Evaluating a Brief, Video-Based Sexual Risk Reduction Intervention and Assessment Reactivity with STI Clinic Patients: Results from a Randomized Controlled Trial

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Abstract We report results from a randomized controlled trial designed to evaluate the efficacy of a video-based sexual risk reduction intervention and to measure assessment reactivity. Patients ($N = 1010$; 56 % male; 69 % African American) receiving care at a sexually transmitted infection (STI) clinic were assigned to one of four conditions formed by crossing assessment condition (i.e., sexual health vs. general health) with intervention condition (i.e., sexual risk reduction intervention vs. general health promotion). After completing their assigned baseline assessment, participants received their assigned intervention, and

subsequently returned for follow-up assessments at 3, 6, 9, and 12 months. Participants in all conditions reduced their self-reported sexual risk behavior, and the incidence of new STIs declined from baseline through the follow-ups; however, there was no effect of intervention or assessment condition. We conclude that further risk reduction will require more intensive interventions, especially in STI clinics that already provide excellent clinical care.

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Resumen Presentamos los resultados de un estudio experimental aleatorizado con grupo de control diseñado para evaluar la eficacia de una intervención basada en un video para reducir el comportamiento sexual de riesgo y para medir reactividad. Se crearon cuatro condiciones experimentales al cruzar las condiciones de evaluación (es decir, salud sexual versus salud general) con las de intervención (es decir, reducción de comportamiento sexual de riesgo versus promoción de la salud general). Los pacientes, ($N = 1010$; 56 % hombres; 69 % afroamericanos) que recibían atención en una clínica de infecciones de transmisión sexual (ITS), fueron asignados a unas de las cuatro condiciones experimentales. Después de completar la evaluación inicial a la que fueron asignados, los participantes recibieron la intervención correspondiente y posteriormente regresaron para el seguimiento a los 3, 6, 9 y 12 meses. Los participantes en todas las condiciones redujeron su comportamiento de riesgo sexual, medido mediante un cuestionario que completaron ellos mismos, y la incidencia de nuevas infecciones de transmisión sexual se redujo comparando cada seguimiento con la línea base. Sin embargo, no se observó efecto de la intervención o condición de comparación. Llegamos a la conclusión de que para reducir en mayor medida el comportamiento de riesgo sexual se requieren intervenciones más intensivas, sobre

todo en las clínicas de ITS en las que ya se proporciona una excelente atención clínica.

Keywords Prevention · Sexual risk reduction · HIV · Randomized controlled trial (RCT) · Sexually transmitted infection (STI) · Sexually transmitted disease (STD) · Assessment reactivity · Sexual behavior

Introduction

HIV and other sexually transmitted infections (STIs) remain stubbornly persistent [1]. HIV leads to AIDS, and other STIs (e.g., chlamydia, gonorrhea) can cause pelvic inflammatory disease, chronic pelvic pain, ectopic pregnancy, and infertility in women; epididymitis in men; and cancer in men and women. The personal, social, and economic burden of these diseases is high [2]. Most new HIV infections and other STIs result from sexual risk behavior, including unprotected vaginal and anal intercourse, multiple sexual partners, and sexual partner concurrency. Given the epidemiology and consequences of HIV and other STIs, the continued development and dissemination of effective sexual risk reduction interventions remain a public health priority [3].

Public STI clinics provide opportune settings for sexual risk reduction. People attending such clinics tend to report high rates of unprotected intercourse, many lifetime sexual partners, and multiple recent partners. Many patients are low-income and racial and ethnic minorities who are disproportionately infected with HIV [1]. Many patients are subsequently re-infected [4–6], and any STI increases the likelihood of HIV transmission and acquisition [7, 8]. Given these facts, it is not surprising that STI clinic patients are infected with HIV at rates that are higher than those observed in the general population [9].

Behavioral interventions implemented in STI clinics reduce sexual risk behavior and lower STI rates [10–14]. However, the impact of such interventions is limited by at least four factors. First, intensive interventions (i.e., those requiring multiple sessions, e.g., [15]) are often infeasible due to staffing constraints and the burden they impose on patients (e.g., transportation, child care, lost wages); attendance at intensive interventions is usually poor even with monetary and other incentives [13, 14, 16–20]. Second, brief interventions (i.e., those lasting ≤ 1 h) are more feasible but tend to have small effects [21, 22]. In a recent meta-analysis, the mean effect for brief interventions (BIs) on STI reinfection was $d = 0.10$ [23]. Thus, BIs need to be improved to enhance their public health impact. Third, most studies have focused on condom use. However, sexual partner concurrency enhances risk for STI and HIV transmission [24–27] and interventions that target partner

concurrency (as well as condom use) to reduce STI incidence are limited. Fourth, behavioral interventions are usually preceded by detailed assessments; completing these assessments may lead to behavior change [28]. Whether pre-intervention assessments—common to research studies—are “reactive” [29–31] and how much change can be expected with an intervention in the absence of an intensive assessment, remain unknown. Disentangling assessment reactivity effects from intervention effects is needed to develop realistic expectations of intervention efficacy when implemented in contexts that do not include such assessments. Thus, to advance prevention science and practice, it is necessary to optimize intervention feasibility and efficacy and to determine the extent to which assessment reactivity is responsible for reductions in risk behavior.

Enhancing the Feasibility and Efficacy of Behavioral Interventions

One way to optimize the feasibility of behavioral interventions within a busy but resource-constrained clinic environment is to use technology. Compelling, culturally sensitive media can capture patients’ interest, enhance their motivation, and provide risk reduction strategies at relatively low cost [32–36]. Compared to intensive counseling interventions, video-based BIs afford increased privacy, greater patient acceptance [16] ease and reliability of administration, lower cost, and less staff time.

The efficacy of an intervention is optimized when it targets the determinants of the behavior to be changed. Theory [37, 38] as well as meta-analytic research [39, 40] suggest that interventions that include motivational and behavioral skills components increase condom use more than interventions lacking these components. Thus, interventions must directly target motivation and skills for correct and consistent condom use and for avoiding sexual partner concurrency. Video interventions, especially those employing an “Edutainment” approach [41], can target these determinants by promoting identification with characters and modeling effective coping [42].

Research has begun to evaluate video-based (including Edutainment-based) interventions for sexual risk reduction. In one study with a quasi-experimental design, patients exposed to a 23-min Edutainment video had 10 % fewer STIs compared to controls [36]; however, the effect observed was small and the authors could not confirm whether patients viewed the video in its entirety. In another study, female adolescents who received a video intervention were less likely to report an STI [33] but this trial was underpowered for biological outcomes, and count measures of sexual behavior were not obtained. In our own work [16] we found that a brief, purely informational video was effective at reducing sexual risk behavior and STI

rates. Despite these encouraging findings, not all trials have yielded positive effects [43], effect sizes have been small [22], and most studies have not measured (or were underpowered for) STI outcomes; thus, in addition to the need to refine this technology to capitalize on its feasibility and optimize its efficacy, stronger interventions and better designs are needed.

Clarifying the Effects of Pre-intervention Assessments and Assessment Reactivity

Most research trials employ detailed baseline and follow-up assessments. The purpose of such detailed assessments is to evaluate the efficacy of behavioral interventions and, sometimes, to increase the research yield of an expensive prevention trial. One potential concern is that such detailed assessments might lead to “reactivity,” compromising the evaluation of the intervention. Indeed, prior research has found that completing health behavior assessments and self-monitoring of behavior are associated with behavior change [44–46]. One explanation for this inadvertent effect is that detailed assessments may prompt respondents to reflect on their prior behavior, which triggers a deep processing of risk behavior that enhances perceived vulnerability and motivation for risk reduction.

Despite its potential importance to interpreting the results of risk reduction intervention trials, sexual behavior assessment reactivity has not been well-studied. The available evidence does suggest that detailed sexual health (SH) assessments may lead to reactivity, that is, changes in sexual behavior. First, in three small uncontrolled studies, completing a detailed sexual behavior questionnaire was observed to increase perceptions of HIV risk [29–31]. However, these studies were not conducted in conjunction with an intervention, nor did they investigate behavioral outcomes. Second, results from randomized controlled trials (RCTs) of HIV prevention interventions in which both intervention and control groups improved similarly from baseline to post-assessment [47–49] leave open the possibility that detailed assessments may have led to behavior change; however, causal inferences about the effects of pretest assessment cannot be drawn from these designs. Third, one study conducted repeated assessments as an intervention among individuals who were HIV positive [50]; although completing more assessments was associated with greater reductions in sexual risk behaviors, selection bias could have influenced these results. Taken together, prior research suggests that sexual behavior assessments may sensitize respondents and lead to sexual behavior change, but definitive research is lacking.

Purposes of this Study

The primary purpose of the study was to evaluate a video-based BI, developed in consultation with media experts to optimize its authenticity and personal relevance. Extensive formative research was conducted to incorporate motivation and skills-related determinants of partner concurrency and condom use among STI clinic patients [51–54]. Use of a RCT design allowed us to test the prediction that the video-based sexual risk reduction BI would lead to greater reductions in sexual risk behaviors and decreased incidence of STIs than a general health (GH) promotion video control condition. Both biological and behavioral outcomes were assessed repeatedly during the year-long follow-up period.

The secondary purpose of the study was to test whether completing a detailed SH assessment leads to risk reduction by itself. We disentangled the unique and combined effects of the assessment and the intervention using a modified Solomon four-group design [55]. Thus, half of participants were assigned to receive a baseline assessment involving extensive (but typical) sexual health and behavior questions, whereas half were assigned to a GH baseline that included a minimal number of questions on key sexual health and behavior outcomes. One-half of each of these groups was then randomly assigned to the sexual health BI or to a general health BI condition. We predicted a sensitizing effect of the SH assessment such that it would enhance the efficacy of the sexual health BI; therefore, we predicted an interaction between assessment and intervention conditions, reflecting the largest effect of the intervention in the group receiving the SH assessment, and a smaller effect of the intervention in the group receiving the GH assessment [56].

HIV researchers have seldom used the Solomon design. The few studies to do so have had methodological problems, including small sample sizes, short follow-ups, poor return for follow-ups, and lack of behavioral and/or biologic outcomes [57–61]. Clarifying the impact of detailed assessments can increase understanding of the mechanisms of behavior change, aid in the interpretation of the behavioral intervention literature, and guide public health practice. For both study purposes, the external validity and disseminability of the results is enhanced by conducting the RCT in a publicly-funded STI clinic.

Methods

Research Design

The Solomon four-group design can separate the effects of assessment and intervention [55]. For this study, we modified the Solomon four-group design to identify effects

of testing and testing by condition interactions. Specifically, half of the participants completed a detailed sexual behavior assessment whereas half completed a GH assessment that focused on a range of health behaviors (e.g., diet, exercise, sleep). Nested in both surveys were a small number of questions about sexual behavior essential to evaluating study outcomes. Thus, patients were assigned to one of four conditions formed by crossing assessment condition (SH vs. GH) with intervention condition (SH vs. GH; Table 1).

We chose to have one-half of patients complete the GH survey, rather than being assigned to a no assessment condition, for four reasons. First, because participants were patients attending a clinic, they needed to be asked questions about their sexual behavior as part of 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, assessing minimal sexual risk behavior allowed us to enroll fewer participants while affording sufficient statistical power to detect intervention-related change from baseline to follow-up(s). Fourth, having a GH 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 GH-focused assessment that also included only a few questions about sexual behavior. In this way, we hoped to minimize assessment reactivity (in the GH survey), while capitalizing on the benefits of having sexual behavior data at baseline for all participants.

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

Participants

Participants were patients attending a STI clinic in New York state. Inclusion criteria were: (a) age 16 or older; and (b) 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.

Ninety-seven percent (2,677 of the 2,766 patients who were approached) agreed to the screening; of these, 1,322 (49 %) were eligible, and 1,010 (76 %) were consented and randomized (see Fig. 1). 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 sample included men (56 %) and women (44 %; Table 2). Most participants self-identified as African American (69 %), Caucasian (19 %), or Hispanic (8 %). The 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 %).

Measures

The measures were constructed in order to address both study purposes. Thus, in order to describe the sample and evaluate the risk reduction intervention, we use a “core” set of measures; in order to test the assessment reactivity hypothesis, we used additional “unique” measures that varied depending upon the assessment condition to which a participant had been assigned.

Core Measures

The core measures allowed us to describe the sample, evaluate the risk reduction intervention, and explore possible moderators of intervention efficacy. Therefore, all participants completed the core items, which included 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 [62], number of drinks per week), drug use

Table 1 Study design

	Intervention condition	
	General health	Sexual health
<i>Assessment condition</i>		
General health	General health assessment + general health video	General health assessment + sexual health video
Sexual health	Sexual health assessment + general health video	Sexual health assessment + sexual health video

Fig. 1 Consort flow diagram

(e.g., frequency of marijuana and cocaine use), sleep (e.g., number of hours per night). Additional items assessed partner violence [63], perceived stress [64], mental health [65], and satisfaction with the intervention [66]. We do not report on these measures in the current report but details can be found elsewhere [67].

Importantly, the core items included seven items used as primary outcomes, assessing sexual behavior (i.e., number of partners; whether partnerships were concurrent (patients who reported >1 partner in the past 3 months were asked whether their sexual relationships overlapped in time); number of unprotected vaginal and anal sex episodes with steady and non-steady partners). These items were nested in the larger survey of health behaviors in order to minimize assessment reactivity.

In addition to the self-report measures, the core measures also included STI testing. At baseline, participants were tested for STIs per standard CDC-approved protocol.

At all follow-ups, urine specimens were tested for chlamydia (CT) and gonorrhea (Gc), and clinic records were reviewed at the end of the 1 year follow-up period for CT, Gc, trichomoniasis, syphilis, and HIV. For data analytic purposes, STI test results were grouped into three distinct time frames for analyses: (a) tests administered at study entry or within 30 days of study entry were considered baseline tests; (b) tests administered during the next 6 months (between 31 and 213 days after study entry) were considered short-term follow-ups; and (c) tests administered 7 months (214 days) or longer after study entry were considered long-term follow-ups.

Unique Measures

The unique set of items was designed to provide a strong test of the assessment reactivity hypothesis, and to allow testing of meditational mechanisms. The content of the

Table 2 Sociodemographic characteristics of study participants at baseline, overall and by condition ($N = 1,010$)

	Total sample, <i>n</i> (%)	General survey, General DVD, <i>n</i> (%)	General survey, Sexual DVD, <i>n</i> (%)	Sexual survey, General DVD, <i>n</i> (%)	Sexual survey, Sexual DVD, <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 \$30,000/year	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

unique measures varied by condition (i.e., SH assessment vs. GH assessment).

Patients assigned to the **SH 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 identified by the Information–Motivation–Behavioral Skills (IMB) model of health behavior change [37] including informational [68–70], motivational [54, 71–73], and behavioral skills measures

[74–79]. These measures have been used in prior research by our team [80–82] and others, and form a battery that is typical of many behavioral intervention trials. Thus, these sexual history and contextual measures provide a good test of the assessment reactivity hypothesis. The number of unique sexual assessment items ranged from 138 to 152 (contingent on skip patterns).

In contrast, patients assigned to the **GH survey** responded to items assessing detailed diet [83], physical

activity [84], sleep [85], alcohol use and alcohol problems [86, 87], drug use [88], smoking, social support [89], and neighborhood disorder and violence [90]. Additional details on these measures can be found elsewhere [67]. Overall, these measures provided a control for the length of the SH assessment, as the number of unique GH items ranged from 96 to 154, depending on skip patterns.

Interventions

Following the assigned baseline assessment, patients viewed one of two video interventions: (a) SH-focused or (b) GH-focused. Intervention content was based on focus groups conducted with clinic patients that revealed barriers to engaging in healthier behavior, as well as strategies used by participants to overcome those barriers [51, 53]. The interventions were delivered in place of HIV pretest counseling during a clinic visit.

The two interventions were similar in structure and style; only the health content differed between the interventions. Both interventions were 22 min 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 [41]. Actors, images, and music were selected to appeal to an urban and youthful sensibility.

Both interventions were guided by the IMB model [37]. In addition, messages reflected principles from Self-Determination Theory [91] and Motivational Interviewing [92] to avoid eliciting resistance; thus, for example, during the dramatic segments, characters empathized with other characters' challenges, acknowledged characters' autonomy, challenged perceived norms, and provided options. Characters articulated the pros and cons of their own behavior, explored their ambivalence about their behavior and, consistent with Social Learning Theory [93] represented coping rather than mastery models.

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

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. Although the intervention portrayed heterosexual couples, the risk reduction strategies were appropriate to men and women, regardless of age or sexual orientation. The video intervention, titled "Be the Change," can be viewed online at this URL: <http://youtu.be/9nbyZW07nNc>.

General Health Intervention

The GH intervention addressed physical activity, healthy eating, smoking, alcohol use, managing stress, and (very briefly) safer sex. The latter was ethically necessary given the study venue and clinical mission; that is, 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. Other informational segments provided material 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).

Procedures

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

Screening and Recruitment

A Research Assistant (RA) called patients from the waiting room to a private room where she explained that a study was being conducted to improve health in the community. Willing patients were screened for eligibility. Eligible patients were invited to join the study following a thorough consent process [94].

Baseline Assessment

Participants then provided contact information so they could be invited to participate in follow-up surveys. Next,

participants 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 [95]). 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.

Intervention

After completing the ACASI, patients watched the 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.

Follow-ups

Patients were given a 4-week window during which they could return to the clinic for each follow-up. A reminder letter was mailed 2 days before the start of the follow-up window. If a participant did not return within 2–3 days of the start of the follow-up window, an RA contacted them by phone. At the follow-ups, each participant provided a urine sample for chlamydia and gonorrhea testing, and then completed an ACASI consistent with his or her assigned condition. An RA confirmed contact information, and gave each participant an appointment for his or her next follow-up and \$30 for his/her time.

Chart Review

With patient consent, medical records were reviewed to identify additional incident STIs during participants' year of study participation.

Data Analyses

Power

To determine sample size a priori, we conducted 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 $d = 0.2$) [96] of the intervention on STI incidence; this equates to an absolute reduction of 6–7 % in the incidence of STIs among those in the SH intervention group as compared to those in GH intervention group. To achieve 80 % power to detect this difference given a Type I error rate of 0.05, 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 1,000 patients randomized to four groups (250 per group) provided sufficient power for the multilevel regression models for the behavioral outcomes; that is, assuming 75 % retention (~188 per group), power = 0.80, Type I error = 0.05, and 5 assessments, a sample size of 1,000 will yield sufficient power to find even a very small effect (Cohen's $f = 0.04$) for the time $\times$ group interaction term in a standard repeated-measures ANOVA; thus, we recruited an adequate number of participants to assess the behavioral outcomes.

Primary (Outcome) Analyses

To examine changes in the behavioral outcomes (i.e., number of sexual partners; concurrent sexual relationships; unprotected sex [overall, with main partners, with outside partners]) by intervention and measurement condition, negative binomial and logistic generalized estimating equations (GEEs) were employed, using the SAS macro PROC GENMOD [97]. Using GEEs controls for the repeated within-subject measurements through the use of robust standard error estimates. Additionally, the GEE approach uses all data collected for each participant (regardless of whether all follow-ups were completed). We modeled counts of partners and unprotected sexual acts using the negative binomial distribution and the binary concurrency variable using the binomial distribution. A first-order autoregressive correlation structure (AR-1) was utilized due to the evenly-spaced assessment points.

Effects of intervention condition (SH vs. GH) would be indicated by significant time $\times$ intervention interactions; effects of assessment condition (SH vs. GH) by significant time $\times$ assessment interactions; and an interaction between intervention and assessment by significant time $\times$ intervention $\times$ assessment interactions. We also examined two-, three-, and four-way interactions between sex and intervention, assessment, and time. These interaction terms were excluded when non-significant to maximize the statistical power for detecting intervention effects [98]. Because we did not anticipate linear changes over time, time was treated as categorical. Wald tests of all

intervention $\times$ time and assessment $\times$ time interactions provided omnibus tests of intervention and assessment effects.

Because alcohol use differed between those completing the SH and the GH assessments at baseline, we controlled for AUDIT-C scores in all analyses (as well as AUDIT-C $\times$ time interactions when they were significant). We also controlled for age, income, education, unemployment, race/ethnicity, sexual orientation, and marital status when they were associated with outcomes. We report unstandardized beta coefficients (*Bs*) for counts of partners and events and odds ratios (*ORs*) for concurrency, along with 95 % confidence intervals. When making multiple pairwise comparisons between individual time points, we utilized the Benjamini-Hochberg procedure [99] to control the false discovery rate. For models examining unprotected sex with main and outside partners, only those reporting main or outside partners, respectively, were included.

To examine differences in rates of STI diagnosis by intervention and assessment condition, logistic regression models were employed, using the SAS macro PROC LOGISTIC [100]. Because STI diagnoses were relatively rare, Firth's penalized likelihood approach was used to address potential bias in parameter estimates [101, 102]. Only participants with STI tests both at baseline and during the follow-up periods of interest were included in these models. Models controlled for significant demographic variables as well as baseline STI diagnosis. We report *ORs* and 95 % confidence intervals.

Exploratory Analyses

Exploratory analyses used GEE models to investigate potential intervention effects on theoretical constructs from the IMB model for those completing the SH assessment, including information (HIV knowledge); motivation (condom attitudes, condom use intentions, concurrency intentions, subjective and objective norms, risk perceptions); and behavioral skills (condom strategies, self-efficacy). Again, effects of intervention condition (SH vs. GH) would be indicated by significant time $\times$ intervention interactions. Additionally, across all models, we tested for potential moderation by including three- and four-way interactions between potential moderating factors (demographics, substance use, mental health), intervention condition, assessment condition, and time.

Missing Data and Data Management

Study retention was strong; participants completed an average of 4.11 (of 5) assessments ($SD = 1.38$). Completion rates at 3, 6, 9, and 12 months were 82, 78, 75, and 75 %, respectively. Among those completing each

assessment, rates of missing data on outcomes were low (<4.8 % for unprotected sex with outside partners and <1.2 % for all other outcome variables). As noted previously, use of GEEs meant that participants were not excluded from models based on missing behavioral outcome data. Four participants had missing data on some covariates and were excluded from models involving those covariates. In STI models, participants were excluded if they were missing either a baseline test or all follow-up tests during the time frame of interest. Participants with missing data (due to missing assessments or skipped items) were younger and more likely to have income $>\$15,000$ per year, to be employed, to be White, to be sexual minorities, and to have outside partners at baseline than were those with complete data (all $ps < 0.05$). However, there were no differences between those with and without missing data in terms of intervention or assessment condition, other demographic factors, other baseline sexual behaviors, or baseline alcohol use.

Participants were also excluded from the analyses if they received an assessment at any time point that did not match their randomized measurement condition (1.7 %, $n = 18$) or were multivariate outliers at multiple time points (0.7 %, $n = 7$). Those excluded from analyses were more likely to be married, $\chi^2(1) = 4.80$, $p = 0.03$; were older, $t(24.67) = -2.91$, $p = 0.01$; and reported more partners at baseline, $t(24.53) = -2.91$, $p = 0.04$; there were no differences between those excluded and not in terms of intervention or assessment condition, other demographic factors, other baseline sexual behaviors, or baseline alcohol use. Outliers on the counts of number of partners and number of unprotected sex acts (i.e., those more than three times the interquartile range from the 75th percentile) were truncated to three times the interquartile range from the 75th percentile plus one [103].

Results

Preliminary Analyses

Randomization resulted in groups that were equivalent on nearly all characteristics (see Tables 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 no differences among groups in GH behavior (diet, exercise, smoking, marijuana use, or sleep), except for alcohol use. Compared to patients in the GH assessment condition, patients in the SH assessment condition scored higher on

Table 3 Sexual behavior patterns of 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	0.70 (.32)	0.68 (.31)	0.69 (.32)	0.73 (.31)	0.69 (.34)
Unprotected sex with steady partner ^a (proportion episodes), past 3 months (0–1)	790	0.77 (.32)	0.75 (.33)	.77 (.32)	0.81 (.29)	0.76 (.34)
Unprotected sex with casual partners ^b (proportion episodes), past 3 months (0–1)	732	0.53 (.40)	0.53 (.39)	0.51 (.41)	0.53 (.40)	0.54 (.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)

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

the AUDIT-C ($M_{\text{sexual health}} = 4.8$; $M_{\text{general health}} = 4.3$), $F(1, 897) = 8.31$, $p < 0.01$, and were more likely to be classified as having a likely alcohol use disorder (49 % in SH vs. 42 % in GH assessment condition), $\chi^2(1, N = 1004) = 4.57$, $p < 0.05$. Therefore, we used AUDIT-C score as a covariate when conducting outcome analyses.

Participants reported high levels of sexual risk behavior (Table 3), including an average of 2.7 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 %), and 47 % of participants reported concurrent partnerships. 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.

In general, patients were satisfied with both interventions. However, group differences emerged with patients in the SH condition reporting greater satisfaction; patients who viewed the SH intervention reported more of their

needs were met, $F(1, 1005) = 37.17$, $p < 0.001$, greater satisfaction, $F(1, 1003) = 18.47$, $p < 0.001$, said that they were more likely to return to the clinic, $F(1, 1005) = 9.76$, $p < 0.01$, found the intervention more interesting, $F(1, 1004) = 50.40$, $p < 0.001$, believed that they learned more, $F(1, 1005) = 27.47$, $p < 0.001$, and had more positive feelings about the intervention, $F(1, 1003) = 10.42$, $p < 0.01$.

Primary (Outcome) Analyses

Table 4 summarizes the adjusted means at all time points overall and for each condition.

Number of Sexual Partners (Past 3 Months)

The GEE model (Table 5) showed no effect of intervention or assessment condition on the number of sexual partners, Wald $\chi^2(4) = 1.94$, $p = 0.75$ and Wald $\chi^2(4) = 4.14$, $p = 0.39$, respectively; there was also no interaction between intervention and assessment condition, Wald $\chi^2(4) = 6.58$, $p = 0.16$. However, there was a significant effect of time, Wald $\chi^2(4) = 77.29$, $p < 0.001$, which was accompanied by a significant interaction between sex and time, Wald $\chi^2(4) = 10.07$, $p = 0.04$. Controlling for relevant covariates, women reported fewer sexual partners at 3,

Table 4 Sexual behavior means over time, overall and by condition

	Baseline	3 months	6 months	9 months	12 months
Number of sexual partners					
Across conditions	2.56 ^a (0.06)	2.12 ^b (0.05)	2.09 ^b (0.06)	1.99 ^b (0.06)	1.83 ^c (0.05)
GH Video/GH ACASI	2.61 (0.12)	2.19 (0.13)	1.92 (0.13)	1.98 (0.13)	1.84 (0.10)
GH Video/SH ACASI	2.49 (0.11)	2.04 (0.11)	2.18 (0.13)	1.83 (0.10)	1.78 (0.09)
SH Video/GH ACASI	2.54 (0.10)	2.14 (0.10)	2.18 (0.11)	2.11 (0.12)	1.79 (0.09)
SH Video/SH ACASI	2.61 (0.13)	2.13 (0.10)	2.09 (0.13)	2.04 (0.13)	1.90 (0.10)
Concurrency					
Across conditions	48 % ^a (2 %)	33 % ^{bc} (2 %)	36 % ^b (2 %)	32 % ^{bc} (2 %)	30 % ^c (2 %)
GH Video/GH ACASI	51 % (3 %)	32 % (3 %)	32 % (3 %)	29 % (3 %)	28 % (3 %)
GH Video/SH ACASI	47 % (3 %)	31 % (3 %)	41 % (4 %)	34 % (3 %)	32 % (3 %)
SH Video/GH ACASI	51 % (3 %)	35 % (3 %)	41 % (4 %)	35 % (4 %)	31 % (3 %)
SH Video/SH ACASI	43 % (3 %)	34 % (3 %)	31 % (3 %)	30 % (3 %)	30 % (3 %)
Unprotected sex with all partners					
Across conditions	15.87 ^a (0.61)	14.46 ^{ab} (0.68)	15.70 ^a (0.79)	14.06 ^{ab} (0.69)	13.48 ^b (0.65)
GH Video/GH ACASI	14.86 (1.16)	15.70 (1.61)	16.38 (1.62)	14.34 (1.38)	13.48 (1.35)
GH Video/SH ACASI	16.89 (1.27)	12.89 (1.21)	15.24 (1.56)	14.09 (1.44)	13.22 (1.29)
SH Video/GH ACASI	16.10 (1.16)	13.23 (1.17)	14.63 (1.48)	12.77 (1.27)	13.32 (1.24)
SH Video/SH ACASI	15.71 (1.27)	16.31 (1.47)	16.62 (1.68)	15.13 (1.39)	13.91 (1.34)
Unprotected sex with main partners					
Across conditions	17.13 (0.71)	16.73 (0.83)	18.22 (0.95)	16.95 (0.87)	15.98 (0.79)
GH Video/GH ACASI	15.78 (1.46)	17.75 (1.92)	19.56 (2.05)	17.61 (1.75)	17.11 (1.77)
GH Video/SH ACASI	18.59 (1.44)	15.41 (1.48)	17.40 (1.84)	16.87 (1.73)	15.82 (1.51)
SH Video/GH ACASI	17.40 (1.37)	15.84 (1.45)	16.70 (1.70)	15.03 (1.72)	14.32 (1.42)
SH Video/SH ACASI	16.87 (1.40)	18.07 (1.74)	19.37 (2.03)	18.50 (1.76)	16.82 (1.65)
Unprotected sex with outside partners					
Across conditions	2.99 ^a (0.14)	1.67 ^b (0.12)	2.05 ^{bc} (0.16)	2.02 ^{bc} (0.16)	2.37 ^c (0.19)
GH Video/GH ACASI	2.88 (0.25)	1.64 (0.25)	1.73 (0.33)	1.83 (0.32)	2.64 (0.41)
GH Video/SH ACASI	2.81 (0.24)	1.47 (0.20)	2.07 (0.29)	1.80 (0.29)	2.39 (0.34)
SH Video/GH ACASI	3.06 (0.30)	1.51 (0.21)	2.44 (0.34)	2.13 (0.31)	2.41 (0.42)
SH Video/SH ACASI	3.22 (0.30)	2.13 (0.28)	2.02 (0.33)	2.38 (0.35)	2.09 (0.37)

Least squares (adjusted) means and standard errors from GEE models (Table 5) are reported. "Across conditions" numbers with different superscripts differ significantly in pairwise comparisons with Benjamini–Hochberg correction for multiple comparisons ($\alpha = .05$). There are no significant differences within any time point based on Intervention (video) or Assessment (ACASI) conditions

6, 9, and 12 months than they did at baseline; fewer partners at 9 months than they did at 3 months; and fewer partners at 12 months than they did at 3 or 6 months, indicating a continuous decrease over the follow-up period (Fig. 2a). In contrast, men reported fewer partners at 3, 6, 9, and 12 months than they did at baseline, indicating an initial decrease that was maintained but not increased over the follow-up period (Fig. 2a). Considering the sample as a whole, participants reported fewer partners at 3, 6, 9, and 12 months than they did at baseline and fewer partners at 12 months than they did at 3, 6, or 9 months (Table 4; Fig. 2b).

Sexual Concurrency (Past 3 Months)

The GEE model (Table 5) showed no effect of intervention or assessment condition on the probability of having concurrent sexual partners, Wald $\chi^2(4) = 2.00$, $p = 0.83$ and Wald $\chi^2(4) = 3.33$, $p = 0.50$, respectively; there was also

no significant interaction between intervention and assessment condition, Wald $\chi^2(4) = 8.35$, $p = 0.08$. However, there was a significant effect of time on concurrency, Wald $\chi^2(4) = 97.48$, $p < 0.001$. Controlling for relevant covariates, participants were less likely to have concurrent relationships 3, 6, 9, and 12 months than they were at baseline and less likely to have concurrent relationships at 12 months than they were at 6 months (Table 4; Fig. 2c).

Unprotected Vaginal and Anal Sex (Past 3 Months)

The GEE model (Table 4) showed no effect of intervention or assessment condition on the total number of unprotected sexual acts, Wald $\chi^2(4) = 0.37$, $p = 0.98$ and Wald $\chi^2(4) = 0.65$, $p = 0.96$, respectively; there was also no significant interaction between intervention and assessment condition, Wald $\chi^2(4) = 8.66$, $p = 0.07$. However, there was a significant effect of time on the number of

Table 5 Time, intervention condition, assessment condition, and demographic characteristics as predictors of number of sexual partners, concurrency, and unprotected sex among patients participating in a randomized controlled trial at a public STI clinic

	Number of sexual partners (<i>N</i> = 979)		Concurrency (<i>N</i> = 985)		Unprotected sex—all partners (<i>N</i> = 985)		Unprotected sex—main partner (<i>N</i> = 925)		Unprotected sex—outside partners (<i>N</i> = 865)	
	Wald	<i>B</i> (95 % CI)	Wald	<i>OR</i> (95 % CI)	Wald	<i>B</i> (95 % CI)	Wald	<i>B</i> (95 % CI)	Wald	<i>B</i> (95 % CI)
Time (ref: BL)	77.29***		97.48***		16.20**		6.76		74.55***	
3 months		−0.13* (−0.24, −0.03)		0.45*** (0.31, 0.65)		0.06 (−0.16, 0.27)		0.12 (−0.14, 0.38)		−0.56*** (−0.85, −0.27)
6 months		−0.31*** (−0.46, −0.16)		0.45*** (0.32, 0.64)		0.10 (−0.11, 0.31)		0.22 (−0.02, 0.45)		−0.51* (−0.91, −0.12)
9 months		−0.33*** (−0.48, −0.18)		0.39*** (0.27, 0.58)		−0.04 (−0.24, 0.17)		0.11 (−0.12, 0.34)		−0.45* (−0.80, −0.10)
12 months		−0.40*** (−0.54, −0.26)		0.38*** (0.27, 0.55)		−0.10 (−0.33, 0.13)		0.08 (−0.17, 0.33)		−0.09 (−0.43, 0.26)
SH video	0.71	−0.02 (−0.14, 0.09)	0.04	1.03 (0.71, 1.48)	0.00	0.08 (−0.13, 0.29)	0.08	0.10 (−0.14, 0.34)	1.18	0.06 (−0.20, 0.31)
SH ACASI	0.07	−0.05 (−0.17, 0.08)	0.16	0.88 (0.61, 1.26)	0.27	0.13 (−0.08, 0.34)	0.36	0.16 (−0.07, 0.40)	0.01	−0.03 (−0.27, 0.21)
Time × SH video	1.94		2.00		0.37		0.52		3.66	
3 months × SH video		0.00 (−0.13, 0.14)		1.11 (0.69, 1.77)		−0.25 (−0.53, 0.03)		−0.21 (−0.53, 0.11)		−0.15 (−0.55, 0.26)
6 months × SH video		0.15 (−0.01, 0.31)		1.49 (0.90, 2.46)		−0.19 (−0.48, 0.09)		−0.26 (−0.57, 0.06)		0.29 (−0.21, 0.79)
9 months × SH video		0.09 (−0.08, 0.26)		1.28 (0.78, 2.12)		−0.20 (−0.48, 0.09)		−0.28 (−0.59, 0.08)		0.09 (−0.36, 0.55)
12 months × SH video		0.00 (−0.15, 0.15)		1.11 (0.67, 1.82)		−0.09 (−0.40, 0.21)		−0.30 (−0.60, 0.05)		−0.15 (−0.62, 0.32)
Time × SH ACASI	4.14		3.33		0.65		0.79		1.91	
3 months × SH ACASI		−0.03 (−0.17, 0.12)		1.09 (0.67, 1.76)		−0.33** (−0.61, −0.05)		−0.30 (−0.63, 0.02)		−0.08 (−0.48, 0.31)
6 months × SH ACASI		0.17** (0.003, 0.34)		1.74** (1.08, 2.83)		−0.20 (−0.50, 0.10)		−0.28 (−0.59, 0.03)		0.20 (−0.29, 0.70)
9 months × SH ACASI		−0.03 (−0.20, 0.14)		1.45 (0.87, 2.41)		−0.15 (−0.44, 0.15)		−0.21 (−0.51, 0.10)		0.01 (−0.46, 0.48)
12 months × SH ACASI		0.01 (−0.20, 0.19)		1.38 (0.83, 2.28)		−0.15 (−0.46, 0.16)		−0.24 (−0.56, 0.07)		−0.07 (−0.54, 0.39)
SH video × SH ACASI	0.06	0.07 (−0.10, 0.25)	2.89	0.81 (0.48, 1.36)		−0.15 (−0.45, 0.15)	1.52	−0.19 (−0.52, 0.13)	0.08	0.08 (−0.28, 0.43)
Time × SH video × SH ACASI	6.58		8.35		8.66		6.79		5.19	
3 months × SH video × SH ACASI		−0.01 (−0.20, 0.19)		1.27 (0.66, 2.45)		0.56** (0.18, 0.94)		0.47** (0.04, 0.90)		0.37 (−0.19, 0.94)
6 months × SH video × SH ACASI		−0.24** (−0.48, 0.004)		0.51 (0.26, 1.01)		0.35 (−0.06, 0.76)		0.46** (0.04, 0.88)		−0.44 (−1.11, 0.22)
9 months × SH video × SH ACASI		−0.03 (−0.27, 0.21)		0.78 (0.38, 1.60)		0.34 (−0.08, 0.76)		0.44 (0.00, 0.89)		0.05 (−0.58, 0.68)
12 months × SH video × SH ACASI		0.02 (−0.21, 0.25)		0.97 (0.47, 1.97)		0.22 (−0.21, 0.64)		0.43 (−0.01, 0.88)		−0.12 (−0.79, 0.55)
Male	80.14***	0.33*** (0.24, 0.42)	63.05***	2.31*** (1.88, 2.84)	11.36***	0.21*** (0.09, 0.34)	13.88***	0.24*** (0.11, 0.37)	18.36***	0.36*** (0.20, 0.53)
Time × male	10.07*		—		—		—		—	
3 months × male		−0.08 (−0.17, 0.02)	—	—	—	—	—	—	—	—
6 months × male		0.01 (−0.11, 0.13)	—	—	—	—	—	—	—	—
9 months × male		0.10 (−0.02, 0.22)	—	—	—	—	—	—	—	—
12 months × male		0.09 (−0.02, 0.21)	—	—	—	—	—	—	—	—
Age	15.70***	−0.08*** (−0.12, −0.04)	—	—	19.07***	−0.16*** (−0.23, −0.09)	24.49***	−0.18*** (−0.25, −0.11)	—	—
Minority	—	—	—	—	—	—	2.71	−0.13 (−0.29, 0.03)	11.47***	−0.32*** (−0.51, −0.14)

Table 5 continued

	Number of sexual partners (<i>N</i> = 979)		Concurrency (<i>N</i> = 985)		Unprotected sex—all partners (<i>N</i> = 985)		Unprotected sex—main partner (<i>N</i> = 925)		Unprotected sex—outside partners (<i>N</i> = 865)	
	Wald	<i>B</i> (95 % CI)	Wald	<i>OR</i> (95 % CI)	Wald	<i>B</i> (95 % CI)	Wald	<i>B</i> (95 % CI)	Wald	<i>B</i> (95 % CI)
Sexual minority	54.27***	0.43*** (0.32,0.55)	18.55***	1.98*** (1.45,2.70)	—	—	—	—	—	—
Unemployed (BL)	10.89***	0.12*** (0.05,0.20)	—	—	—	—	—	—	—	—
AUDIT-C (BL)	8.21**	0.02** (0.01,0.03)	19.75***	1.08*** (1.04,1.12)	12.68***	0.04** (0.01,0.06)	11.61**	0.04* (0.01,0.07)	5.30*	0.03* (0.01,0.06)
Time × AUDIT-C	—	—	—	—	14.68**	—	15.15**	—	—	—
3 months × AUDIT-C	—	—	—	—	—	0.02 (−0.01,0.05)	—	0.02 (−0.02,0.05)	—	—
6 months × AUDIT-C	—	—	—	—	—	0.02 (−0.01,0.06)	—	0.02 (−0.02,0.06)	—	—
9 months × AUDIT-C	—	—	—	—	—	0.01 (−0.02,0.05)	—	0.02 (−0.02,0.06)	—	—
12 months × AUDIT-C	—	—	—	—	—	−0.04* (−0.08,−0.003)	—	−0.04* (−0.08,−0.002)	—	—

Wald tests provide omnibus tests of effects. Degrees of freedom for Wald tests are 4 for all effects involving time and 1 otherwise. Unstandardized betas (*B*s) and 95 % confidence intervals are reported for number of sexual partners and unprotected sex and odds ratios (*OR*s) and 95 % confidence intervals for concurrency

SH Video viewed the sexual health video, *SH ACASI* completed the sexual health measurement, *Age* age/10; *Minority* self-identifies as American Indian, Asian, African-American, Mixed or Multiracial, or Latino/Latina; *Sexual Minority* self-identifies as homosexual, bisexual, or uncertain of sexual orientation; *AUDIT-C* baseline score on the Alcohol Use Disorders Identification Test (from 0 to 12), centered; — indicates variables or interactions not included in particular models

*** $p < 0.001$ ** $p < 0.01$ * $p < 0.05$

^a Where omnibus Wald tests and coefficients conflict, posthoc pairwise comparisons of least squares means showed no significant differences between conditions at any time point

unprotected sexual acts, Wald $\chi^2(4) = 16.20$, $p < 0.01$. Controlling for relevant covariates, participants reported fewer acts of unprotected sex at 12 months than they did at baseline and 6 months (Table 4; Fig. 2d).

Similarly, the GEE model (Table 5) showed no effect of intervention or assessment condition on the number of unprotected sexual acts with main partners, Wald $\chi^2(4) = 0.52$, $p = 0.97$ and Wald $\chi^2(4) = 0.79$, $p = 0.94$, respectively; there was also no interaction between intervention and assessment condition, Wald $\chi^2(4) = 6.79$, $p = 0.15$. Additionally, controlling for relevant covariates, there was no change in the number of unprotected sexual acts with main partners over time, Wald $\chi^2(4) = 6.76$, $p = 0.15$ (Table 4; Fig. 2e).

Finally, the GEE model (Table 5) showed no effect of intervention or assessment condition on the number of unprotected sexual acts with outside partners, Wald $\chi^2(4) = 3.66$, $p = 0.45$ and Wald $\chi^2(4) = 1.91$, $p = 0.75$, respectively; there was also no interaction between intervention and assessment condition, Wald $\chi^2(4) = 5.19$, $p = 0.26$. However, there was a significant effect of time on the number of unprotected sex acts with outside partners, Wald $\chi^2(4) = 74.55$, $p < 0.001$ (Table 4; Fig. 2f). Controlling for relevant covariates, participants reported fewer unprotected sex acts with outside partners at 3, 6, 9, and 12 months than they did at baseline. However, they reported more unprotected sex acts with outside partners at 12 months than they did at 3 months.

Sexually Transmitted Infections

Although not a primary outcome, we first tested whether the number of STI testing dates differed based on intervention or assessment condition. There was no effect of the intervention or assessment condition on the number of STI testing occasions, $F(1,971) = 0.51$, $p = 0.47$ and $F(1,971) = 0.03$, $p = 0.86$, respectively; there was also no interaction between intervention and assessment, $F(1,971) = 0.60$, $p = 0.44$. Adjusting for relevant covariates, participants viewing the SH video and completing the SH assessment received an average of 4.76 tests ($CI_{95\%} = 4.53, 4.99$) throughout the entire study period, those viewing the SH video and completing the GH assessment received an average of 4.69 tests ($CI_{95\%} = 4.46, 4.92$), those viewing the GH video and completing the SH assessment received an average of 4.59 tests ($CI_{95\%} = 4.36, 4.82$), and those viewing the GH video and completing the GH assessment received an average of 4.70 tests ($CI_{95\%} = 4.47, 4.93$).

As shown in Table 6, there were no significant differences in the probability of STI diagnosis at short-term follow-ups (i.e., 1–7 months post-intervention) or across all follow-ups based on intervention condition, assessment condition, or the interaction between intervention and assessment. Adjusting for covariates, at short-term follow-ups, 10 % of participants

Fig. 2 Sexual behavior means over time among patients participating in a randomized controlled trial at a public STI clinic. Means are adjusted for all significant demographic covariates. There were no significant differences between those in different intervention or measurement conditions. Time points with different letters differ

significantly in pairwise comparisons with Benjamini-Hochberg correction for multiple comparisons. There were no significant differences over time in the number of unprotected sexual acts with main partners

viewing the SH video and completing the SH assessment, 11 % of participants viewing the SH video and completing the GH assessment, 7 % of participants viewing the GH video and completing the SH assessment, and 11 % of participants viewing the GH video and completing the GH assessment were diagnosed with an STI. Across all follow-ups, 17 % of participants viewing the SH video and completing the SH assessment, 17 % of participants viewing the SH video and completing the GH assessment, 15 % of participants viewing the GH video and completing the SH assessment, and 13 % of participants viewing the GH video and completing the GH assessment were diagnosed with an STI.

When examining long-term follow ups (i.e., 7–12 months post-intervention), a marginally significant interaction between intervention and assessment condition ($p < 0.10$) accompanied significant main effects of intervention and assessment on STI diagnosis. Follow-up analysis of least-squares means indicated that participants who viewed the GH video and completed the GH assessment had a lower probability of being diagnosed with STIs at long-term follow-ups as compared to those in all other conditions, $ps < 0.05$. At long-term follow-ups, 4 % of participants viewing the GH video and completing the GH assessment were diagnosed with STIs, as compared to 9 % of participants in all other conditions.

Exploratory Analyses of Mediation and Moderation

Mediation

Exploratory analyses investigated whether intervention condition was related to the hypothesized antecedents of sexual risk behavior targeted in the intervention, including information (HIV knowledge); motivation (condom attitudes, condom use intentions, concurrency intentions, subjective and objective norms, risk perceptions); and behavioral skills (condom strategies, self-efficacy). We identified no consistent pattern of intervention effects on these hypothesized mediators.

Moderation

In addition, to facilitate understanding of who is most likely (and unlikely) to benefit from the intervention, we conducted moderator analyses. Specifically, we tested whether a number of demographic, substance use, and mental health variables interacted with intervention or assessment condition, indicating a differential response for certain subgroups of patients. In addition to sex, moderators tested included age; race; income; education; baseline alcohol use (AUDIT-C scores, frequency of drinking, frequency of binge drinking, disordered drinking); baseline drug use (marijuana and

Table 6 Intervention condition, assessment condition, baseline STI diagnosis, and demographic characteristics as predictors of STI diagnoses at short- and long-term follow-ups

	Short-term Follow-ups (<i>N</i> = 852)	Long-term Follow-ups (<i>N</i> = 784)	All Follow-ups (<i>N</i> = 874)
% (<i>N</i>)	11 % (<i>N</i> = 93)	10 % (<i>N</i> = 80)	17 % (<i>N</i> = 151)
	<i>OR</i> (95 % <i>CI</i>)	<i>OR</i> (95 % <i>CI</i>)	<i>OR</i> (95 % <i>CI</i>)
SH Video	0.96 (0.54,1.71)	2.21* (1.06,4.62)	1.31 (0.79,2.17)
SH ACASI	0.62 (0.32,1.19)	2.32* (1.09,4.95)	1.17 (0.69,1.99)
SH Video*SH ACASI	1.57 (0.64,3.82)	0.44 (0.16,1.17)	0.83 (0.40,1.71)
Male	0.70 (0.45,1.09)	–	0.73 (0.51,1.05)
BL Diagnosis	2.25*** (1.42,3.55)	2.15** (1.31,3.53)	2.21*** (1.51,3.24)
Age	0.97* (0.95,0.999)	0.93*** (0.89,0.96)	0.96*** (0.94,0.98)
Minority	–	2.96* (1.11,7.93)	–
Education < HS	1.76* (1.06,2.90)	–	1.54* (1.03,2.30)
Sexual Minority	–	2.21* (1.19,4.11)	–
AUDIT-C	0.90* (0.83,0.98)	0.97 (0.89,1.06)	0.93* (0.87,0.99)

Adjusted odds ratios and 95 % confidence intervals from logistic regression models are reported

Short-term follow-ups between 1 month and 7 months following study entry; *long-term follow-ups* more than 7 months following study entry; *Any STI* chlamydia, gonorrhea, HIV, syphilis, and trichomoniasis (women only); *SH Video* viewed the sexual health video; *SH ACASI* completed the sexual health assessment; *BL Diagnosis* baseline diagnosis (at or within 1 month of study entry) with any STI; *Minority* self-identifies as American Indian, Asian, African-American, Mixed or Multiracial, or Latino/Latina; *Education < HS* less than a high school education; *Sexual Minority* self-identifies as homosexual, bisexual, or uncertain of sexual orientation; *AUDIT-C* baseline score on the Alcohol Use Disorders Identification Test (from 0 to 12)

*** $p < 0.001$ ** $p < 0.01$ * $p < 0.05$

crack/cocaine); and baseline depression, anxiety, and perceived stress. There were no clear patterns of differences in any sexual behaviors based on intervention or assessment condition for any subgroups of participants.

Discussion

The results of this study demonstrated that participants in a sexual risk reduction trial reduced their sexual risk behavior regardless of intervention condition (sexual risk reduction video vs. GH promotion video) or assessment condition (intensive SH and behavior questions vs. intensive GH and behavior questions) over 1 year. Over this follow-up period, this at-risk group of participants reduced their number of sexual partners as well as their engagement in concurrent sexual partnerships. In addition, participants reduced their number of episodes of unprotected sex overall and with outside (i.e., non-steady) partners. Most of the reductions in sexual risk behavior were maintained throughout the entire year of follow-up. Few differences emerged in STI diagnoses over the year of follow-up by intervention or assessment condition. Although participants completing the GH assessment and viewing the GH DVD were diagnosed with fewer STIs from 7 to 12 months post-intervention relative to the other groups, there were no differences in

sexual behavior by group; thus, the most parsimonious explanation for this one, minor difference appears to be chance.

Contrary to expectation, the intensive intervention condition did not improve upon the changes in sexual risk behavior or STI diagnosis observed in the less intensive comparison condition. This null finding replicates several other sexual risk reduction RCTs where all participants, regardless of intervention condition, reduced their sexual risk behavior. [48, 49, 80, 104] Exploratory analyses showed that there were also no associations between intervention condition and the hypothesized antecedents of sexual risk reduction, including informational, motivational, and behavioral skills variables, and that patterns of intervention response did not differ based on demographic characteristics, alcohol or drug use, or mental health.

The overall pattern of results does not allow us to draw strong inferences regarding this decline in sexual risk across all conditions. It is likely that several related experiences—receiving services at a STI clinic, being tested for (and possibly diagnosed with) a STI, and participating in a longitudinal research study with four return visits to the STI clinic—all played a role in the decline in sexual risk behavior observed in this study. Participating in a research study and desire to please the researchers may also have led to reports of behavior change but cannot explain reductions in incident STIs.

Also contrary to expectation, we did not find that completing a detailed SH and behavior assessment led to (greater) sexual behavior change. This finding stands in contrast to evidence from the diet, exercise, and substance use literatures that completing a detailed health behavior assessment affects health behavior [44–46]. Thus, HIV prevention researchers can be modestly confident that completing detailed SH and behavior self-report questions does not, in and of itself, lead to sexual behavior change (at least in this population sub-group). However, participants in our study were patients attending an STI clinic, and all patients received STI and HIV testing and treatment. In addition, they did complete a small set of items about sexual behavior and return to the clinic for subsequent STI testing (these were necessary in order to evaluate the intervention). Thus, it is possible that there were assessment effects that were obscured by the larger effects of receiving services at an STI clinic, being diagnosed with an STI, and participating in a clinical trial. Our study design does not allow us to rule out the possibility that the routine assessment of recent sexual risk behaviors received at the STI clinic as a part of standard care as well as the brief assessment needed to evaluate the intervention may have been sufficient to increase the motivation to change among all of the participants.

Our study had several important strengths, including a large and diverse sample of individuals who were at risk for STIs. We were able to retain 75 % of these individuals over their year of study enrollment, which is impressive given the challenging life circumstances (e.g., poverty, housing instability, crime) faced by many of our participants, as well as the lengthy follow-up interval. Together, the sample size and retention rates afforded adequate power to detect intervention and assessment effects. The use of a modified Solomon four-group design permitted isolation of potential intervention effects from potential assessment effects. The use of biologic samples and chart reviews to supplement self-reported behavioral data is another study strength. Finally, we used an ACASI assessment, which has been associated with greater (and presumably more accurate) reporting of socially stigmatized behaviors [105, 106].

We also acknowledge several study limitations. There was no pure control intervention; that is, because patients were attending an STI clinic, we were ethically bound to provide them with basic information about sexual risk reduction. However, the sexual risk reduction component of the GH (control) video was limited to information about HIV disease, transmission, and prevention. Importantly, motivational and skills elements, recognized as the most potent intervention components [38] were not included in the control video. Our control assessment was also not pure in the sense that participants in the GH assessment

condition also received a small number of questions regarding recent sexual risk behavior and underwent STI testing, both of which were necessary for ethical clinical care and for evaluation purposes.

It is encouraging that the combination of attending an STI clinic, participating in a research study, and viewing a brief video-based intervention led to behavior change across participants. However, it is unlikely that all participants reduced their sexual risk behavior, or reduced their sexual risk behavior to the same degree. Although we were not able to identify moderators of intervention efficacy, future research should focus on identifying who benefits from brief, targeted, culturally appropriate video-based sexual risk reduction interventions, and who is in need of more intensive intervention. Such information could be used to plan a stepped or adaptive intervention [107] which would maximize cost efficiency by delivering less intensive (and correspondingly less expensive) interventions to those who are likely to benefit from minimal intervention, and delivering more intensive interventions to those who did not or are unlikely to benefit from a video-based intervention.

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