

Title: Integration of an Electronic Screening-Brief Intervention-Referral to Treatment Program into an HIV Testing Program to Reduce Substance Use and HIV Risk Behavior among Men Who Have Sex with Men: Protocol for Intervention Development and a Pilot Randomized Controlled Trial

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Title: Integration of an Electronic Screening-Brief Intervention-Referral to Treatment Program into an HIV Testing Program to Reduce Substance Use and HIV Risk Behavior among Men Who Have Sex with Men: Protocol for Intervention Development and a Pilot Randomized Controlled Trial

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Abstract

Background: Men who have sex with men (MSM) are disproportionately affected by HIV and drug and alcohol use, but few effective HIV prevention interventions for MSM who use substances exist. SBIRT (Screening, Brief Intervention, and Referral to Treatment) is an early intervention for non-treatment-seeking individuals with problem substance use (PSU) and for timely referral to treatment for those with substance use disorders. Electronic SBIs (e-SBIs) reduce implementation challenges such as extensive training, demands on staff time, and inconsistency in the delivery of the BI while remaining as effective as in-person SBIs. An e-SBI tailored for MSM at the time of HIV testing might be particularly opportune to strengthen his motivation to reduce his substance use and HIV risk behavior.

Objective: The study seeks to develop a tailored e-SBI program to reduce substance use and HIV risk behavior among MSM seeking HIV testing at Nexo Asociacion Civil, our community partners in Argentina (Primary); assess the feasibility and acceptability of integrating e-SBI into the Nexo HIV testing program (Primary); and assess the feasibility and acceptability of implementing an adapted Men's Health Project (MHP) at Nexo (Secondary). Lastly, we will explore preliminary findings on substance use and sexual risk reduction outcomes (Exploratory).

Methods: This mixed-methods study has two stages. During Stage 1 (Development), we will develop the e-SBI, adapt MHP, train counselors to deliver MHP, and pilot the e-SBI with 50 MSM coming to Nexo for HIV testing. At each step of the development process, participants will complete quantitative assessments of acceptability and qualitative feedback interviews that will inform revisions to the e-SBI to maximize the acceptability and impact of the intervention. During Stage 2 (RCT Pilot), we will randomize 200 MSM coming to Nexo for HIV testing. They will complete a baseline assessment then their assigned intervention (e-SBI vs. screening only) and followed for 6 months. We will also conduct in-depth interviews with up to 45 participants, 15 with participants from either study condition who entered or completed MHP and/or other substance abuse treatment and 15 from each arm who met criteria for MHP but did not request it.

Results: The study began recruitment in October 2022 and we are nearing completion of the Stage 1 pilot study. The Stage 2 pilot RCT will launch in March 2024 with all data collection completed by May 2025.

Conclusions: Completion of this study will allow us to assess the acceptability and feasibility of implementing the e-SBI during HIV testing encounters. We will build the necessary research infrastructure for a subsequent RCT to assess the efficacy of the e-SBI to reduce substance use and HIV sexual risk behavior among MSM in this setting. Clinical Trial: The study was registered at clinicaltrials.gov on September 16, 2022. The identifier number is NCT05542914.

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ABSTRACT

Background: Men who have sex with men (MSM) are disproportionately affected by HIV and drug and alcohol use, but few effective HIV prevention interventions for MSM who use substances exist. SBIRT (Screening, Brief Intervention, and Referral to Treatment) is an early intervention for non-treatment-seeking individuals with problem substance use (PSU) and for timely referral to treatment for those with substance use disorders. Electronic SBIs (e-SBIs) reduce implementation challenges (e.g. staff training, demands on staff time, and inconsistency in delivering the BI) while remaining as effective as in-person SBIs. An e-SBI tailored for MSM at the time of HIV testing might be particularly opportune to strengthen his motivation to reduce his substance use and HIV risk behavior.

Objective: To develop a tailored e-SBI program to reduce substance use and HIV risk behavior among MSM seeking HIV testing at Nexo Asociacion Civil, our community partners in Argentina (Primary); assess the feasibility and acceptability of integrating the e-SBI into the Nexo HIV testing program (Primary); and assess the feasibility and acceptability of implementing an adapted Men's Health Project (MHP) at Nexo (Secondary). Lastly, to explore preliminary findings on substance use and sexual risk reduction outcomes (Exploratory).

Methods: This mixed-methods study has two stages. During Stage 1 (Development), we will employ the User Centered Rapid App Design process consisting of focus groups (N=16), individual interviews (N=24), and a pilot deployment of the e-SBI (N=50), to iteratively develop the e-SBI. Quantitative and qualitative assessments at each step will inform revisions to the e-SBI. Additionally, we will use the ADAPT-ITT framework to adapt MHP. During Stage 2 (RCT Pilot), we will randomize 200 MSM coming to Nexo for HIV testing. They will complete a baseline assessment then their assigned intervention (e-SBI vs. screening only) and followed for 6 months. We will also conduct in-depth interviews with up to 45 participants, 15 with participants from either study condition who entered or completed MHP and/or other substance abuse treatment and 15 from each arm who met criteria for MHP but did not request it.

Results: The study began recruitment in October 2022 and we are nearing completion of the Stage 1 pilot study. Preliminary findings from Stage 1 show high acceptability of the e-SBI. Data analysis of the Stage 1 pilot is now beginning. The Stage 2 pilot RCT will launch in March 2024 with all data collection completed by May 2025.

Conclusions: Completion of this study will allow us to assess the acceptability and feasibility of implementing the e-SBI during HIV testing encounters. We will also build the necessary research infrastructure for a subsequent RCT to assess the efficacy of the e-SBI to reduce substance use and HIV sexual risk behavior among MSM in this setting.

Trial Registration: The study was registered at clinicaltrials.gov on September 16, 2022. The identifier number is NCT05542914.

Keywords: HIV; Substance use; Community health; Implementation science; e-Health

INTRODUCTION

Men who have sex with men (MSM) are disproportionately affected by HIV and drug and alcohol use.¹⁻¹¹ Given the association between substance use and HIV risk behavior among MSM,¹²⁻²⁵ the dearth of effective HIV prevention interventions for substance using MSM is striking. But, as in the general population, identifying and engaging MSM with problematic substance use (PSU) into treatment is a significant challenge²⁶⁻²⁸ that results in most MSM with PSU never receiving treatment.²⁹

The Substance Abuse and Mental Health Services Administration (SAMHSA) recommends

Screening (S), Brief Intervention (BI), and Referral to Treatment (RT; SBIRT) as an early intervention for non-treatment-seeking individuals with risky alcohol and drug use and for timely referral to more intensive treatment for those with substance use disorders.³⁰ However, implementing SBIRT is a challenge; the BI is often missed and not evidence based, which can diminish its effectiveness. For example, when SBIRT was implemented in STD clinics in NYC, of 66,989 positive screens, only 17,474 received the BI.³¹ In medical settings, factors such as limited staff time, commitment to implementation, training requirements, difficulty in learning evidence based BIs, skepticism of the effectiveness of SBIRT, and poor fidelity to recommended brief intervention guidelines are all obstacles to the successful implementation of SBIRT.³²⁻³⁹ These factors also limit the BI offered in a particular setting. BIs can range from providing normative feedback to the individual on their level of severity (at times just a written report), brief advice (10-15 minutes), or a single 30-45 minute session. Yet, studies show that interventions that go beyond normative feedback and provide an empathic³³ or motivational component,³⁴ or consist of multi-session interventions for high-risk users have better outcomes but can be difficult to implement. As a result, sizeable percentages of patients in a setting go unscreened; those with who meet criteria for a BI may not receive it; the BI may be delivered inconsistently; and the BI may not be of sufficient intensity to reduce substance use among those with low or moderate risk use or improve entry into substance abuse treatment among those with high-risk use or dependence.³⁵

Electronic SBIs (e-SBIs) reduce implementation challenges such as extensive training, demands on staff time, and inconsistency in the delivery of the BI,^{32,36-42} while remaining as effective as in-person SBIs.⁴³⁻⁴⁶ Because an e-SBI demands only that a staff member provide an individual with a tablet or computer space to complete both the screening and BI, more individuals can be screened and receive the BI. For example, in an implementation pilot study that used e-SBI in rural clinics, approximately 92% of patients were screened, with over 95% of screen-positive women receiving the tablet-based brief intervention, which far exceed rates in trials of person-delivered SBIRT (Ondersma, personal communication). Furthermore, eSBIs are consistently rated highly for acceptability among users and may facilitate greater disclosure of PSU than in person SBIs due to concerns of being judged by providers. As such, an e-SBI tailored for PSU and sexual risk behavior among MSM at the time of HIV testing, when a contemplative client is already concerned about his risk behavior and cares enough about his health to seek an HIV test, might be particularly opportune to strengthen his motivation to reduce his substance use and HIV risk behavior.

The need for such an intervention is particularly acute in Argentina and Latin America, where there is little implementation of evidence-based interventions for MSM with PSU. In *Proyecto LINKS*, our study of 500 MSM in Buenos Aires,⁴⁷ 61% of the men reported drug use and over 40% reported poly-drug use during the prior two months. Marijuana, tranquilizers, cocaine, and *pasta base* (cocaine sulfate) use was particularly prevalent. and over 20% of users of these substances used them daily.⁹ Most participants in the study consumed alcohol during the past two months, 32% of them reported drinking at least weekly and drinking enough to “feel it a lot,” “get drunk,” or “feel like you might pass out.” Substance use was higher among participants who were younger, unemployed, had greater mood variability, and did not identify as gay.⁹ HIV prevalence, at 17% (31% among gay-identified men), and incidence, at 4.53/100 person-years (5.60/ 100p-y in gay-identified men) was also alarming.⁴⁸ These findings highlight the critical need for effective, evidence-based HIV prevention interventions for substance using MSM in Argentina.

The proposed study seeks to address this glaring gap by employing a user-centered process to develop and pilot a tablet-based e-SBI program tailored to MSM awaiting their HIV test at Nexo Asociación Civil, our community partners in Buenos Aires who conduct over 1500 HIV test per year with MSM. The e-SBI will integrate substance use and sexual risk behavior screeners and individually tailored Motivational Interviewing (MI) as the BI. Furthermore, we will adapt and pilot the implementation of the Young Men’s Health Project (YMHP),⁴⁹ a four-session MI-based intervention that effectively reduced substance use and condomless anal intercourse among MSM

who use substances, as a brief treatment provided at Nexo for participants with moderate-risk substance use or to build motivation to enter specialized substance abuse treatment among those with high risk or dependence.

Study Objectives

As an NIH r34 (Clinical Trial Planning Grant), the main goal of the study is to develop and pilot all the study components and build the necessary research infra-structure for a subsequent randomized controlled trial (RCT) to assess the efficacy of the e-SBI to reduce substance use and sexual risk behavior. The Specific Aims of this R34 study are to:

1. Develop a tailored e-SBI program to reduce substance use and HIV risk behavior among MSM seeking HIV testing.
2. Conduct a pilot Randomized Controlled Trial of e-SBI vs. screening only (3:1 ratio) to assess the acceptability and feasibility of integrating e-SBI into the Nexo HIV testing program and the feasibility of a future large-scale efficacy trial of the e-SBI.
 - a. percent of MSM testing clients at Nexo who accept entry into the study (recruitment rate);
 - b. percent of participants who complete e-SBI (retention rate);
 - c. retrospective acceptability ratings of the two RCT conditions. (Primary)
3. Assess the feasibility and acceptability of implementing MHP at Nexo, as measured by
 - a. the percent of MSM with moderate or high-risk substance use who enter MHP from either RCT condition (recruitment rate);
 - b. the percent of MHP participants who complete all four sessions;
 - c. prospective acceptability of MHP among participants in either RCT condition;
 - d. retrospective acceptability of MHP among those who received it;
 - e. percentage of sessions conducted by each MHP counselor that meet criteria for MI proficiency on the Motivational Interviewing Treatment Integrity (MITI.4) ratings.

METHODS

Study Design

This is a 3-year study begun on August 1, 2022 that consists of two stages. Stage 1: Development will consist of developing the e-SBI, the adaptation of YMHP into MHP, training counselors to deliver MHP, and piloting the e-SBI with 50 MSM coming to Nexo for HIV testing. During the Stage 2: RCT Pilot, we will randomize 200 MSM coming to Nexo for HIV testing at a 3:1 ratio (eSBI: Screening Assessments Only-SA) to assess the feasibility and acceptability of e-SBI among MSM coming to Nexo for HIV testing and establish and pilot the RCT process for a future trial. As a secondary aim, we will assess uptake, acceptability, and feasibility of delivering MHP to participants with moderate risk substance use and subsequent referrals to substance abuse treatment among participants with high-risk substance use or dependence. Lastly, we will explore preliminary findings on substance use and sexual risk reduction outcomes.

At the outset of the study we will convene a Community Advisory Board (CAB) composed of six members, including representatives from a local community-based organization focused on policy, training, and social marketing regarding substance abuse; a representative from the Department of Sexual Health, AIDS, and STIs at the Ministry of Health of the City of Buenos Aires; and four MSM who report using drugs and alcohol recreationally (this criteria will not be known to others). The CAB will meet with study investigators (in-person or via videoconferencing) quarterly through the study. The CAB will be responsible for reviewing and providing feedback on e-SBI, MHP, and the assessment instruments that will be used in the study before they are used with study participants.

The study was registered at clinicaltrials.gov on September 16, 2022. The identifier number is NCT05542914.

Ethical Considerations

Ethics Committee Approvals. The study was reviewed and approved by the Florida State University IRB and the Ethics Committee at Nexo Asociación Civil.

Participant Consent. All participants were provided with a written informed consent form to read prior to study participation. The consent form included an overview of the study, study procedures, risks of participation, procedures implanted to minimize risks of participation, a statement of voluntary participation, and contact information for the Principal Investigators in Argentina and the U.S. along with contact information for the respective IRBs. Consent was documented with the signature of the participant and research staff.

Participant Privacy and Confidentiality. The results of the study may be published or presented, but no information that may identify individual participants will ever be provided or released in publications or presentations. To protect the privacy and confidentiality of participants study staff will keep any records containing identifying information in a locked cabinet accessible only to research staff. The computer programs used in the tablet-based intervention are compliant with U.S. regulations on personal health information, as are the servers on which the data is stored. All data captured on the tablet, although it does not include identifying information, is encrypted in transit to maintain confidentiality. Any other study data will be stored in a secure computer that will be protected by passwords. All records will be kept confidential. Consistent with the guidelines of the U.S. National Institutes of Health, after removing all identifying information, the remaining de-identified information collected during the study could be used for future research studies or distributed to another investigator for future research studies without additional consent.

Participant Incentives. All incentives will be paid in cash in Argentine pesos. Stage 1 participants: Focus group participants will receive \$25; Individual interview participants will receive \$20; e-SBI pilot participants will receive \$10 and an additional \$10 for those who complete a qualitative interview. Stage 2: RCT participants will receive \$15 for completing the baseline assessment and e-SBI screeners, \$15 for the Month 3 follow-up assessment, and \$20 for the Month 6 follow-up assessment. Participants who complete the Month 6 IDI will receive an additional \$20.

Components of the Intervention

Motivational Interviewing (MI). MI is the basis for both the e-SBI and MHP. MI is “a collaborative, goal-oriented method of communication aimed at strengthening an individual’s motivation for and movement toward a specific goal by eliciting and exploring the person’s own arguments for change.”⁵⁰ In an MI session, a clinician guides rather than pushes a client towards change, sidestepping resistance and actively working with the patient’s strengths to build self-efficacy towards the desired outcome. MI uses standard tools of counseling and psychotherapy (i.e., open-ended questions, affirmations, reflections, and summaries) strategically to elicit and reinforce change talk (patient statements that argue against the status quo, such as “I have been doing crazy things when I use drugs” or for behavior change, such as “I want to have sex sober so I don’t want to worry the next day about whether I got HIV”) and to inhibit sustain talk (patient statements that argue against change, such as, “Sex a little high is fun”). Process research on mechanisms of action in MI show that more change talk^{51,52} and less sustain talk during a session are related to better outcomes.^{51,53} Also, counselor behaviors such as advising, confronting, directing, and warning clients are associated with greater sustain talk,⁵⁴⁻⁵⁵ whereas affirming a client’s strengths or effort, emphasizing client control, and supporting are associated with increased change talk.⁵⁵⁻⁵⁶ Thus, to facilitate behavior change, the goal of an MI counselor is to interact with the client in a way that fosters change talk and inhibits sustain talk.⁵⁷ These key aspects of MI will inform the programming of the narrator in the e-SBI (described below), the revision of MHP, and the training of MHP counselors.

e-SBI. The e-SBI will be created using the Computerized Intervention Authoring System, V.3 (CIAS 3.0), an authoring tool that allows creation and editing of electronic screening and intervention packages without the need of a programmer. Interventions built using CIAS feature a synthetic text to speech engine that reads all questions and speaks aloud to the participant (via headphones), synchronous interactivity, natural language reflections, branching logic, a clean user interface, and the ability to easily incorporate images, text graphs, figures, or videos. CIAS is consistent with human-computer interaction literature suggesting that interactive, lifelike software can engage users and promote behavior change.⁵⁸⁻⁶² Thus, CIAS uses an optional interactive cartoon character capable of over 50 specific animated actions (e.g., smile, wave, read a message, express concern, etc.) that does the talking for the entire program. The character acts as narrator and guide throughout the process and provides occasional comic relief. Everything the character does is specifically programmed during the development phase, including interacting with participants in an MI consistent manner and reflecting participant’s change talk derived from their responses to the assessments. For example, using the participant’s responses, the narrator might be programmed to say: “You don’t drink very often, but when you do, you drink a lot (from Alcohol Use Disorder Identification Test-AUDIT responses) and you are noticing that it is impacting your physical health and your relationship with others (from responses to the Short Inventory of Problems).” CIAS has been used with thousands of participants (primarily low SES) and has consistently received high satisfaction ratings.⁶³⁻⁶⁷

Young Men's Health Project (YMHP). YMHP is a 4-session MI-based intervention that was the first intervention to demonstrate reductions in substance use and sexual risk behavior among non-treatment-seeking substance using MSM.⁴⁹ Compared to a time and content-matched control group, YMHP recipients were 18% less likely to use drugs and 24% less likely to engage in unprotected anal intercourse (UAI). On days when drug use and sex co-occurred, drug use reductions led to decreases in UAI. Secondary analyses showed that drug use among partnered participants was stable but declined significantly at all follow-up timepoints among single men.⁶⁸ We will adapt and implement YMHP as an in-house brief treatment for participants with PSU, either as a stand-alone treatment (for those with moderate-risk use) or as an intervention to link those with high-risk use or dependence to Substance abuse treatment.

Stage 1: Development.

Development of the e-SBI. Development of the e-SBI app will be guided by the User Centered Rapid Application Development process (UCRAD).⁶⁹⁻⁷³ UCRAD merges the streamlined, iterative Rapid Application Development approach with the User Centered Design approach which engages intended users throughout the app development process. This integrated approach aims to develop successful apps with good functionality, simple features, and a usable interface.⁷⁰ As such, intended users are given access to prototypes of the app, allowing them to provide feedback before the next iteration of the app. The process is relatively brief, approximately six to nine months. UCRAD uses a three-phase process, as follows:

- A. Pre-design and interface prototyping: Data are gathered from key stakeholders to understand the requirements of the app in terms of content and interface. While continuing to assess the user's needs, the developers offer potential solutions for the design. By the end of this stage, an initial prototype is developed based on the initial requirements.
- B. System architecture and coding: The prototype is shared with intended end-users to obtain their feedback. The developers update the prototype according to the feedback provided and begin system coding to develop a more finished version of the app. This version is returned to the users for another round of feedback and development. The result of this stage is an advanced, but often incomplete product with basic system architecture and system specifications.
- C. Deployment: The app is implemented in the field to obtain further feedback from potential end-users and further development of the application is conducted to reach a final product.

Pre-design and interface prototyping. To accomplish this phase, we will obtain feedback from the CAB regarding the study screening instruments and preliminary plans for the e-SBI content. After incorporating their feedback, we will conduct two focus groups (FGs) with MSM (N=16) recruited from Nexo testing clients who are 18+ years of age and self-identify as a male. They will complete a substance use screener consisting of the illicit drug use question on the NIDA-modified ASSIST brief screen and the AUDIT-C (a 3-item alcohol use screen). Those who indicate using illicit drugs at least monthly and/or receive a score ≥ 4 on the AUDIT C will be eligible to participate. After completing informed consent, they will each complete paper and pencil versions of the screening instruments planned for inclusion in e-SBI, including:

- *NIDA-modified Alcohol, Smoking and Substance Involvement Screening Test (ASSIST)*^{74,75} substance use assessment, which has high consistency in detecting moderate and high substance use, and high concordance (90–98%) and correlation (ICC 0.90–0.97) for tobacco, alcohol, and drug risk scores.⁷⁶ A self-administered computer ASSIST was found to have 0.93 interclass correlation with the interviewer administered version.⁷⁷
- *Alcohol Use Disorders Identification Test (AUDIT)*,^{78,79} is a widely used tool developed by the World Health Organization to identify persons whose alcohol consumption has become

hazardous or harmful to their health. AUDIT is a 10-item screening questionnaire with 3 questions on the amount and frequency of drinking, 3 questions on alcohol dependence, and 4 on problems caused by alcohol.

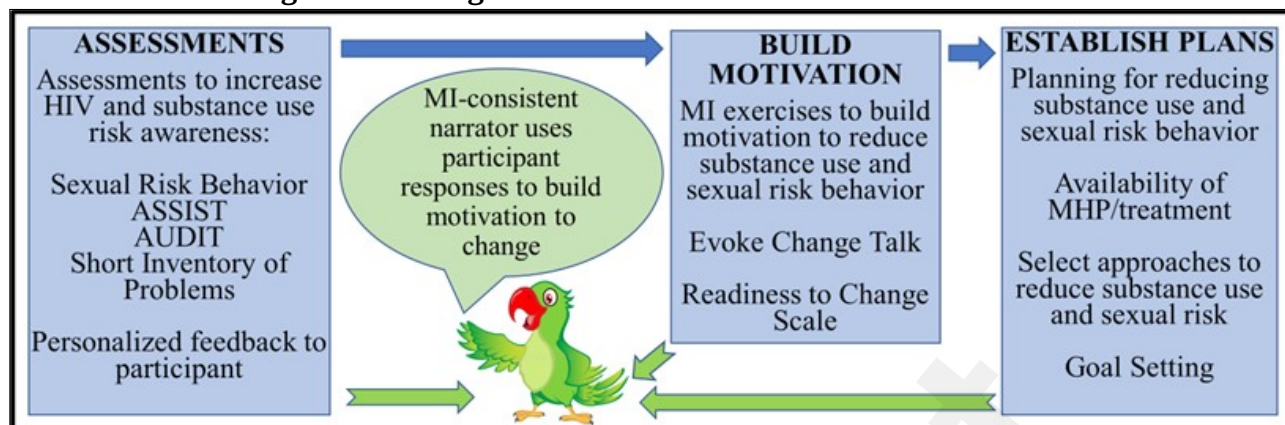
- *Short Inventory of Problems-Alcohol and Drug Use (SIP-AD/MSM)*⁸⁰ is a 10-item version of the SIP-AD⁸¹ ($\alpha = .95$) derived through Item Response Theory was found to be highly valid and reliable among non-treatment-seeking MSM. The SIP assesses the frequency (0=Never; 3=Daily/Almost Daily) of commonly experienced consequences of alcohol or drug use across physical, intrapersonal, interpersonal, social responsibility, and impulse dimensions.
- *Sexual Practices Assessment Schedule (SPAS)*,^{82,83} which asks about the number of partners and occasions of oral, anal, and vaginal sex with male, female, and transgender sexual partners in the past two months, use of condoms during sexual intercourse, and assumed HIV status of the partner.
- *Readiness to Change Rulers* for alcohol use, sexual risk behavior, and drug use. Although they vary in their specific wording, single item readiness to change rulers that ask respondents to place themselves on a scale of change from 1-7 or 1-10 have shown concurrent and predictive validity for alcohol use,⁸⁴⁻⁸⁷ drug use,^{84,88-90} and sexual risk behavior.^{86,91} These scales are also often used in MI interventions to strategically evoke change talk and increase motivation to change problem behaviors.

The 90-minute audio-recorded FGs will: 1) explore participants' reaction to the screeners and their impact on risk perception and motivation to reduce PSU and risk behavior; 2) evoke content for the BI component to develop menus of options for reasons to change and potential approaches to reduce PSU and sexual risk behavior from which e-SBI users can choose. Within 48 hours of completing the FG, we will initiate a rapid analysis of this data^{92,93} using a qualitative matrix^{94,95} onto which participant's responses and recommendations will be entered to quickly organize and summarize FG findings. These findings will be used to build the prototype of the e-SBI.

System architecture and coding. This iterative app development process will be conducted with waves of 6 MSM also recruited from Nexo testing clients, with the same inclusion criteria as in the FGs. They will be recruited during two-week intervals to maintain a steady pace of feedback and revisions. Participants will complete the intervention on the tablet. Then, they will complete a 7-item self-report instrument used by the CIAS developers⁶⁵ that assesses how much participants 1) liked the e-SBI, 2) found it interesting, 3) easy to use, 4) made up of understandable questions, 5) respectful, 6) annoying, and 7) humorous; each rated from 1=not at all to 5=very much. Afterwards, participants will be debriefed during an audio-recorded interview to explore: 1) their responses to the acceptability assessment; 2) overall reactions to e-SBI; 3) emotional reactions as e-SBI progressed, including heightened risk awareness, concern, or motivation to reduce substance use and sexual risk behavior; and 4) recommendations for improving the ability of the e-SBI to engage MSM with high-risk drug and/or alcohol use into treatment. Interview data will undergo the same matrix-based, rapid analysis process used for the FG to quickly inform the next revision of the e-SBI. This process will be repeated with waves of 6 participants until mean scores on each acceptability question are ≥ 4.0 (≤ 2.0 on annoying), which we expect within 3-4 cycles. Figure 1 depicts our current conceptualization of the e-SBI, with specific content informed by Stage 1 findings. Development of the e-SBI will be guided by Choice Theory,⁹⁶ which has been used extensively to inform goal choice interventions,^{97,98} including MI interventions to reduce substance use among MSM.^{76,77} Rather than pre-set outcome expectations (ie., abstinence), goal choice interventions highlight personal choice and goal setting to engage individuals to reduce drug and alcohol use. Goal choice interventions are equally effective as those that are abstinence-based and allowing individuals to set their own treatment goals appears to increase success rates.^{101,102}

Figure 1. Conceptualization of the e-SBI intervention to reduce substance use and HIV sexual

risk behavior among MSM in Argentina.



Deployment. The initial version of the e-SBI will be deployed with 50 MSM coming to Nexo for HIV testing, to be used while they await their HIV test. Based on findings from LINKS and Nexo screening data, we estimate that at least 50% will report using drugs, 80% alcohol and that 20-25% will report PSU. As such, a sample of N=50 will allow us to explore reactions to the e-SBI from MSM with no, low-risk, and moderate/high risk substance use. After undergoing informed consent, these individuals will complete the eSBI, a brief quantitative acceptability assessment, and then proceed to have their HIV test (to minimize participant distress). Afterwards, up to 25 of these participants will be randomly selected (5 with low-risk substance use, 20 with moderate or high-risk substance use) to undergo an audio-recorded IDI that will be guided by the Theoretical Framework of Acceptability¹⁰³ (TFA; see components in Table 1), which has been used to guide qualitative and mixed methods research on acceptability of healthcare interventions,¹⁰⁴⁻¹⁰⁷ Data from these interviews will also go a rapid qualitative analysis as previously described for the FGs.

Table 1. Components of the Theoretical Framework of Acceptability

Affective Attitude: How the individual feels about the intervention
Burden: Perceived amount of effort that is required to participate in the Intervention
Ethicality: Extent to which the intervention has a good fit with an individual's value system
Intervention Coherence: Extent to which the participant understands the intervention and how it works
Opportunity Costs: Extent to which benefits, profits, or values are given up to engage in the intervention
Perceived Effectiveness: Extent to which the intervention is perceived as likely to achieve its purpose
Self-efficacy: The participant's confidence that they can perform the behaviors required to participate in the intervention

Adaptation of YMHP to MHP. In consultation with our CAB, the research team will adapt YMHP, guided by the modified ADAPT-ITT framework (see Table 2).¹⁰⁸ The adaptation will focus on three main areas: 1) tailoring YMHP to Argentine MSM (including translation, cultural relevance for MSM over 29 years old); 2) we will adapt YMHP from a stand-alone intervention to an intervention within an SBIRT program by minimizing duplication with e-SBI content and incorporating content to improve linkage to specialized Substance abuse treatment for participants with high-risk substance use or dependence; and 3) adding content to address its poorer efficacy among partnered MSM.

Table 2. Overview of ADAPT-ITT Framework

Phase	Methodology
Assessment	Completed as part of our earlier studies and discussions with stakeholders.

Decision	
Administration	Theater test to obtain feedback
Production	Produce revised intervention, maintain fidelity to core elements and underlying theory. Develop quality assurance and process measures
Topic Experts	Involve topic experts in adapting the intervention
Integration	Integrate content from topical experts; integrate new assessments based on revised content
Training	Train staff to deliver the intervention
Testing	Test revised intervention in pilot study

Administration. To obtain feedback from members of the target population and key stakeholders, we will video-record a mock YMHP session (conducted in Spanish) that will be shown to the CAB, Nexo counselors (most of whom identify as gay men), and the study Co-Investigators. As they watch the videos, audience members will be asked to complete a feedback form, divided by portions in the session, so that they can provide feedback on issues they felt needed to be adapted from the original. Afterwards, we will discuss recommendations to address the issues raised.

Production. Feedback obtained during the Administration phase will inform Draft 1 of MHP. The revised intervention will be translated into Spanish and manualized to standardize the counseling sessions and provide support and guidance for the counselors.

Topic Experts and Integration. Draft 1 of MHP will be reviewed by substance abuse experts on the CAB, Nexo counselors, and Co-Investigators to identify any other components of the intervention that need revision. Feedback from this review will be integrated into the intervention to create Draft 2, which will be pilot tested during the Stage 2 RCT.

Training of MHP counselors. Training of MHP counselors will be consistent with research on learning MI, which recommends a 2-day workshop with follow-up feedback and coaching.^{109,110} As such, we will conduct a 4-day training with MHP providers, the first two days will focus on general MI principals and skills and the last two days on specifics of MHP. Counselors will then conduct at least two mock cycles of MHP which will be audio-recorded and uploaded to a secure Internet site for the MI trainer to rate using the Motivational Interviewing Treatment Integrity V.4 (MITI-4) scale,¹¹¹ which captures the counselor's level of fidelity to MI and establishes specific criteria for "Proficiency" in MI. These ratings will be used to assess MI skills that need further development, which will guide the videoconference coaching sessions.

Testing. While the primary aims of this study focus on the e-SBI component, as a secondary aim we will assess the potential uptake and acceptability of MHP during the Stage 2 pilot RCT.

Stage 2: RCT Pilot

With the e-SBI finalized, MHP adapted, and MHP counselors trained, the study will proceed to the Stage 2 RCT comparing e-SBI to screening assessment (SA) only (see Consort Diagram for overview). We will assess feasibility and acceptability of e-SBI and conduct a preliminary exploration of substance use and sexual risk reduction outcomes. Based on findings from LINKS and Nexo data, we estimate that 50% or participants will report using drugs, 80% alcohol, and that conservatively, 20-25% will report moderate- or high-risk use based on the ASSIST and AUDIT criteria, respectively. As a secondary aim, we will assess uptake, acceptability, and feasibility of delivering MHP at Nexo and subsequent linkage to Substance abuse treatment among those with high-risk substance use or dependence. RCT processes are shown below.

Recruitment. To ensure the flow of participants is manageable during the study in the context of an HIV testing program, we will recruit up to four participants per day, three days per week, adjusting as necessary based on recruitment patterns to ensure recruitment of all 200 participants.

MSM coming to Nexo for HIV testing and who are 18 years of age or older will be offered participation in the study. These clients will be given a flyer that, consistent with goal choice interventions, will create a low threshold for study participation by stressing personal choice, goal selection, and an intervention tailored specifically for MSM to figure out how to best reduce behavior that puts them at risk of HIV infection. Clients who wish to participate will complete informed consent, be randomized immediately, and given a tablet logged on to their respective study arm (and disposable headphones) to complete their study procedures. Clients who decline participation will undergo the standard HIV testing process at Nexo. Research staff will record the number of clients who refuse participation.

Baseline Assessment. Participants in both conditions will complete a demographics questionnaire then a self-administered tablet-based 30-day *Timeline Followback (TLFB)*¹¹² to track days of drug use, number of alcoholic drinks, and HIV risk behavior, defined as anal sex with: 1) an HIV positive partner who they were not sure had an undetectable viral load, or 2) a partner who had not tested HIV negative within the past three months). The TLFB has demonstrated good test–retest reliability, convergent validity, and agreement with collateral reports for daily drinking,¹¹³ and for sexual behavior.¹¹⁴ The TLFB will be used to assess primary substance use and sexual risk behavior outcomes (which are exploratory outcomes in this study). After completing the e-SBI, participants in the intervention condition will also complete a brief quantitative assessment of acceptability (8 items) based on the Theoretical Framework of Acceptability.¹¹⁵

RCT Study Conditions. Participants will be randomly assigned into one of two study arms.

Intervention group participants. After completing the baseline assessment, the tablet will immediately lead these participants to the e-SBI as finalized in Stage 1. The CIAS branching logic will allow the e-SBI to tailor the BI based on factors such as participants' substance use risk level (based on ASSIST and AUDIT score), risk perception, and readiness to change. Thus, the BI may range from affirming and sustaining motivation among those with low-risk substance use to actively motivating and encouraging (in an MI-consistent manner) those with moderate or high-risk use to speak with a research assistant to obtain an appointment for MHP. The e-SBI will also target the participant's sexual risk behavior and help them develop a risk reduction plan, regardless of their substance use. Then, they will proceed to the usual HIV testing process at Nexo.

Control group participants. After completing the baseline assessment, the tablet will lead these participants to the same screening instruments as in the e-SBI but with no MI-based BI. Due to ethical considerations, control group participants with moderate or high-risk substance use based on the ASSIST or AUDIT scores will receive brief feedback on the tablet stating their level of risk, availability of MHP at Nexo, and instructions to see the receptionist for an appointment, if desired. Then, they will proceed to the usual HIV testing process at Nexo.

Referral for MHP. All individuals with moderate or high-risk substance use will be recommended for MHP (either actively motivated to enter MHP through the MI component of the e-SBI for those in the intervention condition or recommended to enter treatment and made aware of the availability of treatment at Nexo for those in the control condition). MHP sessions will be conducted in-person at Nexo (later sessions can occur remotely, based on the participant's preference) and will follow the intervention manual as finalized at the end of Stage 1, with sessions expected to be 60 minutes in duration. As in the YMHP efficacy study, the four MHP sessions can be conducted over a period of up to two months. To maximize retention, participants will be offered reminder calls or texts prior to each scheduled visit. For participants with moderate risk substance use, MHP will focus on reducing substance use and sexual risk behavior. For participants with high-risk use or dependence, MHP sessions will focus on building motivation to enter substance abuse treatment. After accepting the referral, the participant and Nexo staff will contact the treatment provider to obtain an appointment at the clinic of the participant's choosing (i.e., closer to home). Nexo staff will offer to accompany the participant to the appointment to provide a "warm hand-off" to facilitate linkage to care. To ensure intervention fidelity, all MHP sessions will be audio-recorded, uploaded to

a secure website, and rated with the MITI-4. MITI ratings will be conducted throughout the study and used to inform the weekly videoconferencing coaching sessions for the MHP counselors to improve and sustain MI skills.

Follow-Up Assessments. All participants, including those who enter MHP or Substance abuse treatment, will repeat the self-administered 30-day TLFB at 3- and 6-months after enrollment to assess drug use, alcohol use, and sexual risk behavior. At 6-months they will also complete the screener instruments in the e-SBI, and TFA-based quantitative retrospective acceptability assessments of e-SBI and MHP (if they entered MHP), all of which will be self-administered. We will also conduct IDIs with up to 45 participants (or less if saturation is reached), 15 with participants from either study condition who entered or completed MHP and/or Substance abuse treatment and 15 from each arm who met criteria for MHP but did not request it. Also guided by the TFA, we expect these IDIs will be similar to those conducted in the Stage 1 e-SBI pilot, however, revisions will be made to the IDI guide based on how well the questions elicited the desired material from Stage 1 participants. The use of one framework to guide all of these IDIs and the qualitative data analysis will allow us to more rigorously compare participants with PSU who entered MHP and/or Substance abuse treatment and those who did not to identify factors that might impact their decision to enter MHP. IDIs will be conducted at Nexo, audio-recorded, and transcribed.

Data Analysis.

Qualitative data analysis for Stage 2 IDIs. For the Stage 2 pilot RCT, transcripts from the audio-recordings will be reviewed for accuracy and uploaded onto Dedoose for management and analysis. Codebook development will begin when 10 transcripts are available. First level codes will be guided by the TFA components, while second and third level codes will emerge from themes identified in the narratives. An initial set of codes will be generated independently by two research staff, compared, then synthesized to compile shared coding categories and sub-categories, all with definitions, inclusion and exclusion criteria, and examples. As transcripts become available, coding will continue, refining the codebook definitions that will be used to process the remainder of the manuscripts. Coders will discuss discrepancies until they achieve 80% intercoder convergence. As per Patton,¹¹⁶ we will identify indigenous (i.e., participant generated) as well as analyst-constructed typologies. Once data is coded, analysis of coding reports will include categorization, abstraction, comparison (especially between groups in the Stage 2 RCT), integration, iteration, and refutation of themes.

Integration of quantitative and qualitative data. We seek to exploit the richness of our mixed-methods approach, with quantitative and qualitative findings enriching each other. Quantitative assessments allow us to systematically explore variables of interest across all participants. Qualitative data will add nuance and new insights to quantitative findings. During data analysis, interpretation of quantitative results will be enriched by the summary of codes for specific components of the e-SBI. In Dedoose, we will categorize participants based on their responses in the quantitative assessment (e.g. severity of drug or alcohol use; ratings on readiness to change rulers), and use these categories to compare and contrast themes and concepts that emerge from the qualitative data.

Quantitative data analysis.

Primary Aims. The primary aim for the study is to assess the feasibility and acceptability of integrating e-SBI into the HIV testing process at Nexo by estimating and comparing 1) percent of MSM testing clients at Nexo who accept entry into the study among those who are asked (recruitment rate); 2) percent of participants who complete e-SBI (retention rate); 3) the mean score of 7-item e-SBI acceptability ratings between MSM participating in e-SBI and those in screening only group. The secondary aim is then to assess the feasibility and acceptability of implementing MHP at Nexo by estimating and examining the group difference with respect to 1) the percent of

MSM with moderate or high-risk substance use who enter and/or complete MHP; 2) percent of high risk enrollees in MHP who proceeded to Substance abuse treatment; 3) mean acceptability of MHP and Substance abuse treatment among those who received it (based on quantitative assessment to be developed); and 4) percentage of sessions conducted by each MHP counselor that meets criteria for MI proficiency Motivational Interviewing Treatment Integrity (MITI.4) ratings. Estimation will be accomplished by generating the point estimate with its corresponding 95% confidence interval. We will use a t-test for continuous outcome, and Fisher's exact test for binary outcomes for the above comparisons. Adjustment for covariates if necessary, with control baseline values, will be accomplished by multiple linear (continuous outcomes) or logistic (dichotomous outcomes) regression.

Exploratory Aims. While this study will not recruit a large enough sample to provide adequate power for assessing the efficacy of e-SBI, we will use data from the 30-day TLFB to explore changes in days of drug use, days of alcohol use, days of heavy alcohol use (5 or more drinks) and occasions of anal intercourse with a risky partner. To examine the efficacy on the above outcomes, the generalized linear model (GLM) with log link function will be constructed and the generalized estimating equation (GEE) methods will be used to estimate model parameters and their standard errors to account for correlation introduced by accessing the participants at multiple time points. Accompanying each of these tests will be point and interval estimates for the parameters of interest (i.e., ratio of two group rate ratios). Although the hypotheses consider several simultaneous measures of effect, for routine reporting of these results, there will be no adjustment for multiple comparisons.

Power Considerations. The primary goal for this pilot work is to collect preliminary data regarding feasibility, acceptability and target outcomes for the proposed intervention. We will use these pilot data to rule out unusually large or small true effects through standard 95% confidence interval procedures. We will confirm extrinsic effect sizes are contained within our confidence intervals from the pilot. We will examine the distribution of each variable and calculate summary statistics by intervention condition. We will estimate key intervention parameters with sample means and proportions together with two-sided 95% confidence intervals and test the primary null hypotheses at the traditional two-sided level $\alpha=.05$ (simulation of the subsequent RCT). For planning the RCT, we will also consider one-sided 90% confidence limits for mission-critical design parameters such as standard deviations and reference group endpoint rates and proportions in the conservative direction. This is because we intend to plan sample size for the RCT so that power will be "excellent" (at least 80% power) for the clinically relevant effect size to be specified. This strategy will make proper allowance for the limited sample size of the pilot study with its consequent uncertainties, and still yield appropriate sample sizes for the RCT. "Mission-critical" parameters include proportions for dichotomous variable (e.g., recruitment rate and retention rate); means and standard deviations for continuous outcomes (e.g., days of drug use, days of alcohol use, acceptability of MHP and Substance abuse treatment). Large sample sizes are not required to locate these parameters approximately, but adequately, for planning the subsequent trial, whereas testing the study hypothesis in the pilot will generally not have sufficient statistical power. Estimation of mission-critical design parameters with point and confidence interval estimates will be considered highly important; continuous outcome measures make it feasible to detect promising effect effects even in small samples. For the continuous measures, means and standard deviations (sd) will be estimated. For approximately normally distributed variables, an upper one-sided 90% confidence limit for the sd, s_U , will be constructed from $s_U = s \sqrt{c_{2n,.10}/2}$, where s is the sample sd and $c_{2n,.10}$ is the upper 10th percentile of the chi-squared distribution with n degrees of freedom. For approximately log-normally distributed variables, a logarithmic transformation will be applied to achieve approximate symmetry and normality. For the dichotomous variables (such as the primary and secondary outcomes, or the PDR performance criteria), exact binomial methods will be employed for the CIs for proportions. As an example, the width of the 95% confidence interval

around a point estimate of 50% (e.g., MSM with moderate or high-risk substance use who complete e-SBI and then enter MHP) would be 43%-57% with 200 participants.

RESULTS

The study began recruitment for Stage 1 in October 2022. Currently, we are nearing completion of Stage 1. As part of the Stage 1 development process, we conducted two focus groups (N=16) and two waves of individual interviews (N=12). Consistent with the protocol, we ended the individual interviews after two of four possible waves because acceptability scores were consistently high (mean score was greater than 4 out of 5 for all participants). At present, we have almost completed the Stage 1 pilot. At the conclusion of Stage 1, we will conduct a rapid qualitative data analysis^{92,93} to assess any additional changes that need to be made to the e-SBI prior to the Stage 2 RCT, which we expect to launch in March 2024. At that time, we will also begin a deeper analysis of the Stage 1 data from focus groups, individual interviews, and the Stage 1 pilot and include that in a future mixed-methods manuscript to describe the intervention and its acceptability among the intended audience. We expect all data collection to be completed by February 2025 and study results to be available by June 2025.

DISCUSSION

This study begins to address a critical need for interventions that reduce both problem substance use (PSU) and HIV risk behavior among MSM in Latin America by adapting two evidence-based interventions, e-SBI and YMHP, for MSM in Argentina seeking HIV testing. Given that many MSM seek HIV testing in LGBT community agencies, these interventions have the potential to reach large numbers of MSM, help them reflect on their use of drugs and alcohol, and help link those with PSU to an evidence-based intervention (MHP). The provision of substance abuse treatment within an LGBT community agency can help facilitate entry and retention in treatment as sexual minority men will not be concerned about discrimination and microaggressions they might face at agencies serving the general public. If proven efficacious in a future RCT, the implementation of these intervention in such agencies will help address a key contributor to HIV risk behavior and infection as well as reduce drug and alcohol use among MSM, who are disproportionately affected by HIV and substance use.

Strengths. A key strength of this study is the iterative development of the intervention based on end-user feedback to ensure its high acceptability among its intended users. Feedback from end-users is essential to create an intervention that achieves its aim of heightening risk awareness of problem substance use to motivate reductions in use in a respectful, non-judgmental manner without creating resentment or defensiveness.

An additional strength is that the study and the intervention were developed in close collaboration with a community HIV testing center, where the intervention is designed to be delivered. Development within a community HIV testing program provides an early assessment of implementation challenges that need to be overcome to maximize access to the intervention and minimize burden on organizational processes and resources.

Lastly, the e-SBI was developed using the Computerized Intervention Authoring System (CIAS). Since this system was designed for use by non-programmers, the CIAS minimizes costs for developing, revising, and maintaining electronic interventions. Additionally, it has been designed with long-term sustainability in mind. For example, contrary to a custom-designed platform for a specific task, the CIAS is a broad platform for use by many people; supporting just this single platform will automatically support availability of everyone's work. Its ongoing development is still funded by the U.S. National Institutes of Health for two years and additional funding will be

obtained to continue its support. Additionally, a yearly fee for funded projects provides income to support CIAS long term, especially given the high interest in its use. Lastly, the source code will soon be made publicly available at no cost, thus it can be installed on a local server. This sustainability plan addresses a key challenge to other e-interventions whose support falters once study funding has concluded, impeding the use of the interventions in community settings.

Limitations. This study and intervention has been designed in close collaboration with our community partners in Argentina. As such, there may be specific characteristics of our community partners and their client population that may limit the generalizability of findings to other community HIV testing programs. As a voluntary research study, HIV testing clients with PSU may decide not to participate in the study, limiting the potential utility of this approach to identifying and engaging MSM with PSU to reduce their substance use. Lastly, acceptability data (both quantitative and qualitative) is particularly subject to social desirability. To minimize this risk, we will highlight for participants the importance of sharing their experiences and opinions openly, whether these were positive or negative.

CONCLUSIONS

Completion of this Clinical Trial Planning Grant (NIH R34) will allow us to develop and pilot all the study components and build the necessary research infra-structure for a subsequent randomized controlled efficacy trial (RCT) to assess the efficacy of the e-SBI to reduce substance use and HIV sexual risk behavior among MSM coming to a community agency for HIV testing.

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ICB is the Principal Investigator of the study, led the design of the study and the development of the interventions, and led the writing of this manuscript.

ROM is a Co-Investigator on the study and the site Principal Investigator in Argentina. He significantly contributed to the study design and leads the implementation of the study. He critically reviewed the manuscript, provided feedback, and approved the final version.

VB is collaborating with the implementation of the study and leads the qualitative component of the research assessing acceptability of the interventions. She critically reviewed the manuscript, provided feedback, and approved the final version.

SN is a Co-Investigator who collaborated on the study design as it pertains to the adaptation and implementation of YMPH. She critically reviewed the manuscript, provided feedback, and approved the final version.

YW is the data manager for the study. She has collaborated in the design of the various data capture components of the study and will provide data management and statistical support for the study. She critically reviewed the manuscript, provided feedback, and approved the final version.

DATA SHARING

Once the study is completed, the data sets generated during and/or analyzed during the study will be available from the corresponding author on reasonable request. We will compile structured de-identified datasets and make them available for additional/secondary data analyses. For data sharing, the research team will follow the “standards for privacy of individually identifiable health information.” The Principal Investigator and the research team will develop a process to review and approve data release based on concept sheets submitted by interested investigators and whether the data request is for new lines of analysis. Formal data sharing agreements will be developed to guide and encourage further data mining of the proposed datasets for various purposes.

CONFLICTS OF INTEREST

None to declare

ABBREVIATIONS

ADAPT-ITT	Assessment, decision, administration, production, topic experts, integration, training, testing
AUDIT	Alcohol Use Disorders Identification Test
BI	Brief Intervention
CAB	Community Advisory Board
CIAS	Computerized Intervention Authoring System
e-SBI	Electronic Screening and Brief Intervention
FG	Focus group
GEE	General estimating equation
GLM	Generalized linear model
IDI	In-depth interview
MHP	Men’s Health Project

MI	Motivational Interviewing
MITI	Motivational Interviewing Treatment Integrity
MSM	Men who have sex with men
NIDA ASSIST	National Institute of Drug Abuse Alcohol, Smoking and Substance Involvement Screening Test
PSU	Problem substance use
RCT	Randomized controlled trial
SBIRT	Screening-brief intervention-referral to treatment
SIP-AD	Short Inventory of Problems-Alcohol and Drug Use
SPAS	Sexual Practices Assessment Scale
STD	Sexually transmitted disease
TFA	Theoretical Framework of Acceptability
TLFB	Timeline follow back
UAI	Unprotected anal intercourse
UCRAD	User Centered Rapid Application Development
YMHP	Young Men's Health Project

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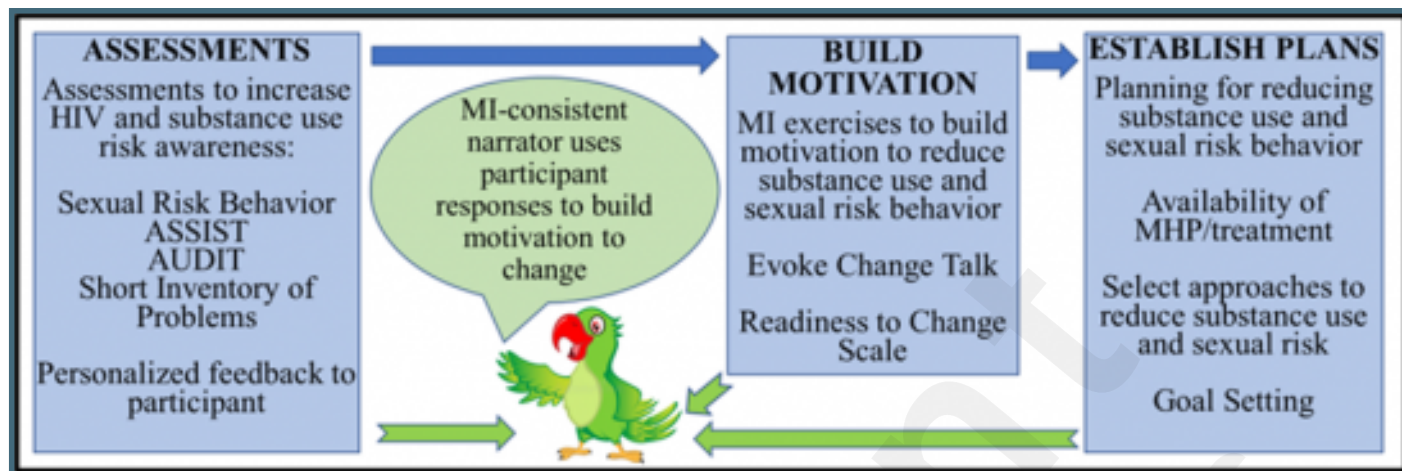
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Supplementary Files

Figures

Conceptualization of the e-SBI intervention to reduce substance use and HIV sexual risk behavior among MSM in Argentina.



Multimedia Appendixes

Reviewers' comments.

URL: <http://asset.jmir.pub/assets/1ba3eea03242ac79d8abce7c9b06e5b6.pdf>



CONSORT (or other) checklists

CONSORT Diagram for Proposed Phase 2 Pilot RCT of e-SBI (Reflexiones).

URL: <http://asset.jmir.pub/assets/43e6b74237c3d3ccf4aa7f788ce91ecb.pdf>