Official Title:	Community Mobilization for Improved Clean Cookstove Uptake, Household Air Pollution Reduction, and Hypertension Prevention
NCT Number:	NCT05048147
Study Number:	21-00586
Document Type:	Study Protocol and Statistical Analysis Plan
Date of the Document:	• May 29, 2024

Community Mobilization for Improved Clean Cookstove Uptake, Household Air Pollution Reduction, and Hypertension Prevention

Principal Investigators:	*Olugbenga Ogedegbe, MD, MPH* *NYU School of Medicine* *Olugbenga.Ogedegbe@nyulangone.org* *Christopher O. Olopade, MD, MPH* *University of Chicago Medical Center* *Email: solopade@bsd.uchicago.edu*
Additional Co-Investigators:	*Angela Aifah, PhD, MA* *New York University School of Medicine* *Angela.Aifah@nyulangone.org* *Juliet Iwelunmor, PhD* *Behavioral Science and Health Education* *St. Louis University* *Email:* ijuliet@wust.edu *Dr. Oladosu Ojengbede, MB.BS* *University of Ibadan College of Medicine* *Email: ladosu2002@yahoo.co.uk* *Dr. Ololade Wright, MB.ChB, MPH* Lagos State University Teaching Hospital Email: loladewright@gmail.com *Dr. Rajesh Vedanthan, MD, MPH* *New York University School of Medicine* *Email: Rajesh.Vedanthan@nyulangone.org* *Dr. Erinn Hade, PhD* *New York University School of Medicine* *Email: Erinn.Hade@nyulangone.org* *Dr. Stephen Wall, MD* *New York Universty School of Medicine* *Email: Stephen.Wall@nyulangone.org*
NYULMC Study Number:	**s21-00586**
Funding Sponsor: *[If applicable]*	*National Heart, Lung, and Blood Institute – NIH* *Catherine Stoney, Program Official* *stoneyc@mail.nih.gov* *+1-301-435-6670*

Statement of Compliance

This study will be conducted in accordance with the Code of Federal Regulations on the Protection of Human Subjects (45 CFR Part 46), any other applicable US government research regulations, and institutional research policies and procedures. The Principal Investigator will assure that no deviation from, or changes to the protocol will take place without prior agreement from the sponsor and documented approval from the Institutional Review Board (IRB), except where necessary to eliminate an immediate hazard(s) to the trial participants. All personnel involved in the conduct of this study have completed Human Subjects Protection Training.

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List of Abbreviations

AE	Adverse Events
BP	Blood Pressure
BC	Black Carbon
CAT	Community Action Teams
CF-CS	Clean Fuel- Clean- Stove
CHEW	Community Health Extension Worker
CH_4	Methane
CHO	Community Health Officer
CM	Community Mobilization
CO_2	Carbon Dioxide
CVD	Cardiovascular Disease
EPIS	Exploration, Preparation, Implementation and Sustainment (EPIS)
HAP	Household Air Pollution
HEO	Health Education Officer
HTN	Hypertension
ICS	Improved Cook Stove
LASUCOM	Lagos State University College of Medicine
LGA	Local Government Area
LMIC	Low-and Middle-Income Country
MOH	Ministry of Health
NCD	Non-Communicable Disease
NO_2	Nitrogen Dioxide
OC	Organic Carbon
PM	Particulate Matter

Protocol Summary

Title	Community Mobilization for Improved Clean Cookstove Uptake, Household Air Pollution Reduction, and Hypertension Prevention
Short Title	Community Mobilization for Improved Clean Cookstove Uptake, Household Air Pollution Reduction, and Hypertension Prevention
Brief Summary	Using a focused implementation research framework, the EPIS (Exploration, Preparation, Implementation and Sustainment) model in a type-2 hybrid design, we will conduct this study in 3 phases: 1) A pre-implementation phase that will use the Exploration and Preparation domains of EPIS to: a) explore barriers and facilitators of CF-CS use, and b) develop a culturally-tailored CM strategy for CF-CS use; 2) An Implementation phase that will use the Implementation domain of EPIS to compare in a cluster RCT of 32 peri-urban communities (640 households), the effect of CM vs. a self-directed condition (i.e. receipt of information on CF-CS use without CM) on adoption of CF-CS use; and systolic BP reduction; 3) A post-implementation phase that will use the Sustainment domain of EPIS to evaluate the effect of CM strategy vs. self-directed condition on sustainability of the CF-CS use in 640 households across the randomly assigned 32 peri-urban communities in Nigeria. The University of Ibadan and Lagos State University College of Medicine (LASUCOM) working with the MOH will oversee research coordination in Nigeria.
Phase	Type-2 hybrid design
Objectives	**Aim 1:** Conduct a needs assessment on community readiness for the adoption of CF-CS use in peri-urban communities in Lagos; develop and pilot test a culturally-tailored CM strategy using EPIS framework. Among 640 households across 32 peri-urban communities in Lagos. **Aim 2:** Compare in a cluster RCT, the effect of CM vs. self-directed condition on adoption (primary outcome) of CF-CS use. Hypothesis 1: Adoption of CF-CS use will be higher in communities randomized to CM than those in the self-directed communities at 12 months. **Aims 3** will compare the effect of CM vs. self-directed condition on systolic BP reduction (secondary outcome) of CF-CS use. Hypothesis 2: Mean systolic BP will be lower in the households of communities randomized to CM than those in self-directed communities at 12 months. **AIM 4** will evaluate the sustainability of CF-CS use one year after completion of the trial. Hypothesis 3**:** Sustainability will be higher in communities randomized to CM than those in self-directed group at 24 months.
Methodology	In this study, we will use CM to engage in the community dialogues, organize outreach facilitation, and advocacy for the adoption of CF-CS across participating households. Our choice of CM strategy is deliberate because, unlike western culture, African cultures are largely based on communal hierarchy.
Endpoint	The primary outcome is adoption of CF-CS use [defined as utilization of CF-CS for more than 50% of cooking activities in the household]. The secondary outcomes are mean change in systolic BP from baseline to 12 months assessed with automated devices in two adult members of each household; and sustainability of CF-CS use [defined as maintenance of adoption] at 24 months.
Study Duration	24 months
Participant Duration	12 months
Population	640 households in 32 peri-urban communities in Lagos, Nigeria
Study Sites	32 peri-urban communities
Number of Participants	640 households
Description of Study Agent/ Procedure	Community mobilization
Reference Therapy	Self-directed control condition
Statistical Analysis	**Aim1. Analytic Plan for the Pre-Implementation Phase (Qualitative Data Analysis)** **Aim 2:** The primary analysis will consist of a generalized linear mixed-effects regression model with a logit link examining adoption of the CF-CS at 12 months.

	Aim 3: In aim 3, we will evaluate the association between intervention condition and SBP reduction, our secondary outcome, using a generalized linear repeated measures mixed-effects regression model. **Aim 4:** In aim 4, we will evaluate the association between intervention condition and sustainability of CF-CS use at 24 months, our secondary outcome.

Schematic of Study Design

Figure 1: EPIS Conceptual Framework

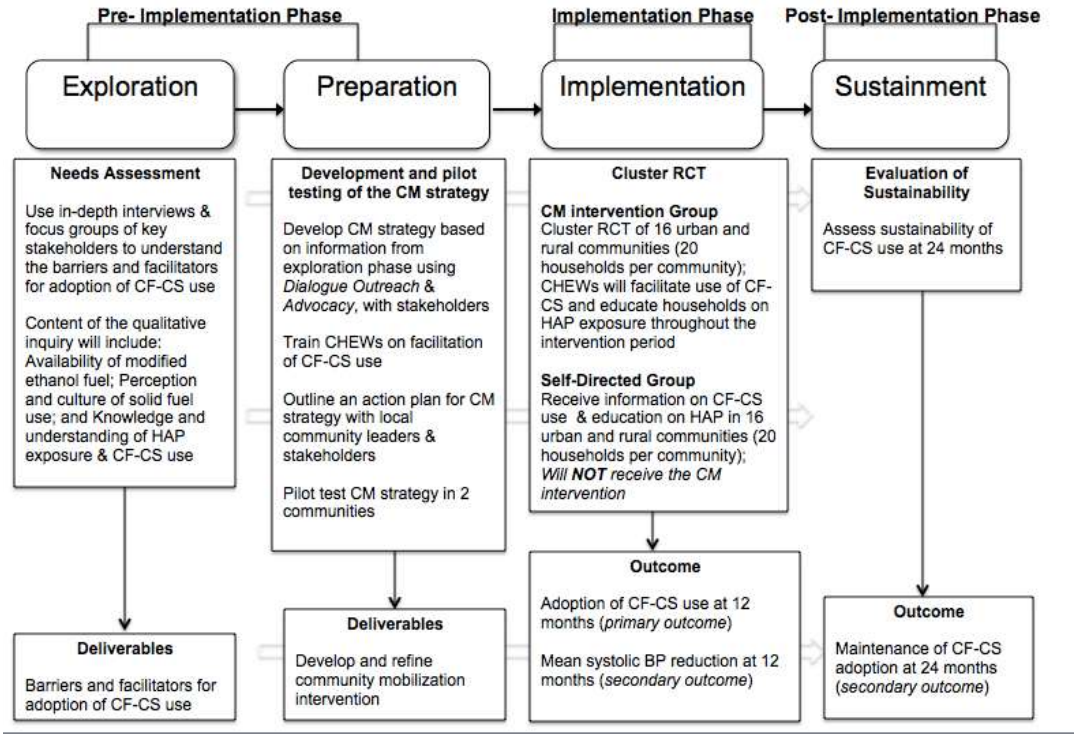
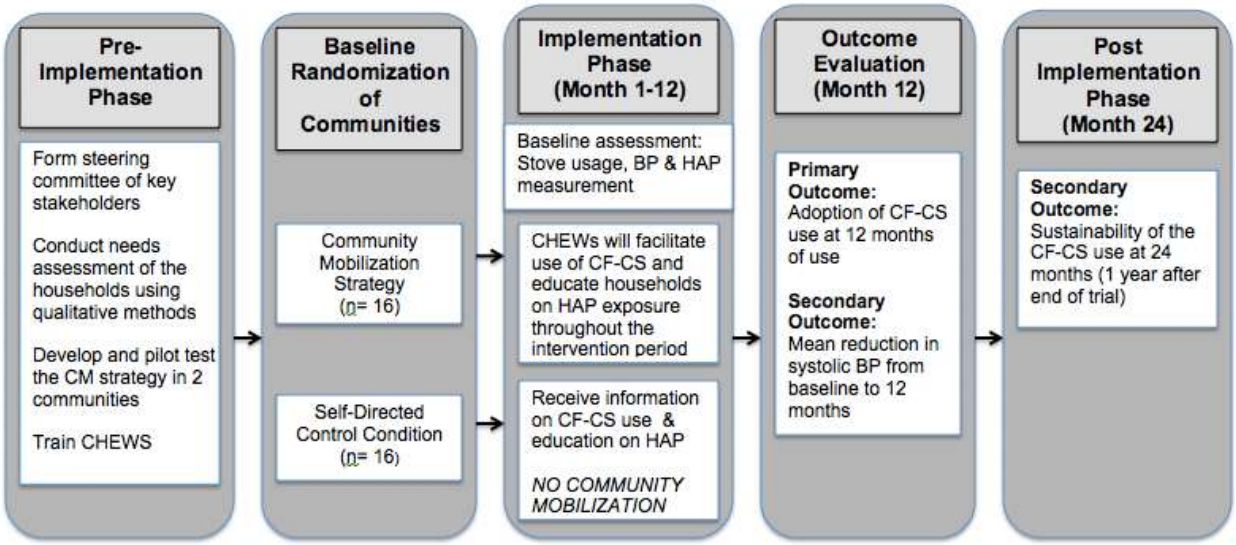


Figure 2: Study Flow



1. Key Roles

Role	Name	Contact Information
Principal Investigation (MPI)	Dr. Olugbenga Ogedegbe	Institution: New York University School of Medicine Address: NYU Langone Health, New York, NY Phone: +1 646-919-7607 Email: Olugbenga.Ogedegbe@nyulangone.org
Principal Investigation (MPI)	Dr. Christopher Olopade	Institution: University of Chicago Address: University of Chicago Medical Center Email: solopade@bsd.uchicago.edu
Co-Investigator	Dr. Juliet Iwelunmor	Institution: St. Louis University Address: College of Social Justice and Public Health Phone: +1 240-528-0123 Email: ijuliet@wustl.edu
Co-Investigator	Dr. Oladosu Ojengbede	Institution: University of Ibadan Address: College of Medicine Email: ladosu2002@yahoo.co.uk
Co-Investigator	Dr. Ololade Wright	Institution: Lagos State University Address: Lagos State University College of Medicine and Lagos State University Teaching Hospital Email: ladosu2002@yahoo.co.uk
Co-Investigator	Dr. Erinn Hade	Institution: New York University School of Medicine Address: NYU Langone Health, New York, NY Phone: 646-501-3742 Email: erinn.hade@nyulangone.org
Co-Investigator	Dr. Rajesh Vedanthan	Institution: New York University School of Medicine Address: NYU Langone Health, New York, NY Phone: +1 646-501-3890 Email: Rajesh.Vedanthan@nyulangone.org
Co-Investigator	Dr. Stephen Wall	Institution: New York University School of Medicine Address: 227 E 30th Street, First Floor, New York, NY 10016 Phone: (646) 501-4044 Email: Stephen.Wall@nyulangone.org

2 Introduction, Background Information and Scientific Rationale

2.1 Background Information and Relevant Literature

Sadly, Household Air Pollution (HAP) from cooking[2] causes 4.3 million premature deaths annually. In Africa, 75% of households are exposed to HAP, a major risk factor for CVD and other noncommunicable diseases (NCDs).[3] Between 1980 and 2010, Africans exposed to HAP increased from 333 million to 646 million.[1] Many African countries are experiencing an epidemic of NCDs like chronic obstructive pulmonary disease, stroke, and HTN attributed to HAP exposure.[2] In Nigeria, 90 million households cook with solid fuels,[4] and NCDs cause 24% of deaths,[5] and 40% of adults have HTN - the leading CVD risk factor.[5]

HAP causes elevated BP in Africa. According to 2002 and 2005 reports from the WHO, 640 million people with HTN live in LMICs, and this number is predicted to double by 2025.[6] Over 25% of adults in Africa have HTN.[8] Based on the Global Burden of Disease, Nigeria had a 95% increase in mortality from 1990 to 2015 among adults with uncontrolled HTN.[7,8] Although uncontrolled HTN can be caused by unhealthy lifestyle behaviors,[9] exposure to HAP is associated with elevated BP.[10] Both short- and long-term exposure to HAP has a negative effect on cardiovascular health.[10] Inhaled particulate matter (PM) from solid fuels used in cookstoves is

associated with elevated BP and increased heart rate hours post-exposure.[10,11] Our group showed an association between household fuel use, cardiovascular mortality and cerebrovascular accident.[12] We also reported a negative effect of HAP (PM2.5 and CO levels) on cardiac function.[13]

Use of improved cook stove (ICS) technology can reduce HAP, BP and CVD risk. The use of clean (i.e. high-efficiency and low emission) cookstoves can reduce HAP.[14] Improved cookstoves have proven efficacy in terms of fuel efficiency and reductions in PM and CO emissions.[15] Despite effectiveness of ICS technology and proven efficacy in HAP reduction and improved health outcomes, there is limited evidence of its effect on CVD outcomes in LMICs.[6,11] In a systematic review we conducted on the implementation of ICS technology in LMICs, only three trials were retrieved from 461 studies; and all three showed significant reduction in BP.[16] In another study by our group, use of clean cookstoves led to BP reduction.[17,18] Finally, we showed that, due to the integrated exposure-response curves of HAP and BP, much greater reductions in HAP are required than can be achieved by clean cookstoves alone in people with high HAP levels.[19] Hence, a combination of clean fuel and clean stoves (CF-CS) is preferred strategy, as we propose in this application. In the context of this study, which is set in Nigeria, we define CF-CS as 1) Liquified Petroleum Gas (LPG) or 2) ethanol-based fuel (bioethanol) and the corresponding ethanol-based cookstove. We provide participants to choose between the LPG or biofuel and stove options for this context because they are the most commonly used clean cooking technology in Nigeria. Providing two clean options to the participants also accommodates for fluctuating prices of the two fuels in the country and allows participants to choose the clean option that is best suitable or affordable to them at the time of screening.

Despite their effectiveness widespread adoption of ICS in LMICs is limited. Given the beneficial effect of ICS technology on HAP and CVD risk reduction, strategies that facilitate their adoption and sustained use in Africa are needed. However, studies evaluating the widespread adoption of CF-CS use in Africa are lacking. This proposal provides a unique opportunity for us to fill this research-to-practice gap by evaluating the effectiveness of a practical and replicable strategy for implementing use of CF-CS in households exposed to HAP in Nigeria - the most populous nation in Africa. Systematic reviews show that effective implementation strategies are typically multi-level, and are tailored to the context of the built-environment.[20] However, communities in Africa lack the resources and expertise to coordinate multilevel system changes without assistance. One implementation strategy that may overcome this barrier is CM – a capacity-building process that ensures community input, buy-in and participation in the strategic development, and implementation of context-specific interventions, thereby improving the chances for sustainability.[21-23]

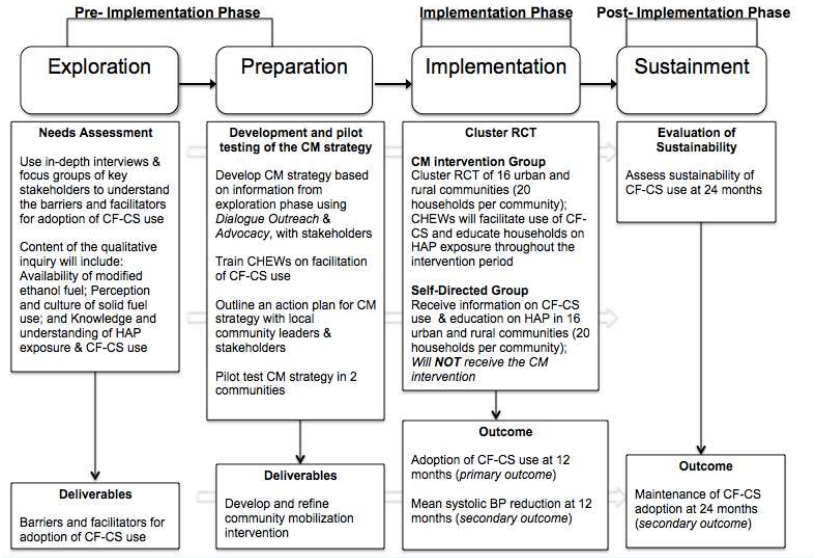
CM could facilitate increased adoption and sustainability of clean cook stove use in Africa. We define CM as *"strategies that engage and galvanize community members to take action towards achieving a common goal."* [21,24] CM strategies focus on building community readiness and resources to take action on issues of shared concerns, while modifying social and structural barriers to adoption and sustainability.[21] Several studies have shown that CM strategies plus partnership building and key stakeholder engagement, are critical facilitators of behavior change, and improve health outcomes.[21,24-29] In LMICs, CM strategies have led to successful adoption of health interventions,[29,30] improved maternal health,[31] reduction of HIV-related stigma,[26] and reduced harmful gender norms, while promoting HIV testing at the community level.[29,30] Despite its proven effectiveness as an implementation strategy, the use of CM for the adoption of CF-CS remains untested in LMICs. CM strategies help communities identify and undertake appropriate actions in relation to shared problems through (a) reliance on peer support, for example, social support on CF-CS uptake by community members; (b) use of community resources to facilitate adoption and sustained use of CF-CS; and (c) collaboration between community residents and health workers in designing CM strategies that generate demand, and facilitate long-term adoption of CF-CS.[21,24,29,32] In this study, we will use CM to engage in community dialogues, organize outreach facilitation, and advocacy for the adoption of CF-CS across participating households. Our choice of CM strategy is deliberate because, unlike western cultures, African cultures are largely based on communal hierarchy. In Africa, community-based projects (as proposed here) are traditionally driven by community leaders, local chiefs and communal support rather than solely by individual

decision-makers. For example, in Cameroon the support of traditional rulers' was influential to the sustainability of healthcare projects in villages.[33] This exemplifies the influence of traditional leaders as partners in healthcare and education in LMICs.[34]

2.2 Conceptual Framework

The conceptual framework for the proposed study will be based on an implementation research framework, the *Exploration, Preparation, Implementation and Sustainment (EPIS) Model*. EPIS is a logic model that facilitates the evaluation of a change process at multiple levels, across time, and through successive stages that build toward implementation, while discerning long-term sustainment.[35-37] We chose EPIS because of its participatory nature and its assessment of CM as a 4-stage process: an Exploration stage (identification of facilitators and barriers to implementing CF-CS use at both the community, and household levels; a Preparation stage (during which the CM strategy is developed and piloted in the target communities); an Implementation stage (a period of training and active facilitation of the CM strategy for CF-CS adoption in individual households); and a Sustainment stage (maintenance of the CM strategy for CFCS use). In each stage, EPIS allows us to identify factors relevant to the success of the CM strategy in the target communities. As shown in Figure 1 (depiction of our conceptual model), we will use EPIS to explore barriers and facilitators to implementing CF-CS at the community and household levels. We will use CM to engage in dialogues and community activities, organize door-to-door outreach, conduct implementation and evaluation and advocacy needs to adopt and sustain CF-CS use at the community and household levels.

Figure 1: EPIS Conceptual Framework



We hypothesize that households randomized to the CM strategy will have: a) higher level of adoption of CF-CS than those in the self-directed condition (primary outcome); b) greater systolic BP reduction (secondary outcome) and higher level of sustainability 1 year after completion of the trial.

For the intervention we propose, we will develop a context-specific CM strategy, and evaluate its effects on the adoption and sustainability of CF-CS use in 640 households across 32 peri-urban communities in Lagos, Nigeria. We will conduct the proposed study in three phases (pre-implementation; implementation and post-implementation phases) based on the EPIS model. First, we will use EPIS to examine community capacity for implementation of CF-CS use in the target communities via a needs assessment of the enabling, and predisposing factors that affect the adoption process. The data gathered will inform development of a context-specific CM strategy that aligns with the community's collective action on reduction of HAP (Exploration and Preparation stages of EPIS). Next, we will evaluate effect of the CM strategy on the adoption of CF-CS use, its clinical effectiveness (BP reduction) and sustainability in 640 households across 32 peri-urban communities in Lagos (Implementation and Sustainment stages of EPIS). To our knowledge, EPIS has not been utilized to guide the adoption and sustainability of evidence-based practices like CF-CS use in Africa.

This study is innovative in terms of the methodology/study design, the nature of the intervention (multilevel); and the outcomes proposed. First, this study combines an established implementation science framework (EPIS) and a community-driven health promotion strategy (community mobilization) into an intervention designed to implement widespread adoption of clean cookstove use in a low-income country. Though extant literature show that the systematic uptake of research findings and evidence-based practices is a desired outcome of implementation research, there is limited evidence of such interventions in Africa.[28] Also, to our knowledge,

EPIS has not been used to guide the adoption and sustainability of evidence-based practices like clean cookstove use in Africa or other LMICs. Our study will be among the first to implement and evaluate the uptake of a proven effective intervention (use of clean cookstove) for HAP reduction in Africa. Second, the proposed study addresses a critical gap in the evaluation of the sustainability of clean cookstove adoption in Africa and other LMICs which is the lack of focus on sustainability. The proposed study will address this gap in the literature by evaluating effect of CM intervention on sustainability of the adoption of clean cookstove use one year after the study is completed. To date, most studies of clean cookstove use have largely focused on their initial adoption rather than sustained use.[38,39] This is an important distinction because adoption studies have typically focused on the barriers and facilitators of initial stove acquisition.[40] To our knowledge, studies targeting the sustainability of clean cookstove use have not been evaluated in Africa. The proposed study will be one of few studies to address this gap in the literature. Third, the proposed intervention is innovative because it is multilevel and addresses household, individual and community-level barriers to adoption of clean cookstove use in an LMIC. Evidence suggests that adoption of clean cookstove technology relies on addressing three major barriers: household characteristics, people's knowledge and perceptions of clean cookstove use, infrastructure with respect to availability of clean cookstoves and direct fueling stations.[38,41,42] As shown in Figure 1, the proposed intervention will target all three categories of barriers to adoption of clean cookstove use at the community-, household- and individual-level. It will create widespread awareness across targeted communities; educate households and community residents of their importance and health benefits. Fourth, the proposed study employs a mixed-methods design with a qualitative phase that explores the priorities of multiple stakeholders, who are *typically under-represented* in implementation and dissemination research in Africa. We will engage multiple stakeholders (ministry of health; community-based organizations, local government officials) in the research process in order to shape and deliver the intervention directly to the community, while fostering community ownership of the intervention.

2.3 Potential Risks & Benefits

2.3.1 Known Potential Risks

Potential risks and protection against risks: Though we expect the level of risk due to this intervention to be minimal, potential risks to the participant may include the following:

Elevated BP: A secondary outcome of this study is reducing SBP, as such; participants are not required to have elevated BP to be eligible for the study. Participants with elevated BP at the beginning of the study will be referred to clinical care as part of this study; however, it is quite conceivable that a participant may have elevated BP readings during the study that will require more aggressive management. Patients with elevated BP will be referred to any of the Lagos State community health centers in the participating communities. This referral system will be addressed by the Lagos State MoH. Study participants will be made aware of this at the consent visit. Similarly, any medical problem that arises during study visits will be referred via the same channels. If at any study visit, BP is elevated >180 SBP or >110 DBP, the participant will be directed to seek medical attention immediately at an affiliated community health center. All such participants will be required to bring to the next study visit a signed document attesting that they sought care. The research assistants and Drs. Ojengbede and Wright will follow-up with the participant's clinician to ensure proper medical follow-up. These data will be reviewed periodically by the Data Safety and Monitoring Board (DSMB) and will be reported to the NYU Institutional Review Board (IRB).

Violation of participant privacy and confidentiality: Loss of confidentiality is the greatest potential risk to study subjects. We will obtain written consent from all study participants who participate in surveys and interviews; however, no identifying information will be included on the transcripts of interviews or surveys. As part of the process involved in obtaining written informed consent, all participants will be reminded that their responses are confidential and that they may refuse to participate in the project or withdraw at any time without explanation, and further, that such an action will in no way affect their treatment or future interactions with their providers. Also, if a participant is uncomfortable during a research encounter, they may stop at any time. All survey data

entered into the research database will be protected by confidential entry codes. Names will be replaced with identification numbers. All health record data will be de-identified prior to transfer from the data warehouses to the central repository managed by NYU. Locked file cabinets will be used to store materials with identifying information (e.g., participant consent forms). Only members of the research team will have access to participant's personal information file. Study data will be transmitted to Dr. Hade and Calvin Colvin (data analyst) for data processing using only secure methods (e.g., encrypted email). All electronic audiotaped data will be saved on a secure server housed by NYU Langone Hospital (NYULH) and backed up daily or weekly depending upon the receipt of data. Immediately following each interview, the interviewer will complete field notes that highlight the main themes. The field notes will be transcribed, and entered into Dedoose, for data analysis. Our expectation is that the data will be available for sharing approximately one year after the project's conclusion. Participant health information will be confined to a secure server that is not connected to the Internet. All computers are password protected and on a private LAN network. No file and database servers are accessible to the public through the Internet. Prior to inclusion in any data set (internal and external), data will be stripped of all identifying information. Finally, the web-based surveys will be accessed via a Health Insurance Portability and Accountability Act (HIPAA) compliant application. The data collected for this study will be used strictly for the purposes stated in this grant application and will only be available to University of Ibadan (UI), Washington University in Saint Louis University (WashU), University of Chicago, LASUCOM, and NYU. IRB approval will be sought prior to any data collection involving human subjects. Finally, all identifiable participant health information will be obtained and managed in accordance with the HIPAA Privacy Rule, 45 CFR Parts 160 and 164.

Anxiety: There is a potential risk that participants may feel uncomfortable or anxious during the audiotaped sessions and/or semi-structured interviews. To mitigate this potential challenge, the study staff member who conducts the semi-structured interviews will be trained to act professionally and address all participants' concerns. Participants will also be reminded that the tapes are only for research purposes and will not influence their relationship with the provider. Moreover, participants will be reassured that the tapes will be saved in a secure and confidential database that only the study staff will have access to, and that have the right to ask that the tapes be deleted if they feel sensitive information was discussed during the session that they do not want the research team to hear.

Recruitment and informed consent: Research Coordinators and Local Government Area (LGA) staff will be responsible for recruitment of subjects and data collection. Researchers are required to be trained in Human Subjects and HIPAA policies and procedures and the handling of data to ensure the confidentiality in order to obtain IRB approval from NYULH. Communities' key leadership personnel and staff will be told about the study at a group meeting. Participation is voluntary and written consent is obtained from participants prior to conducting baseline procedures, and after a detailed explanation of the study is provided by the research staff. Survey data will be entered into a password protected laptop computer or tablet using a web-based portal housed on a secure NYULH server. Once potentially eligible participants are identified, the study coordinator will provide a more in-depth description of the study to the participant in clear, easy-to-understand language. If the participant remains interested in participating, the study coordinator will provide a copy of the consent form for the participant to read; if the participant asks for help or indicates that they have a problem reading the consent form, the study coordinator will read the consent form to the participant. If the participant agrees to participate, s/he will sign the consent form or provide a thumbprint in lieu of a signature for participants who cannot read or write.

2.3.2 Known Potential Benefits

Potential benefits of the proposed research to the subjects and others: The intervention is expected to benefit the participants by reducing HAP through the adoption and sustained use of CF-CS and reducing SBP. The intervention is expected to benefit the participants. The ultimate aim is to develop a CM strategy that can be delivered nationally at little expense; thus, the benefit to others will occur when the intervention becomes a

routine part of activities at the communities. Overall, the benefits of understanding effective methods for helping vulnerable populations reduce their cardiovascular risk far outweigh the remote possibility of a breach of confidentiality. The study may also have relevance to other communities by testing new strategies to enhance implementation of evidence-based interventions for improving household air quality and reducing HTN risk in high-risk populations.

3 Objectives and Purpose

AIM 1: Conduct a needs assessment on community readiness for the adoption of CF-CS use in peri-urban communities in Lagos; develop and pilot test a culturally-tailored CM strategy using EPIS framework. Among 640 households across 32 peri-urban communities in Lagos:

AIM 2 will compare in a cluster RCT, the effect of CM vs. self-directed condition on adoption *(primary outcome) of CF-CS use*. Hypothesis 1: Adoption of CF-CS use will be higher in communities randomized to CM than those in the self-directed communities at 12 months.

AIM 3 will compare the effect of CM vs. self-directed condition on *systolic BP reduction (secondary outcome)*. Hypothesis 2: Mean systolic BP will be lower in the households of communities randomized to CM than those in self-directed communities at 12 months.

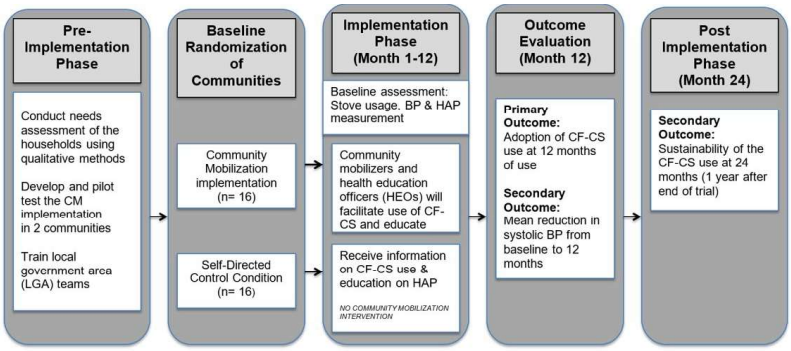
AIM 4 will evaluate the sustainability of CF-CS use one year after completion of the trial. Hypothesis 3**:** Sustainability will be higher in communities randomized to CM than those in self-directed group at 24 months.

4 Study Design and Endpoints

4.1 Study Design

Using a focused implementation research framework, the EPIS model, in a type-2 hybrid design, we will conduct this study in 3 phases: 1) A pre-implementation phase that will use the Exploration and Preparation domains of EPIS to explore barriers and facilitators of CF-CS use at the household and community level, and develop a culturally-tailored CM strategy for CF-CS use; 2) An Implementation phase that will use the Implementation domain of EPIS to compare in a cluster RCT of 32 peri-urban communities among 640 households, the effect of CM vs. a self-directed condition (i.e. receipt of information on CF-CS use without CM) on adoption of CF-CS use (primary outcome); and systolic BP reduction (secondary outcome); 3) A post-implementation phase that will use the Sustainment domain of EPIS to evaluate the effect of CM strategy vs. self-directed condition on sustainability of the CF-CS use in at 24 months (secondary outcome).

Figure 2: Study Flow



The CM strategy will include: (1) Community advisory board [comprising local community-based organizations, government officials, and residents], that will provide leadership support and buy-in for adoption of CF-CS use; (2) Trained MoH CHEWs, CHOs, HEOs, CMs, and Medical Officers of Health (MOHs), who

will form community action teams (CAT) to facilitate the implementation of CF-CS use via provision of support, knowledge exchange and performance feedback to the primary cooks in participating households; (3) Community dialogues with residents and households focused on shared concerns on the significance and importance of CF-CS use. As shown in Figure 2, all 32 communities enrolled in the study will begin the study as part of the pre-implementation phase for 12 months, after which they will be randomly assigned to either the CM intervention (N=16) or the self-directed condition (N=16). Once randomized, the communities will participate in the 12-month implementation phase (intervention period) to evaluate the adoption of CF-CS use, followed by a 12-month post-implementation period to assess its sustainability. The primary outcome is the *adoption* [defined as utilization of CF-CS for more than 50% of cooking activities]. The goal of 50% is based on existing data from low-income countries, and our pilot data where we observed an adoption rate of 65%. Prior research has shown that most interventions which provide participants with an improved/CF-CS cook stove do not result in replacement of the traditional cook stove. Rather, the intervention cook-stove is incorporated into household cooking alongside the traditional stove, a practice referred to as "stacking. Previous trials have reported significant intervention effects on both BP and HAP even when participants stack their stoves. There is no data on what adoption goal constitutes significant public health impact, but, based on the field testing done from our pilot data in Lagos, if households were to switch entirely to clean fuel and/or stove use, it is estimated they would reduce their carbon dioxide-equivalent and black carbon equivalent emissions by 70 and 80%, respectively, suggesting substantive climate impacts could be achieved with more complete displacement of current cooking technologies in urban Nigeria. As a result, we believe that utilization of the CF-CS for even 50% of cooking activities in the household will yield demonstrable benefits to participant's health. Utilization of CF-CS will be assessed with iButtons stove usage monitors (SUMs). The secondary outcomes are *mean change in systolic BP* from baseline to 12 months; and *sustainability* [maintenance of adoption of CF-CS use at 24 months in participating households]. There are 5 IBILE districts, and we will recruit all 32 communities from these districts. We will leverage Lagos State MoH's connection with their constituents to facilitate recruitment.

4.2 Study Endpoints

The **primary outcome** is adoption of CF-CS use [defined as utilization of CF-CS for more than 50% of cooking activities in the household]. Utilization will be measured with iButtons SUMs. For this purpose, all traditional stoves and the CF-CS will be equipped with the iButtons SUMs to assess their use across the intervention period.

The **secondary outcomes** are *mean change in systolic BP* from baseline to 12 months assessed with automated devices in two adult members of each household; and *sustainability* of CF-CS use [defined as maintenance of adoption] at 24 months.

5 Study Enrollment and Withdrawal

5.1 Eligibility Criteria

Eligible households must have at least two adults (one been the primary cook), who will be identified in each community by the LGA members and the research staff given their experience and knowledge of their respective communities. A total of 640 households will be recruited (20 per community). The households and adult participants must meet the following eligibility criteria:

- primary adult must be a female cook;
- must not have a paid housemaid;
- family size must be a minimum of 2 and no more than 7 members;
- family must use unclean cooking methods, such as kerosene, charcoal, or firewood as primary cooking fuel;
- family must not currently use a clean cooking method, such as LPG or electric stove etc.
- the person spoken to at enrollment must be the home key decision maker;

- must have no plans for relocation in the next year.

Key informants will be selected from:
- Composition of the steering committee
- Local leaders
- Community residents

5.2 Vulnerable Subjects
Inclusion of vulnerable populations: Participants with cognitive impairment are not eligible to participate.

5.3 Strategies for Recruitment and Retention
Participants will be recruited at the level of household, with two adults per household (one being the primary cook of the household, and one another adult in the household). Recruitment of individuals from the household will be similar to the strategy we adopted in our previous trial in Ibadan.[91] For this purpose, two Research Coordinators (RCs) from Lagos State University College of Medicine (LASUCOM) will conduct the screening, consent, enrollment, and all study assessments. Drs. Ojengbede and Wright will oversee recruitment and retention activities of the RCs.

- Recruitment of Communities**:** We will recruit peri-urban communities in Lagos State. There are 5 IBILE districts in Lagos State. We will recruit all 32 communities from these local government areas. Drs. Ojengbede and Wright will meet with community leaders to provide study overview.
- Recruitment of Households and participants: Eligible households must have at least two adults (one being the primary cook), who will be identified in each community by the LGA members and research staff given their experience and knowledge of their respective communities. A total of 640 households will be recruited (20 per community). The households and adult participants must meet the following eligibility criteria: primary adult must be a female cook; must not have a paid housemaid; family size must be a minimum of 2 and no more than 7 members; family must use unclean cooking methods, such as kerosene, charcoal, or firewood as primary cooking fuel; family must not currently use a clean cooking method, such as LPG or electric stove etc. the person spoken to at enrollment must be the home key decision maker; must have no plans for relocation in the next year.
- Key Stakeholders: Key community stakeholders will be selected from the steering committee members in addition to local leaders and community residents. Drs. Ojengbede and Wright will oversee the selection of key stakeholders.

5.4 Duration of Study Participation
Each CM will work with their assigned households for 12 months. The intervention will be implemented in three waves, with the intervention period of one year at each community.

5.5 Total Number of Participants and Sites
A total of 640 households across 32 peri-urban communities in Lagos (20 households per community) yielding a total sample size of 1,280 adults.

6 Study Procedures and Schedule

6. 1 AIM 1: **Conduct needs assessment on community readiness for the adoption of CF-CS use in peri-urban communities in Lagos; develop and pilot test a culturally tailored CM strategy using EPIS framework.** This Aim will be conducted in the pre-implementation phase, during which we will use EPIS to

examine community capacity for implementation of CF-CS use in the target communities via a needs assessment of the barriers and facilitators that affect the adoption process (Exploration domain of EPIS). The data gathered will then be used to inform the development of a context-specific and culturally tailored CM strategy that aligns with the community's collective action on reducing HAP. Next the CM strategy will then be piloted in a two communities (Preparation domain of EPIS).

6.1.1. Pre-implementation phase study design: In this phase we will use qualitative methods to conduct a needs assessment and implementation process likely to influence adoption of the CF-CS. We will assemble a group of key stakeholders, conduct semi-structured interviews and focus groups with them in order to identify community readiness for adoption of CF-CS, develop a CM strategy informed by data from the qualitative study and then pilot the CM strategy in one peri-urban community. Data from the qualitative inquiry in this phase of the study will inform the types of community strategies that will be effective for that context and the best strategy for the clean cookstove distribution among households. We describe each step for the pre-implementation phase below.

6.1.1.1 Formation of a Steering Committee (SC) comprised of 2 representatives from community-based organizations (two peri-urban); 2 CHEWs, 1 MOH personnel, 3 community leaders and 3 residents from participating districts and the research team. The SC will inform all phases of the study. It will also: a) help maximize the fit of CF-CS adoption by incorporating organizational, and community knowledge; b) provide feedback on the findings as they emerge; c) ensure development of a CM strategy that is feasible and actionable (i.e. core elements that are easily implemented) and d) help monitor study progress in order to enhance buy-in at both the community and household levels. The SC will meet every 3 months in Year 1, and every 6 months in Years 2-5.

6.1.1.2. Semi-structured interviews and focus groups with key community stakeholders and household adults who make day-to-day cooking decisions (needs assessment): The goal of the needs assessment is to identify community capacity and readiness for the adoption of CF-CS within households and communities. We will conduct two sets of semi-structured interviews and focus groups with a purposive sample of key stakeholders (see composition of SC members in addition to local leaders and community residents) and household adults – all of which will take place before the pilot testing of the CM strategy. One set of interviews and focus groups will be with community leaders while the other set will be conducted with household adults, who make day-to-day decisions about use of the CF-CS in their respective households. The interviews and focus groups will explore: 1) members' knowledge, perception, and attitudes regarding HAP and CF-CS use; 2) enabling and predisposing factors that affect the adoption process; 3) intervention characteristics (adaptability of the CF-CS to the local context); and 3) implementation process likely to influence adoption of the CF-CS use in the communities.

For the community leaders, the interview and focus group discussions will focus on community leaders' understanding of the purpose of the CF-CS program and its value in their community; their perception of the adoption of CFCS and its impact on their health and lifestyle; and suggestions on how they can become engaged in facilitating the adoption of CF-CS within their communities. Community leaders will be asked to participate in interviews and focus group discussions. The interviews and focus groups will be conducted separately and will last about 60 minutes and will be audio-taped. Immediately following each interview, the interviewer will complete field notes that highlight the main themes. The field notes will be transcribed, and entered into Dedoose, for data analysis. These data will inform the development of the intervention - a context-specific CM strategy for CF-CS.

For the household adults, who make day-to-day cooking decisions, we will ask them questions during the interviews and focus group discussions on the following topics: their ability to use the clean cookstove; their cooking practices; the affordability of the clean cook stoves and ethanol fuel; the barriers they perceive to the use of CF-CS in their households, their understanding of the purpose of the CF-CS program and its value in their

respective households; their perception of the adoption of CF-CS in their households; and its impact on their health and lifestyle; and suggestions on how they can become engaged in facilitating the adoption of CF-CS within their households. Household adults will be asked to participate in interviews and focus group discussions. The interviews and focus groups will be conducted separately and will last about 60 minutes and will be audio-taped. These audio-tapes will be transcribed verbatim, and entered into Dedoose, for data analysis. These data will inform the development of the intervention - a context-specific CM strategy for CF-CS.

6.1.1.3 Pilot testing of the CM strategy among key stakeholders and household adults: Based on findings from the data analysis above, we will develop a community mobilization strategy tailored to the needs of the community. 10 households in total (5 that receive the CM strategy and 5 that do not) from 2 different communities will participate in the pilot. All households will be visited by CHEWs who collect sociodemographic, anthropometric, BP, health history, health behavior, and cooking behavior data. Research Coordinators will visit the households to collect data on HAP and stove use. Intervention households will be visited by CMs and HEOs in addition to CHEWs. These two sets of implementers will deliver the CM strategy developed from the qualitative interviews. Pilot testing will allow for refinement of the CM strategy and unmask challenges that might be faced during the Implementation and post-implementation phases of the trial.

Examples of the types of CM strategies that may be developed include: 1) Formation of community coalitions, community working groups, or outreach volunteers with local opinion leaders to foster support among social networks, and community-based organizations; 2) Use of direct community engagement via door-to-door canvassing, community meetings, formal health presentations and the facilitation of health discussion groups; and 3) Raising community awareness via marketing and communication strategies (i.e. distributing flyers and posters at local community centers).

6.2.2. Qualitative Data Analysis: Full details are provided in the *Statistical Design and Power Section.* Briefly, the focus group discussion and in-depth interviews will be transcribed and entered into Dedoose, for data analysis. Two approaches to data analysis will be taken: (1) Rapid analysis using an Action Research approach; (2) In-depth coding using inductive coding approaches. For the rapid coding approach, moderator notes from the interviews will be compiled into an action research matrix. Three research team members will collaboratively identify barriers and facilitators to CS-CF use raised by the interviewees. The team members will then identify themes from the notes. The rapid coding process will be overseen by an expert in action research. For the in-depth coding, we will use the framework approach to qualitative data analysis,[112] a five-step process that involves: (i) familiarization, (ii) developing a theoretical framework,[112] (iii) indexing, (iv) summarizing data in an analytical framework, and (v) data synthesis and interpretation. Following the framework approach,[112] the data will be independently coded by 2-3 research members on Dedoose to reduce the potential for bias. Inter-rater reliability will be determined based on a sub-set of the data, and discrepancies in coded data will be resolved by consensus. All transcripts will be coded into concepts reflecting the aim of the pre-implementation phase. For example, responses will be coded according to intervention characteristics (e.g. core components of CM relevant to local needs in Nigeria) likely to influence CF-CS uptake within households. The identified concepts will then be grouped into categories and themes uniting the categories will be determined. Once identified, the analysis from the in-depth coding will be triangulated with the rapid-coding analysis to confirm and enhance the concepts developed. A detailed analysis of the interviews should generate a conceptual model of the barriers and facilitators of adoption of the CF-CS use and an adapted CM strategy tailored to the local context.

6.2.2.1. Expected deliverables from the pre-implementation phase Details of this analytic approach is provided in the *Statistical Design and Power Section* include. These include (1) use of the Steering Committee to provide guidance on development of the CM strategy that is tailored to the local context in Lagos; (2) semi-structured interviews with key stakeholders to determine community and individual household readiness, and identify ways to improve integration of CF-CS use into households; and (3) pilot testing and refining of the developed CM strategy.

6.3. Implementation Phase

AIM 2: Among 640 households across 32 peri-urban communities in Lagos, evaluate in a cluster parallel RCT, the effect of CM strategy versus self-directed condition on adoption of CF-CS at 12 months. Hypothesis 1: Adoption of CF-CS use will be higher in communities randomized to CM than those in the self directed communities at 12 months.
AIM 3: Among 640 households across 32 peri-urban communities in Lagos, evaluate in a cluster parallel RCT, the effect of CM strategy versus self-directed condition on systolic BP reduction at 12 months. Hypothesis 2: Mean systolic BP will be lower in the households of communities randomized to CM than those in self-directed communities at 12 months.

6.3.1. Sample size and power calculations: Details are provided in the *Statistical design and Power* section. Although the primary outcome of the proposed study is rate of adoption of CF-CS use, we are not aware of any RCTs of interventions that have determined the rate of adoption of CF-CS use. Moreover, studies which have rigorously defined adoption utilizing objective data from iButtons sensors have been primarily observational in nature and have not reported effect sizes for interventions aimed at increased CF-CS adoption.[102,113] Due to a lack of information in prior literature, we were unable to generate estimates for the effects sizes (ES) or intraclass correlation coefficient (ICC) of any intervention aimed at CF-CS adoption. As such, sample size estimates and power calculations are provided for the secondary outcome of systolic BP reduction. Based on these assumptions and calculations we have established recruitment goals of 32 communities (16 in each arm) with 40 participants/community. This means recruiting 20 households per community since 2 individuals will be sampled from each household (the primary cook and one other adult). This yields a total sample size of 32 x 40 = 1,280 adults (640/group), providing more than 90% power to detect a moderate effect size of 0.4 with an assumed ICC = 0.06 and a 20% attrition rate. Because this trial has a multi-level design (participants nested within household which is nested within community), this may result in an increased level of ICC. However, even with an assumed ICC=0.12, the current sample size would provide > 80% power to detect a moderate effect size of 0.4 with a 10% attrition rate of participants.

6.3.2. Recruitment and retention strategies are described in detail in our Recruitment and Retention Plan. Participants will be recruited at the level of household, with two adults per household (one being the primary cook of the household, and one another adult in the household). Recruitment of individuals from the household will be similar to the strategy we adopted in our previous trial in Ibadan.[91] For this purpose, two Research Coordinators (RCs) from LASUCOM will conduct the screening, consent, enrollment, and all study assessments. Drs. Ojengbede and Wright will oversee recruitment and retention activities of the RCs.

Recruitment of Communities**:** We will recruit peri-urban communities in Lagos State. Currently, there are 242 Wards under the 20 official local government areas in Lagos State. We will recruit all 32 communities from these Wards. Drs. Ojengbede and Wright will meet with community leaders to provide study overview. The communities will be selected from areas geographically distant from one another.

- Recruitment of Households and participants: Eligible households must have at least two adults (one being the primary cook), who will be identified in each community by the LGA members and research staff given their experience and knowledge of their respective communities. A total of 640 households will be recruited (20 per community). The households and adult participants must meet the following eligibility criteria:
- primary adult must be a female cook; must not have a paid housemaid; family size must be a minimum of 2 and no more than 7 members; family must use unclean cooking methods, such as kerosene, charcoal, or firewood as primary cooking fuel; family must not currently use a clean cooking method,

such as LPG or electric stove etc. the person spoken to at enrollment must be the home key decision maker; must have no plans for relocation in the next year.

- Key Stakeholders: Key community stakeholders will be selected from the steering committee members in addition to local leaders and community residents. Drs. Ojengbede and Wright will oversee the selection of key stakeholders.

6.3.3. Baseline visit: At baseline, we will measure the following variables: a) use of traditional stoves and CF-CS stoves using the iButtons SUMs for a month. There will be a period of no more than 1 week wherein only traditional stove use will be measured and after which the CF-CS stove will be introduced and measured along with the traditional stoves; b) the level of HAP exposure using Purple Air monitors, and c) BP of two adults in each household including the primary cook . Study staff will confirm eligibility status and obtain informed consent from two adults in the participating households. As shown in Figure 2, each community will be randomly assigned in a 1:1 ratio to either the CM intervention or the self-directed condition (presentation of information on CF-CS use without CM). The randomization sequence is generated by Dr. Hade (Co-Investigator), and kept in a secure electronic location following CONSORT guidelines. Randomization will minimize any baseline differences between both groups. However, we will also run post-hoc analyses examining the representativeness of our sample. Details about the randomization process can be found in the *Statistical Design and Power* section.

6.3.4. Description of the CM intervention and the Self-Directed condition.

6.3.4.1. Components of the CM Intervention: Each community (20 households/community) randomized to the CM intervention will be assigned 1 community mobilizers i.e. a ratio of 1 mobilizer to 20 households to deliver the intervention thus yielding a total of 16 community mobilizers to serve 320 households. We will recruit the community mobilizers, HEOs, CHEWs and CHOs from Lagos State's Local Government Area (LGA) teams operated by Lagos State MOH. Overall, community mobilizers will be supervised by HEO's, and the two teams will implement the community mobilization strategy in the intervention arm. CHEWs will be supervised by CHOs, and together will provide standard care for the control arm. All LGA members have experience conducting community outreach visits and engaging community leaders in health promotion in Nigeria.

6.3.4.1.2. CM Intervention Protocol: In order to implement the CM intervention protocol, the community mobilizers, HEOs, CHEWs and CHOs will complete an intensive 3-day training course focused on adoption of the CM strategy to *assess shared concerns* about HAP and CF-CS, *initiate community action plans* that will be facilitated by CATs and conduct *dialogues and door-to-door outreach visits* with community members on the importance and proper use of CF-CS, while *engaging community leaders* on the facilitators and barriers to CF-CS adoption. The community mobilizers and HEOs will also identify and train the CAT teams in their assigned communities. Eligible communities randomized to the CM intervention will receive the following: 1) Visits by community mobilizers. In these visits, the mobilizers will *Engage* the households, *Evaluate* their use of CF-CS, and *Enhance* their ability to use CF-CS. Engagement involves vising the households once in a month. Evaluation involves asking households how often they use CF-CS, and Enhancement involves identifying barriers to CF-CS use and working with households to overcome those barriers. 2) Visits by HEOs. In these visits, the HEOs will identify barriers to CF-CS use and discuss solutions to those barriers. The HEOs will also educate households on the harms of HAP. :

6.3.4.1.3. Duration of CM intervention: Each CM and HEO will work with their assigned households for 12 months. The intervention will be implemented in three waves, with the intervention period of one year at each community. Each CM will conduct a minimum of 13 visits with participating households and and HEO will conduct a minimum of 6 site visits to participating households. plus monthly in-person support meetings with the CAT teams throughout the intervention period. They will provide support to their assigned communities and CATs to implement the CM intervention. **D3.4.1.4. Training and supervision of** community mobilizers and HEOs**:** We will conduct training workshops for community mobilizers and HEOs at the beginning of the study for 3 full days in Year 1, then followed by 1.5-day booster sessions in Years 2-4. The workshops will assist

trainees to achieve competencies in community mobilization topics such as: effective communication skills; consensus building and goal setting; problem-solving and promoting teamwork. The workshop will also focus on the Clean cookstove protocol which includes *visiting* and *inspecting* participants' households, *training* households to efficiently use the clean cookstove device, and *education on* HAP. This effort will be led by Drs. Ogedegbe and Iwelunmor, while Dr.Wright will provide oversight of the LGA teams. He will set up regular weekly meetings with the CHEWs to review their schedules, anticipated challenges, and need for assistance.

6.3.4.1.4. Process of stove distribution: Project GAIA and Mrs. Titi Adeyeba will assist with the distribution of the cookstoves. For this purpose, we will adapt strategies for stove distribution based on previous studies.[119,120]. Project GAIA will also provide the support of these stoves through a fuel supply chain, and work with the CHEWS and the investigators to provide training on their use. Specifically, we will create with the help of the CATs and CHEWS, social awareness campaigns in participating communities via live product demonstrations. The campaigns will focus on sensitizing the public to the sources and health effects of HAP as well as the benefits of using the CF-CS in the households.. Upon the initial contact with eligible households who consent to participate, community mobilizers and HEOs will conduct live product demonstrations in order to create excitement and initial user knowledge of the CF-CS technology. Prior to distribution, Project Gaia, Mrs. Adeyeba, and the CATs will identify distribution centers across participating communities, collate a distribution list of possible beneficiaries of the stoves in the study catchment area and, along with project staff, will create a roster for stove distribution days. On distribution days, CAT teams will use skits and role-plays to demonstrate the before and after use of the stoves, after which smart tablets will be used to complete distribution forms for participants. The distribution forms will capture demographics, household identification. Once participants receive the stoves, they will await a visit from their assigned community mobilizers to educate them on the use of the stove.

6.3.4.2. Self-directed Condition: Baseline procedures, participant recruitment and stove distribution will be similar to those described above. Households in these communities will receive information on the appropriate use of CF-CS as well as education material on the health effects of HAP. The ONLY difference is that the communities randomized to this group will not receive the community mobilization intervention, which consists of any activity performed by community mobilizers and HEOs. After the initial introduction to the program with initial training in the use of the clean cookstove at baseline, communities in this group will receive the clean cookstove program manual and participant workbook but will not be exposed to community mobilization during the intervention period. **D3.5. Analytic plan for the implementation phase (Aim 2 and Aim 3):** The primary aim of our analysis is to determine the effect of the CM intervention on adoption of CF-CS use (primary outcome) compared to self-directed condition at 12 months (**Aim 2**). The secondary aim is to evaluate the effect of CM intervention on systolic BP reduction (secondary outcome) compared to self-directed condition at 12 months (**Aim 3**).

6.3.5.1. Primary outcome measure (Aim 2) is the rate of adoption of CF-CS use in participating households at 12 months. Adoption is defined as utilization of the CF-CS for more than 50% of cooking activities based on the metric developed by the Global Alliance for Clean Cookstoves.[121] Prior research has shown similar levels of adoption for improved cookstoves in low and middle-income countries[103,122,123]. Additional details about this criterion for adoption can be found in the *Statistical design and Power* section. Utilization of CF-CS will be measured with iButtons SUMs. iButtons are small, circular thermometers which can be mounted in standardized locations on the surface of a stove and take continuous measurements of the temperature of the stove surface.[124] For this purpose, all traditional stoves and the b CF-CS in the participating households will be equipped with the iButtons SUMs (model DS1921G, Maxim Integrated, CA) to assess their use. Trained study staff will collect iButtons temperature data for approximately 1 month at baseline and 12 months. The percentage of CF-CS use will be determined utilizing the Super Learner-based sums analysis platform SUMSARIZER.[125] This ensemble machine learning algorithm is designed to analyze large datasets in an

optimized manner to detect cooking events accounting for ambient temperature in the community.[102] Proportion of CF-CS use (measure of adoption) will be defined as the amount of time the CF-CS is used relative to the total cookstove use in the household (Proportion= $Duration_{CF\text{-}CS}$ / [$Duration_{CF\text{-}CS}$ + $Duration_{traditional}$]). A subset of 80 households will use the iButton SUMS continuously from baseline through 12 months. These households will be visited approximately every 3 months and SUMS data from the most recent preceding month will be extracted an analyzed as detailed above. Additional details about the definition and measurement of Aim 2 is outlined in the *Statistical design and Power* section.

6.3.5.1.1. Analytic plan for the primary outcome (Aim 2): Analysis of the primary outcome is outlined in the *Statistical design and Powe*r section. Briefly, comparisons of the rate of adoption between the CM intervention group and the self-directed group will be conducted using generalized linear mixed effects regression model with a logic link. Adoption will also be defined continuously as proportion of CF-CS use and minutes of CF-CS use. These comparisons will be conducted using generalized linear mixed effects regression. For both analyses, a fixed effect will be specified for CM intervention group and random effects will be specified for community and household in order to control for clustering of participants within households and clustering of households within communities. Analyses will also be adjusted for important household-level and person-level covariates which may influence rates of adoption. We will examine for covariate balance between the CM and self-directed groups in order to identify potential confounders. Covariates will include participant characteristics, household characteristics, lifestyle behaviors, and comorbidity.

6.3.5.2. Secondary outcome measure (Aim 3) is the between-group difference in systolic BP reduction. This is the measure of clinical effectiveness of the CM intervention. It will be assessed as the mean change in systolic BP from baseline to 12 months between the CM intervention group and the self-directed group. BP readings will be assessed with a validated automated BP device as we did in our previous trials.[49] Analysis of the secondary outcome is outlined in the *Statistical design and Powe*r section. BP measurements: Three readings will be taken by trained research coordinators using an automated BP monitor with the participant seated comfortably for 5 minutes prior to the measurements, following the American Heart Association guidelines.[126] The average of three BP readings will be used as the measure for each study visit. The same procedure will be followed at baseline, 3-, 6-, 9-, and 12-month study visits.

6.3.5.2.1. Analytic plan for the secondary outcome (Aim 3) is the between-group difference in systolic BP reduction from baseline to 12 months. Analysis of the secondary outcome is outlined in the *Statistical design and Powe*r section. Briefly, changes in systolic BP between the CM intervention group and the self-directed condition group will be assessed using a generalized linear repeated measures mixed effects regression model with a fixed effect for intervention condition and random effects specified for community and household to control for clustering of participants within households and clustering of households within communities. Analyses will also be adjusted for important covariates which may influence levels of BP.

6.3.5.3. Measures of intervention fidelity: We will assess intervention fidelity via the following measures: HAP will allow us to address the effect of the intervention (use of CF-CS) on air quality. We will address this with the HAP monitors attached to the house. Community mobilization surveys will be used to assess CM intervention fidelity via survey of the CMs and HEOs.

6.4. Post-Implementation Phase

AIM 4: Among 640 households across 32 peri-urban communities in Lagos, will evaluate in a cluster RCT, the sustainability of CF-CS use one year after completion of the trial. Hypothesis. 3: Sustainability of CF-CS use will be higher in communities randomized to CM than those in self-directed condition at 24 months.

6.4.1. Analytic plan for the post-implementation phase (Aim 4): Sustainability is measured and defined in the same manner as adoption. Sustainability of adoption of CF-CS use will be assessed at 24 months (one year after the completion of the CM intervention). Sustained adoption at 24 months will be defined based on proportion of CF-CS who continue to use the CF-CS for at least 50% of cooking activities in the households. Similar to data collection for adoption of CF-CS use, trained research assistants will collect iButton data for all households during a 1-month measurement period, occurring 24 months after recruitment. Details of the analysis are provided in the *Statistical design and Powe*r section. Rates of sustained adoption will be compared between the intervention group (CM implemented presentation of CF-CS) and the control group (CF-CS presentation without CM) using a generalized linear mixed effects regression model with a logit link. A fixed-effect will be specified for intervention condition and random effects will be specified for household and community to control for clustering of participants' households and clustering of households within communities. Analyses will also be adjusted for important household-level and person-level covariates which may influence rates of sustainability.

6.4.2.1. CM Intervention characteristics measure: Two tools will be used to measure the CM intervention. One tool for community mobilizers and one tool for HEOs. The tool for community mobilizers assesses their completion of Engaging, Evaluating, and Enhancing households around CF-CS usage. The second tool will assess whether HEOs carried out their duties of visiting and educating the households, as well as supervising community mobilizers.

Activity	Year1				Year 2				Year 3				Year 4				Year 5			
	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
Refine Protocol and obtain IRB Approvals																				
Training of Study Staff																				
Pre-implementation Phase Activities																				
Implementation Phase Activities																				
Post-implementation Phase Activities																				
Final Data Analyses for Aims 1-4																				
Dissemination of Study Results																				

7 Assessment of Safety

Data Safety and Monitoring Plan (DSMP)

In compliance with NIH requirements, we will establish a data and safety monitoring plan (DSMP). The purpose of the DSMP is to ensure the safety of participants and the validity and integrity of the data. Personnel involved in the monitoring activities will include:

- The Principal Investigators (PIs) on this application
- Designated medical monitor (a physician in our program who will provide consultation on medical risks and who will review adverse events)
- Internal Committee (The PIs, and the Co-Investigators on the present proposal)
- Institutional Review Board (IRB)

The data and safety-monitoring plan will comprise the following elements:

- Reporting of adverse events to the IRB and to NIH trials: Adverse events will be reported to the IRBs. Summaries of adverse events reports will be made to NIH in the yearly progress report or at the end of year 5, in the final report, unless the nature of a particular event is such that it bears reporting to NIH immediately.
- A detailed plan to deal with serious events that may arise. The plan will include a step-by-step algorithm to deal with such events.
- The PIs and the co-Investigators will meet yearly to review adverse events reports, patient complaints if any, and dropout rates. Data will be provided at those meetings by the investigators on key variables. We

do not foresee any harm as a result of this intervention. Dr. Hade will evaluate confidentiality and integrity of the database, and the procedures for recording and storing confidential files. The investigators will also review the elements of the plan to deal with emergencies.

Protect the confidentiality of the trial data and the results of monitoring.

Oversight of study protocol will be monitored by an independent Data Safety Management Board (DSMB), which will be formed to monitor the safety of the study subjects, the validity and integrity of the study activities, as well as the data from the study. The general responsibilities of the DSMB are to:

- Review the research protocol and plans for data and safety monitoring.
- Evaluate the progress of the study, including periodic assessments of data quality and timeliness, participant recruitment, accrual and retention, participant risk versus benefit, performance of trial sites, and other factors that can affect study outcome.
- Monitor external factors to the study when interpreting the data, such as scientific or therapeutic developments that may have an impact on the safety of the participants or the ethics of the study. For example, a systematic trend showing poorer, rather than increased, BP control or cardiovascular risk profile, in the intervention vs. the control condition.
- Make recommendations to the NHLBI, IRB, and investigators concerning continuation or discontinuation of the trial(s).
- Protect the confidentiality of the trial data and the results of monitoring by ensuring that computerized data files (quantitative and qualitative) are password protected. Any back-ups made of the computerized data will be put on separate hard drives which will also be password protected. Only named research staff will have access to the data onsite and offsite.

8 Statistical Considerations

8.1 Overview of Study Design

The proposed project will use a two-group, cluster-randomized control trial to evaluate the effectiveness of a community mobilization (CM) facilitated introduction of a clean fuel clean stove (CF-CS) versus self-directed condition (i.e., introduction of a CF-CS with information on use but without the CM facilitation) on adoption of CF-CS use (primary outcome). Secondary outcomes that will be measured are: change in SBP levels from baseline to 12 months (the end of the intervention phase) and sustainability of CF-CS adoption at 24 months (one year after completion of intervention phase). The trial will enroll 1,280 participants from 640 households in 32 communities (20 households and 40 participants per community). Each household will be provided with a clean cookstove and two individuals from each household (the primary cook for the household and one other individual) will be assessed on the primary and secondary study outcomes. The CM intervention will be completed by trained CMs and HEOs. Measurements of, SBP, and other self-report measures will be collected by trained CHEWs at baseline, 3 months, 6 months, 9 months, and 12 months. Measurements of stove usage and HAP will be collected by trained research assistants at baseline and 12 months for all households. However, a subset consisting of 80 households (20 from each cohort), will have follow-up stove usage monitoring every 3 months and follow-up HAP measurements once during follow-up.

8.2 Randomization

Randomization will occur at the level of the community. Each community will be randomly assigned to one of the two arms: introduction of the CF-CS with CM facilitation (intervention) or the self-directed introduction of CF-CS (control) (see Figure 2). Randomization will be stratified by cohort to ensure balance across time. Randomization will also be conducted in blocks determined by geographic proximity of the communities. The communities will be randomized in a 1:1 ratio to either the CM facilitated CF-CS utilization or the self-directed control condition group. The sequence of randomization will be generated by Dr. Hade, and kept in secure electronic format inaccessible to study sites, in accordance with CONSORT guidelines.[1] Because of the nature of

the intervention, it is impossible to blind the participants, members of the CAT team, and the study coordinators to the group assignment.

8.3 Outcome measures

The **primary outcome** is adoption of CF-CS use at 12 months. Adoption of CF-CS use is defined as having utilization of the CF-CS for more than 50% of cooking activities.[2] This cut-point was chosen based on prior literature examining cook stove adoption in low and middle-income countries, which found participants used their intervention cook stove for 40-60% of cooking activities at follow-up[3-5]. Prior research has shown that cook stove interventions lead to "stacking", wherein the new stove is incorporated into household cooking rather than replacing the traditional stove [3,4,6-10]. As a result, intervention stoves are seldom used for 100% of cooking activities. Rather they are used in conjunction with already existing stoves. Use rates for intervention stoves relative to traditional stoves have been shown to be associated with time (with rates falling over time) [3,4,6], type of cooking activity (foods with cultural/practical links to traditional stoves are less likely to be prepared on intervention stoves)[4,6-8], and by cultural associations with the use of traditional stoves[6]. Prior studies have shown that even when households continue using a traditional stove as well as the intervention stove (aka "stacking"), cook stove interventions still produce significant reductions in participant BP[9] and in HAP[11]. Percentage of use will be defined using measurements provided by iButton sensors (model DS1921G, Maxim Integrated, CA) attached to both traditional cooking stoves already in the home and the CF-CS provided during the study. iButtons are small, circular thermometers which can be mounted in standardized locations to the surface of a stove and take continuous measurements of the temperature of the stove surface. iButtons have been well described and utilized in previous studies of cook stove use.[12-16] We will measure the operating temperatures of both the traditional cook stove already present in the home and the CF-CS provided in the study. Data will be collected from the sensors in home visits by trained research assistants who have deployed iButtons previously. Data will be extracted from the iButtons after one month of measurements at baseline and 12 months for all households. For the subset of 80 households with iButton measurements during follow-up, data will be extracted every 3 months. This data will correspond to the last month in each 3-month period.

Data must be extracted from the iButton in monthly intervals due to the memory limit of the device. The extracted data will be aggregated and the percentage of CF-CS use will be determined utilizing the SuperLearner-based sums analysis platform SUMSARIZER.[17] This ensemble machine learning algorithm is designed to analyze large datasets in an optimized manner to detect cooking events accounting for ambient temperature in the community, as described in previous research.[12,14] Proportion of CF-CS use will be defined as the amount of time the CF-CS is used relative to the total cook stove use in the household (Proportion= $\text{Duration}_{\text{CF-CS}}$ / [$\text{Duration}_{\text{CF-CS}}$ + $\text{Duration}_{\text{traditional}}$]).

Stove usage data obtained during the 1-month data collection periods at baseline and 12 months will be used to define percentage of use for adoption. Individuals who utilize the CF-CS for 50% or less of the time will be classified as non-adopters. Adoption of CF-CS will also be measured continuously as both proportion of CF-CS use and as minutes of CF-CS use.

The **secondary outcomes** are the between-group change in SBP (SBP reduction from baseline to 12 months) and sustained adoption of CF-CS use at 24 months. The SBP reduction in patients will be assessed as mean change in SBP from baseline to 12 months. BP readings will be assessed with validated automated BP device which has been used in previous trials at baseline, 3 months, 6 months, 9 months, and 12 months.[18] BP measurements: Three readings will be taken by trained CHEWs using an automated BP monitor with the patient seated comfortably for 5 minutes prior to the measurements, following the American Heart Association (AHA) guidelines.[19] The average of the three BP readings will be used as the measure for each visit. Sustainability of CF-CS use is defined as adoption at 24 months (as described above). Levels of CF-CS sustainability will be assessed utilizing home visits and stove usage data collected by research assistants via iButton during a 1 month assessment window at 24 months.

8.4 Power calculations and sample size justification

The intervention will be delivered by CHEWs in communities and thus the appropriate design is a cluster randomized trial where the unit of randomization is the community. Thus, there are two important study design features: *K*, the number of communities, and *m*, the number of participants per community. Specifically, the *m* participants will be nested (grouped) within the *K* communities. This nesting will lead to additional dependency in outcomes within a community; the degree of this dependency will determine the necessary increase in sample size to maintain the same level of power as would be available if the unit of randomization had been independent individual participants rather than participants within communities. To estimate the sample size *N* in a standard individual randomized design, one must specify effect size (ES) (e.g., the standardized mean difference between the groups), the alpha level (alpha = .05, two tailed) and the desired level of power. In a cluster-randomized trial, one must additionally specify the average number of individuals within each group (e.g., community) who will participate (the cluster size *m*) and the intra-class correlation (ICC) that reflects the degree of dependency of the individual observations within the groups (communities). There is some uncertainty associated with the ES, *K*, and the ICC.

No previous trials have utilized a CM facilitated intervention to encourage CF-CS adoption. In addition, other trials aimed at encouraging use of cleaner fuel cooking stoves have often had varied definitions of what constitutes adoption of those stoves. Studies which have rigorously defined adoption utilizing iButton sensor data have been primarily observational in nature and have not reported effect sizes for interventions aimed at increased CF-CS adoption.[138,140] Due to a lack of information in prior literature, we were unable to generate estimates for the ES or ICC of any intervention aimed at CF-CS adoption.

As a result, we have decided to base power estimates for the current study utilizing estimates of ES, K, and ICC from the literature regarding our secondary outcome, change in SBP. Based on previous research, treatment interventions utilizing clean cook stoves to reduce SBP have found observed between-group treatment differences of 3.7 mmHg, 5.5 mmHg and 5.9 mmHg.[146-148] Utilizing data from a large clustered trial focusing on reducing SBP in a Nigerian sample, we estimated that the sample for the current study would have a standard deviation for SBP of 12.5 mmHg.[149] Based on these estimates of treatment effects and pooled standard deviation for SBP, we believe that the current intervention will demonstrate effect sizes ranging from small to moderate (Cohen's d =0.3 to 0.5).

Our best estimates from the literature and from recruiting participants in other cluster-randomized trials in Nigeria suggest that we can expect an average cluster size (*m*) of about 40 participants/community and an ICC of between .03 and .08. If we set our alpha level (Type I error rate) at 0.05 (two-tailed) and our desired power at .80, we obtain the following estimates of the total sample size needed for the study using the package "clusterPower" in R, version 3.5.1.[150, 151]

Table 3. Sample size calculations

		ICC					
		0.03	0.04	0.05	0.06	0.07	0.08
Effect Size	0.3	576	672	864	1,184	1,888	5,024
	0.4	256	288	320	352	384	416
	0.5	160	160	160	192	192	192

Based on these assumptions and calculations we have established recruitment goals of 32 communities (16 in each arm) with 40 participants/community. This would mean recruiting 20 households/community since 2

individuals will be sampled from each household (the primary cook and one other individual). This yields a total sample size of 32 x 40 = 1,280 participants (640/group), providing more than 90% power to detect a moderate effect size of 0.4 with an assumption of ICC = 0.06 and a 20% attrition rate of participants. As this trial has a multi-level design (participants nested within household and household nested within community), this may result in an increased level of ICC. However even with an assumed ICC=0.12, the current sample size would provide greater than 80% power to detect a moderate effect size of 0.4 and a 10% attrition rate of participants. While we do not have information on probable ESs or ICCs for CF-CS adoption, the ELAG trial currently in progress has provided estimates for some parameters of cook stove use.[152] Based on these estimates, with an effect size 0.3 and ICC of .06, the current study would have over 80% power to detect a difference in continuous minutes of CFC use between the intervention and control groups.

8.5 General approach

All data will be summarized and presented in tabular and graphical format, using means, standard deviations, medians, and ranges for continuous variable and proportions for categorical variables. We will assess balance with respect to baseline characteristics according to randomized treatment assignment. Analyses will be conducted according to the principle of intention-to-treat, in which every community is analyzed according to the assigned intervention, regardless of the condition actually received. Results for all primary and secondary outcomes will be stratified by important biological variables (age and sex).[153] Important moderators of intervention effects (such as treatment fidelity to the CM intervention and measures of HAP) will be evaluated. Post-hoc analyses will be run examining the characteristics of participants from communities randomized to the CM and self-directed conditions to examine whether our analysis sample is representative of the community they were recruited from and Nigeria as a whole. We will obtain data regarding community and national characteristics from local and national census data.

Aim1. Analytic Plan for the Pre-Implementation Phase (Qualitative Data Analysis)

Sample size estimation: Although sample size in qualitative research is not set a priori, but based on when data saturation is reached, [the point at which further analysis of the data does not yield any new information or does not add anything new to the theory being derived], we have determined a sample size of 48 participants for this phase based on previous studies:[154-157] 1) Steering Committee (n=10); 2) key community stakeholders for semi-structured interviews (n=30)

Qualitative Data Analysis for Aim 1: For the rapid qualitative analysis, we will compile moderator notes and key quotations from the focus group discussions and in-depth interviews into an action research matrix. Three research team members will collaboratively review the matrix to identify barriers and facilitators to CS-CF use raised by the interviewees. The team members will then identify themes from the notes. This process will continue until saturation is reached. Conflicts will be resolved by discussions. The rapid coding process will be overseen by an expert in action research. Once the rapid analysis is complete, results will be summarized in a report and used to develop the CM strategy. For the in-depth qualitative analysis, focus group discussions and in-depth interviews will be transcribed and entered into Dedoose for data analysis. We will use the framework approach to qualitative data analysis,[158] a five-step process that involves: (i) familiarization (a process during which the researcher becomes immersed in the details of multiple sources of data to gain a general understanding of the content and to document initial impressions), (ii) developing a theoretical framework (a process by which the researcher identifies emergent themes in the multiple sources of data using existing theories as a guide.[158] These themes will be continually refined and compared to each other), (iii) indexing (during which the researcher becomes further immersed in the data in order to refine identified themes and sub-themes), (iv) summarizing data in an analytical framework (during which the researcher reduces materials into understandable, but brief summaries of what was said by stakeholders), and (v) data synthesis, and interpretation (which allows for comparison of themes and sub-themes against original transcripts, field notes, and audio recordings to ensure appropriate context.[158] Following the framework approach,[158] as described above, the data will be independently coded by the three research assistants to reduce the potential for bias. Inter-rater reliability will be determined

based on a sub-set of the data, for example, the interviews, and will be repeated until satisfactory agreement among raters is achieved (i.e. 80% of coded data). Discrepancies in coded data will be resolved by consensus. After systematically reading all transcripts, they will be coded into concepts reflecting the aim of this phase. For example, responses will be coded according to intervention characteristics (e.g. core components of CF-CS use in Nigeria) likely to influence the CM intervention delivered at the level of community. Established procedures to enhance the trustworthiness of our analysis will be used,[159] including analyses of codes that do not fit our coding scheme, development of an audit trail documenting analytical decisions, and member-checking presentations to the Steering Committee. The identified concepts will then be grouped into categories and themes uniting the categories will be determined. A detailed analysis of the interviews should generate a conceptual model that elucidates barriers and facilitators to the uptake of CF-CS in Africa and modified CM intervention tailored to the community context to overcome these challenges.

Expected deliverables from the pre-implementation phase (Aim 1) Deliverables from the pre-implementation phase include: (1) use of the Steering Committee to provide guidance on development of the CM strategy that is tailored to the local context in Lagos; (2) semi-structured interviews with key stakeholders to determine community readiness and identify ways to improve integration of CF-CS use into households; and (3) pilot testing and refining of the developed CM strategy.

Aim 2: The primary analysis will consist of a generalized linear mixed-effects regression model with a logit link examining adoption of the CF-CS at 12 months. Adoption will be defined dichotomously with participants being classified based on usage of the CF-CS for more than 50% of all cooking, as defined by iButton data records. We will also run a generalized linear mixed effects regression comparing minutes of CF-CS use between the intervention and control groups. A fixed effect will be specified for intervention condition (CM facilitated introduction of CF-CS versus self-directed introduction of CF-CS) and random effects will be specified for household and for community to account for participant clustering within household and household clustering within community. We will also assess whether adjustment for any baseline characteristics is necessary and will run covariate adjusted models as is warranted. Potential covariates for adjustment will include both household-level (e.g. household income, number of people living in the household) and person-level (e.g. demographics, lifestyle behaviors, anthropometrics, and medical comorbidity) factors to account for potential confounding. Levels of covariates will be examined between the CM and self-directed group to identify potential confounders. If covariate levels are not balanced between the CM and self-directed groups, we will utilize them to adjust our models. Measures of HAP and adherence to CM will be examined as potential moderators of the association between the intervention and CF-CS adoption. Results will be stratified on important biological variables such as age and sex.[153]

Aim 3: In aim 3, we will evaluate the association between intervention condition and SBP reduction, our secondary outcome, using a generalized linear repeated measures mixed-effects regression model. Fixed effects will be specified for time and intervention condition (CM facilitated introduction of CF-CS versus self- directed introduction of CF-CS) and a random effect will be specified for community. We will include an interaction term for intervention arm and time; this, if non-zero, will indicate that the rate of change of SBP over time differs for those in the CM facilitated intervention compared to those in the self-directed condition. We will also assess whether adjustment for any baseline characteristics is necessary and will run covariate adjusted models as is warranted. Measures of HAP and adherence to CM (based on the community mobilization measure) will be examined as potential moderators of the association between the intervention and CF-CS adoption. Results will be stratified on important biological variables such as age and sex.[153] Analyses will also be adjusted for important household-level and person-level covariates which may influence participant SBP. In addition to the potential covariates listed in the analysis plan form Aim 2, we will also evaluate how case-finding, referral, and connection to medical care may influence SBP reduction over time in a sensitivity analysis. This analysis will examine how identification of HTN, referral to treatment and medication treatment might systematically bias our findings. If rates of case-finding, referral and treatment differ between the CM and self-directed groups, we will examine these variables as covariates and potential moderators of the treatment effect.

Aim 4: In aim 4, we will evaluate the association between intervention condition and sustainability of CF-CS use at 24 months, our secondary outcome. The effect of treatment condition on sustainability will be assessed using a generalized linear mixed-effects regression model with a logit link. Sustainability at 24 months will be defined in the same manner as adoption and will be analyzed using the same methods discussed above. Results will be stratified on important biological variables such as age and sex.[153] In addition, analyses will be adjusted for important household-level and person-level covariates which may influence rates of CF-CS sustainability.

9. Quality Assurance and Quality Control

Our data management approach is described in detail in the *Statistical design and Power* section. Dr. Hade, Calvin Colvin (data analyst), and a representative from the LASUCOM team will conduct all database development, data management, and data quality assurance

10. Ethics/ Protection of Human Subject

Institutional Review Board Approvals for this study will be obtained from the NYU School of Medicine (NYU) and Lagos State University College of Medicine.

Informed consent

All household sites will be provided with a model informed consent form (ICF). It is expected that all sites will use identical informed consent forms. If needed, individual sites may adapt the ICF to meet institutional guidelines and policies. Procedural and risk content may not be removed from the model consent form. Informed consent is a process that is initiated prior to the individual agreeing to participate in the study and continues throughout study participation. Extensive discussion of the risks and possible benefits of study participation will be provided to subjects and their families, if applicable. Consent will be obtained in person. A consent form describing in detail the study procedures and risks will be given to the subject. Consent forms used for this study are IRB-approved, and the subject is required to read and review the document or have the document read to him or her. The investigator or designee will explain the research study to the subject and answer any questions that may arise. The subject will sign the informed consent or provide a thumb print for participants that are illiterate. This procedure will be followed prior to any study-related assessments or procedures. Subjects will be given the opportunity to discuss the study with their surrogates or think about it prior to agreeing to participate. They may withdraw consent at any time throughout the course of the study. Consent may be written or given verbally. If written, a copy of the signed informed consent document will be given to the subjects for their records. The rights and welfare of the subjects will be protected by emphasizing to them that the quality of their clinical care will not be adversely affected if they decline to participate in this study. Additionally, all key stakeholders will be provided with a consent and key information form for their involvement in the study.

11 Data Handling and Record Keeping

11.1 Data Management

Methods for data management**:** Dr. Hade, Associate Professor at the Division of Biostatistics in the Department of Population Health at NYU School of Medicine, along with Calvin Colvin, the data analyst at NYU, and a representative from the LASUCOM team will conduct all database development, data management, and data quality assurance activities. The primary objectives of the data management methodology are to insure the completeness, accuracy, and integrity of all study data. To accomplish these objectives, Dr. Hade and Calvin Colvin will work with the research assistants and project investigators to ensure data are completely de-identified and will establish an acceptable data extraction format. For the primary outcome of adoption and the secondary outcome of sustainability, trained research assistants will visit the participant households to collect 1-month of iButton data at baseline, 12-month follow-up, and 24-month follow-up. iButton data will be collected from the traditional cook stoves in the home and the CF-CS. A subset of 80 homes will be visited at 3, 6, and 9 months to collect 1 month of iButton data. This data will then be uploaded to a secure study database. In cooperation with Dr. Michael Johnson, PhD, from Berkeley Air Monitoring Group's data analysis team at the University of California Berkeley, Dr. Hade and Calvin Colvin will work to generate cook event time series

data and integrate these data into larger study database. Dr. Johnson and his team will conduct quality control and provide preliminary analysis of raw HAP data and stove use data in collaboration with Dr. Hade and Calvin Colvin. Dr. Johnson and his team from Berkeley Air will not have access to PHI, nor will they have hands-on roles at NYU locations.
CHEWs will visit participant households at baseline, 3 months, 6 months, 9 months, and 12 months to collect BP measurements using validated automated devices. These will be recorded and stored in the study database. Calvin Colvin and a representative from the LASUCOM team will create the study database and data from the communities will be imported to this database. Dr. Hade, along with the project investigators and Calvin Colvin, will develop comprehensive data quality specifications to review and edit each data element for completeness, timeliness, and accuracy. Range checks, data type checks, required fields, and within- and across-record logic checks will be specified. A computer program will implement the data checking specifications each time data is added to the study database. We will generate reports specifying possible and probable data errors, including invalid data, missing data, outliers, and data in conflict within and across previously entered values.

11.2 Handling missing data

Methods for handling missing data: Although we will attempt to retain as high a fraction of participants as possible, we acknowledge that some attrition is likely, leading to missing outcome values. The generalized linear mixed models proposed for the primary and secondary analyses incorporate an assumption of data that are missing at random (MAR), meaning that the likelihood of a value being missing depends on observable characteristics (e.g., sex or age). In sensitivity analyses, we will assess the impact of different assumptions about the missing data mechanism and will determine the robustness of trial results to these different assumptions.

12. Study Finances

YEAR 1	
SALARY	102,225
FRINGE	32,108
CONSULTANTS	3,000
TRAVEL	1,400
SUBAWARDS	449,307
OTHER DIRECT COSTS	26,100
TOTAL DIRECT COSTS	761,134
INDIRECT COSTS	268,845
TOTAL COSTS	1,029,979

13. Study Administration

Executive Committee (EC) that will comprise of the multiple PIs (Drs. Olopade, Ogedegbe) and the coinvestigators (Drs. Iwelunmor, Vedanthan, Ojengbede, Wright). The EC will oversee the work of all other committees. The subcommittees will report to the EC and each will have responsibility for key programmatic components, as detailed below. It will oversee coordination of all aspects of the project and make sure that clear lines of communication are established among committee members. The EC will meet on a weekly basis during the first quarter of the grant, and then every two weeks thereafter. Toward the conclusion of the study, the EC will be responsible for coordinating publications.

The Steering Committee (SC) comprised of 2 representatives from community-based organizations (one rural and one urban); 2 CHEWs, 1 MOH personnel, 2 community leaders from participating districts and the research team. The SC will inform all phases of the study. It will also: a) help maximize the fit of CF-CS adoption by incorporating organizational, and community knowledge; b) provide feedback on the findings as they emerge; c)

ensure development of a CM strategy that is feasible and actionable (i.e. core elements that are easily implemented) and d) help monitor study progress in order to enhance its buy-in at the community level. The SC will meet every 3 months in Year 1, and every 6 months in Years 2-5.

The Recruitment and Retention Subcommittee will be responsible for overseeing screening, recruitment, and retention of participants in the study, as detailed in our Recruitment and Retention Plan. The subcommittee will be chaired by Dr. Ojengbede and include Drs. Olopade, Ogedegbe, Wright, and Onabanjo. The group will coordinate efforts related to devising culturally tailored recruitment and retention strategies and developing the recruitment communication plan and materials.

The Data Management and Analysis Subcommittee will be chaired by Dr. Hade and will include Drs. Ogedegbe, Ojengbede and Calvin Colvin. The subcommittee will be responsible for the development of the data capture files; development of coding schemes for qualitative analysis; logical checks for missing or problematic data, developing mechanisms for assuring data are obtained within established timeframes, and maintenance of general quality control of electronic and paper data sources. They will also provide interim reports on recruitment efforts, as well as data safety and quality, and will perform the quantitative and qualitative analyses outlined in the *Statistical design and Power section*. Analyses will be generated for annual reports; baseline abstracts manuscripts (starting in year 2) and outcomes abstracts and manuscripts (at the conclusion of the trial).

The Dissemination Subcommittee will be chaired by Drs. Olopade and Ogedegbe and will include Drs. Hade, Iwelunmor, Ojengbede, Vedanthan, Calvin Colvin. As described in our Dissemination Plan, this subcommittee will oversee the development of the dissemination toolkit and the reporting of our study findings on ClinicalTrials.gov, the NYU website, NYU twitter feed, community newsletters among others. We will also create a writing workgroup to generate manuscripts for peer-reviewed journals and presentations at national and regional venues.

14. Supplemental Component: ACT4ICC

The components below describe the procedures for a supplemental study – ACT4ICC to CF-CS, the parent study.

14.1 Synopsis

Title:	**A**ddressing **C**lima**T**e Change **FOR IMPROVED CLEAN COOKSTOVE** Uptake, Household Air Pollution Reduction, and Hypertension Prevention (**ACT4ICC**)
Study Description:	The activities proposed for **ACT4ICC** expand the scope of the implementation phase of the parent project in two important dimensions: **first**, by providing additional climate pollutant data to further investigate the impact of CF-CS use on health and climate; and **second**, building capacity of a local institution for future similar work. The parent study focuses primarily on how the community mobilization intervention may increase the uptake and sustained use of the CF-CSs, with systolic blood pressure measurements a secondary aim.
Objectives:	1) Estimate household concentrations of black carbon (BC) with respect to the experimental and control study arms, and predominant by fuel use types. 2) Estimate potential reductions in short and long-term climate forcing pollution achieved by experimental and control arms, and potential achievable reductions for scaling to regional or national populations. 3) Build local capacity in climate change research
Endpoints:	1) Estimated black carbon concentrations for intervention and control groups 2) Estimated potential reductions of CO_2, CH_4, BC and NO_2 achieved by intervention and control arms

	3) Completed 4-part training of environmental health officers in the parent study: virtual presentations to introduce the team to the instrumentation and procedures; 2) review of documentation regarding instrument functionality and standard operation procedures; 3) initial instrument familiarization by the team with training staff available virtually; 4) practice data collection and review.
Study Population:	A random sample of half of the study households (160 in the community mobilization or experimental group and 160 in the self-directed or control group) will be selected for additional black carbon measurements at the midline sampling of $PM_{2.5}$ data collection.
Description of Sites/Facilities Enrolling Participants:	The proposed activities ACT4ICC will be layered onto the sampling planned for the parent study in Lagos, Nigeria
Description of Study Intervention:	1. Black Carbon (BC) will be measured alongside the PurpleAir monitors currently being used by the parent study. 2. The differences in climate emissions impact between control and intervention groups will be calculated, and additional measurements such as CO2, CH4, and NO2 will be included in these calculations. 3. Environmental health officers in the parent study will be engaged and trained on BC emissions data collection and analysis.
Study Duration:	12 months

Study Timeline

ACT4ICC Study Timeline	Year 1			
	Q1	Q2	Q3	Q4
Planning and Preparation				
Planning logistics of supplement integration				
IRB protocol update				
Aim 1 (BC measurements)				
Development of data collection protocols				
Team training				
Data collection				
Data analysis				
Aim 1.2 (Climate emissions estimates)				
Synthesis of input parameters from study data and literature				
Calculation of emission reductions				
Aim 2 (Capacity building)				
Develop training curriculum for environmental health officers and core LASUCOM staff				
Conduct trainings on measurement and analysis				
Joint-analysis of co-benefits				
Research Products and Dissemination				
Integration of supplemental results into parent study reporting				
Scientific meetings and publications				
Presentation of co-benefits to policy-makers				

14.2. Study Rationale

The activities proposed for ACT4ICC expand the scope of the implementation phase of the parent project in two important dimensions: first, by providing additional climate pollutant data to further investigate the impact of CF-CS use on health and climate; and second, building capacity of a local institution for future similar work. The parent study focuses primarily on how the community mobilization intervention may increase the uptake

and sustained use of the CF-CSs, with systolic blood pressure measurements as a secondary aim. HAP measurements of $PM_{2.5}$ are part of the study design of the parent study given associations with increased systolic blood pressure; however, the parent study is not supported to go a step further and include BC – whereby an understanding of which HAP emissions may have a stronger association with increased blood pressure can be evaluated. BC measurements require specific measurements, assessments, and trainings – an additional step in assessing climate pollutants such as $PM_{2.5}$. Figure 1 provides a schematic of the parent study denoting the key study phase and EPIS domain (Implementation) for which the proposed study will be incorporated, to provide a more robust assessment and better understanding of the association between climate forcing pollutants and health.

Regarding capacity building, environmental health officers to currently engaged in the parent study have the following responsibilities to 1) conduct safety inspections in study households; 2) identify and remove hazards in study households; and 3) conduct training for households on using the improved cook stove technology. However, they are not trained on how to collect and analyze climate pollutant data. To enhance their capacity and that of the core research team on the ground who work closely with the environmental health officers, this proposal will focus on putting together and implementing a training curriculum for their benefit.

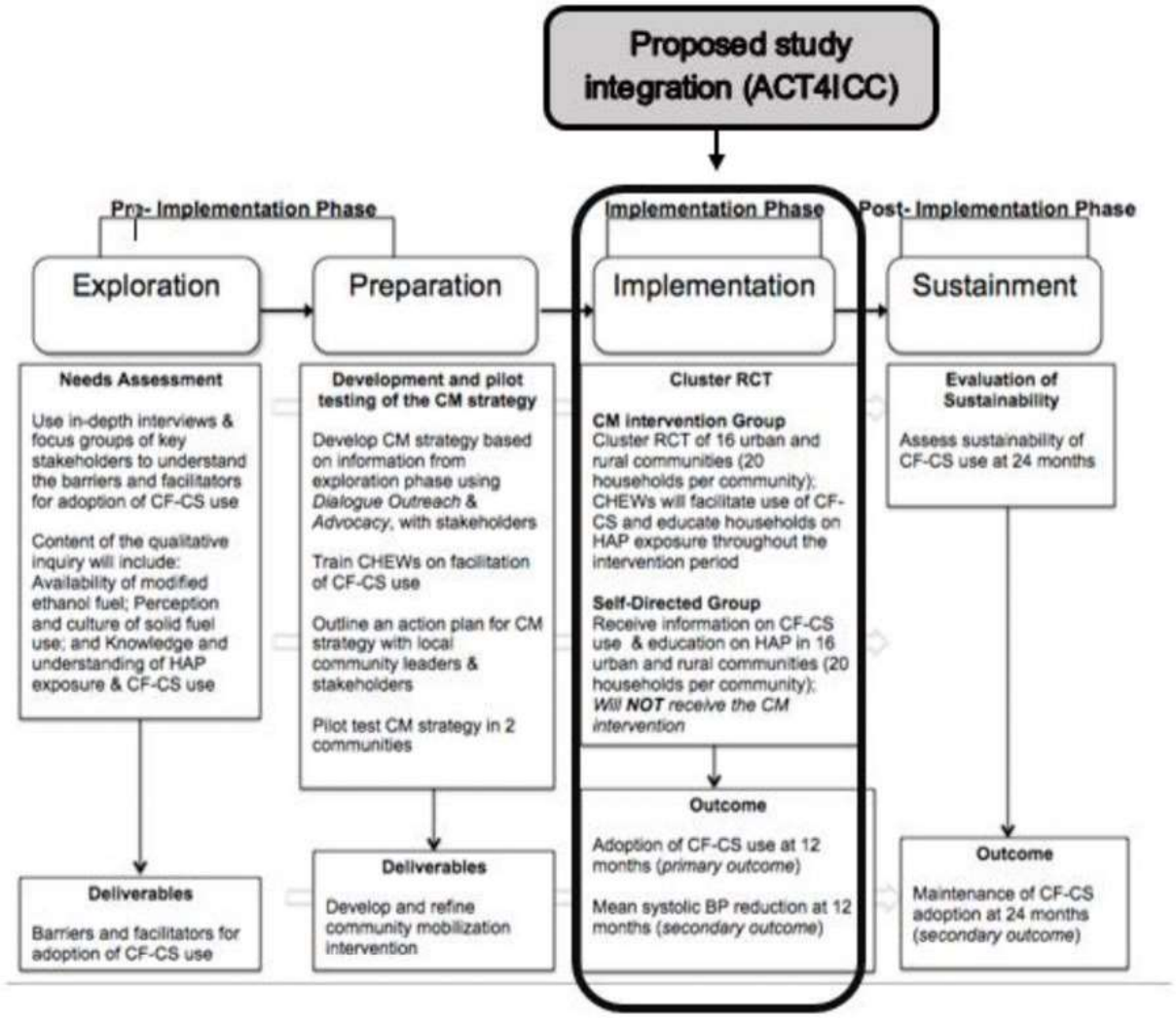


Figure 1: Schematic of proposed study (ACT4ICC) into parent study

While there have been a handful of analyses and modeling efforts which have looked at climate and health co benefits of transitioning from polluting to cleaner cooking fuels, [26-28] to our knowledge there has not been a study which leverages a clean fuel trial to explicitly quantify and package the co-health and climate benefits. In

working with the current sample of study households, i.e., no new recruitments will be warranted, we will be able to optimize the climate pollutant data collected and bolster the analysis of the climate data – to better understand the impact on the parent study's hypertension outcome. For this study, the inputs for estimating health benefits will be derived from the field study, with the associated potential benefits grounded in country specific, high-quality data, providing the foundation for critical policy-relevance.

14.3. Study Background

The use of clean (i.e. high-efficiency and low emission) cookstoves can reduce HAP and improve health outcomes. In our RCT of 271 women in Nigeria, use of "clean fuel-clean-stove" (CF-CS) vs. kerosene-based stoves led to significant blood pressure (BP) reduction and an 80% adoption rate.25 However, its widespread adoption is sub-optimal in Africa because these countries often lack expertise needed to coordinate system changes to implement evidence-based practices without assistance. Community mobilization (CM) strategy may overcome this barrier because it builds community readiness and support for normative changes. Thus, CM may enhance the demand for CF-CS use by modifying community barriers to its adoption.
The proposed activities for ***A**ddressing **C**lima**T**e Change **FOR IMPROVED CLEAN COOKSTOVE** Uptake, Household Air Pollution Reduction, and Hypertension Prevention **(ACT4ICC)*** will be layered onto the sampling planned for the parent study in Lagos, Nigeria, *Community Mobilization for Improved Clean Cookstove Uptake, Household Air Pollution Reduction, and Hypertension Prevention*, which is briefly summarized as follows: Using a focused implementation research framework, **EPIS** (**Exploration, Preparation, Implementation and Sustainment**) model in a type-2 hybrid design, this study is being conducted in 3 phases:
1) A pre-implementation phase that used the Exploration and Preparation domains of EPIS to: a) explore barriers and facilitators of Clean Fuel- Clean- Stove (CF-CS use), and b) develop a culturally-tailored CM strategy for CF-CS use;
2) An Implementation phase that is using the Implementation domain of EPIS to compare in a cluster RCT of 32 peri-urban communities (640 households), the effect of CM vs. a self-directed condition (i.e. receipt of information on CF-CS use without CM) on adoption of CF-CS use; and systolic BP reduction;
3) A post-implementation phase that will use the Sustainment domain of EPIS to evaluate the effect of CM strategy vs. self-directed condition on sustainability of the CF-CS use in 640 households across the randomly assigned 32 peri-urban communities in Nigeria. Stove use monitoring and household PM2.5 concentrations are also being measured before provision of the CF-CS, baseline (post acquisition of the CF-CS but before the CM intervention), and twice post CM intervention.

14.4. Study Objectives

1) Estimate household concentrations of black carbon (BC) with respect to the experimental and control study arms, and predominant by fuel use types.
2) Estimate potential reductions in short and long-term climate forcing pollution achieved by experimental and control arms, and potential achievable reductions for scaling to regional or national populations.
3) Build local capacity in climate change research

14.5. Study Aims and Corresponding Intervention Procedures

Aim 1: Estimate household concentrations of BC with respect to the experimental and control study arms, and predominant by fuel use types.

Intervention procedure: BC measurements will be added to the already planned $PM_{2.5}$ and stove use measurements of the parent study during the midline data collection phase (see the sampling frame for both the parent study and the proposed study below in Table 1). We will use the Ultrasonic Personal Air Sampler (Access Sensors, USA) to collect BC samples. The UPASes will be co-located with the Purple Air monitors, which are currently being placed in study household kitchens for 48-72 hours to measure household concentrations of $PM_{2.5}$. The UPAS draws a sample of air through a filter, resulting in a sample for BC analysis.

Filters will be transported via cold chain and weighed on a 1- microgram resolution microbalance following EPA standard procedures in an environmentally controlled chamber at Colorado State University.[43] BC will be estimated using a SootScan OT-21 Transmissometer (Magee Scientific, USA), which determines black carbon by measuring the attenuation of 880 nm wavelength light through the filter. This procedure is done before and after deployment to account for inter-filter variability.[43, 44] The resulting estimates will be integrated into the parent study database, providing household concentrations of BC to compliment already planned PM2.5 measurements.



Table 1: Parent study & ACT4ICC sampling frame overlap

Formation and Activities for Aim 1.2: Estimate potential reductions in short and long-term climate forcing pollution achieved by experimental and control arms, and potential achievable reductions for scaling to regional or national populations.

Intervention procedure: We will calculate the climate emissions impact in terms of CO2-equivalent using commonly employed methodologies which are likely to be employed under the Paris Agreement to make them as policy-relevant as possible.[36,37] We will include CO2, CH4, and NO2, as well as black carbon (BC) and organic carbon (OC) emissions, with emission reductions calculated as follows:

Emission reductions = Σ (Baseline fuel consumption$_i$ * Emission factor$_i$) - (Intervention fuel consumption$_i$ * Emission factor$_i$), where i denotes the different fuel/stove combinations and the emission factors are converted to CO2-equivalent using the IPCC's 100-year global warming potentials.

Fuel acquisition survey data will be used to estimate fuel consumption and emission factors from the most relevant field studies (e.g. 27,33). Lifecycle emissions from production, processing and distribution transport will also be incorporated using the Clean Cooking Alliances Fuel Analysis, Comparison & Integration Tool (FACIT). [42] FACIT provides interactive access to data and information produced from comparative analysis on environmental impacts related to the production, distribution, and use of multiple fuels used in cookstoves – with consideration for social and economic factors of fuel usage.[45] For wood fuels, CO2 emissions will only be included from the fraction of non-renewable biomass use, which will be the most current available from spatially explicit models.[46]

Formation and Activities for building capacity in climate change research (activities for Aim 2): We will strengthen research capacity in HAP and climate change research by training EHOs and LASUCOM staff in Nigeria.

Intervention procedure: We will achieve this goal by: 1) training environmental health officers engaged in the parent study on BC emissions data collection and analysis and 2) supporting one staff member from the LASUCOM team to be trained in global health and climate change research at WashU, this staff member will obtain a doctoral degree in this priority research area at a US-based institution. During this supplemental work period, the LASUCOM research team and environmental health officers will be trained and equipped with the necessary training, documentation, and materials necessary for BC measurements and analysis.
Training will consist of 4 stages.

1) Virtual presentations to introduce the team to the instrumentation and procedures.
2) Review of documentation regarding instrument functionality and standard operating procedures.
3) Initial instrument familiarization by the team with training staff available virtually.

4) Practice data collection and review. Ongoing support will continue during data collection to help develop deep expertise in practical application of the measurement approaches. Analysis and reporting will be done jointly with the designated climate and health LASUCOM personnel.

14.6 Scientific Rationale for Study Design

Black carbon (BC) is a major component of HAP, and its exposure is associated with systolic and diastolic blood pressure. BC, a constituent of $PM_{2.5}$ (particulate matter with a diameter smaller than 2.5 μm) has been found to be associated with adverse cardiovascular events, particularly high blood pressure.[8] BC affects blood pressure through systemic inflammation and oxidative stress, decreasing flow-mediated dilation of the brachial artery and reduced parasympathetic tone.[15] Studies have reported positive associations between short-term BC exposure, measured as the concentration averaged over seven days preceding each study visit, and systolic and diastolic BP.[16–19] However, evidence of BCs short-and-long term effect on BP in countries in Sub-Saharan Africa, particularly Nigeria, is limited.

Despite high exposures, BC assessments for HAP in Sub-Saharan Africa, especially in Nigeria, are limited. Western Sub-Saharan Africa is the region with the second highest $BC/PM_{2.5}$ exposures, and Nigeria as one of the countries has the highest exposures, with 100% of the population living in areas with $BC/PM_{2.5}$ concentrations exceeding the WHO Air Quality Guideline.[20] A 2018 systematic review specifically on blood pressure and BC concluded that BC exposure is associated with high systolic and diastolic blood pressure.[8] However, only four studies examined this association with household air pollution specifically, as opposed to outdoor/ambient air pollution.[8] Of these four studies, only one was set in an LMIC. There were no studies that explored such association in Africa. Since 2018, there have been multiple HAP trials, but evidence for BCs association with BP in Nigeria is still limited.

Household biofuels are estimated to be responsible for similar quantities of climate-forcing emissions as from the aviation sector,[21] and over 50% of anthropogenic black carbon emissions thought to come from biofuels.[6] While there has been an interest in targeting climate mitigation actions – which provide co-health benefits – these efforts in the household energy sector have been hampered by poor or unclear quantification. For example, there has only been one clean cooking intervention to-date which has been able to explicitly include health benefits as part of its carbon offset program.[22] Providing clear, rigorous co-benefit estimates would help enable policymakers to make informed and justified decisions that maximize public health and climate mitigation.

Building local climate change capacity will accelerate research impact and associated clean cooking policies, and more importantly health outcomes. Given the HAP burden in LMICs such as Nigeria, there is a pressing need for facilitating and enhancing contextualized research that can feed into efforts to improve air quality for households using solid fuels.[23] Leveraging our on-going parent study to focus on training the study engaged environmental health officers and the research team will be critical for sustaining the impact of the parent study. In Nigeria, environmental health officers are responsible for administering and enforcing environmental health policies to protect public health, and provide support that minimizes health and safety hazards.[24] For public health emergencies such as the COVID-19 pandemic, environmental health officers have played a major role in improving population health outcomes and reducing disease burden.[24] Although, environmental health officers are engaged in the parent study, their role and tasks currently do not include BC concentrations – a critical measurement evaluating the impact of climate pollutant on health outcomes.

14.7. End of Study Justification

The end of this study is defined as the completion of the calculations for 1) estimated black carbon concentrations for intervention and control groups; 2) estimated potential reductions of CO_2, CH_4, BC and NO_2 achieved by intervention and control arms; and completion of the 4-part training of environmental health officers in the parent study: virtual presentations to introduce the team to the instrumentation and procedures; 2)

review of documentation regarding instrument functionality and standard operation procedures; 3) initial instrument familiarization by the team with training staff available virtually; 4) practice data collection and review.

14.8. Study Participants

A random sample of half of the study households (160 in the community mobilization or experimental group and 160 in the self-directed or control group) will be selected for additional black carbon measurements at the midline sampling of $PM_{2.5}$ data collection.

14.9 Study Intervention Discontinuation and Participant Discontinuation/Withdrawal

Discontinuation of Study Intervention

Given that the intervention includes consented and eligible participants who have already been working with the parent study staff with the understanding of the risks and benefits, we do not anticipate discontinuation of the study intervention.

Participant Discontinuation/Withdrawal from the Study

Participants may withdraw voluntarily from the study or study investigators (PIs) may discontinue a participant from the study. All cases of study discontinuation and participant loss will be documented separately in electronic formats. In addition, a dedicated Case Report Form (CRF) page will be used to capture the date and the specific underlying reason for discontinuation. This will subsequently be captured into an electronic database (REDCap of University of Abuja), as done for the parent study.

14.10 Data Considerations and Analysis

For Aim 1, BC concentrations will be estimated by randomized group (CF-CS or self-directed use) and by stove and fuel use patterns (e.g. households using predominately ethanol, kerosene, charcoal, or LPG) as determined by the collected stove use data. Estimation of BC by these community and household conditions will employ similar statistical models as outlined in the parent study. The model framework outlined employed a generalized linear mixed model to accommodate correlated measurements on households taken over time, as well as clustered within experimental conditions.

For Aim 1.2, the CO2-equivalent emission reduction estimates will be calculated for the study population, as well as scaled for different potential scenarios to demonstrate the scope of potential impact for Nigeria. They will also be presented alongside the potential health benefits to clearly and explicitly demonstrate how policies and investments in a clean fuel-clean stove intervention such as the parent study can simultaneously improve health and climate benefits.

Raw and processed data will be uploaded and stored on a secure password protected cloud drive along with Purple Air and iButton data. We will investigate relationships between the intervention and black carbon concentrations using mixed-effects models accounting for the clustering of the data within households and communities. Statistical analyses and model development will be performed in R 3.5 or later. Variables will be log-transformed if necessary, prior to inclusion in multivariate models. Imputation of independent variables will be performed if needed (if imputation occurs, all models will be evaluated using datasets with and without imputation). Additional sensitivity analyses will be considered as required by study circumstances, including the effect of outliers, measurement uncertainty, values below detection limits, etc.

14.11 ACT4ICC Key Roles

Contact PI: Gbenga Ogedegbe, MD, MPH
MPI: Christopher O. Olopade, MD

Other collaborators
1) Dr. Erinn Hade
2) Dr. Angela Aifah
3) Dr. Ololade Wright
4) Berkely Air Monitoring Group (BAMG), under the guidance of Dr. Michael Johnson

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18.0 Schedule of Events

TIMELINE AND MILESTONES	YEAR 1				YEAR 2				YEAR 3				YEAR 4				YEAR 5			
	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Start up																				
Convene collaborative kickoff with project partners and subsequent weekly subcommittee meetings																				
Define roles and responsibilities of SC and establish meeting schedule																				
Announce project kickoff broadly/launch site recruitment and retention plan																				
Hire/train research and program staff																				
IRB application submitted/approved																				
Establish study databases, finalize baseline assessment survey and fidelity tracking tools (survey/non-clinical measures)																				
Community Mobilization Strategy Training for CHEWs																				
Pre-implementation Phase																				
Semi-structured interviews with key stakeholders																				
Refine and finalize CM strategy / intervention materials and protocols with participation of the Steering Committee																				
Pilot testing of the CM strategy																				
Implementation Phase (Intervention Period)																				
Baseline assessments of primary and secondary outcomes																				
Randomization of 32 communities																				
Intervention Implementation and measure primary outcome (Adoption of CF-CS at 12 months) and secondary outcome (SBP reduction at 12 months)																				
Site retention activities																				
Post-Implementation Phase																				
Measure sustained adoption of the CF-CS at 24 months																				
Conduct exit surveys																				
Evaluation																				
Complete process evaluation assessments of implementation																				
Final Data Analyses for Aims 1-4																				
Complete annual and end of program reports																				
Dissemination Activities																				

Development of dissemination toolkit components																				
Distribute briefing reports for stakeholders																				
Develop and submit manuscripts																				
Distribute study findings through multiple communication channels																				
Attend national meetings to present findings																				