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A Randomized Controlled Trial of Soap Opera Videos Streamed to Smartphones to Reduce HIV Sex Risk in Young Urban African American Women

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Introduction

African American women are disproportionately affected by human immunodeficiency virus (HIV). Rates of new HIV infections among Black women are 20 times that of white women, and 4 times that of Latinas (Centers for Disease Control and Prevention [CDC], 2013a). Yet, Black women are no more likely to engage in unprotected sex or have multiple partners than their white counterparts (Tillerson, 2008), but are more likely to have sex partners who are at higher risk (CDC, 2013b; Newsome & Airhihenbuwa, 2012). Higher HIV prevalence in Black communities is attributed to stigma, structural and racial disparities (CDC, 2013b). Unprotected sex with HIV infected men accounts for just over 90% of transmission in all 13 to 24 year old and 87.4% in all 25 to 34 year old women (CDC, 2012). Relationships with men and emotional connection are high priorities for many women (Bell, Atkinson, Mosier, Riley, & Brown, 2007; Jones & Oliver, 2007; Jordan, 2010). Since unprotected sex with infected male partners is the leading route of HIV transmission for heterosexual women, it is concerning that unprotected sex is promoted in urban sex scripts as a means to fulfill relationship needs (Bowleg, Lucas, & Tschann, 2004; El-Bassel, Caldeira, Ruglass, & Gilbert, 2009; Emmers-Sommer & Allen, 2005; Jones & Oliver, 2007; Ortiz-Torres, Williams, & Ehrhardt, 2003). While, these scripts rarely succeed in satisfying loneliness and connection in the long term (Jones & Oliver, 2007), high risk sex scripts remain a challenge to reducing HIV sex risk.

Love, Sex, and Choices (LSC) is a 12-episode weekly soap opera video that was created to reduce HIV sex risk behavior in young urban women. The series portrays four archetypical women who face commonly occurring high risk relationship dilemmas with men. Sexual health promotion messages for handling these dilemmas are woven into emotion-laden sex scripts and portrayed through the characters' process of changing risk behavior. The effect of LSC video series on women's unprotected sex with high risk partners was evaluated in a randomized controlled trial (RCT) conducted in 238 high risk predominately African

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American/Black young adult women in the urban Northeast. Weekly video episodes were streamed to smartphones provided to participants during the study (Jones & Lacroix, 2012). The video intervention was compared to 12-weekly, text-based HIV risk reduction messages.

Background

Sex Scripts and Power as Knowing Participation in Change Theory®

Sex scripts are commonly understood expectations for sex behavior (Gagnon & Simon, 2005) that are shaped by one's environment, view of self sexuality, and by how a couple interprets and improvises (Simon & Gagnon, 1986). In an environment of gender inequalities, men control condom use (Biello, Sipsma, Ickovics, & Kershaw, 2010; Ehrhardt, Sawires, McGovern, Peacock, & Weston, 2009; Kim et al., 2007; Krishnan et al., 2008). Adherence to such traditional beliefs about gender roles serves to place a male's needs first and dampen a woman's resolve to engage in condom protected sex. These expectations about gender roles are important in forming sex scripts (Eagley & Wood, 2003; Santana, Raj, Decker, Marche, & Silverman, 2006). Consistent with a scripted view that unprotected sex promotes intimacy, a three city study of low-income, high risk women found that being aware that a male partner was high risk was not associated with condom use, but main partner status was associated with unprotected sex (Ober et al., 2011).

Sex scripts direct how a person interprets an experience because the script associates the event with popular meaning or personal experience (Stacy & Wiers, 2010). With little opportunity for introspective awareness, relevant cues can trigger impulsive emotions that steer a person in the direction of one behavior (Fiske, 2004; Gawronski, Hofmann, & Wilbur, 2006; Stacy & Wiers, 2010).

The Objective is to Reduce Sex Risk Behavior by Changing Sex Scripts

New associations can be created by reframing new sex scripts (Mays, 2004), so that risk reducing behaviors could become a more available response (Stacy, Newcomb, & Ames, 2000). The approach of LSC was to reframe these scripts. Women who succeed at promoting lower risk scripts are more likely to characterize themselves as being aware and powerful (Martyn & Hutchinson, 2001). Being powerful means they make stronger choices and follow through to effect change. According to Barrett (2010), power is the capacity to participate knowingly in change. Power is being aware of what one is choosing to do, feeling free to do it, and doing it intentionally. There are four indivisible dimensions of power: awareness, choices, freedom to act intentionally, and involvement in creating change. Barrett's theory proposes that change occurs in a dynamic process of these four dimensions.

Sex Script Theory and Barrett's Power as Knowing Participation in Change Theory (PKPCT) were integrated into a framework and themes from a content analysis of focus groups with young urban women were conceptualized as lower or higher power sex scripts (Jones, 2006; Jones & Oliver, 2007). In a lower power sex script, a woman envisions herself as having to satisfy her man. In a higher power sex script a woman engages in a process of expanding awareness of her value as a woman, of her choices, and engages the will to pursue these choices; such as, engaging in condom protected sex and HIV testing (Jones & Oliver, 2007). The LSC soap opera series associates these more powerful sex scripts with the needs typically served by unprotected sex to increase likelihood of behavior change. For example, if "raw" sex indicates intimacy, condom protected sex is promoted to indicate caring for each other.

Entertainment-Education (EE) and the Soap Opera

Videos that are designed to entertain while communicating pro-social norms and behaviors are known as entertainment education (EE) (Singhal, Cody, Rogers & Sabido, 2004). For example, a soap opera serial drama with a behavioral message can resonate with audiences (Kuhlmann et al., 2008; Petraglia, 2007) and evoke intense emotion (Vaughan & Rogers, 2000) which stimulates audience involvement and parasocial interaction (PSI) (Vaughan & Rogers, 2000). Parasocial interaction is a one-way interpersonal relationship with the on-screen character and stimulates identification with that character (Auter & Palmgreen, 2000; Brown & Basil, 2010; Moyer-Guse & Nabi, 2010). When a viewer experiences PSI, the character becomes a normative referent (Moyer-Guse, 2008). Both identification and emotional attachment increase acceptance of the message without provoking resistance (Moyer-Guse & Nabi, 2010).

Videos have been effectively used to communicate HIV risk reduction and promote sexual health in several settings (Jones, 2008; Myint-U et al., 2010; Royce, Silverman, & Krauss, 2007; Warner et al., 2008). Relevant television video ads were shown to reduce unprotected sex in older adolescents (Sznitman et al., 2011). The EE approach has gained popularity internationally (Singhal et al., 2004; Vaughan & Rogers, 2000). A radio soap opera in Tanzania was associated with statistically significant increases in contraceptive use (Vaughan & Rogers, 2000) and condom use, as well as fewer sex partners in the broadcast area compared to a control (Vaughan, Rogers, Singhal, & Swalehe, 2000). Men and women who watched ten or more sessions of a television soap opera concerning autoimmune deficiency syndrome (AIDS) in Côte d'Ivoire were more likely to use condoms compared to those who did not watch (Shapiro, 2003). The aim of this study was to conduct a RCT to determine whether LSC, an Internet based 12-episode soap opera video intervention will promote greater reduction in unprotected sex with high risk sex partners at 6 months compared to written HIV prevention messages.

Methods

This RCT compared the 12-week LSC soap opera video series to 12-weekly HIV prevention messages; both delivered to smartphones provided to participants. Data were collected at screening and for those who screened in and were accepted, a short baseline interview followed. Upon completion of the intervention, a 3 month (T2) interview was conducted, and smartphones were returned. Twelve weeks later (at 6 months) a final follow-up interview was conducted (T3).

Participants and Sites

Women, 18 to 29, who had sexual relationships with men during the past 3 months, were able to read English, and who had not previously participated in the study were eligible for the screening interview. Three months is considered an acceptable period of recall (Schroder, Carey, & Vanable, 2003). The women were recruited at two public housing developments, two sexually transmitted disease clinics, a community center, a storefront office, and a food pantry, all located in four contiguous cities in neighborhoods that were predominately African American: Newark, Jersey City, East Orange, and Irvington, New Jersey. The rationale for having multiple, diverse sites, was to obtain a representative sample of women at high risk. Each of these sites was selected due to the setting or location and our previous experience with undertaking studies at these sites. Although data collection was conducted in low-income predominately African American and Black communities, Latinas were not excluded from the study. Prior formative research indicated that sex scripted themes were consistent between Latinas and African American young women who live in the same communities (Jones & Gulick, 2009; Jones & Oliver, 2007).

Recruitment

After approval from the Rutgers University Institutional Review Board, recruitment was conducted from June 2010 to August 2011. Trained research assistants (RAs) who were undergraduate African American and Latina students at Rutgers University, College of Nursing, in Newark, and trained local recruiters who were women with long-time commitment to young people in the community, assisted. The RAs and recruiters attended a 2-hour training session led by the Principal Investigator (PI) and Project Director (PD). Recruiters handed-out flyers to inform potential eligible participants about the study and the scheduled meeting times. A private area was reserved for study related activities at each site. Potential participants were screened by the study team to determine eligibility.

Screening Criteria for Inclusion into the Main Study—On-site screening (as well as the baseline, and subsequent two post-intervention surveys) were conducted using audio computer assisted self-interview (ACASI) on Tablets or laptop computers. A wireless local area network (LAN) was available at each site so several participants could simultaneously log-on and privately take the survey. An automated algorithm categorized the level of HIV sex risk based on responses to the screening interview (Jones, 2012). Those who screened into the 6 month long study were high risk, having had at least one episode of unprotected vaginal sex (UVS) or anal sex (UAS) with a man who had: engaged in sex with other women, and/ or sex with men, and/or used injection drugs in the past three months.

Randomization, Blinding, and Sample Size

This RCT compared the 12-week LSC soap opera video series to 12-weekly HIV prevention text messages both delivered to smartphones. Participants were randomized 1:1 to each treatment arm in varying block sizes of 4 and 6, stratified by sites. A computer-generated list of random assignments was used. Group assignment (video- or text-message group) was placed into sealed security envelopes in sequential order to execute assignments once participants had been deemed eligible in the screening interview and had signed informed consent. The number on the envelope was copied onto the participants contact sheet and then stapled to a copy of the participants' consent. The research staff remained blinded to the participant's assignment until the envelope was opened by the PD at the main office at a later time.

Hypothesis testing at a two-sided $\alpha=0.05$ and at least 100 subjects finishing in each intervention arm (200 total) was anticipated. This would provide power of > 0.80 to detect an effect size (ratio of treatment arm difference in sex risk scores to between subject standard deviation of sex risk scores) of 0.20.

Interventions

Experimental intervention—*Love, Sex, and Choices* was written and scripted by the study team and underwent pilot testing in the target population. The series was divided into 15-to-20 minute episodes that were streamed weekly. The situations, characters, and story development were based on the aforementioned content analysis of focus groups and the theoretical framework (Jones & Oliver, 2007). The actors auditioned for their roles and the series was filmed by a professional filmmaker. The principles of reducing HIV risk were communicated through the archetypal characters and high risk situations. The lead characters model how women become more powerful, meaning more aware of themselves as worthy of respect, making choices intentionally, feeling free to pursue their intentions, and involving themselves in creating change. This process leads to higher power sex scripts in the characters, meaning pursuing intentional choices and health promoting behaviors. The lead characters further model open communication, how to talk about HIV testing with a

resistant partner, and initiating condom use. Results of a previous pilot study had indicated support for this approach (Jones, 2008).

Comparison treatment—12 HIV prevention messages in text. The comparison group received 12 weekly HIV health promotion written messages over the smartphone. The messages were based on CDC recommendations and theoretical framework. An example is: Sexual health means respecting your own rights and feelings. Feeling pressured to have sex means limiting your choices and your freedom to love safely. A man who pressures you to have sex isn't a good man.... If he doesn't like you being you, it may be time to walk. Other messages provided instructions on the correct use of condoms and the importance of HIV testing. The 12 messages were reviewed by ten African American and Latina undergraduate nursing students for ease of comprehension. A detailed discussion of how the mobile platform was developed to stream the video and send the messages to smartphones is available (Jones & Lacroix, 2012).

Intervention Delivery and Data Collection

Data collected on the screening interview included; number of male sex partners, perceived partner risk behaviors (sex with other women, sex with men, and injecting drugs, frequency of vaginal and anal sex, and condom use during the past three months. These items were asked in a partner specific context, considered to be a more reliable approach (Noar, Cole, & Carlyle, 2006), for up to five partners. If participants met eligibility criteria, they were invited to participate in the full 6-month long study and if interested, signed a second informed consent. The participant received a \$15 honorarium for the screening interview (for more detail on data collection see Jones & Lacroix, 2012).

Consent 2 and Baseline Interview—For those who screened into the study, a baseline survey was completed on ACASI. The instruments assessed variables that were consistent with the conceptual framework and had been previously found to relate to sex risk behavior in urban women. These were: The Sexual Pressure Scale in Women–Revised (Jones & Gulick, 2009), the Sex Script Video Response (Jones & Gulick, 2009), and the Sexual Sensation Seeking Scale (Kalichman & Rompa, 1995). On completion, participants were assigned a Motorola DROID™ smartphone and received training on study-related use (see Jones & Lacroix, 2012). The importance of accessing the weekly video or text messages was stressed. Phone and texting functions were disabled but there was access to the Internet and social networking which increased likelihood that the phone would be accessed regularly.

Weekly messages—The survey software was used to send out weekly emails with a link to the written message or the video. For the video arm, after watching the episode, three content related questions were asked in order to assess that the video was watched. An example is *who was Mike messing with?* Similarly, one item was asked after reading the text message. The team tracked reasons for rewatching video episodes (see Jones & Lacroix, 2012). The participant could not progress to the next video or text message until the previous one was completed, but, could review any previous video episode or message any time. If the email was not accessed in two days, a reminder email was sent, then three daily reminders. Finally, the PD contacted the participant by phone, and if no response, the community recruiter was asked to reach her.

Post-Intervention T2 and T3 Interviews—At 3 months, participants returned for the post-intervention follow-up (T2) survey and to return the phone. Upon completion, an honorarium of a \$125 was given. There was no access to the videos or text messages for the next 3 months. At 6 months (T3), participants were asked to return to the site to complete the final follow-up survey (T3) (see Figure 1).

Instruments

Type of partner—(collected at screening, T2, and T3). A main partner is the most important intimate relationship partner. If a woman has only one sex partner but this person is occasional or casual he is considered non-main. A secondary partner is any sex partner that is additional to the main or non-main partner.

Kayla and Steve Sex Script Video and the Sex Script Video Response (SSVR)

—(Jones & Gulick, 2009). This 5-minute video concerns a familiar event that many participants may have likely experienced personally. In the video, Kayla has not seen her partner, Steve, in two weeks and is anxiously awaiting a call from him. While outside, she sees Steve talking to a woman whom she believes Steve is now seeing. That afternoon, Kayla comes home to hear a message from Steve on her phone. Steve is asking if he can come over. The video ends. The participant is asked to conclude what happened. The SSVR is designed to evaluate the extent to which there is belief in a sex script involving unprotected sex. The first 6 items ask what a participant thinks Kayla did, for example, Did Kayla let Steve come over? Did they have sex? Did they use a condom? The next 6 items ask what the viewer would have done. An example of an item is If you were in this situation, would you have sex with Steve? The last 6 items ask what the viewer's friends would have done if faced by the dilemma depicted in the video. Response options are on a 5-point metric, from, *No, Don't think so to Yes*. The higher the score, the greater the expectation of the need to engage in unprotected sex to hold onto a relationship, indicative of a sex script involving unprotected sex. The total SSVR was assessed at baseline only (Cronbach's $\alpha = .85$). But, the 6-item subscale, *What would you have done* (Cronbach's $\alpha = 0.73$) was measured at all three timepoints to assess for change.

The Sexual Pressure Scale in Women-Revised (SPSWR)—(Jones & Gulick, 2009). Sexual pressure is a set of gender specific expectations to engage in sex or fear reprisal of losing perceived benefits of the relationship, abandonment, or coercive threats or force. Sexual pressure is a complex, multidimensional construct. Five response choices range from *definitely no to definitely yes*. Alpha reliability coefficients were 0.88 for the total SPSWR and ranged between 0.78 and 0.84 for the factors. Data were collected at baseline, T2, and T3). *The four factors and examples of items are:*

Show Trust (5 items). Show Trust is the expectation that unprotected sex promotes trust and commitment. Example: I do NOT ask my partner to use a condom because he may think I do not trust him.

Women's Sex Role (5 items). Women's Sex Role is the expectation that it is a woman's responsibility to satisfy her male partner and that sex will provide evidence that she is the best partner for him. Example: A woman needs to please her man sexually to hold onto him.

Men Expect Sex (5 items). Men Expect Sex reflects the expectation that sex is a male partner's relationship priority. There are times my partner makes me feel he will cheat if he gets tired of having sex with me.

Sex Coercion (3 items). Sex Coercion reflects the experience of threats or being hit by the male partner after the woman indicated she did not want to have sex. Example: My partner has physically hurt me (for example, slap, hit, or pushed me) after I told him I would not have sex with him.

The Sexual Sensation Seeking Scale (Kalichman & Rompa, 1995)

The 11-items measure a tendency to seek novel sexual stimulation. It is on a 4-point metric from not at all like me to very much like me. An example is: The physical sensations are the most important thing about having sex, $\alpha = 0.86$. (collected at baseline, T2, and T3).

Demographics—The demographic items were collected at the screening interview to describe the sample with items such as: age, age at first intercourse, ethnicity, hours of work/week, highest grade completed, contraception use, number of children, number of sex partners in past year, average weekly frequency of sex/year, average use of condoms past year, ever been HIV tested, and knowledge of whether the partner had ever been HIV tested. Additionally, these items were collected at all three timepoints: drugs or alcohol before or during sex, HIV testing in past 3 months, partner(s) had HIV tests in the past 3 months, talk with your partner (s) about HIV testing?

Outcome variables were collected at screening and at T2 and T3—The primary outcome was to test the hypothesis comparing treatment arms for change in the VEE score (defined below) from the baseline visit to 6 months post-intervention (T3)

Sex risk was measured by the Vaginal Episode Equivalent (VEE)—(Berkman, 2006; Susser, Desvarieux, & Wittkowski, 1998) with high risk partners. Participants were asked the number of times they had vaginal or anal sex, and of these times, how many times a condom was used. Self-reported sexual behavior is standard in sex risk research. Various measures to improve the validity of self-reported sex behavior included the use of ACASI, asking sex behavior in the context of a specific partner, calendars depicting the past 3 months, and reminders (see Jones & Lacroix, 2012).

The VEE is the sum of all unprotected vaginal sex (UVS) and unprotected anal sex (UAS) acts weighted by the relative HIV transmission risk (vaginal=1 and anal=2). (Oral sex which has low HIV transmission risk was omitted from the VEE for this study). The VEE scores for acts during the previous 3 months was calculated at screening and at T1 and T2. For a given visit the VEE was $\sum [2 (\#UAS)_i + (\#UVS)_i]$ where i enumerates high risk partners, and $\#UAS$ is number of unprotected anal, $\#UVS$ is unprotected vaginal sex acts with high risk partner i , in the past 3 months. The primary outcome was changes from baseline to T2 and T3 in the VEE score with high risk partners as described below.

High risk partner—The perception of partner risk consists of 3 items: How likely is it that your partner had sex with another woman? How likely is it that your partner had sex with men?, and How likely is it that your partner injected drugs in the past 3 months? There is a 4-point response metric, from *definitely not* (0) to *definitely did* (3). The perception of partner risk could range from 0 to 9 however, main or non-main partners who score greater than 0 were considered to engage in risk behavior. All secondary partners were considered to be high risk by the fact that they were multiple sex partners. Only women having unprotected sex with a partner they perceived to have risk > 0 by this system were included into the study.

Evaluation of Love, Sex, and Choices (at 3 months only)—LSC was evaluated for evidence of entertainment, identification, PSI, and message relevance (see Table 1). An example of an evaluation item was Did the videos you watched address problems you think are important to women?

Upon completion of participation, \$125 was given at the 6-month visit. Members of the control group as well as those in the experimental arm received access to the URL to view the complete set of LSC videos.

Statistical Methods

Proportions, means, and standard deviations described the study sample and compared the intervention arms at baseline and for post-intervention levels and changes in study outcomes. Statistical significance was assessed using exact tests for categorical variables and Wilcoxon tests for continuous variables. Due to skewness, VEE was log transformed after adding 0.5 to prevent taking the log of 0. Mean logs were exponentiated to obtain geometric means (GM) which are roughly equivalent to the medians of VEE+0.5. Standard errors for the geometric means were obtained using the delta method (Casella & Berger, 2002; Oehlert, 1992). The primary outcomes of interest were change in log (VEE) from baseline to each of the two follow-up visits. These changes were i) expressed as geometric changes, the ratio of the geometric mean at the follow-up over the geometric mean at baseline, and ii) change from baseline to each follow-up visit within each study arm was separately compared to the null hypothesis of no change, using signed rank tests; and iii) the null hypothesis of equality of changes from baseline to each follow-up visit between study arms, was assessed by Wilcoxon tests.

To test the primary outcome, pooled repeated measures mixed linear models of log transformed VEE behavior at T2 and T3 (using compound symmetry covariance structure) with baseline log transformed VEE and the treatment arm assignment (video versus text) as predictors were fit (the results were essentially similar using generalized estimating equations with working independence correlation to fit the models). Other variables that were relevant to the theoretical framework, and demographic variables shown to be of importance to sex risk behavior, were included as predictors in these models. These were: sex script video response, sexual pressure, sensation seeking, ethnicity, age, employment, age at first intercourse, use of drugs and use of alcohol before or during sex, sex with men who have sex with men, and study site. The final multivariate model of log transformed VEE at T2 and T3, included: baseline log transformed VEE, treatment arm assignment (video versus text), timepoint (T2 versus T3), and those variables with $p < 0.20$ in models of T2 and T3 VEE that adjusted for baseline VEE. Coefficients from the linear models on log transformed VEE outcomes were exponentiated to give multiplicative effects on the geometric mean with standard errors obtained by the delta method (Casella & Berger, 2002).

Results

Out of the 505 women screened, 342 were eligible, 295 signed consent to participate in the 6-month long study and were randomized. Of these, 238 received the treatment and then attended follow-up assessments at 3 and 6 months (see Figure 1).

The mean age was 22.0 years. Most (88.2%) were African American, with the rest largely Latina or Caribbean (8.0%). Most (61.8%) were unemployed. About one-fourth (26.0%) completed 11th grade or less, 86 (36.1%) completed 12th grade, and 78 (32.8%) completed one or two years of college. Just over half the sample (56.7%) did not have children, while 28.2% had one child. Most (92.4%) provided a cell phone number as the primary method of contact.

Beginning with the video arm intervention experience ($n=117$), evaluation of the video indicated popularity, relevance, and evidence of identification and PSI. All but 4 of 117 thought the stories were realistic. All but 8 related to the characters; 89.7 % thought their friends might like to watch. All but one wanted the stories to continue (see Table 1). Video

viewing logs indicated that only 2 of the 117 in the video group missed an episode. Nearly all watched each episode fully once or more than once, meaning they replayed a scene or re-watched the whole episode (see Jones & Lacroix, 2012). The experience of using smartphones to view the videos was also highly rated (for evaluation of smartphone use, see Jones & Lacroix, 2012). Nearly all (96.6%) of the 117 in the video group enjoyed watching the video on the phone.

Table 2 compares both arms with respect to important demographic, substance use, sex behavior, sexual pressure, sex scripts, and sexual sensation seeking at enrollment. There were no statistically significant (at $p < 0.05$) differences between the treatment groups on any of the variables at baseline. The participants tended to have their first sexual intercourse at 14 to 15 years. Roughly 75 to 80% had used alcohol before or during sex, but less than 5% injected drugs before or during sex. All women had at least one male partner considered to be high risk because of known or suspected sex with another woman compared to 25 to 30% having at least one partner considered to be high risk due to known or suspected injection drug use. A surprisingly high portion of women knew or suspected that at least one of their partners was having sex with men, 29.8% of the video arm compared to 41.9% of the text arm, $p = 0.06$. Nearly the entire sample (98.7%) engaged in unprotected vaginal sex and 44.1% had unprotected anal sex with a man they perceived to engage in high risk behavior.

For both arms, the baseline levels of log (VEE) with high risk partners, post intervention levels at T2 and T3, and changes in log (VEE) with high risk partners from baseline to post intervention, are presented in Table 3. Mean log transformed VEE at baseline was 3.10, corresponding to a central tendency of $\sim \exp(3.10) = 22.10$ unprotected VEE sex acts in the past 3 months (including the 0.5 acts added before log transforming) for the text group compared to 3.06, corresponding to a central tendency of $\sim \exp(3.06) = 21.33$ unprotected VEE sex acts in the past 3 months for the video group, $p = 0.68$, at baseline. This means that sex risk behavior for the two treatment groups was essentially the same at baseline.

Following the interventions at T2, mean log (VEE) had dropped substantially to 1.88 (a central tendency of ~ 6.55 unprotected VEE acts in the previous 3 months) in the text and to 1.74 (a central tendency of ~ 5.70 unprotected VEE acts in the previous 3 months) in the video group. These lower levels of log transformed VEE held through T3 with a mean of 1.78 (a central tendency of 5.92 unprotected VEE acts in the previous 3 months) in the text and 1.58 (a central tendency of 4.85 unprotected VEE acts in the previous 3 months) in the video group.

The declines in log (VEE) from baseline to T2 and T3 were each significant within the text and video intervention arms (consistently at $p < 0.001$). At T2, the amount of VEE acts with perceived high risk partners tended to be 27% as high (by ratio of geometric means) as that at baseline (or a 73% reduction) for the video arm and 31% as high as that at baseline (or a 69% reduction) for the text arm, while at T3, it was 22% as high as baseline (a 78% reduction) for the video and 28% as high as that at baseline (72% reduction) for the text arm. This means that within person reduction in HIV sex risk behavior was statistically significant. However the changes to these levels from baseline did not statistically differ between the video and text arm nor between T2 to T3.

Table 4 presents the results of mixed linear models for log (VEE) with perceived high risk partners at T2 and T3 after adjusting for baseline VEE. All variables in Table 2 were considered but only the study intervention and those variables that had a p -value of < 0.20 for association with log (VEE) at T2 and T3 are included in Table 4. It should be noted that the models presented in columns 2–4 are bivariate except when baseline log (VEE) is the

predictor being modeled. For the other predictor variables, adjustment is made for baseline log (VEE) as well as the row covariate to remove any effect of its association with baseline log (VEE) since the baseline log (VEE) highly correlated with log (VEE) at T2 and T3. This is done using mixed models, a procedure that also adjusts for the fact that the T2 and T3 measures from the same person are not independent. These coefficients are presented as multiplicative effects on the Geometric Mean for the original scale by exponentiating the coefficients on the log transformed outcome. The second row columns 2–4 presents the association of the video intervention (vs. text) with log (VEE) at T2 and T3 after adjusting for baseline log (VEE).

The estimated association was 0.82, meaning that if two women have the same VEE at baseline, then on average the woman who receives the video intervention will have a VEE at T2 and T3 that is only 82% as high as one who receives text ($p=0.23$). Once baseline VEE is adjusted for, among the other variables examined, only study site was associated with log (VEE) at T2 and T3. Among women with the same VEE at baseline, those recruited from other sites tended to have from 1.45 to 2.18 times this VEE acts with perceived high risk men than did those recruited from the STD clinics, meaning the intervention had a greater effect at the STD clinics.

Columns 5 to 7 of Table 4 present the full multivariate mixed linear model of log (VEE) at T2 and T3. The study treatment (video vs. text) was included in the model as this was the primary objective of the study. Other variables were included in the multivariate model only if they had a p -value of <0.20 for association with log (VEE) at T2 and T3 in the models shown in columns 2–5 of Table 2 that adjusted for baseline VEE. Most notably, going to row 3, the association of video vs. text intervention with the outcome remained at 0.82. This means that if 2 women were identical on all variables in the model, (i.e., same baseline VEE, same study site, same post intervention visit, same age at first sex, and same baseline log sex script video response score), then the woman who received the video intervention tended to have 82% as high (or 18% lower) a post-intervention VEE than did a woman who received the text ($p=0.23$). Age at first sex and log sex script video response score which had been close to statistically significant in the baseline VEE adjusted models of VEE at T2 and T3 in columns 2–4 of Table 4 (with $p=0.08$ and 0.07) did not retain this association in the multivariate model with the p -values rising to 0.27 and 0.15, respectively, and the magnitudes of the association falling. However, association of post intervention log VEE with study site remained significant in the multivariate model with the strength of the associations and p -values virtually unchanged from those in the baseline VEE adjusted models. The multivariate association of post-intervention visit (T3 vs. T2) was minimal with VEE at T3 tending to be lower, only 87% as high as it was at T2 ($p=0.17$).

Discussion

Love, Sex, and Choices (LSC), a 12-episode soap opera video series, was created to reduce HIV sex risk in urban women. The effect of the LSC video series on women's HIV sex risk behavior was evaluated in a randomized controlled trial conducted in 238 high risk, predominately African American or Black young adult women, aged 18 to 29, in the urban Northeast. The video intervention was compared to 12-weekly, text-based HIV risk reduction messages. The primary study outcome measure of unprotected vaginal and anal sex (VEE) with a high risk partner was significantly lower post-intervention for both treatment arms ($p<.001$) compared to baseline. These reductions were dramatic with median risk behavior falling from about 21–22 unprotected vaginal sex act equivalents in the prior 3 months at pre-intervention to 5–6 such acts post intervention.

While there was 18% greater reduction in VEE pre to post-intervention in the video arm than in the text arm, the difference between video and text was not statistically significant. One possibility at the extreme is that neither intervention had a true effect but that the reduction in behavior was due to the regression to the mean phenomenon (Stigler, 1997) as participants were selected based on high risk behavior at baseline; some may have been at a relative peak at baseline and were due to fall back at follow-up without an intervention. Alternatively, both the video and text interventions could each have influenced behavior change. If so, the lack of statistically significant difference in risk reduction between groups may be explained by study design factors, particularly the lack of a true control (Baker, 2003; Darbes, 2008; Johnson et al., 2008; Noar, Black, & Pierce, 2009; Rosser, 2010), with equally attentive follow-up in both groups, a potential type II failure to observe a real difference, and factors related to video content.

Follow-up focus groups with young, urban women suggested that given their identification and involvement with some or all of the lead LSC characters, having a separate persona in the videos to emphasize certain messages would help to direct focus. An epilogue is thought to increase the likelihood that messages will be adopted (Rogers, 2004). Drawing upon inferences from computer-based pedagogical agents in science (Moreno, 2001), a guide narrator can help to navigate through familiar but complex issues. Therefore, a “guide,” who is a video contemporary young Black woman, has recently been added to the end of most of the LSC episodes, to engage participants in guided discovery: questioning assumptions that underlie the high risk sex scripts, drawing analogies, and focusing attention on critical points enacted by lead characters. The guide-enhanced version of LSC has recently been tested in focus groups with promising results.

Limitations

While there is the potential for error in self-reported data, several procedures were followed to reduce systematic error in self-reporting, such as; enhancing participant's memory recall by placing the items in the context of a particular relationship, using ACASI, limiting the time period of recall to 3 months, and posing questions non-judgmentally by asking the frequency of the behavior rather than incidence (DiClemente, Swartzendruber, & Brown, 2013; Weinhardt, Forsyth, Carey, Jaworski, & Durant, 1998). Generally, use of ACASI increases reliability of responses to items concerning sensitive behaviors (Jones, 2012; Rogers et al., 2005). Accuracy diminishes when participants are asked to recall sex behavior for a period greater than 3 months (Noar, et al., 2006), and a reporting period of less than 3 months presents the risk of not obtaining a representative sample of sex behavior (Schroder, et al., 2003). Concerns about cost and problems with the validity of corroborating self-report with biological markers remain (Brown, Sales, DiClemente, Davis, & Rose, 2012; DiClemente, et al., 2013).

Conclusion

Population specific interventions to reduce HIV sex risk behavior in at-risk, women are needed (CDC, 2011) including more innovative approaches. This is the first study to report results of a serialized video soap opera HIV prevention intervention streamed to smartphones in a RCT to evaluate effect on sex risk behavior. The trend toward increased mobile Internet access continues to grow and is highest among African Americans and young adults, whom are less likely to have broadband Internet access at home (Smith, 2010). Computer-based interventions have been favorably compared to human facilitated interventions for HIV prevention (Lightfoot, 2007; Noar, et al., 2009; Noar, 2011) and health promotion (Portnoy, 2008).

While the differences between the LSC soap opera video series and the comparison HIV prevention written messages were not statistically significant here, risk reduction was 18% greater for the video than the comparison treatment. Of importance, among participants' receiving the LSC soap opera series, their evaluations indicated it was entertaining, they wanted to continue receiving the video episodes, and that they identified with lead characters who model talking about: HIV testing, initiating condom use, and open communication. Thus, a further enhanced LSC may hold promise as an Internet-based intervention that can be adapted for scale-up to reach high risk urban women on their own mobile devices since videos can be streamed to individuals with Internet access. Such a LSC could then be combined with HIV testing and early access to care as a comprehensive approach.

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Figure 1.
Participant flow from recruitment to post-intervention follow-up at 6 months.

Table 1

Evaluation of Video Series 'Love, Sex, and Choices' (N=117) *

<u>Question</u>	<u>Response Choices</u>				
	Definitely No N (%)	Don't Think So N (%)	Maybe N (%)	Probably N (%)	Definitely Yes N (%)
Do the videos you watched address problems you think are important to women?	1 (0.9)	1 (0.9)	1 (0.9)	2 (1.7)	112 (95.6)
Do you think the videos could help a woman make decisions about the man she wants to be with?	0 (0.0)	1 (0.9)	3 (2.5)	18 (15.4)	95 (81.2)
Do you think that watching the videos could help raise a woman's awareness about her choices?	0 (0.0)	0 (0.0)	1 (0.9)	10 (8.5)	106 (90.6)
Were the stories realistic?	2 (1.7)	2 (1.7)	6 (5.1)	10 (8.6)	97 (82.9)
Do you know anyone who has gone through experiences similar to any of the lead characters?	7 (6.0)	3 (2.6)	12 (10.2)	23 (19.7)	72 (61.5)
Could the videos you watched change a woman's attitude about having sex when she does not want to?	2 (1.7)	2 (1.7)	7 (6.0)	19 (16.2)	87 (74.4)
Do you think the videos you watched could make it more likely that a woman will use condoms?	2 (1.7)	2 (1.7)	4 (3.4)	30 (25.7)	79 (67.5)
Do you think the videos could help a woman decide to leave a man who won't use condoms?	1 (0.9)	4 (3.4)	16 (13.7)	33 (28.2)	63 (53.8)
Could the videos help a woman handle herself if a male partner wants to have unprotected sex?	0 (0.0)	3 (2.6)	15 (12.8)	19 (16.2)	80 (68.4)
Did the videos seem too long?	88 (75.2)	26 (22.2)	2 (1.7)	1 (0.9)	0 (0.0)
Would you want the video series to continue?	0 (0.0)	1 (0.9)	7 (6.0)	10 (8.5)	99 (84.6)
Did you like the videos?	0 (0.0)	0 (0.0)	0 (0.0)	3 (2.6)	114 (97.4)
Could you relate to the characters?	17 (14.5)	11 (9.4)	50 (42.8)	17 (14.5)	22 (18.8)
Do you think your friends might like to see the videos?	0 (0.0)	12 (10.3)	13 (11.1)	40 (34.2)	52 (44.4)
Which of the characters could you relate to the most?					
None of the characters	8 (6.9)				
Toni	21 (17.9)				
Diamond	28 (23.9)				
Keyanna	15 (12.8)				
Valerie	8 (6.9)				
I could relate to > than one, cannot decide which	27 (23.1)				
All of the female characters	10 (8.5)				

* Video intervention group only. Full sample, N=238.

Table 2

Descriptive Comparison of Video and Text Arms for Baseline Characteristics (N=238)

Variable	Text(n=121)		Video(n=117)		p-value
	Mean or (%)	(±sd)	Mean or (%)	(±sd)	
DEMOGRAPHIC CHARACTERISTICS					
Age (years)	22.0	(±3.4)	22.1	(±3.6)	0.95 ^a
Age at first sexual intercourse (years)	14.4	(±1.8)	14.5	(±2.2)	0.72 ^a
Highest grade completed	12.15	(±1.17)	12.21	(±1.66)	0.84 ^a
Ethnicity: African American/Black	109 (90.1%)		101 (86.3%)		0.42 ^b
Employment outside the home	44 (36.4%)		47 (40.2%)		0.59 ^b
Study Site					
Community center	17 (14.1%)		22 (18.8%)		0.80 ^b
Public Housing	37 (30.6%)		36 (30.8%)		
Food Pantry	17 (14.1)		12 (10.3%)		
Storefront	23 (19.0%)		20 (17.1%)		
STD Clinics	27 (22.3%)		27 (23.1%)		
SUBSTANCE BEHAVIOR IN LAST 3 MONTHS					
Used Alcohol before or during sex	99 (81.8%)		88 (75.2%)		0.62 ^b
Injected drugs	3 (2.48%)		4 (3.42%)		0.72 ^b
SEXUAL BEHAVIOR IN LAST 3 MONTHS					
Any unprotected vaginal sex with a high risk partner	120 (99.2%)		116 (99.2%)		1.0 ^b
Any unprotected vaginal sex/3 m with a low risk partner	14 (11.6%)		10 (8.6%)		0.52 ^b
Any unprotected anal sex with a high risk partner	49 (40.5%)		56 (47.9%)		0.30 ^b
Any unprotected anal sex with a low risk partner	4 (3.31%)		4 (3.42%)		1.0 ^b
Sexual Pressure Score	25.5	(±15.3)	29.7	(±16.6)	0.09 ^a
Sensation Seeking Score	13.6	(±6.9)	15.1	(±7.5)	0.11 ^a
High Risk Sex Scripts Score	5.04	(±5.9)	6.6	(±7.4)	0.10 ^a
PARTNER SEX AND DRUG BEHAVIOR ^c					
Any male partner had sex with other women	120 (99.2%)		117 (100%)		1.0 ^b
Any male partner had sex with men	36 (29.8%)		49 (41.9%)		0.06 ^b
Any male partner injected drugs	31 (25.6%)		37(31.6%)		0.32 ^b

^a p-value from Wilcoxon test^b p-value form exact test^c Data collected for a maximum of 5 high risk partners

Table 3Pre and Post Intervention VEE with High Risk Partners Expressed as Geometric Means^a

Characteristic	Geometric Mean in Text		Geometric Mean in Video		<i>p</i> -value
	Point Estimate	Std-Err	Point Estimate	Std-Err	
VEE AT DIFFERENT TIME POINTS					
VEE at baseline	21.32	2.83	22.20	3.01	0.68 ^{<i>b</i>}
VEE at T2	6.55	1.02	5.70	0.84	0.56 ^{<i>b</i>}
VEE at T3	5.93	0.91	4.85	0.73	0.39 ^{<i>b</i>}
CHANGE IN VEE FROM PRE TO POST INTERVENTION					
VEE Ratio T2 / Baseline	0.31	0.045	0.26	0.038	0.26 ^{<i>b</i>}
Within Group <i>p</i> -value for Median Ratio Being One	< 0.001 ^{<i>c</i>}		< 0.001 ^{<i>c</i>}		
VEE Ratio T3 / Baseline	0.28	0.042	0.22	0.035	0.31 ^{<i>b</i>}
Within Group <i>p</i> -value for Median Ratio Being One	<0.001 ^{<i>c</i>}		< 0.001 ^{<i>c</i>}		

^aGeometric mean is the mean of log(VEE + 0.5) exponentiated and estimates median behavior^bComparing Text to Video Arm, p-value from Wilcoxon test^cComparing Pre to Post intervention change in each arm p-value from signed rank test

Table 4

Geometric Mean Multiplicative Associations with Post-Intervention VEE Behavior after Adjusting for Pre-Intervention VEE^a

<u>Characteristic</u>	<u>Adjusted for Baseline VEE Models^b</u>			<u>Multivariate Model^b</u>		
	Estimate	(±SE)	<i>p</i> ^c	Estimate	(±SE)	<i>p</i> ^c
Video (vs. Text)	0.82	0.14	0.23	0.82	0.14	0.23
Visit 3 (vs. Visit 2)	0.87	0.10	0.17	0.87	0.09	0.17
Study Site ^d						
Community center	1.45	0.39	0.17	1.45	0.39	0.17
Public Housing	2.18	0.52	0.001	2.01	0.48	<0.001
Food Pantry	1.80	0.54	0.05	1.72	0.51	0.07
Storefront	1.78	0.46	0.03	1.72	0.45	0.04
STD clinics	Baseline			Baseline		
Age at first sex (per year)	0.92	0.04	0.08	0.95	0.04	0.27
Log Sex Risk Video Response (per log unit)	1.16	0.09	0.07	1.13	0.09	0.15

^aFrom exponentiation of parameter estimates from mixed linear regression models (using compound symmetry correlation structure) with Log transformed VEE +0.5 at post intervention Visits 2 and 3 as outcomes. Pre-intervention baseline log(VEE+0.5) is included in all models

^bAll variables in Table 2 were considered for this Table, but only the intervention arm and other variables with *p* < 0.20 are reported here and included in the multivariate model

^cFrom Z-tests made directly on the parameter estimates from the log VEE models

^dOverall *p*-value for study site association with post intervention behavior was 0.02 in the model that adjusted for baseline behavior and 0.05 in the multivariate model by likelihood ratio tests