

Adapting an App-Based Just-in-Time Adaptive Intervention for Stimulant Using Sexual Minority Men Living with HIV: Protocol for the TeaTime Study

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Abstract

Background: In the United States, sexual minority men (SMM) are disproportionately affected by HIV. For this population, intersecting sexual minority and HIV-related stress add to general life stressors to increase health risks. Stress is associated with HIV progression and is linked to transmission risk behaviors (e.g. medication non-adherence and substance use). Substance use is a particularly important risk factor for HIV transmission. In addition to injection drug use risk, recreational use is associated with sexual transmission risk behaviors and increased risk for HIV among SMM. Interventions targeting stress response may be particularly useful for HIV risk reduction among substance-using SMM (SUSMM) living with HIV (LWH). Positive affect interventions have shown promise in reducing stress in the context of chronic illness, including HIV. However, few studies have examined these interventions and their potential health benefits for SUSMM-LWH.

Objective: This protocol is for a project (R34DA053999) which builds on our pilot work in the area of positive affect induction as a potential intervention approach to reduce stress and improve health outcomes among SMM-LWH. The aim of our protocol is to take a community-engaged research (CEnR) approach, using the multiphase optimization strategy (MOST), to iteratively tailor our app-based positive affect intervention, TeaTime, for SUSMM-LWH.

Methods: In Phase 1, we enrolled 10 SUSMM-LWH into an open phase pilot using our existing app-based ecological momentary intervention (EMI), which uses a just-in-time adaptive intervention (JITAI) design. We worked alongside a community advisory board to tailor our intervention content and app design, using focus group feedback. In Phase 2, we are conducting a pilot factorial optimization trial to assess acceptability and feasibility of adding two new features that may enhance our intervention design and delivery. Specifically, we implement a 2x2 factorial design, randomizing 80 SUSMM-LWH to receive (1) random craving prompts and/or (2) smart watch integration.

Results: The project was funded February 2022 and data collection for Phase 1 was completed in December 2023. Phase 2 was launched July 2024, and data collection is ongoing. The results for Phase 1 are expected to be submitted for publication by August 2025.

Conclusions: In this protocol we combine methods from social science, intervention science, and software development into one innovative approach to enhance and optimize an app-based, just-in-time-adaptive, ecological momentary intervention with SUSMM-LWH. Findings from this study will aid us in arriving at a fully optimized intervention ready for evaluation and implementation. In a future RCT, the ecological momentary assessment (EMA) design will also allow us to collect day-level data

on intervention efficacy

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Original Manuscript

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Abstract

Background: In the United States, sexual minority men (SMM) are disproportionately affected by HIV. For this population, intersecting sexual minority and HIV-related stress add to general life stressors to increase health risks. Stress is associated with HIV progression and is linked to transmission risk behaviors (e.g. medication non-adherence and substance use). Substance use is a particularly important risk factor for HIV transmission. In addition to injection drug use risk, recreational use is associated with sexual transmission risk behaviors and increased risk for HIV among SMM. Interventions targeting stress response may be particularly useful for HIV risk reduction among substance-using SMM (SUSMM) living with HIV (LWH). Positive affect interventions have shown promise in reducing stress in the context of chronic illness, including HIV. However, few studies have examined these interventions and their potential health benefits for SUSMM-LWH.

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Methods: In Phase 1, we enrolled 10 SUSMM-LWH into an open phase pilot using our existing app-based ecological momentary intervention (EMI), which uses a just-in-time adaptive intervention (JITAI) design. We worked alongside a community advisory board to tailor our intervention content and app design, using focus group feedback. In Phase 2, we are conducting a pilot factorial optimization trial^{1,2} to assess acceptability and feasibility of adding two new features that may enhance our intervention design and delivery. Specifically, we implement a 2x2 factorial design, randomizing 80 SUSMM-LWH to receive (1) random craving prompts and/or (2) smart watch integration.

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Keywords: mHealth, JITAI, EMI, EMA

Introduction

Background

In the United States (U.S.), gay, bisexual, and other sexual minority men (SMM) are disproportionately affected by HIV compared to the general population.³ For SMM-LWH, intersectional sexual minority and HIV-related stress add to general life stressors to increase health risks.^{4,5} Intersectional minority stress also includes experiences of discrimination for racial and ethnic minorities,^{6, 7} who represent a majority of the SMM-LWH population.^{8,9} Due to the cumulative impact of these intersecting stressors, SMM-LWH experience significant health disparities compared to the general population.^{10,11,12} The 'cumulative stress' hypothesis asserts that chronic and acute stressors in later life have an additive impact on the vulnerabilities already programmed from early life adversity.¹³ Cumulative stress is hypothesized to result in increased allostatic load, operationalized as a cumulative biological burden, resulting in poorer health outcomes (e.g. HIV progression).¹⁴ Further, research supports a bidirectional association between psychosocial stress and HIV progression¹⁵

Stress is not only linked to distal outcomes (e.g. HIV progression),^{15,16} it is also associated with proximal behavioral outcomes that increase the risk of transmission (e.g. medication nonadherence and substance use).^{17,18} Substance use is a predictor of poor HIV medication adherence,^{19,20} and accordingly, substance-using individuals LWH are at higher risk for HIV disease progression.^{21,22} Substance use is also a particularly important risk factor for HIV transmission, as recreational use is associated with other transmission risk behaviors (TRB) and injection drug use has a substantially higher risk of transmission, compared to other TRB. In addition to risk associated with injection drug use among SMM, studies show that recreational substance use is associated with sexual TRB and increased likelihood for HIV among SMM.^{23,24,25} As such, interventions which target stress responses may be particularly useful for HIV risk reduction among substance-using SMM (SUSMM)-LWH.

Stress is also associated with increased substance use cravings.^{26,27} Even minor stressful events have been associated with increased substance use cravings.²⁸ Ecological momentary assessment (EMA) studies show daily cravings are a strong predictor of subsequent substance use.^{29,30} Further, research suggests cravings may mediate the association between stress and substance use.³¹ This may elucidate findings from prior studies, which show a stronger link between cravings and substance use, as compared to stress and substance use.³² It is also important to note that in addition to cravings induced by stress, cravings can also be cue-induced.³³⁻³⁵ However, studies comparing stress-related and drug-related cues on cravings have found greater subjective emotional response and cardiovascular activity in stress-related conditions.³⁵

Research shows positive affect buffers against negative stress-related health outcomes.³⁶⁻³⁸ Positive affect refers to experiences of positive moods such as joy, interest, and alertness,³⁹ whereas mindfulness is a state of focused, non-judgmental awareness for one's thoughts, motivations, and behavior.⁴⁰ Positive affect is associated with better outcomes in substance use⁴¹ and HIV-related health.⁴² For individuals LWH, research indicates positive affect is associated with increased odds of linkage to HIV care and treatment adherence.³⁸ One study found that positive affect was associated with a significant decrease in AIDS-related mortality risk.⁴³ More generally, for people living with a chronic illness, positive affect interventions have shown significant effects on increasing medication adherence,⁴⁴ and lowering reported stress levels due to diagnosis.⁴⁵⁻⁴⁷ Positive affect has also been associated with lower levels of substance use.¹⁹ Further, mindfulness is correlated with positive affect among SMM-LWH.⁴⁸

Description of the Initial Intervention

Moskowitz and colleagues developed an integrative positive affect intervention for people living with health-related stress.^{42,49} The intervention is based on revised Stress and Coping Theory⁴⁷ and the Broaden-and-Build Theory of positive emotion.⁵⁰ These theories describe ways positive emotion supports coping and well-being through building social, intellectual, and physical resources. The intervention content, methods, protocol, and design for this intervention are published elsewhere.⁵¹ Findings from a RCT demonstrate the effectiveness of this integrated intervention for people newly diagnosed with HIV.⁴² These results show a decrease in intrusive or avoidant thoughts related to HIV and increases in positive affect on a day-to-day basis.⁴² Findings also show that effect sizes from the intervention increase over time.⁴²

This intervention was recently tested with SUSMM-LWH.^{41,52} Specifically, this study examined the efficacy of Moskowitz's intervention in boosting contingency management for SMM-LWH who use methamphetamine. The pilot RCT demonstrated feasibility of administering the intervention with SUSMM-LWH, and showed significant increases in positive affect.⁵² In the full trial RCT, those receiving the intervention showed significantly higher levels of mindfulness three months post-intervention, as well as a decrease in cravings and self-reported drug use.⁴¹ This work shows promise for implementing this integrative intervention with SUSMM-LWH, and its potential effectiveness in improving substance use outcomes for this population.

While the in-person delivery of this program has been effective in improving health outcomes, there has been an increased interest in remote intervention delivery. Moskowitz's intervention has already been tailored for e-health web-based delivery.^{6,53} In a recent study, the acceptability and feasibility of this web-based version was tested for individuals living with comorbid HIV and depression, and was both feasible and acceptable for this population.⁵⁴

JITAI EMI Development

More recently, our team sought to adapt this intervention for app-based delivery. Evidence demonstrates the feasibility of mobile interventions specifically among SMM-LWH.⁵⁵ Such interventions have shown suitability, acceptability, and efficacy among SMM-LWH, as they allow a component of privacy.⁵⁵ Mobile apps can also be used to deliver Ecological Momentary Interventions (EMI), which provide an opportunity to offer in-the-moment support to SUSMM-LWH.⁵⁶ EMIs, much like EMAs, are delivered to participants in their daily life; however, instead of simply collecting data, EMIs also include an intervention component. Further, this intervention content can be triggered based on participant responses to the EMA, and in this way, the delivery of the intervention is tailored to when participants need it the most.⁵⁶ This customization of intervention delivery is often referred to as a just-in-time adaptive intervention (JITAI) design.

In our proof-of-concept pilot, we adapted the evidence-based positive affect intervention's web content⁴² for mobile app delivery, using an EMI delivery format and JITAI design.⁵⁷ Our JITAI EMI included 7 modules designed for positive affect induction (e.g. noticing and savoring positive events, acts of kindness, behavioral activation, personal strengths, positive reappraisal, and gratitude). In our pilot, we recruited 22 SMM LWH to engage with the app for a 90-day period. Within the app, participants had access to "on-demand" (i.e. user initiated) intervention content, where they could review the skills anytime. The app also delivered a daily positive message alongside an image from a bank of motivational quotes, each of which referred to one of the intervention skills. Additionally, over the course of the 90-day study, participants received a daily EMA survey, which included questions about stress, positive and negative affect, and medication adherence. Depending on their response to the survey, participants were randomized (at a 2:1 ratio) to receive a brief intervention activity or a control message. Specifically, if a participant reported feeling stressed in the EMA, they were randomized to receive one of 32 JITAI activities. This was part of the microrandomized trial

(MRT) design, which we also tested in this proof-of-concept pilot study. Selection of the specific JITAI activity to be delivered occurred through a process of further micro-randomization. Specifically, once participants were randomized to receive a JITAI activity, they were further randomized with an equal probability ($P=0.14$) of receiving an activity from one of the seven modules within the app. Once randomized to a specific module, the intervention activity to be delivered in that moment was randomly selected from a bank of activities from that module. See **Figure 1** for a diagram depicting our JITAI design and micro-randomization in this study. Findings from our proof-of-concept pilot suggest our app-based JITAI EMI is an acceptable and feasible delivery mode for SMM-LWH.⁵⁷

Objectives

However, we have not yet piloted our app with SUSMM-LWH. Holding an additional marginalized identity (i.e. substance-using) presents unique stressors and additional barriers to intervention.^{58,59} As an example, individuals with substance use disorders often face stigma and discrimination from health care providers.⁶⁰ This added minority stress has a multiplicative effect when compounded by other marginalized identities (e.g. racial & sexual minority status, HIV status). The JITAI EMI design is especially promising for SUSMM-LWH given their experience of these multiple intersecting stressors during the course of the day (e.g. microaggressions, stigma, discrimination). Further, SUSMM-LWH may benefit from the on-demand and in-the-moment support offered by an app-based JITAI EMI. As such, we aim to tailor our existing intervention content and optimize our JITAI EMI design and delivery to reduce stress and substance use among SUSMM-LWH. We also aim to further optimize our intervention by examining the acceptability and feasibility for adding additional features to the intervention that may improve engagement, as well as the app's overall design and delivery.

Methods

Overview of the Study Design

In Phase 1 we conducted an open-phase pilot and engaged community members to help tailor our existing app for SUSMM-LWH. In Phase 2 we are piloting a randomized factorial optimization trial to assess the acceptance and feasibility of adding additional features (i.e., smart watch integration and random craving prompts), to optimize our JITAI EMI's design and delivery. Below we provide a description of the overall study design, describing common approaches and procedures that were implemented across both phases. Specifically, we review the guiding framework, training and fidelity protocols, as well as data storage and safety procedures. We also present the eligibility criteria used across both phases. Following this, we have separately delineated the protocol and procedures for each phase.

Guiding Framework for Intervention Adaptation

This study takes a community-engaged research (CEnR) approach to using the Scrum Agile Framework and Multiphase Optimization Strategy (MOST), combining methods from social science, intervention science, and software development into one innovative approach to enhance this app-based intervention.

Community-Engaged Research. CEnR is an approach to research that is particularly useful in addressing health disparities among disadvantaged populations. In this approach, community partners are actively engaged in the research process and treated as equal partners throughout. CEnR forms a partnership between researchers and communities, where shared decision-making takes place in research. CEnR may involve a CAB and may incorporate feedback from other community members. In this model, the community and researchers act in partnership to jointly explore a

problem in the community. This partnership results in the development of culturally acceptable measures, and community-informed interpretations of the study findings.

Scrum Agile Framework. Scrum is a form of Agile methodology used to manage multicomponent software and product development projects.⁶¹ The Scrum model suggests that projects progress via a series of sprints. During a sprint planning meeting, the product is described in terms of the desired outcome (features to be developed in the next sprint). At the end, features are tested and integrated into the evolving product.

Multiphase Optimization Strategy. We approach the optimization of our JITAI EMI from the MOST, which involves three phases: preparation, optimization, and evaluation. Activities in the first phase include selecting components (e.g. content, design features, etc.) that are candidates for inclusion in the intervention, and development of a conceptual model. Pilot testing is an important feature of the preparation stage. This includes an initial proof-of-concept pilot and open-phase pilot, as well as a pilot to test the feasibility of conducting a larger optimization trial. In the optimization phase of MOST, steps are taken to optimize the intervention to maximize its effectiveness. This is usually done with a factorial optimization trial, fractional factorial trial, micro-randomized trial, or a combination of these methods. The MOST framework also operated on the principle of continual optimization. In the evaluation phase, the effectiveness of the optimized intervention is evaluated via a standard RCT.¹ This study focused on the first phase and second phase of MOST (i.e., preparation and optimization).

Training, Fidelity, and Protection of Human Subjects

Study staff were trained on all relevant procedures for this protocol and were provided with a detailed study protocol guide including: 1) confidentiality and general guidelines for participant contact, 2) screening and scheduling protocols, 3) participant contact and tracking databases in REDCap, 4) eligibility check and consent protocols, 5) baseline and follow-up assessment procedures, 5) semi-structured interviewing, 6) data security and storage, 7) transcription procedures for qualitative interviews, 8) monitoring the study email account, Zoom SMS, and MetricWire instant messenger chat for participant questions.

Ethics Approval Statement. All procedures are approved by the Institutional Review Boards at participating institutions (Rutgers University and New York-Presbyterian at Weill Cornell Medical Center), and all participants must provide informed consent.

Data Collection, Storage, and Measurement

Data collection for the purposes of this study occurs from four primary sources: (1) online screeners and contact surveys; (2) self-reported online surveys; (3) EMA and EMI; and (4) biometric watch data.

Data Collection Tools. In both phases, we collect screener data, contact information, and quantitative survey data using the Qualtrics survey platform. Quantitative survey data from participants are collected at two time points (baseline and 3-month follow-up assessment). Our app is powered by MetricWire, and participants use the app for 90 days, providing both EMA and EMI data via this software platform. MetricWire allows the research team to download self-report EMA data, as well as JITAI EMI engagement data (e.g., intervention activity completion). Half of the participants in Phase 2 receive a Fitbit, which is linked in MetricWire. Biometric inter- and intra-day data are provided to MetricWire (and thus available to the study team) via the Fitbit Research API. We also collected qualitative interview data across both phases. In Phase I, qualitative data consisted of three focus groups and in Phase 2 a semi-structured follow-up interview, both of which were audio

recorded on Zoom and transcribed.

Data Protection and Storage. Identifiable information is collected via a contact form in Qualtrics for the purposes of scheduling assessments, ensuring unique and valid responses, and compensating participants. As a measure of data security, contact information is collected separately from the screener data. Specifically, the screener generates a unique participant ID and once a participant completes this screener, if eligible or if an ineligible participant opts to share their information for future study opportunities, they are forwarded to a new Qualtrics form where they can provide their contact information. The contact form contains only the participant ID as embedded data. This unique identification number is the only link between participant contact information and participant data. As such, screener data are not stored with participant contact information on the Qualtrics server, nor is it ever downloaded as a dataset. Contact information is only stored in a specific contact database designed for scheduling participants, which is powered by REDCap. The study team uses a separate REDCap database for tracking participant activity (consent completed, appointments, randomization condition, and compensation), which does not include participant contact information. All physical and electronic participant data is free of personal identifiers with the exception of the unique identification number. Both Qualtrics and REDCap software complies with HIPAA standards for privacy protection and utilizes secure SSL encryption of all data communications.

Quantitative EMA and EMI survey data are stored on MetricWire's secure and password-protected platform. While this platform is secure, HIPAA compliant, with encrypted data transmission & storage, and uniquely positioned to support scientific research, we have taken extra precautions to ensure participant's confidentiality. When participants are onboarded to the app, they are provided with an anonymous MetricWire email, which they use to log in to the app. In place of participant's name, we enter their unique participant ID. As such, we do not provide any of the participant's identifying information to MetricWire and all data stored on their platform is free of personal identifiers. Biometric data is gathered via the Fitbit Sense 2 smart watch, and available to the study team via the MetricWire software platform. To ensure data security, the study team uses a unique and anonymous university email account for each participant (in the watch condition). This email account is encrypted and used to create a Fitbit account for the participant. Participants names are not entered in during account creation, only their age, weight, and height for the purpose of validating biometric data. Participants are then provided with the study email and password to log in to the Fitbit app. Once an account is set up, MetricWire allows you to link a participant's Fitbit account, providing access to deidentified biometric datasets.

Qualitative interviews are recorded via the study team's Zoom Business account, which utilizes secure SSL encryption and is HIPAA compliant. Recordings were saved as audio only (without video content) and recorded on a password protected computer. Recordings were then moved to a secure university server and deleted from the device. Recordings are saved with only the unique participant ID as the identifier and audio files will be destroyed after quality assurance of transcriptions are completed.

Harmonized Measures. Baseline and follow up measures are harmonized across Phase 1 and 2. Quantitative outcome measures for feasibility and acceptability include the *System Usability Scale*,⁶² *Mobile App Rating Scale*,^{63,64} *Modified Computer Self-Efficacy Scale*,⁶⁵ *Client Satisfaction Questionnaire 8*,⁶⁶ and *eHealth Acceptability Scale*.⁶⁷ Additional key measures are outlined in **Table 1**.⁶⁸⁻⁹⁰

Eligibility Criteria for Phase 1 and Phase 2

Eligibility criteria were largely the same across Phase 1 and 2. Screening was completed via a participant's own computer or mobile device. The screening survey was programmed in Qualtrics. The purpose of the assessment was to obtain data on self-reported measures of demographics, health status, health behaviors, mental health, and other related factors, to determine preliminary eligibility for the study.

Inclusion Criteria. To be eligible, individuals must: 1) be at least 18 yrs; 2) identify as a gay or bisexual or a sexual minority man; 3) be HIV-positive; 4) have daily access to the internet from a smartphone; and 5) provide informed consent. Based on the study team's expertise and the available literature on stimulant use among SMM, we limit inclusion to SMM-LWH reporting stimulant use only. Specifically, individuals must: 5) report at least five days of stimulant use over a 3-month period, in the past 12 months. Note that participants will be excluded if they only report using prescription stimulants (e.g., Adderall).

Exclusion Criteria. Participants are excluded if they are: 1) unable to complete surveys in English; 2) currently enrolled in substance use treatment or an intervention study for HIV risk or drug use. Anyone intoxicated or otherwise unable to provide informed consent will be asked to reschedule. In Phase 1, we administered the Mini-Mental Status Exam for the exclusion of any individuals showing evidence of gross cognitive impairment (i.e., score <20) because these issues could compromise their ability to consent to and actively participate in the study. However, based on feedback from participants and in consultation with our investigative team we decided to drop the Mini-Mental Status Exam for Phase 2.

Phase 1 Procedures

Community Advisory Board

A community advisory board (CAB) was assembled prior to beginning participant recruitment for Phase 1. We recruited members from existing research CABs affiliated with three different universities. Each CAB we recruited from brought specific expertise needed for the current study. The first CAB we recruited from was a research CAB affiliated with the HIV Prevention Trials Network (HPTN) and was comprised of people LWH. The second CAB we recruited from was a research CAB affiliated with the Adolescent Trials Network (ATN), which included members of the LGBTQ community and professionals working in HIV and LGBTQ health services. Importantly, we also were able to recruit several members from an existing research CAB comprised of stimulant-using SMM LWH, affiliated with the START study (R01DA049843).

Recruitment and Enrollment (Phase 1)

In Phase 1, recruitment, consent, baseline appointment and assessment, as well as all focus group meetings, were conducted online. An initial recruitment email was sent to past and/or ineligible participants from the investigative team's contact list, who consented to being contacted for future studies in the last 24-month period. This email referred potential participants to our study with a link to our brief initial screening survey and study contact information. Once participants expressed interest via contacting us or completing the initial screening survey, a study team member reached out to them via phone or email to schedule their baseline appointment. This strategy has been successful in recruiting diverse samples of SMM-LWH for our previous pilot and large-scale studies. At the beginning of the baseline appointment, we provided potential participants with study information, conducted further eligibility screening. Specifically, we confirmed participants age by having each participant presenting a valid form of Identification (e.g., driver's license or other state issued ID, passport, birth certificate, etc.). Additionally we confirmed participants positive HIV status where each participant provided proof of ART prescription or HIV diagnosis (e.g., lab results,

prescription for ART medication, ART medication bottle). If the individual was deemed eligible, we completed an online informed consent form.

Study Setting and Timeline (Phase 1)

In Phase 1, all study appointments were conducted online via Zoom using our Rutgers Zoom service account for our study team. Participants completed a baseline appointment, followed by a 90-day EMI period, including 3 focus group meetings every 30-days. Participation lasted approximately 3 months. Participants will receive monetary compensation via e-gift cards through Tango Card Rewards for completing assessments and other procedures that are based on previous research. To further reduce any issue of coercion, we did not compensate participants for completing any intervention activities. This was done to help alleviate the concern that participants would take part in the intervention due to coercively high amounts of immediate monetary benefit.

Baseline Assessment. In the baseline appointment study staff conducted final eligibility screening and informed consent procedures. Participants were then introduced to the 7 modules on which the EMI is based via a review guide. They thereafter completed a brief (1-2 minute) guided mindfulness activity. At the end of the appointment participants were provided a link to the baseline assessment to complete on their own personal device, and informed that they would be contacted once the 90-day EMI period was set to begin. All final eligibility screening, informed consent forms, and the baseline survey were programmed via Qualtrics and completed online. Participants received \$50 for their completion of the baseline appointment and assessment.

Open-Phase Pilot. The 90-day EMI period began once all 10 participants were recruited and completed their baseline appointment (about 1.5 months after the start of recruitment); this was to ensure the 90-days of EMI and focus group meetings were taking place on the same timeline for all participants, as is important for following the Scrum agile methodology. A week before the EMI period, participants were provided a guide for downloading the app-based EMI via email. In this guide participants were provided step-by-step instructions for downloading the app onto their personal mobile device, they were provided the information regarding completion of EMA surveys (e.g., notifications, expiration, compensation) and they were guided through completing a practice survey as well as how to use and access each of the app features (e.g., on-demand user-initiated content, resources section, in-app messenger). We programmed the participants' EMI period to all begin on the same date. During the 90-day intervention period EMA surveys were delivered once per day and included measures of daily stress, health behavior, and mental health. The surveys were completed electronically via the MetricWire mobile app on each participant's personal smartphone. Over the 90-days EMI period, for every EMA survey completed via the app, participants received \$1 for up to a total of \$90 if they completed all assessments.

Focus Groups and CAB Meetings. After each 30 days of app engagement, participants were scheduled for a focus group meeting which took place via Zoom (audio-only). We help a total of three focus groups. Focus groups were led by a CAB moderator and at least one member of the study team, who elicited participant feedback using a qualitative focus group guide, beginning with broad, open-ended questions, followed by more specific questions. Specifically, participants reviewed the major components of the *Tea Time* intervention: 1) the "on-demand" materials, 2) the intervention activities, and 3) daily positive messages, 4) as well as the app design. In preparation for the focus groups, the research team and CAB reviewed the intervention content and prepared materials for the focus group sessions. This included presenting participants with the intervention content as it was currently programmed, including screenshots of how it presented within the app, as well as live demos of various app features. In addition to this, the app also uses a bank of quotes and images delivered as a 'daily positive message', which are selected at random. The images and quotes were

selected by the research team during the proof-of-concept pilot. The CAB and research team worked together to select new images and quotes, along with those that were currently used in the app and presented them to the focus group for feedback. Focus groups were audio-recorded and transcribed. For each focus group, participants were compensated \$50 for their participation for a total of \$150.

Sprints and Iterative Adaptation. As we gathered feedback, our team used iterative “sprints” following each focus group and CAB meeting to tailor and further optimize the JITAI EMI (see **Figure 2**). After each “sprint,” participants continued using the app to review the app’s updates in this cyclical approach. In keeping with Scrum agile methodology, sprints were timeboxed to no more than a month long. Three planned sprints are presented in the Phase 1 timeline. Consistent with Scrum, a planning meeting was scheduled at the start of each sprint, where team members created a sprint backlog – a list of the tasks to perform during the sprint. During each sprint, the Scrum team (i.e. data team) took a small set of features from idea to coded and tested functionality. At the end of a sprint, the team conducted a sprint review during which new functionality is demonstrated to the research team and CAB, who provided feedback. At the end, features were tested and integrated into the evolving product.

Follow-Up Assessment. Participants completed a follow-up assessment online via Qualtrics and received \$25 for their completion of this assessment. The follow-up assessment included all of measures from the baseline assessment, as well as measures to assess the acceptability and feasibility of the JITAI EMI.

Usability Testing Procedures

Following the completion of open-phase pilot, we conducted usability testing. The data team first prepared the app for alpha testing, which included incorporating any final changes to the app and publishing all changes so that they were accessible to front-end users. Alongside our CAB, we conducted usability testing to ensure that the app was functioning without error, and that data downloads were reflective of our JITAI design choices (e.g. micro-randomization, fixed interval sampling). We piloted the app for 30 days, providing daily feedback to the data team as programming errors were noted. The data team addressed errors in real-time, and the testing team confirmed they had been resolved. This was a 30-day period of iterative development and refinement to finalize all changes to the app. Consistent with Scrum, the team held weekly data meetings to review progress made and set action items for the week. See **Figure 3** for a screenshot of the app, which was finalized prior to launching Phase 2.

Preparation Procedures for Factorial Optimization Trial

In preparation for Phase 2, we piloted study-related procedures for the factorial optimization trial. First, the data team developed all necessary data tools for the factorial trial. Development of these tools happened alongside usability testing. This included developing a screening, contact, and tracking database in REDCap, in addition to programming the study appointment dashboard in Qualtrics, as well as programming the surveys needed for the baseline and follow-up assessments. Part of the pilot procedures included having research team members test these databases, as well as training RAs on how to use them. The data team also programmed the randomizer in Qualtrics. To prepare for randomization of conditions, a second version of the JITAI EMI was developed to include random craving prompts, which only half of the participants would be randomized to receive. The research team tested all data tools, including the randomizer, to ensure skip logic and validation were functioning without error. Three months were allotted for the development and testing of these data tools. Once data tools were finalized, the study investigators coordinated mock appointments with research staff to run through each condition. As part of this training, RAs ran through the baseline appointment protocol for all four conditions.

Phase 2 Procedures

In Phase 2, we are recruiting and randomizing 80 SUSMM-LWH to one of four conditions: EMI (n=20), EMI + random craving prompts (n=20), EMI with smart watch (n=20), EMI with smart watch + random craving prompts (n=20). We will examine acceptance and feasibility for adding each of these components, alone and in combination, to our JITAI EMI. We will also examine the feasibility of enrolling and retaining eligible participants into a factorial optimization trial. Further, we are establishing proof-of-concept for collecting passive biometric data through smart watches.

Recruitment and Enrollment (Phase 2)

Recruitment is being conducted via both online and in-person formats (e.g., provider referrals, email, social media, phone, flyers, contact databases). All forms of recruitment provide our participants with a link or QR code to our brief initial screening survey and/or study team contact information. We are recruiting participants via provider referrals, email outreach, flyers, snowball sampling, existing study contact databases, as well as through social media ads. Referrals for participant recruitment are being provided by the Co-investigator. This entails reaching out to other providers on-site with our informational flyer to provide to any patients who may be eligible, providing direct patient referrals, and placing flyers in the waiting area of their department. We contacted past and/or ineligible participants from prior studies who consented to being contacted for future studies via email outreach. Flyers were passively distributed through community collaborators and organizations on-site and via online listservs and mailing lists. For snowball sampling, as participants are enrolled in the study, they are provided with a study flyer and/or QR code for the screening survey to share with potentially eligible participants in their network.

Study Setting and Timeline (Phase 2)

The study timeline includes a baseline appointment, the 90-day EMI period, and a follow-up appointment. A final eligibility check and consent are conducted at the beginning of the baseline appointment. Participation lasted approximately 3 months. Study appointments are conducted both online via Zoom and on-site at our New York Presbyterian at Weill Cornell Medicine location in a private conference room reserved by the study team. The 90 days of EMI are completed remotely via the Catalyst by Metricwire mobile app on each participant's personal smartphone.

Randomization and Experimental Conditions. After completing the eligibility check, participants are randomized 1:1:1:1, to one of four conditions (JITAI EMI with Random Craving Prompts, JITAI EMI with Smartwatch Integration, JITAI EMI with Random Craving Prompts + Smart Watch Integration, or JITAI EMI Only) according to the 2x2 factorial design. Note that in all conditions, participants will compete a 90-day EMA. The JITAI EMI only group will be considered the "control." The randomization assignments are computer-generated via the study survey software Qualtrics and are monitored by the data team.

Baseline Assessment. During the baseline appointment we conduct final eligibility screening and informed consent procedures. Participants are randomized to 1 of 4 study conditions. For all participants we review the 7 modules on which the EMI is based, and they complete a brief mindfulness activity. As well, we review all app features (e.g., user-initiated content on the homepage, skill spotlight, positive messages, EMA surveys, resources section, in-app messenger), they are guided through downloading the app and completing a practice survey. Participants then take the baseline assessment survey online via Qualtrics.

Smart-Watch Assignment. For participants randomized to a watch condition they also receive a Fitbit Sense 2 smart watch during the baseline assessment, which is used for passive biometric data

collection. Integration of the smartwatch with the MetricWire app is essential to the pairing of EMA and biometric data. As such, participants are given clear instructions on this. Fitbit Sense has the capability of integrating with the MetricWire mobile app, such that participants' passive biometric data can be easily linked with real-time, individual level data from the EMA. Fitbit collects continuous data on physiological stress reactivity, HRV, heart rate, skin temperature variation, and blood oxygen saturation. Fitbit also offers API access, which allows MetricWire to regularly download intraday data from their server without participants having to come into the office to download. In a recent review of smart watch brands used in research, Fitbit was used in twice as many validation studies¹ and is registered in ClinicalTrials.gov studies 10x as often as other brands.

EMA/EMI 90-Day Period. Participants complete a 90-day EMA/EMI period, which is introduced during the baseline appointment and scheduled to begin the day after this appointment. The EMA and EMI are hosted on the Catalyst by MetricWire app, which is a leading platform for EMA data collection and JITAI EMI delivery. MetricWire offers several sensor capabilities that enable passive data collection, including smart watch integration, as noted above. While participants are compensated for their daily EMA (\$1 per EMA survey), there is no monetary incentive for viewing any other prompts delivered by the app (including intervention content or activities).

EMA Design Details: Planned Missing Design. Participant feedback from our proof-of-concept pilot, Positively Healthy, as well as Phase 1 of the current study, informed our decision to explore ways to reduce burden and optimize EMA design. This led us to leverage a Planned Missing EMA design in Phase 2. A Planned Missing EMA design can reduce repetition, which ultimately should reduce participant burden.^{91,92} A Planned Missing EMA design is one in which items are intentionally missed on alternating days, which would not only reduce redundancy and burden for participants, it would also allow researchers to maximize data collection and use validated scales. Essentially, this design would provide participants with different survey items each day. The variety in survey items should improve attention engagement, while reducing boredom and response fatigue, all of which contribute to careless responding.⁹³ Planned Missing designs are also associated with greater quantity and quality in participant response,⁹⁴ and may reduce measurement error and improve variance in EMA data. While this design has become increasingly popular in longitudinal research, limited research has examined utility in EMA.^{95,94,92} In Phase 2, all participants receive a Planned Missing EMA design where each item is asked 2/3 of the time, which ensures each item will have 67% complete data. This will result in each pair of items for a given construct having 33% complete data for covariance estimates, which is standard for a simple matrix design.⁹²

EMA Design Details: Fixed Interval Schedule. Feedback from the proof-of-concept pilot also informed our choice to use a fixed interval EMA design. In the following 90 days after the baseline appointment, all participants receive a daily notification asking them to complete the EMA, which is sent on a fixed interval schedule. Specifically, all participants complete one EMA per day (approx. 5 min), which is delivered at 6PM and expires at 12AM (a 6-hour expiration window) with a reminder sent halfway between EMA opening and expiration if the survey has not yet been completed. Participants report current mood, substance use cravings, and stress (along with other health behavior) in the EMA. A 24-hour recall is used to assess previous day substance use and medication adherence. Note: Participants in the "random craving prompt" condition also receive single item EMA craving prompts delivered three times per day, in addition to the once-daily EMA evening survey. The single item craving prompts are sent randomly between the following three time periods: 8-10am, 2-4pm, and 8-10pm, with a two-hour expiration window after delivery. To avoid the potential burden of excessive notifications, reminders are not sent for the random craving prompts.

JITAI EMI Design Details. If participants report stress or cravings in the EMA, they are microrandomized to receive a JITAI activity ($P=.70$). Selection of a specific JITAI activity occurs via process of further microrandomization. Once a participant is randomized to receive a JITAI activity, they are next randomized to 1 of 8 skills ($P=.125$), and then the JITAI is randomly select one activity from a bank of 4 possible activities ($P=.25$) which are designed to help practice the skill.

Follow-Up Assessment. Participants completed a follow-up assessment after the 90-day EMA/EMI period. The follow-up assessment included completing an online survey and a semi-structured qualitative interview (30-40 minutes) with the RA. These are conducted either in-person at the WCM site or virtually using our study team's Rutgers service, SSO-secure, Zoom account. All interviews are audio recorded (guide attached) using a voice recorder device or via a secure Zoom meeting using audio-only. All participants receive general questions on the acceptability of their treatment condition. We also customize the questions asked to participants across each condition. (e.g., only participants randomized to the smart watch conditions are asked questions relevant to this condition). After completion, participants received \$40 for their follow-up assessment, as well as compensation for any EMAs completed over the study period (\$1 per day).

Planned Analyses

In both phases of the study we plan to conduct qualitative and quantitative analyses to assess the acceptability and feasibility of our JITAI EMI. Planned analyses will also assess the feasibility of our intervention design. Specifically, we will be testing the feasibility of running an MRT embedded within a 2x2 factorial optimization trial.

Qualitative Analyses

Qualitative data will be coded with qualitative content analysis.⁹⁶ We will separately code sections of the qualitative interviews pertaining to the acceptability of each condition, program satisfaction, and perceived relevance of program content. We will also assess feasibility by coding participant responses to questions about barriers and facilitators to app engagement. Specifically, we will begin our process of coding by first analyzing the data for indicators (i.e. parts of participant responses). During this process, similar indicators that emerge across participants will be grouped together, with tentative labels given for each group.⁹⁷ Consistent with qualitative methodology, written coding notes and memos will be kept as a reference throughout analysis. This process will reduce participant data into a smaller subset of themes.⁹⁷ Inter-rater reliability will be assessed using Cohen's Kappa across two coders. We will use methodological triangulation to compare quantitative and qualitative findings, further validating acceptability and feasibility.

Quantitative Analyses

We will first examine the feasibility of recruiting and randomizing our sample into the four conditions. We will begin by developing a consort diagram for our enrollment cascade. Target benchmarks include >70% for eligible participants that consent to the study and >60% for consented participants who are randomized.⁹⁸ We will also conduct attrition analyses to examine the percent of randomized participants that drop out prior to initiation of the intervention, and over the 90-day intervention period. Our target benchmark (>80%) is based on our review of retention rates for other clinical trials.^{99,100} We will conduct randomization checks and examine between-group differences in attrition to ensure there are no significant group differences (e.g. race/ethnicity, education, income, and relationship status) by condition or attrition rate. We will use chi-square tests to examine the proportion of participants in each condition retained through the post-intervention assessment. We will also assess feasibility by examining the adherence to each treatment conditions.

For those in smart watch conditions, feasibility will be defined as the rate of returned watches after

the 90-day period. In our previous EMA studies, we saw a 92% return rate with a sample of SMM-LWH. The target benchmark for this sample of SUMSS-LWH is >80%. We will also assess the feasibility of obtaining passive bio-metric data from smart watches. The study will provide insight on the feasibility of obtaining continual stress reactivity data from smart watches with SUSMM-LWH. A few issues may lead to non-random missingness in the data (e.g. forgetting to charge their watches). We will use Fitbit's API to access stress reactivity data on their server, downloading data regularly to examine missing data patterns.

Feasibility for the EMA portion of the study will be assessed across all conditions by examining the percentage of completed EMA surveys. In our pilot work, participants responded to 66.19% ($Mdn=78.21\%$) of the EMAs; our target benchmark for this study is a completion rate >80%.¹⁰¹ Adherence to the EMI will be defined as the average number of intervention activities that participants responded to, and the average views for positive messages and on-demand material. In our pilot work, participants responded to 83.27% ($Mdn=94.44\%$) of the intervention activities and viewed 68.9% ($Mdn=82.72\%$) of the daily positive messages over the 90-day period. Using this data, as well as that from other m-health studies, our a priori target benchmark for app engagement is a >80% completion rate for intervention activities and positive messages. We will also use completion data to identify the ideal length of the intervention. Should completion rates for the EMA or intervention activities fall below 80% over the 90-day period, we will identify the ideal duration that balances maximal rates for both completion ($\geq 80\%$) and power to detect an effect. Acceptability will be assessed with various measures. For the EMI, a score on the *System Usability Scale* >72.75 is considered the benchmark for "good" or satisfactory.⁶² Regarding app quality, for all subscales on the *Mobile App Rating Scale*, an average of 3 or > is considered acceptable.⁶⁴

Preliminary Outcome Analyses

We will also leverage data collected for this study to support preliminary outcome analyses looking at stress, substance use, adherence. We will use traditional regression-based analyses to examine between person, main and interactive effects for random craving prompts and smart watch integration on self-report outcomes, as well as objective measures of substance use and adherence. We will also conduct multilevel analyses to examine within-person effects of JITAI EMI delivery on same day substance use and adherence (lagged variables). We will also have passive bio-metric data, allowing us to examine stress reactivity in association with participant's response to random craving prompts, as well as JITAI EMI intervention delivery.

Results

The project was funded in September 2021 and data collection will be completed by July 2025. Data analysis is currently under way, and the first results are expected to be submitted for publication sometime between late 2025 to early 2026.

Discussion

Principal Findings

This paper outlines our study protocol for Phase 1 and Phase 2 of the Tea-Time study. In executing this study protocol, we are tailoring our app-based EMI content, as well as optimizing our EMI's JITAI design. Specifically, in Phase 1, we have focused on tailoring our intervention content to the unique needs and preferences of SU-SMM LWH. In doing this, we have taken a CEnR approach, working closely with study participants and a CAB to inform the tailoring of our intervention. In addition to tailoring the content, we have also implemented participants suggestions for improving system usability of the app. In Phase 2, we are piloting a MRT, embedded within a 2x2 factorial optimization trial. Findings from the MRT will provide valuable information, allowing us to further optimize our JITAI design (e.g., decision point, tailoring variables, decision rules, etc.). Finding from

the randomized factorial trial will offer insights regarding whether smart watch integration and/or random craving prompts are feasible to implement in this intervention. These findings will also elucidate whether the combination of these new features is as acceptable to participants, compared to either feature alone. We will also be able to leverage these data to assess preliminary efficacy for proximal and distal outcomes.

Strengths and Limitations

This takes a CEnR approach to using the Scrum Agile Framework and MOST, combining methods from social science, intervention science, and software development into one innovative approach to enhance this app-based intervention. In particular, our implementation of Scrum Agile Framework in combination with the MOST approach to intervention optimization strengthens our study design and protocol. First, these two approaches are highly complementary to one another, as they each propose an iterative process for app intervention adaptation. Additionally, they each provide a unique framework which will guide us in the process of software development, as well as intervention optimization. Scrum is most frequently used within technology-based fields, such as computer science and is a framework for managing multicomponent software and product development projects. This framework will guide us in efficiently managing data-related tasks as we program adaptations to the JITAI EMI and publish different iterations of the app for beta and alpha testing. The MOST approach provides an important framework that is specific to intervention optimization, including our design choices for piloting an optimization trial for our adapted app. Essentially, Scrum provides guidance on how to adapt the app, and MOST provides a framework for selecting what features will benefit from adaptation.

As part of Phase 2, we are piloting the feasibility of running a MRT, embedded within a factorial optimization trial with SUSMM-LWH. To optimize adaptive interventions of high intensity, a MRT is recommended.^{1,2} The MRT is conducted under the n-of-1 framework, and is essentially a factorial design wherein each individual is exposed to each of the intervention conditions, repeatedly, over time.¹ This approach is useful for optimizing features within the JITAI EMI, however, optimization of other features require a standard factorial design. For example, it is not feasible to randomly assign the same user to wear a smart watch on some days and not others over a 90-day assessment. Similarly, given random craving prompts are a feature of the EMA, not the JITAI EMI, this feature is also best evaluated within a standard factorial design. This combined approach to optimization is also a strength of the current protocol and will minimize a need for future optimization trials. As such it is also cost effective. Further, by speeding the optimization process, we come closer to arriving at a fully optimized intervention ready for evaluation and implementation. In a future RCT, the EMA design will also allow us to collect day level data on intervention efficacy.

One potential area of concern is that the participant burden¹⁰² and response fatigue^{103,93} associated with intensive repeated measure designs threaten data validity; in addition, burden and fatigue are also both associated with poorer EMA compliance.¹⁰⁴ Participant burden is an especially important concern for researchers working with SUSMM-LWH, as this population is already disproportionately impacted by health related burden and other acute daily stressors. In addition to this, prior research shows that compliance to EMA is a challenge among substance users more generally,¹⁰⁵ and among SUSMM.¹⁰⁶ Some studies have also found that racial and ethnic minority SMM and SUSMM are more likely to show poor compliance to EMA.^{12,107} Poor compliance poses significant concern regarding feasibility for JITAI EMI delivery with SUSMM-LWH. Given that the success of a JITAI EMI heavily on the validity of EMA data, as well as compliance to the EMA, it is important to optimize EMA methods and design prior to scaling up this intervention for SUSMM-LWH.

Improving EMA compliance is a vital first step in optimizing this JITAI EMI. Compliance can be

improved by reducing participant burden.¹⁰⁴ One approach to minimize burden is to integrate ambulatory assessment into the EMA/EMI, which would facilitate passive data collection.¹⁰⁸⁻¹¹⁰ Smart watches can be used to collect data such as heart rate and physiological stress response,¹¹⁰ which can be used to trigger EMI intervention content.¹⁰⁹ Smart watches also are able to integrate with mobile apps, allowing participants to receive notifications, surveys, and EMI content to their watch, making engagement effortless and accessible. It is our expectation that smart watch integration for those in this 2x2 trial will improve both EMA compliance and EMI engagement.

Compliance is also related to design choices.¹⁰⁴ In our proof-of-concept pilot, participants stated they often missed their EMA due to its timing (random interval sampling) and expiration. In the current protocol, we have attempted to address this issue. We have implemented participant feedback for our EMA scheduling, moving from a random interval design to a fixed interval design. A fixed interval design allows participants to set aside dedicated time to complete the EMA and may improve compliance. Of course, this change introduces certain limitations, as random interval EMA is believed to provide better ecological validity. This is being addressed in-part with our 2x2 design which is testing the integration a random interval craving prompts, in addition to the fixed interval evening survey. Importantly, random craving prompts will trigger intervention content and thus will be an important feature for delivering in the moment support for SUSMM-LWH. We expect that this combined sampling approach (e.g. fixed + random interval) may further optimize our JITAI EMI.

Conclusions

Ultimately, the aim of this project is to arrive a fully optimized EMI that is both culturally relevant and acceptable for our target audience, by eliminating sources of community – program mismatch in our intervention content. Additionally, we aim to further optimize the intervention by adding two additional features that may improve engagement and effectiveness, while minimizing participant burden and other potential barriers to engagement. If we are successful in these aims, this app-based JITAI EMI will offer a cost-effective intervention approach, which can provide SUSMM LWH support in real-time, in their daily lives, when it is most needed.

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Authors' Contributions

KMS, JTM, HJR, AC, and BM conceptualized and designed Phases 1 and 2 of the current study protocol. KMS, BM, and SG coordinated the study at Rutgers University. JA coordinated the study at Weill Cornell Medicine. KMS and HP designed the data safety protocols and procedures. HP developed all necessary data tools and managed data for the study. All authors assisted in the development of this paper and have approved the final manuscript.

Conflicts of Interest

None to Declare

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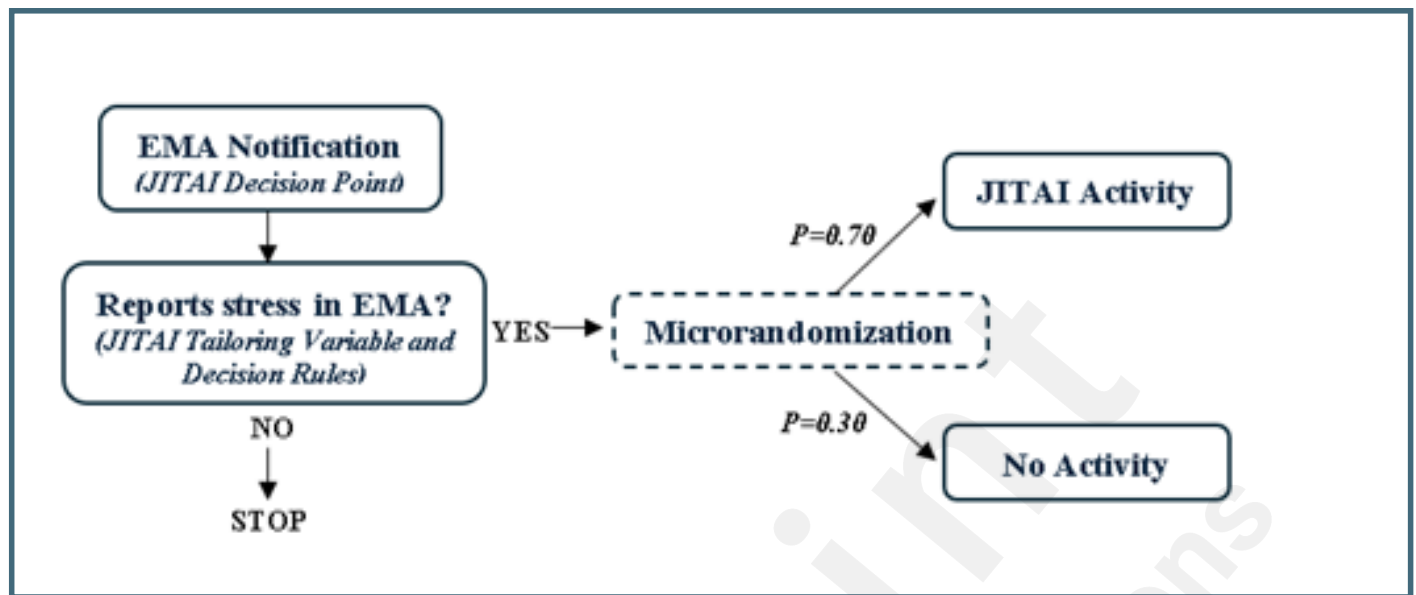
Table 1. Measures for the baseline (BL) and follow up (FU) assessments.

Variable	Between Person Measures	BL	FU
Demographic	Age, race/ethnicity, employment, education, income, substance use, relationship status, sexual orientation, gender	X	
Stress	<i>The Perceived Stress Scale</i> ⁶⁸	X	X
HIV Specific Stress	<i>The HIV/AIDS Stress Scale</i> ⁶⁹ <i>Everyday Discrimination Scale (HIV)</i> ⁷⁰ <i>The HIV Stigma Scale 12-item</i> ⁷¹	X X X	X X X
Racial/Sexual Minority Stress	<i>Internalized Homophobia Scale</i> ^{72,73} <i>Everyday Discrimination Scale (Sexual Orientation, Race)</i> ⁷⁰	X X	X X
Mindfulness	<i>Five Facet Mindfulness Questionnaire</i> ⁷⁴ <i>The Toronto Mindfulness Scale</i> ⁷⁵ <i>Cognitive and Affective Mindfulness Scale Revised</i> ⁷⁶	X X X	X X X
Self-Compassion	<i>Self-Compassion Scale Short-Form</i> ⁷⁷	X	X
Gratitude	<i>The Gratitude Questionnaire-6</i> ⁷⁸	X	X
Affect	<i>Positive and Negative Affect Schedule</i> ⁷⁹	X	X
Substance Use	<i>Drug Abuse Screening Test (DAST)</i> ⁸⁰ <i>Shortened Inventory of Problems-Alcohol and Drugs</i> ⁸¹		
Depression	<i>Center for Epidemiologic Studies Depression Scale - Revised</i> ⁸²	X	X
Adherence	<i>Simplified Medication Adherence Questionnaire</i> ⁸³	X	X
Variable	Within Person EMA Measures		
Stress	<i>EMA-Adapted Perceived Stress Scale</i> ⁸⁴ <i>Modified HIV Stigma Scale for EMA</i> ⁸⁵ <i>Measures of Daily Intersectional Stigma</i> ⁸⁶ <i>Daily Discrimination Related to HIV, SGM identity, and Race/ Ethnicity</i> ^{87,88,89}		
Affect	<i>Alternative Momentary Affect Measure</i> ⁹⁰		
HIV TRB	<i>Medication Adherence, Previous Day Substance Use, & Sexual Behavior</i>		

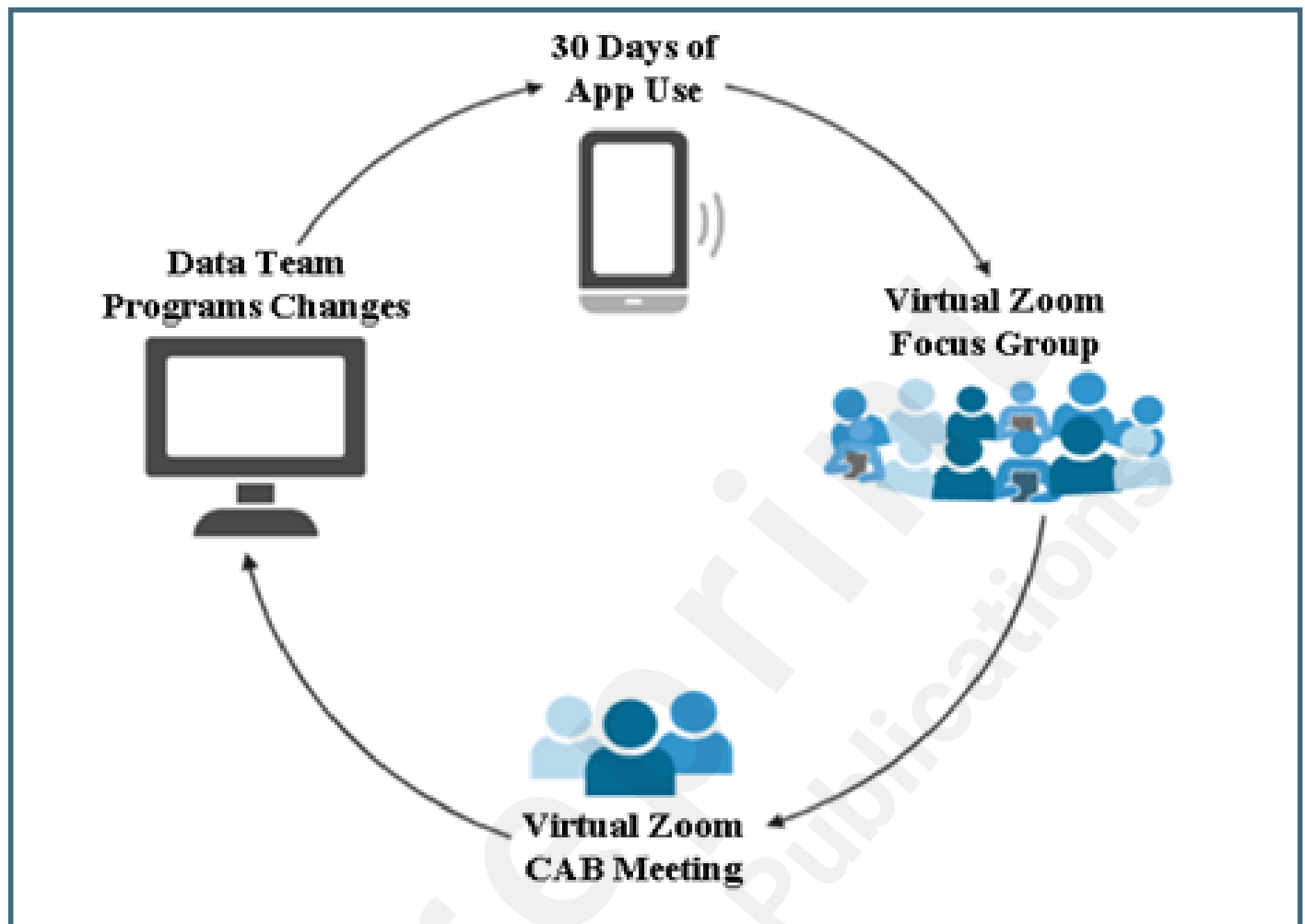
Supplementary Files

Figures

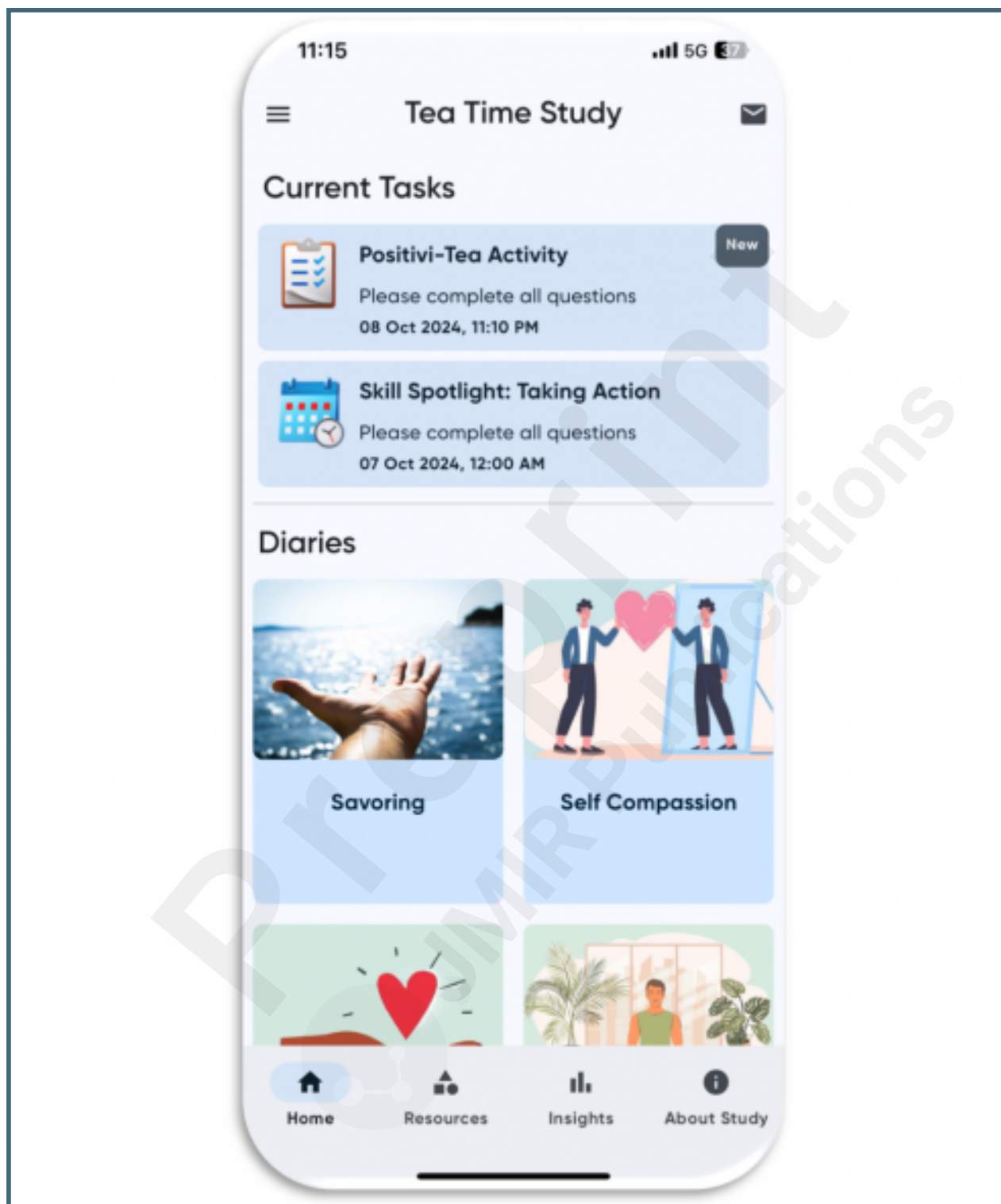
JITAI design for micro-randomization in the proof-of-concept pilot.



Flow for sprints and iterative adaptation in Phase 1 of the study protocol.



Screenshot of the finalized app, prior to launching Phase 2.



Multimedia Appendixes

National Institute of Health Peer Review.

URL: <http://asset.jmir.pub/assets/4c25927426e58926c630cfe52b1264ea.pdf>

