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Optimizing the Scientific Yield from a Randomized Controlled Trial (RCT): Evaluating Two Behavioral Interventions and Assessment Reactivity with a Single Trial

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Abstract

Randomized controlled trials (RCTs) remain the gold standard for evaluating intervention efficacy but are often costly. To optimize their scientific yield, RCTs can be designed to investigate multiple research questions. This paper describes an RCT that used a modified Solomon four-group design to simultaneously evaluate two, theoretically-guided, health promotion interventions as well as assessment reactivity. Recruited participants ($N = 1010$; 56% male; 69% African American) were randomly assigned to one of four conditions formed by crossing two intervention conditions (i.e., general health promotion vs. sexual risk reduction intervention) with two assessment conditions (i.e., general health vs. sexual health survey). After completing their assigned baseline assessment, participants received the assigned intervention, and returned for follow-ups at 3, 6, 9, and 12 months. In this report, we summarize baseline data, which show high levels of sexual risk behavior; alcohol, marijuana, and tobacco use; and fast food consumption. Sexual risk behaviors and substance use were correlated. Participants reported high satisfaction with both interventions but ratings for the sexual risk reduction intervention were higher. Planned follow-up sessions, and subsequent analyses, will assess changes in health behaviors including sexual risk behaviors. This study design demonstrates one way to optimize the scientific yield of an RCT.

Keywords

randomized controlled trial; Solomon four-group design; sexual risk behavior; health behaviors; assessment reactivity

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Introduction

Randomized controlled trials (RCTs) require large samples and multiple measurements to assess intervention effects; consequently, RCTs are often costly. In addition to addressing primary aims (i.e., intervention efficacy), well-designed RCTs often include secondary aims, such as the testing of hypothesized mechanisms of action (i.e., to discover *why* an intervention worked). Investigators often seek to optimize the return-on-investment from RCTs by planning ancillary studies with both planned and exploratory analyses. This strategy seeks to get “more bang for the research dollar.” This paper overviews the design of an ongoing RCT of a sexual risk reduction intervention that aims to optimize the scientific yield from a single trial.

Sexually transmitted infections (STIs) remain a major public health concern. Collectively, 19 million Americans are infected with an STI annually.[1] The prevalence of HIV is estimated to be 1.2 million people and the incidence is 50,000 annually.[2] If untreated, STIs can lead to complications such as pelvic inflammatory disease, infertility, and cancer.[3] STIs also increase susceptibility to HIV infection,[4] an infection that has resulted in more than 600,000 deaths in the U.S. since the beginning of the HIV/AIDS epidemic.[5] In addition to these health consequences, STIs burden the U.S. health care system with an annual direct medical cost of \$17 billion.[6] STI clinics are opportune settings in which to evaluate sexual risk reduction (SRR) interventions. Patients attending such clinics report high rates of sexual risk behavior [7, 8] and elevated STI rates.[7, 9] In addition, patients are frequently low-income and racial minorities, subgroups that are disproportionately affected by STIs and HIV [3, 10] as well as other health burdens.[11]

Although SRR interventions are effective in increasing condom use and reducing STIs,[12] many of these interventions require staff training and time; therefore, they have not been widely adopted after initial efficacy research has been completed. Using video-based technology to deliver interventions may optimize the feasibility, disseminability, and reach of these interventions. Prior research has found that video-based SRR interventions reduce sexual risk behavior and STIs.[13-15] However, not all video-based interventions have been effective, effect sizes are small, and most studies are underpowered for STI outcomes. Thus, there is a need to refine this technology to capitalize on its feasibility while enhancing its effectiveness.

Most evaluations of SRR interventions include a detailed assessment of sexual behavior. Although important for evaluation purposes, completing a detailed behavioral assessment may lead to changes in attitudes and behavior.[16] There is evidence of “pretest sensitization” effects for numerous health behaviors (e.g., physical activity, drinking, [17-19]) but our understanding of assessment reactivity in the context of sexual behavior remains limited.

Given the need for innovative SRR interventions and the need to better understand assessment reactivity, we designed a RCT (a) to evaluate the efficacy of a video-based SRR intervention, (b) to evaluate reactivity to a detailed sexual health survey, and (c) to evaluate the efficacy of a video-based general health promotion intervention for socioeconomically disadvantaged patients. This paper describes the study design, methods, measures, and participants; and presents data from the baseline assessment on baseline demographics, health behaviors, and intervention satisfaction.

Material and Methods

Research Design

The classic Solomon four-group design allows for the evaluation of the separate effects of assessment and intervention.[20] In this design, participants are assigned to one of four conditions created by crossing assessment (no pretest vs. pretest assessment) by intervention (intervention vs. control condition). The intervention + no pretest group reflects the effect of the intervention only; the control + pretest group reflects the effect of the assessment only; and the intervention + pretest group reflects the effect of both the intervention and assessment.

For this study, we modified the Solomon four-group design. Specifically, half of the participants completed a comprehensive sexual behavior assessment while half completed a general health assessment that focused on a range of health behaviors (e.g., diet, exercise, sleep, substance use). Nested in both surveys were a small number of questions about sexual behavior used to evaluate study outcomes. Thus, patients were assigned to one of four conditions formed by crossing assessment condition (sexual health-focused survey vs. general health-focused survey) with intervention condition (sexual health-focused vs. general health-focused; Figure 1).

We chose to have one-half of patients complete the general health survey, rather than being assigned to a “no assessment” condition, for several reasons. First, because participants were patients attending an STI clinic, all patients were asked questions about their sexual behavior as part of their routine care; thus, given the setting, there was an ethical imperative to assess sexual behavior in all patients. Second, collecting minimal data on sexual behavior at baseline allowed us to assess whether randomization was successful. Third, this design allowed us to enroll fewer participants while affording sufficient statistical power to detect intervention-related change from baseline to follow-up; because we collected sexual behavior data from all patients, we could conduct within-subjects analyses on the entire sample. Fourth, the general health assessment made the time demands of the baseline experience equivalent for all participants. In light of these considerations, we decided that, instead of using a “no assessment” condition, one-half of patients would complete a time-matched general health-focused assessment that also included only a few questions about sexual behavior. In this way, we minimized assessment reactivity (in the general health survey), while capitalizing on the benefits of having sexual behavior data at baseline for all participants.

In addition to the baseline assessment, patients were re-assessed at 3, 6, 9, and 12 months post-intervention. Those assigned to the sexual health-focused survey completed the sexual health survey on all occasions, and those assigned to the general health-focused survey completed the general health survey on all occasions. In addition, participants completed a brief satisfaction survey immediately following receipt of their intervention.

Participants

Participants were patients attending a public STI clinic located in New York state. Inclusion criteria were: (a) age 16 or older; and (b) reported sexual risk behavior in the past 3 months (i.e., had vaginal or anal sex with more than one person or had vaginal or anal sex with someone who had other partners, and did not use a condom every time for vaginal or anal sex). Exclusion criteria were: (a) HIV positive; (b) impaired mentally; (c) planning to move out of the area; and (d) currently receiving inpatient substance use treatment services. Our goal was to recruit a sample that reflected the demographics of patients attending the STI clinic.

Measures

All participants completed core items as well as a unique set of items (that varied according to the condition to which they were assigned).

The core items asked about demographics (e.g., race/ethnicity, education, employment), diet (e.g., fast food frequency), physical activity (e.g., frequency of moderate physical activity), smoking (e.g., frequency and number of cigarettes), alcohol use (e.g., AUDIT-C [21]; number of drinks per week); drug use (frequency of marijuana and cocaine use); sleep (e.g., number of hours per night); and seven items about sexual behavior (i.e., number of partners; whether partnerships were concurrent; number of unprotected vaginal and anal sex episodes with steady and non-steady partners). Additional items assessed partner violence,[22] perceived stress,[23] and mental health.[24] as well as a survey assessing their satisfaction with the intervention.[25]

The unique set of items varied by condition. Patients assigned to the **sexual health survey** responded to items assessing sexual history (e.g., age at first sex, number of lifetime partners, sex trading, HIV testing, STI diagnoses) as well as the constructs suggested by the Information—Motivation—Behavioral Skills (IMB) model of health behavior change [26]. Information was assessed with validated questionnaires [27-29]. Motivation was assessed for both condom use and partner reduction. Motivation for condom use was assessed with condom attitudes [30-32]; intentions to use a condom; perceived subjective and descriptive norms for condom use; and perceived risk of contracting an STI. Motivation for partner reduction was assessed with descriptive and subjective norms for partner concurrency; attitudes towards concurrency [33]; and behavioral intentions. Behavioral skills for condom use were assessed with items that tapped correct use [34, 35]; access to condoms; condom influence skills [36, 37]; and self-efficacy [38]. Skills for partner reduction included items tapping self-efficacy for, and environmental constraints on, monogamy. The number of unique sexual assessment items ranged from 138 to 152 (contingent on skip patterns).

Patients assigned to the **general health survey** responded to items assessing diet (food consumption [39], weight and height, weight loss importance, confidence, intentions), physical activity (activity levels [40], self-efficacy and intentions), and sleep (assessed with the Medical Outcomes Study (MOS) scale [41]). Alcohol use and problems were assessed with established measures [42] [43]. Importance, confidence, and intentions for reducing alcohol use as well readiness to change were assessed. Drug use was assessed with the Drug Abuse Screening Test [44] (DAST). For patients who smoked, we assessed smoking cessation importance, confidence, and intentions. Other health behaviors assessed included dental exams and seatbelt use. Patients rated their overall health, access to healthcare, and anticipated life expectancy. Social support was assessed with the MOS survey.[45] Neighborhood disorder and violence were assessed with the City Stress Inventory.[46] Life satisfaction and health value were also assessed. Overall, the number of unique general health items ranged from 96 to 154, depending on skip patterns.

Sexually transmitted infections (STIs)—At baseline, participants were tested for STIs per standard protocol. At all follow-ups, urine specimens were tested for chlamydia (CT) and gonorrhea (Gc), and clinic records were reviewed for CT, Gc, trichomoniasis, syphilis, and HIV.

Primary and Secondary Outcomes

The primary outcome will be incident STI. The secondary outcomes will be the number of sexual partners and the frequency of unprotected acts.

Interventions

Following completion of the baseline assessment, patients viewed one of two video interventions: (a) sexual health-focused or (b) general health-focused. Intervention context was based on focus groups conducted with clinic patients that had elicited barriers to engaging in healthier behavior, as well as strategies used by participants to overcome those barriers [47, 48]. For this study, the interventions were presented in place of HIV pretest counseling.

The interventions were similar in structure and style; only the health content differed between the interventions. Both interventions were 22 minutes in length, and included didactic segments, one-on-one interviews, and dramatic segments. The latter embedded risk reduction messages within a narrative that was engaging, similar to the strategy used in edutainment.[49] Actors, images, and music were selected to appeal to an urban and youthful sensibility.

Both interventions drew on the IMB model.[26] In addition, messages were delivered using principles from Self-Determination Theory [50] and Motivational Interviewing [51] to avoid eliciting resistance; for example, during the dramatic segments, characters empathized with characters' challenges, acknowledged characters' autonomy, challenged the uniformity of perceived norms, and provided a menu of options. Characters articulated the pros and cons of their own behavior, explored their ambivalence about their current behavior, and, consistent with Social Learning Theory [52], represented coping rather than mastery models.

The interventions were developed through a collaboration between behavioral scientists and a media production company. The scientists chose the content of the intervention, including the theoretical constructs to be targeted, the barriers to behavior that needed to be addressed in the interventions, and the incorporation of theoretical principles. The media company tailored the language and dramatic segments to the target audience, and led the pre-production (e.g., casting), filming, and post-production activities (e.g., editing, incorporating graphics and music).

Sexual health intervention—To promote condom use and reduce the number of partners, the intervention targeted IMB constructs. Informational components included data regarding HIV and STI rates, and facts about HIV transmission and prevention. Motivational elements were addressed through vignettes based on formative research. Characters identified barriers to condom use (e.g., condoms reduce pleasure and imply a lack of trust) and to partner reduction (e.g., a man's nature is to have multiple partners), and also provided suggestions for overcoming these barriers. Skills elements were addressed through a demonstration of the correct way to use male and female condoms and a dramatic segment demonstrating how to discuss condom use with a partner.

General health intervention—The general health intervention addressed physical activity, healthy eating, smoking, alcohol use, managing stress, and safer sex. Informational segments provided information about the effects of these health behaviors. Dramatic segments depicted barriers to and solutions for each health behavior. Skills were addressed by providing suggestions for steps that participants could take to become healthier (e.g., taking the stairs; drinking water instead of soda). Because the research took place in an STI clinic, we were ethically bound to provide patients with information about safer sex but this component provided basic information on HIV disease, transmission and prevention.

Procedures

All procedures were approved by the Institutional Review Boards of the participating institutions, a Federal Certificate of Confidentiality was obtained to protect participant privacy, and the trial was registered at ClinicalTrials.gov (NCT00947271).

A Research Assistant (RA) called patients from the waiting room and escorted them to a private room where she explained that a study was being conducted to improve health in the community. If willing to answer a few questions, patients were screened for eligibility. Eligible patients were invited to join the study following a thorough consent process [53]. Participants then provided contact information so they could be contacted for follow-up surveys.

Next, patients completed a calendar of salient events over the past 3 months (e.g., birthdays, holidays) to orient them to the timeframe used in many of survey items (to improve accuracy of responding [54]). The RA helped patients navigate through sample questions on a laptop computer using audio computer-assisted self-interview (ACASI). During the ACASI, patients could listen to questions and response options read aloud if they wished, allowing patients with lower literacy to participate. After patients were comfortable answering the sample questions, they were left alone in the exam room to complete the ACASI. Participants were encouraged to buzz the RA at any time if they had questions.

After completing the ACASI, patients watched their video-based intervention, and then completed a brief satisfaction survey. They were reimbursed \$30 for their time and given an appointment for their 3 month follow-up. They then completed the clinic visit, including an intake, physical examination, STI and HIV testing, and medical treatment (if indicated). Clinic visits were conducted by a nurse or nurse practitioner.

Patients were given a 4-week window during which they could return for follow-up. A reminder letter was mailed two days before the start of the follow-up window. If participants did not return within 2-3 days of the start of the follow-up window, RAs contacted them by phone. At the follow-ups, participants provided a urine sample, and then completed an ACASI consistent with each patient's assigned condition. RAs confirmed contact information, and patients were given an appointment for their next follow-up and reimbursed \$30 for their time.

Chart review—With patient consent, medical records will be reviewed to identify additional incident STIs during participants' year of study enrollment.

Data Analyses

Power calculations—To determine the sample size, we conducted *a priori* power analyses based on the smallest anticipated effect size (i.e., **STI outcomes**). The minimum sample needed to detect effects was estimated using power analysis of proportions from two samples. Our goal was to detect a small effect (Cohen's $d = .2$) [55] of the intervention on STI incidence; this equates to an absolute reduction of 6-7% in the incidence of STIs among those in the sexual health intervention group as compared to those in general health intervention group. To achieve 80% power to detect this difference given a Type I error rate of .05, approximately 393 participants would be needed per group. We expected approximately 25% attrition from the study by 12 months based on past research (however, even for these patients, we knew that we would have medical chart data); therefore, we recruited 500 participants for each intervention condition.

We confirmed that 1000 patients randomized to 4 groups (250 per group) will provide sufficient power for the multilevel regression models for the behavioral outcomes; that is,

assuming 75% retention (~188 per group), power = .80, Type I error = .05, and 5 assessments, a sample size of 1000 will yield sufficient power to find even a very small effect (Cohen's $f = .04$) for the time $\times$ group interaction term in a standard repeated-measures ANOVA; thus, there is an adequate number of participants to assess the behavioral outcomes.

Current analyses—The analyses reported herein will: (a) describe baseline characteristics of the sample; (b) confirm that randomization produced equivalent groups; (c) determine relationships among baseline behaviors, attitudes, and skills; and (d) determine whether participants were satisfied with the interventions. Summary statistics (e.g., means, standard deviations) describe the sample. Analyses of variance and chi-square analyses determine whether groups differed at baseline and whether patients were equivalently satisfied with both interventions. Correlations investigate relationships among baseline variables.

Future analyses—We will test three *a priori* hypotheses: (1) patients who view the sexual health intervention will have fewer incident STIs and greater decreases in sexual risk behavior (i.e., fewer sexual partners and fewer unprotected acts) relative to patients who view the general health intervention; (2) the sexual health assessment will result in greater decreases in sexual risk behavior relative to the general health assessment; and (3) the combined sexual health assessment and intervention will yield the greatest decreases in sexual risk behavior.

Separate analyses will be used for biological and behavioral outcomes. To model the STI outcome for Hypothesis 1, logistic regression will be used. Given the interest in STI incidence (i.e., new STIs diagnosed after baseline), STI diagnoses at 3, 6, 9, or 12 months as well as additional incident STIs identified through chart review will be pooled to indicate any diagnosis (i.e., a dichotomous outcome). Hypothesis 1 will be tested by including intervention condition as the predictor of follow-up incidence rates.

To test the effects of the sexual health intervention on the behavioral counts (sex partners, unprotected acts), we will use standard multilevel regression models, which allow for repeated assessments to be nested within each participant; for the (dichotomous) concurrency outcome we will use multilevel logistic regression (MLR), which provides a framework for the prediction of a dichotomous outcome while modeling repeated-measures data. MLR involves use of a standard multilevel or random-effects regression with a logit link function to yield residuals that adhere to standard regression assumptions. In contrast to the STI analysis, these regressions will include the baseline data and will model change using an intercept estimate to represent behavior at baseline and slopes to represent linear changes over the subsequent 9 months. Because we expect larger changes initially (i.e., at 3 months) and more gradual changes across the follow-ups, we will model change using two slopes (i.e., a discontinuous model). Thus, change will be modeled with three components: (a) a baseline intercept value, (b) an immediate effect as the change from baseline to 3 months, and (c) a long-term effect as the change from 3 to 12 month follow-ups. We expect no group differences in the baseline intercept estimates given randomization. However, we expect patients who received the sexual health intervention to have larger negative slopes than the general health intervention, from baseline to 3 months, as well as more maintenance of intervention effects from 3 months to 12 months. Finally, because the dependent variables represent different aspects of sexual risk behavior, they will be analyzed separately and results will be compared across models for cross-validation.

Hypotheses 2 and 3 will be tested by adding the type of assessment and the assessment $\times$ intervention interaction to the discontinuous multilevel model as predictors of change from (a) baseline to 3 months and (b) 3 to 12 months for the behavioral outcomes.

Results

Recruitment

Ninety-seven percent (2677 of the 2766 patients who were approached) agreed to the screening; of these, 1322 (49%) were eligible, and 1010 (76%) were consented and randomized (see Figure 2). The most common reason for declining to participate was time (63% of those who refused). One-half of consented participants were assigned randomly to each assessment condition; of those assigned to each assessment condition, one-half were randomly assigned to each of the two intervention conditions. The follow-up assessments are ongoing.

Participant Characteristics

Demographics—The sample included men (56%) and women (44%; Table 1). Patients self-identified as African American (69%), Caucasian (19%), and Hispanic (8%). Average age was 28.5 years. Many were socioeconomically disadvantaged, with 52% unemployed, 54% reporting an income of <\$15,000/year, and 64% having a high school education or less. Six percent were married; 57% of participants had children with the average number of children 2.4. The majority self-identified as heterosexual (87%). These characteristics reflect the characteristics of patients seen at the STI clinic.

Sexual behavior—Participants reported high levels of sexual risk behavior (Table 2), including an average of 2.7 sexual partners in the past 3 months (median = 2.0). Most reported having a steady partner (79%) as well as a casual partner in the past 3 months (77%). Nearly half of participants reported concurrent partnerships (47%). Patients reported 16.4 episodes of unprotected sex in the past 3 months (median = 9.0); 70% of their sexual episodes were unprotected. Among those with a steady partner, participants reported an average of 18.0 episodes of unprotected sex with that partner in the past 3 months (median = 10.0); 77% of their sexual episodes with a steady partner were unprotected. Among those with casual partners, participants reported an average of 3.0 episodes of unprotected sex with casual partners in the past 3 months (median = 2.0); 53% of sexual episodes with casual partners were unprotected.

General health behavior—Patients also reported high rates of health compromising behaviors (Table 3); for example, they reported eating breakfast an average of 3.4 days per week (median = 3.0). Over two-thirds (69%) reported consuming fast food at least weekly and 10% reported that they eating fast food daily or almost daily. The sample was relatively active, with 47% engaging in vigorous activity for 20 minutes at least a few times a week and 15% reporting nearly daily vigorous activity; 57% reported engaging in moderate activity for 30 minutes at least a few times a week, and 25% reported nearly daily moderate activity.

Sixty-one percent reported smoking cigarettes regularly (once a week or more), with an average of 6.9 cigarettes smoked per day (median = 6.0). Ninety percent reported having a drink in the past year, with a mean of 6.0 drinks per week (median = 3.0); 38% drank an average of 0 to 2 drinks per week, 34% drank an average of 3 to 6 drinks per week; and 27% drank an average of 7 drinks per week. Based on scores on the AUDIT-C for the last year, 58% of patients met criteria for hazardous drinking and 45% met criteria for an alcohol use disorder. Over half of the sample (52%) reported using marijuana in the past year, with 23% of these reporting daily use. In contrast, only 7% used cocaine or crack cocaine in the past year.

Participants also reported poor sleep habits, with only 41% getting the recommend 7-9 hours of sleep per night; 54% of the sample got less than 7-8 hours of sleep. Only 35% of the sample reported that they felt rested upon waking most or all of the time.

Effects of Randomization

Randomization resulted in groups that were equivalent on nearly all characteristics (see Tables 1, 2, and 3). There were no differences among groups in sociodemographic characteristics (sex, race, ethnicity, education, employment, income, marital status, sexual orientation, age, children) or sexual behavior (number of partners past 3 months, number of episodes of unprotected sex, proportion of episodes of unprotected sex, partner concurrency). There were few differences among groups in general health behavior (diet, exercise, smoking, marijuana use, or sleep). The only baseline difference was in alcohol use. Compared to patients in the general health assessment condition, patients in the sexual health assessment condition scored higher on the AUDIT-C ($M_{\text{sexual health}} = 4.8$; $M_{\text{general health}} = 4.3$), $F(1, 897) = 8.31$, $p < .01$, and were more likely to be classified as having an alcohol use disorder (49% in sexual health vs. 42% in general health assessment condition), $\chi^2(1, N = 1004) = 4.57$, $p < .05$. Therefore, we will control for alcohol use when we conduct outcome analyses.

Correlations among Health Behaviors at Baseline

We examined correlations among health behavior variables (Table 4). As expected, sexual behavior variables (unprotected sex, number of sex partners) were positively correlated, substance use variables (AUDIT-C, smoking, marijuana use) were positively correlated, and physical activity variables (vigorous and moderate activity) were positively correlated. In addition, sexual risk behavior variables were positively correlated with substance use variables. Fast food consumption was positively correlated with sexual risk (unprotected sex and number of partners) and marijuana use; fast food consumption was negatively correlated with feeling rested upon waking. No other correlations among health behavior variables were significant.

Correlations among Sexual Risk Behaviors and Motivation and Skills Constructs

We also examined correlations among sexual risk behavior variables and related motivation and skills constructs (Table 5). As expected, number of episodes of unprotected sex with a steady partner in the past 3 months was negatively related to: (a) positive attitudes towards condom use with a steady partner; (b) behavioral intentions for condom use with a steady partner; and (c) condom use confidence with a steady partner. Number of episodes of unprotected sex with outside partners was negatively related to: (a) positive attitudes towards condom use with outside partners; (b) behavioral intentions for condom use with outside partners; and (c) condom use confidence with outside partners. Number of sex partners was positively related to: (a) more positive attitudes towards partner concurrency; and (b) stronger intentions to have multiple partners. Number of sex partners was negatively related to: (c) self-efficacy for having a single partner.

Intervention Satisfaction

In general, patients were satisfied with both interventions. However, group differences emerged with patients in the sexual health condition reporting greater satisfaction (see Table 6); patients who viewed the sexual health intervention reported more of their needs were met, $F(1, 1005) = 37.17$, $p < .0001$, greater satisfaction, $F(1, 1003) = 18.47$, $p < .0001$, were more likely to come back, $F(1, 1005) = 9.76$, $p < .01$, found the intervention more interesting, $F(1, 1004) = 50.40$, $p < .0001$, learned more, $F(1, 1005) = 27.47$, $p < .0001$, and had more positive feelings about the intervention, $F(1, 1003) = 10.42$, $p < .01$.

Discussion

This RCT will answer our primary research question: Can an edutainment-based intervention promote sexual risk reduction among low-income patients at an urban STI clinic? The intervention uses technology to overcome some of the limitations of traditional risk reduction interventions [56]; that is, traditional approaches (i.e., individual and group counseling) require extra staff (or extra training for busy nursing staff) and longer visit times for patients and providers.[8, 56] Moreover, group-based interventions often do not appeal to patients who may be embarrassed to be in a STI clinic and often cannot return for multiple sessions, even when financial incentives are provided.[8] The limitations of both individual- and group-based counseling have led to limited uptake of clinic-based sexual risk reduction interventions.[56] In contrast, a video intervention requires neither extra staff nor training, and can be delivered while patients are waiting to see their nurse or obtain test results. If efficacious, a video-based intervention can be easily disseminated and delivered with minimal cost.[57]

In addition to addressing our primary research question, this design will allow us to investigate several ancillary questions, including: (a) Does a detailed sexual history assessment lead to changes in sexual risk behavior (i.e., assessment reactivity)? (b) Does a detailed health behavior assessment leads to changes in other health behaviors (e.g., physical activity, sleep, smoking, alcohol use)? (c) Is the general health intervention, designed specifically for this trial and utilized as a control intervention, efficacious in improving other health behaviors (e.g., diet, physical activity, substance use)? and (d) Are changes in the hypothesized antecedents of sexual behavior change (e.g., information, motivation, and behavioral skills) the mechanisms through which the intervention exerts its effects? As NIH funding for research diminishes and the number of grant submissions increases [58], creative research designs and methodologies that allow for the investigation of multiple important questions in a single RCT and optimize scientific yield may help to make grant applications more competitive.

Participants reported high levels of health compromising behaviors. Consistent with previous findings, participants in the current trial reported high rates of sexual risk behavior, including multiple partners and frequent episodes of unprotected sex.[7, 8] In addition, patients reported high levels of other health compromising behaviors, including high rates of alcohol, marijuana, and tobacco use, high rates of fast food consumption, and low rates of adequate sleep. In this study, 45% of participants met criteria for an alcohol use disorder, compared to 15% to 23% found in national samples.[59] More than half of participants (52%) reported using marijuana in the past year; in national samples, 9% reported any illegal drug use in the past month.[60] Further, 61% of participants reported smoking cigarettes weekly or more frequently in the past 3 months, a rate that is considerably higher than the 24% of smokers reported in a nationally representative sample.[61] In this study, 69% of participants reported consuming fast food at least weekly, compared to 41% of participants in a representative community sample.[62] Only about two-fifths (41%) of participants got the recommended amount of 7-9 hours of sleep per night.[63] High rates of alcohol and drug use have been documented in prior studies among STI clinic patients,[64] but to our knowledge this is the first study to document high rates of other health compromising behaviors among these patients.

In contrast to other health behaviors, physical activity was higher than the general population.[65] Anecdotally, few of our participants have cars; walking to and using public transit can help people to meet goals for daily physical activity.[66] Although it is encouraging that our patients reported higher rates of physical activity, the majority of participants reported numerous behaviors that could compromise their health. Research

shows that socioeconomically disadvantaged individuals tend to engage in high rates of health compromising behaviors;[67-69] these high rates of health compromising behaviors may, at least in part, explain the numerous health disparities that exist by race and socioeconomic status.[11]

Consistent with prior research, substance use and sexual risk behaviors co-varied.[70-72] Ample evidence suggests that alcohol use is often associated with positive expectancies, sexual disinhibition, and increased sexual risk taking.[73-75] Somewhat surprisingly though, other health behaviors did not cluster; although a few of the other health behaviors were related, correlations were small with no consistent pattern of association. The modest associations among other health behaviors contrasts with limited prior research that has suggested that health promoting and health compromising behaviors tend to cluster together, [61, 76, 77].

Motivation and skills variables were also related to current condom use and number of sexual partners, corroborating previous findings.[26, 78, 79] We targeted these variables in our risk reduction intervention because of their association with sexual risk behavior. We anticipate that sexual behavior-related motivation and skills are the mechanisms through which our sexual risk reduction intervention will lead to behavior change; once data collection is completed, we will test whether these variables act as mediators between intervention condition and outcomes.

Patients expressed high levels of satisfaction with both the intervention and control interventions. We believe this reflects the formative research we did with clinic patients. The interventions included stories and challenges that were representative of participants, described in culturally-consonant language; anecdotally, patients who viewed the interventions often told our RAs that they could relate to the characters portrayed in the interventions. Although patients were satisfied with both interventions, the sexual risk reduction intervention was rated more favorably, perhaps because it was perceived as more relevant to participants' immediate sexual health concerns; in contrast, the general health intervention, which covered diet, physical activity, alcohol and tobacco use, and stress, may not have been as timely; that is, patients came to the clinic to receive sexual health services, not services related to general health.

Conclusions

We recruited a large sample of STI clinic patients to participate in an RCT to evaluate a novel, video-based sexual risk reduction intervention. The majority of participants were socioeconomically disadvantaged and primarily African-American, population subgroups that can sometimes be difficult to recruit and retain in research, [80, 81] even though these communities are disadvantaged with respect to health disparities and health care access. Effective health behavior interventions are needed for this population; in addition to high rates of sexual risk behavior, STI clinic patients in our study reported numerous other health compromising behaviors. Although many of the outcomes are self-reported, and therefore subject to recall and social desirability biases, self-reported outcomes will be supplemented with biologic data (i.e., STI outcomes). Our research design will allow us not only to investigate the efficacy of our sexual risk reduction intervention, but also to investigate the efficacy of a general health intervention, to investigate mechanisms of action, and to investigate the effects of a detailed sexual history assessment on behavior change. Thus, our research design optimizes the scientific yield obtained from this RCT.

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		Intervention Condition	
		General Health	Sexual Health
Assessment Condition	General Health	General Health Assessment + General Health DVD	General Health Assessment + Sexual Health DVD
	Sexual Health	Sexual Health Assessment + General Health DVD	Sexual Health Assessment + Sexual Health DVD

Figure 1.
Study design: fully randomized 2×2 design permitting testing of three study hypotheses

Figure 2.
Consort chart (flow diagram)

Table 1Socodemographic characteristics of study participants at baseline, overall and by condition ($N = 1010$)

	Total sample	General survey, General DVD	General survey, Sexual DVD	Sexual survey, General DVD	Sexual survey, Sexual DVD
	<i>n</i> (%)	<i>n</i> (%)	<i>n</i> (%)	<i>n</i> (%)	<i>n</i> (%)
Gender					
Female	443 (44%)	107 (42%)	129 (51%)	100 (40%)	107 (43%)
Male	567 (56%)	147 (58%)	125 (49%)	152 (60%)	143 (57%)
Race					
Caucasian	189 (19%)	49 (19%)	43 (17%)	43 (17%)	54 (22%)
African American	691 (69%)	168 (66%)	177 (70%)	180 (71%)	166 (67%)
Other	127 (13%)	36 (14%)	33 (13%)	29 (12%)	29 (12%)
Hispanic					
Yes	82 (8%)	25 (10%)	17 (7%)	16 (6%)	24 (10%)
No	927 (92%)	229 (90%)	237 (93%)	236 (94%)	225 (90%)
Education					
Less than high school	284 (28%)	70 (28%)	66 (26%)	68 (27%)	80 (32%)
High school / GED	359 (36%)	98 (39%)	88 (35%)	96 (38%)	77 (31%)
At least some college	366 (36%)	86 (34%)	100 (39%)	87 (35%)	93 (37%)
Employment					
Unemployed	525 (52%)	128 (50%)	125 (49%)	146 (58%)	126 (51%)
Employed	483 (48%)	126 (50%)	129 (51%)	105 (42%)	123 (49%)
Income					
< \$15,000/year	527 (54%)	128 (52%)	130 (53%)	148 (60%)	121 (50%)
\$15,000/year to	307 (31%)	74 (30%)	81 (33%)	65 (27%)	87 (36%)
\$30,000/year	145 (15%)	43 (18%)	34 (14%)	32 (13%)	36 (15%)
Married					
Yes	59 (6%)	13 (5%)	12 (5%)	16 (6%)	18 (7%)
No	950 (94%)	241 (95%)	242 (95%)	235 (94%)	232 (93%)
Self-identified sexual orientation					
Homosexual	30 (3%)	8 (3%)	6 (2%)	9 (4%)	7 (3%)
Bisexual	82 (8%)	20 (8%)	23 (9%)	17 (7%)	22 (9%)
Heterosexual	878 (87%)	223 (88%)	218 (87%)	220 (88%)	217 (87%)
Don't know	16 (2%)	3 (1%)	5 (2%)	4 (2%)	4 (2%)
Children					
No	434 (43%)	115 (45%)	105 (41%)	109 (44%)	105 (42%)
Yes (at least 1)	572 (57%)	139 (55%)	149 (59%)	140 (56%)	144 (58%)
	<i>M</i> (SD)	<i>M</i> (SD)	<i>M</i> (SD)	<i>M</i> (SD)	<i>M</i> (SD)
Age (years)	28.5 (9.5)	27.9 (8.9)	28.0 (9.2)	29.3 (9.7)	28.9 (10.0)
Number of children ^a	2.4 (1.7)	2.3 (1.6)	2.6 (1.6)	2.5 (1.9)	2.3 (1.8)

^a only for those ($n = 572$) who had children

Table 2Sexual behavior patterns of study participants at baseline, overall and by condition ($N = 1010$)

	Total sample		General survey, General DVD	General survey, Sexual DVD	Sexual survey, General DVD	Sexual survey, Sexual DVD
	<i>n</i>	<i>M</i> (SD)	<i>M</i> (SD)	<i>M</i> (SD)	<i>M</i> (SD)	<i>M</i> (SD)
Sexual partners, past 3 months	1009	2.7 (2.0)	2.7 (2.0)	2.6 (1.7)	2.6 (1.9)	2.8 (2.4)
Unprotected sex (no. episodes), past 3 months	998	16.4 (19.8)	15.6 (19.6)	15.9 (19.0)	17.3 (19.6)	16.8 (21.0)
Unprotected sex with steady partner ^a (no. episodes), past 3 months	790	18.0 (21.4)	17.0 (22.0)	17.7 (20.7)	18.8 (20.6)	18.7 (22.3)
Unprotected sex with casual partners ^b (no. episodes), past 3 months	732	3.0 (3.7)	3.0 (3.5)	2.9 (3.6)	2.8 (3.4)	3.5 (4.2)
Unprotected sex (proportion episodes), past 3 months (0-1)	998	.70 (.32)	.68 (.31)	.69 (.32)	.73 (.31)	.69 (.34)
Unprotected sex with steady partner ^a (proportion episodes), past 3 months (0-1)	790	.77 (.32)	.75 (.33)	.77 (.32)	.81 (.29)	.76 (.34)
Unprotected sex with casual partners ^b (proportion episodes), past 3 months (0-1)	732	.53 (.40)	.53 (.39)	.51 (.41)	.53 (.40)	.54 (.41)

	<i>n</i> (%)	<i>n</i> (%)	<i>n</i> (%)	<i>n</i> (%)	<i>n</i> (%)
Had a steady partner, past 3 months	796 (79%)	203 (80%)	202 (80%)	200 (80%)	191 (76%)
Had casual partners, past 3 months	769 (77%)	200 (79%)	191 (75%)	194 (78%)	184 (74%)
Had concurrent partners, past 3 months	478 (47%)	126 (50%)	120 (47%)	124 (49%)	108 (43%)

Note. Outliers > 3X the interquartile range (IQR) from the 75th percentile truncated to 3X IQR from the 75th percentile + 1. *M* = mean.

^a only for those ($n = 796$) reporting a steady partner

^b only for those ($n = 769$) reporting a casual partner

Table 3General health behavior patterns of study participants at baseline, overall and by condition ($N = 1010$)

	Total sample		General survey, General DVD	General survey, Sexual DVD	Sexual survey, General DVD	Sexual survey, Sexual DVD
	<i>n</i>	<i>M</i> (SD)	<i>M</i> (SD)	<i>M</i> (SD)	<i>M</i> (SD)	<i>M</i> (SD)
Ate breakfast, no. days past week	1009	3.4 (2.1)	3.4 (2.0)	3.2 (2.1)	3.5 (2.2)	3.6 (2.2)
Cigarettes smoked/day, average ^a	644	6.9 (5.7)	6.9 (5.8)	6.1 (4.9)	7.8 (6.5)	6.9 (5.9)
Drinks/week, average ^{b*}	894	6.0 (6.7)	5.7 (6.2)	4.9 (5.6)	6.4 (7.3)	6.9 (7.5)

	<i>n</i> (%)	<i>n</i> (%)	<i>n</i> (%)	<i>n</i> (%)	<i>n</i> (%)
Fast food consumption, weekly or more	698 (69%)	167 (66%)	180 (71%)	177 (71%)	174 (70%)
Vigorous activity, weekly or more	473 (47%)	132 (52%)	119 (47%)	107 (43%)	115 (46%)
Moderate activity, weekly or more	579 (57%)	145 (57%)	149 (59%)	146 (58%)	139 (56%)
Smoke cigarettes, weekly or more	612 (61%)	156 (61%)	142 (56%)	163 (65%)	151 (60%)
Hazardous drinking, past year ^c	584 (58%)	147 (59%)	132 (52%)	152 (61%)	153 (61%)
Alcohol use disorder, past year ^d	453 (45%)	111 (44%)	100 (39%)	122 (49%)	120 (48%)
Marijuana use, past year	517 (52%)	131 (52%)	121 (48%)	133 (53%)	132 (53%)
Crack cocaine or cocaine use, past year	71 (7%)	17 (7%)	14 (6%)	23 (9%)	17 (7%)
Slept 7-8 hours/night, past month	370 (37%)	97 (38%)	102 (40%)	82 (33%)	89 (36%)
Rested upon waking, most or all of the time	353 (35%)	91 (36%)	80 (32%)	98 (39%)	84 (34%)

Note. Outliers > 3X the interquartile range (IQR) from the 75th percentile truncated to 3X IQR from the 75th percentile + 1. *M* = mean.

^a only for those who reported smoking in the past 3 months

^b only for those who reported having a drink in the past year

^c based on AUDIT-C score of 4 or more for men or 3 or more for women

^d based on AUDIT-C score of 5 or more for men or 4 or more for women

* $p < .05$

Table 4Correlations among selected health behaviors at baseline ($N = 885$)

	Unprotected sex	Sex partners	Alcohol use	Smoking	Marijuana	Fast food	Vigorous activity	Moderate activity	Feel rested
Unprotected sex (no. episodes)	1.0								
Sex partners (number)	.09**	1.0							
Alcohol use (AUDIT-C)	.07*	.13***	1.0						
Smoking frequency	.14***	.07*	.21***	1.0					
Marijuana use frequency	.12***	.12***	.10**	.32***	1.0				
Fast food frequency	.09**	.09**	.01	.03	.15***	1.0			
Vigorous activity frequency	.02	.04	.05	-.02	.05	-.05	1.0		
Moderate activity frequency	-.03	.01	-.02	-.03	-.03	-.05	.52***	1.0	
Feel rested upon waking	-.05	.01	.02	-.05	-.03	-.08*	.02	-.02	1.0

AUDIT-C = Alcohol Use Disorders Identification Test – Consumption.

*
 $p < .05$

**

 $p < .01$

 $p < .001$

Table 5

Correlations among sexual risk behavior variables and motivation and behavioral skills constructs

Condom use with steady partner (n = 381)				
	Unprotected sex	Condom attitudes	Behavioral intentions	Condom confidence
Unprotected sex with steady partner (number of episodes)	1.0			
Condom attitudes with steady partner	-.31 *	1.0		
Behavioral intentions for condom use with steady partner	-.37 *	.28 *	1.0	
Condom use confidence with steady partner	-.34 *	.51 *	.51 *	1.0
Condom use with outside partners (n = 351)				
	Unprotected sex	Condom attitudes	Behavioral intentions	Condom confidence
Unprotected sex with outside partners (number of episodes)	1.0			
Condom attitudes with outside partners	-.35 *	1.0		
Behavioral intentions for condom use with outside partners	-.34 *	.32 *	1.0	
Condom use confidence with outside partners	-.33 *	.47 *	.54 *	1.0
Partner Concurrency (n = 496)				
	Sex partners	Concurrency attitudes	Behavioral intentions	Self-efficacy
Sex partners (number)	1.0			
Concurrency attitudes	.46 *	1.0		
Behavioral intentions for concurrency	.34 *	.51 *	1.0	
Self-efficacy for monogamy	-.24 *	-.54 *	-.39 *	1.0

*
 $p < .0001$

Table 6DVD satisfaction by intervention group ($N = 1007$)

	<u>Possible Range</u>	<u>Sexual Health DVD</u>		<u>General Health DVD</u>		<u>Cohen's d</u>
		<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>	
To what extent did educational information and counseling meet your needs	1-4	3.61	0.58	3.36	0.72	0.38**
How satisfied were you with educational information and counseling	1-4	3.83	0.39	3.70	0.53	0.28**
Would you come back to our program	1-4	3.77	0.45	3.67	0.51	0.21*
How interesting was the DVD	1-4	3.55	0.70	3.22	0.80	0.44**
How much did you learn	1-4	3.19	0.80	2.92	0.83	0.33**
What is your general feeling about the DVD	1-4	3.65	0.52	3.54	0.54	0.21*

 M = mean.*
 $p < .01$ **
 $p < .0001$