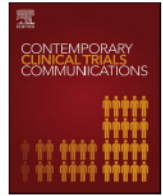


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Development and feasibility testing of a PrEP uptake and adherence intervention for women with trauma-related mental health conditions: Protocol for a randomized controlled trial

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ABSTRACT

Background: Experiencing trauma increases susceptibility to HIV among women in the Southern U.S, through factors such as condomless sex, coerced sex, and substance use. Despite the effectiveness of pre-exposure prophylaxis (PrEP), uptake remains low due to various barriers such as low perceived risk, lack of awareness, perceived stigma, and systemic inequities. Tailored interventions are crucial for improving access to PrEP for this vulnerable population.

Methods: The purpose of the study is to develop an integrated mental health clinic-based behavioral intervention for increasing PrEP uptake and adherence among trauma-experienced women in the Southern US. It will also assess the feasibility, acceptability, and preliminary efficacy of the intervention.

The primary aims are to (1) conduct qualitative interviews with 25 trauma-experienced women and 10 providers to explore their knowledge and attitudes about PrEP, to learn about provider practices related to HIV prevention, and to obtain feedback about the potential design of the intervention; (2) develop a mental health clinic-based behavioral PrEP uptake and adherence intervention guided by our findings from Aim 1 and the Information-Motivation-Behavioral Skills (IMB) model; and (3) test the preliminary efficacy, feasibility, and acceptability of the intervention using a randomized controlled trial with 60 women.

Conclusions: This intervention aims to address a critical gap in HIV prevention by targeting PrEP uptake and adherence among cisgender women with a history of trauma. The findings will inform future interventions designed for this population, promoting greater engagement in HIV prevention services.

Trial registration: This study is registered on ClinicalTrials.gov (NCT06558825).

1. Introduction

In the United States, women who reside in southern states and who have lower socioeconomic status bear a disproportionate burden of HIV-related health and social consequences [1]. Although only 38% of the US population lives in the South, the region accounts for 52% of new HIV diagnoses. Southern residents are also less likely to receive timely HIV treatment and experience nearly three times higher HIV-related mortality than other regions [2]. In 2022, women comprised 18% of new HIV diagnoses, with 83% of cases attributed to heterosexual contact and 16% to injection drug use. Notably, the South accounted for 55% of all new HIV diagnoses among cisgender women in the US [3]. Cultural, structural, socioeconomic, and political factors contribute to this regional disparity [4]. Gender-based inequities, including relationship power and control differentials, and physical or sexual violence further

increase HIV vulnerability among women [5].

Experiencing physical or sexual intimate partner violence (IPV), is a well-established risk factor for HIV among women [6,7]. Compared to women in the general US population, women living with HIV are more likely to have a history of IPV, childhood physical or sexual abuse, or other traumatic events [8]. Beyond behavioral factors, trauma may also weaken immune responses, increasing susceptibility to HIV [9,10]. The combination of substance use, violence, and HIV/AIDS, known as the "SAVA syndemic" perpetuates underutilization of HIV prevention strategies and limits engagement in the healthcare system [11]. Despite effective biomedical and behavioral advances, few HIV prevention strategies have addressed the specific needs of women who have experienced trauma [12].

Pre-exposure prophylaxis (PrEP) is a medication containing emtricitabine/tenofovir, disoproxil fumarate (FTC/TDF). For women, it is

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most commonly prescribed in pill form to be taken once a day and, when taken as prescribed, is 99% effective in reducing the risk of HIV acquisition [13,14]. An independently-controlled HIV prevention method is especially relevant for women in relationships with power imbalances. Despite known efficacy, uptake of daily oral PrEP remains low. In 2018, only 6.6% of women with PrEP indications were provided a prescription in 2018 [15]. Evidence suggests that low perceived risk and concerns about side effects are barriers to PrEP use [16–18]. This highlights a significant unmet prevention need.

For women in the southern United States with histories of trauma, individual and systemic factors that heighten HIV vulnerability also act as barriers to adequate engagement in prevention services. Structural and contextual factors such as poverty, race and gender-based inequities, discrimination, and lack of empowerment compound to restrict access to HIV prevention strategies [19–26]. Increasing availability and access to effective tools, such as PrEP, is essential to addressing these barriers [27]. Individual and interpersonal barriers include, but are not limited to, lack of knowledge about PrEP, perceived stigma, medical mistrust, and low perceived personal risk [28–31]. Women report a preference for conversations about HIV prevention to be initiated by medical providers. However, many providers who have frequent access to populations who could benefit from PrEP (e.g. mental health and substance use treatment providers) do not routinely address HIV prevention or refer patients for PrEP care, resulting in missed opportunities for engagement [16]. Women also report anticipated stigma from providers and disapproval by partners and family [32,33]. Additionally, conservative cultural attitudes in the region can encourage HIV stigma, and prevent disclosure of sexual practices and drug use, leading to decreased rates of testing and treatment-seeking [34]. The disproportionate burden of new HIV diagnoses among cisgender women in the southern US indicates a need to focus on this population. However, research to guide effective PrEP delivery among women is limited [35].

Adherence to PrEP is essential for effective HIV prevention. However, two demonstration trials examining PrEP in women were unable to show the effectiveness of oral PrEP due to low adherence [36,37]. A meta-analysis of oral PrEP use found only a 61% reduction in HIV acquisition risk among women who reported 75% adherence to a daily PrEP regimen based on self-report measures [38]. Research shows that women are less likely than men to remain engaged in PrEP care after three months, though those receiving mental health treatment were more likely to show better persistence [39].

A new treatment approach is needed to increase PrEP access for this population. Advances in biomedical HIV prevention approaches have been key in reducing the number of new HIV diagnoses each year. However, optimal progress towards eliminating HIV in the US will not be realized until all populations, and particularly those who are most vulnerable, are able to access this valuable prevention tool. Mental health conditions common in this population (e.g. depression, anxiety, Post Traumatic Stress Disorder (PTSD) can hinder HIV testing, prevention, and treatment adherence [40,41]. Integrating HIV prevention services into the mental health treatment setting shows promise for improving outcomes and reaching women engaged in trauma-related treatment and who have an increased likelihood of HIV acquisition.

The primary purpose of this study is to develop and pilot test a behavioral intervention to promote PrEP uptake and adherence among women with trauma-related mental health disorders. Once the intervention is developed, the study will examine the feasibility, acceptability, and preliminary efficacy of a behavioral intervention designed to increase knowledge and motivation and provide behavioral skills necessary to initiate and sustain PrEP use.

1.1. Conceptual framework

The proposed intervention will be guided by the Information-Motivation-Behavioral Skills (IMB) model. (See Fig. 1). The IMB model has been used as a theoretical framework for various intervention strategies. According to the IMB model, information, motivation, and skills are vital determinants of health behavior change [42]. In HIV research, the IMB model has been used to inform interventions for medication adherence in persons living with HIV [43] and has preliminary evidence for utility with PrEP uptake and adherence interventions [44–46]. Within the context of the IMB model, the integrated intervention will improve PrEP uptake and adherence among trauma-experienced women by providing relevant information about HIV risk and prevention, PrEP as a viable prevention option, and the importance of PrEP adherence. The intervention will enhance individual and social motivation to use PrEP and adhere to the medication regimen while improving engagement in HIV self-protective behaviors and skills. Further, by directly providing access to PrEP services within the behavioral health setting, HIV prevention and PrEP care will be readily available to a population with an elevated likelihood of HIV acquisition.

2. Overall study design

This three-phase study includes collection of formative data in Phase 1, design of the intervention in Phase 2, and a randomized controlled trial in Phase 3. Phase 1 involved conducting qualitative interviews with participants to explore barriers and facilitators to PrEP care and intervention preferences. [41] Phase 2 involves developing a mental health clinic-based behavioral PrEP uptake and adherence intervention guided by our findings from Phase 1 and the IMB model. Phase 3 involves testing the preliminary efficacy, feasibility, and acceptability of the integrated intervention. See Fig. 2)

3. Methods

3.1. Study setting

All study procedures will be conducted via HIPAA-compliant videoconference or in person in the Trauma and Resilience Center in the Louis A. Faillace Department of Psychiatry. Houston, TX, is located in Harris County, TX, one of the 57 geographical areas in the US identified as high HIV-prevalence areas requiring additional intervention to reduce the number of new cases of HIV, according to the nation's Ending the HIV Epidemic Plan [27].

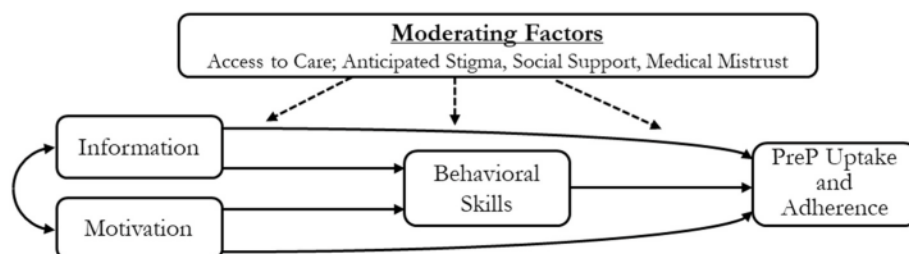


Fig. 1. IMB model of PrEP uptake and adherence.

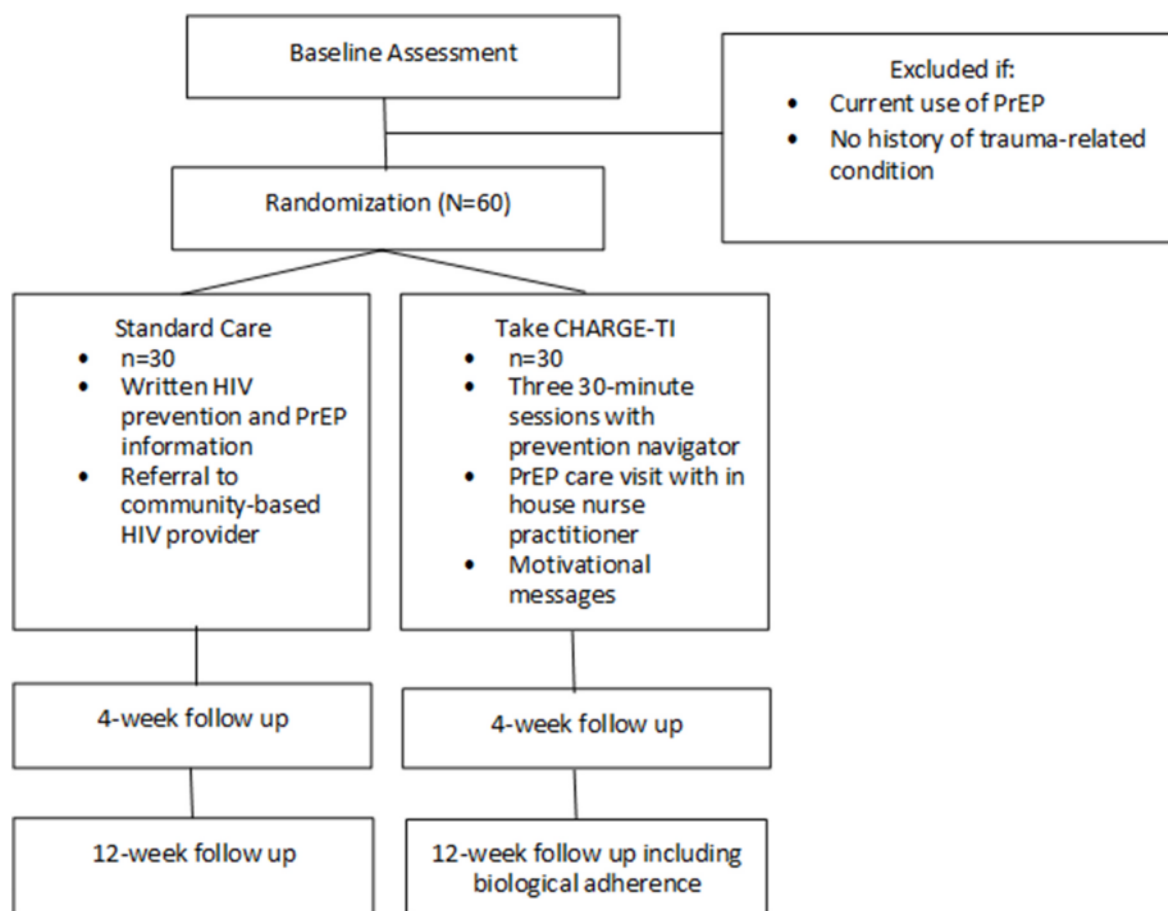


Fig. 2. Trial overview.

3.2. Participants

The target enrollment is 25 participants for Phase 1 and 60 participants for Phase 3. Eligibility criteria include (1) assigned female sex at birth; (2) ≥ 18 years of age; (3) current or recent behavioral health treatment; (4) have a history of trauma; (5) HIV-negative (by self-report for Phase 1 and 4th generation HIV screening for Phase 3 participants); (6) sexually active with an opposite sex partner within the past 6 months; (7) not using PrEP for HIV prevention at the time of screening; (8) eligible for PrEP based on having at least one CDC-defined criteria for PrEP; (9) fluent in English; (10) own or have regular access to a smart phone. Eligible persons must not (1) be HIV positive; (2) be concurrently participating in another HIV prevention program; (3) have severe cognitive impairment that would interfere with their ability to consent, understand study procedures and/or effectively participate in therapy; (4) have psychological distress that would prohibit them from participating in the study; (5) be unable or unwilling to meet study requirements. Additionally, 10 mental health and substance use disorders treatment providers will be enrolled in Phase 1.

3.3. Phase 1: Formative research

3.3.1. Phase 1a. In-depth qualitative interviews

This phase of the study was conducted between June 2022 and February 2023. We recruited 26 cisgender women to complete in-depth qualitative interviews to provide their personal and detailed perspectives about PrEP and our proposed integrated intervention. The interviews lasted between 45 and 60 min, and participants were compensated \$25 for their participation.

The interview guide was informed by IMB constructs. From the

Information domain, interviewees were asked about their knowledge and awareness of PrEP, including perceived effectiveness, views on who should take PrEP, and their perspectives on potential side effects and drug interactions. In the *Motivation* domain, interviews explored attitudes about PrEP, beliefs about outcomes, perceptions of stigma, and social support from partners, family, and friends. In the *Behavioral Skills* domain, the interviews explored perceived self-efficacy for taking PrEP, including taking daily doses, setting reminders, following up with appointments, and coping with side effects.

Feedback regarding the potential design and format of the intervention was elicited from participants and providers. The interviewer asked participants about the acceptability of receiving PrEP services within the behavioral health clinic setting. Interviews explored participants' thoughts about integrating behavioral health treatment with HIV prevention services and preferences for in-person versus remote (e.g., telemedicine; mobile app) delivery of motivational enhancement interventions to improve PrEP uptake and adherence. Interviewers also obtained feedback about how the content of the sessions could be tailored to be more appealing to women engaged in behavioral health treatment for trauma-related conditions.

3.3.2. Phase 1b. Data analysis

Qualitative data were analyzed with MAXQDA. Analyses used a thematic analysis approach, which involved identifying themes through an iterative process comprised of multiple stages of data collection, theme refinement, and categorization of the data. The investigators used the IMB framework to organize emergent themes with coding schemes developed by the PI and the team based on the literature and topics included in the interview. Two independent coders applied the coding scheme to a subset of the initial transcripts. The scheme was then refined

based on feedback and input from the research team, and a coding manual was developed [47]. The results from the qualitative data analysis were used to inform refinements to the integrated intervention. A future manuscript will present the findings from phase 1 of the study.

3.4. Phase 2: Intervention development

3.4.1. Integrated intervention

The objective of Aim 2 is to refine the intervention. The integrated intervention promotes PrEP uptake and adherence by providing a behavioral intervention based on IMB model principles and informed by participant and provider feedback, paired with PrEP care provided in the behavioral health clinic setting. This intervention is expected to address barriers to care, which include low PrEP knowledge, lack of awareness of PrEP eligibility, perceived stigma, mistrust of healthcare providers and healthcare systems, concerns about medication adherence and side effects, low perceived personal HIV risk, and lack of access to PrEP services.

Based on information obtained in Phase 1 and the IMB model, the study team will develop a trauma-informed behavioral health clinic-based intervention (Take CHARGE-TI) that will provide PrEP-related information, motivational messaging, and behavioral skills necessary to use PrEP effectively. The intervention will include a PrEP service component to be delivered within the behavioral health clinic by a nurse practitioner, leveraging the existing clinical and HIV prevention infrastructure and removing accessibility barriers. This intervention will be provided alongside standard behavioral health treatment.

The intervention consists of three weekly 30-min sessions, which can be delivered via a HIPAA-compliant videoconferencing platform. The sessions aim to increase knowledge of PrEP, increase positive attitudes towards PrEP, and decrease behaviors that place individuals at risk for HIV infection, ultimately promoting PrEP uptake and PrEP adherence.

3.4.2. IMB framework

The behavioral health clinic-based intervention is informed by IMB domains. Specifics on how each domain informs the development of the intervention are outlined in Table 1.

3.4.3. Motivational messages

The intervention includes a library of more than 200 motivational messages and brief videos, adapted from the UCARE4LIFE study [48], and supplemented with the CDC's #ShesWell: PrEP for Women campaign to promote the uptake of PrEP among women. A sample of these messages was provided to Phase 1 participants, who gave their feedback on the language and acceptability of the messages. The

Table 1
Intervention components based on the information-motivation-behavioral skills (IMB) model.

IMB Domain	Description
Information	Provides basic HIV prevention information, including how PrEP works, eligibility criteria, safety and efficacy, and the importance of daily adherence. Tailored content addresses the benefits of self-controlled HIV prevention methods for women who have experienced trauma.
Motivation	Incorporates motivational counseling and contingency management to support desired behaviors. Incentive-based motivation delivered via Scene Health's HIPAA-compliant asynchronous video directly observed therapy with participants submitting videos of them taking medications for review by research staff. Information addressing perceived versus actual personal risk is also expected to motivate health promoting behaviors.
Behavioral Skills	Builds self-efficacy by training participants to communicate safer sex preferences, remember medication schedules, identify supportive individuals, and manage side effects. Provides skills for healthcare follow-up including prioritizing medical appointments among competing demands.

messages are intended to motivate participants to attend their appointments with the nurse practitioner, take PrEP as prescribed, continue their behavioral health treatment, speak with the nurse practitioner regarding side effects or questions, and decrease behaviors that may increase their susceptibility to HIV infection.

3.5. Phase 3: Pilot testing

3.5.1. Study design

Phase 3 will use a randomized controlled trial design to test feasibility, acceptability, and initial efficacy of the intervention. The trial will involve two study groups. Group 1 will participate in the Take CHARGE-TI intervention, and Group 2 will be given basic information about HIV risk and PrEP and will be referred to a community-based HIV prevention organization for additional PrEP services.

3.5.2. Participants, recruitment, and screening

Phase 3 will recruit 60 women with a history of behavioral health treatment for a trauma-related mental health condition (e.g., depression, post-traumatic stress disorder) with behaviors or circumstances that place them at risk for HIV. The inclusion and exclusion criteria are outlined above. Individuals who participated in Phase 1 of the study will be excluded from Phase 3. The primary recruitment site will be the Trauma and Resilience Center (TRC), a clinical research site with weekly patient staffing meetings that include all clinical staff along with representatives from each recruiting study. All TRC patients are asked to consider signing a consent to be contacted for relevant research opportunities. Additionally, we will utilize the Department of Psychiatry and Behavioral Sciences clinic-wide Research Registry in our recruitment efforts. Eligible participants who opted in to be contacted for research studies will be contacted for the study. The research assistant will describe the study by informing eligible participants that this is an HIV prevention study focusing on women with current or past treatment for a trauma-related mental health disorder. Participants will be informed that participation in the study will not directly impact their regular behavioral health treatment. After screening, eligible women will be randomized to the integrated intervention or standard treatment. Randomization will be computer-generated and controlled by the study statistician through the randomization function on REDCap. We expect to have 30 women in each study arm.

3.5.3. Intervention- take CHARGE-TI

3.5.3.1. Motivational counseling sessions. Participants randomized to the Take CHARGE-TI intervention will receive three motivational counseling sessions (~30 min each) focused on HIV prevention, PrEP, and partner communication information delivered by a trained study counselor with expertise in HIV prevention and trauma-informed behavioral health counseling. The study counselor will assist the participant with downloading the Scene Health app and completing a profile. As many women's traumatic events are expected to include a history of IPV, the trauma-informed intervention includes strategies related to safety while taking PrEP, including whether and how to inform partners of PrEP use. Women with IPV concerns prior to enrolling in the study or who report IPV during the study will be provided additional referrals and support by trained mental health providers who are experienced with this population.

3.5.3.2. PrEP care visit. After the third session, the participant will be scheduled for their initial visit with the nurse practitioner, who will conduct a clinical assessment to include 4th generation HIV screening, a basic metabolic panel to include serum creatinine, Hepatitis B and C screening, STI testing (Syphilis, gonorrhea, and Chlamydia), and a pregnancy test per CDC guidelines. Lab results will be reviewed by the nurse practitioner. If individuals test positive for HIV, they will receive

counseling from the risk reduction specialist, who will explain the meaning of the results and assist with linking to an HIV care provider. The individual will be informed that additional testing will likely be done with the HIV care provider to confirm the diagnosis. Individuals who have a confirmed positive HIV result will not be eligible for the study. Participants who meet with the nurse practitioner and have no contraindications for PrEP will be provided a prescription after lab results are available. The decision to use daily oral PrEP or long-acting injectable PrEP will be made using a shared decision-making process between the participant and the nurse practitioner. A prevention navigator will be available to assist participants with navigating insurance and financial assistance programs. This initial PrEP care visit will take place in the same building that houses the TRC. Follow-up visits not requiring lab draws with the nurse practitioner and or prevention navigator will be conducted either in person or virtually, according to the participant's preference. Bus passes and parking vouchers are provided on an as-needed basis.

3.5.3.3. Adherence support and motivational messages. The participant will be instructed to show that the prescribed medication has been picked up (video message within the Scene Health app). Participants who are prescribed PrEP are also asked to upload daily adherence videos for 12 weeks after starting the medication. Additionally, adherence will be lab verified using therapeutic drug monitoring via dried blood spot (DBS) testing 12 weeks after starting the medication.

All participants will receive motivational messages. For individuals who start PrEP, messaging will include behavioral skills for managing side effects, communicating with partners, mental health, safer sex, and medication and healthcare appointment reminders. Participants who do not start PrEP will receive educational and motivational messages related to HIV prevention, communicating with partners, mental health, and safer sex. All participants will have the option to select the frequency of message delivery and can opt out of messaging at any time via the app.

3.5.3.4. Monetary incentives. Each participant will receive \$25 for initial questionnaires, \$15 for the initial PrEP nurse visit with labs, \$10 for providing proof of the initial prescription fill, \$1/day for uploading daily adherence videos indicating pill-taking for 12 weeks (\$84 maximum possible), \$30 for DBS testing showing acceptable levels, \$15 for the 3-month follow-up visit, and \$50 for completing the follow up data collection (\$219 total possible). Individuals in the intervention condition will continue to receive their mental health treatment services in the TRC.

3.5.4. Standard care

Participants in the standard care condition will receive written HIV prevention and PrEP information, a referral list for community-based HIV prevention providers, and a \$10 gift card to offset the cost of transportation to their initial appointment. Participants in the standard condition will be contacted by the research assistant to verify appointment attendance and will be given instructions on providing proof that their PrEP prescription was picked up (uploaded via a link to REDCap). Participants in standard care will be sent a link weekly to a survey asking them whether they took their PrEP medication for the previous week.

3.5.4.1. Monetary incentives. Participants in the standard condition will receive \$25 for initial questionnaires, \$15 for the initial PrEP provider visit with labs, \$10 for providing proof of the initial prescription fill, \$1/day for completing the PrEP adherence survey link (non-contingent on pill-taking), \$30 for a dried blood spot test showing acceptable levels; \$15 for the 3-month follow-up visit, and \$50 for completing the follow-up data collection (\$219 total possible). Individuals in standard care will continue to receive their regular behavioral health services.

3.6. Data collection

Participants in both arms will complete baseline surveys and follow-up surveys administered at 12 weeks post-baseline. Data sources to examine efficacy will include a computer-assisted self-interview (self-report measures), pharmacy records, Scene Health app data, and medical records.

Master's (or higher) level clinicians will conduct a comprehensive diagnostic interview using the Mini International Neuropsychiatric Interview (MINI) [49] and the NIDA Modified Assist [50]. This will be used to confirm mental health and/or substance use diagnosis and to determine the severity of substance use-related problems. Other data collection will include baseline assessment of outcome variables and potential moderators. See Table 2.

3.6.1. Primary outcomes

The primary outcomes of interest are intervention feasibility (enrollment rate, session attendance, use of Scene Health, study retention) and intervention acceptability (client satisfaction scores).

3.6.2. Secondary outcomes

Secondary outcomes of interest include (1) PrEP uptake, defined as obtaining a prescription and taking the first dose; (2) lab-confirmed PrEP adherence, defined as having adequate levels of TFV concentrations (>1000 ng/ml) [51] measured at 12 weeks post-PrEP initiation. Urine concentrations of TFV at >1000 ng/ml indicate recent use of PrEP (high adherence), detectable levels of TFV but <1000 ng/ml indicate low adherence, and undetectable levels of TFV suggest non-adherence [51]; (3) daily reported PrEP adherence as measured by proportion of videos uploaded (intervention group) and proportion of self-reported daily adherence (intervention and standard care group).

3.6.3. Other outcomes

Other outcomes of interest include changes in perceived HIV risk, PrEP knowledge, PrEP attitudes, and PrEP anticipated stigma at the 12-week post-intervention follow-up.

3.7. Data analysis Plan

Generalized linear mixed modeling (GLMM) will evaluate effects of predictors (e.g., treatment) on outcomes (e.g., proportion of participants filling their PrEP prescription). GLMM has the flexibility to employ family and link functions to best fit alternative outcome distributions if necessary (e.g., Binomial with logit link for dichotomous outcomes; Poisson with log link for count outcomes). GLMM may also account for correlated observations via inclusion of multilevel effects (e.g., a random intercept for person id for longitudinal analysis of adherence over time). Survival modeling (i.e., Kaplan-Meier estimator; Cox proportional hazards regression) will evaluate retention.

Following the statistical literature for randomized trials [52], analyses will use dual frequentist and Bayesian inference. Frequentist results yield the probability of the data (or data more extreme) given the null hypothesis, while Bayesian results directly yield the probability of an alternative hypothesis [53,54]. As a default, weakly informative priors will be used for all Bayesian analyses (e.g., regression coefficients: $b \sim N[\mu = 0, \sigma^2 = 10]$; error/dispersion terms: $\sim \text{Half-Normal}[\mu = 0, \sigma^2 = 10]$) to emphasize the influence of the present data on posterior probabilities. Sensitivity analyses will evaluate a range of prior distributions to ascertain the degree to which analyses are robust to prior specifications [55]. Evaluation of Bayesian posterior distributions will permit statements regarding the probability that effects of varying magnitudes exist, given the data. Evaluation of assumptions for frequentist models will use graphical evidence (e.g., residual plots) and formal statistical tests.

Table 2
Overview of study procedures and measures.

Construct	Measure	Study week	Source
Eligibility			
Mental health and/or substance use disorder	Mental health and/or substance use diagnoses (M.I. N.I.)	0	Intake records
PrEP eligibility	HIV screening, viral hepatitis screening, pregnancy screening, STD screening	0	Lab results
	Behavioral risk factors	0	Nurse interview
Safety			
Liver function	Blood and urine-based tests performed by nurse	4, 12	Lab results
HIV status		4, 12	Lab results
Pregnancy test	practitioner	4, 12	Lab results
PrEP Knowledge and Attitudes (based on barriers identified in Aim 1)			
PrEP knowledge	PrEP knowledge Questionnaire [52]	0, 12	REDCap Surveys
PrEP Attitudes	PrEP Attitudes Measure [53]	0, 12	REDCap Surveys
PrEP Stigma	PrEP Anticipated Stigma Scale (PASS) [54]		REDCap Surveys
PrEP adherence self-efficacy	ASK-20 [55]	0, 12	REDCap Surveys
HIV risk behaviors	Risk Assessment Battery [56]	0, 12	REDCap Surveys
HIV risk perceptions	Perceived Risk of HIV Scale [57]	0, 12	REDCap Surveys
Initial Efficacy (Aim 3)			
PrEP uptake	PrEP Prescription filled and self-reported initial dose of PrEP taken		Pharmacy record Self-report
PrEP adherence (behavioral)	Video confirmed dose (intervention)	4-12	Scene Health reports
	Self-reported dose (intervention and standard treatment)	4-12	Weekly online survey
PrEP adherence (lab confirmed)	DBS test TFV concentrations (>1000 ng/ml)	12	Lab results
Feasibility Measures (Aim 3)			
Enrollment rate	Proportion screened who are eligible Proportion eligible who consent		Study records
Session attendance	Proportion of motivational enhancement sessions attended		Study records
Use of app	Proportion of medication adherence videos uploaded		Scene Health reports
Study retention	Proportion of participants who remain in the study at 12-week follow-up		Study records
Acceptability Measures (Aim 3)			
Client satisfaction	Client satisfaction questionnaire	4, 12	REDCap Surveys
Other covariates			
Substance use severity	ASSIST [58]	0, 12	REDCap Surveys
Alcohol	AUDIT [59]	0, 12	REDCap Surveys
Health Literacy	REALM [60]	0	REDCap Surveys
Medical Mistrust	Group Based Medical Mistrust Scale [61]	0, 4, 12	REDCap Surveys
Trauma	LEC/PCL5 [66,67]	0, 4, 12	REDCap Surveys
Depression	PHQ-9 [64]	0, 4, 12	REDCap Surveys

4. Results

A total of 26 participants were recruited to complete Phase 1, qualitative interviews that informed the final intervention. Findings from Phase 1 will be reported in a future manuscript.

In September 2024, we received IRB approval to conduct Aim 3 of the intervention. Recruitment started in October 2024, with preliminary results anticipated by January 2026. We plan to publish all findings in future manuscripts and disseminate findings at future conferences and to all community partners.

5. Discussion

Our innovative behavioral intervention, based in mental health clinics, aims to overcome the structural and social barriers often associated with low PrEP uptake and adherence among women with history of trauma. By integrating PrEP services within mental health treatment settings and leveraging digital health technology to support adherence and remove potential concerns (e.g., side effects, confidence in PrEP adherence, stigma from providers, family, and friends), we seek to reduce health disparities for HIV prevention among cisgender women.

The current study has several limitations. Given that this is a pilot study of HIV-negative cisgender women living in Houston, Texas, USA, findings may not be generalizable to other regions. Additionally, participants in the standard care group will provide self-reported data, which may be subject to recall bias. Additionally, participants must speak English to meet eligibility requirements, thus potentially limiting the generalizability of findings for Hispanic/Latina women who may only speak Spanish.

Despite these limitations, this study has several strengths. First, there are limited studies specifically focused on developing effective behavioral interventions for HIV prevention for women with trauma-related conditions. Second, the intervention uses an app that can help support PrEP adherence by providing information, motivation, and behavioral skills necessary to increase the likelihood of starting and staying on PrEP.

6. Conclusions

Ensuring PrEP uptake and adherence is necessary for effective HIV prevention among women with trauma-related conditions. An integrated intervention is needed to increase access to PrEP and other HIV prevention services for women who are at risk for HIV. While advances in biomedical HIV prevention have reduced new diagnoses, ending the epidemic depends on ensuring all populations have access to both biomedical and behavioral tools. By integrating PrEP care with behavioral health services, this intervention has the potential to reduce HIV-related disparities among women with trauma-related conditions who are susceptible to HIV.

Ethics approval

This study is approved by the University of Texas Health Science Center at Houston Committee on the Protection of Human Subjects (HSC-MS-21-0544). This study is registered on [ClinicalTrials.gov](https://www.clinicaltrials.gov/ct2/show/study?term=NCT06558825) (NCT06558825).

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CRedit authorship contribution statement

Angela M. Heads: Conceptualization, Formal analysis, Funding acquisition, Investigation, Methodology, Project administration, Writing

– original draft, Writing – review & editing. **Kaixuan An:** Formal analysis, Writing – original draft, Writing – review & editing. **Mandy J. Hill:** Methodology, Writing – review & editing. **Julie A. Gameon:** Formal analysis, Writing – review & editing. **Constanza de Dios:** Methodology, Writing – review & editing. **Robert Suchting:** Methodology, Writing – review & editing. **Ron Acierno:** Conceptualization, Formal analysis, Funding acquisition, Investigation, Methodology, Project administration, Writing – original draft, Writing – review & editing.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Data availability

No data was used for the research described in the article.

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