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Results of a pilot test of a brief computer-assisted tailored HIV prevention intervention for use with a range of demographic and risk groups

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Abstract

There is a need for brief HIV prevention interventions that can be disseminated and implemented widely. This article reports the results of a small randomized field experiment that compared the relative effects of a brief 2-session counselor-delivered computer-tailored intervention and a control condition. The intervention is designed for use with African American, non-Hispanic white and Hispanic males and females who may be at risk of HIV through unprotected sex, selling sex, male to male sex, injecting drug use or use of stimulants. Participants (n=120) were recruited using a quota sampling approach and randomized using block randomization, which resulted in 10 male and 10 female participants of each racial/ethnic group (i.e. African-American, non-Hispanic white and Hispanic) being assigned to either the intervention or a control arm. In logistic regression analyses using a generalized estimating equations approach, at 3-month followup, participants in the intervention arm were more likely than participants in the control arm to report condom use at last sex (Odds ratio [OR] = 4.75; 95% Confidence interval [C.I.] = 1.70, 13.26; p = 0.003). The findings suggest that a brief tailored intervention may increase condom use. Larger studies with longer followups are needed to determine if these results can be replicated.

Keywords

HIV prevention; brief interventions; computer-tailored; African-Americans; Hispanics; males; females

Introduction

As of October, 2012, the CDC Compendium of Evidence-Based HIV Behavioral Interventions risk reduction chapter included 74 interventions that have demonstrated efficacy in reducing HIV risk behaviors [1]. Many of these are designed for specific risk groups (e.g. men who have sex with men [MSM], people who inject drugs [PWID], commercial sex workers, etc.) and demographic groups (e.g. African-American women, African-American men, Hispanic men, Hispanic women, etc.). These interventions have

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demonstrated efficacy in reducing sexual behaviors and injecting practices that place people in these groups at risk of HIV infection or transmission [2–6]. Despite evidence of their efficacy and efforts to promote their use, widespread diffusion and adoption of evidence-based interventions has been slow [7]. One reason is that many of these interventions are complex, multi-session and resource intensive, which may make them difficult to implement in settings with very limited resources [8]. In rural areas, where specific demographic and risks groups are often present in low concentrations, health departments and community-based organizations may lack the resources to offer specialized interventions for every group. In addition, some specialized interventions require relatively high levels of monitoring to ensure that the intervention is implemented with the fidelity needed to achieve optimal efficacy [9, 10]. Smaller organizations may lack the resources that are needed to deliver and monitor interventions that require high levels of monitoring. Moreover, interventions that are designed for one demographic or risk group may not be suitable for others. For example an efficacious intervention for a non-Hispanic white gay-identified man may not be appropriate for an African-American woman who uses crack cocaine or a Hispanic heterosexual male who injects heroin. Accordingly, there is a need for an intervention that can be used with multiple demographic and risk groups and can be delivered by a single interventionist.

In the past, these challenges have left HIV prevention and STI service providers in many areas with little choice but to use generic interventions. This is changing now with the widespread use of computers that allow interventions to be tailored to the characteristics of each individual [11]. While these interventions hold great promise, they have generally been designed to be tailored to the characteristics of individuals within certain demographic or risk groups [11] rather than the broad range of people that HIV prevention and STI service providers may encounter.

This paper reports intervention effects on condom use in a small randomized field experiment that tested a brief counselor-delivered cue-card driven, computer-tailored intervention. The intervention is designed for use with both genders, three major racial/ethnic groups in the United States and a variety of risk groups including sex workers, MSM, PWID and stimulants users. It also incorporates counseling and testing for HIV, hepatitis B virus (HBV), hepatitis C virus (HCV), herpes simplex virus 2 (HSV-2) and syphilis. The pilot test was conducted in a city. However, we also conducted a feasibility and acceptability test in which the intervention was delivered by counselors for a community-based organization to 25 participants in several rural counties in central North Carolina.

Methods

Pilot test

Recruitment—Participants for the pilot test were recruited using a combination of methods including project flyers that were posted in the community, referrals from current participants and referrals from the local health department, a women's center and other service providers. All participants were recruited in Raleigh, North Carolina between August 2010 and March 2011.

Compensation and Protection of Human Subjects—Participants received $25 as compensation for the time spent during the baseline interview, $20 for completing Session 1, $15 for completing Session 2 and $40 for completing the 3-month follow-up interview. All aspects of the study were approved by the Office of Research Protection at RTI International.

Eligibility Requirements—To be eligible for the Computer-assisted Tailored Cue-card Health (CATCH) study, a participant was required to self-report: being male or female (people who identified as transgender or transsexual were excluded); a minimum age of 18 years; being African-American, non-Hispanic white, or Hispanic; engaging in male to male sex, exchanging sex for money or drugs, injecting drug use, or stimulant drug use; speaking and understanding English well; living in Wake County, North Carolina; and having had unprotected anal or vaginal sex within the prior 30 days.

Randomization and Sampling—To insure that the intervention and control arms included equal numbers of men and women in each of the three racial/ethnic groups (i.e. African-American, non-Hispanic white and Hispanic), we used quota sampling to recruit 20 men and 20 women of each of the three racial/ethnic groups for a total of 120 participants. We used a block randomization approach in which half of the 20 participants within each of the six cells (i.e. 2 gender x 3 racial/ethnic categories) were randomized to the delayed-treatment control arm and half were randomized to the intervention arm. The randomization resulted in equal numbers of males and females of each racial ethnic group in the two study arms. For ethical reasons, participants assigned to the delayed treatment control arm were offered the intervention and biological testing after completion of their 3-month followup interview.

Theoretical basis of intervention—The CATCH intervention is based on social cognitive theory. It uses education, which comprises information transmission to increase knowledge and skill building to influence behavior-specific self-efficacy and outcome expectations [12]. In addition to providing general information regarding drug use and diseases, the cue-cards include information that is designed to increase awareness regarding perceived threats (perceived susceptibility and perceived severity) related to HIV, other STIs and blood-borne infections, which enhances motivation to reduce risk behaviors. The cue-cards also include information regarding risk reduction strategies. The provision of information on risk reduction strategies coupled with skill-building exercises (e.g., demonstrations and rehearsals of correct condom application, syringe cleaning, and condom negotiation) increases perceived self-efficacy to cope with the perceived threats [13, 14].

Intervention format—The CATCH intervention is a 2-session cue-card driven computer-assisted tailored intervention that is designed to be delivered with fidelity by an interventionist with minimal training and minimal monitoring. Each session takes between 15 to 45 minutes depending on the number of different risk behaviors a person reports and the specific tests (e.g. HIV, HBV, HCV, syphilis, HSV-2) that are performed. The information in Session 1 is tailored to each participant's gender, race/ethnicity (i.e. African-American, Hispanic, non-Hispanic white) and risk behaviors and the specific tests (e.g. HIV, HCV, HBV, syphilis, herpes) that are performed. Session 2 is tailored to a participant's specific combination of test results.

Before starting Session 1, basic information—gender (male or female), race/ethnicity, gender of sex partners, and other behaviors in which they may engage (e.g. injecting drug use, sex work, or stimulant use)—is gathered from a participant and entered into a startup form (see Figure 1) that is programmed for use with PowerPoint. The information that is entered into the startup form determines the specific sequence of slides that the interventionist reviews with the participant. For example, a Hispanic male who has sex with both men and women and reports injecting drug use would only see cards for Hispanic males (i.e., cards with pictures and words relating specifically to Hispanic men). These cue-cards would include information about risk reduction strategies for people who inject drugs

and men who have sex with other men as well as with women. Information presented in both sessions is delivered by an interventionist.

To simplify programming, we developed separate modules for each of the six race/ethnicity and gender combinations in the study. An example of the tailoring algorithm for Session 1 is shown in Figure 2 and an example the list of slides and who would see them is shown in Table I. Examples of actual slides are shown in Figure 3

Within each of the six race/ethnicity gender modules, Session 1 of the intervention was tailored to the gender of a participant's sex partners (i.e. male, female or both) and whether the participant reported exchanging sex for money or drugs, injecting drugs or using stimulant drugs (e.g. crack cocaine, powder cocaine, methamphetamine). This resulted in 24 possible combinations within each of the six modules for a total of 144 different combinations. Session 2 was tailored to each participant's specific combination of test results. At Session 1, we offered testing to participants assigned to the intervention arm. Participants assigned to the delayed treatment control arm were offered testing after they completed their 3-month followup interview. Participants had the option of refusing any or all tests. For tailoring purposes, the results of each test were classified as positive, negative or not tested. Additional information regarding the specific tests and results is provided in the section on testing.

Intervention development—We contacted developers of a number of the evidence-based interventions that are available through the US Centers for Disease Control and Prevention (CDC) Diffusion of Effective Behavioral Interventions (DEBI) website (www.effectiveinterventions.org) to obtain intervention materials and permission to adapt them for use in this intervention. We were particularly interested in HIV and STI risk reduction material that was tailored to particular gender and racial/ethnic groups. In the development stage, we used cultural and educational elements from the following interventions: STRIVE [15], RESPECT [16], Mujeres Unidas Por La Salud, SAFE [17], BART [18] and SHIELD [19].

The cue-cards were developed as Microsoft PowerPoint slides (Microsoft Corporation, Redmond, WA), and the intervention can be delivered on any computer using PowerPoint viewer (freely available from Microsoft).

The cue-cards were reviewed by 12 expert reviewers. The reviewers included people who work with each of the demographic and risk groups. Afterwards, we revised the cue-cards to incorporate comments from the reviewers. The revised cue-cards were then pre-tested with members (n=19) of the different demographic and risk groups. We made final revisions based on the results of the pretest.

Intervention content—The introductory section in Session 1 included information on HIV, hepatitis A, hepatitis B, hepatitis C, syphilis, gonorrhea, chlamydia and genital herpes. The information was tailored to an individual's gender and race/ethnicity and included local HIV prevalence and other statistics based on the individual's race and gender. After the introduction, the next section presented sex risk reduction information with particular partners (either women, men, or both). Each participant saw and discussed risk reduction information specific to the gender of his or her sex partners. This section included male and female condom demonstrations as well as role plays and rehearsals of correct condom application and condom negotiation. The final section presented information and role plays that centered on the particular behaviors a participant reported (i.e. injecting drug use, stimulant use, and exchanging sex for money or drugs). Participants only received information that was relevant to their specific risk activities.

The information in Session 2 was tailored to the results of the tests that were performed on the blood sample from Session 1. Session 2 was conducted 5–10 days after Session 1. Similar to Session 1, the interventionist entered a participant's test results into the computer prior to starting the session. The interventionist then provided each participant with information that was tailored to his or her specific test results. The information covered in Session 2 described the meaning of each test result (positive or negative). People with a negative result were given information regarding how to avoid infection. People with a positive result were given information regarding how to stay healthy and slow disease progression, how to prevent transmitting the infection and how to disclose their status to their sex partners. People who tested positive for HCV antibodies were given information as if they had chronic HCV infection and referred for HCV RNA testing. Participants who tested positive on one or more tests were offered referrals to appropriate local services for further evaluation and treatment. The information in Session 2 was not tailored by gender, race or ethnicity.

HIV, hepatitis and STI tests—Participants in the intervention arm were asked to give blood samples for HIV antibody, syphilis, HBV surface antigen (HBsAg), HCV antibody and herpes testing following their first intervention session. The HIV screening test was the immunochemiluminometric assay (ICMA) Human Immunodeficiency Virus 1/O/2 (HIV-1/O/2) antibody test; ICMA positive tests were confirmed with a Western Blot. Samples were tested for hepatitis B and C using enzyme-linked antibody assays (ELISA). Syphilis screening was performed with a rapid plasma reagin (RPR) test. The confirmatory test was the treponema pallidum particle agglutination assay (TPPA). Testing for herpes was performed using the HSV-2 ELISA. All biological samples were processed by Laboratory Corporation of America (LabCorp, Burlington, NC). Participants assigned to the delayed-treatment control arm were offered the intervention and testing after they had completed their followup interview and all activities related to the research.

Data collection—Participants completed an interview at enrollment and a follow-up interview three months later. Interviews were administered using audio computer-assisted self-interview (ACASI) technology, which has been shown to reduce social desirability in responses [20, 21]. The questionnaire covered basic demographic information, drug and alcohol use, sex risk behaviors, injection risk behaviors, psychological distress, stage of change regarding sex risk, histories of childhood trauma, health-related quality of live and HIV and STI testing and status. The sex risk behavior section included detailed questions on their most recent sexual encounters with up to four different partner types (i.e. a main partner, a casual partner, someone the participant received money or drugs from in exchange for sex and someone the participant gave money or drugs in exchange for sex).

Analyses—Because of the small sample and its diversity in terms of demographic characteristics and risk group composition, primary outcome analyses were limited to behaviors that were applicable to a wide range of participants. The primary outcomes were differences at the 3-month followup interview in the occurrence of consistent condom use during vaginal and anal intercourse during the previous 30 days and condom during vaginal and or anal intercourse at last sex with a main partner, casual partner, someone to whom the participant sold sex and someone from whom the participant purchased sex. Encounters that involved two women were excluded. As secondary outcomes, we assessed condom use during anal sex in encounters that involved two men and we assessed changes in injecting drug use. To minimize the effects of recall, only encounters that occurred within the last 30 days were included in the analysis. Since many participants reported on more than one partner type but few reported on all four partner types, we used a generalized estimating equations (GEE) approach that allowed us to include everyone in a single model, while

adjusting for within-subject correlation [22, 23]. We used an unstructured working correlation structure for the analyses. We also conducted exploratory subgroup analyses using 2 × 2 contingency tables and odds ratios to examine the impact of the intervention on each demographic and risk group.

Test of the feasibility and acceptability of the intervention

This intervention was designed to be used in rural areas and non-traditional testing sites such as mobile units, common space in apartment complexes when testing campaigns are conducted, homeless shelters or a variety of other settings where HIV testing may be offered outside of a clinical setting. In a previous study we found that it was more expensive to recruit high risk samples in rural areas [24], so we conducted the pilot test in a city. To ensure that the intervention would be appropriate for use in rural areas, we assessed its acceptability and the feasibility of implementing it in a community-based organization (CBO) in a rural setting. HIV/STI test counselors for the Chatham Social Health Council (CSHC), a CBO that provides HIV and STI counseling and testing in several rural counties in central North Carolina, conducted the feasibility test of the intervention. We trained two CSHC counselors on the intervention and one of them delivered it to 25 people who were tested in the CSHC non-traditional testing program, which conducts testing from a mobile unit (i.e. a van) at sites including apartment complexes and public parks in several rural counties. Following Session 2 of the intervention participants completed a questionnaire that included 11 questions, with open-ended responses—which were collapsed into categories for reporting purposes—pertaining to their experience with the intervention to assess its acceptability.

Examples of the questions include: (1) Have you been able to use any of the information you received last week as part of Session 1?; (2) Was there anything you especially liked/disliked about the sessions? What?; (3) To what extent did the sessions you received tell you something that you didn't already know?; (4) Were there any parts of the sessions that were confusing or hard to understand? Can you give me an example?

Participants in the feasibility and acceptability study were not randomized and did not complete a followup interview to assess intervention efficacy.

Results

Participants

The block randomization was successful and resulted in equal numbers of males and females of each racial/ethnic group assigned to each study arm. There were no significant differences in other socio-demographic characteristics or sex risk behaviors between arms. However, crack cocaine use, heroin use and injecting drug use were significantly higher in the control arm than in the intervention arm. Fifty-eight participants (97%) assigned to the intervention arm agreed to be tested for HIV, HBV, HCV, syphilis and HSV-2 at baseline. Biological testing and participation in the intervention among people who were assigned to the control arm were not part of the research. The intervention and testing were offered as a service to participants in the delayed-treatment control arm after they completed their followup interview. Thirty participants (61% of those completing a followup interview) in the delayed-treatment control arm participated in the intervention and testing. Overall prevalence was 7% for HIV, 3% for HBV surface antigen, 19% for HCV antibodies, 7% for syphilis and 57% for HSV-2. Characteristics of the sample are shown by study arm in Table II.

Attrition

The overall follow-up rate was 88% (105/120). Only 82% (49/60) of participants assigned to the control arm completed a followup interview compared with 93% (56/60) of participants assigned to the intervention arm. These differences were marginally significant (p = 0.053). Follow-up rates differed significantly (p = 0.012) by race with 95% (38/40) of African-Americans, 95% (38/40) of non-Hispanic whites and 75% (30/40) of Hispanics completing a 3-month follow-up interview. Of the 15 people who did not complete a followup interview, there were five in the control arm and one in the intervention arm who we were unable to locate. A CONSORT diagram for participation in each activity of the study is shown in Figure 4.

Intervention outcomes: sex risk

In logistic regression analyses that adjusted for consistent condom use at baseline, participants in the intervention arm were somewhat more likely than participants in the control arm to report consistent use at followup (Odds ratio [OR] = 3.06; 95% Confidence Interval [C.I.] 0.86, 10.92; p = 0.084). In GEE logistic regression analyses that adjusted for partner type, at followup, participants in the intervention arm were over four times more likely than participants in the control arm to report condom use at their last sexual encounter involving vaginal and or anal intercourse (OR = 4.75; 95% C.I. = 1.70, 13.26; p = 0.003). In GEE analyses of encounters that involved a man and a woman and adjusted for partner type, compared with participants in the control arm, participants assigned to the intervention arm were more likely to report using condoms (OR = 4.15; 95% C.I. 1.46, 11.78; p = 0.008). The unadjusted and adjusted results for each outcome are shown in Table III.

We also conducted exploratory analyses that used simple contingency tables, which did not adjust for within subject correlation, to assess intervention effects separately for each partner type, racial/ethnic group, gender and risk group. In all 10 subgroup analyses, the percentage of participants in the intervention arm reporting condom use was higher than the percentage in the control arm (Table IV). The odds ratios were lowest in subgroup analyses for condom use with a main partner (OR = 1.96; 95% C.I. = 0.61, 6.30), for African-Americans (OR = 2.87; 95% C.I. = 0.87, 9.45) and for men (OR = 2.92; 95% C.I. = 0.96, 8.84). In the 12 MSM encounters (6 per study arm), 0% in the control and 67% in the intervention arm reported using condoms. These subgroup analyses are presented to give the reader a sense of the response to the intervention within each group. Due to the small numbers in many of the cells, the p-values and odds ratios should be interpreted cautiously.

Intervention outcomes: injection risk

At baseline, 21 people in the control arm and 11 people in the intervention arm reported injecting in the previous 30 days. Among those who were injecting, the frequency was somewhat lower in the control arm than in the intervention arm with a mean of 4.9 (standard deviation [S.D.] = 5.5) injections in the control arm and a mean of 10.8 (S.D. = 8.1) in the intervention arm t= −2.35, df=29, p = 0.026). Five of the injectors in the control arm and one of the injectors in the intervention arm did not complete a followup interview. Of those who were not injecting at baseline and completed a followup interview, 12% (4/33) in the control arm and 0% (0/46) in the intervention arm were injecting at followup. Of those who were injecting at baseline, 25% (4/16) in the control arm and 11% (1/9) were injecting at followup. With only five people who reported injecting at followup, statistical analyses of injection risk are not appropriate.

Propensity score adjustment to assess potential impact of imbalance of confounders across study conditions on condom use at followup

The slightly higher percentages of participants in the control arm that reported use of crack cocaine, heroin and injecting drug in the previous 30 days suggest that the randomization did not achieve balance between study arms on some important potential confounders. This is not surprising given the small sample. Nonetheless it raises the possibility that these differences could have influenced the intervention effects on condom use. Accordingly, we conducted additional analyses using propensity score weighting to adjust for these differences. This approach is widely used in observational studies to adjust for differences between who are exposed to a treatment or risk and those who are not [25–28]. The differences between the unweighted and weighted analyses were relatively small. For example, the results for the unweighted analyses of consistent condom use during the last 30 days were: OR = 3.25 (95% C.I. = 0.94, 11.24; p = 0.063 while results for the weighted analyses were OR = 4.42 (95% C.I. = 1.06, 18.35; p = 0.041). Similarly, the results for the unweighted analysis of condom use at last sex were: OR = 6.30 (95% C.I. = 2.14, 18.55; p = 0.001) while results for the weighted analysis were OR = 4.42 (95% C.I. = 1.75, 11.17; p = 0.002).

Feasibility and acceptability

The CSHC counselor was able to deliver the intervention as part of the mobile testing program without any problems. The intervention was delivered both from a van and in common space at apartment complexes in several rural counties. This suggests that the intervention may be feasible for use in field settings as well as in an office setting like the one used for the pilot test. One participant in the acceptability study refused to answer questions regarding the intervention that were asked at the end of the second session. Of the 24 that responded, 23 reported that they had already been able to apply information they had learned at Session 1. Nineteen participants reported that they learned something new during the intervention and 19 reported being either satisfied or very satisfied with it. Fifteen participants were satisfied with the length of the sessions, but nine thought the sessions should be shorter. Of 17 who had been tested for at least two of the five infections previously, 14 preferred this counseling over their previous experience. Twenty participants reported that they would be willing to take part in the intervention again, even without any incentive.

Discussion

Compared with participants assigned to the control arm, participants assigned to the intervention arm were more likely to report condom use and less likely to report unprotected intercourse during recent sexual encounters at followup interviews completed 3 months after taking part in the intervention. These findings are consistent with other studies, which have shown that brief interventions using a client-centered or tailored approach may be efficacious [16, 29]. Although the numbers were too small to draw firm conclusions, compared with participants in the control arm, participants in the intervention arm who reported MSM encounters were more likely to use condoms during anal intercourse. The number of people who reported injecting at followup was too small draw any meaningful conclusions regarding the effect of the intervention on injection risk.

Limitations

The slightly lower followup rates 82% (49/60) in the control arm than in the intervention arm 93% (56/60) raise the possibility of differential attrition. In general this is more of a concern when followup rates are lower in the intervention arm. We are not aware of any

studies that suggest that people in a control group who are doing better are more likely to drop out.

While the intervention shows promise, future studies will require longer followup periods in order to determine if the effects are sustained [30]. The intervention will also need to be compared with standard practice. Meaningful subgroup analyses of the intervention's impact on specific demographic and risk groups will require much larger samples.

As with most studies of interventions to reduce HIV risk among people who use drugs, people who engage in transactional sex and MSM, this study relies on self-reports of behavior change. Several studies that compared self-reports of unprotected sex with biomarkers found evidence of underreporting of unprotected sex [31–33]. Data in this study were collected using ACASI technology, which has been shown to minimize socially desirable responses and increase reporting of potentially embarrassing and stigmatizing behaviors [20, 31, 34], nonetheless it is likely that risk behaviors may be underreported. One possible solution to problems associated with underreporting would be to use incident STIs as a biological outcome. However, such a study would probably require a very large sample, which would make it very expensive. Another limitation arises from the fact that the sample was not recruited using probability sampling techniques. So the extent to which the findings may be generalized to other groups is unknown.

The intervention was designed to address both sex and injection risk behaviors, however, too few people in the sample reported injecting at follow-up to assess, with any confidence, changes in sharing of syringes or other injection equipment. Similarly, due to the small sample, analyses by risk group, gender and racial/ethnic group are only exploratory and the results should be interpreted cautiously.

Participants were randomized to receive the intervention or to a delayed-treatment control condition. By design, participants assigned to the delayed treatment control condition did not receive any intervention until after they had completed their 3-month followup interview. Therefore, although it appears that the intervention works better than no intervention, we do not know if it would work better than standard care. In addition, most participants (97%) who were assigned to the intervention arm were tested for HIV, HBV, HCV, syphilis and HSV-2 as part of the intervention; whereas participants in the delayed treatment control condition were not offered testing at baseline. However, we conducted subgroup analyses (not shown) of participants in the intervention condition to assess the impact of HSV-2 (the most common STI in the sample) test results on risk behaviors, and there was no association.

Conclusions

It is important to note that because the intervention is very brief and it is designed to be used with most demographic and risk groups, it is unlikely to be as powerful as more intensive or specialized interventions.

Given those caveats, the results of this pilot study suggest that the intervention may be efficacious in reducing risk behaviors. If the intervention proves efficacious and cost effective in a larger randomized field experiment, it could provide a useful tool for HIV prevention in rural areas and other areas where risk groups are present in relatively low numbers as well as other settings where it is impractical to offer a range of more specialized or intensive interventions.

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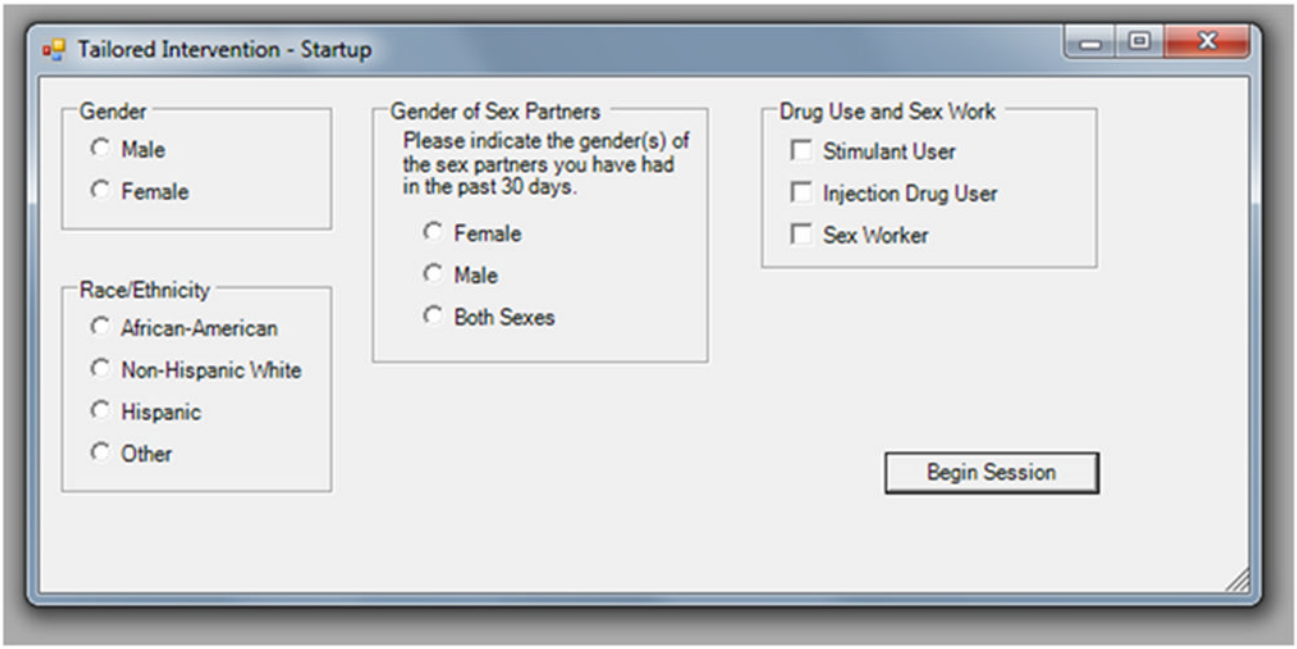


Figure 1. Pre-intervention startup screen to select demographic and risk behaviors of a participant

Note: The information selected here automatically determines the information that will be presented and the order in which it is presented.

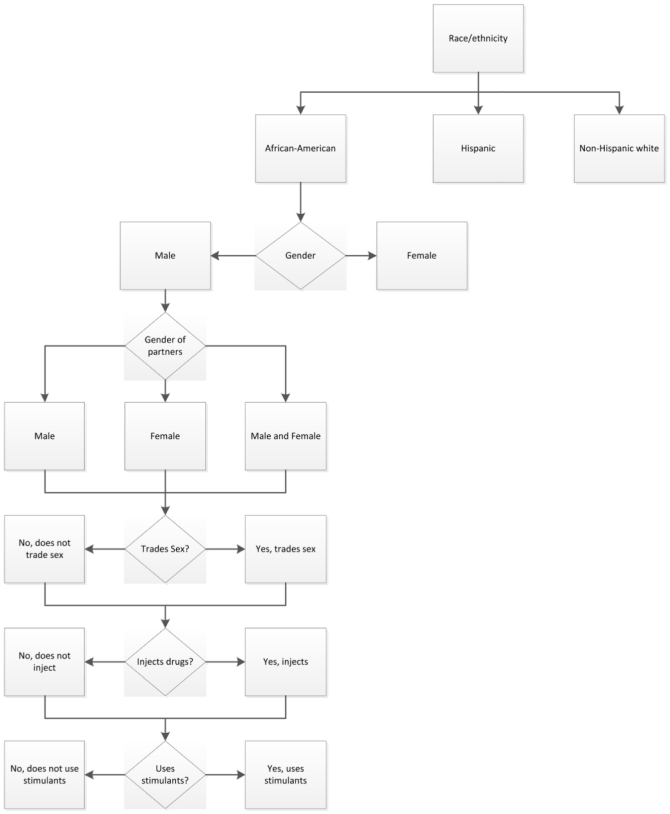


Figure 2. Algorithm for intervention Session 1*

*The intervention is divided into six modules—one module for males and one for females within each of the three racial/ethnic groups. The diagram above illustrates the decision tree an African-American male. Each of the decisions are based on the characteristics selected the startup screen before the intervention actually starts. The information that is entered in the startup form automatically determines the specific slides that are displayed, which are automatically tailored to the characteristics of the participant. The interventionist and the participant review the material on the slides together

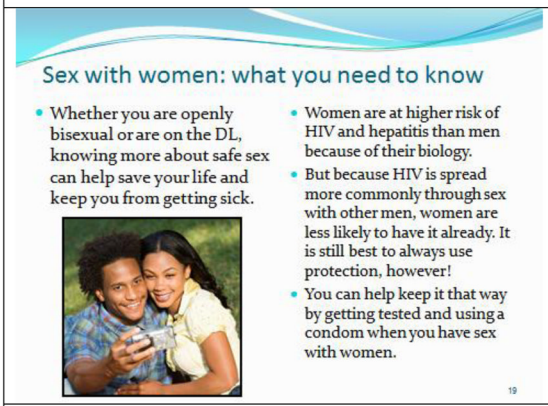
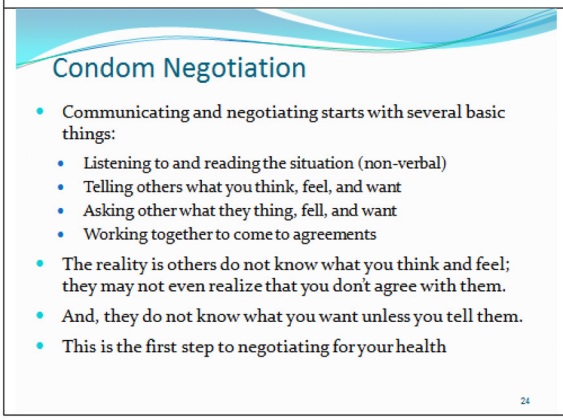
Example Slide	Description of who would or would not see the slide
	An African-American man who has sex with men and with women would see this slide, but a man who only has sex with men would not see it. A non-Hispanic man who has sex with men and women would see a similar slide with a different picture and slightly different text (i.e. it would not include the DL or “down low” terminology.)
	A man who has sex with men only or who has sex with men and women would see this slide. A man who only has sex with women would not see it.
	Everyone would see this slide plus 3 more on condom negotiation.

Figure 3.
Example of slides from the tailored intervention of the Computer-assisted Tailored Cue-card Health Study

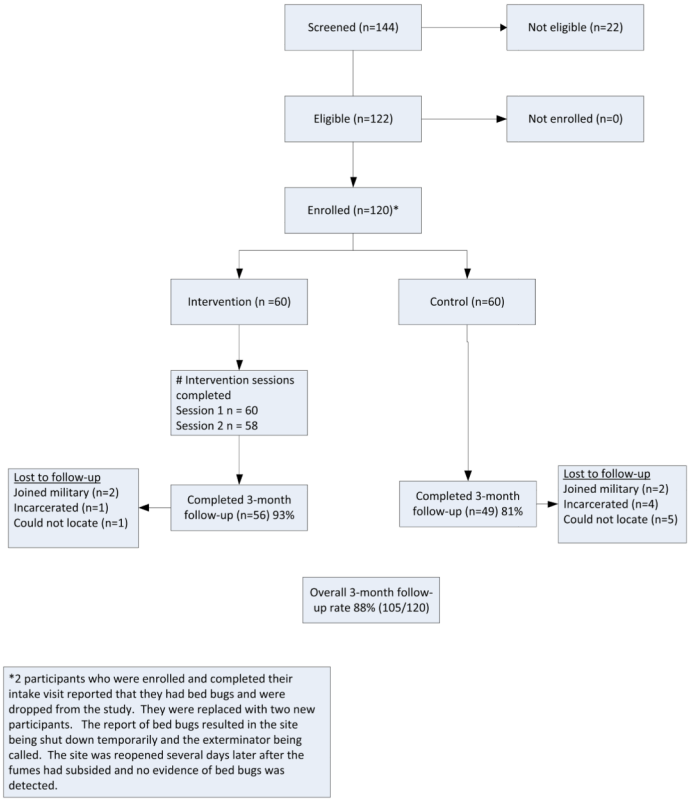


Figure 4.
CONSORT diagram of participation by study arm in the Computer-assisted Tailored Cue-card Health Study

Table I

List of slides for Session I with specific examples of slides that would be seen by an African-American male MSM who does not inject or use stimulants and an African-American MSMW who injects drugs and smokes crack. (from the Computer-assisted Tailored Cue-card Health Study)

			African-American male examples	
Slide#	**Content**	**Topic**	**MSM no drug use or sex trading**	**MSMW, PWID, smokes crack cocaine**
1	Introduction Slide		X	X
2	Preview to Session I		X	X
3	HIV/AIDS Information	Disease Info	X	X
4	Hepatitis Overview	Disease Info	X	X
5	Hepatitis A	Disease Info	X	X
6	Hepatitis B	Disease Info	X	X
7	Hepatitis C	Disease Info	X	X
8	HIV/Hepatitis Transmission 1	Disease Info	X	X
9	HIV/Hepatitis Transmission 2	Disease Info	X	X
10	Syphilis	Disease Info	X	X
11	Herpes	Disease Info	X	X
12	Tailored Risk Slide 1	Tailored	X	
13	Tailored Risk Slide 2	Tailored	X	
14	Tailored Risk Slide 1	Tailored		X
15	Tailored Risk Slide 2	Tailored		X
16	Tailored Risk Slide 1	Tailored		
17	Tailored Risk Slide 2	Tailored		
18	Sexual Activity Risk	Sex Risk	X	X
19	Sex with Women	MSMW Risk		X
20	Sex with Men	MSM/MSMW Risk		X
21	Condom Use Exercise	Sex Risk	X	X
22	Condom negotiation Slide 1	Sex Risk	X	X
23	Condom negotiation Slide 2	Sex Risk	X	X
24	Trading Sex	CSW Risk		
25	Trading Sex	CSW Risk		
26	Injection Drug Use Risk	IDU Risk		X
27	Injection Drug Use Risk Reduction	IDU Risk		X
28	Syringe Cleaning Exercise	IDU Risk		X
29	IDU Treatment and Support	IDU Risk		X
30	Stimulant Drug Use Risk	Stimulant Risk		X
31	Stimulant Drug Use Risk Reduction	Stimulant Risk		X
32	Review and Session II Preview		X	X

Table II

Comparison of the participants in the delayed treatment control and computer tailored intervention arms of the Computer Assisted Tailored Cue-card Health Study*

Socio-demographic characteristics	Delayed-treatment control (n= 60)	Computer-tailored intervention (n=60)	Pearson Chi-square/t-value	p-value
% female	50	50		--
% African-American	33	33		--
% Hispanic	33	33		--
% non-Hispanic white	33	33		--
Mean age (S.D.) in years	38.8 (12.6)	38.2 (11.0)		0.788
% High school graduate	38.3	41.7	0.139	0.709
% unemployed	68.3	73.3	0.363	0.547
% married or living as married	15.0	11.7	0.288	0.591
HIV, HBV, HCV, syphilis and HSV-2 test results[a]				
% HIV positive	6.9	6.9	0.000	1.000
% HBV surface antigen positive	3.4	3.4	0.000	1.000
% HCV antibody positive	17.2	19.0	0.038	1.000
% syphilis positive	3.4	8.6	0.806	0.369
% HSV-2 positive	58.6	56.9	0.024	0.878
History of substance abuse treatment and incarceration				
% ever in substance abuse treatment	55.0	65.0		0.264
% ever in jail or prison	78.3	70.0	1.087	0.297
Alcohol and drug use past 30 days				
Mean # days drank 5 or more drinks (S.D.)	8.6 (10.2)	7.7 (9.1)	0.486	0.628
% used crack cocaine	81.7	65.0	4.261	0.039
% used powder cocaine	55.0	43.3	1.634	0.201
% used heroin	21.7	8.3	4.183	0.041
% used amphetamine or methamphetamine	15.0	8.3	1.294	0.255
% injected	35.0	18.3	4.261	0.039
Sexual behavior past 30 days				
Mean # sex partners (S.D.)	6.4 (15.2)	5.0 (8.2)	0.636	0.526
Mean # partners unprotected sex (S.D.)	3.5 (5.0)	3.3 (7.5)	−0.014	0.989
% any unprotected vaginal or anal intercourse	91.7	93.3		0.729
% male to male sex (% based on 30 males per study arm)	40.0	50.0	0.606	0.436
% traded sex for money or drugs	68.3	58.3	1.292	0.256

Socio-demographic characteristics	Delayed-treatment control (n= 60)	Computer-tailored intervention (n=60)	Pearson Chi-square/t-value	p-value
% traded drugs or money for sex	43.3	50.0	0.536	0.464

* Participants were enrolled in Raleigh, North Carolina in 2010 and 2011

Table III

Results of main outcomes analyses for condom use at followup

Logistic regression analysis for consistent condom use for all intercourse during last 30 days

(n = 71 participants who were sexually active at followup)

	coefficient	Wald Chi-square	df	Odds ratio (95% C.I.)	p-value
Unadjusted	1.79	3.464	1	3.25 (0.94, 11.24)	0.063
Adjusted for consistent condom use at baseline	1.12	3.399	1	3.06 (0.86, 10.92)	0.084

Generalized estimating equations logistic regression analysis for condom use during vaginal and anal intercourse at last sexual encounter with up to 4 partner types (main partner, casual partner, sex purchaser, sex seller)[a]

(n = 121 encounters)

	coefficient	Wald Chi-square	df	Odds ratio (95% C.I.)	p-value
Unadjusted	1.486	9.892	1	6.30 (2.14, 18.55)	0.001
Adjusted for partner type	1.559	8.874	1	4.75 (1.70, 13.26)	0.003

Generalized estimating equations logistic regression analysis for condom use during vaginal intercourse at last sexual encounter with up to 4 partner types (main partner, casual partner, sex purchaser, sex seller[b]

(n = 107 encounters)

	coefficient	Wald Chi-square	df	Odds ratio (95% C.I.)	p-value
Unadjusted	1.295	6.765	1	3.65 (1.38, 9.68)	0.009
Adjusted for partner type	1.423	7.148	1	4.15 (1.46, 11.78)	0.008

[a] includes heterosexual and MSM encounters

[b] excludes MSM encounters

Table IV

Subgroup analyses of condom use at last sex (vaginal and or anal) by partner type, race/ethnicity, gender and for MSM encounters

Partner Type	intervention n (%)	control n (%)	Odds ratio (95% C.I.)	Pearson Chi-square†	p-value
Main partner					
unprotected	19 (57.6)	16 (72.7)	1.96 (0.61, 6.30)	1.310	0.252
protected	14 (42.4)	6 (27.3)			
Casual partner					
unprotected	4 (23.5)	14 (82.4)	15.17 (2.84, 81.10)	11.806	0.001
protected	13 (76.5)	3 (17.6)			
Sold sex to partner					
unprotected	0 (0)	6 (66.7)	--	9.333	0.009≠
protected	8 (100)	3 (33.3)			
Bought sex from partner					
unprotected	1 (16.7)	7 (77.8)	17.5 (0.86, 941.81)*	7.137	0.041≠
protected	5 (83.3)	2 (22.2)			

Subgroup analyses by race/ethnicity

Race/ethnicity	intervention n (%)	control n (%)	Odds ratio (95% C.I.)	Pearson Chi-square†	p-value
African American					
unprotected	11 (45.8)	17 (70.8)	2.87 (0.87, 9.45)	3.086	0.079
protected	13 (54.2)	7 (29.2)			
non-Hispanic white					
unprotected	9 (40.9)	21 (80.8)	6.07 (1.66, 22.12)	8.078	0.004
protected	13 (59.1)	5 (19.2)			
Hispanic					
unprotected	4 (22.2)	5 (71.4)	8.75 (1.21, 63.43)	5.297	0.058≠
protected	14 (77.8)	2 (28.6)			

Subgroup analyses by gender

Gender	intervention n (%)	control n (%)	Odds ratio (95% C.I.)	Pearson Chi-square†	p-value
Female					

Subgroup analyses by gender

Gender	intervention n (%)	control n (%)	Odds ratio (95% C.I.)	Pearson Chi-square†	p-value
unprotected	13 (36.1)	26 (83.9)	9.20 (2.84, 29.76)	15.619	< 0.001
protected	23 (63.9)	5 (16.1)			
Male					
unprotected	11 (39.3)	17 (65.4)	2.92 (0.96, 8.84)	3.678	0.055
protected	17 (60.7)	9 (34.6)			

Subgroup analyses for encounters involving two men

Male to male anal sex	intervention n (%)	control n (%)	odds ratio (95% CI)	Pearson Chi-square†	p-value
unprotected	2 (33.2)	6 (100)	--	6.000	0.061≠
protected	4 (66.7)	0 (0.0)			

†Fisher's exact used when expected cell sizes were < 5.

≠Fisher's exact test

Note: Subgroup analyses are only to provide insights into how the intervention may impact risk with different partner types among different demographic and risk groups. Odds ratios and p-values for all subgroup analyses are for comparison purposes only and should be interpreted cautiously. None of the results are adjusted for multiple comparisons.