

Study Title: Integration of Electronic SBI(RT) into an HIV Testing Program to Reduce Substance Use and HIV risk Behavior among MSM in Argentina.

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2. SPECIFIC AIMS

Men who have sex with men (MSM) are disproportionately affected by HIV and drug and alcohol use in the U.S., Europe, and Latin America.¹⁻¹² Given the association between substance use and HIV risk behavior among MSM,¹²⁻³⁴ 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 challenge³⁵⁻³⁷ that results in a great majority of MSM with PSU never receiving treatment.³⁸

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.³⁹ SBIs effectiveness in reducing risky alcohol use is well established.³⁹⁻⁴⁵ Their efficacy in reducing drug use is not as consistent^{46,47} but they have demonstrated efficacy in studies with specific populations, such as post-partum women⁴⁸⁻⁵⁰ and individuals in mental health treatment,⁵¹ and have shown large pre-post reduction in illicit drug use and heavy drinking in large-scale demonstration projects funded by SAMHSA.⁵²⁻⁵⁵ Electronic SBIs (e-SBIs) reduce implementation challenges such extensive training, demands on staff time, and consistency in the delivery of the BI,⁵⁶⁻⁶³ and are as effective as in-person SBIs.⁶⁴⁻⁶⁷ with less draw on limited resources. As such, 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,⁶⁸ 61% of the men reported drug use in the past two months, and over 20% of users of marijuana, tranquilizers, or cocaine sulfate used daily.¹² Prevalence of use among participants aged 18-25 was equally concerning; among those who currently use substances, 26% drank at least weekly to the point of “feeling it a lot,” “feeling drunk,” or “feeling like they were going to pass out,” while 74% used drugs once per week or more.⁶⁹ 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.⁷⁰ 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 developing and piloting a table-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),⁷¹ a four-session MI-based intervention that effectively reduced substance use and condomless anal intercourse among substance-using MSM, as a brief treatment provided at Nexo for participants with moderate-risk substance use or to build motivation to enter specialized substance abuse treatment (SATx) among those with high risk or dependence. This study will allow us to pilot all the study components and build the necessary research infra-structure for a subsequent randomized controlled efficacy trial (RCT). The Specific Aims of this R34 study are to:

1. Develop a tailored e-SBI program for MSM seeking HIV testing to reduce substance use and HIV risk behavior. (Primary)
2. Conduct a pilot RCT of e-SBI vs. screening only (3:1 ratio) to assess the feasibility and acceptability of integrating e-SBI into the Nexo HIV testing program as measured by 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; and e) percentage of sessions conducted by each MHP counselor that meet criteria for MI proficiency on the Motivational Interviewing Treatment Integrity (MITI.4) ratings. (Secondary)

The proposed study extends our long-standing collaboration with Nexo, with whom we successfully completed two NIH funded studies. Since MSM often access HIV testing through similar LGBT organizations, using this existing infrastructure to identify and engage MSM with PSU in brief, effective, substance use and HIV risk reduction interventions could significantly reduce HIV infection and PSU among this population.

3. RESEARCH STRATEGY

3.1. SIGNIFICANCE

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. These interventions are being tailored to MSM awaiting HIV testing, which is a particularly opportune time to help them reflect on factors (such as PSU) that can increase their risk of HIV infection. Given that many MSM seek 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 care. If proven efficacious in a future RCT, the implementation of these intervention in such agencies will reduce drug and alcohol use, key contributor to HIV risk behavior and infection among MSM.

3.1.1. Our prior research demonstrates high prevalence of substance use among MSM in Argentina.

Figure 1 reports findings from *Proyecto LINKS*,¹² showing that rates of substance use among MSM in Argentina are high; over half the men reported using drugs in the prior two months and over 40% reported poly-drug use. Alcohol, marijuana, tranquilizers, cocaine, and *pasta base* (cocaine sulfate) use was particularly prevalent. Most participants 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.” Participants who used alcohol, marijuana, cocaine sulfate, or tranquilizers, did so frequently (Figure 2). Substance use was higher among participants who were younger, unemployed, had greater mood variability, and did not identify as gay. As stated, substance use among those 18-25 years of age was equally alarming.⁶⁹

These findings stand in contrast to those of a nationally representative study on substance use in Argentina,⁷² (N= 12,589) which found lifetime prevalence of alcohol, marijuana, and cocaine use among 18-49 year-olds (who constituted over 90% of our sample) at about 80%, 14%, and 5% respectively. Past year use was approximately 66%, 6%, and 2%. Lifetime and past year use of *pasta base*, heroin, tranquilizers, crack, ecstasy, hallucinogenics, and inhalants, was less than 4% and 2% respectively. Our findings suggest that substance use is higher among MSM than the general Argentine population.

3.1.2. Substance use is associated to HIV risk behavior.

The association between substance use and HIV risk behavior is well-established.¹³⁻³⁴ In Project EXPLORE, HIV incidence was almost four times higher among participants who used club drugs or drank heavily once per week or more compared to those with no drug or alcohol use.⁷³ In Proyecto LINKS, frequency of drug use was associated with more sex partners, higher frequencies of unprotected anal and vaginal intercourse with men and transvestites (the term used in Argentina at the time of the study), especially among the non-gay-identified MSM in the study. Frequency of alcohol use, however, was not associated with HIV risk behavior, possibly due to the study capturing only global substance use data which may overlook associations that might have emerged through situational or event-level assessments.¹² This relationship between substance use and HIV risk has led to calls for the use of substance abuse treatment as an HIV risk reduction strategy for MSM.^{15,16,71,74,75}

3.1.3. Intervening with MSM with PSU is critical but engaging them into treatment is a challenge.

Recent studies highlight the challenge of engaging MSM with PSU to reduce their substance use. In one study of an intervention to reduce alcohol use, of 198 potential participants who completed an informed consent process and met eligibility criteria for alcohol abuse, 109 (55%) did not enroll in the study because they were not interested in treatment.⁷⁶ Similarly, 141 of 291 (48%) potential participants in a study to reduce club drug use completed a baseline assessment but then refused randomization into the interventions.⁷⁷ Grov, et al.,³⁷ highlight the difficulties faced in this latter study. After little success recruiting participants using marketing materials

Figure 1. Prevalence of substance use

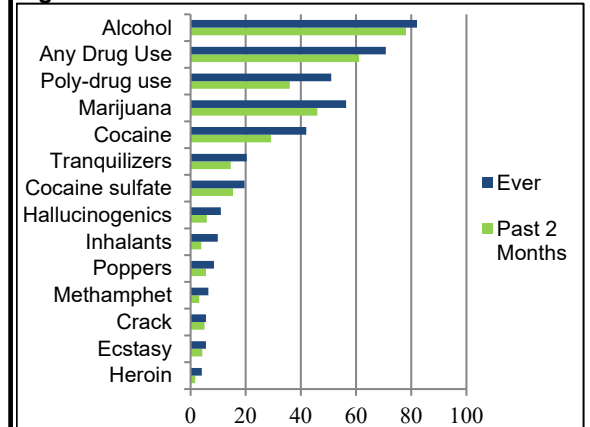
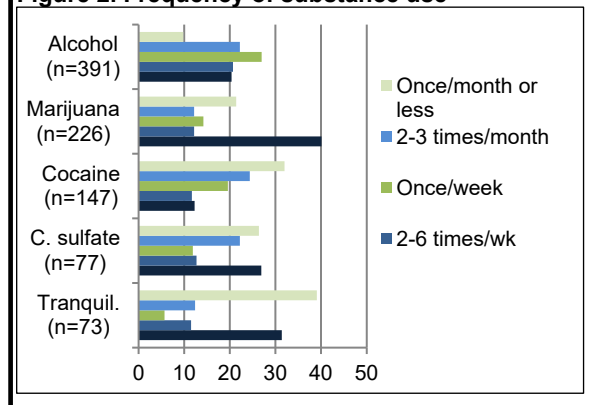


Figure 2. Frequency of substance use



carefully developed through focus groups with MSM, the researchers shifted to recruiting MSM into a study assessing drug use among gay/bi men and then, based on their responses, invited those who reported drug use to participate in the treatment study, which was a more effective approach, increasing the mean number of participants recruited per month from 2.5 to 6.3. This ongoing challenge led NIDA to convene an expert panel to discuss this issue and potential solutions.³⁵

MSM with PSU also avoid seeking treatment. Data from the National Epidemiological Survey on Alcohol and Related Disorders shows that among men who identified as gay, bisexual, or unsure, with any lifetime substance abuse disorder, only 27%, 37%, and 25%, respectively, sought treatment for it. While these figures are higher than those among heterosexually identified men (17%), they highlight that, as in the general population, the great majority of MSM with PSU do not seek treatment.³⁸ Thus, the challenge remains on how to best identify and engage substance using MSM in interventions to reduce their use, especially in community settings where the approach used by Grov and colleagues is not feasible.

3.1.4. SBIRT is effective in identifying and engaging individuals with PSU to reduce use.

SBIRT programs aim to screen everyone entering a setting (i.e., a hospital emergency room, primary care office) in order to identify those with PSU and link them to substance abuse treatment (SATx). SBIRT programs have not been effective in linking individuals with PSU into treatment.⁷⁸⁻⁸² However, there is a strong evidence base for just the SBI components of SBIRT to reduce alcohol consumption among moderate-risk drinkers compared to control groups,³⁹⁻⁴⁵ with the effects seen up to 12 months.⁸³ For example, a meta-analysis on the efficacy of BIs found that alcohol consumption decreased by 3.6 drinks per week from baseline; 12% fewer adults reported heavy drinking episodes; and 11% more adults reported drinking less than the recommended limits over 12 months compared with control participants.⁸⁴ The efficacy of SBI in reducing drug use is less consistent. For example, in the ASPIRE study, which focused on primary care population of non-treatment seeking individuals, there was little reduction in days of use pre- and post-BI as well as no differences between conditions (10-15 minute brief negotiated interview, 30-45 minute MI session with possible booster, or no BI) and minimal decrease in days of use between baseline and 6-month follow up.⁴⁷ However, more recent SBIs have been efficacious in reducing drug use among individuals in mental health treatment⁵¹ and electronic SBIs have shown efficacy with women in primary care⁸⁵, reproductive health centers.^{66,86} and women who are post-partum⁽⁴⁸⁻⁵⁰⁾ Furthermore, large-scale implementation studies of SBIRT report significant reductions in drug use among patients undergoing SBI.⁵²⁻⁵⁵ For example, in one study,⁵⁵ of 459,599 patients screened across 6 medical center sites, 22.7% screened positive for PSU, 15.9% were recommended for a brief intervention, 3.2% for brief treatment, and 3.7% to referral to specialty treatment. Among those reporting baseline illicit drug use, rates of drug use at 6-month follow-up were 67.7% lower ($p < 0.001$) and heavy alcohol use was 38.6% lower ($p < 0.001$). Similarly, SBIRT implemented in STD clinics in New York City resulted in improvements in multiple outcomes at 6-month follow-up, including reduced substance use, fewer mental health problems, fewer unprotected sexual acts,^{87,88} and reductions in STI infection.⁸⁹ Even with the challenges of engaging high risk users into SATx, such findings have led National Institute for Alcohol Abuse and Alcoholism, the U.S. Prevention Services Task Force, and SAMHSA to recommend its implementation across a variety of settings, conditions, and populations.

However, implementing SBIRT is a challenge, which can diminish its effectiveness. 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.⁵⁶⁻⁶³ 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 include a go beyond normative feedback only to provide an empathic⁹⁰ or motivational component,⁹¹ or multi-session interventions for high-risk users, who are most in need of SATx, whether these are multiple BIs⁸⁴ or brief treatment (4-6 60-minute sessions),⁹² all improve 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 given the constraints of the setting, may not be of sufficient intensity to achieve its desired outcomes, reduction in substance use among those with low or moderate risk use or entry into SATx among those with high-risk use or dependence.⁸²

3.1.5. This study addresses these challenges to improve SBIRT outcomes.

We have developed the components of this SBIRT program based on best practices identified in the research literature, including the use of MI in the BI (versus just information or personalized feedback), e-SBI (which

standardizes the delivery of SBI), and colocated brief treatment (MHP) to facilitate engagement and provide evidence-based brief treatment for substance use and sexual risk reduction among MSM with moderate risk substance use or to motivate entry into SATx outside of Nexo.

3.1.5.a. Use of e-SBI to minimize use of scant resources and maximize standardization and fidelity of BI. 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). For example, when SBIRT was implemented in STD clinics in NYC, of 66,989 positive screens, only 17,474 received BI.⁸⁷ Furthermore, efficacy is not sacrificed, as eSBIs have been shown to be effective in reducing alcohol and drug use^(48-50,83,93) and equal in efficacy to in-person SBIs.⁶⁴⁻⁶⁷ 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.

3.1.5.b. Involvement of substance using MSM in the development of eSBI. Unlike typical SBIRT programs, we will work closely with the target population to develop a tailored and engaging eSBI to raise MSM's awareness of risky substance use, assess its impact on their life, and motivate them to achieve their substance use and HIV risk reduction goals.⁹⁴ This approach was used by the developers of the CIAS platform we will use in their initial studies and their studies have shown high acceptability of the interventions as well as positive outcomes.⁹⁵⁻⁹⁸

3.1.5.c. Integration of brief treatment (MHP) at Nexo. Brief MI interventions (typically 4-sessions) have been shown to be an effective stand-alone treatment for at-risk to mildly dependent MSM who use club drugs, including individuals who were actively using cocaine and methamphetamines,^{71,77} and alcohol⁷⁸ with intervention effects sustained at the 12-month follow-up period. Co-located or integrated services facilitate effective referrals for in SBIRT program.⁹⁹⁻¹⁰¹ Furthermore, the availability of an effective, brief treatment specifically tailored to MSM and provided at an LGBT organization may overcome concerns about discrimination or microaggressions at general SATx programs that might otherwise lead MSM in need to eschew treatment.¹⁰²⁻¹⁰⁴ Successful referrals for individuals with high-risk use or dependence requires interventions with multiple sessions, as such, in the revised MHP we will incorporate specific content for motivating these individuals to enter specialized SATx.

3.2. INNOVATION

This study will be innovative in numerous ways. It will be the first study to:

- Develop an e-SBI program specifically tailored to address PSU and HIV risk behavior among MSM. While a few interventions exist to for PSU among MSM, this is the first e-SBI to focus on this population.
- Integrate a substance abuse e-SBI program into a community HIV testing program. Given that MSM usually seek out LGBT organizations for their HIV testing due to concerns about discrimination, this integration of an MSM-focused, e-SBI in an HIV testing program at an LGBT organization can significantly impact the identification of substance using MSM and their engagement in interventions to reduce their use and HIV risk behavior.
- Implement evidence-based interventions to reduce substance use and HIV risk behavior among MSM in Latin America, a first step that could lead to reshaping the way in which PSU and substance use disorders are treated in Argentina and in Latin America.

3.3. APPROACH

3.3.1. The Research Team. This study would continue the successful and productive collaboration between Dr. Balán and Nexo who, along with our colleagues at the *Institute for Biomedical Research on Retroviruses and AIDS* (INBIRS) at the University of Buenos Aires, successfully completed two NIH-funded studies. *LINKS* results have been reported throughout this proposal and were disseminated via 14 peer-reviewed publications,^{12,68-70,105-113} 12 professional conferences,¹¹⁵⁻¹²⁶ and in meetings with government officials and stakeholders in Argentina. The *Sex and Alcohol Study* (R21 AA018075; PI: Balán) explored venues frequented by MSM where alcohol use and sexual activity occur to identify factors contributing to the creation of high risk sexual spaces to guide the development of HIV prevention interventions specifically for such settings.^{114,127} Prior to our collaboration, INBIRS and Nexo had conducted the largest studies of HIV among MSM in Buenos Aires, one on HIV prevalence among 694 MSM¹²⁸ and the other a vaccine preparedness trial with 333 MSM that were recruited and followed for a year, with over 90% retention.¹²⁹ Nexo continues as the premier site in Buenos Aires for HIV testing among MSM, conducting over 1500 HIV tests per year was one of the sites initially selected by the National AIDS Program in

2013 to pilot the use of rapid HIV testing which is now the standard method of HIV testing in the country.

Drs. Balán and Naar are recognized experts in MI. Dr. Balán has developed numerous MI interventions for NIH-funded studies, including: integrating MI and psychopharmacology treatment^{130,131} to improve retention of Latino patients in anti-depressant treatment (R21-MH066388, R01-MH077226, PI: Lewis-Fernandez); linking dually diagnosed methadone patients into psychiatric care (R01-DA020783, PI: Blanco); and integrating MI and Brief Behavioral Activation Therapy for depression¹³² for dually diagnosed patients (R01-DA023973; PI: Blanco). He also developed an eSBI intervention to engage individuals with problem gambling into care and trained and oversaw the delivery of a brief MI intervention as part of an SBIRT program for adolescents with substance use and sexual risk behavior (R01 DA041065, PIs; Hoffman and Sandfort). A member of the Motivational Interviewing Network of Trainers, he also conducted MI training in Argentina at a substance abuse day treatment program and with the HIV testing counselors at Nexo. Dr. Naar is an internationally renowned researcher who, as a PI or Co-Investigator, has been involved in most of the MI-based interventions developed to support HIV prevention and treatment adherence, particularly among young MSM. Her *Step it Up* U19¹³³ (part of the Adolescent Trials Network) is currently studying in-person and remote implementation of YMHP. Dr. Naar has also previously used the eSBI platform we will use in this study to improve treatment adherence among young MSM living with HIV.¹³⁴

3.3.2. Overview of Study.

This proposed study consists of two stages. **Stage 1: Development** will consist of developing e-SBI, the adaptation of YMHP into MHP, training counselors to deliver MHP, and piloting 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 SATx 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: 1) Graciela Touzé, President of Intercambios Asociación Civil an NGO focused on policy, training, and social marketing regarding substance abuse; 2) Dr. Fabián Portnoy, Director of 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 Dr. Balán (in-person or via videoconferencing) and Lic. Marone 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. They will each be paid \$50 per meeting.

3.3.3. Components of the Intervention

3.3.3.1. 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.”¹³⁵ 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^{136,137} and less sustain talk during a session are related to better outcomes.^{136,138} Also, counselor behaviors such as advising, confronting, directing, and warning clients are associated with greater sustain talk,^{139,140} whereas affirming a client’s strengths or effort, emphasizing client control, and supporting are associated with increased change talk.^{140,141} 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.¹⁴² 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.

3.3.3.2. e-SBI. The proposed study will use 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. When used in medical settings CIAS can generate a range of reports for patients and/or medical providers, giving feedback on risks endorsed by patients. CIAS programs are HIPAA compliant with encryption of all data in transit and at rest and are hosted on a HIPAA-compliant cloud server. CIAS is based on five specific theories or models (see Table 1) and is consistent with human-computer interaction literature

suggesting that interactive, lifelike software can engage users and promote behavior change. 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 reads each item to the participant (using headphones for privacy), 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

Table 1. Theories/principles driving app development platform (CIAS)		
Theory/Model	Postulates	CIAS Capability
Common Factors Theory ¹⁴³	Non-specific therapeutic factors such as empathy, optimism, and working alliance explain much of the benefits of psychotherapy.	Prominently features a 3-dimensional narrator who responds synchronously, expresses emotion, has multiple lifelike movements, and can communicate empathy & respect.
Media Equation Theory ¹⁴⁴	People respond to computers as if they were social actors particularly when the computer is voice enabled.	Narrator talks aloud, interacts in a lifelike way, and delivers non-trivial reflections based on multiple prior responses.
Elaboration Likelihood Model ¹⁴⁵	Tailoring health communication content to the individual increases perceived relevance and therefore efficacy.	Branching and tailoring, including spoken use of the participant's name, to present information in a highly tailored and personalized manner.
Dual Coding Theory ¹⁴⁶	Providing information both verbally and visually promotes encoding and recall.	Ability to upload videos or images that the narrator can point to and elaborate on.
Cognitive Load Theory in Instructional Design ¹⁴⁷	Limiting extraneous stimuli can enhance focus, attention, and learning.	Clean, simple appearance; material is presented visually and aurally to minimize literacy-related obstacles

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 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 deploys readily on Android or Apple mobile operating systems. Content developed using CIAS is centralized and immediately available to all users, without relying on users to download each update. It also means that individual packages can be easily disseminated as a simple link (URL), thus clinic staff can prompt patients to access a simple website through which they could complete the e-SBI intervention. CIAS has been used with thousands of participants (primarily low SES) and has consistently received high satisfaction ratings.^{95-98,134} See letter of support from the CIAS developer.

3.3.3.3. Young Men's Health Project (YMHP).

YMHP is a 4-session MI-based intervention (see outline in Table 2) that was the first intervention to demonstrate reductions in substance use and sexual risk behavior among non-treatment-seeking substance using MSM.⁷¹ 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.¹⁴⁸ YMHP is listed

Table 2. Outline of the YMHP Sessions (60-minute sessions)
Session 1: Introduction to MHP; emphasize personal responsibility & autonomy for changing behavior; get to know client; priority clarification, elicit client's views of 1 st problem (substance use or sexual risk behavior); evoke change talk; build commitment to change; summary
Session 2: Review session 1 and client's week; Review feedback report; client's view of 2 nd problem (the one not discussed in the prior session); evoke change talk to build motivation to change; pros/cons exercise about problem behavior; assess readiness to change; summary
Session 3: Review session 2 and client's week; build/sustain commitment to change substance use and sexual risk behavior; develop change plan; re-assess readiness to change; summary
Session 4: Review session 3 and client's week; assess progress toward change; affirm successes; assess barriers to change and re-evaluate plan; summarize all 4 sessions; prepare for possible relapse; discuss appropriate referrals; termination.

in the CDC Compendium of Evidence-based Interventions and is currently part of the Adolescent Trials Network *Scale It Up* U19 (PI: Naar) in which they are comparing in-person to remotely delivered YMHP.¹⁴⁹ As described in 3.3.4.2., 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 SATx.

3.3.4. Stage 1: Development.

3.3.4.1. Development of e-SBI. Development of e-SBI app will be guided by the User Centered Rapid Application Development process (UCRAD).^{150,151} UCRAD merges the streamlined, iterative Rapid Application Development (RAD) approach¹⁵² with the User Centered Design approach (UC)^{153,154} 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.¹⁵¹ 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 application 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 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 application. 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 application is implemented in the field to obtain further feedback from potential users and further development of the application is conducted to reach a final product.

3.3.4.1.A Pre-design and interface prototyping. To accomplish this phase of UCRAD will obtain feedback from the CAB regarding the study screening instruments (see below) 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. 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 (sample instruments are included in Appendix 1):

- *NIDA-modified Alcohol, Smoking and Substance Involvement Screening Test (ASSIST)*^{155,156} 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.¹⁵⁷ A self-administered computer ASSIST was found to have 0.93 interclass correlation with the interviewer administered version.¹⁵⁸
- *Alcohol Use Disorders Identification Test (AUDIT)*,^{159,160} 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)*¹⁶¹ is a 10-item version of the SIP-AD¹⁶² ($\alpha = .95$) 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)*,¹⁶³ 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. Reliability of the initial version was established by means of a one-week test-retest of 29 participants and individual interviews of primary partners.¹⁶⁴ The SPAS has been adapted to different studies, including for *Proyecto LINKS*.
- *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,¹⁶⁵⁻¹⁶⁸ drug use,^{165,169-171} and sexual risk behavior.^{167,172} 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. FG participants will receive a \$25 incentive. Within 48 hours of completing the FG, we will initiate a rapid analysis of this data^{173,174} using a qualitative matrix^{175,176} onto which participants responses and recommendations will be entered in order to quickly organize and summarize FG findings. These findings will be used to build the prototype of the e-SBI.

3.3.4.1.B System architecture and coding. This Phase 2 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 developers⁹⁷ 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 four main areas: 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 who high-risk drugs 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 intervention. 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. These participants will receive an incentive of \$20. Figure 3 depicts our current conceptualization

of the e-SBI, with specific content informed by Phase 1 findings. Development of the e-SBI will be guided by Choice Theory,¹⁷⁷ which has been used extensively to inform goal choice interventions,^{178,179} 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 appear to be equally effective as those that are abstinence-based and allowing individuals to set their own treatment goals appears to increase success rates.^{180,181}

3.3.4.1.C. 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 conducted by Lics. Marone or Barreda. These IDIs will be guided by the Theoretical Framework of Acceptability¹⁸² (TFA; see components in Table 3), which was derived from a review of the literature on acceptability, and views acceptability as “a multi-faceted construct that reflects the extent to which people delivering or receiving a healthcare intervention consider it to be appropriate, based on anticipated or experienced cognitive and emotional responses to the intervention.”¹⁸²; p.4

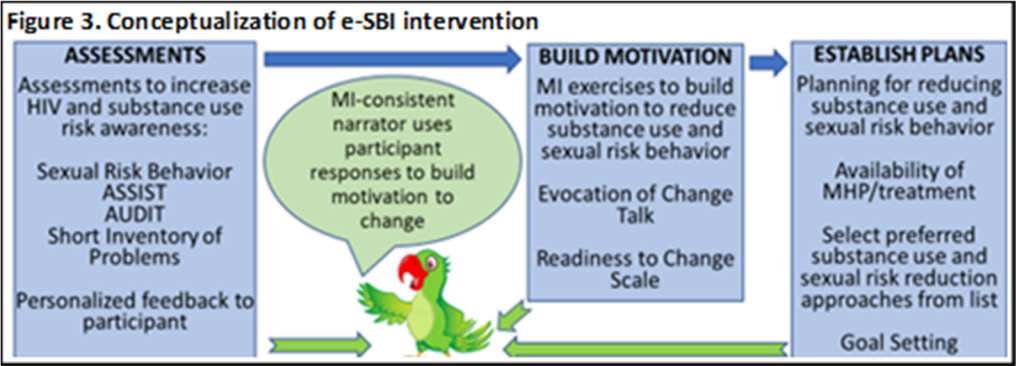


Table 3. TFA components

Affective Attitude: How the individual feels about the intervention
Burden: The perceived amount of effort that is required to participate in the Intervention
Ethicality: The extent to which the intervention has a good fit with an individual's value system
Intervention Coherence: The extent to which the participant understands the intervention and how it works
Opportunity Costs: The extent to which benefits, profits, or values must be given up in order to engage in the intervention
Perceived Effectiveness: The 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

The TFA has been used to guide qualitative and mixed methods research on acceptability of healthcare interventions, with each domain reworded into a Likert-type item to assess each component of the model.¹⁸³⁻¹⁸⁶ It can also be adapted to explore prospective, concurrent, or retrospective acceptability. These IDIs will be transcribed and uploaded to Dedoose for analysis (see section 3.3.6.1. for details). Additionally, we will use findings from these IDIs to finetune wording for a TFA-based quantitative assessments of acceptability that we will incorporate into the assessment battery during the Stage 2 RCT. Participants will receive a \$10 incentive for e-SBI; IDI participants will receive an additional \$10. Note: To provide them with needed services, participants with moderate or high-risk substance use will be offered MHP. However, due to timeline constraints, we will only conduct brief interviews to obtain preliminary feedback from participants who enter MHP as well as from counselors who deliver it in order to inform any additional adaptations prior to its implementation and formal assessment of its acceptability and feasibility during the Stage 2 RCT.

3.3.4.2. Adaptation of YMHP. MI interventions are used effectively globally^{187,188} including in Argentina,¹⁸⁹ and MI and SBIRT have been effective with Latinos in the U.S.^{130,131,190-193} which suggests that YMHP may be easily tailored to the Argentine context. In consultation with our CAB, Dr. Balán, Lic. Marone, and Nexo counselors will adapt YMPH, guided by the modified ADAPT-ITT framework¹⁸⁴ (see table 4). 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 YMPH 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 SATx for participants with high-risk substance use or dependence; and 3) adding content to address its poorer efficacy among partnered MSM.

Table 4. 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

3.3.4.2.A. Administration. To obtain feedback from members of the target population and key stakeholders, Dr. Balán (an experienced MI provider) will video-record YMHP sessions (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, Lic. Barreda will lead a discussion of recommendations to address the issues raised.

3.3.4.2.B. 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.

3.3.4.2.C. Topic Experts and Integration. Draft 1 of MHP will be reviewed by substance abuse experts on the CAB, Nexo counselors, and Co-Investigators (Drs. Balán and Naar and Lic. Marone) 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.

3.3.4.2.D. 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.^{195,196} As such, Dr. Balán 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. Dr. Balán will be accompanied by Dr. Naar for the MHP training, who will also meet with organizational staff and counselors to advise on challenges to implementing and conducting 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 Dr. Balán to rate using the Motivational Interviewing Treatment Integrity V.4 (MITI-4) scale,¹⁹⁷ which captures the counselor's level of fidelity to MI and establishes specific criteria for "Proficiency" in MI. Dr. Balán will also use these sessions to train Lic. Barreda to conduct MITI ratings during the Stage 2 RCT. These ratings will be used to assess MI skills that need further development, which will guide the weekly videoconference coaching sessions.

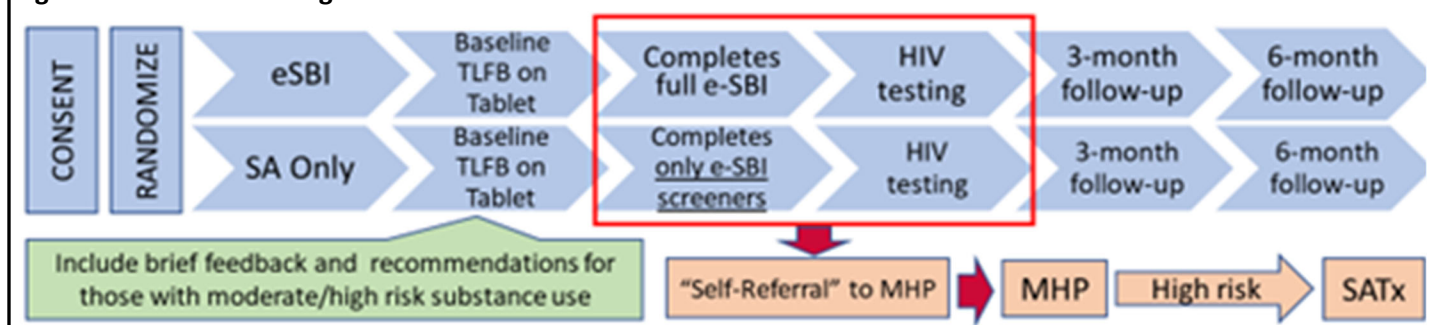
3.3.4.2.E. Testing. While the primary aims of this study focus on the e-SBI component, as a secondary aim we

will to assess the potential uptake and acceptability of MHP during the Stage 2 pilot RCT (see section 3.3.5.4.).

3.3.5. 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. 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 screening data, we estimate that 50% of 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 also assess uptake, acceptability, and feasibility of delivering MHP at Nexo and subsequent linkage to SATx among those with high-risk substance use or dependence. RCT processes are shown below.

Figure 4. Overview of Stage 2 RCT



3.3.5.1. 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.

3.3.5.2. Baseline Assessment. Participants in both conditions will complete a demographics questionnaire then a self-administered tablet-based 30-day *Timeline Followback (TLFB)*¹⁹⁸ 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.¹⁹⁹ and for sexual behavior.²⁰⁰ As in similar studies,^{71,76,77} the TLFB will be used to assess primary substance use and sexual risk behavior outcomes (which are exploratory outcomes in this study). After completing their respective condition (described below) all participants will complete two brief quantitative TFA-based Likert-type assessment to be developed from IDI findings in the Stage 1 pilot of e-SBI. First will be on retrospective acceptability of e-SBI or screening only worded generally for relevance to both groups (e.g., Participating in local project name...“took me away from other things that are important to me,” “...helped me realize how my substance use is impacting my life”). Then, after reading a brief description of MHP on the tablet, they will complete a similar prospective acceptability assessment of MHP.

3.3.5.3. RCT Study Conditions.

3.3.5.3.A. 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 to develop a risk reduction plan, regardless of their substance use. Then, they will proceed to the usual HIV testing process at Nexo.

3.3.5.3.B. 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, just the questions read to them neutrally. 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.

3.3.5.4. 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 using a HIPAA compliant platform such as Zoom Healthcare) 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 SATx, which would be provided at SEDRONAR (Secretariat of Comprehensive Policies on Drugs)-affiliated clinics in Buenos Aires, which provide substance abuse treatment free of charge. After accepting the referral, the participant and Nexo staff will contact SEDRONAR 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 and uploaded to a secure website where they can be accessed by Dr. Balán for review and by Lic. Barrera for rating with the MITI-4. MITI ratings will be conducted throughout the study and used to inform the weekly videoconferencing coaching sessions that Dr. Balán will conduct with the MHP counselors.

3.3.5.5. Follow-Up Assessments. All participants, including those who enter MHP or SATx, 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 programmed in RedCap and 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 SATx 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 SATx and those who did not to identify factors that might impact their decision to enter MHP. IDIs will be conducted at Nexo by Lic. Barrera, audio-recorded and transcribed. As incentives participants will receive \$15 for completing the baseline assessments and screeners, \$15 for completing the Month 3 assessments, and \$20 for completing the Month 6 assessments; those who complete an IDI at Month 6 will receive an additional \$20.

3.3.6. Data Analysis.

3.3.6.1. Qualitative data analysis for IDIs. Data analysis for IDIs conducted during the Stage 1 pilot of e-SBI and those conducted at Month 6 of the Stage 2 RCT will be similar but conducted separately for the two data sets. 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,²⁰¹ 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.

3.3.6.2. 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.

3.3.6.3. Quantitative data analysis.

3.3.6.3.A. 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 SATx; 3) mean acceptability of MHP and SATx 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.

3.3.6.3.B. 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.

3.3.6.3.C. 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 SATx). 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, sU , will be constructed from $sU = s \sqrt{c2n,.101/2}$, where s is the sample sd and $c2n,.10$ 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.

3.3.7. Addressing Potential Challenges.

3.3.7.1. Participant Recruitment. Given that Nexo performs over 1500 HIV tests per year with MSM, we expect that we will easily recruit the proposed sample size. If we note slower-than-expected recruitment during the Stage 1 pilot, we will prepare a targeted marketing campaign at Nexo using post cards and posters asking MI-based evocative questions to help Nexo testing clients ponder their HIV risk behavior and announce the availability of Nexo based services geared towards risk reduction.

3.3.7.2. Participant Retention. Our Nexo partners are experienced in retaining study participants, having successfully conducted a cohort study with over 90% retention over 12 months. As designed, this study inherently possesses components that have been found to aid in retention,¹²³⁻¹²⁵ including gay staffing to ensure cultural congruence, continuity in staff members who assist participants. We will also incorporate other approaches, such as monetary incentives, study branding that highlights benefits of the study, and maintaining contact with participants between study assessments. We describe these further in the Recruitment and Retention section.

3.3.7.3. Lack of uptake of MHP. The primary aims of the study focus on the e-SBI component; with uptake of MHP as a secondary aim. Our colleagues at Nexo have existing protocols to refer clients with PSU to specialized treatment at SEDRONAR clinics. We expect that the e-SBI and availability of MHP at Nexo will increase that. Nonetheless, assessing this uptake is an aim of the study. We will also obtain invaluable information during the Month 6 IDIs with individuals with PSU who did not request MHP to assess what contributed to that decision.

3.3.7.4. Changes in the availability of PrEP. Currently, PrEP is not available in Argentina. Its availability would significantly alter the HIV risk reduction component of the e-SBI. Because the CIAS is easily editable, it would allow us to integrate PrEP information, planning, and uptake into the e-SBI. This addition would depend on the timing of PrEP availability vis-à-vis the study timeline (would not do if PrEP became available late in the RCT)

3.3.8. Conclusion and next steps.

The proposed R34 study will begin to address a critical need for interventions to reduce drug and alcohol use among MSM with moderate or higher risk use by intervening at the time of HIV testing, a particularly opportune time when MSM are already contemplating their risk behavior and the potential consequences of their actions. The study will pilot the use of two evidence-based interventions, e-SBI and YMHP, that have established efficacy in reducing substance use and HIV risk behavior. This study will allow us to pilot all the study components and build the necessary research infra-structure for a subsequent fully-powered efficacy trial of e-SBI and MHP. Since MSM often access HIV testing through community-based LGBT organizations such as Nexo, using that existing infrastructure to identify and engage MSM with PSU in brief, effective, substance use and HIV risk reduction interventions could significantly reduce HIV infection and PSU among this population. This would be highly impactful not only in Argentina and Latin America, where few evidence-based interventions have been implemented to reduce HIV risk behavior among MSM and where PrEP remains unavailable, but also in the U.S. and other countries where such interventions have not been integrated into HIV prevention continuum of care.

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Statistical Design and Power Analysis.

A. 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 SATx; 3) mean acceptability of MHP and SATx 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.

B. 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.

C. 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 SATx). 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.