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Comparison of a theory-based (AIDS Risk Reduction Model) cognitive behavioral intervention versus enhanced counseling for abused ethnic minority adolescent women on infection with sexually transmitted infection: results of a randomized controlled trial

Jane Dimmitt Champion, PhD, DNP, RN, FNP, AH-PMH-CNS, FAAN[Professor] and
Texas Tech University Health Science Center, School of Nursing, Lubbock, Texas, USA

Jennifer L. Collins, PhD, RN[Post-doctoral Research Fellow]
Texas Tech University Health Science Center, School of Nursing, Lubbock, Texas, USA

Abstract

Background—Ethnic minority adolescent women with a history of sexual or physical abuse and sexually transmitted infections represent a vulnerable population at risk for HIV. Community-based interventions for behavior modification and subsequent risk reduction have not been effective among these women.

Objectives—To evaluate the effects of a theory-based (AIDS Risk Reduction Model) cognitive behavioral intervention model versus enhanced counseling for abused ethnic minority adolescent women on infection with sexually transmitted infection at 6 and 12 months follow-up.

Design—Controlled randomized trial with longitudinal follow-up

Settings—Southwestern United States, Metropolitan community-based clinic

Participants—Mexican-and-African American adolescent women aged 14–18 years with a history of abuse or sexually transmitted infection seeking sexual health care

Methods—Extensive preliminary study for intervention development was conducted including individual interviews, focus groups, secondary data analysis, pre-testing and feasibility testing for modification of an evidence-based intervention prior to testing in the randomized controlled trial. Following informed consents for participation in the trial, detailed interviews concerning demographics, abuse history, sexual risk behavior, sexual health and physical exams were obtained. Randomization into either control or intervention groups was conducted. Intervention participants received workshop, support group and individual counseling sessions. Control participants received abuse and enhanced clinical counseling. Follow-up including detailed interview and physical exam was conducted at 6 and 12 months following study entry to assess for infection. Intention to treat analysis was conducted to assess intervention effects using chi-square and multiple regression models.

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jane.dimmitt-champion@ttuhsc.edu, Telephone: 001-830-279-7543.

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Results—409 Mexican-(n=342) and African-(n=67) American adolescent women with abuse and sexually transmitted infection histories were enrolled; 90% intervention group attendance; longitudinal follow-up at 6 (93%) and 12 (94%) months. Intervention (n=199) versus control (n=210) group participants experienced fewer infections at 0-6 (0% vs. 6.6%, $p=0.001$), 6-12 (3.6% vs. 7.8%, $p=0.005$, CI 95% lower-upper .001-.386) and 0-12 (4.8% vs. 13.2%, $p=0.002$, CI 95% lower-upper, .002-.531) month intervals.

Conclusions—A cognitive behavioral intervention specifically designed for ethnic minority adolescent women with a history of abuse and sexually transmitted infection was effective for prevention of infection. These results provide evidence for development of evidence-based interventions for sexually transmitted infection/HIV. Implications include translation to community-clinic-based settings for prevention of adverse outcomes regarding sexual health of adolescent women.

Keywords

Adolescent; Randomized Controlled Trial; Sexual Risk Reduction; Cognitive Behavioral Intervention; Ethnicity

Introduction

Ethnic minority adolescent women experience a disproportionate rate of sexually transmitted infections (STI) in the United States. Hispanic or African-American women 15 to 19 years old are more likely (5-19 times) to be living with HIV/AIDS or have gonorrhea/Chlamydia (6-14 times) than non-Hispanic Whites (Centers for Disease Control and Prevention, 2009).

Descriptive and intervention research has demonstrated that sexual risk behavior and subsequent HIV/STI represent a combination of interrelated factors involving personal histories, behaviors and environmental context. Sexual and non-sexual precursors include beliefs and attitudes, poverty and accompanying lack of access to healthcare, education, relationships with family and friends, homelessness (Herbst, et al., 2007; D. Kirby, 2001; Rauer, Karney, Garvan, & Hou, 2008), power differentials, age of partner, substance abuse, history of abuse, and inadequate skills in safer sex negotiation (Champion, et al., 2005; Koniak-Griffin, et al., 2003; Morrison-Beedy & Nelson, 2004; Royce, Perlmuter Silverman, & Krauss, 2007). Adolescent women with a history of abuse are more likely than those without to engage in sexual risk behavior and experience STI necessitating an additional intervention focus (Albarracin, Kumkale, & Johnson, 2004; Champion, Shain, & Piper, 2004; Champion, Artnak, Shain, & Piper, 2002; Champion, 2007; Ohene, Halcon, Ireland, Carr, & McNeely, 2005; Testa, VanZile-Tamsen, & Livingston, 2005). This paper describes development and efficacy testing of an evidence-based cognitive behavioral HIV/STI risk reduction intervention specifically designed for ethnic minority adolescent women with a history of abuse and STI.

Background

Description of contextual factors contributing to sexual behavior has motivated ongoing modification of HIV risk reduction interventions (DiClemente, et al., 2009). HIV risk reduction intervention trials have demonstrated reductions in STI, new sex partners, substance use during sex, unprotected sex and self-reported pregnancies, increases in HIV knowledge and intentions to use condoms (DiClemente, et al., 2004; Jemmott, Jemmott, Braverman, & Fong, 2005; Jemmott, Jemmott, & O'Leary, 2007; Royce, et al., 2007; Shain, et al., 2004; Villarruel, Jemmott, & Jemmott, 2006; Y. Wu, et al., 2003).

HIV risk reduction interventions have focused on ethnic minorities including African-American (DiClemente, et al., 2004; DiClemente, et al., 2009; Jemmott, et al., 2007; Marcus, et al., 2004; Wu, et al., 2005) Hispanic (Villarruel, et al., 2006) and ethnically mixed adolescents (Jemmott, III, et al., 2005; Koniak-Griffin, et al., 2003; Royce, et al., 2007; Shain, et al., 2004). These studies have targeted adolescents from community health agencies (Villarruel, et al., 2006; Wu, et al., 2003), medicine clinics (Jemmott, III, et al., 2005; Jemmott, et al., 2007; Royce, et al., 2007; Shain, et al., 2004), local schools (Koniak-Griffin, et al., 2003; Villarruel, et al., 2006) and churches (Marcus, et al., 2004).

Interventions demonstrating highest reductions in sexual risk behavior and STI included a skills component (Darbes, et al., 2008; Jemmott, III, et al., 2005; Johnson, et al., 2003; Kirby, Laris, & Roller, 2007; Lyles, et al., 2007; Robin, et al., 2004) tailored to the target population in terms of cultural and peer norms (Darbes, et al., 2008; Herbst, et al., 2007). Although most interventions are lengthy (1 to 80 sessions), they have been adapted to meet the needs of healthcare delivery sites by including fewer sessions (DiClemente, et al., 2009; Jemmott, III, et al., 2005; Jemmott, et al., 2007; Robin, et al., 2004; Royce, et al., 2007).

Behavioral outcomes to measure efficacy of HIV risk reduction interventions include delayed initiation and frequency of sex, condom and contraceptive use and knowledge and beliefs about HIV/STI (Darbes, et al., 2008; Herbst, et al., 2007; Lyles, et al., 2007; Robin, et al., 2004; Shepherd, Weston, Peersman, & Napuli, 1999). However, the relationship of sexual risk behavior and HIV/STI is complex (Bonell & Imrie, 2001; R. DiClemente, et al., 2004; Fishbein & Jarvis, 2000; Kotchick, Shaffer, & Forehand, 2001; Pequegnat, et al., 2000). Therefore, biological outcomes are indicated for measurement of intervention efficacy as is not known what conditions impact behaviors and subsequently reduce prevalence of infection. Recommendations are for interventions aimed at reducing HIV/STI prevalence rather than simply changing behavior (Fishbein & Jarvis, 2000).

Few studies have utilized biologic outcomes as measures of efficacy for HIV/STI risk reduction interventions (DiClemente et al., 2004; Jemmott, et al., 2005; Royce, et al., 2007). The feasibility of biologic outcomes has been limited by low HIV/STI incidence in study populations. Among abused adolescents, Wingood et al., (2006) found higher STI incidence in control versus intervention groups. Champion (2007) found a higher incidence of STI re-infection for abused than nonabused ethnic minority adolescent women with STI in a randomized trial of behavioral interventions for HIV/STI prevention.

Purpose

Previous findings of trials of behavioral interventions for HIV/STI risk reduction indicate ethnic minority adolescent women with a history of abuse and STI are at high risk for HIV/STI. The purpose of this study was to describe the relationship of a history of abuse, sexual behavior and STI outcomes for ethnic minority adolescent women and incorporate these findings into an evidence-based intervention (Project SAFE) (Shain et al., 1999). Subsequent efficacy testing of the modified cognitive behavioral HIV/STI risk reduction intervention, Project IMAGE, was conducted among African-and Mexican-American adolescent women with a history of abuse and STI.

Methods

Preliminary studies for Project IMAGE intervention development

Practical information concerning the processes for successful intervention modification through clinical research trials and associated recruitment and retention strategies requisite for intervention development is imperative. This preliminary study section includes a brief

overview of methodological strategies used to modify Project SAFE, an evidence-based behavioral intervention for ethnic minority women to Project IMAGE, an intervention for adolescents with a history of STI and abuse. Institutional Review Board approval for development and efficacy testing of these interventions was obtained from the University of Texas Health Science Center at San Antonio and the San Antonio Metropolitan Health District, San Antonio, Texas, USA.

Project SAFE intervention—Project SAFE is unique as it is an ethnic minority-women-specific intervention designed to be culturally relevant and found to be effective through testing of multiple intervention modifications via sequential randomized controlled trials. Project SAFE interventions are based upon the AIDS Risk Reduction Model and are grounded in knowledge of the target populations' behavior and culture. Biological markers such as STI and detailed measures of sexual behavior serve as primary intervention outcome variables (Shain et al., 2002; Shain et al., 1999; Shain et al., 2004).

Project SAFE was initially tested in a randomized controlled trial among Mexican-and African-American women with STI (Shain et al., 1999). Results of this trial found that overall, participants receiving the Project SAFE intervention were significantly less likely to be re-infected with STI. The Centers for Disease Control subsequently designated Project SAFE as effective for prevention of HIV/STI among ethnic minority women. Secondary analyses were conducted following completion of this trial to identify women who did not benefit from the intervention. Although Project SAFE was successful with the sample as a whole, physically or sexually abused adolescents using drugs or alcohol (14-18 years) had the highest STI and unintended pregnancy rates and were not benefiting from the intervention (Shain et al., 2004). Project SAFE was subsequently modified to create Project IMAGE for reduction of abuse, HIV/STI and unintended pregnancy among ethnic minority adolescent women with a history of STI and abuse. The methodological processes utilized for this process included qualitative (individual interviews and focus groups) and quantitative methodologies (secondary data analyses, pre test and pilot-testing). These combined methodologies were required to capture the complexity of sexual behaviors of this vulnerable population (Champion, & Collins, 2010).

Project IMAGE intervention—Secondary quantitative analyses of data from Project SAFE studies (Shain et al., 2002; Shain et al., 1999; Shain et al., 2004) were performed to examine the associations of a number of demographic characteristics and sexual risk behaviors with history of sexual or physical abuse in adolescent women (aged 14-18 years) with STI enrolled in these studies. Comparisons of abuse and non-abused adolescent women indicated that those who had been abused had less stable lives, including psychological stress, lower incomes, higher risk sexual behaviors and substance use, greater genitourinary symptomatology, treatment noncompliance, barriers to health care, more dysplasia, lower contraceptive use, and higher unintended pregnancy and STI rates than non-abused (Champion et al., 2005).

A more comprehensive measurement tool was needed to characterize participants with respect to abuse to determine its effect on STI infection. Therefore, individual interviews and focus groups were conducted at the area Battered Women's Shelter for development of an abuse screen addressing not only sexual, but also physical and psychological abuse among ethnicity minority women with STI. This screen was then pre-tested with over 100 women at the metropolitan health district STI clinic prior to study utilization. The Abuse Screen consists of 10 items (overall alpha .81). Initial Principal Components factor analysis with varimax rotation produced two factors, a 6-item sexual abuse factor (Chronbach's alpha .82) and a 4-item combined physical and psychological abuse factor (alpha .62). The 2-item physical abuse and 6-item sexual abuse scales were combined into an 8-item scale to

measure physical and sexual abuse (alpha .82). Psychological abuse was measured with the remaining 2 items.

Qualitative data provided an additional approach to an understanding of cultural norms. A qualitative study was conducted to provide a more in-depth understanding of the psychosocial and situational factors that are associated with high-risk sexual behaviors. Previous secondary analyses as described previously had identified substance use, abuse recurrence and contraceptive use among abused adolescents with STI as factors that are associated with high-risk sexual behaviors (Champion et al., 2004). Based upon these findings, individual interviews were conducted with a convenience sample of Mexican-American and African-American adolescent women (n=34) aged 14-18 with a history of abuse and STI recruited from the metropolitan STI clinic. Additional qualitative study utilizing individual interviews with women previously participating in Project SAFE studies who were <18 years old at study entry and reported a history of physical or sexual abuse were conducted. Life-history methodology was used with each of these groups to identify themes subsequently integrated into the adolescent intervention protocol (Champion, Shain & Piper, 2004). The Project SAFE intervention was ultimately revised to include two workshop sessions, 2 or more individual counseling sessions and 3-5 support group sessions. Participants initially attended the workshops. Both workshops were designed for 4-8 persons and of 3-4 hours duration. Basic sexual risk behavior reduction information was provided in each of these sessions. These workshops were followed by the support group sessions and participants could attend as many of support group sessions as they wished. Each support group session was designed for approximately 4-8 persons and focused on each group's interests concerning sexual risk behavior, treatment compliance, genitourinary symptomatology, health-seeking behavior, HIV/STI, interpersonal relationships, contraceptive use, pregnancy, substance use and abuse. Individual sessions were provided on a flexible basis by either the investigator(s) or a licensed therapist experienced in providing psychotherapeutic interventions. These sessions focused on a participant's expressed needs and referral was made as needed.

Following modification of the Project SAFE intervention, pre-testing of Project IMAGE with the target population was conducted followed by focus groups. Mexican-and African-American adolescent women (n=25) aged 14-18 years who were seeking health care through the metropolitan health district had a current STI and a history of abuse were included. These informal semi-structured group interviews were useful in identifying needed changes in the content of the intervention.

Pre-test findings were incorporated into the intervention and preliminary evaluation of intervention efficacy was conducted via feasibility testing with a 6 months follow-up. Participation in the intervention was offered to the target population. Mexican-and African-American adolescent women (n=70) seeking health care through the metropolitan health district who had a current STI and a history of abuse were included. A targeted physical examination, including STI screen, Pap smear and pregnancy testing was performed. Contraception was provided to interested participants. Participants received clinical counseling at the initial and each follow-up visit. Ninety-eight percent attended one workshop sessions while ninety-two percent attended both workshop sessions. Workshops were scheduled to allow participants to attend within 2-3 weeks following study entry. Most (87%) participants attended one or more support group sessions. Support groups were conducted every week.

Ninety percent returned for post-intervention baseline testing following the intervention. Eighty-two percent of participants returned for the 6-month follow-up visit and findings were compared to those in our previous studies for adolescents with a history of abuse. Results

were encouraging with very positive results for intervention participation and follow-up with this extremely high-risk population. No untoward effects of the intervention were identified. Reported contraceptive use was higher while sexual risk behaviors, substance use and abuse recurrence were lower. Unintended pregnancy and STI rates identified lower trends than in our previous studies. Completion of the intervention pretesting led to randomized controlled trial testing of the intervention presented in this paper. The following discussion provides a description of the methodology used for implementation of the randomized controlled trial.

Efficacy testing of the intervention: randomized controlled trial

Sample size—In determining sample size requirements to test the research hypotheses, infection data from previous study (Shain et al., 2002) was used to estimate expected rates in the proposed study. The sample and data collection methodology was nearly identical to this study. Previous data showed a 12-month crude re-infection rate of 43% (Intervention=43.0%, Control=43.5%) among 220 women aged 14-18 with a current STI and a history of sexual or physical abuse. The study hypothesis was that the proposed adolescent intervention would reduce the overall rate of re-infection from 43% to 30% - a decline of 30%. This hypothesized reduction was informed by clinical experience with this population, as well as the observation that among non-abused adolescents, the overall 12-month re-infection rate was 30% (Shain, et al., 2002). The intervention target of 30% re-infection over 12 months for abused adolescents was therefore tenable, and consistent with the aim of the study to overcome the effects of sexual and physical abuse on STI recurrence.

Based on the conditional assumptions of $\alpha=.05$, and 80% power to detect a clinically relevant reduction of re-infection by 30% from recently observed incidence (43% versus 30%), recruitment of 458 women to the study (229 to the control group, and 299 to the adolescent intervention) was required to detect the hypothesized effect. We anticipated recruiting a total sample size of approximately 600 to accommodate a potential 20% attrition rate among participants.

Recruitment and randomization—Recruitment for this study was accomplished in conjunction with the Metropolitan Health District and included ethnic minority adolescent women with STI or abuse. There were basically two reasons for utilization of this recruitment protocol. 1) The sampling protocol for recruitment of adolescent women with either a history of abuse or STI was utilized to potentiate recruitment of a high risk population (ethnic minority adolescent women with STI and abuse) generally difficult to access within a community setting. Our previous work with the Metropolitan Health District found that a high percentage of ethnic minority adolescent women presenting with a history of STI also had a history of abuse and vice versa i.e., many ethnic minority adolescent women reporting a history of abuse also had a STI. Therefore, recruitment of ethnic minority adolescents with either a history of STI or abuse was intended to provide a study sample of adolescents with both a history of STI and abuse. 2) Once recruited into the study, per protocol, participants with either a history of STI or abuse were randomized to the intervention or control group and completed the study. Potential benefits of the intervention for ethnic minority adolescent women with either STI or history of abuse had been identified in our previous studies and the literature. It was therefore deemed unethical to deny the opportunity for study participation to those who had either versus both a history of STI and abuse.

We worked with the health district to identify potential participants for whom study information was provided and questions answered. African-and Mexican-American adolescent women seeking health care at a health district clinic were provided an information sheet concerning the study. They were then asked to sign an information sheet if

interested in contact by the investigators. Those indicating interest and willing to be contacted were assessed for eligibility by the research staff and contacted. Enrollment began in July 2005 and ended in March 2008 (see Figure 1).

Parental consent was obtained, when either a parent or guardian accompanied the participant. We did not obtain parental consent when a parent or guardian was not accompanying the participant. In this situation, the participant was seeking sexual or reproductive health care independently and was therefore considered an emancipated minor. Parental consent was not indicated in this situation. All information was confidential except for disclosures of sexual or physical abuse that had not been previously reported to authorities. Potential participants were clearly informed about the maintenance of confidentiality when approached for study participation. This information was also contained in the consent form. With the participants' permission, we collected basic demographic data on eligible participants who declined study participation such as age, ethnicity and HIV/STI status. A certificate of confidentiality was obtained for the study from the National Institute of Health.

Following study entry we re-screened participants for abuse. We provided currently abused women with information about all resources available in the area, and if they were willing, called the appropriate agencies, scheduled an appointment in their presence, and, depending on their situation, transported them directly to the Battered Women's Shelter. We reported all cases of minor abuse to the appropriate authorities. When abuse occurred during the study, we followed the same protocol. We have dealt with abused women for more than 15 years and these procedures have worked well without incidence of adverse effects.

Testing of the intervention took place in a community-based research clinic. All clinical care (examinations and treatment), clinical specimen collection, and interviews for the project were performed in the dedicated research clinic. This clinic was devoted solely to clinical research and was located across the street from the health district central offices and STI clinic. The community-based research clinic was established to allow for greater control over all aspects of clinical care and adherence to research protocols.

Ongoing collaboration between the research clinic staff and health district personnel were critical study components. The research clinicians were nurse practitioners who followed health district guidelines. Because the research clinic acted as a satellite of the health district, all clinical records of study participants were freely shared between the two clinics. The health district laboratory processed all specimens. All necessary partner tracking or partner notification was performed by the research clinic and health district personnel.

Following receipt of informed consent for study participation, a physical examination, including HIV/STI screening (gonorrhea, Chlamydia, Trichomonas, syphilis and bacterial vaginosis), pregnancy testing, and a pap smear was performed. Although our primary STI outcome variable was new infection with gonorrhea or Chlamydia, it was important to assess concurrent infections in order to identify symptomatology independently and to help characterize participants' risk profile regarding the number of different infections they contracted.

Openly valuing the time these young women take to be in the study acknowledges the importance of their participation in the study. All participants were interviewed using instrumentation that utilizes participant-interviewer interaction. Self-administered computerized questionnaires were not used because of beliefs that participant-interviewer interaction increases retention and decreases question misinterpretation. The high retention rates (90%) in the preliminary study supported this belief. The interview required 1^{1/4} to 2 hours. Participants were compensated \$50 for their time at initial, 6 and 12 month follow-

ups. Incentive payments were provided as it is very important to demonstrate to participants that their time and effort is valued. A great deal of effort was placed on participant retention, using time-tested techniques. Participants were asked to provide up to 5 names and addresses of people who would always know their whereabouts. This list was updated every time a participant called to discuss a problem or schedule a visit. Participants were called at 3 and 9 months to say “hello” and to update all contact information. They were also given pre-paid, change-of-address postcards to notify the study staff when they moved. Interviewers were also trained to make participants aware of how much they were helping us and other people. When participants relocated, long-distance telephone interviews were conducted and arrangements were made with their clinic to send HIV/STI-screen results. Although these procedures were labor-intensive and costly, they were much less expensive than high attrition rates. Moreover, high attrition introduces bias that cannot always be controlled for in analyses.

Established procedures were following for training of interviewers. Extensive instructions were provided. Interviewers spent approximately 2 weeks observing interviews and then were directly observed while conducting interviews. For several months after the interviewer’s initial training, the investigators randomly chose interviews to review for completeness and internal consistency. All interviewers were gender matched to participants, respected equality among all persons, and extended courtesy and warmth to all participants in order to provide a comfortable setting to discuss questions regarding sexuality, substance use, abuse and HIV/STI. Research associates had to project sincere compassion when working with participants. When a client misunderstood a question, for example, the interviewer explained that it is difficult to create good questions and sometime these were not very clear. This allowed clarification without making the client feel she/he is at fault. Teamwork among staff members was critical when caring for this vulnerable group of adolescent women.

Randomization was accomplished at the end of the initial visit via participant selection of “intervention” start-times from several dates within two weeks of enrollment, blinded to group status. Study and control group “intervention” start-times were pre-assigned to dates randomized and balanced during the enrollment period across time of day, days of the week, weeks of the month, and months of the year. After selecting a start-time, the participant was informed of her group assignment. This process was used to 1) maximize group equality in motivation (all women had to agree to select a start-time) and to 2) minimize resentment with group assignment (participants made the “selection”).

Intervention implementation and evaluation—Study-group participants began the intervention (Table 1) within three weeks of study randomization. Control-group women were told that they can receive the intervention at study completion. The workshop and support group sessions provided for control group participants are identical to those provided for the intervention group and are conducted by the same facilitator. We did not provide a monetary incentive for control-group participants’ attendance at these sessions; however, participants did receive non-monetary incentives as part of the sessions. Although not a blinded study, the group status did not appear on interviews or clinic records. Participants were asked their group status only at the end of follow-up interviews to ascertain intervention benefits. Our intervention facilitators were not necessarily of matched ethnicity, (African-or Mexican-American) for workshops and support groups.

All participants received enhanced clinical counseling at each visit. Because our previous studies indicated that our intervention significantly affected infection, we felt it was unethical to deprive control women of information we knew was critical. Thus, at baseline counseling the nurse-clinician asked all women who were treated elsewhere if they took all

their medicine, if they had sex before completing treatment, if their partner was treated, and if they had sex with him either before or during treatment. Because treatment could have occurred up to 30 days earlier, we re-treated all women with high-risk responses. High-risk responses include reports that treatment has not been completed or unprotected sex has occurred prior to completion of partner or self treatment.

All study-group participants were asked to return to the clinic after completion of the intervention for a follow-up physical examination including HIV/STI screen, pregnancy testing, contraception counseling and interview to establish a post-intervention baseline. All other participants were asked to return for an STI test of cure one week after study entry. Follow-up visits at 6 and 12 months following study entry were conducted for all participants. Participants were encouraged to return to the research clinic during the course of the study for contraception, pregnancy testing and examination and treatment of suspected STI. However, should study participants receive physical examinations or treatment for STI or pregnancy at other health care providers during this 12-month study interval, a request for these medical records was made after obtaining appropriate permission from the participant. This process allowed more complete ascertainment of the STI and pregnancy status of participants. Each participant received a total incentive payment of up to \$120.00 (2 workshop, 3 support group and 2 individual counseling sessions) for the behavioral intervention, \$25.00 for the post-intervention testing and each follow-up visit at 6, and 12 months following intervention completion to compensate for time and assist with bus or cab fare or babysitting. We also provided an area in the clinic for child care while participants completed intervention or follow-up protocols. Evidence of the success of these strategies is exemplified in the high intervention participation and follow-up rates documented in our studies.

Data analysis

We evaluated study group status (intervention vs. control) to confirm successful randomization. We assessed for substantial differences between groups in important variables including high-risk behavior (i.e., sexual behavior and substance use), psychosocial/situational factors (i.e., anxiety, depression and abuse), socio-demographic variables (i.e., age, education, and household income) and history of STI.

Benefits of the intervention for ethnic minority adolescent women with both a history of STI and abuse had not been assessed and so were included exclusively in this analysis consistent with the study purpose. Analyses of intervention effects were performed on an intent-to-treat basis. In secondary analyses we examined effect of participation in any or no intervention session.

Prior to fitting multivariate models, we conducted dichotomous analyses evaluating the relationship between study group and STI infection. After achieving a thorough understanding of the important relationships observed in the data, we proceeded to multivariate modeling of the intervention impact. We fit multivariable logistic models controlling for confounders based on theoretical considerations, and based on relationships observed in bivariate data analyses. We made separate longitudinal analyses for the 0-6, 6-12 and 0-12 month follow-ups, to assess the changing impact of the intervention over time.

Our previous analyses (Champion, 2007; Shain 2004) identified substance use as a powerful predictor of STI infection risk as well as abuse and participation in any intervention component. Therefore in the present analyses, we considered it important to evaluate these variables as effect modifiers and confounders.

All models examining the association between study group and STI infection tested for effect modification by age, ethnicity, any substance use (alcohol, drugs or cigarettes) and physical or sexual abuse history. Current school attendance, history of runaway and emotional abuse history were initially included in these analyses however were removed due to insignificant contributions to the model. We considered effect modification to be present based on a nominal global p-value of .05. We tested for effect of any intervention session as a dichotomous variable including participants who received any intervention versus intervention participants who did not attend any intervention component and control participants. The analytic package used for statistical analysis was PASW Statistics, Version 18.

Results

A total of 559 participants were enrolled in the study (Figure 1). This analysis includes 409 participants, African-American (n=67) or Mexican-American (n=342), who had both a history of STI and abuse. Basic socio-demographic, sexual risk behavior, abuse history and psychosocial characteristics of subjects are shown in Table 2 by study group status.

Average age of participants was 16.46 (SD =1.34) years, 63.2% were in any kind of school and 20.5% were employed. The majority of women in the study had histories of abuse (76%) including sexual (58.9%), physical (76.8%) and emotional (82.4%). The majority had been arrested (56.2%) or ran away from home (54.5%). Substance use included marijuana (82.6%), alcohol (77.5%), cigarettes (74.6%), cocaine (41.1%), benzodiazepine (45%), heroin (13.4%) or ecstasy (16.1%). Participants reported they were made to have sex (29.1%), had sex when high and out of control (13.9%), first sex when younger than 11 years (4.4%), first sex forced (10.8%), sex with friends for benefits (36.2%) or had a steady or regular partner in past 3 months (77.4%) with whom this relationship has been off and on (31.4%). Total number of sexual partners (lifetime, mean=7.17 range 1-125; last year, mean 2.7 range 0-30) was high. The average age of first sex was 13.8 years. The CESD depression scale (mean 24.59, SD=9.36) and SCL-R-90 (mean= 90.02, SD=70.08) psychological distress scales identified high levels of depression or psychological distress.

Participants were randomized into intervention (n=199, 48.7%) and control (n=210, 51.3%) arms (Figure 1). High follow-up rates were achieved at 6 (93.0%) and 12 month (93.7%) follow-ups. These adjusted rates account for participants we were unable to contact as they had moved out of the city/state, had no contact numbers/addresses or were incarcerated at 6 (16.4%) or 12 (15.4%) month follow-ups. Unadjusted rates at follow-up for 6 (78%) and 12 (81%) months were high.

Comparisons of intervention versus control group participant baseline characteristics were conducted (Table 2). Intervention participants reported significantly ($p<.05$) more experiences of any abuse (82.9% vs. 71%), (physical abuse 82.9% vs. 71.0%; sexual molestation 33.2% vs. 25.6%), run away from home (63.1% vs. 46.4%) or cigarette (78.9% vs. 70.5%) or alcohol (81.4% vs. 73.8%) use than control. More control versus intervention group participants were currently in school (68.1% vs. 58.1%).

Sexually transmitted infection was calculated as a dichotomous variable (yes, no) to reflect any new infection documented at offsite, problem or scheduled follow-up visit at 6 and 12 months. Sexually transmitted infection data were available for 318 women for 0-6 month, 333 women for 6-12 month, and 333 women for 0-12 month (baseline through 12 months cumulatively) follow-up assessments. Chi-square analyses of STI infection during the 0-6 month interval found intervention (n=155) versus control (n=163) group participants had lower infection rates (Intervention (n=0) 0%; Control (n=11) 6.6%, $p=0.001$).

Corresponding STI infection rates for the 6-12 month interval found intervention (n=166) versus control (n=167) group (Intervention (n=6) 3.6%; Control (n=13) 7.8%, $p=0.079$) had lower infection rates. Cumulative 0-12 month analyses found intervention (n=166) versus control (n=167) group infection (Intervention (n=8) 4.8%; Control (n=22) 13.2%, $p=0.006$) was also lower.

Regression analysis was not conducted for the 0-6 month interval because the infection rate in the intervention group for this study interval was zero. The exact number of women in specific regression analyses was reduced somewhat due to occasional missing data on other covariates. Multi-nominal logistic regression analysis including age, ethnicity, substance use (including alcohol, drug, cigarettes) and history of sexual or physical abuse, identified study group type (control vs. intervention) as a predictor of infection at the 6-12 month interval (χ^2 (5, $N = 333$) = 16.776, $p = .005$) (Table 3). Study group type was significant with partial effects of age, physical abuse history, and any intervention while sexual abuse history approached significance.

Odds ratios for the 6-12 months post-intervention period indicated participants who were younger (1.4 times) or had a history of physical violence (3.5 times) were more likely to experience STI. Control and intervention group participants who did not have any intervention were more likely to experience STI. Participants who had a sexual abuse history approached significance for having a higher likelihood of STI.

Multi-nominal logistic regression analysis controlling for age, ethnicity, substance use (including alcohol, drug, cigarettes) and history of sexual or physical abuse, also identified study group type (control vs. intervention) as a predictor of infection at the 0-12 month interval (χ^2 (5, $N = 287$) = 18.421, $p = .002$) (Table 4). A sexual abuse history had significant partial effects. Substance use, receiving any intervention and ethnicity approached significance.

Odds ratios indicated participants with sexual abuse history were 74% more likely to experience infection than those without this history. Control group participants were 96% more likely than intervention to experience infection. Intervention group participants who did not attend any intervention component were 96% more likely to experience STI. Substance use and ethnicity approached significance for prediction of STI infection in the regression model.

Subset analyses found lower incidence of STI infection among intervention versus control participants with sexual abuse history (15.7% versus 9.7%, $p=0.157$). Fewer intervention versus control participants without sexual abuse history experienced STI (0% vs. 9.8%, $p=0.017$). Differences by ethnicity included higher STI infection rates among Mexican-American control versus intervention groups (14.2% versus 6.6%, $p=0.043$). Concerning substance use, more control than intervention participants in both low (1-4 substances; 14.7% vs. 6.2%) or high (>4 substances; 11.8% v 5.1%) substance use categories experienced STI infection in the 0-12 month interval.

Discussion

Extensive preliminary studies were conducted for modification and subsequent efficacy testing in a randomized trial of an evidenced - based cognitive behavioral intervention for ethnic minority adolescent women with a history of STI and abuse. The incidence of sexual, physical or emotional abuse along with substance use including drugs, alcohol and cigarettes and high risk sexual behavior was extremely high among participants. Randomization was effective with the exception of significantly higher levels of physical abuse, sexual molestation, alcohol and cigarette use, runaway and lower rates of school attendance among

intervention participants at study entry. Remarkably high rates of follow-up and intervention attendance were achieved with this vulnerable high risk group. These rates are particularly impressive considering the nature of the multi-level behavioral intervention including workshops, support groups and individual counseling sessions. The STI infection rates found among both intervention and control groups are lower than those documented in our previous clinical trial including adolescent women with STI and abuse; 42.7% at 1 year follow-up (Champion, 2007). The previous study sample included only adolescent women who had a current STI compared to the current study in which women had any history of STI (current and previous). Based on prior evidence from preliminary studies, it was hypothesized that STI would be reduced by 30% among participants. This hypothesis was supported for both intervention and control groups at all study intervals (0-6, 6-12, 0-12). Infection rates were significantly lower overall for the intervention versus control group participants in this study. Enhanced effects of participation in the intervention group were found for those attending at least one intervention component. Findings of extremely low STI incidence at 0-6 month interval are important for both intervention and control groups. Extensive clinical counseling was provided to the control group concerning STI infection. Additionally, control participants were asked to return to the clinic for a test-of-cure for any STI occurring during the study. Intervention participants had the opportunity to participate in workshops, support groups and counseling sessions during the 0-6 month interval at which time they were tested if they desired for STI and also at the completion of the intervention sessions to provide a baseline for estimation of intervention effects. This study protocol was extremely effective in preventing STI infections for intervention participants.

Sexually transmitted infection at 6-12 versus 0-6 month follow-up was increased among both control and intervention groups. Contributing variables in analysis of these infections rates included age and participation in at least one of the study intervention component. Consistent with these results, cumulatively, STI infection at 0-12 months was increased among both control and intervention groups however significantly higher for those in the control group. Those who did not have any type of intervention component were 11 times more likely to experience infection at 12 months post-intervention. Infection occurring in the absence of intervention (6-12 month interval) signifies the need for ongoing intervention for this high risk group. Younger age predicted STI infection during this study interval. Additional interventions conducted at intervals over an extended timeframe may be indicated for younger participants. These interventions may assist those who are temporarily empowered to make changes during receipt of the intervention and active support of staff, however subsequently resume earlier behavior amid peer norms.

Other variables contributing to infection included physical and sexual abuse. Physical and sexual abuse history predicted STI infection. Control group participants with these histories had higher rates of STI infection than intervention. This is important as although participants were in the control group, they still received abuse counseling at study entry and were referred for additional counseling as indicated. These results indicate that behavioral risk reduction interventions with a focus on sexual and physical abuse are important for sexually or physically abused adolescent women. The utilization of counseling only as received by the control group may not be sufficient for achievement of a reduction in STI infection on a community level for these adolescents. Multi-level interventions including counseling, workshops and support group were more effective in prevention of STI infection in this study.

Substance use was high among participants, particularly those who had a history of abuse. Concerning substance use, overall, among those reporting any level of use (1-4 substances; >4 substances), control participants in both groups experienced higher levels of STI infection than intervention. This finding is important as the study interventions appeared

effective in reduction of STI in the context of significant substance use in association with abuse history.

Comparisons by ethnicity found that more Mexican-American control versus intervention participants experienced STI infections. Importantly these results identify effectiveness of the intervention for prevention of STI infection among Mexican-American participants in this study. There were no differences identified for African-American participants by study group in part due to decreased power as a result of small ethnic group size.

Study limitations include those inherent in efficacy trials of behavioral interventions. These include the homogeneity of the study sample and controlled conditions of the randomized controlled trial. These characteristics of efficacy trials limit effectiveness in translation of interventions to a heterogeneous population on a community level (Glasgow, Lichtenstein, & Marcus, 2003).

Conclusions

This study adds a dimension to the conditions by which behavior, as a function of history, potentiates STI outcomes. This data supports the necessity of identification of client abuse histories as powerful predictors of STI. These findings respond to the need to evaluate intervention efficacy via behaviors and biologic outcomes through an understanding of the conditions by which behaviors reduce infection prevalence. Participation in an intervention aimed at modifying behavioral patterns associated with infection demonstrated efficacy with not only with those in the intervention but also those in the control condition. Control group participants who received enhanced clinical and abuse counseling benefitted as demonstrated by extremely low infection rates post intervention.

The study intervention, Project IMAGE represents the culmination of a program of research dedicated to exploring cultural and peer norms among ethnic minority adolescent women with abuse and STI histories and integrating prevention skills and norms into the intervention. One of the strengths of the study is the theoretical supported offered by the AIDS Risk Reduction Model The AIDS Risk Reduction Model specifically includes constructs of familial, cultural, and individual history as mediators of STI. Comparisons between the current study and other HIV risk behavior trials are limited as other trials have not considered the effect of abuse and STI histories on STI outcomes in the context of cognitive behavioral intervention delivery. The current study results may be compared to other studies based on similarity in sample characteristics, high-risk nature of behavior and substance use by participants.

This study provides evidence that a multi-level cognitive behavioral intervention specifically designed for ethnic minority (Mexican-and African-American) adolescent women may impact behavior for prevention of STI among a high risk, vulnerable group. These results provide evidence for further development and translation of evidence-based interventions for community-based prevention of HIV/STI. Implications are for translation to community-clinic-based settings for implementation for prevention of adverse outcomes regarding sexual health of adolescent women.

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What is already known about the topic?

- Ethnic minority adolescent women with a history of sexual or physical abuse and sexually transmitted infections represent a vulnerable population at risk for HIV/STI.
- Community-based interventions for behavior modification and subsequent risk reduction have not been effective among these women.

What does this paper add?

- A cognitive behavioral intervention specifically designed for Mexican-and African-American adolescent women with a history of abuse and sexually transmitted infection was tested in this randomized controlled trial and found to be effective for prevention of infection.
- These results provide evidence for further development and translation of evidence-based interventions for community-based prevention of sexually transmitted infection/HIV.
- These evidence-based cognitive-behavioral interventions can be translated to community-clinic-based settings for prevention of adverse outcomes regarding sexual health of adolescent women.

Figure 1.
CONSORT Flow Diagram

Table 1

Project IMAGE Intervention

I. Overview: Project Image is grounded in knowledge of the target populations' behavior and culture. Knowledge of African- and Mexican-American culture informed conceptualization of behavior change in terms of adolescent perceptions of costs versus benefits. A great deal of emphasis is placed upon understanding and dealing with male-female power relationships in African- and Mexican-American culture. The greatest cost of behavior change to an adolescent woman may be the consequences of saying "no" to non-safe sex or questioning her partner about his other relationships. The cost, the potential risk of losing a partner, may be greater than the benefit of behavior change. Rather than losing a partner, an adolescent may perceive and choose pregnancy as a way to keep a partner.

The impact of violence in the lives of adolescent women is compounded by their history of abuse and the potential for a current partner to become violent. The complexity of situational factors such as level of education, job skills and other sources of support further complicate the effect of violence on these women's lives. To the extent that perceptions of poverty-related stress, self-esteem deficits, and substance abuse issues are also present, the threat of violence or the loss of a partner may appear worse than the possible contraction of another STI, even HIV. The intervention respects cultural norms seeking neither to change culture nor to change social and economic situations and the stresses that result from being poor. Rather, interventions were created to utilize cultural strengths that promote health and enhance self-esteem.

A cultural strength of members of the African- and Mexican-American culture, the valuation of childbearing and children was incorporated into the intervention. The possible loss of fertility, harm to the fetus, and emotional or physical hardship to the existing children if their mother contracts a STI or AIDS presents issues that women in these cultures confront creating vulnerable situations. This emphasis on childbearing issues is used to remind the adolescents of the benefit of reducing risk behavior or maintaining low risk behavior. The intervention stresses contraceptive use, reconsidering choice of partner and skills training in meeting new partners with whom having and up-bringing of children would be more viable.

II. Location: All intervention components including physical examination, workshop and support group sessions, individual counseling, and problem follow-up visits were conducted at a dedicated research clinic devoted solely to clinical research located across the street from the health district central offices and STI clinic.

III. Informed consent and study entry

IV. Rescreening for physical, sexual or emotional abuse

V. Physical examination and semi-structured, one-on-one interview at study entry and at 6 and 12 month follow-up visits

- 1.5-2 hours in duration (exam by nurse, interview by research staff)
- STI/HIV screening (gonorrhea, Chlamydia)
- pregnancy testing and pap smear
- pap smear
- enhanced clinical counseling
- re-treat all bacterial STI for participants with high-risk responses

VI. Two Workshop sessions

- Sessions follow in close proximity; optimally one week apart
- Sessions begin 1-3 weeks after study entry
- 4-8 participants are included in each session
- Each session is 3-4 hours in duration
- All sessions are conducted by a facilitator in round table format using principles of motivational interviewing
- Each participant receives \$25 per workshop session

Session 1: Awareness and Perception of Risk: Focuses on making participants realize that they are at risk of serious and even deadly infection. It builds on cultural strengths of young people and their concerns about achieving their goals, living up to expectations and helping their friends and younger siblings. It also shows participants that their problems are part of a much larger one that threatens their generation, families and communities. This session addresses disease transmission and protecting oneself and one another from becoming infected with STIs and reducing the risk of HIV. Participants are encouraged to recognize the important roles they play, to take control of their lives, and to start protecting themselves, their families and their future children.

- Raise awareness that minorities are disproportionately affected by STI/HIV.
- Illustrate risk as related to poverty. Address myths. (Ex: People do not become infected with STI from toilet seats; STI cannot be prevented by cleaning after sex; it is not possible to tell whether a person has a STI based on how they 'look'; withdrawal before orgasm, douching or voiding after sex does not prevent pregnancy.)
- Explain how people can get STI/HIV, including associations with substance use, interpersonal violence and multiple partner relationships.
- Discuss the selection of sex partners, importance of testing prior to sexual behavior and inability to judge risk based on how a person looks, acts, or speaks.

- Provide information about STI: their transmission, behavior that increases the risk of acquisition, symptoms (color illustrations of signs and lesions), and consequences for women and fetuses.
- Conversation about unintended pregnancy and timing of pregnancy
- Increase awareness of personal risk by associating the current STI with the potential for future infection (including HIV). Emphasize the effect on future childbearing.
- Summarize what has been presented and distribute evaluation forms. Ask participants what parts of the session were effective and what might need to be removed.

Session 2: Commitment to change: Strategies to Reduce Risk Behavior: Provides participants with basic information on sex, drugs, STI, HIV, contraception and ways to prevent infection and unintended pregnancy. Participants learn how to use condoms properly and for pleasure. They also learn how to obtain information about their partner's history and to make decisions about sex. This session gives participants the tools for communication to keep themselves safe from STI/HIV, unintended pregnancy and emotionally unhealthy relationships.

- Talk about what prevents STI/HIV and unintended pregnancy (abstinence, monogamy, condom use, STI testing, short-term abstinence, condom use until STI testing results are clear, avoid anal sex, use condoms and lubrication, avoid douching)
- Consider questions to ask partners about sexual behaviors and history: (Ex/sex with a man or prostitute; time in prison; previous STI; number of current and prior partners; HIV testing; sex with HIV positive partners; history of getting drunk or high and out of control; intravenous drug use; travel outside the country; condom use with other partners; and checking for symptoms.
- Emphasize the importance of completing treatments for STI and the time frame to wait to engage in sex after STI.
- Talk about condom use including: application and for pleasure (practice on plastic models of the penis) and barriers to condom use and how to overcome them.
- Reflect about romantic relationships: what women want from a relationship, working with a jealous partner, signs of an unhealthy relationship, tolerating poor behavior from partners due to misplaced trust, low self-esteem, how to avoid conflict, violence, or loss of a partner.
- Share sexual decision-making skills
- Empathize about how STI, HIV and getting pregnant can change participant lives
- Converse about how participants can find support in friends and family.
- Reflect on what has been presented and ask participants what specific goals they intend to achieve between now and their next relationship
- Distribute evaluation forms

VII. Problem follow-up visits: STI screening, pregnancy testing, and STI treatment as needed

VIII. Three to five support group sessions

- Support groups begin approximately 1 week following completion of both workshop sessions
- Conducted once a week by facilitator using principles of motivational interviewing
- Support group topics are generated by relevancy to each group and naturally include: sexual risk behavior, treatment compliance, genitourinary symptomatology, health-seeking behavior, STI/HIV, interpersonal relationships, contraceptive use, pregnancy, substance use and abuse
- Participants receive \$15 per support group session

IX. Two or more individual counseling sessions

- Initiated by the participant
- Conducted by facilitator
- Focus on participant expressed needs
- Referrals made as indicated

Table 2
Demographic and Psychosocial Characteristics by Study Group

	Total (%) (n=409)	Workshop (%) (n=199)	Control (%) (n=210)	P Value*
Sociodemographics				
Age, years (mean)	16.46	16.50	16.42	.58
Monthly take home pay (mean)	301.64 67 (16.4)	229.29 28 (14.1)	369.33 39 (18.6)	.066 .137
Mexican-American	342 (83.6)	171 (85.9)	171 (81.4)	
Currently in school	258 (63.2)	115 (58.1)	143 (68.1)	.023
Has had steady partner 90 day	312 (76.3)	149 (74.9)	163 (77.6)	.183
Currently employed	82 (20.5)	36 (18.5)	46 (22.4)	.195
Psychosocial/Situational factors				
Ever been arrested, incarcerated	215 (52.6)	108 (54.3)	107 (51)	.283
Ever run away from home	222 (54.5)	125 (63.1)	97 (46.1)	.000
Ever use marijuana	338 (82.6)	166 (83.4)	172 (81.9)	.393
Ever use cigarettes	305 (74.6)	157 (78.9)	148 (70.5)	.033
Ever drink alcohol	317 (77.5)	162 (81.4)	155 (73.8)	.042
Ever use heroin	55 (13.4)	31 (15.6)	24 (11.4)	.139
Ever use cocaine	168 (41.1)	86 (43.2)	82 (39.0)	.225
Ever use methamphetamine	56 (13.7)	29 (14.6)	27 (12.9)	.359
Ever use ecstasy	66 (16.1)	25 (13.1)	40 (19.0)	.065
Ever use benzodiazepine	184 (45.0)	92 (46.2)	92 (43.8)	.347
Ever anal sex	101 (24.7)	56 (55.4)	45 (44.6)	.072
Group sex	35 (8.6)	18 (9.0)	17 (8.1)	.434
Oral-Anal	26 (4.3)	17 (8.6)	9 (6.4)	.056
Sex with injection drug user	45 (11.0)	25 (6.1)	20 (4.9)	.39
Sex with bisexual man	12 (2.9)	4 (2.0)	8 (3.8)	.27
Sex with friends for benefits	148 (36.2)	75 (37.7)	73 (34.8)	.304
Ever sex with a woman	62 (15.3)	34 (17.3)	28 (13.4)	.173
Number male partners lifetime	7.18	6.46	7.86	.580
Number male partners 1 year	2.73	2.62	2.83	.46
Number male partners 3 months	1.3	1.30	1.30	.92
Age at first sex with a man	13.82	13.80	13.84	.824
Number female partners lifetime	2.475	2.15	2.90	.134
Number female partners 1 year	1.83	1.21	1.27	.875
Number female partners 3 months	.367	.294	.462	.273
Age at first sex with a woman	14.87	15.0	14.7	.717
Ever use condoms	373 (91.0)	172 (86.4)	201 (95.3)	.001
Pregnant now	76 (18.7)	44 (22.7)	32 (15.4)	.122
Ever pregnant	185 (45.1)	94 (47.2)	93 (47.1)	.224
Potential Covariates				
Sexually molested	120 (29.3)	66 (33.2)	54 (25.6)	.058

	Total (%) (n=409)	Workshop (%) (n=199)	Control (%) (n=210)	P Value*
First sex at <11 year of age	18 (4.4)	8 (4.0)	10 (4.8)	.452
Forced first sex	44 (10.8)	21 (10.6)	23 (11.0)	.512
Emotional abuse history	337 (82.4)	163 (81.9)	174 (82.9)	.451
Physical abuse history	314 (76.8)	165 (82.9)	149 (71.0)	.003
Sexual abuse history	241 (58.9)	123 (61.8)	118 (56.2)	.146
CESD (mean)	25.2	25.62	24.64	.290
SCLR-90 (mean)	90.02	90.66	89.44	.845

* Chi-Square or T-test as appropriate

Table 3
Nominal Regression Predicting Infection during 6-12 months post-intervention using age, history of physical violence, history of sexual violence, study group assignment, and receiving any intervention as predictors

Predictor	B	Wald X ²	P	Odds Ratio	95% CI
Age	.365	4.071	.044	1.440	1.011-2.052
Physical violence	1.266	5.906	.015	3.545	1.278-9.839
Sexual violence	-.897	2.573	.109	.408	.136-1.220
Intervention group	-3.864	6.762	.009	.021	.001-.386
Any intervention	-3.297	5.090	.024	.037	.002-.649

Table 4
Nominal Regressions Predicting Infection during 0-12 months post-intervention using history of sexual violence, ethnicity, substance use, receiving any intervention and study group assignment as predictors

Predictor	B	Wald X ²	P	Odds Ratio	95% CI
Sexual violence	-.1, .358	6.706	.010	.257	.092-.719
Ethnicity	-1.280	3.162	.075	.278	.068-1.140
Substance use	.194	2.891	.089	1.214	.971-1.519
Any intervention	2.424	3.166	.075	11.295	.782-163.160
Intervention group	-3.359	5.833	.016	.035	.002-.531