Study Title: Expanding population-level interventions to help more low-income smokers quit

NCT#: NCT04311983

Version: 01/04/2022

Smoke-Free Homes

PI: Matthew Kreuter
IRB ID #: 202002125

Project Details

1. Demographics

1.1 Project Title:
Expanding population-level interventions to help more low-income smokers quit

1.2 Short Title (required):
Smoke-Free Homes

1.3 Project is primarily:
Social Science/Behavioral (includes History/Anthropology)

1.4 Type of Study:
Other Interventional

1.4.a Is your research study one in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes (NIH clinical trial definition).
Yes

1.5 Select how you plan to obtain consent:
- Script for use either in person or over the phone with no signature

2. Source(s) of Support

2.1 Source(s) of Support

Type/Source	Grant Title	Name of PI on Grant	Status
Federal Agency NIH, National Cancer Institute (NCI)	Expanding population-level interventions to help more low-income smokers quit	Matthew W Kreuter	AWARDED

3. Research Team

3.1 Principal Investigator

Name	E-mail	Title	School
Matthew Kreuter	mkreuter@wustl.edu	Eugene S. and Constance Kahn Family Professor	Brown

3.4 Team Members

Research Team Members

Role	Name	Role Desc	Student	Email	Title	School	Department	Contact	C P Inv
PI	Matthew Kreuter, MPH, PHD		No	mkreuter@wustl.edu	Eugene S. and Constance Kahn Family Professor	Brown School	Brown School Administration	Yes	

Team Member Financial Interest

Name	Financial Interests
Matthew Kreuter, MPH, PHD	none

4. Other Information

4.6 Will a Certificate of confidentiality be used for this research?
Yes, certificate automatically issued by funding agency

4.7 Does this project need to be registered on ClinicalTrials.gov?
Yes

4.7.a Who is the Responsible Party for registering this study in ClinicalTrials.gov?
Principal Investigator

4.8 Do any of the objectives of this study involve the diagnosis, prevention, screening, evaluation, treatment or support of cancer patients?
Yes

4.9 Are more than 30% of the patients involved in this study likely to have an active cancer diagnosis?
No

4.14 Mark all that apply to your study:

1. Protocol

1.1 Is there a separate, written protocol that will be submitted in addition to this form? (Note: a grant application is not considered to be a protocol)
No

1.2 Select up to three key words below that best describe this research study:
- Psychology
- Clinical
- Public Health
- Social Work

1.3 Provide a short summary/abstract of the purpose and procedures of the study proposed in this IRB application.

- DO NOT include information on studies not proposed in this application.
- Use LAY terminology only. This must be easily understandable by IRB community members and nonscientists.
- DO NOT cut and paste technical abstracts from source of support applications that may not be understood by a general audience.

The current application is for testing an intervention to help more low-income smokers get closer to quitting. Despite a decrease in the rates smoking cigarettes in the general population, smoking rates in low-income populations are still comparatively high. The standard practice for smoking cessation programs is state tobacco Quitlines, but these services are generally only offered to those who are ready to quit smoking in the next 30 days, effectively excluding 70-80% of low-income smokers. This study will provide an alternative to people who aren't ready to quit yet, called Smoke-Free Homes. Smoke-Free Homes involves helping people to ban all smoking inside their home, which will reduce second-hand smoke exposure for non-smokers, including children, who live in the home. In addition, the smokers themselves are more likely to reduce the number of cigarettes they smoke and get closer to quitting.

The intervention is a Hybrid Type 2 design, which means that we will compare the standard practice intervention (the state Quitline; Arm 1) with the expanded service alternative (the Quitline in addition to Smoke-Free Homes; Arm 2) among 1,980 low-income smokers across nine states. Participants will be randomly assigned to each Study Arm. The study outcomes are 7-day and 30-day point prevalence of smoking abstinence, number of cigarettes per day, number of 24-hour quit attempts, and acceptance of the interventions. Participants will be recruited from nine state United Way 2-1-1 agencies. The Quitline (standard service) will be delivered by our study partner Optum, a health-care services company that runs the state Quitlines. 2-1-1 callers who are daily smokers and interested in participating will be contacted by our study team who will conduct surveys by telephone with participants at Baseline, 3-month follow-up, and 6-month followup.

1.4 Specify your research question(s), study aims or hypotheses:
Aim 1: Compare quit rates in Quitline only vs. Quitline + Smoke-Free Homes groups
A. What proportion report 7-day and 30-day point prevalence abstinence at 3- and 6-month follow-up?
B. What proportion report making a quit attempt (of at least 24 hours) at 3- and 6-month follow-up?
C. What is the average change in cigarettes smoked per day at 3- and 6-month follow-up?
D. Among those who decline Quitline services at baseline, what proportion report abstinence, quit attempts, and decrease in cigarettes smoked per day at 3- and 6-month follow-up?
Aim 2: Compare acceptance and use of Quitline services, and pro-cessation beliefs cumulatively over the study period in Quitline only vs. Quitline + Smoke-Free Hoes groups.
A. What proportion accept Quitline services?
B. Among those who accept Quitline services, what proportion use 0, 1, or 2+ sessions of counseling?
C. Among those still smoking at 6-month follow-up, how does readiness to quit, pessimism about quitting, and ambivalence about smoking differ by group?

Aim 3. Evaluate the economics of adding Smoke-Free Homes to standard practice.
A. What are the costs and benefits per smoker and quitter from Quitline and society perspectives?

1.5 Background and significance and/or Preliminary studies related to this project:
Cigarette smoking in the U.S. follows a socio-economic gradient. Adult smoking prevalence is 26-28% among the poor, least educated, and those on Medicaid or uninsured, compared to 14% in adults above the poverty level and 7% in those with a college degree. Compared to other smokers, low-income smokers begin smoking at a younger age, have greater nicotine dependence, lower self-efficacy for quitting, lower readiness to quit, are less likely to use evidence-based quitting methods, and succeed less often when trying to quit. Smoking-related cancers are more common and more often diagnosed at a later stage in low-income and low-education populations.6,7,55 Medicaid alone spends tens of billions of dollars annually treating smoking-related illnesses. Cancer is the largest contributor to a growing gap in U.S. life expectancy by education,8 and smoking has a significant independent effect.

The main factors keeping low-income smokers from quitting are norms, stress and lack of assistance. Expanding population-level tobacco treatment practice to include Smoke Free Homes directly addresses norms. In most U.S. populations and places, smoking is relatively uncommon and/or not permitted. But in social networks of low-income smokers, it is prevalent, normative and acceptable, especially at home and work. In our recently completed U01 studies of Smoke Free Homes in low-income populations in five states, 66% of participants reported that half or more of their friends and relatives smoke. In our ongoing R01 study of low-income smokers, 42% live with at least one other smoker, and of those who are employed, 75% work with other smokers. Smoking norms like these are associated with higher rates of indoor smoking and lower rates of cessation among low-income smokers, in part because they feel less pressure to quit.

Although 83% of U.S. households now have smoke free home rules, only 46% of households with smokers have bans, and just 37% of households with low-income smokers have them. We hypothesize that expanding population-level cessation services to include Smoke Free Homes will engage more low-income smokers in proven interventions and yield greater cessation than current standard practice. Our proposed approach is based on six broad claims supported by strong evidence from multiple disciplines:
1. Most low-income smokers are not ready to quit. Readiness to quit is the strongest predictor of making a quit attempt. Compared to smokers not thinking about quitting, those planning to quit in the next 30 days are six times more likely to try quitting and four times more likely to succeed.66 But low-income and low-education smokers are significantly less likely to be planning to quit. Studies in diverse populations and settings consistently find that only 20-30% of low-income smokers are ready to quit in the next 30 days. In current standard practice, these smokers are ineligible to receive cessation services and offered nothing to help them prepare to quit. NCI's Tobacco Control Research Priorities for 2016-2025 call for interventions that "reach and engage" ambivalent smokers and facilitate "transition from unmotivated smoker to abstinence" (Priority 6-2).

2. Creating a Smoke Free Home is easier than quitting smoking. Studies in community health centers, safety net hospitals, subsidized housing, the VA system and homeless shelters consistently find that low-income smokers have low confidence in their ability to quit and rate quitting as "very hard." In sharp contrast, creating a smoke free home is viewed as less difficult and confidence for banning in-home smoking is high. In our team's SFH studies, participants were confident (7.8 on a 1-10 scale) they could make their home smoke-free. Other research has reported nearly identical confidence scores across 10 in-home smoking situations. In separate studies, only 21% of participants said it would be "difficult" or "very difficult" to adopt a home smoking ban or "too hard" to comply with a full smoking ban. In more motivated populations, parents who smoke rate adopting a smoke-free home as not difficult (4.9 out of 10, where 10=most difficult) and most say making their home smoke-free is "manageable" and a "first step" towards quitting. Among low-income individuals who adopt home smoking bans, only 1 in 5 report difficulty sticking to the ban.

3. Low income smokers are motivated to protect children and non-smokers. In studies of low-income Whites, African Americans, Hispanics and American Indians in urban and rural settings, protecting a family member or child from tobacco smoke is by far the main reason for thinking about and adopting a home smoking ban. Even in low-income neighborhoods where smoking is normative and there are few restrictions on where people can smoke, smoking around children is viewed as less acceptable. In graphic warning label studies among low-income smokers, labels on cigarette packages depicting how smoking affects children and others were the most effective in making low-income smokers think about quitting and feel motivated to quit.

4. Sequential request strategies increase effectiveness. The study goal is to get low income smokers to quit. We hypothesize that more will use cessation services if they first accept a Smoke Free Homes intervention. This is supported by 50 years of Foot-in-the-Door (FITD) research. FITD is a sequential request strategy to achieve behavioral compliance without pressure. People first receive a small request they are likely to accept, then a larger request that is the actual target behavior sought. Completing the larger request is more likely among those who first complete the smaller request than among those who receive only the larger request.

FITD can help people quit smoking. In a randomized study, 63% of smokers who agreed to a small request (no smoking for two hours) later agreed to a larger request (no smoking for 24 hours). Only 27% agreed to stop for a day when that was the only request. The effect persisted for actual smoking: 28% of FITD smokers quit for a day compared to 12% who received only the request to quit for 24 hours. Findings from a community-based smoke free homes initiative in low-income neighborhoods support FITD: of 523 smokers who made a smoke free home pledge (the initial small request), 12% went on to set a quit date and 6% quit within four weeks.

Three conditions maximize FITD effects: (1) having individuals perform – not just agree to – an initial request that requires some effort to complete; (2) emphasizing that performing the initial request shows that a person is capable of completing the larger request; and (3) making the larger request a natural extension of the initial request. Our design and interventions reflect this; creating a smoke free home is the small request and quitting smoking is the large one. NCI's Tobacco Control Research Priorities for 2016-2025 seek "sequential treatment strategies" to increase use of evidence-based interventions by unmotivated smokers (Priority 6-3).

5. Smoke Free Homes increase success in quitting. Evidence from cross-sectional and longitudinal studies shows an association between having a smoke free home and making a quit attempt, longer duration of quit attempts, and abstinence from smoking. Having a smoke free home is also associated with reduced relapse among ex-smokers and reduced cigarette consumption among continuing smokers. This is in part because smokers most likely to have home smoking bans are lighter smokers or in advanced stages of readiness to quit, but also due to genuine "treatment effects" like reducing exposure to smoking and other smokers, making it less convenient to smoke at home, and disrupting smoking patterns and cues.

To understand how establishing a smoke free home affects cessation in low-income smokers, we analyzed data from our team's Smoke Free Homes intervention trials (pooled n=941 with no home smoking ban at baseline). Controlling for study group and correlates of cessation and Smoke Free Homes, creating a Smoke Free Home increased quit rates at 3-month follow-up nearly 4-fold (15.6% vs 4.5%; OR=3.9, 95% CI=2.1,7.3) and even more at 6-month follow-up (26.1% vs 5.1%; OR=6.6, 95% CI=4.1,10.3). Most promising for the proposed study, among smokers who had never tried quitting at baseline, those who created a Smoke Free Home were significantly more likely to report a quit attempt at follow-up than those who did not create one.

6. Expanding treatment offerings in population-level tobacco services will attract more low-income smokers. Business scholars have shown that because customer needs and preferences vary, offering a variety of products or services attracts more customers and increases sales. These principles apply to reducing smoking in low-income Americans; by offering Smoke Free Homes, quitlines will engage more smokers than with cessation alone. NCI's Tobacco Control Research Priorities for 2016-2025 call for testing "population wide approaches" that increase "uptake and reach of existing evidence-based treatments" (Priority 1-1).

Led by Dr. Kegler (PI: U01 CA154282), our team developed Some Things are Better Outside (hereafter, Smoke Free Homes or SFH). Based on Social Cognitive Theory and the Transtheoretical Model,SFH consists of goalsetting, role modeling, persuasion, environmental cues and reinforcement delivered over six weeks via a telephone coaching call and three mailings. Its impact was evaluated in three separate RCTs and its potential for scale-up evaluated in a national dissemination study (Table 1), all in low-income 2-1-1 populations. Across all RCTs, over half of participants reported annual household income <$10,000; most were African American (83% in Atlanta; 61% in NC; 65% in TX) or Hispanic (12% in TX). The dissemination study did not assess income, but 54% of participants were African American, 24% had <HS education, 39% had a HS diploma or GED only, and 78% rented their home.

An initial efficacy trial was conducted in Atlanta, with SFH delivered by a university research team to adults in households that allowed smoking and had at least one smoker and one non-smoker. Compared to a no-intervention control group, those who received SFH were more likely to report a home smoking ban at 3-month (30% vs. 15%, p<=0.001) and 6-month follow-up (40% v. 25%, p<0.01).1 Self-reports were validated with air nicotine monitors. Next, we conducted a randomized effectiveness trial in North Carolina with SFH delivered by a 2-1-1 helpline. Again, those receiving SFH were more likely than controls to report a home smoking ban at 3-month (38% vs. 19%,p<.001) and 6-month (43% vs. 33%, p<.05) follow-up. A third RCT, in Texas, sought to replicate the NC findings in a different region and population. As before, those receiving Smoke Free Homes were more likely than controls to report home smoking bans at 3-month (47% vs. 25%, p<.001) and 6-month (63% vs. 38%, p<.001) follow-up. Findings remained significant in intent-to-treat and sensitivity analyses in which those lost-to-follow-up or reporting enforcement challenges were designated as failures. Process evaluations showed that SFH was well-received and worked for both smokers and non-smokers.

Given the consistent intervention effects across three separate RCTs in over 1,500 households, we launched a dissemination trial in five 2-1-1s in four states (AL, FL, OH, OK) selected through a competitive RFA process to deliver SFH for one year and track outcomes. They enrolled 2,345 households, delivered SFH, and reached 1,543 households (66%) at 2-month follow-up; 61% reported a home smoking ban and 11% reported quitting.

Three secondary findings from these studies are highly relevant to the proposed study. First, although changes in smoking are not addressed by SFH nor were aims of the studies, all three RCTs found greater reductions in cigarettes smoked per day at follow-up in the SFH group (-2.9 per day) vs. controls. Confidence in quitting was higher at 3-month follow-up in the SFH vs. control group, and there were more quit attempts. In all study groups, those creating a home smoking ban had higher quit rates (see above). These findings bolster our claim that a smoke free home can help smokers progress towards quitting. Second, in all RCTs, the control group established home smoking bans at a high rate. We believe this was due to an extensive battery of questions they answered about home smoking bans at three time points (87 items in Atlanta; 96 in NC; 139 in TX). This "intervention via assessment" led to family discussions and thoughts about home smoking bans. In the current study, we avoid such reactance by asking <5 SFH questions see "Measures").

Helping the poor quit smoking: specialized quitlines and meeting basic needs. This ongoing RCT (CA-201429; Kreuter, PI) is 16 months into a 39-month accrual period and provides valuable data directly relevant to the proposed study. First, we are successfully recruiting low-income smokers from 2-1-1. Through Oct. 2018, 734 have been consented from a single 2-1-1 in Missouri, and 3- and 6-month follow-up rates (73% and 60%) have met targets. Given the proposed study's more inclusive eligibility (adding smokers not ready to quit) and plans to recruit from nine (vs. one) 2-1-1s, we are highly confident about recruiting 1,980 smokers. Second, low-income smokers who call 2-1-1 are using the quitline intervention. Among 194 smokers randomly assigned to the standard quitline condition to date (identical to QL in the proposed study), 58% have taken a quitline call, 27% have taken 2 or more calls, 72% signed up for text messages on quitting and 52% read the quit guide. Third, the need for Smoke Free Homes is substantial. Despite the entire sample planning to quit in the next 30 days, data through Oct. 2018 show that 75% allow smoking in their home, 43% live with one or more other smokers, and 78% of workers have coworkers who smoke. An intervention like SFH is much needed. Although the proposed study will benefit from methods, measures and effect sizes from the current R01, the studies are quite different. In the current R01 we've excluded 1,880 low-income daily smokers since June 2017 because they were not planning to quit in the next 30 days (n=1,516) or weren't interested in a quit smoking program (n=364). The proposed study would enroll such

smokers and offer them an alternative, SFH. A 9-state sample and two evidence-based interventions embedded within a quitline also distinguish the proposed study.

1.6 Literature cited/references (if attaching a grant enter N/A):
N/A

1.7 Describe EACH of your participant populations

- Include description of any control group(s)
- Specify the Inclusion/Exclusion criteria for EACH group

All participants will be recruited from United Way 2-1-1 lines in 9 states and must be at least 21 years old, English speaking, not in crisis, not pregnant, smoke cigarettes every day of the week, not have a total home smoking ban, be comfortable receiving calls from smoking expert and project team, and be willing to provide phone numbers to be reached.
Participants in Arm 1 of the study will be offered standard service: their state's tobacco quitline. Participants in Arm 2 will be offered the quitline first and if they decline, they will be offered Smoke-Free Homes.

1.8 Check all materials that will be used in recruiting participants:
- Telephone script

Attachment Name	Category	Version	Date Attached
2-1-1 screening for SFH_UpdateTRACKCHANGES_5.14.21.rtf	Recruitment Script: Phone	7	05/14/21

1.9 Describe where the consent discussion will occur (check all that apply):
- By phone

1.10 Participants and/or their legally authorized representative will have (check all that apply to the consent process):
- As much time as they desire to consider enrolling in the study, including:
  - An opportunity to thoroughly review the consent materials with knowledgeable members of the research team, and with family and/or friends as appropriate
  - Sufficient time to have all of their questions answered

1.11 Provide a detailed description in sequential order of the study procedures following the consent process - DO NOT cut and paste from the Consent Document.

Describe study populations separately if they will be participating in different procedures

DESCRIBE:

- Control populations, if applicable
- Any randomization, if applicable
- What participants will be asked to do/what happens in the study (in sequential order)
- The time period over which procedures will occur
- Long-term follow-up and how it occurs

The recruitment and study procedures will occur for about 3 years and 3 months. Participants will be asked to participate in the study for a total of six months that may include completing the quitline coaching sessions which can take 1-4 months, Smoke-Free Homes which involves 3 mailings and 1 coaching call over the course of 6 weeks, and follow-up at 3 and 6 months; however, they can withdraw from the study at any time.

Study Arm 1 will be the control group who will be offered their state tobacco quitline services following the baseline assessment. They will be given the option to enter this program. If they choose to do so, a Quit Coach from Optum will reach out to them and provide between 1 and 4 coaching calls to help them quit smoking. The specifics of each state quitline may vary slightly but the calls are scheduled to be flexible with the participant's availability. Quit Coaches use motivational interviewing and cognitive-behavioral techniques to help the participant set a quit date and be ready to quit. Programs also may have a printed Quit guide booklet, offer nicotine replacement therapy (NRT) like nicotine gum or patches, and provide texting and/or emailing services. Participants are also given a number that they can call whenever they need to.

Study Arm 2 will be the treatment group and they will also be offered their state tobacco quitline. What differs in this condition is that if participants are not interested in the quitline, they will be offered Smoke-free homes (SFH), which includes 3 mailings at 1 week, 4 weeks, and 6 weeks after enrollment and a coaching call at 2 weeks after enrollment. The SFH coach will discuss the steps of making their home smoke-free, goal-setting, and potential challenges and solutions.

All participants who complete the baseline assessment will be sent a $25 grocery store gift card.

The first follow-up assessment will occur 3 months after the baseline assessment. The primary study outcomes are cessation-related. Participants will be asked if they smoked at all in the past 7 days and past 30 days to assess point prevalence abstinence. They will also be asked how many cigarettes per day they use if they still smoke and if they were able to create a smoke-free home if they are in the treatment group. Those who report any smoking in the past 7 days will be asked if they quit for at least 24 hours since the previous survey and to report on their nicotine dependence

measured by the Heaviness of Smoking Index (cigarettes per day; time elapsed between waking and smoking). These items from the Fagerstrom Test of Nicotine Dependence are reliable over time with good predictive validity. All participants will report use of any pharmacologic cessation aids (i.e., NRT, bupropion, Chantix). Successful quitters (7 days) will report their confidence in staying quit and all others will report readiness to quit. Reactions to the quitline and smoke-free homes interventions and staff will be assessed with measures from our previous studies assessing usefulness (e.g., was it helpful?), satisfaction (would you recommend it to others?) user experience (were they easy to talk to?); coaches (similarity, liking, expertise, sincerity, trustworthiness); and intervention appropriateness (relevant to my life and situation, designed for someone like me). Participants who complete the assessment will be sent a $25 gift card. Those who didn't quit smoking in the control group will be asked if they would like to try the quitline again. Those who didn't quit who were in the treatment group will be offered whichever program they weren't offered at baseline.

The second follow-up assessment will occur at 6 months after baseline and will again be asked about smoking abstinence and their success in creating a smoke-free home. Those who report that they don't smoke will be offered to take an at-home urine cotinine test to verify their lowered nicotine levels. If participants are willing to participate, they will be mailed a urine test to measure their cotinine levels, which is a metabolite of nicotine. The urine test, which can be purchased at any local pharmacy over-the-counter, will be mailed to participants with instructions for sending the results. The study team will not receive any biological samples or testing materials in the mail. Instead, participants will be instructed to send a picture of their results to the study email account and/or phone account. The photo will include only the results: a photo of the dipstick next to the results card. No personal identifiable information will be included in the photo. The results will be linked to the participants study ID via their phone number from which the photo was sent. Consent will be obtained prior to sending the testing kit in the mail via phone script. Results will be recorded in participants study record. Incentives will be mailed to participants after result has been received by study team. Those who report a smoke-free home will be offered an in-home air monitoring kit. The study team will call participants to walk them through placing the monitor as well as how to send it back to use in one week. The study team will then send the filters from the kit to a lab for processing. A gift card will be sent once results are received.

1.12 Will participants be randomized?
Yes

1.13 Will any of the following be used to collect information from the participant or others?

- Screening questions or screening/eligibility questionnaires
- Surveys
- Questionnaires
- Stimuli
- Any other written assessments

Yes

Attachment Name	Category	Version	Date Attached
SFH 6mo followup_CLEAN12.4.20.docx	Subject Data Collection Instruments	5	12/09/20
SFH baseline with text for callers 5-7-21 TRACK CHANGES.docx	Subject Data Collection Instruments	1	05/12/21
SFH baseline with text for callers 5-7-21 TRACK CHANGES-1.docx	Subject Data Collection Instruments	5	05/12/21
SFH_3mo followup Draft 6 071720_clean.docx	Subject Data Collection Instruments	5	09/09/20

1.14 Does this project involve creating any audio, video, or photographs?
Yes

1.15 Does the study include any form of deception (e.g., providing participants with false information, misleading information, or withholding information about certain study procedures)?
Examples:

- Procedure includes a cover story that provides a plausible but inaccurate account of the purposes of the research.
- Participants will be provided with false information regarding the particular behaviors of interest in the research.
- Procedures include a confederate pretending to be another participant in the study.
- Participants will be told that the research includes completion of a particular task, when in fact, that task will not be administered.
- Study is designed to introduce a new procedure (or task) that participants are not initially told about.

No

1.16 Indicate any payments or reimbursements to participants (check all that apply)

- Gift or Debit Card

1.17 Does this study have a plan to have an individual or committee review combined data from all participants on a periodic basis (such as summary or aggregate safety and/or efficacy data)?
No

1.18 What have you done to minimize any risks?

- Other - If a participant answers the depressive symptom screener item that they feel down, depressed, or hopeless most day or every day, then at the end of the survey, after they've gone through the offers for quitline and/or

smoke-free homes but before they give their address for the gift card, a new screen will appear that says: "Sometimes people who have been feeling a little down or depressed can benefit from talking to someone like a counselor about their feelings. Would you be interested in some numbers to call or websites to help connect you with someone like that?" The participant will select yes or no. If yes, the interviewer will have at least 1 state specific behavioral health referral as well as the following national hotlines; the interviewer will use their judgment on which would be most appropriate: Domestic Violence (1-800-799-7233), Suicide Prevention (1-800-273-8255), Substance Abuse and Mental Health(1-800-662-4357). These numbers will also be printed out and available at each of the calling stations. If a participant reveals during the course of the phone call that they are experiencing severe depression, suicidal thoughts, or would like help with substance abuse or domestic violence, then the interviewer will provide the appropriate referral.

- No forseeable risks
- Psychological consultation and/or referrals readily available

1.19 What are the potential benefits related to this project for:

- the participant (if any)
- benefits to society (if any)

All participants will be given the opportunity to receive free Quitline services and some will also be given the opportunity to create a smoke-free home. Both of these options will provide a significant health benefit to the participants and those who live in the home. This study will show whether Quitlines can effectively provide an alternative to quitting smoking for those who aren't ready to quit yet, reducing exposure to secondhand smoke.

1.20 Provide a summary of the analysis methods you will use, including, if applicable, the data points or outcomes you will analyze.

Aim 1. The primary effectiveness research question in this Hybrid Type 2 randomized trial is whether adding a Smoke Free Homes intervention to standard population-level cessation services will increase the proportion of low-income smokers who quit by 6-month follow-up. In this analysis, the independent and dependent variables are dichotomous; the strata variable is participants' state of residence, also a proxy for benefits offered by their state quitline. The primary outcome, self-report abstinence at 6-month follow-up, will be validated by urine cotinine test: Level 3-6 on the test strip will indicate continued smoking and Level 0-2 will confirm abstinence. Agreement between self-report and cotinine test result will be assessed using the Kappa statistic, with values > 0.75 viewed as excellent.

Aim 1 will use intention-to-treat analyses, providing the most conservative estimate of intervention effects. With randomization and a large sample, we expect baseline characteristics to be similar by group. We will test for this using t-tests for continuous variables and chi-square tests for categorical variables. If significant differences are found, we will include those variables as covariates in all analyses. For Aim 1A (abstinence from smoking) the Cochran–Mantel–Haenszel test will be used to test the conditional association between study group and abstinence at 3- and 6-month follow-up, controlling for states. A Breslow-Day test will be used to examine whether there is a common odds ratio (OR) across states. Finding greater odds of abstinence across states for the group receiving both Quitline and Smoke Free Homes would support the hypothesized intervention effects. If the Breslow-Day test is significant, we will estimate state-specific ORs. To control for other potential covariates, we will regress abstinence at 3- and 6-month follow-up on study group and other covariates using logistic regression. In the regression model, 8 dummy variables for states will be created to account for differences in state Quitlines. Adjusted odds ratios (OR) and 95% confidence intervals (CI) will be reported to quantify the associations. Study group effects for Aim 1B (made a quit attempt or did not) will be examined in a series of analyses similar to those described for Aim 1A. Finding a greater odds of quit attempts in the Quitline and Smoke Free Homes group across states would support hypothesized effects. For Aim 1C, cigarettes smoked per day is a count dependent variable (DV) measured at baseline, 3- and 6-month follow-up and assumed to follow the Poisson distribution. If the assumption of Poisson distribution is met, we will regress the DV on study group, states and other potential covariates and allow the β for study group as a random effect using random-effect Poisson regression. Otherwise, we will fit random effect negative binomial regression to the data. Finding a larger decrease in cigarettes smoked per day in the combined group (vs. Quitline alone) would support the hypothesized effect. Analyses for Aim 1D will replicate those for Aims 1A-C, but be conducted in only the subset of participants from both groups who declined quitline services when offered at baseline. Regression analyses for Aim 1D will also test baseline variables described previously (see "Baseline survey"), because quitline acceptance rates may differ by group. These comparisons provide the best estimate of the added benefit of offering Smoke Free Homes to smokers who are not yet ready to quit.

Aim 2. The primary implementation research question in this Hybrid Type 2 trial is whether demand for and engagement in quitline services – operationalized as acceptance and use – differs by study group. In Aim 2A, the DV is dichotomous (accepts Quitline/does not). Using the same analytical strategies and statistical methods described for Aim 1A, we will examine cumulative probabilities of accepting quitline services during the study period by group, adjusting for baseline covariates. Finding a greater likelihood of accepting quitline services in the combined group (vs. Quitline only) will support our hypothesis. For Aim 2B, the DV is whether participants use 0, 1 or 2+ quitline counseling sessions, and will be treated as an ordinal variable. Counseling sessions include all inbound and outbound phone interactions between a quit coach and participant. Among those who accept quitline services, we will regress number of quitline sessions used by the end of the study on study group and other baseline measures using ordinal logistic regression. The proportional odds assumption will be tested using the score chisquare test. If it is met, adjusted ORs and 95% CIs will be reported from the ordinal logistic regression model. Otherwise, multinomial logistic regression will be used to compare different probabilities (e.g., 0 vs 1 and 0 vs 2+ sessions), adjusting for potential baseline covariates. Finding greater odds of using more sessions in the Quiltine and Smoke Free Homes group will support our hypothesis. Aim 2C examines our hypothesis that integrating a Smoke Free Homes intervention into an existing tobacco treatment system will move smokers who are not yet ready to quit incrementally closer to quitting. Readiness to quit, pessimism about quitting and ambivalence about smoking are continuous DVs for this aim. Among participants still smoking at the end of the study, the level of readiness, pessimism and ambivalence at 6-month follow-up will be regressed on study group, states, baseline DV and baseline

characteristics using ordinary least square regression. Finding greater readiness to quit, greater ambivalence about smoking, and less pessimism about quitting in the Quitline and Smoke Free Homes group (vs. Quitline only) would support our hypothesis.

Aim 3. Economic evaluation is essential in assessing implementation feasibility and sustainability. We will assess cost-effectiveness (using CEA) of adding the Smoke Free Homes intervention to quitline services compared to Quitline alone from the QL provider perspective, and conduct a cost-benefit analysis (CBA) of SFH compared to QL alone from both the individual and societal perspectives. Short- (during program) and long-term horizons (multiple years) will be considered, using accepted methods of economic evaluation.208-210 From a provider perspective, QL and SFH programs incur a sunk cost of program setup that is invariant to the number of participants. Fixed cost data will be obtained from past accounting records of Optum. If SFH does not incur additional fixed costs above QL, fixed costs are ignorable in the CEA and CBA as they cancel out between interventions. Variable costs depend on scope and number of activities. Coaching calls are core to the QL, but the number can vary by state. SFH involves one call and three mailings (postage, printing costs). Costs per call in QL and SFH will be measured by length in minutes, average wage (including fringe benefits) of a coach, and the additional time spent on unsuccessful attempts to reach a participant. In terms of cost-effectiveness, Aim 1 will provide effectiveness data, so the CEA ultimately yields the cost per successful quit.

1.21 Provide the rationale or power analysis to support the number of participants proposed to complete this study.
Based on previous reserach, in both groups, 25% of participants will accept QL when offered (Pilot 1, ongoing cessation R01); 42%, 31% and 27% will take 0, 1 and 2+ QL calls, respectively (ongoing cessation R01); and 12%, 13% and 31% will report quitting, respectively (ongoing cessation R01). In the QL+SFH group, 65% of those who decline QL will accept SFH (Pilot 2, SFH trials); of those accepting, 37% will create a SFH and 63% will not, with corresponding quit rates of 26% and 5% (SFH trials). We assume all who decline QL and SFH will quit at a very low rate (2%). Using these data to estimate cessation after a first offer of QL and SFH yields intent-to-treat quit rates of 5.9% (SFH) and 11% (QL+SFH). Even if no other cessation occurs, the study is powered to detect this difference. If we assume the same intervention use and quit rates apply for a second offer of QL and SFH (at 3-month follow-up), intent-to-treat quit rates would be 9.6% (SFH) and 17.5% (QL+SFH), also within the study's power. We are confident that the final quit rates for each group will fall between these values.

We used G*Power to calculate the sample size required to detect study group quit rate differences of 6 vs 11% (minimum expected), 8 vs 14%, and 10 vs 17% (maximum expected) at three levels of power. As shown, with 1,116 participants (558 per group) completing 6-month follow-up, we can detect a 6 vs 11% difference with 85% power. Power will be greater for larger differences. Attrition is expected to be 40% at 6-month follow-up, thus a baseline sample of 1,980 assures enough participants at follow-up (n=1,188) even if attrition is slightly higher than projected.

1.23 Will any data from this project be stored for use in future research studies?
Yes - contribution for future use is mandatory for participation in the study

1.24 Does this project involve the collection or use of biological samples or genetic data?
No

1.25 Are you requesting institutional certification to contribute human data or samples to a repository or database for broad sharing (public or restricted access)?
No

2. Participants

2.1 Will there be any adult participants?
Yes

2.1.a How many adult participants do you expect to consent or enroll under a waiver for this project?
1980

2.1.b What is the age of the youngest adult participant?
21.0

2.1.c What is the age of the oldest adult participant?
No age limit

2.2 Will there be any minor participants?
No

2.3 Will there be any emancipated minor participants?
No

2.7 Do you plan to recruit/enroll non-English speaking people?
No

2.8 Do you propose to enroll any of the following in this study as participants?

- Employee of the PI or employee of a research team member

- Individual supervised by PI or supervised by member of research team
- Individual subordinate to the PI or subordinate to any member of the research team
- Student or trainee under the direction of the PI or under the direction of a member of the research team

No

2.9 Is this project about pregnant women?
No

2.10 Will this project involve fetuses?
No

2.11 Does this project involve the use of fetal tissue from any source?
No

2.12 Does this project recruit adult participants who may be incompetent or have limited decision-making capacity on initial enrollment into the study?
No

2.13 Does this project involve prisoners as participants?
No

3. Performance Sites

3.1 Indicate type of site(s) where research will occur (check all that apply):
- Academic Institution

3.2 Where will project procedures take place (check all that apply)?
- Danforth Campus
- U.S. off-campus - Optum will conduct the Quitline services via phone; United Way 2-1-1's across 9 states will be recruiting over the phone.

3.3 Is this project also being conducted by other researchers at their own sites (e.g. a multi-site collaborative project)?
Yes

3.3.a What is your site's role(s) for this project (check all that apply)?
- Coordinating Center

3.3.b Indicate the requirements for participating sites to report unanticipated problems to the coordinating center/lead site:

Timeframe	Contact Method
• Within 1 week	• Email • Phone

3.3.c Indicate the requirements for the lead site to report unanticipated problems to the participating sites:

Timeframe	Contact Method
• Within 2 weeks	• Email • Phone

3.3.d Indicate the requirements for the lead site to communicate protocol modifications to the participating sites:

Timeframe	Contact Method
• Greater than 2 weeks	• Email • Phone

3.3.e Indicate the requirements for the lead site to communicate interim results to the participating sites:

Timeframe	Contact Method
• Greater than 2 weeks	• Email • Phone

3.3.f Indicate the requirements for the lead site to communicate other new information to the participating sites:

Timeframe	Contact Method
• Greater than 2 weeks	• Email • Phone

3.3.g What are participating site roles for this project?
- Other - Representatives from Emory University will listen to audio recordings of the Smoke-Free Homes coaching call and provide feedback to the coach(es).

5. Privacy & Confidentiality

5.1 Indicate your plans to protect the privacy interests of the participants during the conduct of the study (check all that apply):
- Only the minimum necessary private information is collected for the purposes of the study
- Any procedures or interventions conducted as part of the study will be conducted in private setting to the extent possible
- Recruitment/consent will occur in a private setting
- Participants will be able to ask questions in a private setting

5.2 Are you collecting or using the Social Security Number of any participants for any purpose?
Yes

5.2.a Provide the intended usage of SSN:
- To provide compensation to participants

5.3 Project uses paper or hard copy consents, surveys, data collection forms, research subject binders, or other hard copy materials (check all that apply):
No

5.4 Project collects, stores and/or transmits electronic data on mobile devices, desktop computers, servers including cloud servers, email, or any other information in electronic form (check all that apply):
Yes
- Data are encrypted
- Password protected
- Access is limited to research team only

5.5 Project collects or uses biologic specimens (check all that apply):
No

5.6 Identify any additional protections in place for data and or samples (check all that apply):
- Data Use Agreement (DUA)
- Formal research staff training process