Tobacco Cessation in Public Housing

NCT04889638

1/10/2024

JHM IRB - eForm A – Protocol

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1. Abstract

Lower socioeconomic populations continue to remain at high risk for tobacco use and suffer disproportionately from tobacco-related disease. Evidence is lacking of ways to optimally deliver behavioral and pharmaceutical-based cigarette smoking cessation interventions in real-world environments among disadvantaged cohorts where geographic, socioeconomic and technological disparities often undermine the effectiveness of evidence-based smoking cessation efforts. Our study focuses on residents of public housing in Baltimore City, a population who face multiple socioeconomic stressors and of whom up to 1/3 are assumed conventional cigarette users.

Our project uses a partnership between the Housing Authority of Baltimore City (HABC) and Johns Hopkins School of Medicine to enact a remote (off-site) cessation program in Douglass and Brooklyn Homes – two public housing complexes under the management of HABC. Our program will institute evidence-based practices in an accessible manner for the residents at both sites. Our program's key features include the remote recruitment, prescription, delivery and management of evidence-based nicotine pharmacotherapies, and provision of cessation counseling.

2. Objectives

To assess the feasibility of a remotely administered study design with a particular focus upon:

a) Recruitment of smokers expressing a motivation to reduce or quit smoking
b) Consent process
c) Nicotine and non-nicotine pharmacotherapy selection, screening, prescription, delivery, storage management (participation education, side-effecting monitoring), and return of unused drug supplies
d) Administration and perceived utility of motivational interviewing regarding smoking reduction and cessation
e) Delivery of study reimbursement
f) Utility of weekly text reminders of study participation and final endpoint
g) Acceptability of outcome measures.
h) Acceptability and evaluation of joint project oversight with HABC

3. Background

Pilot Study: Feasibility of our study's remote recruitment, implementation, dissemination and joint academic-HABC oversight

We had completed a 4-week pilot study last year (2019)on-site at Douglass Homes *(one of two study sites to be used during this proposal)*. This pilot served as the premise of this work and its findings helped inform the design of this project. Our pilot delivered on-site weekly nicotine replacement therapies [NRTs] (gums, lozenges and patches), along with as-needed, on-site psychosocial services delivered by Maryland Legal Aid and Catholic Charities. Among the 40 participants we recruited, we achieved a 79.5% retention rate by the final week of the study. Baseline exhaled CO levels did not significantly decrease from baseline (mean= 9.2 +/- 3.4 ppm) to the final 4-week time point (mean= 7.0 +/- 5.7 ppm); however, there were notable technical issues appreciate with CO measurements. Technical issues included too rapid/slow exhalation of maneuvers despite coaching and inability to fully blow into the device mouthpiece.

The key findings that were agreed upon by all stakeholders included:

1. There was *non-optimal usage of NRTs despite on-site delivery*. This was primarily attributed to insufficient understanding of the role of each NRT product and misconceptions of NRT side effects
2. Participants did not maximally avail of offered psychosocial services. Referrals to offsite services were not undertaken. Legal service needs were often accomplished after one interaction with Maryland Legal Aid.
3. Participants preferred efficient administration of study methodology, whereby they wanted to rapidly receive quality tobacco education and NRT products.
4. Weekly reminders for study follow-up events were required and were well received.
5. The largest time point of participation occurred when a low-value reimbursement (incentive) was offered for study participation.
6. NRT products alone were insufficient to control nicotine addiction. A non-nicotine prescription medication (e.g. Chantix®) could have been helpful in this population but this was not provided.
7. Inadequate usage and non-optimal delivery of cessation-directed behavioral counseling

Ongoing tobacco treatment clinics in multiple Baltimore City public housing sites (McCollough and Monument East) [PI: Galiatsatos]

Dr. Galiatsatos is the Medical Director of the Bayview Medical Center-based Johns Hopkins Tobacco Treatment Clinic. The clinic is comprised of a multi-disciplinary team of nurses, physicians and other certified tobacco treatment specialists. They provide personalized smoking cessation plans that meet the patient's individualized needs. The clinic formulates personalized combinations of behavioral and pharmacologic treatments that maximize the likelihood of smoking cessation. The clinic has successfully expanded its treatment philosophy to the community by implementing weekly cessation clinics in three East Baltimore-based housing sites.

4. Study Procedures

- **STUDY DESIGN**

Overview: A pilot study is being conducted to determine the feasibility of recruitment, implementation, evaluation, dissemination and joint academic-community HABC oversight of a tobacco smoking intervention within Baltimore public housing. The intervention will be a quasi-experimental study using a pre-post intervention (no active comparator group). The project will be divided over *7* time points.

TIME POINT 1

Recruitment & screening

Recruitment will be undertaken in a two-fold manner:

1. Study flyer: Housing Authority of Baltimore City (HABC) had assisted in designing a study flyer used in the first pilot study performed in 2019. The flyer has been modified to reflect the current objectives and methodology. It includes references to both in-person and remote components of the intervention. References to reimbursement have been removed to better reflect HABC insight into enhancing the recruitment of participants who have the internal motivation to reduce smoking behaviors. The study flyer includes a contact phone number for participants to discuss the intervention with the study team and learn of the dates for in-person screening & recruitment.
2. Personalized promotion by HABC on-site staff: Both study sites have on-site, HABC service coordinators who are familiar with the residents and aware of individual smoking concerns. They will use an established verbal script to promote the study among known smokers in Douglass and Brooklyn Homes (**see "Supplementary Document 1" for copy of verbal script**). The verbal script reflects the study's on-site intervention and its remote components. These in-person interactions will also include the provision of the study flyer and emphasizing the dates for in-person screening and consent. If needed, the study flyer will be reviewed by the service coordinator (e.g., difficulty with reading or understanding the contents). The service coordinators will *not* be involved in screening or consent.

COVID-19 PRECAUTIONS:

Location: We will preferentially implement all on-site work outdoors using a canopy tent. If there is inclement weather, the on-site work will occur within the community centers at Douglass and Brooklyn Homes. The study team will abide by HABC's existing recommendations for the number of individuals allowable within indoor communal settings. Participants will be maintained 6-feet apart and will adhere to Baltimore City recommendations for the wearing of masks within indoor settings, Outdoor events will also utilize the same COVID precautions for personal distancing and mask wearing.

Screening: COVID screening will occur prior to engaging in study activities that are being undertaken at a table in which both the study team and participants are seated in proximity to each other. COVID-19 screening will occur > 6 feet from where participants will be seated for screening and recruitment. Screening will involve the implementation of a COVID-19 screening questionnaire that is based on the content used in Johns Hopkins outpatient clinic settings. Screening will also include the assessment for fever using a temporal thermometer,

which will be cleaned between individual usage. If a participant screens positive for any COVID-19 related concerns and/or is febrile, they will not be allowed to proceed with the study. Those screening positive for COVID-19 will be provided 2 recommendations: 1) COVID-19 testing at one of the Baltimore City-recommended locations (a link for Baltimore City testing locations will be provided: https://coronavirus.baltimorecity.gov/where-get-tested-covid-19-baltimore-city) 2 seeking or discussing medical care from their primary care physician, urgent care center, or emergency room. Participants will also be provided the date(s) for further study time points that correspond to the missed event. If they continue to demonstrate COVID-19 concerns, the same advice for testing and medical attention will be recommended. If no further study dates are available for inclusion into the study, participants will be provided the contact information to the Johns Hopkins Bayview Medical Center's Tobacco Cessation Clinic and Maryland Quitline.
Personal Protective Equipment: Study staff will wear a mask and face shield during the engagement of study activities with participants.

Screening will occur in-person over a minimum of 2 possible dates within a 1-week time interval. . The selected screening criteria was purposely kept broad to maximize generalizability and include the following:

3. ≥18 years of age
4. Self-reported smoker with either daily or weekly cigarette use, as well as expressed desire to reduce or quit smoking
5. Proof of residence at Douglass or Brooklyn Homes - as confirmed by verbal acknowledgement by the service coordinators at each site.
6. Working mobile phone with texting ability for the duration of the study
7. Active health insurance (for pharmacotherapy billing) – See "***Notes 3 and 4*** below"

Exclusion criteria:

8. Pregnant – women will verbally acknowledge that they are *not* pregnant or trying to become pregnant in the next 8 weeks from the time of screening and recruitment to ensure no intake of nicotine and non-nicotine pharmacotherapy
9. Breastfeeding – women who are verbally acknowledge they are breastfeeding will be excluded from the study. This exclusion factor is in place secondary to breastfeeding concerns associated with the study's usage of nicotine and non-nicotine pharmacotherapy
10. Ongoing participation in a tobacco cessation program or related tobacco intervention study. Past participation in previous iterations of the protocol is not an exclusion criteria.
11. No active health insurance.
12. Unable to verbally state that they are willing to reduce or quit smoking upon recruitment and screening
13. Adults lacking capacity to consent
14. Non-English speakers
15. Self-reported usage of *only* non-combustible tobacco products, such as smokeless tobacco or Electronic Nicotine Delivery Devices (ENDS).

16. Anticipated relocation outside of Douglass or Brooklyn Homes prior to the final study visit
17. Clinical condition(s) that serve as absolute contraindications for the usage of NRT and non-NRT products and non-NRT products (Chantix®) (Reference: PMID 36280333)
    a. *Absolute contraindications of NRT products:*
        - *NRT gum: Dysphagia and subsequent aspiration risk*
        - *NRT lozenge: Dysphagia and subsequent aspiration risk*
        - *NRT transdermal patch: Severe diffuse skin disease*
        - *Women who are pregnant or breastfeeding.*
    b. *Absolute contraindication of Chantix®*:
        - *Inability to swallow pills*
        - *History of serious hypersensitivity or skin reactions to* Chantix®
        - *Women who are pregnant or breastfeeding*

**NOTE 1: We will cease enrollment at 60 participants. Our aim is to enroll 30 participants at Douglass Homes and 30 participants at Brooklyn Homes. We anticipate that ≈20% of screened participants (12 people) will not continue participation at the start of the intervention. This allows enrollment and follow-up of 48 participants.*

**NOTE 2: Our 1st pilot at Douglass Homes did not result in any participant being excluded for being pregnant or breastfeeding. We do not anticipate more than 2 participants being excluded based on pregnancy or breastfeeding status. All women excluded for these criteria will be provided local smoking cessation resources in case they again start to smoke (800-QUIT-NOW or Tobacco Treatment Clinic at Bayview Medical Center)*

*NOTE 3: Proof of insurance will be requested in the form of either the actual insurance card or animage of the front and back of their insurance card. The pictures of the health insurance card will be uploaded in CRMS. The information will be used for pharmacotherapy billing

*NOTE 4: Although we will not enroll those without active health insurance, we will provide contact information for the Maryland Health Connection (https://www.marylandhealthconnection.gov/). The Maryland Health Connection (administered by the Maryland Health Benefit Exchange) is the health insurance marketplace for the state.

If they meet *all* screening criteria, they will then undergo a pharmacologic screening questionnaire (**see "Supplementary Document 2"**) to determine what type of tobacco treatment "controller" medication would be appropriate (NRT transdermal patch or Varenicline (Chantix®). This screening questionnaire is used in the Tobacco Treatment Clinic at Bayview Medical Center (Medical Director: Dr. Galiatsatos)for similar purposes. We are undertaking this step at this time point to ensure timely prescription and delivery of NRT products and/or Chantix®, if needed, prior to the start of the intervention.

***NOTE 1:** All participants will receive an as-needed medication to address "acute" nicotine urges (NRT gum or lozenge) and a "controller" medication to address the overall nicotine addiction (NRT transdermal or Chantix®)*

***NOTE 3:** Participants will be notified of their chosen "acute" and "controller" medication during the 4-week intervention. They will be provided a drug information handout that contains details of the drug, including common and rare adverse effects seen with the therapy [see "Supplementary Document 4"). Contraindications to therapy will also be verbally reviewed with the participant and a focus on the following 4 categories.*

Absolute contraindications of NRT products:

NRT gum: Dysphagia and subsequent aspiration risk
NRT lozenge: Dysphagia and subsequent aspiration risk
NRT transdermal patch: Severe diffuse skin disease
Women who are pregnant or breastfeeding.

Relative contraindication of non-NRT products:
Recent myocardial infarction (≤ 2 weeks), arrhythmias, angina, ulcers, uncontrolled high blood pressure, overactive thyroid, pheochromocytoma, or a dental condition or disorder.

Absolute contraindication of Chantix®:
Inability to swallow pills
History of serious hypersensitivity or skin reactions to Chantix®
Women who are pregnant or breastfeeding

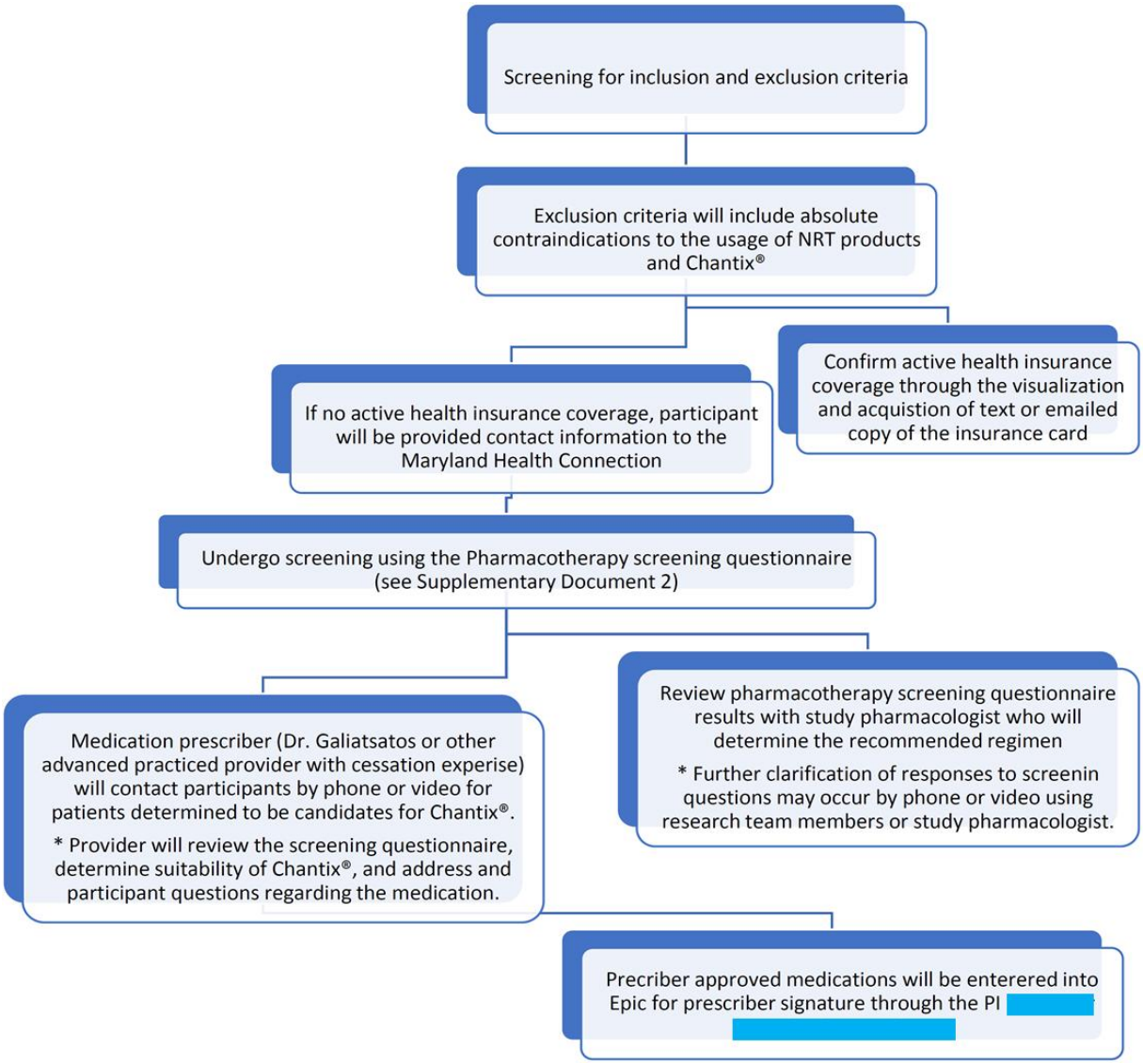
Relative contraindication of Chantix®:
Severe renal impairment (dosage adjustment is necessary)
Underlying neuropsychiatric disease

NOTE: If any absolute or relative contraindications or concerns arise during the screening questionnaire (see "Supplementary Document 2") or during the verbal summary of the contraindications described above, the team will immediately review them with Dr. Galiatsatos, the PI. Modifications in acute and controller therapy dosing may be employed in conversations with our team's medical specialists (e.g., Transdermal patch in replacement of Chantix®)

The answers to the pharmacotherapy screening questionnaire will be reviewed by the PI. If further clarification in the responses are required, a member of the research team will contact the participant. The PI will provide the recommendation for the acute and controller regimens for smoking cessation.

After the cessation regimen recommendations have been determined, the study coordinator or the PI, will contact the participants by phone or video if Chantix is recommended as part of the pharmacotherapy plan. The communication will include reviewing the indications and contraindications to Chantix. This encounter will also allow participants to ask pharmacotherapy-related questions or concerns.

The following figure provides a summary of the prescription workflow*:*



After the screening and final determination of the participant's smoking cessation regimen, the patient will then proceed to the research consent process by JHU-affiliated research staff.

- Participants will be notified that they will undergo a two-step consenting process that includes a Physician/Mid-level provider consent signature because of the inclusion of a prescription medication. The Physician/Mid-level provider will preferentially acquire consent at the time that the main consent process is being conducted on-site by the research team member. If the Physician/Mid-level provider consent cannot be acquired at the time of the main consent process, the provider will conduct a separate remote encounter to acquire consent. For remote consent to occur by the Physician/Mid-level provider, the designee will sign and place the date/time in the appropriate section of the consent under the observation of the on-site research team member. The provider will be provided the original consent form by the research team member and the member will verbally verify the participant signed the consent. The provider will contact participants by their preferred communication method (phone or video conferencing) to complete the consent. The Physician/Mid-level provider will review any additional study participant questions and discuss the risks, benefits and alternatives of the study in full detail. The Physician/Mid-level provider consent form is then signed, dated/timed by the provider. All components of the consent are combined to one document. After the informed consent process is completed, an IRB approved study team member then files the consent document in CRMS, including a note confirming the consent process. The entire consent document is also then filed in the research record. A copy of the fully completed consent form will be mailed to the participant's home address.

Participants will also be notified during the time of consent that they will be required to return to the same site in which screening & consent had occurred to pick up their prescribed pharmacotherapies. Participants will receive a phone call, text message and/or personally notified by the on-site housing service coordinator of a time and date for the prescription pick-up.

TIME POINT 2

Prescription of nicotine pharmacotherapies:
All participants who complete the screening process will be prescribed two classes of medications:

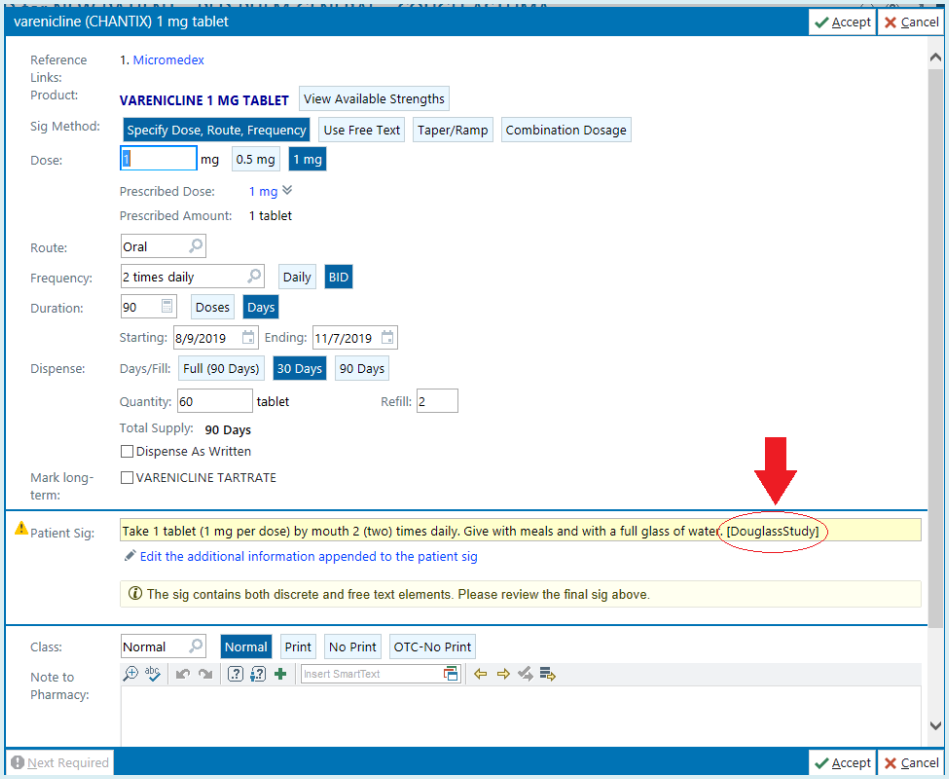
1. one "acute" or rescue NRT to address immediate nicotine cravings (e.g., NRT gum or lozenges)
2. one "chronic" or long-term controller to address the constant level of nicotine cravings or addiction (e.g., NRT transdermal patch or Chantix®)

We will use CRMS as our research management tool *[this applies to all time points].* We have chosen CRMS primarily due to its ability to interface with Epic. We will be able to create participant records in Epic and subsequently prescribe and bill for NRT (gum, lozenge and/or patch) and non-nicotine products (Chantix®). CRMS will allow for clinical research care to be documented and stored in Epic. Research participants in Epic will have a research active flag in Epic to allow other healthcare providers to see the prescribed therapy plan.

Note: See Data Management Section for more details on CRMS

One month supply (no refills) of prescriptions will be signed by Dr. Galiatsatos [PI]. Dr. Galiatsatos is the Medical Director of the Tobacco Treatment Clinic at Johns Hopkins Bayview Medical Center (or an equivalent advanced practiced provider with tobacco cessation expertise and prescribing privileges). Dr. Galiatsatos is a board-certified clinician in the JHH Division of Pulmonary and Critical Care Medicine within the Department of Medicine. Dr. Galiatsatos will be responsible for reviewing the participant screening data and confirming the appropriate medication type and dosage.

All prescriptions will be sent to the Johns Hopkins Monument Street Outpatient Pharmacy. Prescriptions will be marked in the *Patient Sig* section in Epic to notify pharmacy staff that our research team will be picking up the medications for on-site delivery as part of our intervention. When the term, *[HABCstudy],* is seen in the *Patient Sig* section the pharmacy staff will store the therapies at the pharmacy for pick-up and storage by the research team. The *one-month supply of medications (no refills)* will not be available for pick-up directly by the participant. The following is an example of the Epic-based prescription:



NOTE 1: The 1-month supply of medications will packaged in a tamper-proof envelope by the Monument Street Pharmacy staff.
NOTE 2: We anticipate all participants to be on public health insurance given their residence in public housing. Maryland Medicaid will fully cover the cost of a 1-month

supply of NRT gum/lozenge, NRT patch and Chantix®

TIME POINT 3

Part 1: DELIVERING, STORAGE AND RETURN OF UNUSED PHARMACOTHERAPIES
Part 2: START OF THE INTERVENTION (BASELINE VISIT)

COVID-19 PRECAUTIONS: All precautions described above in the screening and recruitment section will be enforced during the on-site activities described at this study time point.

PART 1 – *DELIVERING, STORAGE AND RETURN OF UNUSED PHARMACOTHERAPIES*

Medications will be prioritized for on-site delivery by study staff to participants within the same day of pick-up at the Monument Street Pharmacy – barring unexpected events. Participants will be provided the full one-month study supply of pharmacotherapy by study staff at the same site in each housing complex used in screening & recruitment (outdoor locations will be preferred; if inclement weather, indoor housing community centers will be used). Participants will be notified by phone, text messaging and/or personally notified by the on-site housing service coordinator of the time and date for the prescription pick-up. There will be at least two dates and times for picking up medications to accommodate for participant's personal or professional schedules.

The tamper proof envelope constructed by Monument Street Pharmacy will be inserted into a separate envelope that contain participant identifying information (confirmed in Time Point 1). Participants will provide their signature upon receipt of the medication package to acknowledge receipt of the medication.

Along with the package of medications, a stamped return envelope (addressed to PI: Dr. Galiatsatos) will be provided to allow for participants to return unused medications. Medications received by the PI will be dropped off at a drug disposal unit at Johns Hopkins Monument Street Pharmacy.

If the medications cannot be delivered by the study team on the day of pick-up from the Monument Street Pharmacy, the packaged medications will be stored in a locked cabinet in the locked office of Dr. Panagis Galiatsatos (PI). The office is located in the Division of Pulmonary and Critical Care Medicine within the Asthma and Allergy Building (4940 Eastern Avenue, AAAB, 4B.69, Baltimore, MD 21224). Temperatures will be recorded in the office at least on a weekly basis to confirm the environment is appropriate for drug-storage.

PART 2 – *START OF THE INTERVENTION (BASELINE)*

There are 4 steps that will occur in the start of the intervention:

1ST STEP – CONFIRMATION AND SURVEY SCREENING

This step includes the following:

- Confirmation that the participant underwent pre-screening in Time Point 1
  - We will confirm that the participant was pre-screened and consented. This confirmation will occur by asking the participant to verbally state their name, date-of-birth and place of residence. This information will be captured during the screening and stored in CRMS.
- Continued self-report of daily cigarette usage
  - If the participant reports that they are no longer smoking cigarettes, they will be provided the contact information of local smoking cessation resources in case they again start to smoke (800-QUIT-NOW or Tobacco Treatment Clinic at Bayview Medical Center). The medications will be dropped off at a drug disposal unit at Johns Hopkins Monument Street Pharmacy.
- Baseline survey completion that contains questions about sociodemographic and smoking characteristics (**see "Supplementary Document 3"**).
  - Participants will complete baseline surveys that capture sociodemographic and smoking characteristics (see "Supplementary Document 3"). Participants will be allowed sufficient time (no limit) to complete the survey. For participants with difficulty reading the survey, the questions will be read aloud and the responses will be recorded. We anticipate that the survey will take no more than 5-10 minutes to complete since we purposely are acquiring fewer but impactful questions to minimize participant study burden.
- ***RE***-confirmation of any potential contraindications for the prescribed NRT and non-nicotine pharmacotherapies – as chosen during screening. This review of contraindications will occur by our research team.

  This step will duplicate the review of absolute and relative contraindications undertaken during the screening process:

  - *Absolute contraindications of NRT products*
    - *NRT gum: Dysphagia and subsequent aspiration risk*
    - *NRT lozenge: Dysphagia and subsequent aspiration risk*
    - *NRT transdermal patch: Severe diffuse skin disease*
    - *Women who are pregnant or breastfeeding.*

  - *Relative contraindication of non-NRT products:*
    - *Recent myocardial infarction (≤ 2 weeks), arrhythmias, angina, ulcers, uncontrolled high blood pressure, overactive thyroid, pheochromocytoma, or a dental condition or disorder.*

  - *Absolute contraindication of Chantix®:*
    - *Inability to swallow pills*
    - *History of serious hypersensitivity or skin reactions to* Chantix®
    - *Women who are pregnant or breastfeeding*

- *Relative contraindication of Chantix®*:
  - Severe renal impairment (dosage adjustment is necessary)
  - Underlying neuropsychiatric disease

- ***NOTE**: If contraindications are noted, the team will immediately review them with the study's advanced practice provider (physician and/or pharmacist). If contraindications exist and the medical specialists determine the patient is not a suitable candidate any longer for the prescribed pharmacotherapies, the patient will be disenrolled from the study; they will be provided contact information of local smoking cessation resources (800-QUIT-NOW and Tobacco Treatment Clinic at Bayview Medical Center). Modifications in acute and controller therapy dosing may be employed in conversations with our team's medical specialists (e.g., transdermal NRT patch in replacement of Chantix®).

2ND STEP – DRUG EDUCATION AND SIDE-EFFECT MONITORING

The in-person baseline visit will include education about potential common and rare side effects of the prescribed medication. This is based on drug information that will be available to the patient in the enclosed package sent to the patient with nicotine pharmacotherapies (**see "Supplementary Document 4"**). ***See Drugs/Substances/Devices and Risks sections in this protocol for more information on side effects.***

Participants will be provided a 24-hour contact phone number to discuss concerns about side effects with our study team for the duration of the 4-week study. The study team will refer these concerns within 24 hours to the PI or study coordinator. They will assist in providing recommendations regarding the continued administration, replacement or discontinuation of the medication). Participants will receive a text and/or voice response to the identified concern within 1 day of receipt. Participants may be advised to stop therapies. If both controller and rescue medications are stopped, the patient will be disenrolled from the study. If disenrolled, they will be provided contact information of local smoking cessation resources (800-QUIT-NOW or tobacco treatment clinic at Bayview).

NOTE: All adverse effects or concerns about pharmacotherapy will be documented. The time, date, description of issue and response will be included in the documentation. All concerns will be documented within CRMS.

3RD STEP – CESSATION-DIRECTED MOTIVATIONAL INTERVIEWING

Brief motivational interviewing (MI) will also be delivered by the on-site research staff. The MI principles are derived from principles from the MDQuit.org program (see mdquit.org/cessation-programs/brief-interventions).

We will assist by enhancing motivation, ability and confidence through the following methods:

- Offer personalized, relevant feedback about the importance of quitting

- Explore the individuals' perceived pros and cons of smoking and quitting
- Discuss the 4 R's of quitting tobacco use
    i. Relevance: Help the individual identify why quitting tobacco is relevant to him/her.
    ii. Risk: Encourage the individual to verbalize possible negative outcomes of tobacco use.
    iii. Rewards: Help the individual identify the possible benefits of quitting tobacco use.
    iv. Roadblocks: Help the individual to identify possible obstacles to quitting, including those from his/her past quit attempts.

4TH STEP – DRUG AND STUDY VISIT REMINDERS

Participants will also be reminded that at all future study visits will occur remotely.

Participants will also be asked if they prefer to have the remaining study visits occur remotely by phone or video conferencing by Zoom. Participants will be notified that they will receive at least weekly text-messaging reminders providing updates regarding prescribed pharmacotherapies and study visit reminder dates/times.

They will be made aware that they will be contacted by text message (preferred) or phone on a scheduled basis as each week progresses. Messages will be of 2 types:

- *Type 1*: Reminder of the two offered dates & times of the following week's study visit video conference or phone call. The participant will choose one of the two dates for the study visit. Reminders will be sent 72 hours and 24 hours prior to each event.

- *Type 2*: For those prescribed Chantix®, follow-up will occur every 72 hours. The text or phone messages will ask if experiencing any medical issues on therapy [See Drugs/Substances/Devices and Risks sections in this protocol for more information on adverse effects]. The voice or text messages will state the question, "Are you experiencing any side effects or are you having any problems with taking Chantix?" If they text back "Yes", the participant will receive a phone call by our research staff. The concerns will be reviewed with our medical specialist. The medical specialists may call the participant for further details and/or relaying the treatment plan. Concerns about the clinical status may warrant referral to the JHH Emergency Room or the Tobacco Treatment Clinic at Bayview Medical Center if acute medical care concerns arise.
    - If the medical recommendation is to discontinue BOTH the "acute" and "controller" pharmacotherapy, the patient will be disenrolled from the study. Participants who are disenrolled will be contacted by phone at the end of the intervention to employ the survey used at the final time point (See "Supplementary Document 6"). They will be provided contact information of local smoking cessation resources, including the state quitline (800-QUIT-NOW) and Tobacco Treatment Clinic at Bayview Medical Center.
        - *NOTE: We do not anticipate the discontinuation of both the "acute" and "controller" therapies based on our initial smoking cessation pilot at Douglass*

(see Preliminary data). Based on the low frequency of observed side effects, there is a very low likelihood of a participant not being a good candidate for NRT patch ("controller") or NRT gum/lozenge ("acute"). This means that an individual who may not qualify for "Chantix" could be converted "NRT transdermal patch", while continuing on their NRT gum/lozenge.

TIME POINT 4 – follow/up visit

WEEKLY FOLLOW-UP VISIT

Each weekly follow-up visit will occur remotely based on participant preference for a videoconference platform (Zoom) or mobile phone. Two separate times for study visit will be offered to allow participants the option to choose a time more preferable to their schedule. If Zoom is not preferable or communication issues arise, standard audio phone-based options without video capacity will be instituted. There will be NO video or audio recordings of any of the study visits. Paper or electronic copies of participant answers will be stored in CRMS.

The intervention at these follow-up visits will have 4 key features:

1. Survey completion that contains questions about interval smoking characteristics (**see "Supplementary Document3"**).
2. Pharmacotherapy education that reinforces appropriate medication administration and commonly observed side effects. ***See Drugs/Substances/Devices and Risks sections in this protocol for more information on side effects.***
3. Cessation-directed motivational interviewing

1ST STEP – CONFIRMATION AND SURVEY SCREENING

- Participants will check-in with research staff to confirm that they were enrolled at the baseline study event (Week 0).

- A short survey (approximately 5 minutes) will be undertaken to acquire key smoking characteristics (**see "Supplementary Document3"**). The survey will ask about the usage of the prescribed pharmacotherapies and possible explanations for non-optimal adherence. The survey will also query the degree of nicotine dependence. The study follow-up visits are using shortened surveys to capture immediately relevant study outcomes, reduce study fatigue, and to improve participant acceptability of the project.

  Surveys will be displayed on the video conference call if Zoom is the preferred modality for the study. For participants with difficulty reading the survey, the questions will be read aloud and the responses will be recorded. For phone-based visits, our research team will read the questions aloud and record the answer choices.

- We will also confirm if any updates in contact information has occurred.

2ND STEP – DRUG EDUCATION AND SIDE-EFFECT MONITORING

- Confirmation of the prescribed pharmacotherapies will be undertaken. This will also include self-reported frequency of daily usage of controller and rescue medications.

  NOTE: We will confirm that NRT products and Chantix was prescribed to the correct participants through the completion of medication dispensing form (see "Supplementary Document 5"). The form also provides documentation that drug education has occurred.

- All participants will undergo repeat education on the appropriate means to self-administer the medications and commonly observed side effects.

  We will again educate participants that they may avail of our 24-hour phone number to access research staff if concerns or questions arise regarding pharmacotherapy. Research staff will review concerns with medical specialists and respond through either text messaging and/or phone calls. If both controller and rescue medications are stopped, the patient will be disenrolled from the study. If disenrolled, they will be provided contact information of local smoking cessation resources in case they again start to smoke (800-QUIT-NOW or tobacco treatment clinic at Bayview).

  NOTE: All adverse effects or concerns about pharmacotherapy will be documented. The time, data, description of issue and response will be included in the documentation.

3RD STEP – CESSATION-DIRECTED MOTIVATIONAL INTERVIEWING

- Brief motivational interviewing (MI) delivered by research staff.

  .

  We will assist by enhancing willingness or motivation, as well as ability or confidence through the following methods:
  - Offer personalized, relevant feedback about the importance of quitting
  - Explore the individuals' perceived pros and cons of smoking and quitting
  - Discuss the 4 R's of quitting tobacco use
    - Relevance: Help the individual identify why quitting tobacco is relevant to him/her.
    - Risk: Encourage the individual to verbalize possible negative outcomes of tobacco use.
    - Rewards: Help the individual identify the possible benefits of quitting tobacco use.
    - Roadblocks Help the individual to identify possible obstacles to quitting, including those from his/her past quit attempts.

4H STEP – STUDY VISIT REMINDERS

a) Participants will again be reminded that they will be contacted by text message (preferred) or phone on a scheduled basis as each week progresses. Reminder

of the two offered dates & times of the following week's study visit. The participant will choose one of the two dates for the study visit. Reminders will be sent 72 hours and 24 hour prior to each phone call or videoconference.

b) For those prescribed Chantix®, follow-up will again occur every 72 hours. The text or phone messages will ask if experiencing any medical issues on therapy [See Drugs/Substances/Devices and Risks sections in this protocol for more information on adverse effects]. The text messages will state the question, "Are you experiencing any side effects or are you having any problems with taking Chantix?" If they text back "Yes", the participant will receive a phone call by our research staff. The concerns will be reviewed with our medical specialists. The medical specialists may call the participant for further details and/or relaying the treatment plan. Concerns about the clinical status may warrant referral to the JHH Emergency Room or the Tobacco Treatment Clinic at Bayview Medical Center if acute medical care concerns arise.
    - If the medical recommendation is to discontinue BOTH the "acute" and "controller" pharmacotherapy, the patient will be disenrolled from the study. They will be provided contact information of local smoking cessation resources. They will be provided information for the state quit line (800-QUIT-NOW) and the Tobacco Treatment Clinic at Bayview Medical Center. Participants who are disenrolled will be contacted by phone at the end of the intervention to employ the final survey used at the time=+4 week point **(See "Supplementary Document 3")**

Participants will again be provided with a 24-hour phone contact to communicate with our research team. Participants will be able to text regarding any concerns about the study. Participants will receive a text and/or voice response to the identified within 1 day of receipt. All concerns will be documented and reviewed with the PIs and/or identified medical specialists of the research team.

TIME POINT 5 – follow/up visit

WEEKLY FOLLOW-UP VISIT

All elements of this time point mirror the description represented above (TIME POINT 4). The only difference is that one interval text messaging type will be used. *We will no longer ask Chantix® users about medication concerns every 72 hours, if they have not reported any adverse effects to date on therapy*. Participants will continue to receive reminders at 72 hours and 24 hours prior to the next scheduled follow-up study visit.

TIME POINT 6 – follow/up visit

WEEKLY FOLLOW-UP VISIT

All elements of this time point mirror the description represented above (TIME POINT 5)

TIME POINT 7 – FINAL follow/up visit

FINAL VISIT

This final study visit will occur by videoconference (Zoom) or a phone call. Two separate times for the study visit will be offered to allow participants the option to choose a time more

preferable to their schedule. The intervention at this time point will have 3 key features:

1. Survey completion that contains questions about smoking characteristics and completion of open-ended questions that explore the feasibility of the study pilot (**see "Supplementary Document 3"**).
2. Referral to 800-QUIT-NOW or Tobacco Treatment Clinic at Bayview Medical Center if continued smoking cessation resources are requested
3. $15 cash equivalent reimbursement for study participation.

1ST STEP – CONFIRMATION AND SURVEY SCREENING

- Participants will check-in with research staff to confirm their enrollment in the study.

- A short survey (approximately 5 minutes) will be undertaken to acquire key smoking characteristics (**see "Supplementary Document 3"**). The survey will ask the usage & frequency that the prescribed pharmacotherapies are being used, as well as query the degree of nicotine dependence over the 4-week pilot period. Surveys will be displayed on the video conference call if Zoom is the preferred modality for the study. For participants with difficulty reading the survey, the questions will be read aloud and the responses will be recorded. For phone-based visits, our research team will read the questions aloud and record the answer choices.

- Participants will also be asked 10 open-ended questions that will assess study feasibility (**see "Supplementary Document 3"**). Questions will be real aloud and the responses will be summarized solely in a written format by the research team. The questions explore participant thoughts on the objective, data collection, recruitment, pharmacotherapy experience (administration, education, delivery and monitoring), motivational interviewing, study schedule and text messaging/phone follow-up.

2ND STEP – UNUSED DRUG SUPPLIES

- Participants will be encouraged to return any unused drug supplies. The medications will be able to be returned in a pre-stamped envelope that was provided with the initial medication package prior to the study. The return envelope is to labelled to the attention of the PI (Dr. Galiatsatos). The unused medications will be dropped off at a drug disposal unit at Johns Hopkins Monument Street Pharmacy.

3RD STEP – POST-PILOT CESSATION RESOURCES

- All participants will be provided contact information of local smoking cessation resources for continued participation in the cessation effort. They will be provided information for the state quit line (800-QUIT-NOW) and the Tobacco Treatment Clinic at Bayview Medical Center.

4TH STEP – REIMBURSEMENT OF STUDY VISIT PARTICIPATION BY EMAIL OR

TEXT MESSAGING.

- $15 cash equivalent reimbursement for study participation.

- ***Data and Safety Monitoring Plan***

  For the proposed research, Dr Galiatsatos will take the responsibility for coordinating and assuring data storage and access. We do not expect the project to produce more data than can be appropriately managed by the research team. This research will generate data resulting from surveys and questionnaires.

  Clinical Research Management System (CRMS) is being used for data management and research implementation. CRMS will contain the following information:
  - Protocol information from eIRB2
  - Registry of study participants
  - Management of study accruals
  - Consent tracking
  - Secure location for study-related documents (e.g. surveys, questionnaires and screening tools)
  - Pre-configured and adhoc reports
  - Multiple interfaces with Epic, including sending data to Epic about the study and the study participants

  Written surveys, questionnaires and screening tools completed by participants (or assisted by research staff) will be scanned into CRMS. All written material will be destroyed after scanning has been completed. Files will only be shared with research team members listed on the IRB application.

  SAFE, the Secure Analytic Framework Environment, will also be used as a secure environment to analyze and share sensitive data (e.g. PHI) with research staff. Statistical analyses and report generation/sharing will occur on the SAFE network. Data will be stored in SAFE in one of the following formats: Stata, Microsoft Excel, PowerPoint, Microsoft Word and/or Acrobat PDF.

  Data analysis will occur individually and collectively in group meetings. Analysis will occur only at JHU. Results may be tabulated and summarized for ease in understanding the analysis. All analysis will occur within SAFE desktop software apps.

  Findings of the de-identified data will be used among research team for the development of larger-scaled tobacco intervention studies. Data containing PHI will not be shared outside of the JHU research team. All public discussions and/or scientific publications will use de-identified datasets.

  All affiliates within the Housing Authority of Baltimore City will only be provided de-identified, aggregated data.

  Data will be maintained on SAFE desktop for five years after the conclusion of the project.

- **STUDY DURATION AND NUMBER OF STUDY VISITS REQUIRED OF RESEARCH PARTICIPANTS**

  a) Duration of Study Participation
  The total duration of study subject participation is 6 weeks – including screening, consent and intervention phases.

  b) Number of study visits
  A total of 6 study visits will occur over the 6-week duration of the study.
    - Visit 1: Screening and consent
    - Visit 2: Baseline time point of the intervention (including delivery of pharmacotherapies)
    - Visit 3: Follow-up time point of the intervention
    - Visit 4: Follow-up time point of the intervention
    - Visit 5: Follow-up time point of the intervention
    - Visit 6: Final intervention time point

  All participants will be screened, consented, receive their cessation pharmacotherapy and undergo their baseline study visits in-person. All remaining study visits will occur remotely through video conferencing or standard audio phone calls.

- **BLINDING, INCLUDING JUSTIFICATION FOR BLINDING OR NOT BLINDING THE TRIAL, IF APPLICABLE.**

  This is a pre-post study design with no active comparator. All participants will receive the intervention. There is no blinding during the trial.

- **JUSTIFICATION OF WHY PARTICIPANTS WILL NOT RECEIVE ROUTINE CARE OR WILL HAVE CURRENT THERAPY STOPPED.**

  Not applicable

- **JUSTIFICATION FOR INCLUSION OF A PLACEBO OR NON-TREATMENT GROUP.**

  Not applicable

- **DEFINITION OF TREATMENT FAILURE OR PARTICIPANT REMOVAL CRITERIA.**

  Participants will be removed if any of the following criteria are met:
  a) Smoking cessation reported at the start of the intervention (BASELINE VISIT)
  b) Based on reported adverse medication effects, our medical specialists may recommend for discontinuation or modification of the pharmacotherapy regimen.

Participants who are recommended to discontinue *BOTH* the "acute" and "controller" pharmacotherapy will be disenrolled from the study.

- **DESCRIPTION OF WHAT HAPPENS TO PARTICIPANTS RECEIVING THERAPY WHEN STUDY ENDS OR IF A PARTICIPANT'S PARTICIPATION IN THE STUDY ENDS PREMATURELY.**

  If the participant's participation ends prematurely, they will receive their reimbursement from their final study visit. They will also be provided the contact information of local smoking cessation resources, include the state quitline (800-QUIT-NOW) and Tobacco Treatment Clinic at Bayview Medical Center.

  For participants who complete the study, they too will be provided the contact information of local smoking cessation resources, include the state quitline (800-QUIT-NOW) and Tobacco Treatment Clinic at Bayview Medical Center.

  Subjects may withdraw from the study at any time without impact to their care.

5. INCLUSION/EXCLUSION CRITERIA

Inclusion criteria:

1. ≥18 years of age
2. Self-reported smoker with either daily or weekly cigarette use, as well as expressed desire to reduce or quit smoking
3. Proof of residence at Douglass or Brooklyn Homes - as confirmed by verbal acknowledgement by the service coordinators at each site.
4. Working mobile phone with texting ability for the duration of the study
5. Active health insurance (for pharmacotherapy billing)

Exclusion criteria:

1. Pregnant – women will verbally acknowledge that they are *not* pregnant or trying to become pregnant in the next 8 weeks from the time of screening and recruitment to ensure no intake of nicotine and non-nicotine pharmacotherapy
2. Breastfeeding – women who are verbally acknowledge they are breastfeeding will be excluded from the study. This exclusion factor is in place secondary to breastfeeding concerns associated with the study's usage of nicotine and non-nicotine pharmacotherapy
3. Ongoing participation in a tobacco cessation program or related tobacco intervention study. Past participation in previous iterations of the protocol is not an exclusion criteria.
4. No active health insurance.
5. Unable to verbally state that they are willing to reduce or quit smoking upon recruitment and screening
6. Adults lacking capacity to consent
7. Non-English speakers

8. Self-reported usage of *only* non-combustible tobacco products, such as smokeless tobacco or Electronic Nicotine Delivery Devices (ENDS).
9. Anticipated relocation outside of Douglass or Brooklyn Homes prior to the final study visit

6. DRUGS/ SUBSTANCES/ DEVICES

- **The rationale for choosing the drug and dose or for choosing the device to be used.** Nicotine and non-nicotine pharmacotherapy to treat tobacco addiction will be prescribed in Epic by Dr. Galiatsatos [PI], Medical Director of the Tobacco Treatment Clinic at Bayview Medical Center. Dr. Galiatsatos is a faculty member in the Division of Pulmonary Critical Care & Medicine.

  Pharmacotherapy oversight will also be led the PI, an expert in pharmacotherapy for tobacco dependence and smoking cessation.

  The selection and prescription of pharmacotherapies will approximate an approach currently employed the PI. The PI currently provides medical care in two public housing complexes in Baltimore: Monument East and McColloh Homes.

  Patients will undergo a multistep process to screen and monitor adverse effects on therapy. The medications chosen based on initial screening will be prescribed and delivered to participants. Prior to initiating the administration of the medications, participants will again be evaluated for the presence of absolute or relative contraindications of the prescribed pharmacotherapy regimen (BASELINE VISIT: Time Point 3) . Participants will be provided a 24-hour contact phone number to report concerns or adverse effects on therapy. All concerns will be reviewed by the PI within 24 hours of receipt.

  All pharmacotherapy is FDA approved and dosing will be based on FDA drug labelling.

  - NRT gum or lozenge:

Baseline to end of study = 4 weeks	
STEP 1	**Determine dosage**
	Do you smoke your 1st cigarette within 30 minutes of waking up? Yes → Use 4 mg gum or lozenge No → Use 2 mg gum or lozenge
STEP 2	**Frequency of administration**
	Take the recommended dose (1-piece) by mouth every 1-2 hours

  - NRT patch:

Baseline to end of study = 4 weeks	
STEP 1	**Determine dosage**

	Do you smoke ≥ 10 cigarettes per day? Yes → Use 21 mg patch No → Use 14 mg patch
STEP 2	**Frequency of administration**
	Apply one new patch per day

- Chantix®:

Baseline to end of study = 4 weeks	
STEP 1	**Dosing & administration**
	Day 1 – 3: 0.5 mg by mouth daily Day 4 – 7: 0.5 mg by mouth twice-daily Day 8 – 30: 1 mg by mouth twice-daily

- **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

- **Justification and safety information if non-FDA approved drugs without an IND will be administered.**

  Not applicable

7. STUDY STATISTICS

a. Primary outcome variable

The primary endpoint will be study feasibility. Feasibility will be measured using open-ended questions administered by the research team and targeting the study stakeholders (study participants, community stakeholders and research team). The answers will serve as a means to evaluate the need for further modification in the recruitment, screening, consent, study implementation and evaluation phases of future study testing..

b. Exploratory outcome variables

Pre- & post-changes in nicotine dependence levels – Results will be stratified by baseline smoking behaviors, sociodemographic characteristics and socioeconomic stressors. For group-wise comparisons, t-test or analysis of variance will be used. Regression analyses will be performed to investigate the relationship between baseline measures and changes in smoking characteristics as the pilot study progressed.

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

This study will not be powered for significance. The primary purpose of this study is to assess feasibility of the pilot study design.

d. Early stopping rules

Not applicable

8. RISKS

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

NRT Gum or Lozenge

Although adverse effects from NRT gum or lozenge are uncommon. These may include:

a) Nausea
b) Abnormal dreams (vivid, unusual, strange)
c) Constipation
d) Flatulence
e) Vomiting
f) Rash
g) Hypersensitivity reactions
h) Sleep walking
i) Accidental injury
j) Interaction with alcohol
k) Seizures
l) Changes in mood
m) Hallucinations
n) Paranoia
o) Delusions
p) Homicidal ideation
q) Aggression
r) Hostility
s) Agitation
t) Anxiety
u) Panic
v) Suicidal Ideation
w) mouth ulcers
x) jaw muscle aches
y) dizziness
z) hiccups
aa) headache
bb) gastrointestinal symptoms (nausea, vomiting, diarrhea, dyspepsia)
cc) dyspnea or difficulty breathing
dd) abnormal heart beat (tachycardia, arrhythmias or palpitations)
ee) rash

NRT Patch

Reported adverse effects include the following:

a) Skin irritation
b) dizziness,
c) gastrointestinal symptoms (nausea, vomiting, diarrhea, dyspepsia)
d) headaches
e) rash
f) abnormal heart beat (tachycardia, arrhythmias or palpitations)
g) dyspnea or difficulty breathing

Chantix

Adverse reactions

- Most common adverse reactions (>5% and twice the rate seen in placebo-treated patients) were nausea, abnormal (e.g., vivid, unusual, or strange) dreams, constipation, flatulence, and vomiting.

Warnings & precautions

- Neuropsychiatric Adverse Events: Postmarketing reports of serious or clinically significant neuropsychiatric adverse events have included changes in mood (including depression and mania), psychosis, hallucinations, paranoia, delusions, homicidal ideation, aggression, hostility, agitation, anxiety, and panic, as well as suicidal ideation, suicide attempt, and completed suicide. They will be advised to seek immediate medical attention if they experience signs and symptoms of neuropsychiatric events.
- Seizures: New or worsening seizures have been observed in patients taking CHANTIX. CHANTIX should be used cautiously in patients with a history of seizures or other factors that can lower the seizure threshold. They will be advised to seek immediate medical attention if they experience signs and symptoms of seizure activity.
- Interaction with Alcohol: Increased effects of alcohol have been reported. We will instruct patients to reduce the amount of alcohol they consume until they know whether CHANTIX affects them.
- Accidental Injury: Accidental injuries (e.g., traffic accidents) have been reported. We will instruct patients to use caution driving or operating machinery until they know how CHANTIX may affect them.
- Cardiovascular Events: Patients with underlying cardiovascular (CV) disease may be at increased risk of CV events; however, these concerns must be balanced with the health benefits of smoking cessation. We will instruct patients to notify our team ***and*** their healthcare provider of new or worsening CV symptoms. They will be advised to seek immediate medical attention if they experience signs and symptoms of myocardial infarction (MI) or stroke.
- Somnambulism: Cases of somnambulism have been reported in patients taking CHANTIX. Some cases described harmful behavior to self, others,

or property. We will instruct patients to discontinue CHANTIX and notify their healthcare provider if they experience somnambulism.

- Angioedema and Hypersensitivity Reactions: Such reactions, including angioedema, infrequently life-threatening, have been reported. We will instruct patients to discontinue CHANTIX and immediately seek medical care if symptoms occur.
- Serious Skin Reactions: Rare, potentially life-threatening skin reactions have been reported. We will instruct patients to discontinue CHANTIX and contact a healthcare provider immediately at first appearance of skin rash with mucosal lesions.
- Nausea: Nausea is the most common adverse reaction (up to 30% incidence rate). Dose reduction may be helpful.

b. Steps taken to minimize the risks

- *Reporting of Adverse Events, Adverse Device Effects and Unanticipated Problems*

Definition of medication adverse event: An adverse event (AE) is any symptom, sign, or experience that develops during the course of administering NRT (gum, lozenges or patches) or non-nicotine pharmacotherapies (Chantix®)

The following report will be supplied as a narrative for all NRT-reported adverse events:

- Study identifier
- A description of the event
- Date of onset
- Current status
- Whether study medication was discontinued
- Whether alternative NRT or non-nicotine pharmacotherapy was prescribed
- Investigator assessment of the association between the event and study intervention

Patients will undergo a multistep process to screen and monitor adverse effects on therapy. The medications prescribed & delivered based on initial screening will only be recommended for administration after participants undergo confirmation of appropriateness of drugs selection at the time of the baseline study visit (WEEK 3). Participants will be provided a 24-hour contact phone number to reports concerns or adverse effects on therapy. All concerns will be reviewed by the PI within 24 hours of receipt.

All adverse events will be followed until resolution, stabilization, or until it has been determined that the study intervention or participation is not the cause. Further action and/or candidacy for an alternative pharmacotherapy (e.g. Chantix® changed to NRT patch) will occur under the direction of the medical specialists (PI).

We will also ensure that Chantix is being administered to the correct participants and drug education is being delivered at each study visit through the completion of medication dispensing form (**see "Supplementary Document 5"**). The form requires the signature of the study team member who will verify administration and education of the medication to the correct participant.

c. Plan for reporting unanticipated problems or study deviations

All unanticipated problems and study deviations will be reviewed by the PI Dr. Galiatsatos.

We have built the protocol to accommodate minor deviations. For example, our protocol is still maintained despite participants unable to attend the study visits or if all outcomes are not obtained during the 4 week trial. These will be reported in an IRB continuing review.

Major deviations will be reported immediately to the IRB. A major deviations are events that cause or could cause harm to subjects or others or that affect the fidelity of our research.

d. Legal risks such as the risks that would be associated with breach of confidentiality

Not applicable

e. Financial risks to the participants

There are no financial risks for participants

9. BENEFITS

Description of the probable benefits for the participant and for society

- There may be the possibility of direct benefit of this research protocol to a similar population of tobacco smokers in public housing depending on the findings of this study. This pilot study is testing the feasibility of this multicomponent intervention for future, scaled-up testing in more public housing zones in Baltimore City.

10. PAYMENT AND RENUMERATION

Detail compensation for participants including possible total compensation, proposed bonus, and any proposed reductions or penalties for not completing the protocol

- Participants will receive a maximum of $15 for their participation in the study. Renumeration will occur at only the final time point:

- There are no penalties for not completing the protocol.

11. COSTS

Detail costs of study procedure(s) or drug (s) or substance(s) to participants and identify who will pay for them

- The pharmacotherapies will be billed to Maryland Medicaid. We anticipate all participants, whose income qualify for public housing, use Maryland Medicaid or Medicare as their health insurance. Patient are required to pay nothing ($0) for a 1-month supply of NRT gum/lozenge, patch *and* Chantix®.
  - In the rare case, that a participant is using a commercial health insurance, we still anticipate $0 copay. Two current commercial health insurances (Humana Medicare and Medimpact) have co-pay ranging from $47 - $54 for NRT products. In these cases, we will apply for vouchers using the assistance of JHH Community Pharmacy Resources.