened (n = 3556) and enrolled (n = 1242) participants

Question no.		Total n (%) or mean (SD)	Not enrolled n (%) or mean (SD)	Enrolled n (%) or mean (SD)	*P* Not accounting for clustering
	Interview language				
5	Bengali	3038 (85.5)	1950 (84.3)	1088 (87.7)	.005
	Hindi	516 (14.5)	364 (15.7)	152 (12.3)	
8	Sex (male)	1544 (43.4)	782 (33.8)	761 (61.3)	<.001
10	Age (mean and SD)	48.3 (9.8)	46.3 (9.3)	51.9 (9.7)	<.001
	Education				
	None	1719 (48.3)	1159 (50.1)	560 (45.1)	
11	1-5 y	577 (16.2)	387 (16.7)	190 (15.3)	.001
	6-8 y	457 (12.9)	288 (12.5)	169 (13.6)	
	9-10 y	457 (12.9)	261 (11.3)	196 (15.8)	
	>10 y	346 (9.7)	219 (9.5)	127 (10.2)	
	Community				
	Bengali Hindu	1777 (50.0)	1072 (46.4)	705 (56.8)	
12	Bengali Muslim	944 (26.6)	674 (29.1)	270 (21.7)	<.001
	Marwari	92 (2.6)	62 (2.7)	30 (2.4)	
	Other	738 (20.8)	504 (21.8)	234 (18.8)	
	Refused	4 (0.11)	1 (0.04)	3 (0.24)	
	Marital status				
13	Married	3075 (86.5)	2002 (86.6)	1073 (86.4)	.92
	Not married	481 (13.5)	312 (13.5)	169 (13.6)	
14	Work status				<.001
	Works	1460 (41.1)	806 (34.8)	654 (52.7)	
	Income				
	≤25,000	616 (17.3)	402 (17.4)	214 (17.2)	
	26,000-50,000	1116 (31.4)	754 (32.6)	362 (29.2)	
15	>50,000-100,000	1060 (29.8)	673 (29.1)	387 (31.2)	<.001
	>100,000-200,000	390 (11.0)	227 (9.8)	163 (13.1)	
	>200,000	171 (4.8)	106 (4.6)	65 (5.2)	
	Refused	202 (5.7)	152 (6.6)	50 (4.0)	

N, Number; SD, standard deviation.

enrolled in the study. As group clustering did not influence enrollment in the study, *P* values were presented that did not account for clustering. Enrolled versus not enrolled individuals were significantly different on all variables except marital status. A greater proportion in the enrolled population spoke Bengali (88% vs 84%), were male (61% vs 34%), were employed (53% vs 35%), and were older (52 years vs 46 years). The population that was not enrolled had a greater proportion with no education (50% vs 45%) and a similarly greater proportion with an annual income of Rs. 50,000 or less (50% vs 46%).

Discussion

Our study has several strengths. To our knowledge, it is the first study that uses CHWs to target hypertension, diabetes, and smoking in an integrated manner. The study uses a robust cluster randomized design that is adequately powered to evaluate the impact of the intervention on all 3 risk factors. It is a real-world–based study that is rooted in the existing health care system and seeks to leverage its strengths and buttress its weaknesses instead of trying to create a parallel system. Another strength is the attention paid to the recruitment and training process for CHWs, along with tracking fidelity to implementation. Furthermore, the interventions are simple but intensive and can potentially address many of the lacunae that even advanced health care systems in the world face, especially in regard to continuity of care, tackling undiagnosed risk factors in the community, systematic identification and treatment of smokers, cost-effectiveness, and family education and involvement. Finally, the staggered nature of the intervention is an innovation in CHW-based research and, if successful, could be used to test other noncommunicable disease imperatives such as mental health and cancer screening.

The design of the project also allows for easy scalability in the future, which can be done in different settings with the addition of more clusters. These new cohorts of clusters can be used to test design modification and help in dissemination, leading to continuous quality improvement and opportunities for continued investigation.

Project SEHAT will generate evidence to determine if CHWs can effectively target multiple risk factors in an effective manner and the cost-effectiveness of such an approach. Its findings will have implications for noncommunicable disease intervention strategies not just in other low- and middle-income countries but potentially in advanced health care systems tackling some of the same issues.[23]

Funding

The study is being funded by Marwari Yuva Manch, which is a nongovernmental organization based in West Bengal, India.

Appendix. Supplementary data

Supplementary data to this article can be found online at http://dx.doi.org/10.1016/j.ahj.2016.10.027.

References

1. Lozano R, Naghavi M, Foreman K, et al. Global and regional mortality from 235 causes of death for 20 age groups in 1990 and 2010: a systematic analysis for the Global Burden of Disease Study 2010. Lancet 2012;380:2095-128, http://dx.doi.org/10.1016/S0140–6736(12)61728-0.
2. *Noncommunicable diseases. Geneva: World Health Organisation. 2015. [http://www.who.int/mediacentre/factsheets/fs355/en/ Accessed on 08/24/2016].*
3. Samb B, Desai N, Nishtar S, et al. Prevention and management of chronic disease: a litmus test for health-systems strengthening in low-income and middle-income countries. Lancet 2010;376:1785-97, http://dx.doi.org/10.1016/S0140–6736(10)61353-0.
4. Ghaffar A. Burden of non-communicable diseases in South Asia. BMJ 2004;328:807-10, http://dx.doi.org/10.1136/bmj.328.7443.807.
5. Anjana RM, Pradeepa R, Deepa M, et al. Prevalence of diabetes and prediabetes (impaired fasting glucose and/or impaired glucose tolerance) in urban and rural India: phase I results of the Indian Council of Medical Research–INdia DIABetes (ICMR-INDIAB) study. Diabetologia 2011;54:3022-7, http://dx.doi.org/10.1007/s00125–011–2291-5.
6. Khatri GR, Frieden TR. Controlling tuberculosis in India. N Engl J Med 2002;347:1420-5, http://dx.doi.org/10.1056/NEJMsa020098.
7. Patel AR, Nowalk MP. Expanding immunization coverage in rural India: a review of evidence for the role of community health workers. Vaccine 2010;28:604-13, http://dx.doi.org/10.1016/j.vaccine.2009.10.108.
8. Bang AT, Bang RA, Baitule SB, et al. Effect of home-based neonatal care and management of sepsis on neonatal mortality: field trial in rural India. Lancet 1999;354:1955-61, http://dx.doi.org/10.1016/S0140–6736(99)03046-9.
9. Gaziano TA, Abrahams-Gessel S, Denman CA, et al. An assessment of community health workers' ability to screen for cardiovascular disease risk with a simple, non-invasive risk assessment instrument in Bangladesh, Guatemala, Mexico, and South Africa: an observational study. Lancet Glob Health 2015.
10. Labhardt ND, Balo J-R, Ndam M, et al. Task shifting to non-physician clinicians for integrated management of hypertension and diabetes in rural Cameroon: a programme assessment at two years. BMC Health Serv Res 2010;10(1).
11. Jafar TH, Hatcher J, Poulter N, et al. Community-based interventions to promote blood pressure control in a developing country: a cluster randomized trial. Ann Intern Med 2009;151:593-601.
12. Balagopal P, Kamalamma N, Patel TG, et al. A community-based participatory diabetes prevention and management intervention in rural India using community health workers. Diabetes Educ 2012;38:822-34.
13. Siddiqi K, Khan A, Ahmad M, et al. Action to stop smoking in suspected tuberculosis (ASSIST) in Pakistan: a cluster randomized, controlled trial. Ann Intern Med 2013;158:667-75.
14. Weijer C, Grimshaw JM, Eccles MP, et al. The Ottawa statement on the ethical design and conduct of cluster randomized trials. PLoS Med 2012;9:e1001346, http://dx.doi.org/10.1371/journal.pmed.1001346.
15. Ranking of districts by literacy rate in 2001 and 2011. http://censusindia.gov.in/2011-prov-results/prov_data_products_wb.html. [Accessed on 8/24/2016].
16. State of literacy. http://www.censusindia.gov.in/2011-prov-results/prov_results_paper1_india.html. [Accessed on 8/24/2016].
17. Sundararaman T, Ved R, Gupta G, et al. Determinants of functionality and effectiveness of community health workers: results from evaluation of ASHA program in eight Indian states. BMC Proc. BioMed Central Ltd; 2012. p. O30.
18. Pronovost P, Needham D, Berenholtz S, et al. An intervention to decrease catheter-related bloodstream infections in the ICU. N Engl J Med 2006;355:2725-32.
19. Adams G, Gulliford MC, Ukoumunne OC, et al. Patterns of intra-cluster correlation from primary care research to inform study design and analysis. J Clin Epidemiol 2004;57:785-94.
20. Gulliford MC, Ukoumunne OC, Chinn S. Components of variance and intraclass correlations for the design of community-based surveys and intervention studies: data from the Health Survey for England 1994. Am J Epidemiol 1999;149:876-83.
21. Parker DR, Evangelou E, Eaton CB. Intraclass correlation coefficients for cluster randomized trials in primary care: the Cholesterol Education and Research Trial (CEART). Contemp Clin Trials 2005;26:260-7.
22. Murray DM, Rooney BL, Hannan PJ, et al. Intraclass correlation among common measures of adolescent smoking: estimates, correlates, and applications in smoking prevention studies. Am J Epidemiol 1994;140:1038-50.
23. Singh P, Chokshi DA. Community health workers—a local solution to a global problem. N Engl J Med 2013;369:894-6.