Testing C-Raven, a Virtual Tobacco Cessation Intervention, in the Community

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JHM IRB - eForm A – Protocol

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1. Abstract

a. Provide no more than a one page research abstract briefly stating the problem, the research hypothesis, and the importance of the research.

In Baltimore City public housing units, smoking prevalence often exceeds 30%, but access to cessation services can be limited by numerous barriers including time constraints, limited transportation, and associated costs. One solution to increasing access to cessation services and cancer screening is to offer tobacco cessation interventions at the housing sites. Computer-delivered interventions (CDI) for tobacco cessation are effective, and provide accessible, replicable, and scalable interventions that can be tailored to patients and delivered in non-clinical settings. Augmentation of CDI with community health workers (CHW) can extend the intervention beyond the computer-delivered services, including connecting patients with lung cancer screening and visits with primary care clinicians. Our team has developed a two-session virtual counselor-led CDI for tobacco cessation (VCTC) that includes in-session/experiential use of nicotine replacement therapy and CHW support. This intervention has been found to be both acceptable and feasible among individuals in two Baltimore City clinics. We now plan to transfer this intervention out of clinical settings to the communities where people live, in this case low-income housing units.

In anticipation of a future two-arm type 1 hybrid effectiveness-implementation randomized controlled trial comparing a VCTC augmented with CHW support to a waitlist control in low-income housing units in Baltimore City, we propose a pilot study consisting of two phases: 1) focus groups and 2) an intervention feasibility pilot that will generate preliminary data to inform our proposed intervention. Specifically, we will first develop a shared decision-making approach to low-dose chest CT (LDCT) lung cancer screening with community focus group feedback. We propose to conduct focus groups (N=2) with the target population of individuals who smoke and live in public housing in Baltimore to collect acceptability data on LDCT shared decision-making and an existing tool, as well as the proposed intervention. We will also collect information about sociocultural and personal barriers to LDCT screening and management of LDCT outcomes. We will then conduct a feasibility pilot study of the entire VCTC and CHW intervention with a sample of participants (N=15) to collect data on the feasibility of recruitment, intervention engagement and completion, and short-term smoking cessation outcomes. Individuals will be assessed at baseline, one month, and three months. At the end of three months, we will conduct follow-up interviews with a subset of pilot participants to collect qualitative data on intervention acceptability. We will also conduct exit interviews with housing

staff to gather qualitative feedback on intervention implementation and community attitudes toward smoking, lung cancer screening, and VCTC. Based on the information collected in these efforts, we will make iterative improvements to the existing intervention, aligned with user-experience design procedures.

2. Objectives (include all primary and secondary objectives)

Phase 1: To obtain feedback on an existing tool for shared decision-making for LDCT so that it can be tailored to Baltimore City residents with current or former tobacco use, as well as to gain insight on smoking and smoking cessation in the community of interest through focus groups (N=2) with individuals currently living in public housing in Baltimore City.

Phase 2: To conduct a feasibility pilot study of a VCTC and CHW intervention with a sample of participants (N=15) to evaluate feasibility, recruitment strategies, intervention engagement and completion, and short-term (3-month) smoking cessation and lung cancer screening outcomes. We will also interview housing staff at the end of three-month follow-up to gather qualitative feedback on intervention implementation and community attitudes toward smoking, lung cancer screening, and VCTC.

3. Background (briefly describe pre-clinical and clinical data, current experience with procedures, drug or device, and any other relevant information to justify the research)

The deleterious effects of smoking on health are well established, yet smoking rates remain high among low-income and minority populations. In Baltimore City, 36% of low-income residents and 52% of African Americans smoke, rates that are exceptionally high compared with the national smoking prevalence of 11.5% among US adults in 2021. Numerous barriers impede uptake and delivery of smoking cessation services, including access to medical care, transportation barriers, and cost. Even within health care settings, there are barriers including lack of provider time to address tobacco use, insufficient staff training, and lack of replicability of intervention content. To address these barriers, computer-delivered interventions (CDI) show promise in providing accessible, replicable, scalable interventions that can be tailored to patients and potentially at reduced cost compared with person delivered interventions.

With prior Maryland Cigarette Restitution Funding (CRF), we developed a 2-session virtual counselor led tobacco cessation intervention (VCTC) to deliver evidence-based smoking cessation counseling. VCTC content follows the information, motivation, and behavioral skills model with systematic content adaptation for low-income smokers in Baltimore City. The VCTC software structure uses treatment algorithms allowing client preference to drive content presentation and approximate MI style by providing choice. In cooperation with a user experience designer, we also added a virtual counselor, an avatar named Edna Poe “trained” in MI to improve engagement and interest, and improve health outcomes. The counselor was tailored, tested, and approved by our target population in Baltimore City. Intervention development went through a 5-step process: 1) The development process began with a review of evidence-based core components of smoking interventions. 2) To gather tailoring information, we conducted 14 in-depth interviews and 2 focus groups with low-income smokers from an urban HIV clinic and two Churches in Baltimore City. These revealed that participants

perceived little health benefit in smoking cessation, and were unaware that many smoking-related health consequences were reversible. All participants noted that smoking was their only way to cope with stress and that the stress in their lives was substantial. Finally, participants noted the lack of available resources and social support for smoking cessation. 3) The qualitative data were used to tailor and program VCTC and text messages (TM). 4) Using established measures to assess human computer interaction, we then tested VCTC for usability, acceptability, and usefulness in smoking cessation (8 individuals, thematic saturation achieved). Overall satisfaction with the intervention was high, with a mean score of 4.75/5 on a 1-5 Likert scale with 1 being "not at all" and 5 "very much". Participants found the system easy to use, all noted that they planned to use some of the information from the intervention to change how much or often they smoked (mean score 5/5 on 5-point Likert scale), and expressed interest in a follow-up computerized counseling session (4.75/5). On qualitative feedback, participants noted that the virtual counselor was less judgmental than a human. They specifically liked a) the "Turn Back the Clock" video that was created to describe the reversible effects of smoking noting that it was very inspirational and provided new information, and b) the "3-D's," --Delay, Discuss, Do Something Else--a behavioral technique to manage cravings. 5) We integrated this community feedback for final modifications.

We pilot tested the first session of the intervention among 40 people with HIV receiving in an urban clinic in East Baltimore. Participants were randomized to intervention or usual care. Our primary outcomes were readiness to change, and confidence in changing tobacco use, using a visual analog scale at one and two months post intervention. At one month, 89% of intervention participants compared to 74% of control participants had a quit attempt ($p=0.21$). Based on these results demonstrating increased readiness and confidence, we developed a second session focused on use of pharmacotherapy that presents information on craving, the cycle of addiction, the effects of smoking on health, and various pharmacotherapies. This session also includes an experiential guide for using pharmacotherapies that reviews proper use of nicotine replacement therapy (NRT), and real-time application of patch and use of gum or lozenge. As part of this intervention package, we trained and provided ongoing supervision to CHWs in motivational interviewing to extend the VCTC beyond the two sessions, provide cessation support, and to provide linkage to tobacco treatment services including the local Quitline. We created two manuals: 1) Tobacco Training Manual for CHWs and 2) a CHW Counseling Guide developed with CHWs.

The C-Raven package was piloted in two clinics: The Tobacco Treatment and Lung Cancer Screening Clinic (TTLCSC) at Bayview Medical Center and the Johns Hopkins Broadway Program for Addictions. The rationale for implementation in the tobacco treatment clinic was to determine whether current services could be augmented with behavioral counseling to enhance retention on NRT and/or varenicline and other pharmacotherapy among individuals in this program. The rationale for implementing the intervention at the Johns Hopkins Broadway Program for Addiction was to test the intervention in a community-based setting where there is a high need for smoking cessation programs.

Outside of the C-Raven project, a member of our study team, Dr. Panagis Galiatsatos, has previously implemented a tobacco cessation program in two Baltimore City housing units with high Area Deprivation Indices. The intervention included training of healthcare providers to deliver 90-minute group sessions on tobacco dependence management, followed by 20-minute

individual sessions as requested by participants. Linkages were established with the state's QuitLine and primary care providers for medication, if desired. Forty-seven individuals participated in that intervention, and 75% started pharmacotherapy, with an overall 38% quit rate at 6 months. This demonstrates the feasibility of delivering a tobacco cessation intervention in housing unit in Baltimore.

In terms of lung cancer screenings with low-dose CT scans, Dr. Galiatsatos has developed a facilitated referral process as part of a tobacco treatment clinic within the Johns Hopkins Healthcare System that has yielded high rates of screening completion. This experience will inform the LDCT shared decision-making component of the proposed study.

Proposed Next Step: Expanding on this prior work, we propose to assess acceptability of and to pilot the C-Raven VCTC, CHW intervention, and LDCT shared decision making directly in the community, in a public housing setting. If successful, the intervention could be eventually be deployed in housing units across the city, making it available to many more individuals in communities with high rates of smoking.

4. Study Procedures

a. Study design, including the sequence and timing of study procedures (distinguish research procedures from those that are part of routine care).

Phase 1: To obtain feedback on an existing tool for shared decision-making for LDCT so that it can be tailored to Baltimore City residents with current or former tobacco use, as well as to gain insight on smoking and smoking cessation in the community of interest through focus groups (N=2) and individual or small group meetings with individuals currently living in public housing in Baltimore City.

Study design: Qualitative via focus groups (N=2) and individual meetings

Setting: The focus groups will take place virtually with residents of two public housing units in Baltimore City. Potential recruitment sites with whom we have established contacts include: Monument East Apartments, Chase House Apartments, McCulloh Homes, City Arts 1&2, and/or Foxwell Memorial Apartments. A member of our study team has longstanding experience with community engagement around tobacco cessation in the city's housing units. The individual or small group meetings will take place in the community room or other public area with reasonable privacy at the public housing unit.

Eligibility: Inclusion Criteria are: 1) Age 50 or older, 2) Current tobacco use with >100 cigarettes smoked in their lifetime, 3) English speaking (intervention currently in English only and housing units are in largely English-speaking neighborhoods). Exclusion Criteria are: 1) Current engagement in formal smoking cessation program, 2) Major cognitive or psychiatric impairment, 3) Severe hearing impairment or communication difficulty

Recruitment: We aim to recruit a total of 12-16 participants (6-8 participants per focus group). Participants will be recruited through flyers posted in and around the housing units describing the study and distributed to tenants by housing unit staff. Flyers will describe the study and contain a

study phone number to call. Information may also be distributed by study staff during non-study-related health and wellness activities conducted at the sites. At initial contact, a study staff member will discuss the study purpose and determine study eligibility. If eligible, the staff member will proceed to discuss requirements, review risks and benefits, and obtain verbal informed consent from interested participants. After the focus groups, we propose to reach out by phone to those who originally consented to schedule an additional time to get more detailed feedback specifically on the guide.

Consent process: After confirming eligibility with screening questions, teleconsent (via Zoom video conferencing) will be obtained prior to the focus groups. Teleconsent will be used instead of in person consent to avoid unnecessary in-person encounters specifically for a consent procedure. A consent script describing the study will be read to participants by the consenting study staff. After the consent script has been read, participants will be given adequate time to consider the research study and ask questions prior to verbally consenting; we will not proceed with the verbal consent until the potential participant affirms that they do not require more time and that all questions have been answered. Participants will be asked to summarize their understanding of the study and associated risks. The consent process is estimated to last approximately 10-15 minutes or as much time will as needed to ensure participants' understanding of the study purpose, requirements, risks and benefits. Participants will be informed that the focus groups will be recorded and transcribed. Group leaders will not use names during the focus groups. Participants will also be asked not to use names to refer to each other, and personal identifiers will be excluded from the transcript. Following consent, additional demographic and smoking history questions will be asked to characterize the participants. Finally, they will be scheduled to participate in one of the focus groups. For the individual or small group meetings, we do not propose additional consent. We would remind the person of what they had agreed to and ask them if they would be willing to have a follow-up meeting given the limitations of the focus group setting for them to see, read and comment on the guide.

Focus group procedures: Focus groups will be conducted via Zoom video conferencing and will be recorded. The automatic transcription feature of Zoom will be used and then transcripts reviewed for completeness and accuracy. The groups will be run by Dr. Ellison-Barnes. No names will be used during the focus groups and participants will be specifically asked not to use names to refer to each other. Names and any personal identifiers will be excluded from the transcripts. We will discuss attitudes toward and prior experiences with lung cancer screening, as well as specific feedback on an existing shared decision-making tool. We will also query participants regarding smoking in the community, ways to engage the community in smoking cessation efforts, thoughts about computer delivered interventions for smoking, and the best places to deliver the intervention. The focus group guide has been uploaded into the IRB application. Notes will be taken during the group by the research assistant. Participants will receive $50 via a Visa Gift Card for focus group participation.

Individual or small group meeting procedures: Individual or small group meetings would be conducted in person with 2-4 participant(s) and 2 study team members. The meeting would not be recorded; however, the staff would take detailed notes and ask the participant to make notes/suggestions directly on the decision guide which will be printed out on paper. The notes on both would be labeled only with the individual's study id and for used tracking purposes only.

We anticipate the meeting will take about 1 hour. We would give them a $50 Visa Gift Card for participation in this meeting.

Focus group analysis: Two investigators will independently review focus group transcripts for major themes. Inconsistencies will be examined and resolved through consensus. We anticipate holding two focus groups of 6-8 participants each to achieve thematic saturation. From these themes, the VCTC and CHW intervention and LDCT shared decision-making approach will be modified to address the needs of this particular population and setting.

Individual/small group meeting analysis: The study team will review and discuss the feedback and suggestions from each participant who is interviewed and revise the decision guide until consensus is reached by the study team. The revised materials will be submitted for IRB review before use in Phase 2.

Phase 2: To conduct a feasibility pilot study of a VCTC and CHW intervention with a sample of participants (N=15) to evaluate feasibility, recruitment strategies, intervention engagement and completion, and short-term (3-month) smoking cessation and lung cancer screening outcomes. At the end of three-month follow-up, we will also conduct exit interviews with housing staff to gather qualitative data on intervention implementation and housing community attitudes toward smoking cessation, LDCT, and VCTC.

Study design: Intervention pilot (N=15 participants)

Setting: As in Aim 1, the pilot will take place with residents from select public housing sites in Baltimore City.

Eligibility: Inclusion Criteria are: 1) Age 50 or older, 2) Current tobacco use with >100 cigarettes smoked in their lifetime, 3) English speaking (intervention currently in English only and housing units are in largely English-speaking neighborhoods, 4) Considering smoking cessation, and 5) Planning to remain in current housing unit for 6 months. Exclusion Criteria are: 1) Current use of pharmacological treatment for tobacco cessation, 2) Contraindication to nicotine replacement therapy, 3) Current engagement in formal smoking cessation program, 4) Major cognitive or psychiatric impairment, 5) Severe hearing impairment or communication difficulty, and 6) Investigator discretion

Recruitment: We aim to recruit a total of 15 participants. Participants will be recruited through flyers posted in and around the housing units and distributed to tenants by housing unit staff. Flyers will describe the study and contain a study phone number to call. Information may also be distributed by study staff during non-study-related health and wellness activities conducted at the sites. At initial contact, a study staff member will discuss the study purpose and determine eligibility. If eligible, the staff member will proceed to discuss requirements, review risks and benefits, and obtain informed consent from interested participants.
We also aim to recruit 2-4 housing staff (one from each site/community). Study staff will discuss the study purpose, requirements, risks, and benefits of participation. We will then obtain informed consent from interested housing staff.

Consent process: After confirming eligibility with screening questions via phone, potential participants will be offered the option of reviewing the study information and consent form over a Zoom video conference. Regardless of whether they choose to review this information in advance, all potential participants will complete the consent process and sign the consent form at the beginning of their first in-person visit, which will be conducted on-site at their housing community. Participants will be offered the option to receive an electronic copy of the consent form via email ahead of the in-person meeting. After the study information and consent form have been reviewed, participants will be given adequate time to consider the research study and ask questions prior to signing the consent form; we will not proceed with having them sign the form until the potential participant affirms that they do not require more time and that all questions have been answered. Participants will be asked to summarize their understanding of the study, its purpose, and associated risks. The consent process is estimated to last approximately 10-15 minutes or as much time will as needed to ensure participants' understanding of the study purpose, requirements, risks and benefits. After informed consent is obtained, the participant will answer additional screening questions to determine study eligibility and, if eligible, be offered the opportunity to participate in the pilot intervention.

We will also obtain informed consent (either in-person or by tele-consent) from housing staff to participate in a virtual, 1-hour exit interview conducted at the end of three-month follow-up.

Baseline Assessment: This will occur on the same day as the in-person portion of the consent process. Initial evaluation will comprise the research assessments detailed in Table 1, including demographics, a clinical history, a tobacco use history, and a number of tobacco-related measures. Assessments will be self-administered via tablet computer.

Intervention:

Computer-Delivered Intervention (CDI) Session 1: Following the baseline assessment, participants will receive computer-delivered counseling via a study-provided iPad delivered in a private room. VCTC consists of 1) a menu-driven, web-based intervention that is delivered by a virtual counselor. The intervention takes 20 minutes to complete. At the conclusion of session 1, the participant will be offered nicotine patches provided by the study (1 month supply, remainder given at follow-up visits). The initial dosing of the nicotine patches will be determined based on cigarettes consumed per day (>10: 21mg patch, 5-10: 14mg patch, <5: 7mg patch). If there is any question regarding eligibility or appropriate dosing, the CHW will consult with a study physician (Dr. Ellison-Barnes or Dr. Galiatsatos). With the CHW, the participant will learn correct application, and will monitor their NRT experience in discussion with the CHW.

Computer-Delivered Intervention (CDI) Session 2: Session 2, delivered approximately one week later, focuses on the cycle of addiction and use of pharmacotherapy (e.g., NRT, bupropion, varenicline). This intervention also takes about 20 minutes to complete. At the conclusion of session 2, the participant will be offered nicotine gum or lozenges provided by the study (1 month supply, remainder given at follow-up visits). This session also includes an in-session experience of using NRT gum or lozenge, with CHW guidance to ensure correct use.

Community Health Workers (CHWs): A CHW will meet with each participant for both Sessions 1 and 2 and will do the following: 1) Teach appropriate NRT use technique as above, 2) Follow up with patients remotely via phone or video conference whenever possible, up to twice weekly for 12 weeks, to discuss barriers/facilitators to maintenance of NRT use and tobacco cessation; 3) Review the modified lung cancer shared decision-making guide from Phase 1 and provide linkage to lung cancer screening if the participant is eligible and interested, including linkage to insurance enrollment assistance, if needed; 4) For individuals requiring follow up for positive

findings on lung CT, work with participants to navigate the process; 5) Link interested participants to the QuitLine; 6) At the end of the study, link to medical providers for additional tobacco cessation therapy if participant interested (e.g., varenicline, bupropion).
Linkage to Lung Cancer Screening: Participants eligible for and interested in CT Lung cancer screening (age ≥50, ≥20 pack year smoking history) will be referred to their primary care physician (PCP) or existing specialist for further discussion and ordering. The CTs are optional and will not be provided as part of the research study. The CHW will assist with linking patients without a PCP or existing specialist with resources to establish care. For participants who choose to proceed with screening, we will request the results of the CT scan to track completion and general result category (Normal/Normal with Minor Findings/Abnormal Needing Short-Term Follow-Up/Abnormal Needing Immediate Follow-Up).
Intervention Retention and Follow-Up: We have protocols in place to maximize intervention retention and follow-up. At the time of enrollment, we will obtain contact information of the participant as well as three alternate contacts. In addition, participants will receive remuneration via Visa Gift Cards for each research assessment ($25 each at baseline, one month, and three months, $25 additional for completion of all three visits).
Research Assessments and Data Elements Collected: We will collect data on participant demographics, smoking history, and clinical history (e.g., tobacco related comorbidities). We will use well-validated instruments to obtain information on tobacco use, nicotine dependence, attitudes towards nicotine replacement therapy, readiness and confidence to quit, nicotine withdrawal, alcohol, other drug use, mental health, quality of life, and self-efficacy (Table 1). Each follow-up assessment will also collect data on recent quit attempts and methods used to quit, use of NRT, adverse events from NRT, and use of the QuitLine. Moreover, follow-up assessments will assess potential study contamination by asking questions specific to the computer delivered intervention (assess key information and skills discussed in CDI). The baseline data collection is expected to take approximately 1 hour. Follow-up data collection will take about 45 minutes.

In terms of lung cancer screening, we will record whether participants were eligible, whether they chose to proceed with screening through their PCP or specialist, and a general indicator of results (Normal/Normal with Minor Findings/Abnormal Needing Short-Term Follow-Up/Abnormal Needing Immediate Follow-Up); full imaging reports will not be retained.

At the end of three months we will conduct follow up interviews with pilot participants to collect qualitative data on intervention acceptability. We will also conduct exit interviews with housing staff to collect qualitative data on intervention implementation and housing community attitudes toward smoking cessation, LDCT, and VCTC.

Table 1: Schedule of study evaluations

Measure	Months		
	Baseline	1	3
Demographics	X		
Smoking History	X		
Clinical History	X		

Tobacco Use History (Smoking Behaviors Questionnaire)	**X**		
Nicotine Dependence (Heaviness of Smoking Index)	**X**		
Lung Cancer Screening Belief Scales	**X**	**X**	**X**
Attitudes Towards NRT	**X**	**X**	**X**
Nicotine Withdrawal Symptoms	**X**	**X**	**X**
Motivational Assessment (Readiness Ruler)	**X**	**X**	**X**
Alcohol Use (Alcohol Use Disorders Identification Test C)	**X**	**X**	**X**
Drug Use (NIDA Quick Screen)	**X**	**X**	**X**
Depression/Anxiety/Quality of Life (PHQ-4, EQ-5D Instrument)	**X**	**X**	**X**
Smoking Abstinence Self-Efficacy Questionnaire (SASEQ)	**X**	**X**	**X**
Tobacco Outcomes		**X**	**X**
Study Contamination Measures		**X**	**X**
Adverse Events		**X**	**X**
Post-Intervention Interviews			**X**

Analytic Plan: Statistical analyses will be carried out as detailed below in section 7.

a. If your study involves data/biospecimens from participants enrolled under other research studies with a written consent or under a waiver of consent, please list the IRB application numbers for those studies. Please note: Certificate of Confidentiality (CoC) protections applied to the data in source studies funded by NIH or CDC will extend to this new study if the funding was active in 2016. If this situation applies, Section 36, question 6 in the application will need to be answered "Yes" and "Hopkins Faculty" should be selected in question 7. No other documents are required.

   Not applicable.

b. Study duration and number of study visits required of research participants.

   Phase 1: Participants will participate in one focus group.
   Phase 2: Participants will have 3 formal study visits over 3 months, plus one additional visit for completion of the second session of the VCTC. Additionally, interested housing staff will participate in one virtual exit interview (approximately one hour) conducted at the end of three-month follow-up.

c. Blinding, including justification for blinding or not blinding the trial, if applicable.

   Not applicable.

d. Justification of why participants will not receive routine care or will have current therapy stopped.

   Not applicable.

e. Justification for inclusion of a placebo or non-treatment group.

   Not applicable.

f. Definition of treatment failure or participant removal criteria.

Participants may withdraw from the program at any time.

g. Description of what happens to participants receiving therapy when study ends or if a participant's participation in the study ends prematurely.

Through CHWs, patients will be offered connections to primary care providers, the Tobacco Treatment and Cancer Screening Clinic (Johns Hopkins Bayview Medical Center), or the Maryland QuitLine to continue nicotine replacement therapy, if desired.

h. If biological materials are involved, please describe all the experimental procedures and analyses in which they will be used.

Not applicable.

5. Inclusion/Exclusion Criteria

Phase 1
Inclusion Criteria: 1) Age 50 or older, 2) Current tobacco use with >100 cigarettes smoked in their lifetime, 3) English speaking (intervention currently in English only and housing units are in largely English-speaking neighborhoods).
Exclusion Criteria are: 1) Current engagement in formal smoking cessation program, and 2) Major cognitive or psychiatric impairment, 3) Severe hearing impairment

Phase 2
Inclusion Criteria: 1) Age 50 or older, 2) Current tobacco use with >100 cigarettes smoked in their lifetime, 3) English speaking (intervention currently in English only and housing units are in largely English-speaking neighborhoods, 4) Considering smoking cessation, and 5) Planning to remain in current housing unit for 6 months.
Exclusion Criteria: 1) Current use of pharmacological treatment for tobacco cessation, 2) Contraindication to nicotine replacement therapy, 3) Current engagement in formal smoking cessation program, 4) Major cognitive or psychiatric impairment, 5) Severe hearing impairment, and 6) Investigator discretion

6. Drugs/ Substances/ Devices

a. The rationale for choosing the drug and dose or for choosing the device to be used. Nicotine replacement therapy will be used in combination with the computer-delivered intervention. The choice of NRT is based on established evidence of its effectiveness in smoking cessation. This study is NOT testing effectiveness of NRT itself, but rather the effect of the VCTC and CHW intervention on enhancing uptake and duration of use of NRT. The initial dosing of the nicotine patches will be determined based on cigarettes consumed per day (>10: 21mg, 5-10: 14mg patch, <5: 7mg patch). If there is any question regarding appropriate dosing, the CHW will consult with a study physician (Dr. Ellison-Barnes or Dr. Galiatsatos).

b. Justification and safety information if FDA approved drugs will be administered for non-FDA approved indications or if doses or routes of administration or participant populations are changed.
Not applicable.

c. Justification and safety information if non-FDA approved drugs without an IND will be administered.
Not applicable.

7. Study Statistics

a. Primary outcome variable.
For both phases, our primary outcome will be intervention acceptability and feasibility. We will examine intervention acceptability and feasibility using both quantitative and qualitative measures described in Table 2 below. Our approach will follow the RE-AIM framework.

Table 2: Measures that will inform acceptability and feasibility

Outcomes	Quantitative Measures	Sampling of qualitative interview content
Reach	1. Feasibility and Acceptability Implementation measure	1. Reasons for engagement or non-engagement [e.g. structural (transportation), social/personal (stigma/family), patient preferences for treatment (where to receive treatment)] (participant) 2. What could be done to increase participation (participant, CHW, study team)
Effectiveness	1. Effectiveness outcomes Including by intervention dose received)	1. Perceptions of why intervention did or did not work (participant, CHW, study team) 2. Barriers/Facilitators to use of individual intervention components (participant) 3. Barriers/Facilitators to intervention participation (participant)
Adoption	1. Measures on adoption, feasibility, acceptability, and appropriateness	1. Barriers to adoption (intervention uptake), steps to enhance uptake, perceived need for intervention, perceived fit in current residential life structure (CHW, study team),
Implementation	1. Number of intervention sessions and phone calls delivered	1. How intervention will need to be adapted; challenges to implementing the intervention per protocol, perceptions of training (CHW, study team) 2. Advantages/disadvantages to delivery in setting, resources and burden of intervention (CHW, study team),

Maintenance	1. Effectiveness outcomes, as described under effectiveness 2. Program Sustainability Assessment Tool	1. Factors that influence sustained behavior change (participant, CHW) and sustained use of the intervention in residential setting (CHW, study team) 2. What would be required for scale-up, external policies and incentives that may influence scale up (CHW, study team)

b. Secondary outcome variables.
   1) Readiness to quit smoking and confidence in ability to quit smoking, 2) uptake of nicotine replacement therapy, 3) continued use of NRT at one month and three months, 4) number of quit attempts, 5) 7-day point prevalence smoking abstinence at 1 month and 3 months, 7) Quit Line uptake, 7) patient engagement with CHW, 8) patient satisfaction

c. Statistical plan including sample size justification and interim data analysis.

Descriptive analyses of quantitative data will be used to investigate the RE-AIM dimensions and constructs of reach/penetration, adoption, appropriateness, acceptability, feasibility, and sustainability across stakeholder levels. Qualitative interviews will be transcribed and based on domains and content on Table 2, we will perform both deductive and inductive coding. The qualitative data will provide context to the quantitative data and in-depth understanding of barriers and facilitators to program implementation in the local context. We will merge and integrate quantitative and qualitative data. Merging will follow a simultaneous bidirectional framework, where both data types are analyzed separately and weighed equally. The qualitative themes will be compared to quantitative assessment results, combined and jointly displayed. We will create a matrix relating qualitative themes to quantitative variables. Findings will inform adaptation of the shared decision-making tool for lung cancer screening, delivery of the CDI intervention in community settings, the role of the CHW in the intervention, and future programming efforts.

Our proposed sample size for the pilot (n=15) is guided by pilot study goals to assess feasibility, acceptability, and ease of implementation of our intervention and to estimate possible effect sizes for future large scale clinical trials, if warranted. The proposed sample size should provide a representative group of individuals living in Baltimore City public housing who are currently smoking to enable examination of recruitment strategies and rates, consent rates, intervention and research follow-up retention rates, data collection and analysis procedures, variance estimates and effect sizes.

d. Early stopping rules.
   We will not have early stopping rules.

8. Risks

a. Medical risks, listing all procedures, their major and minor risks and expected frequency.

During both phases of the project, individuals may experience psychological distress when discussing their smoking or while participating in the smoking cessation intervention. While we expect this risk to be infrequent, we have procedures in place to address this, as below.

During the pilot intervention phase, there is also a risk of nicotine withdrawal symptoms or nicotine replacement therapy side effects. Study participants who attempt to quit smoking will likely experience some withdrawal symptoms that may include anxiety, restlessness, anger, irritability, sadness, problems concentrating, appetite change and weight gain, insomnia, and decreased heart rate. There is no reason to believe that participation in this study would worsen nicotine withdrawal symptoms. Common side effects of the nicotine patch include local skin irritation at the site of the patch, nausea if the dose is too large or if the patient continues to smoke at a high level while using the patch, and disturbed and vivid dreams. Less common side effects include allergic skin reactions. For nicotine gum or lozenges, additional side effects can include mouth sores, hiccups, nausea, or heartburn.

If the participant chooses to proceed with optional low-dose CT for lung cancer screening through their PCP or existing specialist, they face the additional risks of radiation exposure and anxiety associated with waiting for results or further confirmatory testing following a positive screen.

b. Steps taken to minimize the risks.
There are two primary risks to both phases of this study: breach of confidentiality and psychological distress. Participants will be asked to provide sensitive information related to smoking. Efforts will be made to ensure confidentiality. Psychological or emotional distress may occur during focus groups or during pilot testing of the VCTC and CHW intervention given discussions of smoking and cancer risk.

1) Confidentiality: Participants will be asked to provide sensitive information related to smoking. All participants will be assigned unique study identification numbers that will be used for their surveys. No personal identifiers will be revealed in the focus group notes. We will only collect identifying information for 1) the purpose of documenting participant remuneration on receipts and 2) contacting a participant for follow-up during the pilot intervention. Unique study IDs will be created for participants in the pilot; the key linking IDs to identifiers will be stored on the Johns Hopkins secure server, in a file only the study coordinator and investigators have access to. All remuneration receipts will be stored in a locked file cabinet. In addition, all paper files including consent forms and data will be kept in a locked filing cabinet. All study outcomes will be reported as aggregate data. In addition, all investigators and members of the research team will have completed Johns Hopkins University on-line modules on Human Subjects Research and HIPAA. Data from the pilot will be stored in Red Cap, on a secure server.

2) Psychological distress: A participant may become uncomfortable while answering sensitive questions related to tobacco use or cancer risk or while participating in the CDI program. If a person experiences significant distress during the focus group or

during the counseling, the research assessment or focus group will be stopped, and Dr. Ellison-Barnes or another study physician/psychologist will evaluate the participant, and assess if the participant is at risk for harming herself or others. If necessary, emergency medical services will be called.

Additional risks associated with Phase 2 of the study, the pilot intervention, include nicotine withdrawal symptoms or side effects of nicotine replacement therapy. To manage withdrawal, all participants will be offered nicotine replacement therapy which is intended to reduce withdrawal symptoms. The risks of serious adverse effects of nicotine replacement therapy, which is widely available over-the-counter, are small, and its potential health benefits far outweigh its risks. Subjects will be encouraged to review the drug information provided with the product (and offered to review with the CHW) and to report adverse effects to the study team.

For participants who choose to proceed with low-dose CT screening for lung cancer, we will attempt to minimize risk by counseling all participants in advance to prepare them for the process, ordering only low-dose CTs to reduce radiation exposure, and ensuring timely follow-up of any positive screens.

c. Plan for reporting unanticipated problems or study deviations.
Safety and oversight of the study will be provided by the principal investigator, Dr. Ellison-Barnes, and the study team. Any unanticipated problems or deviations from the study protocol will be reported to the Johns Hopkins IRB.

d. Legal risks such as the risks that would be associated with breach of confidentiality.
If participants disclose information about tobacco use in restricted areas of the housing units, they could potentially face consequences of having violated their lease agreement if there were a breach of confidentiality. However, personal identifiers will not be used for the focus groups, and we be using study IDs rather than identifying information for the pilot intervention. We will keep participant contact information in a password protected file on the Johns Hopkins Server.

e. Financial risks to the participants.
There may be costs associated with lung cancer screening if the participant chooses to proceed with this via their PCP or existing specialist; we are unable to offer CT scans as part of the study. Participants without insurance or existing primary/specialty care will be linked with appropriate guidance regarding enrollment and any available financial resources.

9. Benefits

a. Description of the probable benefits for the participant and for society.
Participants may reduce their tobacco smoking, which may improve their overall health and quality of life. Interventions that reduce tobacco use also benefit society, in reducing secondhand smoke exposure as well as tobacco-related morbidity and mortality, which have tremendous societal costs.

10. Payment and Remuneration

a. Detail compensation for participants including possible total compensation, proposed bonus, and any proposed reductions or penalties for not completing the protocol.
Participants will receive remuneration for participation in both the focus groups ($50) and the pilot intervention ($25 each at baseline, one month, and three months, and additional $25 for completion of all three visits).
Housing staff will receive $30 for participating in exit interviews at the end of three-month follow-up.

11. Costs

a. Detail costs of study procedure(s) or drug (s) or substance(s) to participants and identify who will pay for them.
There will be no required costs to participants for participation in this program. Nicotine replacement therapy for those who opt to use it during the intervention will be provided through the study. There may be costs associated with the optional lung cancer screening done through their PCP or existing specialist; we are unable to offer the CT scan as part of the study. Participants without insurance will be linked with appropriate guidance regarding enrollment.

12. Transfer of Materials

Transfer of biospecimens from Johns Hopkins to another organization for research purposes and receipt of biospecimens from an outside organization for your research must adhere to JHU policies for material transfer (https://ventures.jhu.edu/faculty-inventors/forms-policies/) and biospecimen transfer (https://hpo.johnshopkins.edu/enterprise/policies/176/39187/policy_39187.pdf?_=0.622324232879).

Please complete this section if your research involves transfer or receipt of biospecimens.

a. Will you **receive** biospecimens from an external entity for this research? [Yes/No].
If "Yes", please confirm you will secure an MTA/research agreement from the appropriate office (JHTV/ORA) prior to transfer.
See: https://ventures.jhu.edu/technology-transfer/material-transfer-agreements/ .

b. Will you **transfer** biospecimens to an external entity as part of this research? [Yes/No]
If "Yes", please address each of the following:
1) Describe the nature of the research collaboration with the external entity and the rationale for the transfer. (Include an explanation of your intellectual contribution to the design of the research study, resulting data and sharing, and participation in the planned publications.)

2) Please confirm you will secure an MTA through the appropriate office (JHTV or ORA) prior to transfer.
(See: https://ventures.jhu.edu/technology-transfer/material-transfer-agreements/.)

3) If the biospecimens you intend to transfer were obtained through clinical or research procedures at Johns Hopkins and "Other" is selected in Item 4, Section 23, please submit the following items in that Section:

   a. A pdf version of a completed JHTV Online "Material Transfer Agreement Request Form for Outbound Material" https://ventures.jhu.edu/technology-transfer/material-transfer-agreements/ **OR** a copy of the COEUS PD (Proposal Development Summary).
   b. A completed Biospecimen Transfer Information Sheet https://www.hopkinsmedicine.org/institutional_review_board/forms/.
   c. A signed and dated "De-identified Human Subject Certification" https://www.hopkinsmedicine.org/institutional_review_board/forms/
   d. Approval documents from recipient site, if applicable.
   e. Copies of the consent forms associated with the IRB protocols under which the biospecimens were collected, with language appropriate to this transfer highlighted.
   f. The name of the specialist you are working with in ORA to complete a contract/MTA.

Please see the following website for more information about transferring human biospecimens to outside entities: https://www.hopkinsmedicine.org/institutional_review_board/news/announcement_transfer_human_biospecimens_outside_entities.html/ .