

Novel Machine-Learning HIV Intervention for Sexual and Gender Minority Young People Who Have Sex with Men (uTECH): Protocol for Randomized Comparison Trial

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Abstract

Background: Sexual and gender minority (SGM) young people are disproportionately affected by human immunodeficiency virus (HIV) in the United States, and substance use is a major driver of new infections. People who use online venues to meet sex partners are more likely to report substance use, sexual risk behaviors, and sexually transmitted infections (STIs). To our knowledge, no machine learning (ML) interventions have been developed that utilize online and digital technologies to inform and personalize HIV and substance use prevention efforts with SGM young people.

Objective: This study tests the acceptability, appropriateness, and feasibility of the uTECH intervention, a text message intervention using a ML algorithm to promote HIV prevention and substance use harm reduction among 18-29 year old SGM people who have sex with men. This intervention will be compared to YMHP (Young Men's Health Program) alone, an existing Centers for Disease Control and Prevention (CDC) Best Evidence intervention for young SGM people, that consists of 4 motivational interviewing-based counseling sessions. The YMHP condition will receive YMHP sessions and will be compared to the uTECH+YMHP condition, which includes YMHP sessions as well as uTECH text messages.

Methods: In a study funded by the National Institutes of Health, we will recruit and enroll SGM participants (aged 18 to 29 years) in the United States (N=330) to participate in a 12-month two-arm randomized comparison trial. All participants will receive 4 counseling sessions conducted over Zoom with a Masters-level social worker. Participants in the uTECH+YMHP condition will receive curated text messages informed by a ML algorithm that seeks to promote HIV and substance use risk reduction strategies as well as undergoing YMHP counseling. We hypothesize the uTECH+YMHP intervention will be considered acceptable, appropriate, and feasible to most participants. We also hypothesize that participants in the combined condition will experience enhanced and more durable reductions in substance use and sexual risk behaviors compared to participants receiving YMHP alone. Appropriate statistical methods, models, and procedures will be selected to evaluate primary hypotheses and behavioral health outcomes in both intervention conditions using an $\alpha < .05$ significance level, including comparison tests, tests of fixed-effects, and growth curve modeling.

Results: This study was funded in August 2019. As of June 2024, we have enrolled all participants. Data analysis has begun and expected results will be published in Fall 2025.

Conclusions: This study aims develop and test the acceptability, appropriateness, and feasibility of uTECH, a novel approach to reduce HIV risk and substance use among sexual and gender minority young adults.

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Original Manuscript

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Keywords: HIV; mHealth; text messaging; machine learning; mobile app; sexual and gender minority; YMHP; motivational interviewing; substance use; harm reduction

ABSTRACT

Background: Sexual and gender minority (SGM) young people are disproportionately affected by human immunodeficiency virus (HIV) in the United States, and substance use is a major driver of new infections. People who use online venues to meet sex partners are more likely to report substance use, sexual risk behaviors, and sexually transmitted infections (STIs). To our knowledge, no machine learning (ML) interventions have been developed that utilize online and digital technologies to inform and personalize HIV and substance use prevention efforts with SGM young people.

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Conclusions: This study aims develop and test the acceptability, appropriateness, and feasibility of uTECH, a novel approach to reduce HIV risk and substance use among sexual and gender minority young adults.



INTRODUCTION

Sexual and gender minority (SGM) young adults are disproportionately affected by human immunodeficiency virus (HIV) in the United States (US), and substance use is a major driver of new infections. Among men who have sex with men (MSM) in the US, the lifetime risk of receiving an HIV diagnosis is 1 in 6, compared to 1 in 524 among heterosexual men [1]. According to the 2022 Centers for Disease Control and Prevention (CDC) HIV Diagnoses, Deaths, and Prevalence report, nearly 70% of new HIV diagnoses were attributable to male-to-male sexual contact (MMSC) [2]. Young MSM are at particularly high risk for HIV and sexually transmitted infections (STIs). The CDC in the same report found that young people aged 13 to 34 years accounted for nearly half of all new HIV diagnoses in the US in 2022. Transgender women in the United States have also been found to be at increased risk for HIV [3]. A 2021 CDC report found that 4 in 10 transgender women surveyed in seven major U.S. cities are living with HIV [4]. While transgender women made up the large majority of new HIV diagnoses within transgender and gender nonbinary populations at 87%, HIV incidence among all of these identities substantially rose between 2018 and 2022, with a staggering 136% rise in diagnoses among gender nonbinary persons, 33% in transgender men, and 24% in transgender women [2].

In the United States evidence suggests that substance use is associated condomless anal sex and increased numbers of sexual partners [5–9], both of which may increase one's risk of HIV infection. MSM have been shown to be three to four times more likely to report substance use compared to the general population [10–12]. HIV infection among transgender women has also been associated with polysubstance use and sexual risk behaviors [13]. Compared to the populations of cisgender men and transgender women, little has been established in existing literature that examines the effects of sexual risk and substance use behaviors contributing to HIV and STIs in transgender men and gender nonbinary individuals. Our work utilizes the definition of “transgender” as individuals whose gender identity differs from their assigned sex at birth [14], and “gender nonbinary” as an umbrella term for individuals whose gender identity is neither male nor female, encompassing a variety of experiences including but not limited to: identification with multiple genders, no gender, or a gender that changes over time [15].

Lesbian, gay, and bisexual adults in the United States are nearly twice as likely to use online dating sites and apps, compared to their heterosexual counterparts [16]. People who use online venues to meet sexual partners are more likely to report substance use, sexual risk behaviors, and STIs [17–19]. Geosocial networking applications (apps), such as *Grindr* and *Tinder*, use global positioning systems (GPS) to facilitate more efficient dating and networking with others based on proximity, which in turn may increase likelihood of STI acquisition in specific geographic areas [20]. Research has also indicated that some MSM, transgender women, and gender nonbinary people use digital technologies to search for and intentionally use illicit drugs before and/or during sex to sustain, enhance, disinhibit, or facilitate the sexual experience, which may contribute to increased risk of HIV and other STIs through substance-induced disinhibition and increased length of sexual sessions [21,22].

Although online and social media data have been used by researchers in interdisciplinary fields for a range of health-related applications [23–25], to our knowledge no interventions have been developed that utilize machine learning (ML) to inform HIV prevention and substance use harm reduction efforts with both MSM and other SGM. Previous research suggests the feasibility of applying social media and online data mining as a public health surveillance strategy [26–29]. ML, a branch of computer science that utilizes statistical and optimization tools to “learn” patterns and trends from large quantities of data, can be used to identify or predict new patterns or trends [30]. This approach has been used to detect and predict other health-related outcomes, such as pre-term births [31],

healthcare monitoring of chronically ill patients [32] and suicide prevention [33]. On an individual level, insights gleaned from online and social media use patterns can inform cost-effective, scalable interventions that are highly personalized and delivered via technology (i.e., tailored messaging, outreach from health workers).

The use of online and social media data mining and ML approaches within SGM populations for HIV prevention and substance use harm reduction has important implications for public health. Our team previously developed and tested a social media data mining program that correctly identified HIV risk, amphetamine, and methamphetamine use using only social media data [34]. This system was refined and tested for this intervention trial.

There are currently few “best” rated evidence-based risk reduction interventions (EBRRI) in the CDC Compendium of Prevention Research Synthesis for young adult, HIV-negative men who have sex with men. To our knowledge, there is currently one “best” rated EBRRI for young transgender women [35] and no “best” rated EBRRI for other SGM populations, such as transgender men, and gender nonbinary people. One of the few “best” rated EBRRI for young gay and bisexual men is the *Young Men’s Health Project* (YMHP), which is a manualized 4-session intervention that uses motivational interviewing (MI) and problem-solving skills to provide personalized feedback for reducing risk behaviors and promoting HIV prevention skills such as using HIV pre-exposure prophylaxis (PrEP) [36]. It is also the only intervention to show significant effects in reducing both condomless anal sex (CAS) and substance use. YMHP has also been effectively used in remote delivery [37]. The YMHP intervention component, MI, is a proven approach in HIV/STI prevention for many populations [38,39]. However, few research studies have tested the effectiveness of MI for risk reduction with other SGM people, including transgender women, transgender men, and gender nonbinary young people [40,41].

We hypothesize that the uTECH+YMHP intervention will be considered acceptable, appropriate, and feasible by the majority of participants. Furthermore, we hypothesize that participants receiving the combined uTECH+YMHP intervention will show greater and more sustained reductions in substance use and sexual risk behaviors compared to those receiving the YMHP intervention alone. Specifically, we anticipate that the integration of ML-informed text messages will enhance the efficacy of YMHP counseling methods by providing personalized, timely, and contextually relevant support, ultimately leading to improved health outcomes in this sample of SGM minority young adults.

METHODS

The proposed study is a randomized comparison trial to evaluate the acceptability, appropriateness, and feasibility of uTECH, which is a text-based risk reduction intervention that leverages a data mining and ML algorithm to provide personalized prevention messaging to users. uTECH will be compared to an existing best evidence MI intervention (YMHP). Participants will be randomly assigned to one of two conditions: (1) uTECH+YMHP (trial intervention + existing intervention); or (2) YMHP only (existing intervention only). Those in the uTECH+YMHP condition will receive 4 YMHP sessions with a trained masters-level social worker, and tailored text messages. Those in the YMHP arm will only receive 4 YMHP sessions. Participants in both conditions will either contribute keylogged smartphone data through an app called “eWellness” [v1.0.24, 2023], and/or provide data downloads from their most-used online dating and social media accounts. These data will be used to inform and prime the ML algorithm that will be used to make predictions and generate tailored text messages for the uTECH+YMHP condition. The overarching goal of this study is to evaluate the acceptability, appropriateness, and feasibility of uTECH in conjunction with YMHP (condition 1)

compared to YMHP alone (condition 2). This study was registered with ClinicalTrials.gov under NCT04710901.

Target Population: The goal of this study is to recruit 330 participants. Half (165) of the participants will be randomized to receive uTECH+YMHP (condition 1), and the other half (165) will be randomly assigned to receive YMHP-only (condition 2).

To be eligible for the study, participants must be aged 18 to 29 years, identify as SGM, have had anal or oral sex with a man (defined by the participant's interpretation) in the past 3 months, have used substances (such as alcohol, marijuana, amyl nitrate (poppers), methamphetamines, heroin, cocaine, ecstasy, etc.) in the past 3 months, have had sex while using substances in the past 3 months, have a negative or unknown HIV status, and have used a dating app to meet sexual and/or substance use partners in the past 3 months. Participants must also own a smartphone, reside in the United States, be willing to participate in a 12-month study, and able to provide informed consent. Participants that use an Android smartphone as their primary device must consent to install the eWellness app on their phone to remotely collect keystroke and geolocation data throughout the duration of the study. Participants who use an iOS (i.e., Apple) smartphone must provide the study team with at least one set of data from both their primary dating app and their most-used social media account every six months. Failing to meet all the stated criteria would disqualify individuals from enrollment in the study. Exclusion criteria were conceived to build upon existing literature for HIV prevention in SGM while also expanding gender criteria to be inclusive of transgender and gender nonbinary individuals who have sex with men. Our study population aims to capture identities of young adult users of queer-centered dating apps and websites such as Grindr, Scruff, and Sniffies who may be at heightened risk of HIV and STI transmission [17–19], particularly in the context of substance use [5–9].

eWellness App Development: The mobile app, eWellness, was developed during Phase 1 of this study and utilizes the Aware Framework [42], which is an open-source context instrumentation that uses smartphone sensor instruments to infer, log, and share mobile information for application developers and researchers. The Aware Framework has been used in numerous earlier eHealth studies, for example, to predict depression and anxiety [43,44], progression of Parkinson's disease [45], or alcohol use events [46]. We developed eWellness using the AWARE framework and dashboard to record keylogging data (data entered into the user's preferred smartphone keyboard), which is remotely downloaded to secure databases daily. eWellness is also enhanced with a user-friendly interface that provides several "tabs" of information, including a study timeline and incentive chart, a brief survey, and an interactive Google-based map of nearby HIV/STI testing locations, risk reduction supportive services, needle exchanges, and other harm reduction and substance use treatment services.

The data collected through the eWellness app is used to refine and "teach" the ML algorithm to make predictions that can be used to inform the uTECH intervention. During the 12-month design process, we developed a working version of the app and added additional features as they were developed. We recruited SGM people (n=20) over the age of 18 years, who used Android phones, and used websites and apps to seek sexual and/or substance use partners. These Phase 1 participants downloaded the app, which collected data that was used by the study team to further refine the ML algorithm.

Throughout the 12-month study, we also conducted semi-structured interviews with the participants to obtain feedback and preferences on possible app functions. Interviewers followed a questionnaire developed by the principal investigator and research staff. Data from these Phase 1 interviews were

analyzed using rapid qualitative analysis (CITE) and insights were used to refine and finalize the app in preparation for Phase 2.

During Phase 2, the eWellness app will be installed by participants who use Android smartphones. Once installed, the app will collect data continuously for 12 months. The app collects the following: keystrokes (letters and numbers that the user types into their smartphone keyboard), the time and date of information that is typed into the keyboard, the name of the app used when typing in an app, the name of the website the user is on when typing on a website, and geolocation. The app does not collect the following: any data that is not typed directly into the smartphone keyboard, photos/camera data, accelerometer data, video, drop-down menu selections, barometer, audio/microphone data, battery data, text-to-speech data, bluetooth data, address book contacts, gyroscope data, screen time tracking data, gravity sensor data, incoming text messages, magnetometer data, phone logs, proximity sensor data, installation logs, scheduler data, network sensor availability, temperature data, rotation sensor data, wi-fi data, telephony data, or time zone data.

Social Networking App Downloads: Participants who use iOS smartphones will be asked to provide social networking app account downloads from their most frequently used online dating apps (such as *Grindr* or *Tinder*) and social media accounts (such as *Twitter/X*, *Instagram*, *Reddit*, *Facebook*) to send to the research team. The data requests will occur at baseline, 6-month and 12-month follow-up interviews. The exact data request process varies for each app but generally involves the user going into the app settings and requesting a data download that will be sent to the participant's email address. The participant then downloads their data and emails the files to an encrypted email address managed by the research team.

Data requests may include but are not limited to: text-based content of social media posts, profile information, chats and messages they send to others, like/viewing history, advertisement history, and background activity (such as time spent on app, geolocation, and account settings).

Young Men's Health Project (YMHP) Intervention

The YMHP intervention consists of four one-hour counseling sessions that use MI as a collaborative, goal-oriented approach of communication to discuss how participants manage sexual health and substance use in their daily lives. The goal of the YMHP counseling sessions are to explore these issues while supporting participants in making informed decisions for their health [36]. The sessions will be conducted by doctoral students trained in YMHP who hold master's degrees in social work and were supervised by a licensed clinical social worker.

There is a wealth of evidence demonstrating the effectiveness of MI for behavioral change [47]. MI is rooted in the principles of engaging, focusing, evoking, and planning. The practice and implementation of MI uses deep listening skills, effective reflections, and strategies for responding to resistance. Engaging involves building rapport and creating a sense of alliance through approaching participants with an attitude of curiosity, compassion and understanding. Focusing involves exploring the participant's view of their situation and selecting a target behavior for change. Although the main target behaviors are sexual health and substance use, understanding the participant's priorities and goals is essential. Evoking is the act of finding out the participant's own reasons for change and brainstorming how to reach those goals. Evoking can be achieved using open questions and the ASK-TELL-ASK method [48]. Planning involves the creation of a course of action and the anticipation of obstacles. The transition into the planning stage should only be done when the participant is ready and willing to do so.

For this study, YMHP will be tailored and used with young adults across the SGM spectrum and include gay and bisexual men, as well as transgender women, transgender men, and gender nonbinary individuals who have sex with men, reflecting our study population.

The uTECH Intervention

Participants randomized to receive the uTECH intervention (uTECH+YMHP) will receive text messages that use the Informational-Motivation-Behavioral Skills (IMB) Model [49] to improve substance use harm reduction and promote safer sex practices. The IMB Model was developed to use information, motivation, and behavioral skills to promote HIV-related behavior change, positing that when groups at risk for HIV are well-informed, motivated to act on their knowledge, and have necessary behavioral skills to seek out and initiate change, they will successfully overcome obstacles to make behavior change. The IMB Model has been shown to be effective in enhancing protective health behaviors such as adherence to interventions or reduction of risk behaviors with people living with HIV/AIDS [50–52], and people who use substances [53–55].

Staff will follow IMB framework to generate content for the text messages, a process that will be informed by an extensive review of public health messaging, scientific literature, and validated survey instruments tailored for specific sub-groups that will be recruited for this study. The groups include: people who inject drugs, people who do not inject drugs, people who are on PrEP, people who are not on PrEP, transgender and nonbinary people who are on PrEP, and transgender and nonbinary people who are not on PrEP. Each participant will be assigned to one of the above subgroups based on their answers in their baseline interview. The text messages will be sent to participants using Twilio [v8.0.0, 2023] [56], an online communications service that can be programmed to send and receive text messages. Approximately two text messages will be scheduled per week, so that each participant will receive 100 text messages over the course of 12 months.

To obtain feedback, participants will be asked to respond to each text message. Participants will be compensated \$1 per text message to which they reply. Each text message also includes an opt-out option to comply with cell carrier anti-spam policies. The feedback from participants will also be used to enhance the ML algorithm in preparation for fully automated text message generation and assignment.

Table 1: Text Message Content Examples from uTECH Intervention Using the IMB Model

	<i>PrEP Initiation</i>	<i>PrEP Adherence</i>	<i>Sexual Risk Reduction</i>	<i>Substance Use Harm Reduction</i>
<i>Informational</i>	PrEP reduces the risk of getting HIV from sex by about 99% - if	Did you know? The FDA approved injectable PrEP, which is an option for people who are tired of	If you had unprotected sex, you can take PEP (post-exposure	Here's a tip for staying hydrated while drinking: drink one glass of water for
<i>Motivational</i>	Did you know that studies show taking PrEP lowers HIV-related anxiety? Are	Did you know that studies show taking PrEP lowers HIV-related anxiety? Are you less anxious about	Nervous about getting STI testing? It's safer to get tested and know the	If you ever inject with a friend, you could consider doing so at a safe injection site
<i>Behavioral</i>	Reply with the number of the statement that applies to you:	Reply with the number of the statement that applies to you: Have you at any point considered stopping	Reply with the number of the statement that applies to you:	Reply with the number of the statement that applies to you: Have you ever trusted

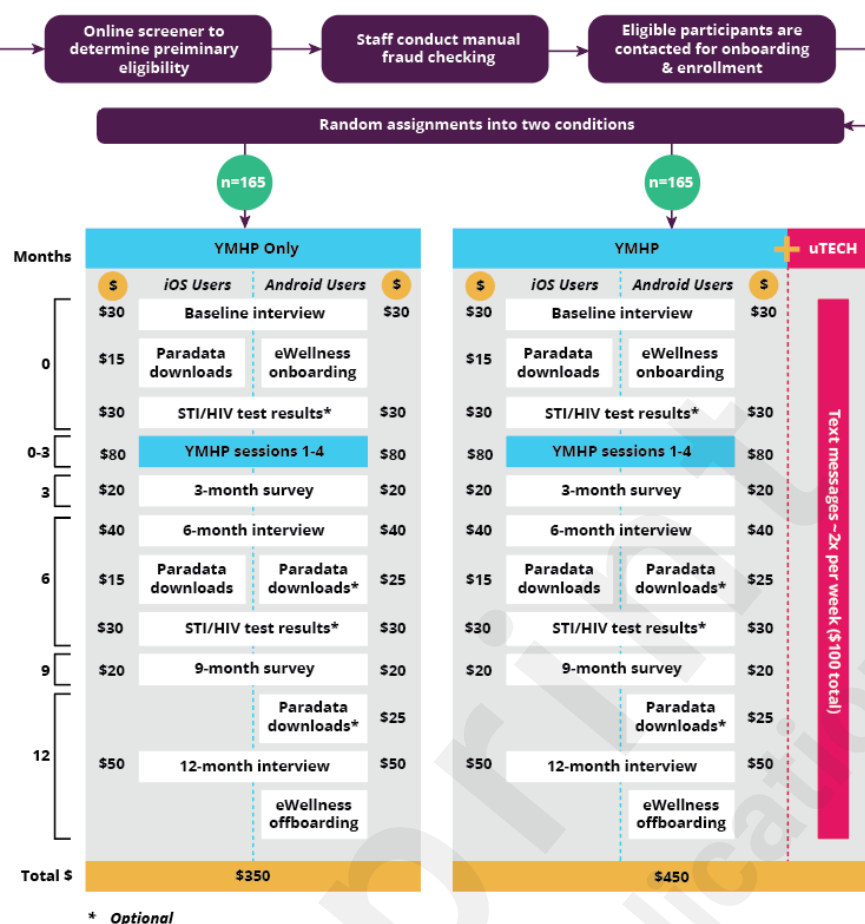
Recruitment

Online outreach: Participants will be recruited through online outreach methods including targeted advertising on social media sites (i.e., *Meta, Grindr, Craigslist, Reddit*) with a focus on Facebook Pages and Groups, or forums that may attract SGM individuals who use substances. The research team will also contact community organizations and prominent users with high follower counts to broaden recruitment efforts on social media sites such as *OnlyFans* and *Instagram*.

In-person outreach: The research team will distribute recruitment materials such as business cards, flyers, and palm cards at events that may attract SGM individuals who use substances, sexual health clinics, lesbian, gay, bisexual, transgender, queer (LGBTQ) centers, substance use treatment centers, non-profit organizations, and retail businesses. Staff will reach out to community-based organizations and retail businesses by phone and email offering to mail recruitment materials to display at their locations to broaden recruitment nationwide.

Referral program: Both participants and non-participants will be given the opportunity to refer others into the study and receive compensation for their referrals. Those interested in the referral program will be given information about the study, a sample message to send to others for referral purposes, and a link to sign up as a referrer so that study staff can compensate them. Participants will be offered the opportunity to receive physical recruitment materials by mail (flyers and palm cards) to refer people within their social networks. Referrers will receive \$20 sent to their payment method of choice (Venmo, Cashapp, Paypal, or Amazon e-gift card) for every person referred into the study that completes their baseline appointment (up to 5 people total).

Figure 1: uTECH participation overview flowchart.



Enrollment Process

Screening

All participants will first complete an online screener survey on Qualtrics [2024], an online survey platform [57]. The screener will provide information about the study and ask the participant questions to determine eligibility and their willingness to provide keystroke and geolocation data (Android users) or social media data (iOS users). If the potential participant meets initial eligibility criteria, the survey will use branching logic to show additional screens for the individual to provide contact information, including email address and phone number.

Research staff will review screener responses daily and closely examine responses to check for fraudulent or false eligibility. Qualtrics collects users' geolocation information and IP addresses, which will be used to input into a third-party fraud checking website, such as Scamalytics [2023] [58]. The information we receive from Qualtrics will be checked using such websites to determine whether their phone number is a voice-over internet protocol (VOIP) (or non-cellular, internet) number, or whether their IP address has been blacklisted for fraudulent activity or uses Virtual Private Network (VPN software), which would enable non-US users to bypass geolocation-based restrictions. "Eligible" screened participants that use a VOIP, VPN, or come from an IP address with high fraudulent activity, will be coded as "fraud" and will not be contacted by study staff.

Those who submit screeners that appear legitimate and who are eligible according to study criteria will be contacted by research staff via phone call, email, or text message to schedule an onboarding. Participants will be provided a link to Calendly [2024] [59], an online calendar scheduling service, to pick a time for their onboarding session, and will receive automated reminders for their appointments.

once booked. All appointments will take place over the Zoom conferencing platform. The interviewer will confirm that the participant will be in a safe and private setting to talk about confidential information for the duration of the call prior to beginning the session.

Randomization

All eligible participants will have their information entered into a password-protected and encrypted database that is only accessible by HIPAA-certified and IRB-approved research staff. Alongside contact information, all participants will be assigned a participant ID number and computer-generated randomized assignment to one of two intervention groups: uTECH+YMHP or YMHP-only. This randomization will be done prior to onboarding, so that the onboarding study staff will know which type of onboarding will be required.

Onboarding Procedures

Preparing for the session: Before the participant joins their onboarding Zoom call, the interviewer will review the crisis management protocol, open up the appropriate forms for the participant's mobile device (iOS or Android), and review the participant tracking sheet to ensure that they have the participant's information from the screener. The interviewer will join the Zoom virtual conference room 5-10 minutes in advance of the participant and will have their camera on for the duration of the call. The participant will not be required to have their camera. When the participant joins the Zoom call, the interviewer will confirm with the participant that they have 60-90 minutes available for the appointment and confirm that the participant is in a safe and private setting.

Consenting (All participants): The interviewer will open the appropriate consent form for the participant's phone type (Android or iOS) and study condition (uTECH+YMHP or YMHP only), which is a survey hosted on Qualtrics, and share their screen on Zoom so that the participant can view it simultaneously. The interviewer will remind the participant that they will receive a copy of the document via email at the end of the call. The interviewer will input the participant ID at the top of the page and review study details while regularly asking the participant if they have any questions. The consent form includes a detailed explanation of all study requirements and how their data will be protected. At the end of the consent form, the interviewer will ask if the participant consents to the study. If affirmative, the interviewer will check the box for "I agree to participate in the study," provide their initials on the survey, and submit the consent survey. If the participant does not consent, then the interviewer will check the box for "I decline to participate in the study," provide their initials on the document, submit the survey, thank the participant for their time, and end the call. The consent process will take approximately 25 minutes. If the participant consents to participate, then the onboarding session will continue.

Installation of eWellness App (Android users only): Participants who use Android smartphones will receive step-by-step instructions on how to install the eWellness app [v1.0.24, released January 2023] on their primary smartphone, where it will remain active and collect data for 12 months. The interviewer will send the participant a short link that they can type in their Android internet browser and download the app. The interviewer will guide the participant through the app download and setup process and troubleshoot any technical issues that may arise. If the interviewer or the participant runs into technical difficulties that cannot be resolved at the time of the interview, the interviewer will continue onto the baseline survey and make a note that they will have to complete the app download within a week's time after consulting with the research team. If the app is compatible with the device and successfully downloads, the interviewer will continue to guide the participant in completing the in-app Wellness Survey. This process will take approximately 15

minutes.

Wellness Survey (iOS users only): The Wellness Survey is a Qualtrics survey version of the in-app Wellness Survey that Android users complete. The participant receives a link to this survey through text message, and the interviewer will instruct the participant to complete this short survey. This process will take approximately 5 minutes.

PrEP Verification (All participants): If the participant endorses current PrEP use, the interviewer will ask the participant to upload a photo of their prescription bottle to the eWellness app, which is routed to a Qualtrics survey that is encrypted with Transport Layer Security (TLS) for all transmitted data. Participants may also choose to block/cover any personal information they do not wish to share with researchers. This process will take approximately 5 minutes.

Social Networking App Download Requests (iOS users only): Participants who use iOS smartphones will receive step-by-step instructions on how to request social networking app downloads from their most frequently used online dating apps (such as *Grindr* or *Tinder*) and social media accounts (such as *Twitter/X*, *Instagram*, *Reddit*, *Facebook*) to send to the research team. The study staff will describe the process specific to each dating app or social media app and either email the instructions to the participant or walk the participant through the process during the Zoom meeting. The participant will then need to download their data and email the files to an encrypted email address managed by the research team. This process will take approximately 10 minutes.

Baseline Interview (All participants): The interviewer will share their screen to display the baseline survey, which is hosted on the Qualtrics platform, and includes a series of questions about demographics, intimate partner history, sexual health, substance use, intimate partner violence, vaccine hesitancy, effects of COVID-19, and eHealth mobile app tracking and notification preferences. The survey also asks the participant for their preferred payment information. After all questions have been answered, the interviewer will stop sharing their screen and submit the baseline survey. This process will take approximately 30 minutes.

YMHP Scheduling (All participants): The interviewer will schedule the participant with their first YMHP session through Calendly, a scheduling website, with an interventionist that is not the baseline interviewer. The participant's first session will be scheduled approximately one week after the onboarding and baseline survey (Week 1). The interventionist and the participant will receive a calendar invite reminder for this session. Subsequent sessions are scheduled between the interventionist and the participant and will take place in Week 2, Month 1, and Month 2 after onboarding. The scheduling process will take approximately 5 minutes.

Closing out the Onboarding (All participants): The interviewer will open the "Locator form" to document the participants' preferred forms of contact, their phone type, and how they heard about the study. The interviewer will remind the participant of the follow-up surveys at 3, 6, 9, and 12 months, their first YMHP session (if applicable), and when to expect payment (approximately 3-5 business days after each data collection point and/or YMHP session). This process will take approximately 10 minutes.

Post-Onboarding Activities (All participants): Immediately after ending the onboarding session with the participant, the interviewer will download the materials completed by the participant and upload them to a secure, password protected cloud-based database (such as Box). Afterward, to ensure confidentiality, the interviewer will delete all materials from their computer. The interviewer will also update the participant's information in a tracking database and send a thank you email to the

participant which will include a copy of the study's consent form and the University of California, Los Angeles (UCLA) Office of Human Research Protection Program (OHRPP) participant bill of rights [60], which details protections for participants within the consent and participation process. This process will take approximately 30 minutes.

STI/HIV Testing (All participants): Participants will be offered the option of sending STI/HIV test results to the study team at their baseline and 6-month appointment dates. While testing is optional, those who do elect to send results will be compensated \$30 at both points (for a total of \$60) for providing test results for HIV, syphilis, chlamydia, and gonorrhea. Participants will be instructed to send their results in the form of a scanned document, screenshot, or PDF to an encrypted email managed by the study team. All identifying information in the file containing results will be redacted by the research team prior to being saved in the study's password-protected, encrypted, cloud-based database. When test results are received, participants will be reminded of their compensation and encouraged to reach out to research staff or their YMHP interventionist if they would like further information or resources.

If requested, participants will be provided HIV, syphilis, gonorrhea, and/or chlamydia prevention and treatment resources. They will also be asked if they have a healthcare provider who they could contact for treatment. If they do not, they will be offered a list of sexual health clinics or providers in their area. Additionally, participants will be offered a partner notification service to anonymously notify recent sexual partners of a possible STI exposure.

YMHP Sessions (All participants): YMHP intervention sessions will be held over Zoom, a video conferencing platform. Session 1 will take place during Week 1 (following onboarding), Session 2 during Week 2, Session 3 during Month 1, and Session 4 during Month 2 (See Figure). All sessions will be audio recorded for intervention fidelity and ongoing intervention training and clinical support. No video or participant names will be captured for the recording. Participants will be asked to change their zoom name to their participant ID prior to recording.

Session 1: Engagement, Focusing and Evoking on the First Target Behavior (sexual health or substance use). The interventionist will remind the participant about the YMHP structure and limits of confidentiality. The interventionist will engage in a priorities card sorting activity to identify participant's three main values, which will guide future motivational enhancement and begin to elicit the participant's view of their first target behavior. After identifying whether they will first tackle sexual health or substance use, the interventionist will assess the participant's readiness for change, discuss a plan for moving forward, and consider goals. At the end of the session, the interventionist will offer a closing summary and schedule the next session for the following week.

Session 2: Second Target Behavior; Continue Focusing and Evoking. The second session will begin with an opening statement to highlight any change talk [48] or goal that was mentioned from the previous session. This session will center primarily on introducing the second target behavior and collaborating on setting the session agenda with the participant. The interventionist will briefly revisit the previous session's topic and check for any changes or recent events since they last met. Then they will ask permission to address the second target behavior, all the while using strategies for eliciting change talk and managing discord. Finally, the interventionist will offer a closing summary at the end of the session, highlighting change talk and any steps taken towards change, and schedule the third session during Month 1.

Session 3: Change Plan. This session will begin by highlighting and integrating change talk on both target behaviors and any ideas or goals the participant has articulated around these behaviors. This

will be done collaboratively to set the agenda for the session together. The interventionist will ask permission to discuss collaborating on a change plan together based on the participant's progress over the last two weeks on both goals. Through evoking the participant's ideas about change, the interventionist will reinforce their self-efficacy for taking steps toward change and offer suggestions on how to adhere to their plan. The interventionist will elicit feedback on a change plan that reflects the participant's goals, priorities, and readiness to change, while anticipating and planning for barriers that may arise in the future. At the end of the session, the interventionist will offer a closing summary highlighting change talk, briefly reiterating the basic plan, and reminding them that the next session will be focused on moving ahead independently.

Session 4: Consolidating Commitment; Relapse Prevention/Termination. The final YMHP session will open with the interventionist summarizing the plan developed previously, collaborating on the session agenda based on the participant's goal updates, and reiterate that this will be the last YMHP session. The participant will discuss how the plan has gone and the interventionist will manage discord as appropriate while affirming the participant for any steps moving forward. The interventionist will evoke the participant's ideas about how to adapt the plan in the future should problems arise and develop a backup plan as appropriate. The session will end with a progress summary of the last four sessions and a space to reflect on the process of termination with the participant.

Automated Text Messages (uTECH+YMHP participants)

Participants assigned to the uTECH+YMHP intervention will receive approximately 2 text messages per week that provide resources promoting sexual wellness and substance use harm reduction. Participants are assigned to specific sub-groups based on their answers to the baseline interview to ensure that text messages are tailored. Participants are compensated \$1 per text message to which they respond, and this amount is disbursed at four time points corresponding to their 3-month, 6-month, 9-month, and 12-month assessments.

Incentives

Incentives vary according to intervention and phone type (See Figure 1). Participants assigned to the YMHP-only condition will receive US \$350 and participants assigned to uTECH+YMHP condition will receive US \$450 including responses to all uTECH messages. The payments for baseline (\$30), 6-month (\$40), and 12-month (Android: \$50; iOS: \$55) interviews are escalated to promote retention in the study. Participants will be paid for each study activity to encourage engagement.

Discharge from the Study

Participants will be discharged from the study after they complete their 12-month assessment and offboarding. At their final interview, Android-using participants will receive instructions on how to uninstall the eWellness app from their phone. The study team will also discontinue sending automated text messages to uTECH+YMHP participants.

Ethical Considerations

The research and ethics presented in this study were reviewed and approved by the South Campus IRB of the University of California, Los Angeles (UCLA; IRB#22-000009). The research has also been granted a Certificate of Confidentiality (CC) from the NIH (Number: CC-OD-22-3555), which deems identifiable information gathered in the course of research not admissible as evidence in any

legal processes. Additional terms were provided to ensure confidentiality for the participants. These terms included protection for all study-related data obtained by all uTECH study staff, which includes employees, students, interventionists, and other professionals staffing the project. All participant data will be de-identified and accessible only to staff who completed training in HIPAA guidelines and human subjects research ethics.

Technical concerns related to data privacy were considered throughout the app development process, which occurred during Phase 1 of this project. In collaboration with the UCLA Information Technology and UCLA Compliance departments, considerations related to data storage and data in transit were considered, including the institution's legal and ethical duties related to the handling of personally identifiable information. Procedures and protocols were established in collaboration with the UCLA Technology Development Group and the UCLA Departments of Computer Science and Engineering.

To enroll in the study, participants would have to review and consent to a study consent form detailing all activities associated with study participation, potential risks and benefits to participation, incentives, and privacy/confidentiality protections granted by the NIH CC, UCLA OHRPP, and study investigators. Participants will be informed during the consenting process that all payments will be made via electronic gift-card disbursement with a breakdown of all payments totaling the amount of \$350 or \$450 depending on study group assignment and phone type.

Primary Outcomes

The primary outcomes that the study will measure are the acceptability, appropriateness, and feasibility of the implementation for uTECH+YMHP and YMHP-only. These primary outcomes will be assessed through surveys conducted at 3-month, 6-month, 9-month, and 12-month timepoints. The study will measure how outcomes differ between uTECH+YMHP and YMHP-only conditions.

Secondary Outcomes

The overall framework of this study recognizes that substance use, and sexual risk behaviors are primary drivers of HIV and other STIs, which will be assessed through self-reported data on sexual risk, substance use, and self-reported HIV and STI diagnosis, verified through independent medical chart review when submitted by participants. Intimate partner violence, stigma, sociodemographic factors, and use of online venues for sex and/or drug-seeking are potential risk factors for HIV and other STIs [61–64]. PrEP use, vaccination, and condom use are potential health protective behaviors. For all participants, we posit that YMHP can also help participants make positive changes toward their self-defined substance use and sexual health goals. For participants in the uTECH+YMHP condition, uTECH can improve participants' skills and motivation to make behavioral changes to improve their health, which may lessen their risk of acquiring HIV and other STIs. Additionally, we posit that in this combined condition positive behavior changes may be more sustainable and durable compared to receiving YMHP without uTECH.

Assessment Measures (Baseline, 3-month, 6-month, 9-month, 12-month)

This study will include three types of assessment: interviews, online surveys, and HIV risk assessments. Interviews (approximately 30 minutes to 1 hour) will be completed at Baseline, 6-month, and 12-month timepoints. Self-completed online surveys (approximately 15-30 minutes) will be completed at 3-month and 9-month timepoints. HIV risk assessment surveys (approximately 5 minutes) will be completed at all 5 timepoints.

Table 3. Primary and secondary outcomes of the study.

Outcomes	Measures	Variables/Value
<i>Primary</i>		
Acceptability, appropriateness, and Feasibility of uTECH text messages	Adapted from Acceptability of Intervention Measure (AIM), Intervention Appropriateness Measure (IAM), and Feasibility of Intervention Measure (FIM) [63]	5-item Likert scale
Acceptability, appropriateness, and feasibility of YMHP	Adapted from AIM, IAM, and FIM [63]	5-item Likert scale
<i>Secondary</i>		
Sociodemographic	Multiple items	Nominal
Sexual risk behavior	Multiple items	Nominal; continuous; dichotomous
Intimate partner violence	IPV-GBM Scale [65]	Ordinal
PrEP and PEP use	Self-reported PrEP and/or PEP use history	Nominal; Continuous; Dichotomous; 6-item Likert scale
STDs	Self-reported STD diagnosis history	Nominal; integer; dichotomous; interval
PrEP stigma	PrEP Stigma Scale [66]	5-item Likert scale
Substance use	The Alcohol, Smoking, and Substance Involvement Screening Test (ASSIST) [67]	Nominal; dichotomous, yes/no for specific substances
COVID-19	Self-reported COVID-19 diagnosis, how COVID-19 has impacted sexual behavior	Dichotomous; qualitative
Mpox (monkeypox)	Vaccination status, history of mpox diagnosis and exposure, perceived risk, stigma	Dichotomous; nominal; interval; 5-item Likert scale
Vaccine confidence	Vaccine confidence index (VCI) [68]	5-item Likert
Vaccination history	Self-reported vaccination	Dichotomous, yes/no for

	status for hepatitis A, B, human papillomavirus, meningococcal B, meningococcal A/C/W/Y, COVID-19	specific vaccines
Seeking sex/drugs on social networks	Websites, chatrooms, message boards, and apps used to meet partners for sex or partying	Nominal
eWellness app features	Types of features (i.e., notifications, device functions), frequency/time of day of notifications, that participant would be comfortable with	Nominal; 6-item Likert scale; dichotomous
HIV risk assessment	MSM Risk Index [69], PWID (IDU) Risk Index [70].	Nominal; ordinal

Expected Timeline

Development of the initial version of eWellness was completed in October 2020 and enrollment for the trial started soon after. The eWellness app continued to undergo refinement and development until Phase 2 began in November 2021. Enrollment will continue until the target sample size is reached, with 12 months of study engagement per participant. We expect to complete data collection 12 months after the last participant has been enrolled in the study, that is, by June 2024, and plan the dissemination of results subsequently.

RESULTS

Statistical Analyses

Statistical methods, models, and procedures will be selected according to the research hypotheses being tested and the types of measures involved. We will set $\alpha < .05$ as the level for statistical significance but will use appropriate corrections for multiple comparisons (eg. Bonferroni and Hochberg correction [71]) to ensure that the actual overall effective type 1 error remains at a .05 level for the tests to be conducted. The frequency and patterns of missing data will be carefully evaluated. To avoid potential bias resulting from missing data, imputation (eg. hot deck or multiple imputation [72]) will be conducted, and statistical significance tests and modeling will be conducted with and without the imputed values. The findings from these analyses will be compared, and any differences will be evaluated. Potential nonlinear relationships between continuous predictors (eg. participants' age) and outcomes (eg. acceptability, appropriateness, and feasibility of uTECH and YMHP) will be evaluated through spline functions (eg. cubic spline).

Planned Analytic Approach

Primary outcomes for the study include acceptability, appropriateness, and feasibility of either intervention condition. In addition, we will examine behavioral health outcomes (sexual risk and

protective behaviors, substance use) in both intervention conditions. Tests of fixed-effects for estimates of time-specific differences will be performed using appropriate contrasts. Trend-changes will be analyzed, driven by variance components (random effects). We will utilize growth curve modeling [73] to examine the effects of treatment on outcomes. Growth curve factors also account for covariation of follow-up observations within participants. Data from 3-, 6-, 9-, and 12-month follow-up assessments will be modeled using latent growth factors using R statistical software [74] [v4.4.0, 2024]. Because the first non-baseline time point in the latent growth curve will be the 3-month follow-up, significant differences in the intercept factor would indicate significant post-intervention effects. Significant differences in slope factors would indicate that the groups follow different trajectories. When this is noted, potential group differences at each follow-up assessment will be evaluated by varying the location of the referent time point.

Missing Data

We will impute any missing values, based on the characteristics of the data and the assumptions of the final analyses, such as using multiple imputation if data are missing at random [75]. While analyses of treatment effects are questions of differences post intervention, baseline data will be utilized to inform and supplement analyses. For example, baseline data will be used to evaluate whether randomization successfully equated groups on demographic variables and other covariates of theoretical significance. We will use baseline data to evaluate correlates of differential attrition, if observed. If randomization fails or attrition produces group differences, models will use baseline data to control for covariates that are non-orthogonal with treatment condition. We will use growth mixture modeling techniques, including latent class growth curve modeling, to evaluate any meaningful patterns in outcome variable responses across time. We will examine whether treatment condition is associated with outcome response pattern.

Mediation and Moderation

For outcomes where statistically significant differences in acceptability, appropriateness, and feasibility are observed (i.e. significant regression coefficients for the treatment variable associated with the participant-level intercept or slope growth factors), post hoc analysis will examine the roles of substance use and technology use as potential mediators. A primary assumption is that uTECH will be associated with improvement in awareness of the ways in which technology influences engagement in HIV risk and substance use behavior [76–78]. For each mediator, validated substance use and technology reports will be entered into the model. Like the approach described for primary outcomes, we will specify latent growth curve factors for the hypothesized mediators to understand covariation of observations within individuals across time. Subsequently, we will examine whether initial differences in the mediators and/or changes in the mediators over time account for associations between the outcome variable and the treatment conditions. We will use strategies for assessing time-varying mediators that permit regression coefficients of the outcome on the mediator to vary over time. Where appropriate, we will examine the utility of applying these techniques. We will utilize parameter constraint approaches [79] to assess statistical significance of indirect pathways. Bootstrapping [80] tests of mediation cannot be conducted with latent-variable mediators and non-normal exogenous variables. When appropriate, we will employ alternative approaches such as Bayesian structural equation modeling (BSEM) and Monte Carlo simulation methods in the presences of non-normality and complex latent variable structures [81]. Participant-level reports of substance use and technology use will be entered into the models and we will examine whether initial levels of substance use and technology use (and/or changes in these variables over time) moderate the association between primary outcome variables and treatment condition by examining the significance of interaction terms between growth factors.

Sample Size Calculation and Power Analysis

For the power calculation, we utilized one primary outcome, acceptability. We used a balanced repeated measures design [82] with pre-treatment baseline measurements. Using a logistic regression generalized linear mixed model [83], we allowed an individual's five measurements (baseline, 3-, 6-, 9-, and 12-month) for acceptability to be correlated via an autoregressive-1 structure. With an initial sample size of 330 (to account for 95% retention), an auto-correlation of 0.1, and a baseline effectiveness of 85%, we aimed to detect a minimum time-averaged difference of 9% in acceptability between any two conditions, maintaining 80% power and an a priori alpha level of 0.05. This calculation was based on pairwise comparisons between uTECH+YMHP vs. YMHP-only. If the autocorrelation [84] between measures within the same individual is as high as 0.5, the sample size was adjusted to detect a minimum difference of 11% between the two conditions. A 9-11% difference between the two conditions is considered statistically significant given the existing evidence supporting YMHP and the relative cost-effectiveness and ease of delivery of the uTECH intervention. The ability to demonstrate a small increase in acceptability of uTECH over YMHP will support the widespread implementation of uTECH in future efficacy trials.

Current Status

This study was funded in August 2019. As of June 2024, we have enrolled 424 participants on a rolling basis. Approximately 71% of study participants have completed 12-months of participation. Data collection is expected to complete in June 2024. Data analysis is currently underway and expected results will be published in Fall 2025.

DISCUSSION

As mentioned above, at the time of writing this manuscript, the study is fully enrolled (N=424), which meets and exceeds the enrollment objective of 330 participants to account for attrition. Data analysis activities to evaluate the stated study hypotheses are currently underway.

uTECH is a response to changing internet/social media habits and aims to leverage ML-enhanced technology for personalized and automated HIV prevention and substance use harm reduction. Websites and social media use recommendation algorithms to personalize nearly every aspect of our online life, from what news we see to what products we want to buy. All internet users already interact with websites and social media that use ML algorithms to predict and personalize content for their users, based on their individual preferences, purchases, and habits. To do this, ML requires an enormous amount of personal data to make accurate and meaningful predictions. The widespread use of recommendation algorithms in social media and websites have also changed how people use the internet, and algorithm-mediated personalized content is now not only widely accepted, but is increasingly how people, especially young adults [85], want to consume media and content. According to a consumer research survey, the vast majority of users are willing to share personal data in exchange for better, more relevant, and curated digital experiences [86].

There are potential challenges to the success of uTECH's implementation trial. First, it employs convenience sampling techniques to recruit the target population, which limits generalizability of the results. In addition, even if recruitment efforts enable us to successfully meet our planned enrollment target, participant data could still fall short of what is needed for ML or for adequate statistical power to detect effects of intervention conditions on outcomes. For example, numerous technical issues could impact data collection. The eWellness app requires additional battery power as it runs in the

background of mobile phones. Certain phone models may automatically turn off data collection to optimize battery usage. Participants could also turn off the eWellness app themselves and forget or be unable to turn it back on.

For iOS users, we rely on the availability of third-party data, which may sometimes be unavailable. For example, during leadership changes at *Twitter*, mass system outages occurred, which impacted the ability of some participants to download their data. Some data downloads (for example, from *Grindr*) take an unknown amount of time to become available to access, and is sometimes a greater burden for participants, since it requires that the participant log-in to access and download their data, and then send it to our secure, encrypted email. This process takes some time, and access could expire if participants miss their email notification from the third-party system. Despite incentives, many participants may not complete all data collection activities, resulting in missing data. Among these, missing text message feedback may impact adaptive ML, and thus reduce the personalization and relevance of text messages participants receive.

This research will contribute as an implementation science demonstration project on the acceptability, appropriateness, and feasibility of an intervention that delivers a moderate- to high-level of relevance and personalization that requires fewer direct contact hours, and has the potential to reach a far greater number of participants than structured, multi-session interventions and/or in-person interventions. In a less resourced environment, or as public funding becomes more constrained, high-impact interventions that require less staffing may be a more efficient option compared to traditional HIV and substance use intervention paradigms. Additionally, this work can potentially be adapted for other public health promotion efforts, including chronic disease management, HIV care adherence, and vaccination promotion.

CONCLUSION

The primary objective of this study is to evaluate the acceptability, appropriateness, and feasibility of uTECH, a text-message-based risk reduction intervention that leverages a machine-learning and data mining algorithm to provide personalized prevention messaging to SGM participants. To our knowledge, this is the first study to utilize ML, online, and digital technologies to provide tailored sexual and substance use harm reduction for these populations. The results of this implementation trial will offer insights for future research within this field, contributing to developments that can reduce HIV risk and substance use. Outcomes and summaries of this implementation trial will be presented and recommendations for future research will be suggested if any knowledge gaps are identified. The potential findings of this implementation trial will be reported in academic papers, which will be submitted to peer-reviewed journals and presented at national and international conferences.

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Data Availability

Due to the sensitive nature of the data, data will not be made available in a public repository after the conclusion of data collection. Instead, access to data will be provided on a case-by-case basis by the

principal investigator, and after the completion of appropriate human subjects and HIPAA certifications and obtaining IRB approval.



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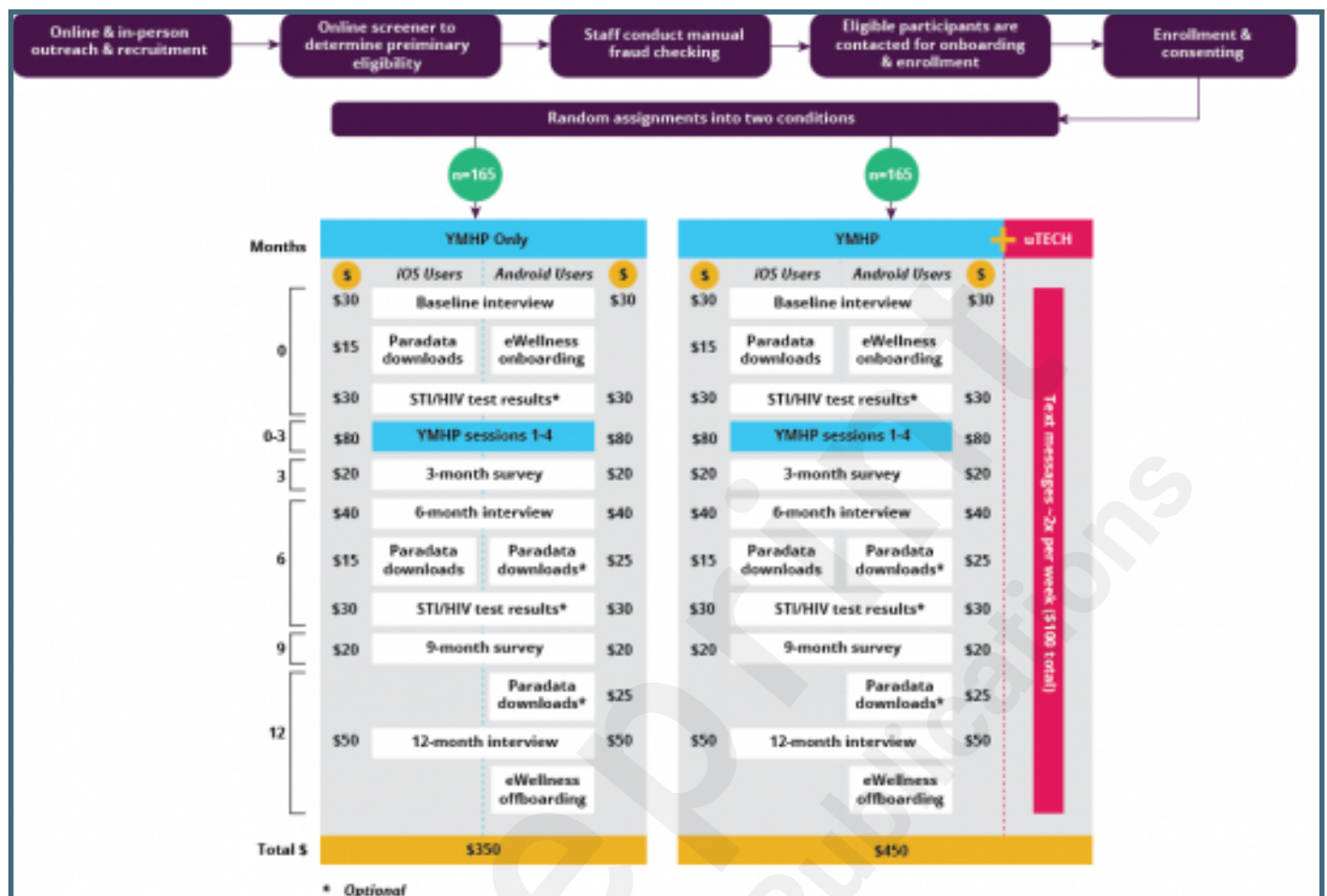
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Figures

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