

An Integrated mHealth Application for Smoking Cessation in Black Smokers with HIV: Protocol for a Randomized Controlled Trial

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Abstract

Background: Black adults who smoke and have HIV face significant stressors (e.g., racial discrimination, HIV stigma) that impede successful smoking cessation attempts and perpetuate smoking-related health disparities. These stressors place Black adults who smoke and have HIV at increased risk of elevated interoceptive stress (e.g., anxiety, bodily sensations) and smoking to manage symptoms. In turn, this population experiences worse HIV-related outcomes. Yet, no specialized treatment exists to address smoking cessation and HIV disease management for Black smokers with HIV.

Objective: The aim of this study is to test a culturally adapted, novel, mobile intervention that targets smoking outcomes, HIV treatment engagement/adherence, and anxiety sensitivity (AS; a proxy for difficulty and responsivity to interoceptive stress) among Black smokers with HIV (i.e., Mobile Anxiety Sensitivity Program for Smoking and HIV; MASP+). Various culturally tailored components of the app will be evaluated for their ability to help users to quit smoking, manage physiological stress, and improve healthcare management.

Methods: The current study is a pilot randomized controlled trial in which Black smokers with HIV (N = 72) will be recruited from an HIV clinic and randomly assigned to use either: (1) the National Cancer Institute's (NCI) QuitGuide app, or (2) MASP+. Study procedures include an online pre-screener, smartphone-based assessments, including daily app-based ecological momentary assessments (EMAs) for 6 weeks (4 EMAs each day), a phone-based qualitative interview at week 6 for participants in all study conditions, and smartphone-based follow-up assessments at 0, 1, 2 (quit date), 3, 4, 5, 6, and 28 weeks post-baseline (26 weeks post-quit).

Results: Primary outcomes include biochemically-verified 7-day point prevalence abstinence, increased use of antiretroviral therapy, and improved attendance at HIV-related health appointments at 26 weeks post-quit. Qualitative data will also be collected and assessed to obtain feedback that will guide further tailoring of app content and evaluation of efficacy.

Conclusions: Results of the present study will determine whether the MASP+ app serves as a successful aid for smoking cessation, treatment engagement, and physiological stress outcomes among Black people with HIV. If successful, this study will provide evidence for the efficacy of a new means of addressing major mental and physical health difficulties for this high-risk population. If results prove promising, data from this study will be used to update and tailor the MASP+ app for testing in a fully powered randomized controlled trial that will evaluate its efficacy in real-world behavioral health and social service settings. Clinical Trial: This trial has been registered at clinicaltrials.gov (NCT: NCT05709002; Protocol ID: QKWEF8XLMTT3).

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Original Manuscript

An Integrated mHealth Application for Smoking Cessation in Black Smokers with HIV: Protocol for a Randomized Controlled Trial

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Abstract

Background: Black adults who smoke and have HIV experience significant stressors (e.g., racial discrimination, HIV stigma) that impede smoking cessation success and perpetuate smoking-related health disparities. These stressors also place Black adults who smoke and have HIV at increased risk of elevated interoceptive stress (e.g., anxiety, uncomfortable bodily sensations). and smoking to manage symptoms. In turn, this population is more apt to smoke to manage interoceptive stress, which contributes to worse HIV-related outcomes among this group. Yet, no specialized treatment exists to address smoking cessation, interoceptive stress, and HIV management for Black smokers with HIV.

Objective: The current study aims to test a culturally adapted, novel, mobile intervention that targets combustible cigarette smoking, HIV treatment engagement/adherence, and anxiety sensitivity (AS; a proxy for difficulty and responsivity to interoceptive stress) among Black smokers with HIV (i.e., Mobile Anxiety Sensitivity Program for Smoking and HIV; MASP+). Various culturally tailored components of the app are undergoing evaluation for their ability to help users to quit smoking, manage physiological stress, and improve healthcare management.

Methods: The current study is a pilot randomized controlled trial in which Black combustible cigarette smokers with HIV ($N = 72$) are being recruited from an HIV clinic and randomly assigned to use either: (1) the National Cancer Institute's (NCI) QuitGuide app, or (2) MASP+. Study procedures include an online pre-screener; active intervention period for 6 weeks; smartphone-based assessments, including daily app-based ecological momentary assessments (EMAs) for 6 weeks (4 EMAs each day); a Zoom-based qualitative interview at week 6 for participants in all study conditions; and smartphone-based follow-up assessments at 0, 1, 2 (quit date), 3, 4, 5, 6, and 28 weeks post-baseline (26 weeks post-quit).

Results: Primary outcomes include biochemically-verified 7-day point prevalence abstinence, HIV-related quality of life, use of antiretroviral therapy, and HIV care appointment adherence at 26 weeks post-quit. Qualitative data is also being collected and assessed to obtain feedback that will guide further tailoring of app content and evaluation of efficacy.

Conclusions: Results of the present study will determine whether the MASP+ app serves as a successful aid for combustible cigarette smoking cessation, HIV treatment engagement, and physiological stress outcomes among Black people with HIV. If successful, this study will provide evidence for the efficacy of a new means of addressing major mental and physical health difficulties for this high-risk population. If results prove promising, data from this study will be used to update and tailor the MASP+ app for testing in a fully powered randomized controlled trial that will evaluate its efficacy in real-world behavioral health and social service settings.

Key words: smoking cessation; Black; HIV; anxiety sensitivity; mHealth; just-in-time adaptive intervention

Introduction

People with HIV/AIDS (PWH) smoke at rates three times higher (33.6% vs. 12.5%) than the general population [1, 2]. This group is also less likely to quit smoking and is more susceptible to the harmful effects of smoking (e.g., increased risk for cancer and lung disease) [1, 3, 4], likely due to the combined impact of several social determinants of health, including behavioral risk factors, limited resources, and diminished access to health care, as well as immune system dysfunction and chronic inflammation caused by HIV [5-10]. Indeed, cigarette smoking is a leading risk factor for HIV-related and non-HIV-related morbidity and mortality among PWH [11, 12], even among those taking antiretroviral (ART) medications [13], and contributes to more life-years lost than HIV-related complications among those effectively treated with ART [13-15]. Further, PWH who smoke are less adherent to ART than non-smokers and experience poorer viral and immunologic response to ART [16, 17], a greater risk of virologic rebound, and more frequent immunologic failure [18].

Among PWH who smoke, those who identify as a racial minority are at elevated risk for negative health consequences of smoking and poorer HIV-related outcomes. Evidence suggests that Black adults with HIV, in particular, experience high rates of discrimination and stigma that lead to the onset and maintenance of maladaptive coping, including smoking [19, 20]. Consistent with these data, Black adults with HIV are more likely to smoke [4], less likely to quit [4, 21-24], and experience greater quit difficulty when attempting to quit than either White smokers or smokers without HIV [21]. Black adults with HIV also have lower rates of compliance with routine HIV care (i.e., ART adherence), retention in long-term care, and are less likely to be viral suppressed relative to other groups [25-28]. This is a public health problem because Black adults account for the highest proportion of new HIV diagnoses (i.e., 42%) and experience higher mortality relative to White adults with HIV [25, 27, 28]. From an intersectional stigma/discrimination perspective and socio-ecological models of social determinants of health [29, 30], Black adults who smoke and have HIV may be at elevated risk for worse HIV disease management and smoking outcomes, and ultimately experience increased health disparities [6].

Emotional models of coping suggest that Black adults with HIV may smoke and continue to smoke despite health problems to manage interoceptive stress and uncomfortable physiological arousal associated with minority status stressors, such as racial discrimination, and HIV-related stigma. One of the most significant constructs related to physiological distress and manifestations of elevated internal distress, including psychopathology, is anxiety sensitivity (AS). AS refers to the fear of anxiety or anxiety-related symptoms [31]. AS amplifies negative mood states via enhanced threat perception [e.g., anxiety; 32, 33], contributing to the development of anxiety and depressive problems [34]. Notably, anxiety and depression significantly contribute to an increased likelihood of poor ART adherence [35]. Among PWH, AS is related to more severe social anxiety symptoms, anxious arousal symptoms, HIV-related stigma, and HIV symptom distress [36, 37]. AS has also been implicated as a contributing factor in smoking initiation, maintenance, and relapse processes [38, 39]. Emerging data indicate that AS is elevated in both Black adults who smoke and PWH who smoke [40], placing this group at greater odds of early lapse and relapse [41, 42]. Without appropriate interventions to address susceptibility to the negative impact of interoceptive stress, Black adults with HIV who smoke and have elevated AS may be inclined to return to smoking to alleviate abstinence-induced increases in anxiety and to manage uncomfortable HIV-related bodily symptoms that may increase with smoking cessation.

Although smoking cessation treatments that target AS exist, they are limited in their reach, adaptability, and potential for adoption and do not consider critical barriers to smoking cessation or HIV treatment engagement and adherence. For example, current AS/smoking treatments focus primarily on multi-session, intensive treatments, particularly those that rely on in-person, clinician-administered psychosocial protocols [43-46]. Participation in these treatments often requires significant time commitments, practical limitations, and expenses [47]. Such burdens are barriers to treatment and may contribute to low treatment participation rates [47]. An additional limitation of current treatments is that no readily available smoking cessation treatments that target AS integrate information to improve HIV treatment engagement or adherence. Given the robust evidence that

targeting AS and promoting smoking cessation may lead to improved HIV outcomes, this is a major limitation. Finally, the required human resources, specialized training, and financial support that is needed to administer currently available AS/smoking treatments discourage the adoption of these treatments in communities most in need, such as those that serve Black adults with HIV who smoke. Therefore, it is essential to develop a digital AS intervention that has the potential to be culturally adapted for this population.

Based on our prior work [48], we modified our previously developed and tested novel, integrated, smartphone delivered intervention for AS reduction and smoking [i.e., Mobile Anxiety Sensitivity Program (MASP); 49] for Black PWH who smoke, integrating HIV information and care support that is culturally tailored to create the new smartphone-based application ('app'): Mobile Anxiety Sensitivity Program for Black adults with HIV (MASP+). MASP+ contains features and content designed to aid Black adults with combustible smoking cessation, HIV care adherence, and AS reduction. The initial efficacy of MASP+ relative to an established control intervention, the National Cancer Institute's (NCI) QuitGuide app, on combustible cigarette smoking cessation, HIV-related outcomes, and AS reduction is now being tested in a pilot randomized controlled trial. We expect that MASP+ participants will report greater biochemically confirmed smoking abstinence at 26 weeks post-quit relative to the QuitGuide group. Additionally, we hypothesize that MASP+ participants will report greater HIV-specific quality of life, ART adherence, and HIV treatment engagement at 26 weeks post-quit relative to the QuitGuide group. Finally, we expect improvement in AS will mediate the relation between treatment and (1) smoking abstinence and (2) HIV-related outcomes, and daily experiences of discrimination (race and HIV) will moderate these relations. We will also examine qualitative and quantitative data to guide refinement and further adaptation of MASP+ and support the development of a high-quality, culturally relevant, and scalable intervention.

Methods

Ethics Approval

The Institutional Review Board (IRB) at the University of Houston (UH) approved the protocol as presented in this study, while the University of Oklahoma Health Sciences Center and Baylor

College of Medicine rely on the UH IRB. This trial has been registered at clinicaltrials.gov (NCT: NCT05709002; Protocol ID: QKWEF8XLMTT3).

Study Eligibility

Study eligibility criteria include being 18 years of age or older, having HIV (confirmed via chart review at the referring clinic), self-identifying as Black or African American, providing a current picture of their cigarette package to verify smoking status [48], possessing at least a 6th grade reading level [≥ 4 on the REALM-SF; 50], experiencing elevated AS ([i.e., Short Scale Anxiety Sensitivity Index (SSASI) score of ≥ 5 ; 51], reporting daily smoking with a minimum of 10 cigarettes per day for at least two years, being motivated to quit smoking) [> 5 on a 10-point scale; 52], willing to complete all study surveys/assessments, agreeing to use nicotine replacement medications (NRT; nicotine patch and lozenges), and agreeing to attempt to quit smoking two weeks after the date of randomization. Exclusion criteria include not being fluent in English, high blood pressure that is not under control (e.g., medicated), experiencing a heart attack (myocardial infarction) within the past two weeks, use of any pharmacotherapy targeting smoking cessation beyond what is provided by this study, legal status that would interfere with participation (e.g., incarceration with restricted access to mobile devices), cognitive impairment [assessed via the 6-item Cognitive Impairment Test; 53], being non-Black, pregnant, or younger than 18 years of age.

Recruitment and Procedures

Participants are recruited at Thomas Street at Quentin Meese Health Center, a clinic in Houston that provides routine medical care to over 5000 PWH. Thomas Street patients are referred to the study by providers and self-referred by accessing advertisement materials placed throughout the clinic. Study materials provide the contact information for UH or a study team member at Thomas Street in case a potential participant has questions about the study. Study advertisements also include a QR code that is linked to a REDCap pre-screener survey. For those who complete the pre-screener and are deemed pre-eligible, study team members at Thomas Street perform a chart review to confirm HIV status. Pre-eligible participants who are confirmed to have HIV are then contacted to complete an enrollment call wherein they provide informed consent and complete the

final eligibility screening for the study (see Figure 1 for Participant Enrollment Flowchart).

Persons who are deemed eligible at the enrollment call download the Insight™ application onto their personal smartphone or study phone. The Insight™ app houses the MASP+ content and is used to administer smartphone-based surveys and EMAs to all participants. Study smartphones are provided to those without a smartphone and those with a smartphone that is incompatible with the Insight™ platform. Insight™ is supported on most Android smartphones (Android versions 6.0-14.0). Participants with a personal phone that is incompatible with Insight™ are sent a study phone. For those using their personal smartphone, study staff instruct participants how to download the app onto their personal phone. Insight™ respects the font size that participants select for their phone. Participants who experience issues reading text in the app due to font size are instructed to increase font size in the phone settings. Once Insight™ is downloaded, participants are given a unique single-use code that enables them to use the app to complete the baseline assessment, which must be completed within 6 days after inputting the code. If participants do not complete the baseline survey within 6 days, they are no longer eligible to participate in the study. All participants are mailed a baseline package that includes a Bedfont iCO quit smokerlyzer, a Greenphire MasterCard, and nicotine replacement therapy (NRT). The Bedfont iCO is used to biochemically verify self-reported abstinence at follow-ups.

Upon completion of the baseline survey and receipt of the baseline package, participants complete a randomization call with study staff. During the randomization call, participants are randomized to receive the MASP+ or QuitGuide interventions based on the randomization chart developed by the study statistician (MWG). Block randomization is employed, stratified by binary sex (assigned at birth). Variable-sized permuted block-randomization (block sizes will vary from 4 to 12) is used. Prior to data analyses, the balance of randomization will be checked and controlled for imbalanced factors by including any factors that differ between groups as covariates. Participants are provided a unique code to access the app to which they are randomized. MASP+ participants have access to all MASP+ features (i.e., Treatment Videos, Coping Toolkit, Quit Tips, Stress Management Trainings) through the Insight™ platform. Participants randomized to the control

intervention (i.e., QuitGuide) have access to limited features (i.e., App Instructions, Payment Tracking, Call Staff, Record Stress) through the Insight™ platform, and receive intervention content (i.e., Track My Craving, Manage My Mood, Learn To Quit) through the QuitGuide app. Participants assigned to the control intervention receive assistance with downloading the QuitGuide app through the Play Store. Both intervention groups use the Insight™ app to complete study assessments, which includes the baseline survey, weekly follow-ups, the 28-week follow-up, and ecological momentary assessments (EMAs). Once the code is entered, research staff orient participants to the app features and the iCO carbon monoxide breath testing device. Participants have access to MASP+ or QuitGuide content through the final follow-up (i.e., 28-week follow-up). At the end of the randomization call, participants are directed to take a brief post-randomization survey, which must be completed within 6 days after the randomization call. Failure to complete the post-randomization survey within 6 days does not affect participant's status in the study.

Following randomization, participants complete 4 daily EMAs for 6 weeks. Participants also complete app-based follow-up surveys each week of the treatment period (i.e., weeks 1-6) and at 26-weeks post-quit (28-weeks post-baseline). Between weeks 6 and 28, all participants are prompted to complete a brief check-in survey each month, which reminds them about available app features and assesses their current smoking status. Participants complete a final series of EMAs (4 per day) for 7 days prior to the 28-week follow-up assessment. The Insight™ app prompts daily EMAs and follow-up assessments for both treatment groups. Additionally, participants complete a Zoom-based qualitative interview to assess their experience with the app and capture recommendations for improving app features and content at 6 weeks post-randomization. Participants who received loaned study smartphones are required to return them following their final follow-up assessment at week 28.

Compensation

Each participant who enrolls receives a Greenphire Mastercard gift card that is loaded with compensation for survey completion. Participants receive \$30 for completing the baseline assessment and \$10 for completing the post-randomization survey. Participants receive \$10 for

completing each weekly follow-up assessment at weeks 1, 2 (quit date), 3, 4, 5, and 6 weeks post-baseline (including the app-based survey, iCO breath test, and Zoom-based qualitative interview at week 6 only). Participants receive \$50 for completing the 28-week follow-up assessment (via Insight™) and iCO breath test. Participants are compensated at the end of week 6 for EMA completion during weeks 1-6 and at the end of week 28 for EMAs completed during week 28. Specifically, participants receive a total of \$60 for completing 50%-74% of the brief EMAs (4 per day x 7 days = 28 weekly EMAs) prompted during weeks 1-6, \$90 for completing 75-89% of EMAs, or \$120 for completing 90% or more EMAs. For week 28, participants receive \$10 for completing 50%-74% of the brief EMAs, \$15 for completing 75-89% of EMAs, or \$20 for completing 90% or more EMAs. Participants can use the "Payment" and "Weekly Survey Payment" buttons on the app's home screen whenever desired to view an up-to-the-moment summary of EMAs presented and their current completion rate. Payments for completed EMAs are loaded onto participants' Greenphire cards following week 6 and week 28.

Study Conditions

Both conditions. Given that clinical guidelines recommend that all smokers attempting to quit should receive and use pharmacotherapy [54], both MASP+ and QuitGuide participants are sent NRT with their baseline package. Transdermal nicotine patches and nicotine lozenges are provided for use during the first 4 weeks post-quit and each participant is given the option order up to 4 weeks of additional NRT. For those in the MASP+ condition, additional NRT can be ordered by clicking a button on the app home screen, which sends an encrypted email to the study team informing them of NRT requests. For those in the QuitGuide condition, NRT orders are placed by calling the number provided to participants and speaking with a member of the study team (see Figure 2). In a prior study, 66% of enrolled participants made use of a similar app button/feature to place NRT orders [55]. Patches and lozenges were chosen for use in this study due to their safety and effectiveness (especially as combination NRT), ease of use, and relatively benign side effects compared to other forms of NRT [56, 57].

NCI QuitGuide condition. The National Cancer Institute's QuitGuide app (available for free by request from the Smokefree.gov server, on Google Play, or from the Play Store) is a free smartphone app that complies with many of the Clinical Practice Guidelines for quitting smoking [54]. QuitGuide aims to orient smokers to their own smoking patterns and support users in developing the skills needed to quit smoking. Participants with a compatible smartphone who are randomly assigned to use QuitGuide are directed to download the app to their personal device. Those who do not own a compatible device receive a study smartphone and are directed to download the QuitGuide app during the randomization call. Information explaining how to use the QuitGuide app is shared and reviewed during the randomization phone call. QuitGuide participants also download and use a modified version of the Insight™ EMA app with all MASP+ intervention features removed, which allows participants to receive EMAs and baseline/follow-up assessments. See Table 1 for a list of QuitGuide features.

MASP+ condition. The MASP+ app was adapted from MASP materials and focuses on smoking cessation, HIV treatment engagement/adherence, and AS reduction among Black smokers with HIV [58, 59]. Specifically, treatment video scripts were updated from MASP to reflect language and life experiences particular to those with HIV (e.g., "Smoking can cause infections, slow down healing, and make it harder for HIV medications to keep your immune system strong."). EMA messages underwent similar tailoring (e.g., "Thinking about the stress of HIV treatment can sometimes feel overwhelming. Relieve your stress by doing one of the relaxation exercises in the app's Coping Toolkit."), and two new features were added to the app's: "How to Improve my Treatment Outcomes" and "Tips on Living with a Chronic Disease."

Within a culturally-adapted framework, MASP+ integrates both standard cognitive behavioral therapy practices for smoking cessation (in accordance with clinical practice guidelines) and transdiagnostic treatment for AS reduction [54]. MASP+ provides participants with: (1) scheduled treatment content; (2) participant-initiated and scheduled stress exposure sessions; (3) personalized messages following each completed EMA (both pre- and post-quit); and (4) numerous 'on demand' features (e.g., Quit Tips and Coping Toolkit) both pre- and post-quit). Culturally tailored components

(e.g., educational content related to menthol tobacco products in the Black community, the history of tobacco marketing directly to Black people, HIV treatment management and HIV disparities, the impact of discrimination and racism on smoking and stress) are featured throughout MASP+. To support cultural tailoring, subject matter experts, including co-investigators specializing in health disparities and HIV research and members of a Community Research Advisory Board, provided feedback on the cultural tailoring of the study materials for Black participants with HIV.

MASP+ App Features

Treatment on a schedule. MASP+ includes 17 videos that are four to six minutes long. These videos provide psychoeducation on topics including nicotine withdrawal, unhelpful thinking, coping with others smoking nearby, managing uncomfortable sensations, chronic stress and HIV, myths about smoking, strategies for cessation and relapse prevention, smoking as a temporary coping mechanism to avoid experiencing negative emotions, thinking flexibly, stress management, stress and smoking, interoceptive exposure techniques, and the importance of using NRT. All videos were based on those deployed in the MASP study; however, scripts and content were updated to reflect the life experiences of Black adults with HIV (e.g., Smoking can cause infections, slow down healing, and make it harder for HIV medications to keep your immune system strong.). Additionally, one video was split into two videos to reduce length of individual videos and thereby reduce participant burden. Two new videos become available each day for the first eight days of the intervention. Participants are able to watch videos as they become available or later by clicking the on-demand “Treatment Videos” button (see Figure 2). There is no limit on how frequently each video can be viewed. The app records date-, time-, and location-stamped information each time a video is watched; this process occurs at both initiation and completion.

Exposure sessions. Empirical studies demonstrate that internet-based stress exposure is well tolerated, acceptable, and effective [60, 61]. The MASP+ treatment videos introduce graduated exposure to anxiety and distress-provoking situations and response prevention to target AS. Originally, these exposure exercises were created for the MASP pilot study [i.e., straw breathing, running in place, head rush, over-breathing, chair spinning; 49]. Participants are instructed to press

the “Stress Management Trainings” button to initiate a stress exposure session (see Figure 2). The MASP+ app randomly selects one of five exercises each time a participant presses the Stress Management Trainings button. The participant are then guided through stress exposures: the app explains to the participant the purpose of the assigned activity and how to perform it, normalizes the physiological symptoms experienced during the exercise, and relates this experience to their quit attempt. As in the MASP pilot [49], when the participant is ready to begin, the app assesses their level of distress (0-100 scale), displays a countdown timer while the exercise is being completed, and then assesses their level of distress again (0-100 scale) following the expiration of the countdown. The app suggests repeating the exercise up to three additional times if the participant's current reported distress is greater than 50 on a 1-100 scale. The aim of this strategy is to increase habituation to feared physiological sensations. Participants in the MASP pilot study accessed the Stress Management Training exercises on 6 out of 13 days prior to their quit date [62]. A recent review of phone-delivered interventions for anxiety and depression showed that treatments involving interoceptive exposure were safe and effective for participants [60, 61, 63].

EMAs with tailored real-time treatment messages. During the pre-quit period (i.e., a participant's first 2 weeks in the study), the MASP+ app delivers a message at the end of each EMA (4 per day) intended to increase motivation and provide information about quitting (e.g., “Everyone experiences negative emotions, such as stress. These emotions do not last forever, but they can lead to relapse. Make a specific plan to cope with such feelings.”). During the post-quit period (weeks 3-6 post-baseline), participants receive tailored messages following each EMA. These messages are based upon their responses to the EMA items they answered, which assess constructs such as ART adherence (e.g., “Did you miss a dose of your HIV medication yesterday?”) and reported likelihood of smoking today (i.e., 0%-100%). HIV-related EMA messages were developed specifically for the MASP+ study. When participants report that they missed a dose of medication, they are prompted to select the reason that they missed their medication (e.g., “Simply forgot,” “Away from home,” et al.). Based on the response(s) they provide, a tailored message is shared with the participant. For example, selecting that a dose was missed due to forgetting leads

the app to display one of several possible messages to encourage participants to take their medication as prescribed (e.g., “Taking your medications every day is a step toward improving your health!”). The type of message (e.g., motivational, coping with urges or stress, tips for HIV care management) that is delivered following each EMA is recorded and uploaded to our server for future analyses that examine the effects of messages on targeted smoking lapse triggers, HIV outcomes, and anxiety/depression in future EMAs. Additionally, participants are instructed to review and practice stress management exercises (i.e., interoceptive exposure exercises) to normalize and learn to manage symptoms of anxiety and withdrawal. These exposure exercises have been deployed without incident in the MASP study [49].

On demand features. On-demand features including, Quit Tips (see Figure 3) and Coping Toolkit (see Figure 4), are available to participants via buttons found on the MASP+ home screen. Each of the available icons provides a specific message related to the content area or an activity to support participants in that moment. The research team has developed hundreds of unique messages that address various triggers for smoking relapse [55, 64]; the large message bank is intended to reduce repetition. Two new on-demand features were developed for this study: How to Improve My Treatment Outcomes and Tips on Living with a Chronic Disease. When selected, these features provide on demand tips and messages of support regarding managing HIV care (e.g., “Set reminders on your phone to help you remember appointments and when to take your medication.”) and coping with health stress (e.g., “Going on a daily walk, even if just for a few minutes, can help you relax and sort through your thoughts!”), respectively. Drs. Garey and Businelle led the development of these messages and activities.

Measures

To reduce the potential for data entry errors and the need to retain paper copies of raw data, baseline and follow-up data are collected via smartphone using the Insight™ mHealth platform application software [65]. Questions appear on the phone screen and answers are provided via touch screen. Table 2 provides the schedule for when each measure is administered. The baseline survey takes approximately 30 minutes to complete; the post-randomization survey takes

approximately 10 minutes to complete; the EMAs takes approximately 2-4 minutes to complete; and the follow-up assessments take up to 15 minutes to complete.

Screening. The pre-screener includes a Demographics Questionnaire that assesses demographics (e.g., sex, age, race/ethnicity), smoking history, motivation to quit, and smartphone and data plan details. The REALM-SF is employed to assess literacy [> 6 th grade English literacy level is required to complete EMAs; 50]. Participants read the REALM words from their phone screen back to the research assistant during the enrollment call. If a participant has trouble reading the words due to vision issues, they have the option to use their phone settings to enlarge the font. The Six Item Cognitive Impairment Test is used to assess significant impairment in cognitive function (participants with scores < 8 will be excluded) [53]. After participants complete the pre-screener, a team member at Thomas Street Clinic performs a chart review to verify HIV status and record relevant details of health history, including history of respiratory illnesses related to smoking (e.g., COPD), height/weight, and the number of missed appointments in preceding months.

Smoking outcomes. During each weekly follow up survey, smoking status is biochemically confirmed via the Insight™ platform and the Bedfont iCO smokerlyzer device. Biochemically confirmed 7-day point prevalence abstinence (PPA) at 26- weeks post-quit is the primary study outcome. This is consistent with best practices as well as most published smoking cessation randomized controlled trials [RCTs; see Clinical Practice Guidelines; 54, 66]. In their baseline package, participants receive the Bedfont iCO smokerlyzer, which they use to verify smoking status at each weekly follow-up assessment (weeks 1-6, and 26 post-quit). At the end of each assessment, participants are directed by the Insight™ app to connect the iCO device to the smartphone (simply by pressing the power button on the device) and complete the iCO test. Date and time of completion is collected and saved to our server alongside test results. Our CO criteria are informed by numerous studies that have used CO cutoffs of < 7 ppm [67-73]. CO level is a validated indicator of smoking status and outcomes and is strongly correlated with cotinine and other biochemical measures that have longer detection windows [74-76].

HIV Outcomes. HIV outcomes are assessed using several measures. HIV-specific Quality of

Life is assessed using the World Health Organization Quality of Life-HIV [77], a questionnaire comprised of 36 items related to the quality of life in individuals with HIV. Items assess psychological well-being, functional limitations resulting from HIV status, pain, and impact of HIV status on interpersonal relationships. ART Adherence is assessed using two measures: the ART Adherence Scale [78], which consists of seven items that assess adherence to ART medication regimens and attendance of HIV-specific medical appointments and the AIDS Clinical Trial Group (ACTG) Adherence Baseline Questionnaire [80], which assesses ART adherence and reasons for missed medication and/or nonadherence across 20 items. HIV treatment engagement is assessed using the Index of Engagement in HIV Care [81], a 10-item scale that asks participants about their experience of HIV care.

Discrimination. Race- and HIV status-based discrimination is assessed using the Everyday Discrimination Scale [82]. This 5-item measure allows participants to report how often they face various forms of discrimination. Consistent with past work [83], the five items were adapted to assess both race-based and HIV status-based discrimination, for a total of 10 items.

Anxiety Sensitivity. We assess AS using the Short Scale Anxiety Sensitivity Index [SSASI; 51]. The SSASI is derived from the ASI-3 and consists of 5 items that measure anxiety sensitivity using a 5-point Likert-type scale [0=very little to 4=very much; 31].

MASP+ Feedback. We assess the perceived utility of MASP+ using the standardized System Usability Scale (SUS; a participant-completed, reliable and valid metric for measuring usability and acceptability of technologies), which is administered during a 6-week follow-up survey [84-86]. Using a 5-point Likert-type scale (1=Strongly Agree to 5=Strongly Disagree), participants indicate their level of agreement with statements about the app's usefulness (e.g., I thought the smoking cessation app was easy to use.).

MASP+ Feedback: Qualitative Interviews. Participant experience is assessed via a Zoom-based qualitative interview conducted at end-of-treatment (week 6). The semi-structured qualitative interview is conducted by trained members of the research team and audio recorded. These interviews focus on ease of interacting with the app, usefulness of app features, how the app can be

improved, how sociocultural factors that affect Black smokers with HIV could be further woven into the intervention, and willingness to refer the app to a friend. Since participants in both study arms use the Insight™ app to complete EMAs and receive intervention content via the Insight™ app or QuitGuide app, qualitative interview questions primarily concern participants' experiences with Insight™ (MASP+ and EMA or EMA only) and QuitGuide (intervention content). During the qualitative interviews, participants provide details about features of the different apps that they did and did not like (e.g., "What did you like about the app?"), how app features impacted relevant study outcomes (e.g., "Which, if any, app features helped you manage your HIV better?"), and how the app(s) they used could be improved (e.g., "How can we make the app fit better with your life experiences?"). Combined with the primary outcomes and other quantitative data, qualitative interview data will be used to refine MASP+, which will then be tested in a large-scale randomized controlled trial.

EMA. At present, EMAs are the most accurate way to measure phenomena in real-time, natural settings [87, 88]. EMA items are less biased than traditional in-person assessments and identify fluctuations in key variables related to study outcomes. EMA data are used to tailor MASP+ treatment content and identify both treatment mechanisms and moments of high risk of smoking lapse.

The EMA methodology employed in this study mimics that used in our previous studies, and by other researchers [49, 55, 64, 89-96]. EMA items assess multiple constructs hypothesized to be related to HIV care and smoking lapse. Three types of EMAs are used in the present study: daily diary, random sampling, and event sampling. Random and daily diary EMAs are prompted and initiated by the app. The phone audibly and visually notifies participants of these EMAs for 30 seconds. If participants do not respond after 5 prompts, the assessment is recorded as "missed." All assessments are date and time stamped for future analyses.

Daily diary. Each morning during weeks 1-6 and 28, participants complete a daily diary EMA, for which they receive a notification 30 minutes after waking. Likewise, participants receive a notification to complete their evening daily diary 75 minutes before their reported bedtime.

Questions from the morning daily diary ask about thoughts, experiences, feelings, and behaviors from both the previous day and the present (e.g., “Did you miss a dose of your HIV medication yesterday?” and “Today, how long ago did you last smoke a cigarette?”). Participants are also asked about smoking cessation medication use, ART adherence, and sleep quality from the prior day. During evening daily diaries, participants are asked about thoughts, experiences, feelings, and behaviors from the same day (e.g., “How is your health in general today?” and “How would you rate your quality of life today?”).

Random sampling. Twice each day during the weeks 1-6 and 28, participants are prompted to complete EMAs that are scheduled to occur randomly during each participant’s normal waking hours. Participants rate their affect by indicating their level of agreement with several statements on a 5-point scale from “strongly disagree” to “strongly agree” (e.g., “I feel stressed”). Additionally, participants are asked about smoking triggers (e.g., “I have an urge to smoke”), current depression level (“Rate your current level of depression (feeling sad)”) and anxiety level (“Rate your current level of anxiety (feeling nervous)”). Participants are also asked to describe their current environment (e.g., home, work) and social setting.

Event sampling. Throughout the treatment period, participants are asked to initiate Smoking Assessments (pre-quit), Lapse Assessments (post-quit), and Stress Assessments (pre- and post-quit). **Smoking Assessments.** Prior to their quit date, participants are instructed to click a Record Cigarette button every time they feel they are about to smoke or have already smoked a cigarette. Ten percent of the time, this triggers a brief survey asking participants about their affect, stress, and experiences while smoking (e.g., “Smoking improved my mood”, “Smoking was pleasurable”). These smoking assessments are date-, time-, and location-stamped for future analyses. **Lapse Assessments.** Participants are instructed to press the Record Cigarette I Am About to Slip or the I Already Slipped button and complete a lapse assessment each time they smoke after their quitting date. Items on these assessments are similar to those presented in the random and smoking assessments and worded to separately assess the participant’s responses immediately before and after the lapse. **Stress Assessments.** Participants are instructed to press the Report Stress button

and complete the resulting assessment each time they “experience a significant increase in stress.”

Importantly, each MASP+ pre- and post-quit EMA is followed by a treatment message that is tailored to the participant's responses and current situation. Those assigned to the QuitGuide group complete EMAs identical to the MASP+ group, though they do not receive tailored intervention messages after completion.

EMA alert settings. During the enrollment call, participants' sleep/wake times for each day of the week are recorded and stored (Note: These sleep/wake times can be changed by calling the study team). This practice is intended to prevent or reduce the chance of the phone ringing while participants are asleep. When an EMA is prompted, participants can delay (“snooze”) EMAs by up to 30 minutes by clicking the Snooze Assessment option on the smartphone screen.

Data loss prevention. To avoid potential data loss as a result of participants losing their phones, each device is programmed to sync and upload encrypted data with our secure server multiple times each day [Note: In most studies, less than 1% of phones have been lost; 48]. These procedures prevent collected EMA data from being lost, allow the researchers to remotely monitor participants' EMA completion rates, and identify when participants need to be contacted for low survey completion. Notably, EMA data is encrypted and password protected on each study phone. Therefore, study data is accessible only to the research team. Lost phones are wiped remotely. Participants who lose their phones are provided up to one replacement.

The Insight™ Platform

The Insight™ mHealth platform was developed by the mHealth Shared Resource at the University of Oklahoma Health Sciences Center (OUHSC) and Stephenson Cancer Center. This platform offers resources to help researchers build, test, and launch technology-based assessment and intervention tools [65]. The mHealth resource employs a sizeable team, including a program manager, 4 project coordinators, and 4.5 computer scientists/engineers. Together, they develop and maintain web and mobile applications and relational databases. These applications are developed using cutting-edge cross-platform design tools.

Smartphone training. Our team has developed and implemented a brief user-friendly training

protocol to aid those with limited smartphone experience. During the randomization call, all participants, depending on condition assignment, receive training on how to use either the MASP+ app or the EMA-only Insight™ app and the QuitGuide app. Both versions of the Insight™ app (MASP+ and EMA only) contain an “App Instructions” button to remind participants how each app feature functions (see Figure 2). In previous studies, similar protocols have resulted in high EMA compliance rates (e.g., 82%-87% of all EMA's completed) in samples of socioeconomically disadvantaged and non-disadvantaged adults [55, 64, 96, 97]. All smartphones used in this study automatically collect data on intervention delivery (e.g., number of times features are used, number of minutes treatment videos are watched).

Data Analyses

To test the hypothesis that MASP+ produce higher rates of smoking abstinence compared to the NCI QuitGuide app, biochemically verified measure of 7-day PPA that is collected during weekly assessments via Bedfont iCO will be used. PPA is defined as no smoking, not even a puff, in the 7 days prior to follow-up assessments and biochemical verification of smoking abstinence (i.e., CO levels < 7 ppm according to an iCO test). We will calculate odds ratio effect sizes (with 95% confidence interval) to estimate between-group differences for PPA at each follow-up assessment. The effect size for the comparison between conditions at the 26 weeks post-quit date assessment will serve as the primary analysis of the impact of treatment condition on smoking cessation.

We will then conduct a series of conditional latent growth curve models (LGM) to examine the impact of treatment condition on abstinence trajectories. First, an LGM will be specified using CO breath tests at 2 (quit date), 3, 4, 5, 6, and 28 weeks. The intercept of these models will be centered on the baseline assessment and will be specified to model linear change across the major assessments. A dummy code representing treatment condition will be specified as a predictor of the intercept and slope factors to quantify the effect of MASP+ on the longitudinal course of abstinence.

The impact of treatment conditions on HIV quality of life, ART adherence, HIV treatment engagement (H2) will be examined used the same sequence of analyses: between condition effect sizes followed by conditional LGM. We will then conduct univariate LGM to explore changes in AS

as a function of treatment (H3), followed by a series of parallel process LGM to examine how changes in AS relate to changes in the smoking/HIV outcomes. The indirect effects of treatment via AS will be evaluated by calculated bootstrapped confidence intervals of the indirect effect using the MODEL indirect command in MPlus.

Mixed Methodology. Triangulation mixed methods quantitative/qualitative data analysis will be employed to evaluate quantitative and qualitative data [98]. Using an explanatory sequential mixed methods design, qualitative data collection and analysis will increase the investigators' understanding of participant experiences of the tailored material for both cultural relevance and relevance to living with HIV.

Quantitative Data. Quantitative data analysis will focus on (1) behavioral markers of engagement with the app (i.e., completion of $\geq 75\%$ of all assigned videos, completion of $\geq 75\%$ of all assigned exercises); (2) self-report evaluations of the app including ease of interacting with the app (i.e., $>75\%$ of all participants agreeing that MASP+ is easy to use based on rating of 3 or higher on the scale), that the MASP+ features (e.g., automated treatment messages that follow EMA, treatment videos) are useful/helpful on a similar scale, and that at least 75% would be likely to recommend the app to a friend; and (3) data from the SUS [99-101]. Low engagement and/or evaluation of MASP+ will be discussed with each participant at the qualitative interview.

Qualitative Data. Qualitative data analysis will focus on participants' experiences of the app and incorporating their feedback to improve the app interface and features. Individual interviews will be transcribed following completion of participant treatment, then reviewed by the research team to monitor data quality. The transcribed interviews will be coded using NVivo v.12. Following a first reading of the transcripts, the interviews will be coded using 2 coding passes [102]. The first coding pass will be utilization-focused [103], with initial codes developed from the question path questions and additional codes based on responses to the System Usability Scale. The qualitative researcher (MKC) will code the interviews then the coding will be reviewed by a second member of the research team trained in qualitative methods. Coding disagreements will then be discussed and resolved. Memos and notes will be reviewed and discussed. A second coding pass will then be

conducted based on additional codes identified during the discussion, which may be process-based or theoretically-based, depending on what emerges from the first round of coding. Following the review of both coding passes, the research team will conduct a thematic analysis in several steps, beginning with the MASP+ participants where themes will be identified both within then between codes. The team will then create data displays and review patterns of responses between related sets of codes [104]. Points of integration between the MASP+ qualitative and quantitative data will be identified and a joint analysis will be conducted and joint displays created [105]. Following the joint analysis, the transcripts will be read again for additional confirming and disconfirming evidence of themes [104], then representative quotes will be selected. The QuitGuide responses will then be analyzed and compared to MASP+ responses.

Sample Size Determination

As this is the first empirical evaluation of the MASP+ intervention in this population, our focus is on determining feasibility of the new intervention and obtaining preliminary estimates of effect sizes on smoking and HIV outcomes and the hypothesized mechanism of change, not to conduct a full scale and statistically powered examination of comparative efficacy. We expect that MASP+ will be superior to NCI QuitGuide on all outcomes examined, but that the effects of MASP+ may vary and be larger for smoking outcomes than HIV outcomes. Based on power calculations conducted using RMASS and simulation studies identifying the sample sizes necessary to detect indirect effects [106, 107], the targeted sample size of 72 would provide sufficient statistical power to detect a medium to large effect ($d \geq .6$), and an indirect effect for H3 if the treatment effect on AS is large ($d = .8$) and the effect of AS on outcomes is medium to large ($d = .5$). Our conclusions will primarily be based on effect sizes and associated confidence intervals and the effect size estimates (and associated CIs) from this trial will be used to guide future, larger trials of comparative efficacy.

Qualitative interviews are conducted with all MASP+ and QuitGuide participants. The recommended minimum size for any subgroup is 20 interviews [108] but based on our prior work [48], interviews vary substantially in the content provided, so interviews will be conducted with all enrolled study participants in MASP+ and QuitGuide to meet saturation of key study questions.

Interviewing all MASP+ participants should be sufficient for saturation of key study questions. The QuitGuide interviews will be used as a comparative group following analysis of the MASP+ content, based on our prior work.

Results

The study is currently in active data collection. As of February 2024, 8 participants have been enrolled in the current trial. Data enrollment is scheduled to be completed by June of 2024 and data collection is scheduled to be completed by December of 2024. Data analysis will be complete by March of 2025.

Discussion

Expected Findings

Data collection is currently underway. Results are expected to indicate that MASP+, relative to QuitGuide, will lead to improved biochemically-verified 7-day PPA, increased adherence to ART, and improved attendance at HIV-related health appointments at 26 weeks post-quit. Qualitative interviews will be integrated with quantitative data to further refine and adapt MASP+ and support the development of an iteration of the intervention that is high-quality, culturally relevant, scalable, and ready for rigorous testing as part of an R01-level grant.

Study Implications

This study is the first to culturally tailor a smoking cessation smartphone-delivered intervention that is integrated with AS reduction skills for Black smokers with HIV and elevated AS. Smartphone interventions like MASP+ have the potential to provide low-cost, scalable treatments to diverse populations who may not be as likely to have access to in-person treatment or may not have health insurance to cover costs. A 2021 survey found that 85% of U.S. adults reported owning a smartphone [109], and other studies have found that smartphone ownership is high among minoritized populations (83% among Black adults) as well as individuals with low socioeconomic status [76% among those earning less than \$30,000 per year; 110]. Given the widespread ownership of smartphones, MASP+ has the potential to overcome traditional barriers to care and enhance the accessibility and reach of culturally appropriate, clinical-grade care for hard-to-reach

populations.

Clinically, the cultural tailoring and integration of AS reduction skills within MASP+ represents a groundbreaking approach. Experiences of AS and related mental health factors (e.g., anxiety, depression, drug withdrawal/craving) can vary over time and between individuals [111]. By assessing these factors throughout the day and providing support as these symptoms arise, MASP+ constitutes a just-in-time tailored intervention for smoking cessation, AS, and HIV management. Such an approach may serve as a potential solution to address the documented health disparities experienced by Black smokers with HIV [6, 112]. MASP+ is also distinguished by the specificity with which it can respond to the unique stressors, needs, and challenges that Black smokers with HIV and AS experience. This underscores the potential for MASP+ to serve as a stand-alone or adjunctive treatment for smoking cessation treatment. Indeed, MASP+ offers personalized care to address factors that impede successful behavior change in a culturally appropriate and person-centered manner, which may carry strong implications for mitigating health disparities for Black smokers with HIV.

Understanding the role of AS in the process of quitting cigarettes and better managing HIV among Black adults with HIV has several theoretical implications. First, this work bridges together disparate, yet complementary work, on AS, smoking, and HIV [114, 115]. As such, findings from the current trial may inform a holistic understanding for how these constructs relate and influence one another. This significantly advances current models for the role of interoceptive distress as a risk factor for worse smoking cessation and HIV-related outcomes [116-119]. Second, several models related to minority stress indicate the need for culturally tailored interventions, particularly those targeting smoking cessation [120-122]. Expanding these efforts to produce tailored interventions for Black smokers with HIV that focus on a mechanism implicated in worse health outcomes among this group, i.e, AS, allows providers and researchers to address documented health disparities among this population in a culturally specific manner [123]. Further study of the mechanisms underlying quit success among Black smokers with HIV and AS will guide future efforts to tailor smoking cessation interventions for this population. The present study will provide insight into which risk factors to

target during smoking cessation treatment among this group, the ideal timing of intervention efforts, and preferred content of intervention messages.

Anticipated Limitations

This study has several limitations. Daily EMAs can be disruptive as they are prompted throughout the day rather than clustered in a single study appointment. This could potentially discourage participation in the daily EMA component of the study. Additionally, some study measures rely on self-report and participants may not respond in “real time.” As an added consideration, recruiting a population as specific as Black PWH who smoke only combustible cigarettes may prove challenging for the study team. Finally, though participants will be responding to items while navigating daily life, thereby increasing ecological validity, this comes at the expense of depriving experimenters of a high degree of control over participants’ environmental conditions.

Conclusions

The present study may provide insights into precision medicine treatment that is not otherwise available by supplying a smoking cessation and HIV management intervention with tailored treatment content based on the psychological and environmental context in real time. Pending tests of its efficacy, an intervention that is automated, scalable, and culturally informed could be easily incorporated into other “real world” settings and aid with the reduction of health disparities. This novel mobile intervention has the potential to address the mental and physical barriers to smoking cessation and treatment engagement that are unique to Black PWH. Despite any potential difficulties in recruiting such a specific group or capturing EMA data, the benefits of this study far outweigh any drawbacks.

Additional work is essential for successful translation and cultural adaption of effective in-person smoking cessation interventions into mobile, remotely delivered treatments like MASP+. Compared to current treatment options, mobile interventions have the potential to produce even greater cessation outcomes and provide wider access for historically oppressed and underserved populations, such as Black smokers with HIV and high AS. In light of prior studies that demonstrate the feasibility of mobile smoking cessation technology [49, 55, 124], mobile treatments that integrate

AS constitute a vital 'next step' for addressing tobacco-related health disparities among Black smokers with HIV. The present study will extend our work in this area as well as the wider field of smoking-emotional disorder comorbidity by adapting and testing a fully automated, culturally tailored, mobile AS smoking cessation intervention for Black smokers with HIV. Future work will focus on testing the MASP+ app in a larger, fully powered efficacy trial; national dissemination of intervention materials; and implementation across diverse healthcare settings.

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Data Availability

Deidentified data will be made available upon request following publication of the primary outcomes paper.

Conflicts of Interest

MSB is an inventor of the Insight™ mHealth Platform and receives royalties related to use of this platform by investigators external to OUHSC. Since MSB is an MPI on this study, he did not receive royalties for the use of the platform to create the MASP+ app.

Abbreviations

AS: Anxiety sensitivity

ART: Antiretroviral therapy

EMA: Ecological momentary assessments

MASP+: Mobile Anxiety Sensitivity Program for Smoking and HIV

NCI: National Cancer Institute

NIMHD: National Institute on Minority Health and Health Disparities

NRT: Nicotine replacement medications

PPA: Point prevalence abstinence

PWH: People with HIV/AIDS

QG: QuitGuide

RCT: Randomized controlled trial

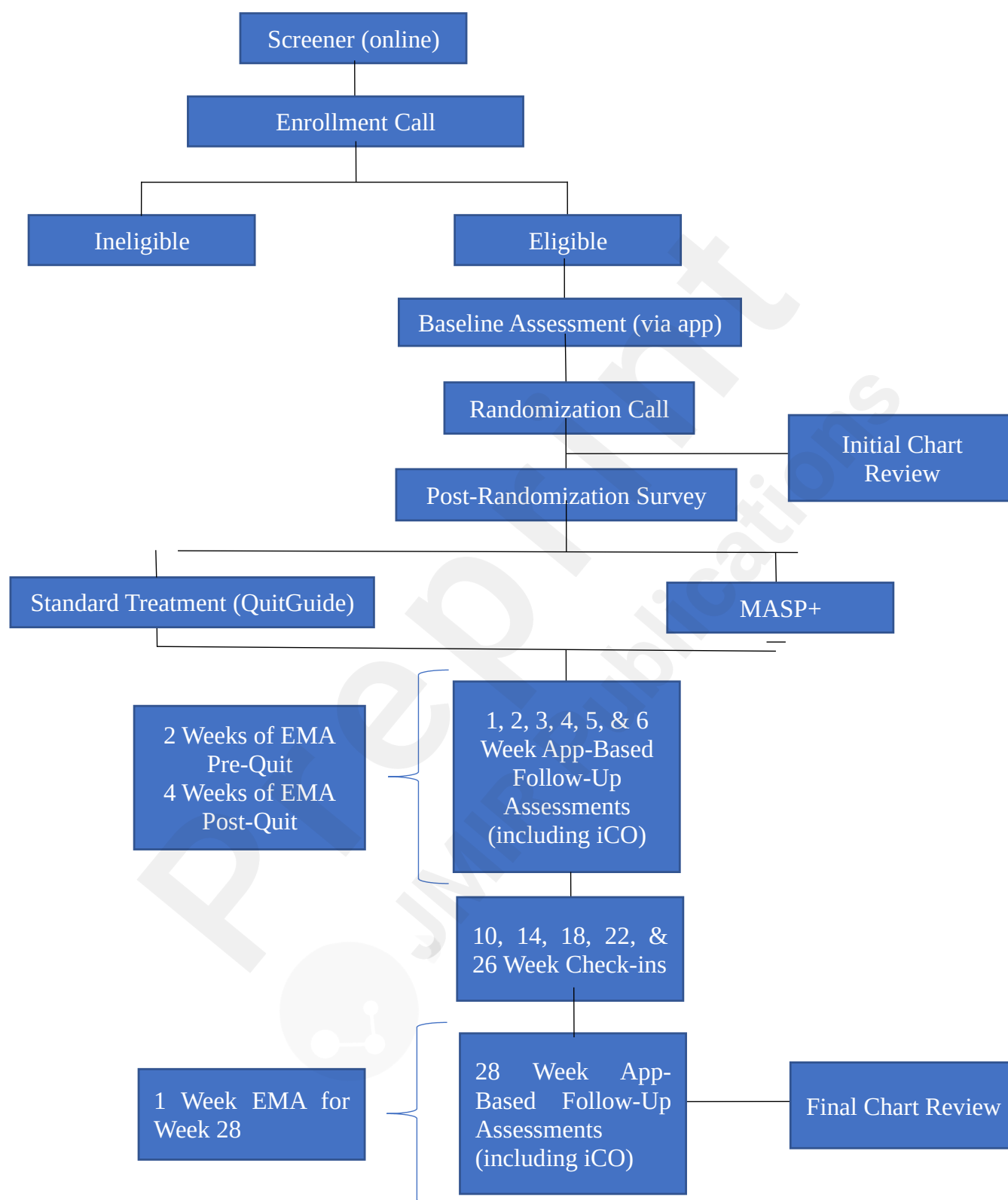
Figure 1. MASP+ Participant Enrollment Flowchart**Figure 2. MASP+ app Home screen**



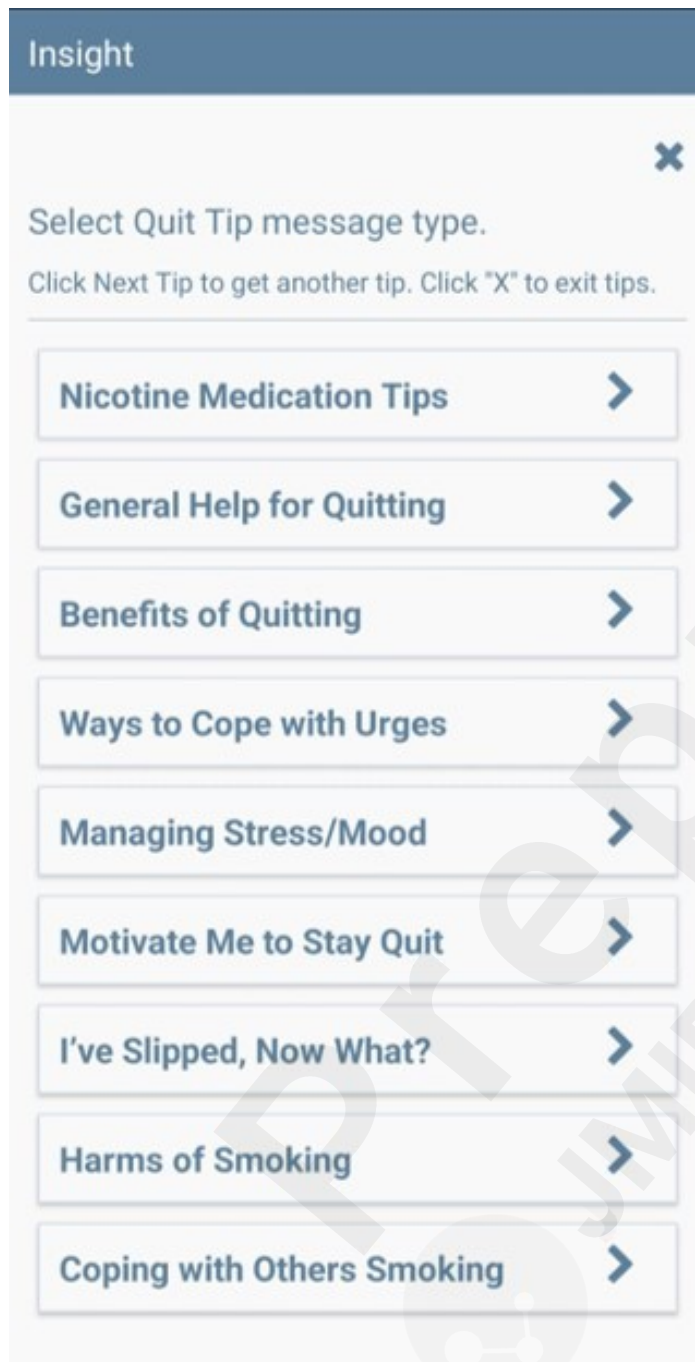
Figure 3. MASP+ Quit Tips Feature

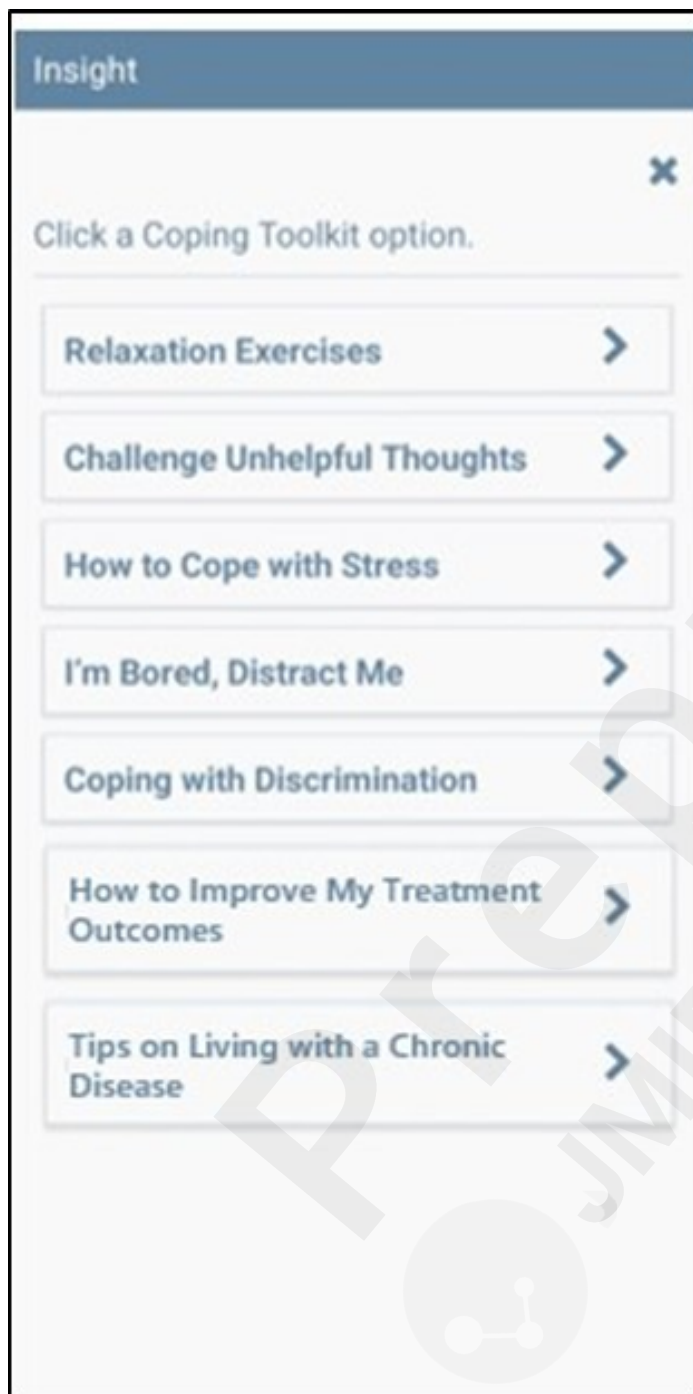
Figure 4. MASP+ Coping Toolkit Feature

Table 1. Comparison of treatment conditions

App Components	MASP+	QuitGuide
EMA	X	X (add on for this study)
Set a quit date	Quit date is set to 2 weeks after randomization	
Share quit information on social media		X
Smoking cessation psychoeducation	X	X
Content specific to Black smokers with HIV	X	
NRT tips and use advice	X	
AS psychoeducation	X	
On demand tips and exercises		
Coping with cravings	X	X
Coping with mood	X	X
Coping with stress	X	
Coping with HIV stigma	X	
HIV care management	X	
Inspirational messages	X	X
Scheduled tips		X
Treatment messages tailored to currently present smoking lapse triggers	X	
Coping toolkit	X	
Guided relaxation and mindfulness exercises	X	
Challenging automatic thoughts	X	
Tips for coping with stress	X	
Interoceptive exposure	X	
Resources to help distract participants if they experience elevated distress	X	
Individualized quit plan		X
Document smoking triggers		X
List reasons for quitting		X
Savings from smoking fewer cigarettes		X
Create journal entries		X

Survey Measures						
Assessment	Items	Screeners	Baseline	Post-Rand	W1-W6	W28
Screeners Survey	41	41				
6CIT (cognitive screener; eligibility)	7	7				
Rapid Estimate of Adult Literacy in Medicine-Short Form ¹³⁴ (eligibility)	9	9				
Demographics/Background Information	19		19			
MacArthur Scale of Subjective Social Status	2		2		2	2
Everyday Discrimination Scale	10		10			
HIV Adherence and Treatment	17			17		17
Qualitative Interview	24(MP) 20(QG)				24 (MPW6) 20(QG)	
ART Adherence	6		6		6 (W6)	6
ACTG Adherence Questionnaire	24		24		19(W6)	19
Index of Engagement in HIV Care	10		10		10 (W6)	10
WHO Quality of Life HIV	36		36		8 (W6)	8
Carbon Monoxide Analysis (Phone Bedfont iCO)	1		1		1	1
SSASI (eligibility)	5	5	5		5	5
System Usability Scale	10				10 (W6)	
Daily Diary EMA						
Assessment	Items	Pre-Quit Morning	Pre-Quit Evening	Post-Quit Morning	Post-Quit Evening	
Smoking Behavior	3	1	1	3	2	
Sleep Quality	2	2		2		
Distress Levels	2	2		2		
HIV Adherence	2	2		2		
Other Substance/Medication Use	4	2	2	2	2	
General Health/Quality of Life	2		2		2	
Discrimination	2		2		2	
Motivation Levels	2		1	1	2	
NRT Use & Side Effects	8			8		
Watch A Brief Video	1	1	1			
Confidence Levels	4			3	4	
Single Item Anxiety assessment	1			1	1	
Single Item Depression assessment	1			1	1	
Location	1			1	1	
Take Lozenge Now	1			1	1	
Random and Event Sampling EMA						
Assessment	Items	Pre-Quit		Post-Quit		
Smoking Behavior & Availability	3	3		3		
Stress & Coping	2	2		2		
Social Interactions	1	1		1		
Motivation Levels	1	1		1		
Other Substance/Medication Use	1	1		1		
Confidence Levels	3	3		3		
Single Item Anxiety assessment	1	1		1		
Single Item Depression assessment	1	1		1		
Location	1	1		1		
Coping Toolkit	1	1		1		
Take Lozenge Now	1			1		
Note: Rand = Randomization; Wx = Week x; MP = MASP+; QG = QuitGuide; EMA = ecological momentary assessment.						

Table 2. Table of measures

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