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RESEARCH STRATEGY

A. SIGNIFICANCE

A.1. HIV and other STIs Threaten Young Women's Health

There are 21 million women aged 18-29 yr. Among adults 18-29, 90% of heterosexually-acquired HIV occurs among women;[12] women 18 to 29 have the highest rates of gonorrhea and chlamydia relative to similarly-aged men and older women. Low-income women are particularly vulnerable.[22,23] Consequences of STIs include reproductive health problems, fetal and perinatal health problems, cancer, and facilitation of the sexual transmission of HIV.[24] The cost of all STIs in the U.S. health care system exceeds $15 billion annually.[25]

A.2. HIV Prevention Interventions for Young Women are Efficacious but can be Strengthened

Sexual risk reduction interventions designed for young women have been evaluated.[26-37] Meta-analyses show that interventions increase condom use, decrease number of partners and, in some cases, reduce STI incidence,[38,39] but they also note that these interventions show only small effect sizes. Most trials report limited participation (especially by individuals who engage in heavy drinking[40]), and limited uptake (by health settings).

a. Small effect sizes suggest that important determinants of risk behavior have not been adequately targeted. One of the strongest determinants of sexual behavior is alcohol use.

Alcohol is the most commonly used substance among young women at elevated risk for HIV: The HPTN 064 Study found that 63% of women reporting binge drinking in the 6 months prior to enrollment; among these, more than one-third reported binge drinking on a daily to weekly basis.[41] Relative to women in other age groups, women 18-29 yrs are the most likely to drink, to binge drink, and to meet criteria for alcohol use disorders (AUDs).[42] Even among lower risk samples, among young women, ~50% drank alcohol and ~20% binged (4+ on an occasion) in the last 30 days.[43] Thus, alcohol use and binge drinking are highly prevalent.

Alcohol use is routinely associated risky sexual behaviors – including concurrency,[44,45] incorrect or non-use of condoms,[16,46,47] more partners[16,48] – and more STIs, including HIV[16,48-53] Although alcohol use has been operationalized in a variety of ways, both lab[54] and clinical[16,55] studies show a dose-response relationship.

Alcohol's effects are more harmful for women relative to men: Women are more likely to experience cognitive/motor impairment due to intoxication;[56] they are also more vulnerable to physical harm, sexual assault, and reproductive problems.[56] Women with an AUD attending a family planning clinic were more likely than those without an AUD to report multiple partners, to take drugs or money for sex, to have removed condoms during sex, and to have unplanned sex due to drinking.[49] The relation between alcohol use and sexual risk behavior is stronger for women than for men: In one study, women binge drinkers had 2x the rates of multiple partners, 4x the risk for anal sex, and 5x the rates of gonorrhea compared to women abstainers whereas binge drinking by men did not affect their sexual behaviors.[17] Thus, alcohol use increased the number of partners for women but not men.[17,57] Heavy drinking women are also more vulnerable to unintended pregnancy and use emergency contraception more than other women.[48]

Alcohol use interacts with relationship factors to uniquely increase women's risk for HIV. Gender-based power imbalances (i.e., due to differences in age, sex roles, physical strength, economic resources) contribute to risk for young women,[58,59] who often must persuade a male partner to use a condom. Data also document the increasing prevalence of sexual hookups—short-term relationships with no expectation of mutual commitment.[60] Hookups are more likely to occur in the context of alcohol use. Condom use is less common with main vs. casual partners,[61,62] and the latest research shows that condom use varies even among "casual" partners (e.g., baby daddy, ex-boyfriend, friend with benefits, one-night stand)[19] based on relationship importance, perceived risk, and trust – characteristics that influence expectations for condom use.[20] Women but not men, who drank before sex were less likely to use condoms with casual partners.[63] Addressing relationship factors and alcohol use is necessary to optimize the efficacy of risk reduction programs for women.

Given the associations between heavy drinking and sexual risk taking, increasing exposure to HIV-prevention counseling programs among heavy drinkers can serve a vital public health function.[40] Despite the important role of alcohol as a determinant, HIV interventions seldom address alcohol use in a direct way or, when they do, group-based interventions do not allow for discussion of alcohol use and sexual risk behavior in a personalized way, tailored to an individual's risk and relationship context. Alcohol content must be integrated to optimize the efficacy of HIV prevention interventions for young, at-risk women.[15,64]

b. Limited uptake suggests the need for more feasible interventions. A second challenge for HIV prevention efforts is the limited participation rates and low uptake of intensive interventions. Most empirically-validated interventions for women involved multiple sessions and occur in groups[39], features that undermine their appeal and feasibility. Even single session interventions that last > 1 hr are poorly attended. For example, an intervention that involved attendance at a 4-hour workshop managed to draw only 55% of interested women, despite the provision of generous financial incentives, child care, and removing other barriers to participation;[9] low participation rates and poor attendance are common for group-based programs. Further, the cost of staffing and providing such groups make their ultimate dissemination unlikely.

c. Summary. Improving the public health impact of HIV prevention interventions for women requires (a) enhancing their efficacy by targeting a key determinant of risk, alcohol use, in the context of complex relationship dynamics, and (b) delivering the intervention in formats and settings that will increase uptake.

A.3. Improving the Efficacy of Interventions by Integrating Alcohol Use and Sex Behavior

Single-focus risk reduction interventions are suboptimal. Those that focus on sexual behavior produce small effects on sexual behavior;[65] when they address alcohol use, the components are not powerfully enough. Similarly, interventions that focus on alcohol use also produce small or no effects on sexual risk behavior.[4 5]

Suboptimal results of single-focus interventions has led to calls for increased integration of alcohol-sexual behavior research,[64] echoing calls for multiple health behavior interventions from experts in other health-behavior domains.[66-69] The rationale for integrated interventions has both theoretical and empirical precedent.

Theoretically, an integrated alcohol use—sexual risk intervention aligns well with models that explain the bidirectional effects of alcohol and sexual behavior. For example, alcohol myopia suggests that intoxication narrows attentional focus to salient cues in the present (e.g., sexual arousal) and blurs distal inhibitory cues (e.g., concern about STIs), undermining decision-making.[70] Also, skills-based models recognize that alcohol intoxication impairs the interpersonal (condom negotiation) and motor (condom application) skills needed for safer sex.[71,72] Alcohol expectancy models posit that intoxicated risk behavior is in part determined by beliefs that sexual pleasure is enhanced when one has been drinking and/or that alcohol disinhibits sexual behavior.[73]

Empirically, one reason to address both sexual behavior and alcohol use together is the fact that alcohol use does not always precede sex, and it is only one cause of sex behavior. Thus, even if an alcohol-focused BI reduced alcohol use (and alcohol-related sexual risk), it probably would not eliminate sexual risk. Second, although alcohol use is often assumed to precede sex, there is evidence of "reverse causality."[74] Thus, sexual behavior (or its anticipation) is known to lead to alcohol use. For example, people may drink to provide an excuse for risky behavior, to enhance sexual pleasure, to disinhibit sexual behavior, or to reduce distress, regret or guilt following sex.[75,76] For young women in particular, sexual behavior also brings them into contact with older, riskier partners,[77] who are often riskier drinkers.[78] However, not all drinking is motivated by sex. Thus, the co-occurrence of alcohol use and sexual behavior is complicated, and often hinges on relationship factors. For example, recent research shows that alcohol use among young women varies as a function of relationship type, with alcohol being used more with casual partners.[79,80] An integrated approach recognizes the complexity of these two, often but not always co-occurring, risk behaviors.

Empirical support for integrated alcohol-sex risk reduction interventions are more limited. A few studies do show benefits but these have been multiple session interventions with at-risk men.[81,82] Studies with women are rare. A small pilot study tested a 5-session integrated intervention with 19 women diagnosed with an AUD[83]; the results were encouraging but such an intensive intervention is infeasible in a public health setting with non-diagnosed but at-risk young women. A second study (male and female college students) compared a BI that had a single-focus on alcohol or HIV to a BI that combined (but did not integrate) content.[84] Although receipt of alcohol content reduced risky drinking, neither the HIV nor the alcohol content (separate or in combination) reduced number of partners or unprotected sex. This intervention did not integrate alcohol and sexual behavior, nor was it gender-tailored; further, this study sampled a population that was at relatively low risk for HIV, limiting its generalizability to settings where STIs are more prevalent.

Overall, the limited efficacy of single-focus interventions, coupled with the conceptual and empirical rationale for integrated interventions, indicates the need to develop an integrated alcohol-and-sexual risk reduction interventions for young, at-risk women in order to optimize sexual risk reduction.

A.4. Increasing Uptake of Interventions for Women

The uptake of an integrated alcohol-sexual risk reduction program for women will be enhanced to the extent it is (a) delivered in a setting that is accessible to young at-risk women and (b) brief (i.e., ≤ 1 hr).

a. Providing interventions in an accessible setting. One setting that can provide an opportune venue for an integrated intervention is the reproductive health / family planning (RHFP) clinic. RHFP clinics serve the sexual health needs of young women. Young women often seek birth control, family planning, and STI services at RHFP clinics. In addition to family planning, pregnancy prevention, and STI care, RHFP clinics provide other gynecologic services (e.g., PAP smears) and tend to be female-friendly, accessible, and lower cost, providing basic health services for low-income women who are especially vulnerable to HIV and other STIs.

Low-income young women are less likely to see a primary care provider than older women,[11,21] yet more than 75% of young women had a RHFP clinic visit in the last year.[21,85] Moreover, young women in RHFP clinics are often at risk for alcohol misuse with 30% to 40% screening positive for at-risk alcohol use[4,17,49,86-88], rates much higher than found in the general population.[49] In our work, 52% of women reported binge drinking in the last 3 months, alcohol use was associated with increased sexual risk behavior,[63] and young women who binge drank were more likely to report multiple partners,[23] corroborating reports from other sexual health settings.[4,17,49] Findings such as these have led public health experts to conclude that sexual health settings, including RHFP clinics, may be "*an ideal setting in which to integrate screening and intervention strategies related to substance use problems among young persons*."[49]

Evidence suggests that screening for alcohol misuse is feasible in STI/sexual health clinics.[86,88] Despite the promise of RHFP clinics as an intervention venue for at-risk young women, no study has implemented a integrated intervention in a RHFP setting and evaluated sexual behavior outcomes. Given the relation between alcohol use and risk behavior for young women, this represents a missed opportunity for HIV/STI prevention.

b. Brief interventions (BIs) are acceptable and feasible. At a time when the public and private sectors need to reduce the cost of health care, the need for BIs is greater than ever. Fortunately, there is evidence of efficacy for BIs for both alcohol use[89,90] and for sexual risk reduction.[65] Indeed, BIs are the most effective individual-level intervention for reducing young adult alcohol abuse.[91]

Brevity limits the amount of material that can be provided during an intervention. Fortunately, with the decreased cost and increased uptake of smartphones, the receding digital divide, and high-speed internet access, technological aids (i.e., texting, websites) can now be used to extend and bolster BIs. Data indicate that 98% of 18-29 yr olds own cell phones, and 83% own smartphones;[92] among low-income young people, 77% own smartphones.[93] However, even low cost "Go" phones provide mobile messaging. Among 18-29 yr olds, 97% of cell phone users receive or send text messages[94]; "texting" is fast, low-cost, and very popular among young people.[95,96] Moreover, 84% of young people access the internet with their phones,[94] and 98% of all 18-29 yr olds access the internet. When online, 72% of 18-29 yr olds report looking for health information, especially on sensitive topics such as substance use and sex;[97] 95% watch videos online, with "how to" videos watched by 78% of this age group.[98] Thus, texting and online videos have an unprecedented "reach" among young people, magnifying the potential public health impact (i.e., impact = reach x efficacy[99]).

Thus, cultural and technologic changes create opportunities to supplement BIs with technology-facilitated content. An emerging body of research suggests the use of mobile messaging for health promotion, especially smoking cessation.[100-119] BIs can also be supplemented and their impact extended with internet resources. For example, in one study, the efficacy of screening for problem drinking was enhanced when it was supplemented with an alcohol risk reduction website.[120] Risk reduction content is available on governmental websites (e.g., CDC, NIAAA) as well as on websites maintained by credible non-profit organizations (e.g., Planned Parenthood). We[10] and others[e.g.,121] have developed risk reduction videos that have been empirically validated, and can be viewed at any time. Such videos model and teach key skills such as condom use, sexual assertiveness, and drink refusal. Video modeling of skills can facilitate learning new health behaviors[122] as well as promoting self-efficacy, consistent with social cognitive theory.[123] Furthermore, mobile messaging has been used successfully to prompt greater interaction with web-based health programs.[124]

In the proposed research, we will use these two tools together, as complementary BI "extenders." Mobile messages (e.g., texts) containing reminders of change goals and embedded links to a rich website, can extend the intervention during the critical weeks following receipt of a clinic-based BI to promote maintenance of initial change. Mobile messaging can draw women to a website that extends the BI beyond the clinic; such a website can model and shape skills is a way that a clinic-based BI often cannot, due to resource constraints.

We considered using technology to deliver the BI as well. We recognize its appeal (e.g., more efficient, standardized content, less staffing). However, we decided that it would be premature to skip over the important step of demonstrating efficacy of an integrated BI with a face-to-face BI before proceeding to a tablet-based BI; that is, if we tested a tablet-based BI and did not find efficacy, we would not know if it was because of the administration modality or the efficacy of a integrated BI. Our primary- and meta-analytic research indicates that, among women, face-to-face BIs produce larger effects than do computer-delivered interventions.[89] Therefore, with this R34, we begin by developing a face-to-face BI that integrates alcohol and sexual risk in a gender-sensitive way; next, we will evaluate this intervention in a fully-powered RCT; then we can adapt and evaluate its delivery using a tablet or other mobile device.

A.5. The Proposed Research

After formative work, we will develop a brief, integrated (alcohol-and-sexual risk) risk reduction intervention for young at-risk women who seek care at a RHFP clinic. The BI will (a) be informed by theory and pilot work; (b) be female-centric; (c) target pathways through which alcohol increases sexual risk (e.g., poor decision making, lessened ability to enact protective strategies); (d) target the co-occurrence of drinking and sex; (e) address a range of partner relationship types; and (f) be supplemented by a technology (mobile messaging and website) extender to address behavioral skills and promote maintenance of initial gains. We will also collect evidence of feasibility and initial efficacy in preparation for a R01-supported efficacy trial.

The proposed research **aligns perfectly with PA-13-078[125]** because it: (a) proposes Stage 1A & 1B research, (b) includes screening, BI, and use of technology, (c) will be done in a "real world" community setting using community providers, (d) focuses on HIV prevention for women who engage in hazardous drinking, (e) incorporates novel intervention components (e.g., partner dynamics) into existing BI models for reducing alcohol risk, (f) involves feasibility and pilot testing for a behavioral intervention, and (g) involves use of technology to extend a BI for alcohol use.

B. INNOVATIONS: We suggest that four aspects of the proposed research are innovative:

B.1. Integration of alcohol and sexual behavior content in a risk reduction intervention targeted to young women. Few interventions explicitly target the strong association between heavy alcohol use and sexual risk behavior with an integrated intervention; most of those that have been done have targeted men.[e.g.,81,82] Currently, there are no empirically-supported integrated interventions for U. S. women.

B.2. Detailed attention to partner type – differentiating among different types of casual partners (e.g., hookups, baby daddy, friends with benefits) – as a key determinant of risk behavior. Although research shows that condom use varies for main and casual partners, an emerging literature reveals that people make more nuanced distinctions about their partners, and this strongly influence condom use.[19,20] In the qualitative phase of our research, we will elicit precise information about the types of partnerships young women report, as well as the co-occurrence of sexual behavior and alcohol use by partner type. We will incorporate this new information in our intervention, and we will assess changes in behavior by partner type in the evaluation plan.

B.3. Implementation in an accessible RHFP setting. Women at RHFP clinics are at high risk for alcohol misuse and negative sexual health outcomes. Research shows the utility of alcohol BIs for college-attending women but the clients of many RHFP clinics differ in important ways from college students, e.g., they tend to be less well-educated, have lower literacy skills, are less like to have access to routine medical care, are more likely to be from a minority racial/ethnic groups and from lower socioeconomic groups, and are more vulnerable to STIs, sexual violence, and unintended pregnancy. Tailoring an integrated alcohol-sex risk reduction intervention to this more vulnerable, community-based population is highly innovative. An integrated intervention for clients in this setting would reach an at-risk population and could be widely disseminated.

B.4. Use of technology "extenders" to enhance the scope of the BI and maintain initial gains. We will use mobile messages to support the risk reduction goals established in the BI and to draw women to a well-resourced website that contains compelling materials (developed previously, vetted and organized to be easy to navigate) to extend the BI conceptually (i.e., by providing skills modules) and make it available around the clock. These "extenders" will broaden the scope of the BI, enhance its external validity by making it available in women's natural environment, and maintain initial gains obtained with the clinic-based BI.

C. PRELIMINARY STUDIES: Although R34 applications do not require pilot data, we collected pilot data and have completed projects that demonstrate the feasibility of the proposed research.

C.1. Alcohol use, sex risk behavior, and their co-occurrence. We recruited 80 consecutive female patients (*M* age = 23 yr; 50% Caucasian) at the proposed site who responded to a survey: 51% exceeded the cut-off for alcohol misuse on the AUDIT-C, indicating a large pool of eligible patients.

Our research with young women documents the co-occurrence of alcohol use and sexual risk. Data from 483 young women, investigating relationship type, alcohol use, and sexual risk, showed that alcohol use predicts sexual hookups (R21AA018257). Data from 735 young women recruited from a RHFP clinic (R01NR008194) showed that (a) 50% of vaginal sex were not condom-protected; (b) 33% reported ≥ 1 sex partner (past 3 months); (c) 28% reported binge drinking, which was associated with both multiple partners and unprotected sex (*p*s<.05); (d) 25% reported drinking before sex (3 months), which was associated with unprotected sex (81% vs. 70%) and multiple partners (46% vs. 26%). Further, with data from 1557 men and women (R01MH068171), we found that gender moderated the alcohol-risky sex relationship, i.e., alcohol use was associated with number of sexual partners only for women (*p*s ≤.03). Exploratory analyses clarified the mechanism(s) by which alcohol use before sex leads to STIs, namely, alcohol use before sex increase's women STI risk in two ways: (a) not using condoms, and (b) not using condoms correctly.

C.2. Intervention design and evaluation. M. Carey is an expert in the development and evaluation of sexual risk reduction interventions;[9,10,35,126] K. Carey is an expert in the development and evaluation of alcohol use interventions.[89,127-129] The proposed work integrates these areas of expertise. In addition, these investigators have designed, implemented, and evaluated more than a dozen interventions with young women (e.g., R01AA012518, R01MH068171, R01NR008194, R01MH54929).

C.3. Use of technology as intervention extenders. Our pilot data also addressed acceptability of mobile messaging. Of the clients surveyed, 99% indicated that they had a cell phone and 71% indicated that they welcomed texts about their health care. In addition, previous experiences includes use of email as BI boosters (R01AA012518) or intervention prompts,[130] and video-based interventions (R01MH068171, U01MH66794). We have worked with programmers, health communications experts, and video production companies to produce gender- and culturally-sensitive, theoretically-based intervention components delivered by technology.

C.4. Clinical expertise. The PI and all Co-Is are fully licensed clinicians. Kaplan is a full-time employee at the clinical site where the work will be done; there she practices as an Advanced Practice Clinician (APN). APNs review patient chief complaint and history and identify any unique needs; perform physical examination, document all findings in medical record, order any appropriate laboratory testing and review and manage results; and implement individual plan of care, including treatment and any needed referrals.

C.5. Summary. Pilot work shows that women in RHFP clinics report alcohol misuse and sexual risk behavior, cell phone use, and willingness to receive texts for health. Our prior research shows (a) the co-occurrence of alcohol use and sexual risk behavior with women, (b) our ability to design and evaluate BIs targeting alcohol use and sexual risk behavior, and (c) our use of technology as intervention extenders. The team includes 5 licensed clinicians. Overall, we are well-qualified to conduct the proposed research.

D. APPROACH

D.1. Methodological Features Common to All Study Aims

a. Venue. Research will take place at the Planned Parenthood Health Center, which serves as RI's largest provider of RHFP and STI services. The Health Center also provides physical exams, gynecologic care, treatment of common illnesses [e.g., cold; flu; bronchitis; ear, sinus, and fungal infections; strep throat; acne; GI (e.g., reflux) and musculoskeletal complaints (e.g., back pain)]. It is an ideal setting to reach at-risk women.

b. Participants (~*N*=90). We will recruit (a) 25 women for Aim 1, (b) 8-15 women for Aim 2, and (c) 50 women for Aim 3. Sample sizes are based on published recommendations for Phase 1 Treatment Development Research.[8]

c. Screening. During routine visits, females aged 18-29 will be invited to complete an anonymous health survey on a tablet computer. This survey will include study inclusion criteria as well as items assessing health behaviors (e.g., smoking, exercise, diet, sleep), to mask inclusion criteria. The **inclusion criteria** are: (a) female, (b) age 18-29 yr, (c) meeting NIAAA definition of "at-risk" drinking (>3 drinks on any day in the last 3 months[18] and/or >7 drinks per week); (d) sexual risk behavior (i.e., last 3 months: vaginal/anal intercourse with >1 partner; vaginal/anal intercourse with a partner who has other partners; inconsistent condom use; new relationship (under 3 months)); (e) English speaking; (f) absence of acute intoxication, depression, or suicidal ideation; and (g) no plans for relocation (Not an inclusion criterion for Aim 1 or Aim 2). Aim 2 will have a

second method of recruitment as well. During Aim 1 some participants opted to complete a form to be contacted for future research. Participants who completed this form will be contacted via telephone and/or email (whichever contact method(s) were provided on the form) to assess if the participant is interested in participating in Aim 2.

Rationale for **exclusion criteria**: (a) Gender: We restrict to women because of their greater risk for alcohol-sexual risk behavior and STIs; we will tailor the BI to the unique needs of women. (b) Age: We exclude those <18 because adolescents differ cognitively from adults, and require interventions tailored to their developmental stage.[132] We exclude women >29 to target women at greatest risk for alcohol and STIs, and so we can use national norms for sexual behavior[133] and alcohol consumption[42], which are available for this age range. (c,d) Alcohol and sexual risk behavior: We exclude those without alcohol misuse or sexual risk because they do not have need for the BI we are developing. (e) Language: The vast majority of patients at the clinic speak English. At this stage of the research, developing materials in more than one language is not feasible. (f) Meaningful participation: We exclude patients who are intoxicated or in acute distress because they may not be able to provide informed consent or reliable data. (g) Relocation: Patients who plan to move in the next 3 months would not be available for follow-up. Once the screening is completed, a message thanking the patient will appear on the tablet screen, and a text will be sent to the RA regarding the patient's eligibility and interest.

d. Consent. The RA will return to the room to collect the tablet computer and, for patients who had met the eligibility criteria and expressed interest, the RA will explain the details of the study (detailed below).

Aim 1: Patients will be told that we are conducting focus groups with young women regarding topics that affect relationships including partnership formation, safer sex, alcohol use, and how these factors may relate to HIV/STIs. We will explain that the goal of the focus groups is to develop a health promotion intervention for women who attend the clinic. In exchange for their time and to offset expenses, they will be compensated $40. (See Aim 1 Recruitment Script)

Aim 2: Patients will be told that there is a study about a new service designed to help women to reduce STI risk, that the study involves completing four possible parts: a computerized survey, meeting with a counselor and receiving feedback about their health behaviors, providing feedback about the session, and providing feedback about the developed technology. Women will be told that the consultation is free, and that they will be invited to provide feedback on the experience. In exchange, they will be compensated $40. Interested patients will hear about study procedures, provide verbal informed consent, and schedule a session.

Aim 3: Patients will be told that study participation will involve two health behavior assessments separated by 3 months; in addition, participants will be assigned (randomly) to receive standard services supplemented by (a) an educational brochure detailing the effects of alcohol on sexual risk and women's health (control) or (b) a meeting with a health educator that includes receipt of feedback about their health behaviors as well as technology extenders to be used in between the two assessments. Women in both conditions will receive $30 for completing the baseline assessment and $40 for completing the follow-up assessment.

All Aims: After procedures are described, women will be asked questions to ensure comprehension.[134] For Aim 1 and Aim 2 those who show understanding and interest will be scheduled for a focus group (Aim 1) or intervention (Aim 2). For Aim 3 those who show understanding and interest will sign a consent form and be scheduled for an assessment. Contact information will be obtained for reminder calls/texts as well as contact information for two "locators" who will be contacted in the event that the participant is unreachable.

D.2. Conduct formative work with heavy drinking young women (Aim 1) [months 4-10]

a. Focus groups (FGs). We will use FGs (rather than individual interviews) to capitalize on the rich discussion that occurs when individuals have a chance to elaborate on or challenge others' thoughts and opinions. FGs will be conducted with women who meet inclusion criteria (described in 1.c) in a private conference room at the RHFP clinic (CBPM Coro-based office will serve as a backup location). FGs will last ~2 hr, and will be audiotaped. Refreshments will be provided, and participants will be compensated $40 for time and expenses. FGs will be co-facilitated by Co-I Morrow (who has expertise conducting FGs addressing women's reproductive health) and Co-I K. Carey (who has expertise in the development and evaluation of BIs for alcohol use). A female study staff member will attend as a note-taker.

The proposed sample size (*N* ~ 30-40) is an approximation based on past experience. Our initial plan is to conduct a total of 6-8 FGs, in two waves of at least three groups; that is, after completing the first three FGs with about 4-6 participants each, we will have the audio recordings transcribed verbatim, review the transcripts,

determine areas that require greater detail, then run three more groups with about 4-6 participants each, until we reach content saturation. This iterative process has served us well in previous research.

The Co-Facilitators will follow a semi-structured facilitation guide to ensure that all key topics are covered (See Aim 1 Focus Group Agenda). A semi-structured agenda ensures that facilitator gather data across the same dimensions for all FGs. The agenda will be written to assist the facilitators but will not be a rigid script that must be adhered to. This ensures that the facilitators gather data on the same topics, but affords flexibility of natural narrative conversation to pursue *a priori* topics, as well as emergent themes. This is a particularly helpful method when attempting to discern an individual's cognitive process, when the unique strategies impacting an individual's decision-making require elucidation. Domains of interest will include:

i. Relationship formation and types: What types of relationships are there? (probes: hookup, friends with benefits, father of child, boyfriend, ex-, one-night stand) How do these relationships differ?

ii. Safer (risky) sex: What is "safer sex"? Why do some people find it easy [difficult] to practice safer sex? (probe: Why do couples find it difficult to use condoms?) What choices do women have if men refuse condoms? (probe: Do you think these are realistic options?) Why do you think someone should (not) use condoms? How would you advise a woman friend about how to go about asking a partner to use a condom?

iii. Relationship types and sexual risk: Is condom use easier [harder] with some relationship/partner types? (probes: boyfriend, ex-boyfriend, father of child, friend-with-benefits, someone I want to have a relationship with, one-night stand). What are the barriers to using condoms for STI protection with each partner type? What can women do to avoid STIs (and pregnancy if desired) with each type of partner?

iv. Alcohol use and relationships: Tell us about how and where young women drink? How does alcohol use relate to sex? to hooking up? to condom use? How does alcohol affect different partner/relationship types? How does drinking alcohol contribute to sexual risk: (a) inconsistent use of condoms, (b) improper use of condoms, (c) having multiple/concurrent partners, and (d) choosing risky partners.

v. BI structure and content: Would you be interested if the clinic provided brief counseling about how to lower your risk for STIs within different types of relationships? How to manage alcohol use to stay healthy? If we offered this, what are some things we should do (or avoid) to appeal to young women? What should we do to make sure women see this as helpful? How can we make it relevant to young women in the community?

vi. Technology extenders: What kind of info about relationships (alcohol use, safer sex) would be most helpful? How often should messages be sent? What would be annoying? What are best ways (e.g., text, Twitter, Facebook) to message? How would you text a friend to be helpful (elicit texts from participants[135])? What websites do you visit? What do you like (dislike) about them? How often do you search for health (relationships, sex, alcohol) topics? What types of online videos have you found helpful? How and where did you find them? How would you organize website so it makes material easy to locate and appeals to you?

Women in FGs will be asked to do card sorts[136] to inform user-friendly website development.

b. Data analyses. We will analyze the FG data using content and thematic analysis (our team brings extensive experience in the analysis of qualitative data[137-147]). Immediately after a FG is completed, team members will debrief, summarizing outcomes from the FG. Debriefs will be written addressing the constructs of interest to the BI and extender development and assessing saturation. These preliminary summaries will be used in intervention development, prior to formal coding and analyses. Once transcripts have been cleaned, we will begin data coding, so that subsequent FGs can capitalize on new information to further refine our understanding. A nested coding structure will be developed. Initial codes will be derived from the agendas; new or refined codes will be accomplished iteratively as the team reviews transcripts. The Investigators will review each transcript, using the coding structure and noting considerations for additional codes / refinements of existing codes. We will discuss any coding discrepancies and agree to a final code set. As transcripts are coded, they will be integrated into the NVivo 10 (QSR Int.) data project. Demographic characteristics will be entered into the NVivo project as attributes so that, as hypotheses are developed, they can be studied in the qualitative data; e.g., the investigative team may develop a hypothesis that women with a certain type of partner may require specific motivational messages. These characteristics can be used to structure the qualitative data into "sets" so that these notions can be evaluated within and between the data sets. Once all transcripts have been coded, thematic analyses of the qualitative data will be performed. Individual codes and/or related codes will be queried and summarized for major themes and patterns, both those originally proposed and emergent themes. All data will be characterized as a function of range and modal

characteristics. This will allow us to consider both the commonalities in the data, as well as any unique data points that should be considered in the development of the BI and extenders.

D.3. Develop an integrated alcohol and sexual risk reduction intervention (Aim 2.a) [months 10-15]

a. Overview. The purposes of Aim 2.a are (a) to use the data obtained from our formative work (Aim 1) to develop a BI with the goals of reducing at-risk drinking and sexual risk behavior, and (b) to implement this BI with 8-15 women to determine feasibility and acceptability and to obtain feedback to revise the BI in advance of further testing (Aim 3). The integrated BI will target the following: (a) reductions in quantity of drinking per occasion, binge frequency, drinking before sex, and alcohol-related consequences; (b) increases in the proportion of condom-protected sex acts, correct use of condoms, and reductions the number of partners; (c) knowledge of how alcohol use impairs decisions to have sex and use a condom, and undermines safety; and (d) how to prepare for situations in which alcohol is used (e.g., having an exit strategy, going with a friend, and bringing condoms when going to bars; protective behavioral strategies[148]).

This intervention development and refinement will involve iterative steps: (a) Our team will review FG transcripts, identify participant-generated challenges and solutions related to alcohol use and sexual risk reduction, and incorporate them into a BI manual. (b) We will administer the BI with 8-15 women, from whom we will invite feedback during a post-BI debriefing. The team will review the feedback and interventionist notes, and suggest modifications to BI protocol throughout the pilot work. (c) We will refine the manual to reflect the lessons learned from the pilot testing. The deliverable of this aim is a fully articulated BI and manual that has demonstrated feasibility and is ready for evaluation.

b. Theoretical underpinnings of BI. Content of the integrated intervention will be guided by theories with strong traditions informing interventions for both target behaviors. The Information-Motivation-Behavioral Skills (IMB) model[149], widely used to guide sexual risk reduction interventions, posits that information, motivation and behavior skills are prerequisites to HIV-protective behavior. Consistent with the IMB model, Fishbein's Integrated Model (IM)[150] suggests that motivational variables include attitude, perceived norms and self-efficacy. We believe that an integration of IMB and IM is warranted given that the **strength of these motivational variables varies by partner type**, that is, self-efficacy predicts condom use with casual partners whereas attitude and partner norms predict condom use with steady partners.[62] Furthermore, theories used to explain alcohol's role in sexual risk taking (e.g., alcohol myopia and expectancy theory[73]) posit that alcohol intoxication reduces attention to distal consequences (e.g., concern about STI) as well as engaging positive expectancies for sexual behavior, which undermine motivation for safer sex practices. Furthermore, alcohol intoxication degrades behavioral skills (e.g., correct condom use[72,151] and condom negotiation[71]), particularly important for women who need the cooperation of a partner to successfully protect themselves from STIs. Thus goals of our intervention include improved attitudes regarding safer sex behaviors and drinking levels, corrected exaggerated social norms with regard to alcohol use and sexual behaviors; enhanced self-efficacy with regard to adopting less risky alternatives to binge drinking and risky sex; and goal setting to promote risk reduction intentions. We will do this in the context of relationships with specific types of partners.

With regard to intervention process, we will use motivational interviewing (MI) to help women to identify behavior change goals and work through ambivalence about change. MI is a collaborative, goal-oriented form of communication that strengthens motivation and commitment toward specific goals; it elicits a woman's own reasons for change in a context that is accepting and respectful of her autonomy.[152] The emerging theory of MI[153] suggests that its influence derives from relational (a collaborative stance that respects autonomy, empathy) and technical components (creating discrepancy to motivate change, reinforcement of change talk leading to commitment to change). This approach is appropriate for the current context in which women may hold mixed feelings about protecting themselves from HIV because they enjoy drinking and/or do not wanting to upset a partner or threaten a relationship. Interventions based on MI have been effective in initiating change in a range of health behaviors, including substance abuse and sexual risk behavior.[154]

c. BI structure and content. Based on the specifics of our formative work we expect to supplement feedback on alcohol-use consequences with consequences involving sexual risk behaviors (including failure to use a condom or use it properly); discuss both alcohol reduction and sexual risk reduction goals in language accessible to our target population; anticipate barriers to condom use and partner reduction (which are likely to be specific to the kinds of relationships the women have with each partner); tailor a change plan to each woman's goals and circumstances and include both reduced alcohol use and/or increasing effective condom use and/or reducing partner number and concurrency in the menu of options.

The BI will last ~45 min, based on work where BI of similar length have been feasible;[9,10] one aim of this research is to evaluate the feasibility of the BI length. Table 1 displays the proposed structure proposed (left column = content elements, right column = how the content will target theoretical determinants of change); we will revise the content and goals before we move from feasibility trial (this application) to the planned R01.

Table 1. Brief Intervention (BI) Content and Therapeutic Goals

Intervention Content	Therapeutic Goal
• orientation to purpose of the BI, to the use of feedback	• Establish collaborative tone, and demonstrate respect for autonomy
• provide personalized feedback on alcohol consumption patterns	• Engage participant with personalized information • Encourage self-reflection • Develop discrepancy between real-ideal self
• provide gender- and age-specific descriptive norms for both alcohol use and sexual behavior	• Correct exaggerated peer norms • Develop discrepancy between self-other
• provide personalized feedback on alcohol-related consequences	• Engage participant with personalized information • Encourage self-reflection • Develop discrepancy between real-ideal self
○ general negative consequences of drinking	• Generate motivation to reduce drinking in order to reduce consequences; change drinking attitudes • Prompt change talk
○ STI-related correlates of drinking (e.g., lack of condom use, regretted sex, risky partners, multiple/concurrent partners)	• Demonstrate link between drinking & sexual outcomes • Discuss possible impact of myopia and expectancies • Prompt change talk
• provide personalized feedback on consistency of condom use and partner selection, concurrency, and number	• Engage participant with personalized information • Encourage risk sensitization
• provide gender- and age-specific norms on number of partners	• Correct exaggerated peer norms • Develop discrepancy between self-other
• offer gender-tailored education about blood alcohol concentration (BAC); social, health, sexual risks associated with binge drinking; safe drinking guidelines	• Change attitudes about drinking with accurate information about effects of alcohol on women • Develop discrepancy between current & possible self • Provide benchmark for reduced drinking/goal setting
• offer gender-tailored education about risk for HIV/STIs from unprotected sex with multiple partners or partners who are not mutually monogamous; safe sex guidelines	• Provide accurate information about risk of STIs for women, how/why condom use and mutual monogamy protects health; change attitudes about risk reduction • Develop discrepancy between current & possible self
• discuss readiness guides for changing alcohol and sexual behavior	• Develop discrepancy between real-desired self • Cultivate change talk
• identify alcohol and/or sexual risk reduction goals (e.g., drink less or not at all [when/where/with whom], use condoms all the time with partner X, negotiate more effectively with a resistant partner)	• Goal-setting enhances motivation • Generate change talk and/or commitment language, establishing behavioral intention
• generate a written personalized plan for reducing risk and discuss strategies to achieve goals; offer menu of options that includes strategies articulated by focus-group women	• Generate SMART[155] goals: specific, measurable, achievable, realistic, and time-targeted • Discussion of protective strategies may enhance skills and support self-efficacy • Written plan allows for later review and reminders
• discuss role of texts as reminders; mention that 3mo follow-up will be an opportunity to assess how she is doing with regard to her goals	• Encourage commitment language; prompt public commitment to change and accountability

d. Pilot testing. Screening, recruitment, and consent will occur as described in D.1.c. We will recruit ~8-15 women who will provide information about alcohol use, consequences, and sexual behavior, including partner-specific risk history using a computer-assisted self-interview (CASI). Measures of alcohol use and sexual behavior sample a 3-month interval to optimize reliability[156-158] and representativeness.[159] As seen in Table 2, we will assess alcohol use and problems, sexual behavior, and client satisfaction. The sexual measures will reflect risk as a function of relationship type. Given the prevalence of hookups and serial monogamy, we will assess start and end dates to measure the gap interval between relationships. This assessment will allow us to tailor risk reduction strategies in the integrated BI, and afford a fine-grained approach to determining BI efficacy. The computer will score the items immediately, and generate personalized feedback (i.e., risk summary, plan) for use by the interventionist during the BI.

A single face-to-face session (~45 min) will then occur with the Project Director who is a licensed mental health counselor. This person will be jointly trained/supervised by K. Carey (an expert in MI and BI for alcohol use) and M. Carey (an expert in BI for sexual risk reduction). Consistent with our previous work[128,129] training will consist of readings, review of the BI protocol, and practice with feedback. All sessions will be audiotaped for supervision, and fidelity rating. Ongoing training/supervision will take place weekly.

At the end of the BI participants will be given a take home packet. The take home packet will include a resource list and condoms. At the end of the BI, participants will complete a survey[160] that will assess the participant's satisfaction with the BI; how informative, interesting, and helpful the BI was; whether they would recommend it to a friend. With open-ended questions, we will solicit suggestions regarding session length, relevance and scope of BI content; and related topics. This information will be used to modify the BI protocol in an iterative fashion. The post-BI survey may be omitted if we reach saturation.

Table 2. Constructs and Measures (How data will be used, research aim, and time of administration)

Construct	Measure	Use	# items		Aim 2	Aim 3		Aim 2 / 3
				Screen	BL	BL	3M	Post
Demographics	Age, Ethnicity, Race, Marital status, Education, Employment, SES, Living Arrangements, Gender/Gender Identity, Reason for visit, Health Insurance	D, M	13	x		x	x	
Alcohol Use	Heavy drinking frequency/quantity	S, F, O	2	x	x	x	x	
	Drinks/week, quantity/frequency, maximum quantity	F, O	4		x	x	x	
	Alcohol quantity before sex	F, O	2		x	x	x	
Alcohol problems	SIP-2R	F, O	26		x	x	x	
Alcohol Protective Strategies	Positive alcohol behavioral strategies, Consumption self-control, Stopping/Limit setting, Harm reduction	F	22		x	x	x	
Sexual behavior	Sex risk: (a) sex >1 partner, (b) sex with someone who had other partners, (c) did not use a condom every time	S	7	x				
	Pregnancy attitudes and intentions	D	9		x	x	x	
	Sex History: Lifetime partner #, Past 3 months partner #, Condom Use past 3 months, alcohol with sex past 3 months, # HIV-positive partners	D, O	13		x	x	x	
	Partners: (a) #, (b) relationship type(s), (c) condom use, (d) involving alcohol, (e) partner STI testing, (f) monogamy, (g) trust, (h) risk of STI	D, F, O	7xP		x	x	x	
	Sex-Related Alcohol Expectancies	M	13			x	x	
STI	Chart abstraction of sexually transmitted infection	D, O	1			x	x	
	Self-report History, Testing frequency and results	D, O	7		x	x	x	
	Sexual Risk Reduction Strategies	F	10		x	x	x	
Information	HIV and STD Knowledge Questionnaires	O, M	18			x	x	
Norms	Descriptive norms for women's number of partners, condom use, partner concurrency, binge drinking	O, M	6			x	x	
	Subjective norms for binge drinking, motivation to comply, condom use, multiple partners	O, M	12			x	x	
Attitudes	Attitude toward heavy drinking	O, M	5			x	x	
	Attitudes toward partner concurrency scale	O, M	10			x	x	
	Health Values	F	5		x	x	x	
	Relationship Values	F	23		x	x	x	
	Condom Attitudes	M	26			x	x	
Self-efficacy	Self-efficacy for drink refusal (DRSEQ-R10)	O, M	10			x	x	
	Self-efficacy for condom use for each partner	O, M	3xP			x	x	
Condom Usage	Assessment of Correct Condom Use	F, O, M	10		x	x	x	
	Condom Influence Strategy Questionnaire	F, O, M	8		x	x	x	
Behavioral Intentions	Condom use for each partner	O	1xP		x	x	x	
	Multiple partners	O	1		x	x	x	
Mental health	Depression / Anxiety (PHQ-9; GAD-7)	S, M	17	x		x	x	
Life Stress	Perceived Stress Scale	D	4	x				
	Social Readjustment Rating Scale	D, M	42				x	
Drug use	Drug history Questionnaire (DHQ)	D, M	14	x		x	x	
Victimization	Revised Sexual Experiences Survey	D, M	12			x	x	

	Childhood Sexual Abuse	D, M	3			x		
	Intimate Partner Violence (HITS)	D, M	5			x	x	
Literacy	Single Item Literacy Screener	S	1	x				
BI process	Client Evaluation of Counseling scale	M	16					x
Satisfaction	Brief intervention and website	O	5		x			x
Web use	Hits, return hits, # pages viewed (collected by server)	O, M						x

How data will be used: S = screen, F = feedback, D = descriptive, O = outcome, M = potential mediator / moderator. P = # of partners.

D.4. Develop text prompts and a website-based BI "extender" (Aim 2.b.) [Months 10 – 15]

a. Overview. The BI will enhance motivation using personalized feedback, normative comparisons, female-relevant info, and goal-setting; however, time constraints limit opportunities to address skills. We will use technology to extend the impact of the clinic-delivered BI by developing two complementary intervention extenders: (a) personalized mobile messages and (b) a companion website that can deliver skills training via modeling. The results of this aim will be a text-messaging system and attractive website for use in Aim 3.

b. Mobile messaging. Personalized texts will be delivered for 3 months after the BI. Such messages are accepted by young people when they are positive, relevant, and brief.[181] We will craft messages with women's help (formative work), with words that resonate with them, knowing that texts are "fingered speech" governed by different "rules."[182] We will use texts to (a) remind women of their self change goals, (b) to inspire and support, and (c) to prompt visits to our website. Each mobile message will end with a link to the website using a URL (unique web address). Texts will be structured with just enough information to intrigue (tease) recipients and drive them to the URL. Texts will be pushed out on a daily basis. Participants do have the option to opt-out of text messages by contacting study staff through the website, by phone, or by email.

c. Website. The 2nd extender will be a website – the most flexible/extensible and least expensive type of content repository. It will build upon and broaden the BI. Organization of the web site will be guided by the formative work. Content will target antecedents of alcohol use and sexual behavior, including IMB constructs.[149,191] For each target, we will include textual, graphic, and (especially) video materials about managing alcohol and sexual risk. Thus, for behavioral skills, we will use high-quality, empirically-validated videos to model intra- (e.g., self-management) and inter-personal (e.g., sexual assertiveness) skills in real world contexts. These videos typically use compelling vignettes,[122] based upon Edutainment principles[192,193] to model skills and address the barriers and facilitators of skill implementation in the real world. These videos will be accessible, 24/7, to women in their natural environment, eliminating the need for women to find resources on their own. As shown in Table 3, we have already identified empirically-validated source materials that model risk reduction skills; thus, for example, we will extract several skills-based video clips from our professionally produced video ("*Be The Change*").[10] We will supplement with content that meets the needs identified during our formative work (Aim 1), and identify additional resources already available. We will favor materials that are engaging, female-friendly, and empirically-validated, such as those identified in Table 3. Similarly, to address information and motivation, we will extract video segments and provide links to patient-oriented and interactive science-based websites (see Table 3) to present information about reducing alcohol use and sexual risk.

Table 3. Representative Sample of Video-based or Interactive Materials

Behavioral Skills	**Source**
Male and female condom use	Be The Change[10] (R01-MH068171)
Managing substance use to reduce sexual risk	
Condom use negotiation with a main partner	
Getting social support for reducing risk	
Condom use negotiation with new partner	Safe in the City (CDC)
Telling a partner about an STI	
How to use a condom and lubricant	
Standard drinks, BAC estimation	Rethinking Drinking (NIAAA)
Safer drinking strategies	
Information (Knowledge)	
HIV testing and understanding test results	What Do You Know About HIV Testing (R21-NR011997)
STIs and STI testing Safer Sex options	Safer Sex Resources (Planned Parenthood)
Definitions of low-risk and high-risk drinking	Rethinking Drinking
Motivation	
Importance of using condoms with every partner	Be The Change[10] (R01-MH068171)
Testimonials of HIV-infected women	

Once materials are assembled, we will work closely with our university web designer to follow best practices in health-related website design;[194] we will build an easy-to-navigate website tailored to women's needs. We will draw upon our previous health communications research (R01-MH068171) to make the website highly appealing, intuitive, and informative. We expect to engage women using interactive FAQs and Q&As, and to develop a chat interface that allows women to ask questions (cf. "Go Ask Alice") that will be answered by our team. These plans will be elaborated and strengthened based on our formative work.

d. Pilot Testing of Technology. Pilot testing of the technology will be added to the pilot testing of the BI described in D.3.d. To pilot test the technology a password protected website has been created based on information learned through our formative research (Aim 1). Participants will be shown this website and be guided through an "over-the-shoulder test" which includes tasks designed to test how well a participant can maneuver through the website as well as their thoughts on content and design (See Aim 2 Over the shoulder Protocol). Half of the participant recruited in Aim 2 will receive BI and then over the shoulder technology testing and half will receive the reverse order. Pilot testing of the technology may be omitted if we reach saturation.

D.5. Randomized Control Trial of the BI, Messaging, and Website Extenders (Aim 3) [Months 13 – 24]

a. Overview. We plan a pilot study to assess the feasibility and acceptability of the BI and website, to obtain preliminary evidence of BI efficacy (on alcohol use and sex behavior outcomes), and to determine feasibility of procedures (e.g., enrollment, BI and website exposure, follow-up rates) for a future RCT.

b. Design. We plan a 2 (interventions) x 2 (baseline, follow-up) design. Women will be randomized, complete baseline, receive intervention (BI or brochure), post-survey (BI arm only), and 3-month follow-up. Measures will assess IMB constructs, alcohol, and sexual behavior, and STIs. Rationale for control: We chose a brochure because it is a science-based (CDC and NIAAA material) alternative that is representative of what clinics currently provide.

c. Sample (*n*=50) was based on published guidelines for treatment development research,[8] which recommend 15-30 per cell for Phase IB research. This also aligns with NIH expectations for R34 research.[7] We recognize that the trial is not adequately powered to detect between-group differences, but it can clarify the potential of the intervention and suggest effect sizes (ES). We also know that ES estimates will have large standard errors.[195] We primarily aim to find a pattern of results that is supportive of the experimental treatment.

d. Participants. We will recruit 50 women using screening, eligibility, recruitment, and consent procedures described in D.1.c. Women who participated in Aim 1 or 2 will not be eligible.

e. Baseline. Participants will complete the CASI on a tablet computer. Measures included in the CASI are listed in Table 2; the measures are reliable and valid, and have been used in prior research with young women. The CASI will take ~45 mins, and will assess background variables, outcomes, mediators, and moderators.

The self-report **outcomes** include sexual behavior; alcohol use; and the co-occurrence of sex and alcohol.

Consistent with PA-13-078[125], we will assess hypothesized **mediators** and **moderators**. We recognize that we will not have sufficient statistical power to test mediation or moderation in this pilot. However, we will evaluate short-term intervention effects on the hypothesized intervening variables, to determine if they have promise as potential mediators for a subsequent RCT.

Potential **mediators** include IMB constructs: (a) information, (b) motivation, and (c) skills. To assess information we will use knowledge questionnaires.[163,164] To assess motivation, we will use measures of norms, attitudes, and behavioral intentions towards alcohol use, condom use, and partner concurrency. Importantly, we will assess condom use norms and intentions by partner type; we will also assess norms, attitudes and intentions towards partner concurrency,[196,197] rarely done in prior intervention studies. To assess behavioral skills for condom use we will use a measure of condom use problems and assess self-efficacy by partner.

Potential **moderators** include demographics (e.g., age, race); sexual history (e.g., number of partners, STI diagnoses, prior victimization);[9,178,198] mental health (depression and anxiety; assessed with PHQ-9 and GAD-7);[175] drug use (DHQ).

f. Intervention. Women randomized to the **control condition** will receive (after the baseline CASI) a Fact Sheet on Alcohol Use and Risks to Women's Health[199] prepared by the CDC. This details gender differences in alcohol intoxication, facts about alcohol use and reproductive health, pregnancy, and other women's health concerns. Control women will then be scheduled for their follow-up session.

Women randomized to the **BI** will receive a ~45 min BI (as detailed in Table 1 and Aim 2) delivered by a health educator. After the BI, participants will be told that they will receive daily mobile messages with health facts of the day for 3 months. Women will be encouraged to visit and use the website. At the end of the BI session, women will complete a post-BI satisfaction survey, be scheduled for the follow-up. For all women, at the end of the session, the RA will thank the participant and reimburse her $30 for completing the CASI.

g. Process measures. We will assess the **fidelity** with which health educators implement the **BI** by reviewing session content against a content checklist based on the manual that to obtain a % adherence score; and using blind ratings that identify behaviors consistent with MI spirit (e.g., empathetic engagement,

eliciting concerns and solutions from patients, collaborative focusing, goal setting) and skills (e.g., open questions, reflective listening, affirmations, summarizing). These process data will be used in supervision and to refine the interventionist training protocol for the R01. We will evaluate the patients' perceptions of the degree to which the interventionist maintained MI style using the Client Evaluation of Counseling scale.[180]

Website use metrics (e.g., URL access, dates, frequency, videos watched, pages viewed) will determine which participants accessed the site, temporal effects of the text prompts, and the patterns of content viewing.

h. Follow-up measures. Three months after baseline, women will return to the clinic for a CASI (see Table 2 for content) as well as a semi-structured qualitative interview. The qualitative interview will be audiotaped. Audio will be uploaded to a secure Lifespan database following the interview. Once study staff have listened to the interview and completed a written debrief and possible transcription the audio will be destroyed. The qualitative interview will consist of open ended questions about the study appointments. Women in the BI condition will complete additional items[160] to rate the website and messaging content quality and appeal, ease of use, and relevance; and respond to open-ended prompts that elicit suggestions for message and website improvement. For all women, at the end of the session, the RA will thank the participant and reimburse her $40. If a participant is unable to return to the clinic for the three month follow-up then the follow-up can be conducted remotely. The participant will be sent a link via email to complete the computerized survey. The participant will be called on the telephone to complete the qualitative interview. Participants will be issued a check for reimbursement for remote follow-ups.

With patients' permission, we will review medical records for STI incidence data (to prepare for subsequent RCT). This follow-up will allow us to refine the procedures for an RCT, establish feasibility of follow-up sessions, and provide preliminary evidence of short-term outcomes.

i. Data analysis. This is a R34 pilot; thus, analyses are not powered to detect treatment effects. We will inspect means and percentages to assess feasibility and acceptability and to obtain preliminary evidence of efficacy.

To determine **feasibility** of the BI and of an RCT, we will calculate the percentage of individuals who were: eligible; consented; attended their intervention; accessed the website; and returned for the follow-up. Based on previous research, we expect ≥ 90% of those assigned to a BI to attend their intervention. Based on our recent trials (R01-MH068171), we expect ≥ 80% of all women to return for the 3-month follow-up.

To determine **acceptability** of the BI, messaging and website, we will calculate Ms for the satisfaction surveys, and inspect responses. We **predict** that the intervention materials will be well-accepted, as shown by mean ratings ≥ 4 on a 5-point Likert scale. To further evaluate the **acceptability** of the messaging and website, we will collect use metrics (e.g., timing and frequency of website access, number of clicks on links for information, video view time).[130] We **predict**, and will construe as acceptable, if women receive messages, link to the website, and view videos all the way through/multiple times.

To obtain preliminary evidence of BI **efficacy**, repeated measures ANOVAs will test intervention and time effects on the primary outcomes (alcohol use frequency, quantity, binge frequency; condom use, number of sexual partners; alcohol use before sex). We **hypothesize** an intervention x time interaction for all outcomes; thus, we **hypothesize** that BI recipients but not controls will reduce alcohol use and alcohol use before sex, increase proportion of protected sex, reduce condom use problems and number of partners.

To prepare for a future trial, we also provide preliminary data on mechanisms of action by testing intervention effects on **hypothesized mediators** (e.g., IMB constructs, attitudes, norms, self-efficacy).

j. Effect sizes and power. We recognize that effect size estimates based on small samples often have large SDs and wide confidence intervals (CIs).[195] We also acknowledge that we will not have power to detect statistically significant results. Nonetheless, pilot data are useful to gauge whether BI effects are encouraging, to examine distribution of outcome variables, to inform future analytic approaches, and to suggest the range of effect sizes that are reasonable to expect in a future trial. Thus, the focus of our analyses will not be on strict significance testing but on estimating effect sizes and CIs.

D. 6. Timeline and Deliverables

a. Timeline (30 months). Months (a) 1-3: train staff, get IRB approvals, initiate screening, finalize FG materials; (b) 4-10: recruit 25 women to 6focus groups, transcribe and analyze data (Aim 1); (c) 10-15: draft BI manual, pilot BI with ~8-15 women, get feedback, revise manual, finalize website (Aim 2); (d) 16-24: recruit 50 women to trial, analyze data (Aim 3); (e) 25-30: prepare and submit manuscripts, plan R01.

b. Deliverables. We will achieve these intervention development goals: (a) generate an integrated alcohol and sexual risk reduction BI, tailored to young women and partner type; (b) generate a web-delivered extender that models behavioral skills and maintains motivation; (c) demonstrate feasibility and acceptability of the BI with women in RHFP setting; (d) assess short-term change on target outcomes (i.e., condom use, number of partners, binge drinking, drinks per week); and (e) assess change in hypothesized mediators of change. These achievements will prepare us to submit a R01 to support a fully powered RCT.