UCSF Helen Diller Family Comprehensive Cancer Center

A community-based trial of a voluntary smoke-free home intervention in permanent supportive housing for formerly homeless adults

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Revision History

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Protocol Signature Page

1. I agree to follow this protocol version as approved by the Institutional Review Board (IRB).
2. I will conduct the study in accordance with Good Clinical Practices (ICH-GCP) and the applicable IRB, ethical, federal, state, and local regulatory requirements.
3. I certify that I, and the study staff, have received the required training to conduct this research protocol.
4. I agree to maintain adequate and accurate records in accordance with IRB policies and federal, state and local laws and regulations.

UCSF Principal Investigator

Maya Vijayaraghavan

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Signature

1.4.21

Date

Abstract

Title	A community-based trial of a voluntary smoke-free home intervention in permanent supportive housing for formerly homeless adults
Study Description	The focus of this proposal is on expanding access to voluntary smoke-free homes to formerly homeless residents residing in permanent supportive housing, and examining the impact of this intervention on reducing tobacco-caused disparities. In this study, we will conduct a multi-site, community-based cluster-randomized wait-list controlled trial of our multi-faceted smoke-free home intervention among 400 permanent supportive housing residents residing in 20 permanent supportive housing sites across the San Francisco Bay Area with the goal of increasing voluntary adoption of smoke-free homes. Our specific aims are: **Aim 1:** Conduct a cluster randomized trial to estimate the effect of our smoke-free home intervention on residents' voluntary adoption of smoke-free homes. **Aim 2:** Evaluate the cost-effectiveness of the smoke-free home intervention. **Aim 3:** Determine characteristics of high and low adopters at the individual level, and social and environmental barriers and enablers of adoption, scalability and sustainability of the intervention.
Study Intervention	The multi-faceted intervention, delivered by study staff includes: 1) one-on-one counseling to permanent supportive housing residents who are smokers on how to adopt a smoke-free home, and 2) training for permanent supportive housing staff on how to provide referrals to cessation services.
Study Population	The proposed study will include all adult participants across the lifespan, without any restrictions based on age, gender or race/ethnicity. Eligible participants will include those who are ≥ 18 years of age. However, no children under the age of 18 years of age will be included in this study of adult cigarette smokers. While PSH residents who participate in the smoke-free home intervention study might have children living with them in their home, the unit of analysis will be the residents and not their children. However, we will gather information both quantitatively and qualitatively on whether children live in their homes, and the influence, if any, that children had on residents' adoption of a voluntary smoke-free home.
Primary Objective	The primary outcome is self-reported voluntary adoption of smoke-free homes for ≥90 days at 6 months follow-up.

Secondary Objectives	The secondary outcome is 7-day point prevalence abstinence at 6 months follow-up, measured as self-report of abstinence at the 6-month follow-up and an expired carbon monoxide of ≤ 5 parts per million (ppm) as abstinence
Recruitment Methods	We will recruit 400 PSH resident participants, with 200 each in the intervention and wait-list control arms (~20 participants per site; Figure 6, Table in Recruitment and retainment section in human subjects). Within each site, all resident participants will be informed about the study and invited to participate. We will recruit participants within blocks of four housing sites per month, with each block containing two intervention and two wait-list control sites, and anticipating roll-out of one such block per month. We anticipate completing recruitment and enrollment of all participants in 6 months, allowing for a one-to-two-month extension to complete these activities. We will offer the intervention to the wait-list control participants once all participants in the intervention sites from the same block have completed their 6-month follow-up. We will recruit 400 resident participants, with 200 participants each in the intervention and wait-list control arms (~20 participants per site). Within each site, study staff will advertise the study to residents the week prior to enrollment by placing flyers at the study site and making announcements at community meetings. After the informational meeting, study staff will be present at the recruitment sites during designated times to screen interested participants for eligibility and enroll those eligible into the study. We have used these study procedures successfully in our pilot study. All staff participants will be recruited at the time of the resident intervention, via email. PSH staff in intervention sites will receive the intervention at the same time as residents in those sites; those in wait-list control sites will receive the intervention once intervention site participants have completed their follow-up assessments. Staff who agree to enroll will be provided information about the study at the time of enrollment, and will complete a written informed consent prior to the training.
Sample Size	We plan to recruit 400 resident participants and 100 staff participants.
Duration of Study Participation	It will take 6 months for the intervention group participants to complete the study, and 1 year for the wait-list control participants to complete the study.

Unique Aspects of this Study	This study is the first to test a smoke-free home intervention in permanent supportive housing for formerly homeless adults.

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1 Introduction

1.1 Background on condition, symptom, behavior, or other primary study focus

The proposed study focuses on cancer healthy equity by examining the impact of a brief intervention to increase voluntary adoption of smoke-free homes among formerly homeless adults living in permanent supportive housing (PSH). PSH is subsidized housing with closely linked or on-site voluntary medical and/or social services for individuals with a history of chronic homelessness.[1,2] In 2017, over 370,000 formerly homeless individuals lived in PSH in the US.[3] Housing First, the most common approach, uses a harm reduction framework and provides housing without preconditions of abstinence from alcohol or substance use or a requirement to engage in supportive services prior to obtaining housing or to maintain housing.[1]

Social determinants of health are associated with high rates of tobacco use among people who experience homelessness.[4] These determinants include extreme poverty and the social marginalization that results from being homeless, increased availability of tobacco products in low-income communities, and limited access to cessation resources and smoke-free housing.[4,5] Approximately 50% of those living in PSH report current smoking.[6] Mortality rates among PSH residents are at least double that of age-matched individuals in the general population [7] and tobacco-caused chronic diseases including cancers and cardiovascular disease contribute to over 60% of the all-cause mortality of PSH dwelling individuals.[7]

Tobacco use also incurs a substantial financial burden. In prior work with PSH residents in the San Francisco Bay Area, we found that residents who smoked spent 12% (median, range 5%-26%) of their monthly income on tobacco.[8] This interfered with residents' ability to pay rent, putting them at risk of eviction.[9] Residents reported prioritizing tobacco purchases over food purchases, increasing risk for food insecurity.[10]

Despite high rates of tobacco use and its detrimental impact on PSH residents' health and financial well-being,[10] PSH typically do not have mandated smoke-free policies restricting indoor smoking in living areas nor do they offer smoking cessation services.[9] Smoke-free policies and smoking cessation services are among the most effective tobacco control interventions. The Department of Housing and Urban Development (HUD)-managed public housing authority housing has a mandated smoke-free policy and, in most HUD sites, that mandate is accompanied with access to cessation resources.[11,12] In contrast, smoke-free policies are uncommon in PSH and most PSH are not equipped to offer cessation services.[9,13]

1.2 Background on study intervention

There are several approaches to implementing smoke-free policies in housing such as having a city ordinance restricting smoking in multi-unit housing or housing providers mandating smoke-free policies on their properties. However, these approaches may be difficult to implement in PSH for several reasons. First, there is concern that mandated policies conflict with PSH's harm reduction framework,[9] potentially increasing risk of unsheltered homelessness if people left PSH because of the policy or were evicted because of a policy violation. Second, PSH staff may lack resources and time to enforce a smoke-free policy even if they put one into effect.[9] However, in the absence of smoke-free policies, PSH residents are unprotected from secondhand smoke exposure unless they voluntarily adopted smoke-free homes. Thus, research is needed to: (a) determine whether individually-directed strategies are effective in

increasing voluntary adoption of smoke-free homes among PSH residents, and (b) determine whether these strategies can be brought to scale within PSH.

In our previous pilot study, we conducted a single-arm trial of an intervention to increase voluntary adoption of smoke-free homes, i.e., a voluntary no-smoking rule in one's home, among 100 formerly homeless adults in PSH.[14] The multi-faceted voluntary smoke-free home intervention acted upon the individual, social and organizational levels to modify tobacco use behavior. The intervention consisted of providing a step-by-step guide to residents on how to voluntarily adopt a smoke-free home as well as training PSH staff on how to refer residents to local cessation resources. At 6 months, 31% of residents adopted a voluntary smoke-free home compared to 12% at baseline.

1.3 Study Rationale

In this study, we will conduct a multi-site, community-based cluster-randomized wait-list controlled trial of our multi-faceted smoke-free home intervention among 400 PSH residents residing in 20 PSH sites across the San Francisco Bay Area.

This proposal is **significant** because it is aimed at mitigating some of the structural inequities that have led to an increase in tobacco-caused cancer disparities in this population. The intervention delivered by study staff includes providing PSH residents the tools to voluntarily adopt a smoke-free home, and training PSH staff to offer referrals to cessation services to residents. By influencing tobacco use behavior at the individual-level, the intervention may have the primary effect of increasing voluntary adoption of a smoke-free home and may also have the secondary effect of increasing smoking cessation. This has the potential to reduce the incidence of tobacco-caused diseases, including cancers.

1.4 Risk/Benefit Assessment

Potential risks: There may be a potential for loss of privacy relating to the information asked in the questionnaires, particularly around issues on mental health disorders, substance use disorders, and previous history of homelessness. Loss of privacy or confidentiality– particularly around mental health, illicit substance use, HIV status, impaired function, and information contained in medical records – could result in embarrassment or social marginalization. In the case of illicit substance use, loss of privacy or confidentiality could result in legal consequences. Because we will ask participants to consent to keep on file their name and contact and tracking information, there may be a potential for loss of confidentiality. Participants may experience symptoms of nicotine withdrawal from reducing consumption or quitting smoking. These symptoms may include irritability, fatigue, headaches or cravings for cigarettes. Participants may also experience hunger as a result of reducing consumption or quitting smoking. There is a low risk of study participants experiencing fatigue and/or boredom during study visits. In addition to the above, we note other risks that may be relevant to our study population. Given the significantly low economic status of our study participants, study incentives may be coercive. We believe that the risk of these events is low given the measures we will put in place to minimize these risks (see below).

Adequacy of protection against risks

1) Procedures for protecting against loss of privacy. Although we collect basic information from PSH resident and staff participants on socio-demographics and factors that can influence smoking cessation such as mental health disorders or substance use disorders, it will be kept to

a minimum to minimize any psychological risk. All interviews will be conducted in a way that is formative without breaching the confidentiality of individuals participating in the study. We will ensure participants that responses to the questionnaires, in-depth, semi-structured interviews or focus groups will not affect their eligibility for receiving services. We will assure participants who decide not to participate that their decision would not affect their ability to seek services. Participation in this study is voluntary.

2) Procedures for protecting against loss of confidentiality. There is a potential for loss of confidentiality, however we will take measures to minimize this risk. Each participant will have a unique alpha-numeric identification (ID) number. We will use the UCSF REDCap secure database to enter personal identifying information and to create questionnaires for each of the studies. Identifying information collected from participants for tracking purposes will be stored separately from research data and will not be associated with the participants' unique study ID number. All questionnaire data will be entered in real-time using an iPad through a secure VPN network. In-depth, semi-structured interviews and focus groups will be audio-recorded. These recordings and their transcriptions will be stored on our secure server at UCSF. The server where data will be stored is backed up nightly. We will periodically go through the study data to make sure there is no personal identifying information. Only study staff will have access to study data. For added protection of confidentiality, we will apply for a Certificate of Confidentiality from the National Cancer Institute.

3) Procedures for protection against legal risk to participants. The questionnaires will include questions about illegal behavior (e.g. the use of illicit drugs). Procedures explained above for protecting privacy of individuals and confidentiality of data will minimize the legal risk to participants. For added protection of confidentiality of data, we will apply for a Certificate of Confidentiality from the National Cancer Institute. Trained study staff will inform participants of legal risks during the informed consent process and will explain that participants can skip out of any interview questions they are not comfortable answering.

4) Procedures for protecting against coercion. Reimbursements may be coercive. There is controversy around whether reimbursements could be coercive or used to purchase illicit drugs when given to indigent populations participating in research. In trying to balance the need to reimburse participants for their time while limiting coercion and/or dangerous behaviors, we have set reimbursement levels comparable to those used in studies in similar populations.[45-47] An alternative to cash reimbursements, we have chosen to reimburse in the form of gift certificates for grocery stores and general pharmacies.

5) Procedures for protecting against hunger. It is possible that individuals who are attempting to quit smoking may experience hunger. Should this issue arise during the intervention, we will provide resident participants a list of resources of free food including food banks for food in bulk, soup kitchens for daily meals, and other free meal programs.

6) Procedures for protecting against withdrawal symptoms. Participants may experience symptoms of nicotine withdrawal from reducing consumption or quitting smoking. These symptoms include irritability, fatigue, headaches or cravings for cigarettes. Participants who experience these symptoms will be referred to their primary care providers to obtain a prescription for nicotine replacement therapy or other medications for cessation and/or to be evaluated for contraindications to these medications. Study staff will ask participants about these symptoms during follow-up visits.

7) Procedures for handling reportable conditions. During the informed consent process, participants will be informed of information that must be reported by law should it be revealed during study visits, including suicidality and homicidality. The PI will train the study staff on how to assess for symptoms of suicidality or homicidality, and the procedures to follow in the event of these occurrences. In addition, the PI will be on call at all times and will be available for consultation.

8) Procedures for protecting against fatigue or boredom. The enrollment study visit will last approximately 1 hour, and the follow-up visits at 3- and 6 months (intervention and wait-list control participants) and 9- and 12-months (wait-list control participants) will last approximately a half-hour to 45 minutes. The in-depth, semi-structured interviews and focus group in Aim 3 will last 60 minutes to 90 minutes. Study staff will inform participants, during informed consent and at each study visit, that they can take breaks or stop participating in the study at any time.
9) Added protections for vulnerable populations. If a participant becomes incarcerated during the course of the study, they will be censored from participation during incarceration. If released from jail/prison during the study timeframe they can choose to re-enroll and a research assistant will repeat the informed consent process using procedures explained above.
10) Protections against COVID-19. We will ensure that all study procedures comply with protocols in place at PSH sites to minimize COVID-19. These procedure may include minimizing the number of days we are on-site to conduct recruitment, maintaining physical distancing protocols, incorporating a universal COVID-19 screen at each encounter, conducting follow-up visits by zoom or telephone, and conducting the staff training by zoom. For participants, who screen positive for COVID-19 symptoms, we will refer participants to their primary care provider/medical homes to get tested and evaluated. For participants who report other needs as a result of COVID-19 (e.g., food, social services), we will request permission to share this information with their case managers and also refer them to their medical homes to get additional support. Moreover, all staff will be required to wear personal protective equipment that is compliant with state guidelines. All participants will be required to wear a mask when interacting with staff and maintain at least 6 feet of physical distance.

2 Study Objectives and Endpoints

2.1 Primary Objective

Primary Objective	Endpoint(s)	Time Frame
1. Self-reported voluntary adoption of smoke-free homes for ≥90 days at 6 months follow-up.	• The proportion of people who adopt a smoke-free home voluntarily	6 months follow-up

2.2 Secondary Objective(s)

Secondary Objective	Endpoint(s)	Time Frame
1. 7-day point prevalence abstinence at 6 months follow-up, biochemially verified using CO ≤ 5 ppm as abstinence	• The proportion of people who achieve abstinence at 6 months follow-up	6 months follow-up

2.3 Exploratory Objective(s)

Exploratory Objective	Endpoint(s)
1. Behavioral outcomes for PSH staff include change in SKAP scores	Measured at baseline, 3 and 6 months follow-up
2. Air nicotine monitoring in a random sample of (~ 200 participants)	6 months follow-up

3 Study Design

3.1 Characteristics

Overview of the intervention. The intervention, delivered by study staff includes: 1) one-on-one counseling to PSH residents who are smokers on how to adopt a smoke-free home, and 2) training for PSH staff on how to provide referrals to cessation services.

Trial design. We have chosen a cluster-randomized, wait-list controlled trial,[75,76] where PSH sites will be randomized into intervention and wait-list control groups. Those in the wait-list control group will receive usual care first and then cross over to the intervention arm.

Setting. Study procedures will take place in a private room at each PSH site.

Study procedures for PSH resident participants. Eligible resident participants include current smokers [(smoked at least 100 cigarettes in lifetime (i.e. the standard definition for a life-time smoker), daily or non-daily smoking in the past 7 days and at least 5 cigarettes per day, verified by expired Carbon Monoxide (CO)≥ 8 parts per million (ppm)] [77] who *smoke in their homes and*

expect to live in the PSH site for at least 12 months, are ≥ 18 years of age, are English proficient, and are able to provide informed consent. Study staff will advertise the study to residents the week prior to enrollment by placing flyers at the site and making announcements at community meetings. Study staff will be present at the recruitment sites during designated times to screen interested participants for eligibility, obtain written informed consent using the teach-to-goal method,[78] and enroll those eligible. The expired CO assessment for eligibility assessment is to ensure that participants recruited are regular smokers who smoke an average of 5 cigarettes per day. To obtain a CO assessment, the participant blows into a handheld CO monitor that records the expired CO reading (Bedfont EC50 Smokerlyser; Bedfont Scientific Ltd). We considered including monolingual Spanish speaking participants in our study, however, the proportion of monolingual Spanish speaking participants is ~ 5% based on estimates from our partner organizations where the study will be conducted. Therefore, we chose to include English speaking participants in this study.

Study procedures for PSH staff participants. Eligible PSH staff participants include service staff (e.g., case managers), who are ≥ 18 years of age, are willing to engage in a 2-hour training, and are able to provide informed consent. Staff in each site will be contacted via email, and invited to participate in a 2-hour training. Study staff will screen PSH staff for eligibility, obtain written informed consent using the teach-to-goal method,[78] and offer dates for the training.

Randomization and allocation. We will randomize 20 PSH sites into intervention and waitlist control arms. We will use the method of restricted randomization—commonly applied in cluster-randomized trials with small numbers of clusters—to ensure an acceptable level of balance across groups at baseline.[76] First, we will create two sets of 10 housing sites balanced on preexisting variables describing relevant characteristics of sites and their residents, e.g., property size, current smoking-related policies, and geographic location. Second, we will randomly assign one set of sites to intervention and the other to the wait-list control.

3.2 Sample Size

We will recruit 400 PSH resident participants, with 200 each in the intervention and wait-list control arms (~20 participants per site). We expect to enroll 100 PSH staff, approximately 5 staff per site.

3.3 Primary Completion

The expected primary completion date is 14 months after the study opens to accrual.

3.4 Study Completion

The expected study completion date is 2 years after the study opens to accrual.

4 Selection and Enrollment of Participants

4.1 Eligibility Criteria

4.1.1 Inclusion Criteria

In order to be eligible to participate in this study, an individual must meet all of the following criteria:

1. Age 18 years or older
2. Ability to understand study procedures and to comply with them for the entire length of the study.
3. Ability of individual or legal guardian/representative to understand a written informed consent document, and the willingness to sign it.
4. Current smokers [(smoked at least 100 cigarettes in lifetime, daily or non-daily smoking in the past 7 days and at least 5 cigarettes per day, verified by expired Carbon Monoxide (CO)≥ 8 parts per million (ppm)] [77] who smoke in their homes.
5. Expect to live in the PSH site for at least 12 months, and
6. English proficient.

4.1.2 Exclusion Criteria

An individual who meets any of the following criteria will be excluded from participation in this study:

1. Contraindication to any study-related procedure or assessment.

4.2 Recruitment Methods

Recruitment schedule. We will recruit 400 PSH resident participants, with 200 each in the intervention and wait-list control arms (~20 participants per site; Figure 6, Table in Recruitment and retainment section in human subjects). Within each site, all resident participants will be informed about the study and invited to participate. We will recruit participants within blocks of four housing sites per month, with each block containing two intervention and two wait-list control sites, and anticipating roll-out of one such block per month. We anticipate completing recruitment and enrollment of all participants in 6 months, allowing for a one-to-two-month extension to complete these activities. We will offer the intervention to the wait-list control participants once all participants in the intervention sites from the same block have completed their 6-month follow-up. We expect to enroll 100 PSH staff. We will obtain information on the total number of residents and staff at each site to provide an estimate of the proportion enrolled in the intervention.

Within each site, study staff will advertise the study to residents the week prior to enrollment by placing flyers at the study site and making announcements at community meetings. After the informational meeting, study staff will be present at the recruitment sites during designated times to screen interested participants for eligibility and enroll those eligible into the study. Study staff will describe the purpose of the study, the study procedures, including risks and benefits, and obtain written informed consent using the teach-to-goal method at the time of eligibility.[78] Participants will complete the baseline questionnaire and will receive the study staff-delivered intervention within one week of enrollment. We have adjusted the timeline for recruitment, intervention delivery and follow-up to account for extra time that we may need to complete study procedures to follow protocols around social distancing that PSH sites may have put in place due to COVID-19.

Data collection reimbursements. We will reimburse all resident participants with [redacted] gift cards for completing the baseline questionnaire, [redacted] the 3-month questionnaire and [redacted] the 6-

month questionnaire. We will reimburse participants [redacted] for each monthly tracking visit in between follow-ups. Participants selected for random air nicotine monitoring at 6 months will be reimbursed [redacted] for placing monitors in their home for 7 days. We will reimburse PSH staff with [redacted] gift cards for completing the baseline questionnaire, [redacted] the 3-month and [redacted] the 6-month questionnaires.

Table: Recruitment and intervention roll-out and follow-up schema [a]	Project Year 1												Project Year 2								
	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3	4	5	6	7	8	9
Recruitment of intervention and wait-list control resident participants																					
Intervention group receives SFH intervention																					
Intervention and wait-list group 3-mo follow-up																					
Intervention and wait-list group 6-mo follow-up																					
Air nicotine monitoring at 6-mo follow-up for a random sample of intervention and wait-list group																					
Staff training in intervention properties and 3- and 6-months follow-up																					
Wait-list group receives SFH intervention after intervention group completes 6-mo follow-up																					
Wait-list control 9-month follow-up																					
Wait-list control 12-month follow-up																					
Staff training in wait-list control properties and 3- and 6-months follow-up																					

[a] The first 7 months of the project, which will be spent setting up the project, is not represented in the schema (please see timetable).

4.3 Inclusion of Women and Minorities

4.3.1 Eligibility of Women and Minorities

The proposed study aims to enroll 400 residents from 20 permanent supportive housing (PSH) sites who are representative of the racial/ethnic and gender diversity of the population in PSH in the San Francisco Bay Area (Aim 1). Because all residents in PSH have experienced homelessness, we believe that estimates of targeted enrollment for our study would be most accurate if it reflected the racial/ethnic and gender diversity of people who have experienced homelessness in the San Francisco, Alameda, San Mateo, and Santa Clara counties where PSH properties are located. We relied on point-in-time counts and assessments of homelessness and housing instability in each county to obtain these estimates. San Francisco county: In 2017, there were 7499 unsheltered or publicly sheltered homeless persons in San Francisco, of whom 35% were white, 34% were black, 3% were American Indian/Alaskan Native, 4% were Asian, 2% were Native Hawaiian/Pacific Islander, 22% were Hispanic/Latino, 22% were mixed race, and 33% were women.[125] Alameda county: In 2017, there were 5629 unsheltered or publicly sheltered homeless persons in Alameda, of whom 30% were white, 49% were black, 3% were American Indian or Alaskan Native, 2% were Asian, 1% were Native Hawaiian/Pacific Islander, 17% were Hispanic/Latino,15% were mixed race, and 41% were women.[126] San Mateo county: In 2017, there were 1,253 unsheltered or publicly sheltered homeless persons in San Mateo county, of whom 72% were white, 16.3% were black, 3.3% were American Indian/Alaskan Native, 2.7% were Native Hawaiian/Pacific Islander, 1.8% were Asian, 3.9% were mixed race, 26.6% were Hispanic/Latino and 25.3% were female.[127] Santa Clara county: In 2017, there were 7,394 unsheltered or publicly sheltered homeless people in Santa Clara county, of whom 47% were white, 14% were black, 3% were American

Indian/Alaskan Native, 20% were Native Hawaiian or Pacific Islander, 3% were Asian, 44% Latino,13% were mixed race, and 34% were female.[128]

4.3.2 Recruitment of Women and Minorities

The study recruitment strategy aims to achieve representation of minority groups that reflects the demographics of the affected population in the catchment area.

4.4 Inclusion Across the Lifespan

4.4.1 Age Range of Participants

The proposed study will include all adult participants across the lifespan, without any restrictions based on age, gender or race/ethnicity. Eligible participants will include those who are ≥ 18 years of age. However, no children under the age of 18 years of age will be included in this study of adult cigarette smokers. While PSH residents who participate in the smoke-free home intervention study might have children living with them in their home, the unit of analysis will be the residents and not their children. However, we will gather information both quantitatively and qualitatively on whether children live in their homes, and the influence, if any, that children had on residents' adoption of a voluntary smoke-free home.

4.4.2 Study Design/Recruitment Considerations Related to Age Groups

The study design and recruitment strategy aim to achieve representation of age groups that reflect the demographics of the affected population.

4.5 Participant Registration

A written, signed, informed consent form (ICF) and a Health Insurance Portability and Accountability Act (HIPAA) authorization must be obtained before any study-specific assessments are initiated. A copy of the signed ICF will be given to the subject and a copy will be filed in the medical record. The original will be kept on file with the study records.

All participants consented to the study will be registered in OnCore®, the UCSF Helen Diller Family Comprehensive Cancer Center Clinical Trial Management System (CTMS). The system is password protected and meets HIPAA requirements.

4.6 Randomization/Assignment to Intervention

See Section 3.1

4.7 Blinding

Not applicable

5 Study Intervention

5.1 Administration and/or Delivery of Study Intervention

Smoke-free home PSH resident intervention. Study staff will deliver a one hour, one-on-one counseling to PSH residents that includes: (1) a step-by-step guide on how to voluntarily adopt a smoke-free home, (2) information on SHS and thirdhand smoke, alternative combustible tobacco and nicotine product use, cannabis-tobacco co-use, effects of SHS on kids and pets,[40-

[43](3) a worksheet on calculating personal costs related to tobacco use, and (4) pledges to designate one's home smoke-free.

Smoke-free home PSH staff intervention. Study staff will conduct a two-hour training for PSH staff on how to provide referrals to smoking cessation programs using materials previously developed from the UCSF's Rxforchange curriculum for service providers.[79] PSH staff play an integral role in residents' lives by facilitating access to services, whether they be mental health, substance use or healthcare services. In keeping with that model, our training is directed toward empowering PSH staff to provide referrals to local cessation services using the ask, advise, and refer approach,[80] which has been shown to increase engagement in cessation treatment. The training will address nicotine addiction, tobacco use among PSH residents, pilot data, brief cessation counseling (ask, advise, and refer), and local resources for cessation. Because PSH resident-PSH staff encounters will take place as part of routine care, we will request permission from a random sample of staff and resident dyads (n=40) to record these interactions to assess fidelity.

Usual care. The current standard of care includes no interventions for smoke-free home adoption or referrals to smoking cessation resources.

5.2 Interventionist Training and Tracking

Training the 'interventionist'. The PI will train study staff to deliver the one-on-one counseling intervention to PSH residents on how to voluntarily adopt a smoke-free home. The PI will also train study staff to deliver a training to PSH staff on how to provide referrals to smoking cessation programs. To assess fidelity of the intervention roll-out, the PI will observe and evaluate study staff during intervention delivery and provide verbal feedback.

5.3 Adherence Assessment

Resident and staff participants will be asked to attend the intervention visit and the training, respectively. We will assess adherence to these sessions among resident and staff participants.

5.4 Concomitant Therapy

Not applicable

5.4.1 Allowed Therapy

Not applicable

5.4.2 Required Therapy

Not applicable

5.4.3 Prohibited Therapy

Not applicable

5.5 Participant Discontinuation/Withdrawal from the Study

Participants are free to withdraw from participation in the study at any time upon request.

An investigator may discontinue a participant from the study for the following reasons:

- Unacceptable adverse event(s)
- Significant study intervention non-compliance, unless varying compliance is an aspect of the study objectives
- Lost-to-follow up; unable to contact participant (see Section 5.6 - Lost to Follow-Up)
- Any event or medical condition or situation occurs such that continued collection of follow-up study data would not be in the best interest of the participant or might require an additional treatment that would confound the interpretation of the study
- The participant meets an exclusion criterion (either newly developed or not previously recognized) that precludes further study participation

5.6 Lost to Follow-up

A participant will be considered lost to follow-up if he or she fails to return for any scheduled visits after their last visit in the study, and study staff are unable to contact the participant after at least 3 attempts. Before a participant is deemed lost to follow-up, the investigator or designee will make every effort to regain contact with the participant (where possible, 3 telephone calls and, if necessary, a letter to the participant's last known mailing address or local equivalent methods). These contact attempts will be documented in the participant's study file. Should the participant continue to be unreachable, he or she will be considered to have withdrawn from the study with a primary reason of lost to follow-up.

We will employ techniques for tracking participants that we have used in past studies to maintain high rates of follow-up: these include monthly face-to-face or telephone check-in visits and locating participants lost to follow-up.[14,35,45-50,102] Participants will be incentivized $5 for each monthly check-in visit, in between study visits. At enrollment, we will ask participants to provide as many forms of contact information as possible including names of family/friends and case managers, telephone numbers, addresses of places where they usually stay or can be found, and to update this information monthly. At the enrollment visit, study staff will request consent to contact participants to remind them about upcoming study visits via cellphone. If participants miss any visit (scheduled study visit or check-in) and the participant has consented to it, study staff will conduct participant tracking. Tracking involves study staff calling people whose name and contact information the participant has given the study staff for this purpose ("contacts"). Staff, when calling on these contacts, will request help in locating the participant and/or will leave a message for the participant. Study staff will tell contacts only that the participant is enrolled in a research study. If the participant has given permission to do so, the study staff may go to look for the participant at a place where the participant has said that he/she frequents. When doing this, the staff may bring along a picture of the participant to assist in locating the participant. With these follow-up procedures, we have achieved rates of retention >85% for longitudinal studies with homeless and PSH participants.[45-50] In our pilot smoke-free home intervention study, we achieved retention rates of 86% and 84% at 3- and 6-months follow-up.[14]

We have developed a **retention plan** to facilitate recruitment/enrollment/ retention and acceptance of the study protocols. Our experience supports our estimates of retention rates of 80% at 6 months. Our 24-point culturally tailored plan includes:

1. Trained ***project staff experienced in working with populations that have experienced housing instability or homelessness, who are acutely aware of***

racial/ethnic disparities, and are familiar with fieldwork locations in PSH (study staff, navigators).

2. ***Staff training in cultural competency regarding racial/ethnic disparities***, culturally-responsive clinical research practices, and HIPAA.
3. A ***Certificate of Confidentiality*** obtained from NIH to protect the privacy of participants against most legal discovery requests and to address patients' concerns with privacy due to immigration status or legal repercussions.
4. Offer participants the option of ***meeting at their preferred*** time to complete follow-up assessments (e.g., after work, after school, on the weekends) and at a location of their preference in their community (e.g., outdoor locations).
5. Use of ***personalized and culturally sensitive mailings*** such as birthdays cards and holiday cards to ensure that patients feel like they are part of our study.
6. ***Community Advisory Board*** to include mostly persons with lived experiences of housing instability and living in PSH, housing staff, community members, key homelessness and housing policy makers, and local tobacco control experts who will review and advise on all study stages including intervention and assessment materials (meeting 2x/year).
7. A study design ***grounded in the local culture*** based on housing input, housing needs, and experience with providing services to low-income residents in PSH.
8. Conduct ***reminders*** (calls/text-messages/e-mails) one week and 24 hours before the brief intervention visit and research assessments. This is to remind participants with busy schedules.
9. Have an ***international toll-free number*** for participants to contact us and call in for coaching sessions, even if they travel outside the United States.
10. ***Monetary incentives*** to complete the baseline ($20), and follow-up assessments at 3-months ($15) and 6-months ($25), and an additional $5 for placement of the air nicotine monitor.
11. ***Use of existing procedures to locate patients lost-to-follow up***, including working with housing staff to identify participants so that study staff can meet them at the PSH site to conduct or schedule the research assessment or schedule the intervention session; and obtaining the updated contact information for study participants and their designated contact person.
12. ***Locator Guides*** with contact information for the participants, emergency contacts, friends and medical providers.
13. Conduct ***Monthly Interim Re-Contact*** calls that are incentivized ($5 visit) for participants at months in between scheduled visits to thank them for participating, remind them of the study incentives, update Locator Guides, and address any questions.
14. Supportive telephone tobacco-use/wellness ***health coaching*** designed partially for participant retention. Follow-up and re-contact efforts for intervention sessions will include weekly written letters or e-mail, followed by telephone calls (three weekly attempts will be made before shifting to monthly contacts).[130]
15. Study instruments and intervention materials designed to the meet the ***literacy needs*** of persons with low educational attainment.
16. ***Update participant contact information*** in Locator Guides at follow-up assessments, coaching sessions, and interim re-contact calls.
17. Extra effort ***tracking participants lost to follow-up*** at homes, shelters, outdoors using paid navigators who had lived experiences of housing instability and living in PSH.

18. Provide patients $***5 for each telephone session***, or yoked re-contact session to defray cost of cell phone minutes.
19. Designated ***tracking/scheduling staff***.
20. Use of laminated ***appointment* study business cards** with study contact information.
21. Collect ***agency contact information*** from patients where they might receive social services.
22. ***Study Website*** with educational materials, community resource links, and contact information for study staff.
23. Making "***home visits" in PSH and/or outdoor locations*** for difficult-to-find patients.

6 Study Procedures and Assessments

6.1 Schedule of Activities

Assessments/Procedures	Screening	Study Intervention Period				End of Study Intervention	Follow-up
Study Visit / Day (Window, # Days)	Visit -1 (Months 1 to 6)	Visit 1 /Months 3-12	Visit 2 / Months 6-15	Visit 3 / Months 9-15	Visit 4 / Months 12-20	Visit 5 /	Every 3 months
Informed Consent[1]	X						
Inclusion/Exclusion Criteria	X						
Adverse Events	X	X	X	X	X	X	X
Randomization/Assignment to Intervention	X						
Administration of Study Intervention to intervention group	X						
Protocol-Specific Assessments/Procedures	X	X	X	X	X	X	X
Administration of study intervention to wait-list control group			X	X			

[1] Informed consent must be obtained prior to any study-specific procedures and may be obtained prior to the screening window.

6.2 Study Procedures and Assessments

6.2.1 Screening Period / Visit -1 (Months 1 to 6)

After an individual provides informed consent, the following activities will be performed during the Screening Period:

- Inclusion/exclusion criteria review
- Adverse Events assessment
- Protocol-specific assessments/procedures
- Randomization/Assignment to Intervention
- Administration of study intervention

6.2.2 Study Intervention Period

6.2.2.1 Visit 1 (Months 3 to 12)

- Adverse Events assessment
- Protocol-specific assessments/procedures

6.2.2.2 Visit 2 (Months 6 to 15)

- Adverse Events assessment
- Protocol-specific assessments/procedures
- Administration of study intervention to wait-list control groups

6.2.2.3 Visit 3 (Months 9 to 15)

- Adverse Events assessment
- Protocol-specific assessments/procedures for waitlist control group (3-month follow-up)

6.2.2.4 Visit 4 (Months 12 to 20)

- Adverse Events assessment
- Protocol-specific assessments/procedures for waitlist control group (6-month follow-up)

6.2.3 End of Study Intervention / Visit 5

- Placement of the air nicotine monitor (6 month follow-up)
- **Air nicotine assessment procedures**. At 6 months follow-up, we will chose a random sample of participants in the intervention and waitlist control groups, approximately 50% of the sample (N=200), stratified by those reporting a smoke-free home for ≥90 days, < 90 days, and not at all to validate self-reports of adoption using passive air nicotine monitoring. These monitors which include a plastic container that contain a sodium bisulfate-coated filter will be purchased from and analyzed via gas chromatography by

the UCSF Hele Diller Family Comprehensive Cancer Center Tobacco Biomarkers Core.[101] Staff will obtain permission at the time of informed consent to place monitors in residents' rooms for 7 days,[32] within one week of completion of the 6-month interview. Monitors will be placed at least 1 foot away from windows, corners of the room, and exits.[32] We will use a threshold of ≤0.9743 μg/m^3 (sensitivity=69.5% and specificity=81.2%) for a home to be smoke-free.[32]

6.2.4 Follow-up

Participants will be followed every 3 months for up to 6 months after discontinuing the study intervention. The following procedures will be performed at each follow-up time point:

- Adverse Events assessment

7 Reporting and Documentation of Results

7.1 Measures and Instruments

Data collection. Questionnaires designed in REDCap will be administered by study staff using an iPad. Intervention and wait-list control participants will complete questionnaires at baseline, 3-, and 6 months follow-up. Wait-list control group participants who cross over to the intervention arm will also complete questionnaires at 9- and 12-months follow-up (3- and 6-months following the intervention).

PSH resident measures. Demographics. We will obtain information on age, sex (sex assigned at birth, current gender), race/ethnicity, education, income from all sources, marital status, and number of smokers in the household. Social determinants of health. We will obtain information on unmet subsistence needs (insufficient access to food, clothing, utilities),[81] social and instrumental support,[82,83] lifetime history of homelessness, length of stay in current residence, other housing circumstances (e.g., loss of housing), and exposure to urban life stressors.[84] Alternative tobacco, nicotine product and cannabis use. We will assess ever and past 30-days use and indoor use of e-cigarettes, cigars/little cigars, smokeless tobacco, pipe tobacco, hookah, blunts, and cannabis. Nicotine dependence and smoking cessation. We will assess Fagerstrom's test for nicotine dependence[85] craving [86], impulsivity [87], cigarette smoking behaviors, cigarette quit attempts (ever, in the past year, and since the last visit), length of the last quit attempt, longest time abstinent, and use of cessation aids.[88] Smoke-free policy measures.[9] We will assess knowledge of current no-smoking policies, frequency of past-month exposure to SHS, attitudes toward smoke-free policies and indoor cannabis use, knowledge and skills related to smoke-free home adoption, and barriers to smoke-free home adoption.[9] Measures related to voluntary smoke-free home adoption.[9,14] We will ask whether participants adopted a smoke-free home voluntarily in the past 90 days and the length of the last adoption, which will be used to define our primary outcome. We will ask those who reported a smoke-free home when they last smoked in their home. We will ask participants to report when they adopted a smoke-free home and when they quit smoking in the past 90 days. We will assess whether they attempted to quit at the same time as they adopted a smoke-free home, adopted a smoke-free home and quit later, or adopted a smoke-free home but did not quit. Expenditures for tobacco use. We will obtain information on the amount of money spent on tobacco in the past week, which we will use to estimate tobacco-related expenditures. Chronic diseases. We

will ask about diagnoses of liver disease, renal disease, cardiovascular disease, hypertension, diabetes, cancer, pulmonary disease, and HIV.[89] Mental health. We will conduct the Mini International Neuropsychiatric Interview v.6.0 (MINI 6.0) [90-93] to assess DSM-IV and ICD-10 psychiatric diagnoses (lifetime and current diagnosis for depression, bipolar I and II, posttraumatic stress disorder, psychotic disorders, and generalized anxiety disorder). Alcohol and substance use disorders. We will administer the Alcohol, Smoking and Substance Involvement Screening Test version 3.0 (WHO-ASSIST) to assess alcohol and substance use.[94-97] To assess alcohol volume consumed, we will administer the Alcohol Use Disorders Identification Test (AUDIT-C).[98,99] Satisfaction and usefulness of the intervention. At 3- and 6-months follow-up, we will evaluate satisfaction using a Likert scale and usefulness using a previously validated item by asking, 'In the past three months, what role did the intervention play in helping you adopt a smoke-free home or quit smoking?' Evaluating exposure to and use of cessation referrals by PSH staff. At 3- and 6-months follow-up, we will ask residents whether they had encounters with PSH staff where they were offered cessation referrals, the number of such encounters in the past 3 months, satisfaction and usefulness of these interactions, and use of these referrals to cessation services since the last visit. COVID-19 response. Given that tobacco smoking increases risk of developing COVID-19 and worsens prognosis from COVID-19 if infected, we will ask participants to describe: (1) ways in which COVID-19 has impacted their tobacco use and cessation behaviors, (2) their awareness of COVID-19, (3) whether they were diagnosed and/or exposed to someone with COVID-19 since the onset of the pandemic, (4) whether they are able to socially distance, (5) their tobacco use and COVID-19 harm perceptions (e.g., perceived risk of COVID-19 to people who are smoking or exposed to SHS), (6) how COVID-19 has impacted rules around smoking in their home, and (7) how COVID-19 has influenced their engagement in the smoke-free home intervention. We included these questions to explore whether the COVID-19 pandemic has motivated a change in smoking behavior, and whether shelter in place restrictions has impacted participants' ability to smoke outdoors.

PSH staff measures: Staff will be asked to complete the Smoking Knowledge Attitudes Practices(SKAP) survey at baseline, 3- and 6-months follow-up.[14,44,69] Staff will report on demographics, role in the facility, smoking history, policies around smoking (e.g., policies restricting e-cigarette and/or cannabis use indoors, provision of on-site cessation services), enforcement of any current smoke-free policies (complaints about the policy, issuance of warnings, or evictions), and barriers to enforcement of current policies. At 3- and 6-months, staff will answer questions on usefulness and satisfaction with the intervention, and whether they referred residents to smoking cessation programs.

8 Adverse Events and Serious Adverse Events

8.1 Definition of Adverse Event

An adverse event (AE) is defined as any untoward medical occurrence associated with the use of an intervention in humans, whether or not considered intervention related.

8.2 Definition of Serious Adverse Event

An AE that results in any of the following outcomes is defined as a Serious Adverse Event:

- Death,

- Life-threatening adverse experience*,
- Inpatient hospitalization or prolongation of existing hospitalization,
- Persistent or significant disability/incapacity,
- Congenital anomaly/birth defect, or cancer, or
- Any other experience that suggests a significant hazard, contraindication, side effect or precaution that may require medical or surgical intervention to prevent one of the outcomes listed above,
- Event that changes the risk/benefit ratio of the study.

*A life-threatening adverse experience is any AE that places the patient or subject, in the view of the investigator, at immediate risk of death from the reaction as it occurred, i.e., it does not include a reaction that, had it occurred in a more severe form, might have caused death.

8.3 Classification of Adverse Events

8.3.1 Severity

Adverse events are graded according to the Common Terminology Criteria for Adverse Events (CTCAE) as developed and revised by the Common Therapy Evaluation Program (CTEP) of the National Cancer Institute.

8.3.2 Attribution

Adverse events are further given an assignment of attribution or relationship to study intervention or procedure. Attribution categories are:

- **Definite** – The adverse event is clearly related to the study intervention or procedure.
- **Probable** – The adverse event is likely related to the study intervention or procedure.
- **Possible** – The adverse event may be related to the study intervention or procedure.
- **Unrelated** – the adverse event is clearly not related to the study intervention or procedure.

8.3.3 Expectedness

An adverse event is considered unexpected if it is not listed in the investigator brochure or package insert(s), or is not listed at the specificity or severity that has been observed, or, if an investigator brochure is not required or available, the event is not consistent with the risk information described in the general investigational plan or elsewhere in the current application.

8.4 Adverse Events Monitoring

This study is a minimal risk level study that does not require monitoring by the HDFCCC Data and Safety Monitoring Committee (DSMC) as per the National Cancer Institute-approved Data and Safety Monitoring Plan. Ultimately, the PI is responsible for the safety and conduct of this study.

8.5 Follow up of Adverse Events

All participants who experience adverse events will be followed with appropriate medical management until resolved or stabilized, as determined by the investigator.

8.6 Documenting and Reporting of Adverse Events

Adverse Events will be documented in the study Case Report Forms (CRFs) and reported to the IRB, HDFCCC DSMC, and collaborators in accordance with all applicable institutional and regulatory requirements.

9 Statistical Considerations

9.1 Sample Size Considerations

9.1.1 Sample Size and Power Estimate

Our study is powered to assess both the primary outcome of smoke-free home adoption ≥90 days and the secondary outcome of point prevalence abstinence at 6-months follow-up. We designed the RCT to detect medium-large effect sizes, which are consistent with estimates from our pilot study [14] and from other studies of brief interventions to increase adoption of smoke-free homes (intervention effect ≥40% versus control effect ~25%).[32,139] Power analyses assumed 80% power; two-tailed alpha of 0.05; N=400 smoking residents recruited from 20 PSH units; 80% retention at 6-months; average 6-month site cluster size of 16 residents; group comparisons of 6-month binary outcomes describing adoption of a smoke-free home for ≥90 days and point prevalence abstinence from preliminary data, expected 6-month control group outcome rates of 12% and 4% for smoke-free home adoption and point prevalence abstinence, respectively; from preliminary data, intra-site outcome correlations of 0.077 (ρ_{SFH}) and zero (ρ_{PPA}); and mixed logistic models including random intercepts for sites. Estimated design effects equaled $1+(16-1)\rho_{SFH}=2.16$ and $1+(16-1)\rho_{PPA}=1.0$, respectively. For the primary outcome of voluntary smoke-free home adoption, the minimum detectable effect for the intervention group is 30.3% compared to 12% for the control group, which compares favorably with 31.3% obtained in our pilot study as well.[14] For the secondary outcome of point prevalence abstinence at 6 months, the minimum detectable effect in the intervention group is 12.6% compared to 4% in the control group, which compares favorably with 16.9% obtained in the pilot study.[14]

9.1.2 Randomization and Blinding

See Section 3.1

9.1.3 Stratification Factors

We will create two sets of 10 housing sites balanced on preexisting variables describing relevant characteristics of sites and their residents, e.g., property size, current smoking-related policies, and geographic location.

9.1.4 Accrual Estimates

We anticipate recruiting all 400 participants within 1 year.

9.2 Interim Analyses and Stopping Rules

Not applicable

9.3 Statistical Analysis Plans

Descriptive analyses and missing data. We will estimate means and proportions, variation, and confidence intervals for demographic and other covariates. We will consider relevant biological variables of age, sex, and race/ethnicity. We will examine patterns of smoke-free home adoption and cessation behaviors at each visit to assess whether quitting took place in the context of voluntary adoption of a smoke-free home. We will determine whether participant baseline characteristics are independent of intervention group assignment (randomization check) and attrition (attrition analysis). Missing data will be accommodated by multiple imputation.[103-105]

9.3.1 Analysis Populations

Not applicable

9.3.2 Primary Analysis (or Analysis of Primary Endpoints)

The primary outcome is self-reported voluntary adoption of smoke-free homes for ≥90 days at 6 months follow-up. Primary analyses include intention-to-treat comparisons. The 3-level data structure—including PSH housing site, residents, and repeated assessments—will be accommodated by mixed logistic models with random intercepts for sites and residents. The primary outcome will be a binary indicator of adopting a smoke-free home which, in an intention-to-treat analysis, will be regressed onto indicators of experimental groups, categorical time (baseline, 3 months, 6 months), and the group-by-time interaction. Any significant intervention group main effect at follow-up and group-by-time interaction effect will be interpreted and described. If any key demographic or risk factors are imbalanced at baseline, we will include a propensity score-based adjustment.[106-108]

9.3.3 Secondary Analysis (or Analysis of Secondary Endpoints)

The secondary outcome is point prevalence abstinence at 6 months follow-up. A secondary analysis will fit a mixed logistic model of the secondary outcome, point prevalence abstinence. Additional analyses will explore mediators (e.g., skills related to smoke-free home adoption, use of referrals to counseling) and moderators (e.g., children or pets at home, indoor cannabis use or other combustible tobacco and nicotine product use) of intervention effects on smoke-free home and point prevalence abstinence outcomes via mixed effects regression models. Replicability of within-group changes on primary and secondary outcomes will be tested by comparing baseline to 6-month changes in the intervention group to corresponding 6- to 12-month changes in the waitlist group.

9.3.4 Exploratory/Correlative Analysis/Assessments

Analyses of PSH staff data will include a pre-post training analysis of the smoking knowledge, attitudes, practices, efficacy, and barriers scale using mixed linear models. We will fit mixed linear regression models to examine factors associated with change in each of the scales, clustering by site and staff participant ID, and adjusting for demographics, staff smoking status, encounters with residents on providing referrals for cessation, and staff role in the PSH site

(e.g., case manager). We will examine unadjusted SKAP scores by PSH staff attendance of training, smoking status, PSH site and geographic location.

We will examine changes

10 Study Management

10.1 Pre-study Documentation

Before initiating this trial, the PI will have written and dated approval from the Institutional Review Board for the protocol, written informed consent form, subject recruitment materials, and any other written information to be provided to participants before any protocol related procedures are performed on any participants.

The PI must comply with GCP/ICH guidelines and all applicable regulatory requirements.

10.2 Institutional Review Board Approval

The protocol, the proposed informed consent form, and all forms of participant-facing materials related to the study (e.g., advertisements used to recruit participants) will be reviewed and approved by the IRB. The initial protocol and all protocol amendments must be approved by the IRB prior to implementation.

10.3 Informed Consent

All participants must be provided a consent form describing the study with sufficient information for each participant to make an informed decision regarding their participation. Participants must sign the IRB-approved informed consent form prior to participation in any study specific procedure. The participant must receive a copy of the signed and dated consent document. The original signed copy of the consent document must be retained in the medical record or research file.

10.4 Changes in the Protocol

Once the protocol has been approved by the IRB, any changes to the protocol must be documented in the form of an amendment. The amendment must be signed by the PI and approved by the IRB prior to implementation.

If it becomes necessary to alter the protocol to eliminate an immediate hazard to participants, an amendment may be implemented prior to IRB approval. In this circumstance, however, the PI must then notify the IRB according to institutional requirements.

10.5 Case Report Forms (CRFs)

The PI and/or designee will prepare and maintain adequate and accurate participant case histories with observations and data pertinent to the study. Study specific Case Report Forms (CRFs) will document study data for safety monitoring and data analysis. All study data will be entered into OnCore® or other CTMS used for the study via standardized CRFs in accordance with the CTMS study calendar, using single data entry with a secure access account.

The information collected on CRFs shall be identical to that appearing in original source documents. Source documents will be found in the participant's medical records maintained by study personnel. All source documentation should be kept in separate research files for each participant.

In accordance with federal regulations, the PI is responsible for the accuracy and authenticity of data entered onto CRFs. The PI will approve all completed CRFs to attest that the information contained on the CRFs is true and accurate.

All source documentation and CTMS data will be available for review/monitoring.

10.6 Record Retention

The PI is required to prepare and maintain adequate and accurate case histories that record all observations and other data pertinent to the investigation on each study participant. Study documentation includes all CRFs, data correction forms or queries, source documents, Sponsor-Investigator correspondence, monitoring logs/letters, and regulatory documents (e.g., protocol and amendments, IRB correspondence and approval, signed participant consent forms). Source documents include all recordings of observations or notations of clinical activities and all reports and records necessary for the evaluation and reconstruction of the clinical research study. The PI shall retain records for a period of 2 years following the conclusion of the study.

10.7 Publications

The preparation and submittal for publication of manuscripts containing the study results shall be in accordance with a process determined by mutual written agreement among the Sponsor-Investigator and collaborators.

11 References

1. Tsemberis S, Gulcur L, Nakae M. Housing First, consumer choice, and harm reduction for homeless individuals with a dual diagnosis. Am J Public Health 2004;94(4):651-6.
2. The McKinney-Vento Homeless Assistance Act. General definition of homeless individuals. 2009. Available at: https://www.hud.gov/sites/documents/HAAA_HEARTH.PDF.
3. The Department of Housing and Urban Development. The 2017 Annual Homeless Assessment Report to Congress. Available at: https://files.hudexchange.info/resources/documents/2017-AHAR-Part-1.pdf.
4. U.S. National Cancer Institute. A Socioecological Approach to Addressing Tobacco-Related Health Disparities. National Cancer Institute Tobacco Control Monograph 22. NIH Publication No. 17-CA-8035A. Bethesda, MD: U.S. Department of Health and Human Services, National Institutes of Health, National Cancer Institute; 2017.
5. Baggett TP, Tobey ML, Rigotti NA. Tobacco use among homeless people--addressing the neglected addiction. N Engl J Med;369(3):201-4.
6. Petersen AB, Stewart HC, Walters J, Vijayaraghavan M. Smoking Policy Change Within Permanent Supportive Housing. J Community Health 2018;43:312-20.
7. Henwood BF, Byrne T, Scriber B. Examining mortality among formerly homeless adults enrolled in Housing First: An observational study. BMC Public Health 2015;15:1209.
8. Petersen AB, Elser H, Nguyen T, Alizaga NM, Vijayaraghavan M. Smoke-Free or Not: Attitudes Toward Indoor Smoke-Free Policies Among Permanent Supportive Housing Residents. Am J Health Promot 2020;34(1):32-41.
9. Alizaga NM, Nguyen T, Petersen AB, Elser H, Vijayaraghavan M. Developing Tobacco Control Interventions in Permanent Supportive Housing for Formerly Homeless Adults. Health Promot Pract 2019:1524839919839358.

10. Petersen AB, Holly Elser, Nguyen T, Alizaga N, Vijayaraghavan M. Smoke-free or not: Attitudes toward indoor smoke-free policies among supportive housing residents. Presented at the American Public Health Association Annual Metting, November 13, 2018 Available at: https://apha.confex.com/apha/2018/meetingapp.cgi/Paper/413104.

11. Department of Housing and Urban Development. Instituting Smoke-Free Public Housing. 24 CFR Parts 965 and 966 [Docket No FR 5597-P-02] RIN 2577-AC97 2015; Available at: https://www.hud.gov/sites/documents/SMOKEFREEPHFINALRULE.PDF.
12. Department of Housing and Urban Development, Office of Public and Indian Housing. Implementing HUD's smoke-free policy in public housing. 2017. Available at: https://www.hud.gov/sites/documents/SMOKEFREE_GUIDEBK.PDF.
13. IARC Handbooks of Cancer Prevention, Tobacco Control, Vo. 13. Evaluating the Effectiveness of Smoke-free Policies. (2009: Lyon, France).
14. Durazo A, Hartman-Filson M, Perez K, Alizaga NM, Petersen AB, Vijayaraghavan M. Smoke-Free Home Intervention in Permanent Supportive Housing: A Multi-Faceted Intervention Pilot. Nicotine Tob Res 2020.[Epub ahead of print]
15. National Academies of Sciences Engineering, and Medicine. 2018. Permanent Supportive Housing: Evaluate the Evidence for Improving Health Outcomes Among People Experiencing Chronic Homelessness. Washignton, DC: The National Academies Press.
16. Stergiopoulos V, Gozdzik A, Misir V, et al. Effectiveness of Housing First with Intensive Case Management in an Ethnically Diverse Sample of Homeless Adults with Mental Illness: A Randomized Controlled Trial. PLoS One 2015;10(7):e0130281.
17. Basu A, Kee R, Buchanan D, Sadowski LS. Comparative cost analysis of housing and case management program for chronically ill homeless adults compared to usual care. Health Serv Res 2012;47(1pt2):523-43.
18. Alcaraz KI, Wiedt TL, Daniels EC, Yabroff KR, Guerra CE, Wender RC. Understanding and addressing social determinants to advance cancer health equity in the United States: A blueprint for practice, research, and policy. CA Cancer J Clin 2020;70(1):31-46.
19. Sebrie EM, Sandoya E, Bianco E, Hyland A, Cummings KM, Glantz SA. Hospital admissions for acute myocardial infarction before and after implementation of a comprehensive smoke-free policy in Uruguay: experience through 2010. Tob Control 2013;22(e1)e16-20.
20. Lightwood JM, Glantz SA. Declines in acute myocardial infarction after smoke-free laws and individual risk attributable to secondhand smoke. Circulation 2009;120(14):1373-9.
21. Hahn EJ, Rayens MK, Wiggins AT, Gan W, Brown HM, Mullett TW. Lung cancer incidence and the strength of municipal smoke-free ordinances. Cancer 2018;124(2):374-80.
22. U.S. Department of Health and Human Services. The Health Consequences of Smoking—50 Years of Progress: A Report of the Surgeon General. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2014.
23. Cheng KW, Glantz SA, Lightwood JM. Association between smokefree laws and voluntary smokefree-home rules. Am J Prev Med;41(6):566-72.
24. Borland R, Yong HH, Cummings KM, Hyland A, Anderson S, Fong GT. Determinants and consequences of smoke-free homes: findings from the International Tobacco Control (ITC) Four Country Survey. Tob Control 2006;15 Suppl 3:iii42-50.
25. Snyder K, Vick JH, King BA. Smoke-free multiunit housing: a review of the scientific literature. Tobacco Control 2016;25(1):9-20.
26. Mills AL, Messer K, Gilpin EA, Pierce JP. The effect of smoke-free homes on adult smoking behavior: a review. Nicotine Tob Res 2009;11(10):1131-41.

27. Hyland A, Higbee C, Travers MJ, et al. Smoke-free homes and smoking cessation and relapse in a longitudinal population of adults. Nicotine Tob Res 2009;11(6):614-8.
28. Vijayaraghavan M, Benmarnhia T, Pierce JP, et al. Income disparities in smoking cessation and the diffusion of smoke-free homes among U.S. smokers: Results from two longitudinal surveys. PLoS One 2018;13(7):e0201467.
29. Vijayaraghavan M, King BA. Advancing Housing and Health: Promoting Smoking Cessation in Permanent Supportive Housing [published online ahead of print, 2020 Apr 30]. Public Health Rep. 2020;33354920922374.
30. Office of Policy Development and Research. Smoke-free Public Housing: Research and Implementation. Available at: https://www.huduser.gov/portal/periodicals/em/winter16/highlight2.html#title 2016.
31. Vijayaraghavan M, Messer K, White MM, Pierce JP. The effectiveness of cigarette price and smoke-free homes on low-income smokers in the United States. Am J Public Health;103(12):2276-83.
32. Kegler MC, Bundy L, Haardorfer R, et al. A minimal intervention to promote smoke-free homes among 2-1-1 callers: a randomized controlled trial. Am J Public Health 2015;105(3):530-7.
33. Vijayaraghavan M, Pierce JP. Interest in Smoking Cessation Related to a Smoke-Free Policy Among Homeless Adults. J Community Health 2015;40(4):686-91.
34. Vijayaraghavan M, Hurst S, Pierce JP. A Qualitative Examination of Smoke-Free Policies and Electronic Cigarettes Among Sheltered Homeless Adults. Am J Health Promot 2017;31(3):243-50.
35. Vijayaraghavan M, Penko J, Vittinghoff E, Bangsberg DR, Miaskowski C, Kushel MB. Smoking Behaviors in a Community-Based Cohort of HIV-Infected Indigent Adults. AIDS Behav 2014; 18(3): 535–543.
36. Creamer MR, Wang TW, Babb S, et al. Tobacco Product Use and Cessation Indicators Among Adults - United States, 2018. MMWR Morb Mortal Wkly Rep 2019;68(45):1013-9.
37. Vijayaraghavan M, Tieu L, Ponath C, Guzman D, Kushel M. Tobacco Cessation Behaviors Among Older Homeless Adults: Results From the HOPE HOME Study. Nicotine Tob Res 2016;18(8):1733-9.
38. Neisler J, Reitzel LR, Garey L, et al. Concurrent nicotine and tobacco product use among homeless smokers and associations with cigarette dependence and other factors related to quitting. Drug Alcohol Depend 2018;185:133-40.
39. Vijayaraghavan M, Neisler J, Wrighting Q, et al. Income associations with cigarette purchasing behaviors and quit attempts among people experiencing homelessness. Addict Behav 2019;95:197-201.
40. Breatheeasymaine.org. Secondhand smoke. 2018. Available from: https://breatheeasymaine.org/wp-content/uploads/2018/07/BE_RackCardSecondhand.pdf.
41. Breatheeasymaine.org. Thirdhand smoke. 2018. Available from: https://breatheeasymaine.org/wp-content/uploads/2018/07/BE_RackCardThirdhand.pdf.
42. Centers for Disease Control and Prevention. Secondhand smoke can infiltrate into other units through hallways and stairwells. 2018. Available from: https://www.cdc.gov/tobacco/infographics/secondhand-smoke/pdfs/secondhand-smoke.pdf?s_cid=bb-osh-shs-graphic-006.
43. Truth Initiative. Secondpaw smoke kills. 2018. Available from: https://truthinitiative.org/research-resources/topic/tobacco-prevention-efforts.
44. Delucchi KL, Tajima B, Guydish J. Development of the Smoking Knowledge, Attitudes, and Practices (S-KAP) Instrument. J Drug Issues 2009;39(2):347-64.
45. Kushel MB, Colfax G, Ragland K, Heineman A, Palacio H, Bangsberg DR. Case management is associated with improved antiretroviral adherence and CD4+ cell counts in

homeless and marginally housed individuals with HIV infection. Clin Infect Dis 2006;43(2):234-42.
46. Kushel MB, Perry S, Bangsberg D, Clark R, Moss AR. Emergency department use among the homeless and marginally housed: results from a community-based study. Am J Public Health 2002;92(5):778-84.
47. Weiser SD, Bangsberg DR, Kegeles S, Ragland K, Kushel MB, Frongillo EA. Food insecurity among homeless and marginally housed individuals living with HIV/AIDS in San Francisco. AIDS Behav 2009;13(5):841-8.
48. Vijayaraghavan M, Penko J, Guzman D, Miaskowski C, Kushel MB. Primary Care Providers' Judgments of Opioid Analgesic Misuse in a Community-Based Cohort of HIV-Infected Indigent Adults. J Gen Intern Med 2011;26(4):412-8.
49. Miaskowski C, Penko J, Guzman D, Mattson J, Bangsberg DR, Kushel MB. Occurrence and characteristics of chronic pain in a community-based cohort of indigent adults living with HIV infection. J Pain 2011; 12(9):1004-16.
50. Vijayaraghavan M, Penko J, Bangsberg DR, Miaskowski C, Kushel MB. Opioid Analgesic Misuse in a Community-Based Cohort of HIV-Infected Indigent Adults. JAMA Intern Med;173(3):235-7.
51. Vijayaraghavan M, Yuan P, Gregorich S, et al. Disparities in receipt of 5As for smoking cessation in diverse primary care and HIV clinics. Prev Med Rep 2017;6:80-7.
52. Alcaraz KI, Vereen RN, Burnham. Use of Telephone and Digital Channels to Engage Socioeconomically Disadvantaged Adults in Health Disparities Research within a Social Service Setting: Cross-Sectional Study. Journal of Medical Internet Research 2020. In Press.
53. Handley MA, Harleman E, Gonzalez-Mendez E, Stotland NE et al. Applying the COM-B model to creation of an IT-enabled health coaching and resource linkage program for low-income Latina moms with recent gestational diabetes: the STAR MAMA program. Implement Sci 2016;11(1):73.
54. Kaplan CP, Livaudais-Toman J, Tice JA, et al. A randomized, controlled trial to increase discussion of breast cancer in primary care. Cancer Epidemiol Biomarkers Prev 2014;23(7):1245-53.
55. Wang EA, Hong CS, Shavit S, Sanders R, Kessell E, Kushel MB. Engaging individuals recently released from prison into primary care: a randomized trial. Am J Public Health 2012;102(9):e22-9.
56. Tuot DS, McCulloch CE, Velasquez A, Schillinger D, Hsu CY, Handley M, Powe NR. Impact of a primary care CKD registry in a US public safety-net health care delivery system: A pragmatic randomized trial. Am J Kidney Dis 2018;72(2):168-77.
57. Satterfield JM, Gregorich SE, Kalkhoran S, et al. Computer-Facilitated 5A's for Smoking Cessation: A Randomized Trial of Technology to Promote Provider Adherence. Am J Prev Med 2018;55(1):35-43.
58. Kreuter MW, Eddens KS, Alcaraz KI, et al. Use of cancer control referrals by 2-1-1 callers: a randomized trial. Am J Prev Med 2012;43(6suppl5):S425-34.
59. Sung H, Penko J, Cummins SE, Max W, Zhu SH, Bibbins-Domingo K, Kohatsu N. Economic Impact of Financial Incentives and Mailing Nicotine Patches to Help Medicaid Smokers Quit Smoking: A Cost–Benefit Analysis. Am Journal of Preventive Medicine 2018;55(6suppl2):S148-S58.
60. Miller LS, Max W, Sung H, Rice D, Zaretsky M. Evaluation of the economic impact of the California tobacco control program: a dynamic model approach. Tob Control 2010;19(Suppl1):i68-i76.
61. Thompson LM, Diaz-Artega A, Weinstein JR, Handley MA. Designing a behavioral intervention using the COM-B model and theoretical domains framework to promote gas stove use in rural Guatemala. a formative research study. BMC Public Health 2018;18(1):253.

62. Mangurian C, Niu GC, Schillinger D, Newcomer JW, Dilley J, Handley MA. Utilization of the behavior change wheel framework to develop a model to improve cardiometabolic screening for people with severe mental illness. Implement Sci 2017;12(1):134.
63. Alcaraz KI, Arnold LD, Eddens KS, et al. Exploring 2-1-1 service requests as potential markers for cancer control needs. Am J Prev Med 2012;43(6suppl1):S469-74.
64. Vijayaraghavan M, Hurst S, Pierce JP. Implementing Tobacco Control Programs in Homeless Shelters: A Mixed-Methods Study. Health Promot Pract 2015;17(4),501-11.
65. Napoles AM, Appelle N, Kalkhoran S, Vijayaraghavan M, Alvarado N, Satterfield J. Perceptions of clinicians and staff about the use of digital technology in primary care: qualitative interviews prior to implementation of a computer-facilitated 5As intervention. BMC Med Inform Decis Mak 2016;16:44.
66. Kim-Hwang JE, Chen AH, Bell DS, Guzman D, Yee HF, Jr., Kushel MB. Evaluating electronic referrals for specialty care at a public hospital. J Gen Intern Med;25(10):1123-8.
67. Wang EA, Hong CS, Samuels L, Shavit S, Sanders R, Kushel M. Transitions clinic: creating a community-based model of health care for recently released California prisoners. Public Health Rep;125(2):171-7.
68. Chan B, Goldman LE, Sarkar U, et al. The Effect of a Care Transition Intervention on the Patient Experience of Older Multi-Lingual Adults in the Safety Net: Results of a Randomized Controlled Trial. J Gen Intern Med 2015;30(12):1788-94.
69. Vijayaraghavan M, Guydish J, Pierce JP. Building Tobacco Cessation Capacity in Homeless Shelters: A Pilot Study. J Community Health 2016;41(5):998-1005.

70. Kertesz SG, Baggett TP, O'Connell JJ, Buck DS, Kushel MB. Permanent Supportive Housing for Homeless People - Reframing the Debate. N Engl J Med. 2016;375(22):2115-2117.

71. Bhatnagar A, Whitsel L, Blaha MJ, Huffman MD, Krishnan-Sarin Suchitra, Maa J, Rigotti N, Robertson RM, and Warner JJ, on behalf of the American Heart Association. New and Emerging Tobacco Products and the Nicotine Endgame: The Role of Robust Regulation and Comprehensive Tobacco Control Prevention: A Presidential Advisory From the American Heart Association. Circulation 2019;139(19):e937-58.
72. ChangeLab Solutions. Available at: https://www.changelabsolutions.org/tobacco-prevention.
73. Americans for Nonsmokers' Rights Foundation. Available at: https://no-smoke.org/about-us/.
74. Michie S, M Van, Strale M, West R. The behavior change wheel: A new method for characterising and designing behavior change interventions. Implement Sci 2011;6:1-11.
75. Donner A and Klar N. Pitfalls of and controversies in cluster randomization trials. Am J Public Health 2004;94(3):416-22.
76. Hayes RJ and Moutton LH. (2009) Cluster Randomized Trials, Second Edition. Chapman&Hall/CRC Biostatistics Series.
77. SRNT Subcommittee on Biochemical Verification. Biochemical Verification of tobacco use and cessation. Nicotine Tob Res 2001;4:149-59.
78. Sudore RL, Landefeld CS, Williams BA, Barnes DE, Lindquist K, Schillinger D. Use of a modified informed consent process among vulnerable patients: a descriptive study. J Gen Intern Med 2006;21(8):867-73.
79. University of California, San Francisco. Rx. for change. Available at: http://rxforchange.ucsf.edu.
80. Fiore MC, Bailey WC, Cohen SJ, et al. Treating tobacco use and dependence: A quick reference guide for clinicians. Rockville, MD: US Department of Health and Human Services, October 2000.

81. Gelberg L, Gallagher T, Andersen R, Koegel P. Competing priorities as a barrier to medical care among homeless adults in Los Angeles. Am J Public Health 1997;87(2):217-20.
82. Gielen AC, McDonnell KA, Wu AW, O'Campo P, Faden R. Quality of life among women living with HIV: the importance violence, social support, and self care behaviors. Soc Sci Med 2001;52(2):315-22.
83. Tsay SL, Halstead MT, McCrone S. Predictors of coping efficacy, negative moods and post-traumatic stress syndrome following major trauma. Int J Nurs Pract 2001;7(2):74-83.
84. Jaffee KD, Liu GC, Canty-Mitchell J, Qi RA, Austin J, Swigonski N. Race, urban community stressors, and behavioral and emotional problems of children with special health care needs. Psychiatr Serv 2005;56(1):63-9.
85. Heatherton TF, Kozlowski LT, Frecker RC, Fagerstrom KO. The Fagerstrom Test for Nicotine Dependence: a revision of the Fagerstrom Tolerance Questionnaire. Br J Addict 1991;86(9):1119-27.
86. Halikas JA, Kuhn KL, Crosby R, Carlson G, Crea F. The measurement of craving in cocaine patients using the Minnesota Cocaine Craving Scale. Compr Psychiatry 1991;32(1):22-7.
87. Patton JH, Stanford MS, Barratt ES. Factor structure of the Barratt impulsiveness scale. J Clin Psychol 1995;51(6):768-74.
88. Al-Delaimy W, Edland S, Pierce JP, Mills AL, White MM. California Tobacco Survey (CTS): 2008. UC San Diego Library Digital Collections. Available at: http://dx.doi.org/10.6075/J0H41PBM.
89. Centers for Disease Control and Prevention (2017). National Health Interview Survey. Available at: https://www.cdc.gov/nchs/nhis/data-questionnaires-documentation.htm.
90. Lecrubier Y, Sheehan DV, Weiller E, et al. The Mini International Neuropsychiatric Interview (MINI). A short diagnostic structured interview: reliability and validity according to the CIDI. European Psychiatry 1997;12:224-31.
91. Sheehan DV, Lecrubier Y, Harnett Sheehan K, et al. The validity of the Mini International Neuropsychiatric Interview (MINI) according to the SCID-P and its reliability. European Psychiatry 1997;12:232-41.
92. Sheehan DV, Lecrubier Y, Sheehan KH, et al. The Mini-International Neuropsychiatric Interview (M.I.N.I.): the development and validation of a structured diagnostic psychiatric interview for DSM-IV and ICD-10. The Journal of clinical psychiatry 1998;59 Suppl 20:22-33;quiz 4-57.
93. Amorim P, Lecrubier Y, Weiller E, Hergueta T, Sheehan D. DSM-IH-R Psychotic Disorders: procedural validity of the Mini International Neuropsychiatric Interview (MINI). Concordance and causes for discordance with the CIDI. Eur Psychiatry 1998;13(1):26-34.
94. WHO Assist Working Group. The Alcohol, Smoking and Substance Involvement Screening Test (ASSIST): development, reliability and feasibility. Addiction 2002;97(9):1183-94.
95. Humeniuk R, Ali R, Babor TF, et al. Validation of the Alcohol, Smoking And Substance Involvement Screening Test (ASSIST). Addiction 2008;103(6):1039-47.
96. Newcombe DA, Humeniuk RE, Ali R. Validation of the World Health Organization Alcohol, Smoking and Substance Involvement Screening Test (ASSIST): report of results from the Australian site. Drug Alcohol Rev 2005;24(3):217-26.
97. The Alcohol, Smoking and Substance Involvement Screening Test (ASSIST): development, reliability and feasibility. Addiction 2002;97(9):1183-94.
98. Aalto M, Alho H, Halme JT, Seppa K. The Alcohol Use Disorders Identification Test (AUDIT) and its derivatives in screening for heavy drinking among the elderly. International journal of geriatric psychiatry 2011;26(9):881-5.
99. Bush K, Kivlahan DR, McDonell MB, Fihn SD, Bradley KA. The AUDIT alcohol consumption questions (AUDIT-C): an effective brief screening test for problem drinking.

Ambulatory Care Quality Improvement Project (ACQUIP). Alcohol Use Disorders Identification Test. Archives of internal medicine 1998;158(16):1789-95.
100. Hammond SK, Leaderer BP, Roche AC, Schenker M. Marker for environmental tobacco smoke. Atmospher Environment. 1986;21:457-72.
101. UCSF Tobacco Biomarkers Core. Available at: http://cancer.ucsf.edu/research/cores/tobacco-biomarkers/.
102. Vijayaraghavan M, Freitas D, Bangsberg DR, Miaskowski C, Kushel MB. Non-medical use of non-opioid psychotherapeutic medications in a community-based cohort of HIV-infected indigent adults. Drug Alcohol Depend 2014;143:263-7.
103. Rubin DB. Inference and missing data. Biometrika 1976;63:581-92.
104. Little R and Rubin D. Statistical analysis with missing data (2nd edition) New York,NY: Wiley 2002.
105. Schafer J. Analysis of Incomplete Multivariate Data. London: Chapman & Hall. 1997.
106. D'Agostino RB. Propensity score methods for bias reduction in the comparison of a treatment to a non-randomized control group. Statistics in Medicine 1998;17(19): 2265-81.
107. Rosenbaum PR. The central role of the propensity score in observational studies for causal effects. Biometrika 1983;60:41-55.
108. Rosenbaum PR and DB Rubin. Reducing bias in observations studies using subclassification on the propensity score. Journal of American Statistical Association 1984:516-24.
109. Cantor SB, Deshmukh AA, Luca NS, Nogueras-Gonzalez GM, Rajan T, Prokhorov AV. Cost-effectiveness analysis of smoking-cessation counseling training for physicians and pharmacists. Addict Behav 2015;45:79-86.
110. Daly AT, Deshmukh AA, Vidrine DJ, Prokhorov AV, Frank SG, Tahay PD, Houchen ME, Cantor SB. Cost-effectiveness analysis of smoking cessation interventions using cell phones in a low-income population. Tob Control 2019;28(1):88-94.
111. Lipscomb J WM, Torrance GW et al. Cost-effectiveness in health and medicine. In: Gold MR, Seigel JE, Russell LB, Weinstein MC, eds. Cost-effectiveness in Health and Medicine. New York: Oxford University Press, 1996: 214-35.
112. Rogers RG, Hummer RA, Krueger PM et al. Mortality attributable to cigarette smoking in the United States. Popul Dev Rev 2005;31:259-92.
113. Fiscella K, Franks P. Cost-effectivess of the transdermal nicotine patch as an adjunct to physicians' smoking cessation counseling. JAMA 1996;275(16):1247-51.
114. Thun MJ, Carter BD, Feskanish D, Freedan ND, Prentice R, Lopez AD, Hartage P, Gapsture SM. 50-year trends in smoking-related mortality in the United States. N Engl J Med 2013;368(4):351-64.
115. Baggett TP, Chang Y, Singer DE, et al. Tobacco-, alcohol-, and drug-attributable deaths and their contribution to mortality disparities in a cohort of homeless adults in Boston. Am J Public Health 2015;105(6):1189-97.
116. Javitz HS, Zbikowski SM, Deprey M, McAfee TA, McClure JB, Richards J, Catz SL, Jack LM, Swan GE. Cost-effectiveness of varenicline and three behavioral treatment formats for smoking cessation. Transl Behav Med 2011;1(1):182-90.
117. Aldridge RW. Homelessness and quality life years: slopes and cliffs in health inequalities a cross-sectional survey. International Journal of Epidemiology 2015;44:i80-i1.
118. Luce BR MW, Siegel JE et al. Estimating costs in cost-effectiveness analysis. In: Gold MR, Siegel JE, Russell LB, Weinstein MC, eds Cost-effectiveness in Health and Medicine New York: Oxford University Press, 1996: 176.
119. Severens JL, Milne RJ. Discounting health outcomes in economic evlauation: the ongoing debate. Value Health 2004;7(4):397-401.

120. Weinstein MC. How much are American willing to pay for a quality-adjusted life year? Med Care 2008;46(4):343-5.
121. Max W, Sung HY, Shi Y. The cost of secondhand smoke exposure at home in California. Tob Control 2015;24(2):205-10.
122. Damschroder LJ, Aron DC, Keith RE, Kirsh SR, Alexander JA, Lowery JC. Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. Implement Sci 2009;4:50.
123. Hsieh HF, Shannon SE. Three approaches to qualitative content analysis. Qual Health Res 2005;15(9):1277-88.
124. Morgan D. Commentary — After Triangulation, What next?. Journal of Mixed Methods Research 2019;13:6-14.
125. Applied Survey Research. San Francisco 2017 Homeless Count & Survey. 2017. Available at: http://hsh.sfgov.org/wp-content/uploads/2017/06/2017-SF-Point-in-Time-Count-General-FINAL-6.21.17.pdf.

126. Applied Survey Research. Alameda County 2017 Homeless Census & Survey. 2017. Available at: https://static1.squarespace.com/static/5176dcd7e4b0e5c0dba41ee0/t/5a736ebe4192029948a5e85f/1517514451369/Alameda+FINAL+REPORT+2017.pdf.
127. County of San Mateo Human Services. San Mateo County 2017 One Day Homeless Count and Survey. 2017. Available at: https://hsa.smcgov.org/2017-one-day-homeless-count.
128. Applied Survey Research. Santa Clara County 2017 Homeless Census & Survey Comprehensive Report. 2017. Available at: https://www.sccgov.org/sites/osh/ContinuumofCare/ReportsandPublications/Documents/2017%20Santa%20Clara%20County%20Homeless%20Census%20and%20Survey%20Report.pdf.
129. Appelbaum, PS and Grisso T. MacArthur competence assessment tool for clinical research (MacCAT-CR). 2001. Professional Resource Press/Professional Resource Exchange.

130. Grant A, Treweek S, Dreishulte T, Foy R and Guthrie B. Process evaluation for cluster-randomized trials of complex interventions: a proposed framework for design and reporting. Trials 2013;14:2-10.

131. Irving JM, Clark EC, Crombie IK, Smith WC. Evaluation of a portable measure of expired-air carbon monoxide. Prev Med. 1988;17(1):109-115.
132. Okuyemi KS, Goldade K, Whembolua GL, et al. Motivational interviewing to enhance nicotine patch treatment for smoking cessation among homeless smokers: a randomized controlled trial. Addiction. 2013;108(6):1136-1144.
133. Okuyemi KS, Thomas JL, Hall S, et al. Smoking cessation in homeless populations: a pilot clinical trial. Nicotine Tob Res. 2006;8(5):689-699.
134. Hall SM, Humfleet GL, Muñoz RF, Reus VI, Robbins JA, Prochaska JJ. Extended treatment of older cigarette smokers. Addiction. 2009;104(6):1043-1052.
135. Hall SM, Humfleet GL, Muñoz RF, Reus VI, Prochaska JJ, Robbins JA. Using extended cognitive behavioral treatment and medication to treat dependent smokers. Am J Public Health. 2011;101(12):2349-2356.
136. MD Spiro. CO Check+. Available at: https://mdspiro.com/image/data/PDFs/MD-MD%20Literature%20CO%20Check+.pdf.
137. Brownell KD, Roberto CA. Strategic science with policy impact. Lancet. 2015;385(9986):2445-2446.

138. Roberto CA, Brownell KD. Strategic science for eating disorders research and policy impact. Int J Eat Disord. 2017;50(3):312-314.
139. Mullen PD, Savas LS, Bundy LT, Haardorfer R, Hovell M, Fernandez M et al. Minimal Intervention Delivered by 2-1-1 Information and Referral Specialists Promotes Smoke-free Homes Among 2-1-1 Callers: A Texas Generalization Trial. Tobacco Control. 2016; 25(Suppl 1): i10-i18.