Effectiveness of an evidence-based HIV prevention intervention when implemented by frontline providers

Jill Owczarzak,¹ Michelle Broaddus,² Sergey Tarima²

¹Department of Health, Behavior, and Society, Johns Hopkins; Bloomberg School of Public Health, Baltimore, MD 21205, USA

²Center for AIDS Intervention Research, Medical College of Wisconsin, Milwaukee, WI 53202, USA

Correspondence to: J Owczarzak, jillowczarzak@jhu.edu

Cite this as: *TBM* 2018;8:917–926
doi: 10.1093/tbm/ibx041

© Society of Behavioral Medicine 2018. All rights reserved. For permissions, please e-mail: journals.permissions@oup.com.

Abstract

Carefully conducted randomized trials have established that sexual behavior change interventions can significantly reduce intervention participants' risk of acquiring HIV. Establishing the *effectiveness* of these evidence-based interventions when implemented by frontline HIV prevention service providers is increasingly important in order to achieve maximum public health impact. This study sought to assess the effectiveness of an evidence-based intervention when implemented by frontline HIV prevention service providers. We evaluated Sisters Informing Sisters on Topics about AIDS (SISTA), an HIV prevention intervention for heterosexual African American women, as implemented by four AIDS service organizations. Women enrolled in HIV counseling, testing, and referral (CTR) at each agency served as contemporaneous controls. Measures included self-reported number of occasions of unprotected vaginal intercourse and number of vaginal sex partners in the previous 90 days. 1,262 participants completed baseline and follow-up assessments across both conditions (SISTA = 537 [57%]; CTR = 725 [62%]). In the full sample of HIV-negative women, CTR participants' odds of having had unprotected sex decreased over time by 38% while SISTA participants' odds of having had unprotected sex did not change. Similar results were found among only those participants who had sex at baseline. Hypothesized interaction effects indicating positive changes in sexual risks over time for SISTA participants were not observed.

Keywords

Effectiveness research, HIV prevention, Frontline service providers, Women

INTRODUCTION

Three decades of carefully-conducted randomized trials have established that sexual behavior change interventions can significantly reduce intervention participants' risk of acquiring HIV [1–4]. To facilitate the dissemination and implementation of these evidence-based interventions (EBIs), the Centers for Disease Control and Prevention (CDC) created a compendium of efficacious, evidence-based HIV prevention interventions [5]. These CDC-endorsed interventions were actively promoted through CDC's Diffusion of Effective Behavioral Interventions (DEBI) program, which provided intervention materials, training, technical assistance for program implementation, and evaluation resources to service providers implementing the intervention. All of the interventions selected for the DEBI program had

Implications

Practice: Service providers should be supported financially and with other resources to offer a diversity of HIV related services that target a range of clients with broad health and social service needs.

Policy: Policy makers and funders should continually assess the extent to which interventions—after disseminated and implemented “in the field”—continue to have the desired impact.

Research: More research is needed to evaluate the ongoing effectiveness of behavioral interventions as delivered by frontline service providers in order to inform whether programs should be continued or thoughtfully deimplemented.

been rigorously evaluated in randomized or quasi-randomized controlled trials [6, 7]. Establishing the *effectiveness* of such EBIs when implemented by frontline HIV prevention service providers is increasingly important in order to achieve maximum public health impact [8–11].

The DEBI program began in 2002 [5] and continued until 2013. In 2013, CDC's Division of HIV/AIDS Prevention (DHAP) shifted its funding priorities in order to align with the National HIV/AIDS Strategy and a “High Impact Prevention” approach that focuses on the most scalable strategies to yield the greatest overall impact and reduce new HIV infections. As part of this process, DHAP removed 10 evidence-based interventions from the list of interventions that it would fund. SISTA was among the interventions CDC decided to no longer support. In the current list of interventions supported by the CDC through training and technical assistance, there are no programs designed specifically for HIV-negative African American women. This study was begun before removal of SISTA from the list of funded interventions, and the current paper may help elucidate the possible impact of withdrawing support for a program targeted for this population.

While the DEBI program has ended, the evaluation of HIV interventions can shed light on important questions in dissemination and implementation science about the effectiveness of interventions as implemented in community settings.

Translational research seeks to study the dissemination and implementation of evidence-based interventions in order to improve population health, and seeks to evaluate the “real world” health outcomes of population health practice [12, 13]. For HIV/AIDS, translation research focuses on understanding how interventions play out at a larger scale and in specific contexts with specific populations [11]. In contrast to traditional public health research, implementation science and translational research employ study designs other than randomized controlled trials (RCTs) that address external validity. Efficacy trials—including RCTs—are typically implemented using tightly controlled protocols by highly expert staff with low variability in setting and target population. Hybrid designs such as simultaneous testing of clinical interventions and implementation strategies [14] have been proposed to decrease the time it takes for interventions to move from the research to implementation and increase the relevance of the intervention for implementing communities. However, such study designs do not answer the question of *how well evidence-based interventions work* when delivered without external support.

METHODS

To answer this implementation question, we evaluated the effectiveness of DiClemente and Wingood’s “SISTA” (“Sisters Informing Sisters on Topics about AIDS”), an evidence-based HIV prevention program for African American women, compared to HIV counseling, testing, and referral (CTR) from 2011 through 2015. SISTA is a five-session small group intervention specifically developed for young African American women [15]. Each of the five sessions incorporates themes of gender and ethnic pride, skills-building and role-playing exercises related to condom use and partner communication around safer sex, and information about HIV transmission. Each session also includes discussions about women’s personal experiences with intimate relationships, HIV risk, and coping with negative situations. CTR is a streamlined model of HIV testing that includes delivering information about HIV, conducting an HIV test, completing a brief risk screening, providing a test result, and delivering referrals tailored to the client’s specific needs [16]. CTR is typically a single encounter (when an HIV rapid test is used, which can produce results in about 20 min).

In the original efficacy trial of SISTA, women between 18 and 29 years old who completed the intervention demonstrated increased consistent condom use, greater sexual communication, and greater sexual assertiveness compared to control groups

[15]. Therefore, CDC designated SISTA as an intervention with sufficient evidence for dissemination to CBOs [17], and included it in the Diffusion of Effective Behavioral Interventions (DEBI) program, a compendium of evidence-based interventions recommended for widespread dissemination [5, 18]. SISTA filled a significant gap in the compendium of HIV prevention programs by targeting a highly vulnerable population that had been neglected from earlier prevention efforts. We focused on SISTA because it was one of CDC’s most popular evidence-based interventions: through 2008, over 400 community-based organizations and 900 individuals had received SISTA training in the USA.

Typically effectiveness studies use a randomized or quasi-randomized design that can limit several threats to internal validity, particularly in baseline differences between groups and self-selection bias. Whether randomized controlled trials (RCTs) are appropriate in community settings is a highly contested topic [19, 20]. RCTs have been critiqued as unable to evaluate complex, multifaceted programs with a range of outcomes and endpoints and unable to accommodate the diversity of program participants that community organizations typically serve. When designing the current study, potential partner agencies raised similar concerns with randomization. They cited resource constraints that prohibited a randomized design: such a study design would require continuous implementation of SISTA groups, and they did not have the funds, time, staff, and other resources to support this approach. The partner agencies received support from a combination of federal, state, and local government entities to implement a specific number of SISTA cycles to a targeted number of women. The evaluation/research component did not provide additional funds to support SISTA implementation; rather, the research project was used to evaluate the program only. Partner agencies also raised concerns that women would perceive that they were being denied access to a well-liked program (i.e., SISTA); they worried that women who were asked to delay participating in SISTA would not return at a later date based on their experience with a “catch as catch can” approach to recruitment. In short, agencies already implementing SISTA would be unable to participate in a study that required them to invest limited resources into additional programs, and were unwilling to deny women participation in SISTA—even if delayed. Moreover, from a research perspective, we wanted to examine the effectiveness of SISTA within conditions that are most “true to life.” Such conditions include motivation and time commitment on behalf of agency clients to participate in the multi-session intervention, the populations and methods that agencies use for recruitment into the intervention, and possible attrition to the intervention due to its length. However, a simple

pre-post-design would introduce additional threats to internal validity such as history effects and maturation over time. Therefore, women who completed HIV CTR at each agency served as a contemporaneous comparison group within an intent-to-treat (ITT) design. CTR was chosen for comparison due to similarities to SISTA: federal and state-funded agencies also receive funds for CTR in addition to EBIs; CTR is anticipated to reach individuals at risk for HIV; and it demonstrates positive effects on risk [21]. Considering that individuals also receive basic information regarding HIV and its prevention, it can be considered a standard of care best practice. Following the ITT approach, all enrolled participants that provided survey data are included in analysis, regardless of their level of attendance at SISTA sessions. ITT approaches are typical in RCTs of clinical treatments, which often deal with barriers such as noncompliance, missed doses, and missing data. ITT provides a more conservative estimate of effects and allows for the fact that noncompliance and missed doses would continue to occur if a tested treatment was recommended as a treatment in the general population. Although this was not a Randomized Controlled Trial, this approach is appropriate because we are interested in the “real world” effectiveness of SISTA, which inherently has the potential for multiple implementation barriers, analogous to the barriers that continue after RCTs of clinical treatments.

Study sites

Between 2011 and 2015, we partnered with 4 AIDS service organizations (ASO) from geographically distinct regions in the USA (Northeast, South, Midwest) [22]. Of the four agencies that participated in the study, three were comprehensive ASOs that offered treatment, care, support, and prevention services to broad populations but that mainly served ethnic and racial minority communities. The fourth organization conducted HIV prevention programs, including SISTA, on a limited scale and also conducted CTR. Most of its work focused on capacity-building both domestically and internationally. Each agency received independent funding to conduct its SISTA program, separate from project funds to support the effectiveness evaluation.

Study participants

For the SISTA condition, all women 18 years and older were eligible to participate. While SISTA was intended for an African American audience, some agencies allowed women of different racial and ethnic backgrounds to participate in the program, particularly if SISTA was conducted at a transitional housing facility or other closed group environment. We allowed all women to complete the baseline and follow-up assessments in order to preserve a sense of group cohesion among participants. For the CTR

condition, all women 18 years and older who identify as Black or African American were eligible to participate. Participants in the SISTA intervention and CTR program were recruited by partner agencies as part of their normal outreach and recruitment activities. These recruitment strategies varied by agency and included conducting SISTA at public housing development community centers, residential drug treatment programs, and university dormitories; offering CTR during community health fairs; and conducting HIV testing at their offices as part of regular services. Most study agencies had established partnerships with local community organizations through which they conducted their SISTA and CTR programs. All participants completed either a self-administered, web-based enrollment, consent, and assessment process or a similar paper-based process, depending on the technology infrastructure of the individual sites where SISTA was conducted. Participants received \$35 for completing the baseline assessment and \$45 for the follow-up assessment. The research study did not compensate participants for completing SISTA or attending the CTR program, although the agencies themselves used various methods (e.g., gift cards, certificates of completion, credit toward court-mandated classes) to compensate women for participating in SISTA or CTR.

Measures

Measures included whether or not participants had unprotected sex in the previous 90 days; number of occasions of unprotected vaginal intercourse in the previous 90 days; number of vaginal sex partners in the previous 90 days; and number of vaginal sex partners that participants had unprotected vaginal intercourse with in the previous 90 days. Additional measures used for weighting analysis (described below) included self-efficacy to use condoms, condom attitudes, perceived susceptibility to HIV, African American woman pride, and HIV knowledge, among others (see Table 1). Some demographic categories were collapsed, including race (Black/African American vs. Other), marital status (Never Married vs. Other), and employment status (Working full or part time vs. Other). The African American woman pride scale was only asked for participants who self-reported as Black/African American. Mean replacement was used for all other participants to avoid loss of data.

Data analysis

We followed a two-step evaluation plan due to the complex, nontraditional design of the research as an assessment of effectiveness, consisting of unweighted analysis and weighted analysis. First, we conducted repeated measures analysis comparing change over time on the outcome variables of interest: whether or not participants had had unprotected vaginal or anal

Table 1 | Measures

	Number of items	Cronbach's alpha (α)/ correlation (r)	Scale Range	Sample Item
African American Woman Pride [31]	7	$\alpha = .76$	1–4	African American women help make America strong
Self-esteem [32]	10	.84	1–4	I deserve as much respect as anyone else
HIV Knowledge [15]	10	.62	0–10	Women cannot pass HIV to men
Susceptibility to HIV	2	$r = .14^{***}$	1–4	I am worried that I might get HIV
Peer Support [33]	4	$\alpha = .54$	1–4	I wouldn't want my friends to know I use condoms (reverse scored)
Testing Attitudes	2	$r = .19^{***}$	1–4	It's important to get tested for HIV
Condom Effectiveness	2	$r = .15^{***}$	1–4	Using a condom every time I have sex would protect me from getting HIV
HIV Protection Self-Efficacy	2	$r = .27^{***}$	1–4	I can protect myself from HIV
Self-Efficacy to negotiate condoms [15]	3	$\alpha = .78$	1–3	How confident or sure are you that you could ask a man to wear a condom?
Self-Efficacy to use condoms [15]	8	$\alpha = .91$	1–3	How confident or sure are you that you could put a condom on an erect (hard) penis?
Comfort talking with partners about sexual topics [34]	7	$\alpha = .89$	1–4	How comfortable are you talking to sex partners about pregnancy prevention?
Comfort talking with partners about condoms [34]	1	-	1–4	How comfortable are you talking to sex partners about using condoms?
Comfort obtaining and having condoms [35]	5	$\alpha = .73$	1–4	I would be embarrassed to buy condoms (reverse-scored)
Condoms affect sexual experience [35]	8	$\alpha = .78$	1–4	Condoms rub and make you feel sore (reverse-scored)

*** $p \leq .001$.

sex in the previous 90 days, number of occasions of unprotected vaginal sexual intercourse in the previous 90 days, number of vaginal sex partners in the previous 90 days, and number of vaginal sex partners that participants had unprotected vaginal intercourse with in the previous 90 days. General linear modeling with repeated measures assessed the effects of time (baseline vs. follow-up), condition (SISTA vs. CTR), and the time by condition interaction. To account for skew in the continuous outcome variables, a negative binomial distribution was used for analyses of these variables. We hypothesized a significant Time by Condition interaction effect for these analyses, such that participants in SISTA would decrease sexual risks to a stronger degree than those in the CTR condition. Analyses were conducted with the full sample of HIV-negative women who have sex with men that provided follow-up data on sexual behavior ($N = 1,190$), and for only those who also indicated they had had sexual intercourse in the previous 90 days at baseline ($N = 736$).

However, the two groups were not randomly assigned. Therefore, numerous baseline differences between groups may affect outcomes and mask potential effects of SISTA compared to CTR, including baseline differences on sexual risks, hypothesized mediators of the SISTA intervention's potential effects, and demographics. We accounted for these effects in the second step of evaluation to account for baseline differences on these potentially

important variables. Bivariate logistic regressions identified variables associated at baseline with condition. Sexual risk count variables with significant skew (i.e., numbers of instances of unprotected sex, partners) were dichotomized at the median only for purposes of calculating these weights. All variables associated with condition at $p < .25$ were entered into a multivariable logistic regression. We chose this less conservative alpha level to capture as many possible confounding baseline variable differences between SISTA and CTR. Variables were then removed individually to minimize the AIC goodness-of-fit indicator, resulting in a final multivariable logistic regression model that best fit the data. Results of the final logistic regression model were used to then weight participants and statistically “equalize” these differences across the two conditions. Weights were equal to the inverse of the probability that a participant received the intervention she actually received, also known as “inverse probability weighting” (IPW). General linear modeling with repeated measures was again conducted, now accounting for these weights, with both the full sample and sexually active subsample.

RESULTS

In total, 2,099 participants completed baseline assessments across both conditions (SISTA participants = 938; CTR participants = 1,161). A total of 1,262 (60%) participants completed the follow-up

assessments across both conditions (SISTA participants = 537 [57%]; CTR participants = 725 [62%]). Among those, 5 were removed due to non-female gender, 35 due to only having sex with women, and 32 due to self-reported positive HIV status, resulting in a sample of 697 CTR participants and 493 SISTA participants (see Table 2 for sample characteristics).

Unweighted repeated measures analysis

All participants

In repeated measures analysis among the full sample of HIV-negative WSM of whether or not participants had had unprotected sex, there were significant Time, Condition, and Time by Condition effects. Main effects indicate higher likelihood of unprotected sex at baseline and among CTR participants. For CTR participants, however, reports of having had unprotected sex went from 55% at baseline to 43% at follow-up (simple Time effect $OR = 0.62$, $p < .001$). For SISTA participants, reports of having had unprotected sex did not significantly decrease (40% at baseline to 37% at follow-up; simple Time effect $OR = 0.89$, $p = .18$). There were no significant Time or Time by Condition effects on number of instances of unprotected vaginal intercourse in the previous 90 days (see Table 3). However, there was a significant Condition effect, demonstrating that participants in the SISTA condition (Mean = 8.73, SD = 22.60, MDN = 0) reported fewer instances of unprotected vaginal sex than those in CTR (Mean = 13.78, SD = 36.48, MDN = 1). Repeated measures analysis of number of partners revealed the same pattern of results, such that participants in the SISTA condition (Mean = 0.84, SD = 2.46, MDN = 1) reported fewer partners than those in CTR (Mean = 1.42, SD = 3.67, MDN = 1), with no significant Time or Time by Condition effects. Overall number of partners with whom participants had had unprotected sex decreased over time (Baseline Mean = 0.89, SD = 3.28, MDN = 0; Follow-up Mean = 0.57, SD = 1.49, MDN = 0). However, there were no Condition or Time by Condition effects on unprotected partners.

Sexually active at baseline participants

In repeated measures binomial regression of whether or not participants had had unprotected sex in the previous 90 days, there was a significant Time effect, but no significant Condition or Time by Condition effects (see Table 3). At baseline, 78% reported having had unprotected sex, and 57% reported so at follow-up. There was a significant decrease in instances of unprotected vaginal intercourse (Baseline Mean = 19.69, SD = 37.30, MDN = 6; Follow-up Mean = 15.67, SD = 36.69, MDN = 2). Over time, participants also reported decreasing numbers of partners (Baseline Mean = 2.00, SD = 3.56, MDN = 1; Follow-up Mean = 1.36, SD = 3.39, MDN = 1). Additionally, participants in the CTR condition reported more partners (Mean = 1.89,

SD = 4.08, MDN = 1) than in the SISTA condition (Mean = 1.29, SD = 1.92, MDN = 1). Finally, participants reported a decreasing number of partners who they had had unprotected sex with (Baseline Mean = 1.42, SD = 4.07, MDN = 1; Follow-up Mean = 0.77, SD = 1.62, MDN = 1). However, there were no significant Time by Condition interactions on any of these effects.

Weighted repeated measures analysis

All participants

In bivariate logistic regressions among the full sample of HIV-negative WSM, several variables were associated with condition at or below $p = .25$ (see Table 2). In the final multivariate model that minimized AIC, race, employment status, susceptibility to HIV, self-esteem, African American woman pride, number of partners, as well as having had sex remained significantly associated with condition.

When participants were weighted to condition in repeated measures analysis, odds of reporting having had unprotected sex in the previous 90 days dropped by 36% from baseline to follow-up (see Table 4). There were no significant effects of Condition or Time by Condition. Additionally, there were no significant effects of Time, Condition, or Time by Condition on outcomes of number of occasions of unprotected vaginal sex, or number of partners. Number of partners participants had unprotected sex with decreased over time, but there were no significant Condition or Time by Condition effects.

Sexually active at baseline participants

In bivariate logistic regressions among HIV-negative WSM who had had sex in the previous 90 days at baseline, several variables were associated with condition at or below $p = .25$ (see Table 2). In the final multivariate model that minimized AIC, race, employment status, number of partners, and susceptibility to HIV remained significantly associated with condition.

When participants were weighted to condition in repeated measures analysis, there was a significant decreasing Time effects. Odds of having had unprotected sex decreased by 70% (see Table 4). There were also significant decreasing Time effects on instances of unprotected vaginal intercourse, number of partners, and number of partners participants had unprotected sex with. However, there were no significant Condition or Time by Condition effects on any of these outcomes.

DISCUSSION

In the full sample of women who were not HIV-positive, CTR participants were more likely to have had unprotected sex than SISTA participants, although over time, the odds of their having had

Table 2 | Sample characteristics at baseline

All HIV-negative women (<i>N</i> = 1,190)	CTR (<i>n</i> = 697)	SISTA (<i>n</i> = 493)	Odds ratio	<i>p</i>
Age	36.34	39.02	0.71	<.001***
Marital Status (ref = Never married)	65%	58%	1.32	.02*
Race (ref = African American/Black)	99%	91%	8.65	<.001***
Employment Status (ref = part or full time)	45%	30%	1.89	<.001***
Housing status (ref = live in own house/apt.)	74%	75%	0.94	.63
Income (ref = less than \$500/month)	47%	50%	1.11	.40
Had sex	69%	53%	0.51	<.001***
Had unprotected sex	54%	40%	0.57	<.001***
Had >3 vaginal intercourse occasions	55%	40%	0.57	<.001***
Had >1 unprotected vaginal intercourse occasions	49%	36%	0.58	<.001***
Had >1 partners	22%	11%	0.44	<.001***
Had >0 partners had unprotected sex with	54%	39%	0.55	<.001***
African American Woman Pride	3.45	3.50	1.25	.09
Self-esteem	3.49	3.42	0.76	.02*
HIV Knowledge	7.35	7.19	0.96	.15 ⁺
Susceptibility to HIV	2.34	2.15	0.73	<.001***
Peer Support	3.31	3.23	0.78	.01*
Testing Attitudes	3.64	3.54	0.76	.006**
Condom Effectiveness	3.14	3.03	0.83	.02*
Protection Self-Efficacy	3.61	3.59	0.93	.49
Self-Efficacy to negotiate condoms	2.77	2.76	0.93	.62
Self-Efficacy to use condoms	2.57	2.54	0.90	.35
Comfort talking with sex partners	3.70	3.66	0.88	.25
Comfort talking about condoms	3.75	3.68	0.85	.06 ⁺
Comfort having condoms	3.36	3.34	0.92	.40
Condoms affect sexual experience	2.84	2.82	0.91	.35
Had abusive partner	8%	5%	1.54	.08 ⁺
HIV-negative women had sex at baseline (<i>N</i> = 726)	CTR (<i>n</i> = 476)	SISTA (<i>n</i> = 260)	Odds ratio	<i>p</i>
Age	34.41	34.64	1.00	.80
Marital Status (ref = Never married)	70%	63%	1.35	.07 ⁺
Race (ref = African American/Black)	99%	92%	6.88	<.001***
Employment Status (ref = part or full time)	46%	37%	1.46	.02*
Housing status (ref = live in own house/apt.)	74%	75%	0.94	.71
Income (ref = less than \$500/month)	48%	51%	1.09	.56
Had unprotected sex	79%	76%	0.82	.31
Had >10 vaginal intercourse occasions	50%	49%	0.98	.89
Had >6 unprotected vaginal intercourse occasions	48%	47%	0.96	.79
Had >1 partners	33%	21%	0.56	.001***
Had >1 partners had unprotected sex with	19%	12%	0.57	.01*
African American Woman Pride	3.45	3.51	1.31	.12 ⁺
Self-esteem	3.48	3.47	0.96	.80
HIV Knowledge	7.49	7.53	1.01	.79
Susceptibility to HIV	2.33	2.13	0.72	.001***
Peer Support	3.34	3.36	1.07	.61
Testing Attitudes	3.66	3.63	0.89	.38
Condom Effectiveness	3.11	3.16	1.09	.41
Protection Self-Efficacy	3.63	3.67	1.17	.29
Self-Efficacy to negotiate condoms	2.78	2.79	1.01	.96
Self-Efficacy to use condoms	2.59	2.59	1.01	.97
Comfort talking with sex partners	3.71	3.71	0.99	.95
Comfort talking about condoms	3.76	3.70	0.86	.20 ⁺
Comfort having condoms	3.37	3.43	1.25	.13 ⁺
Condoms affect sexual experience	2.83	2.81	0.93	.60
Had abusive partner	12%	10%	1.23	.42

⁺*p* < .25, **p* < .05, ***p* < .01, ****p* < .001

Table 3 | Unweighted analysis

	β	95% CI	<i>p</i>
All HIV-negative WSM (N = 1,190)			
<i>Had had unprotected vaginal or anal intercourse</i>			
Time	-0.48	(-0.64, -0.32)	<.001***
Condition	-0.57	(-0.81, -0.34)	<.001***
Time × Condition	0.36	(0.12, 0.60)	.003**
<i>Unprotected vaginal intercourse</i>			
Time	-0.14	(-0.34, 0.07)	.19
Condition	-0.51	(-0.79, 0.24)	<.001***
Time × Condition	0.09	(-0.23, 0.41)	.58
<i>Number of partners</i>			
Time	-0.19	(-0.44, 0.06)	.14
Condition	-0.67	(-0.93, -0.42)	<.001***
Time × Condition	0.31	(-0.13, 0.74)	.16
<i>Number of unprotected partners</i>			
Time	-0.47	(-0.66, -0.28)	<.001***
Condition	-0.36	(-0.92, 0.19)	.20
Time × Condition	0.11	(-0.50, 0.73)	.72
HIV-negative WSM who had sex in previous 90 days at baseline (N = 736)			
<i>Had had unprotected vaginal or anal intercourse</i>			
Time	1.15	(-1.38, 0.91)	<.001***
Condition	-0.19	(-0.55, 0.17)	.31
Time × Condition	0.37	(-0.02, 0.77)	.06
<i>Instances of unprotected vaginal intercourse</i>			
Time	-0.24	(-0.45, -0.02)	.03*
Condition	-0.25	(-0.51, 0.01)	.06
Time × Condition	0.03	(-0.28, 0.35)	.84
<i>Number of partners</i>			
Time	-0.41	(-0.68, -0.14)	.003*
Condition	-0.42	(-0.65, -0.18)	<.001***
Time × Condition	0.10	(-0.27, 0.46)	.59
<i>Number of unprotected partners</i>			
Time	-0.65	(-0.82, -0.48)	<.001***
Condition	-0.11	(-0.65, 0.44)	.71
Time × Condition	0.11	(-0.52, 0.73)	.73

For Condition, reference category = CTR; For Time, reference category = Baseline.

* $p < .05$, ** $p < .01$, *** $p < .001$.

unprotected sex decreased over time by 38% while among SISTA participants odds of having had unprotected sex did not change. CTR participants also reported higher numbers of unprotected vaginal intercourse and partners, although outcomes did not decrease over time. Similar results were found among only those participants who had had sex at baseline. In general, hypothesized interaction effects indicating positive changes in sexual risks over time for SISTA participants were not observed. These results should be interpreted with caution, as there was no random assignment to group. In order to address the possibility of third variable confounders contributing to the observed interaction on likelihood of having had unprotected sex, we weighted participants using inverse probability weighting.

After weighting participants, many main effects of Condition on sexual behaviors disappeared as expected, and there were many significant effects of risk behavior declining over time, especially for participants who had been recently sexually active at baseline. The results of this study further support research that indicates that brief interventions such as CTR can be an effective [21, 23] and cost-effective [24] HIV prevention intervention with broad reach, including for the most vulnerable populations [25].

Study limitations and strengths

Interpretation of findings should take several considerations into account. First, the study populations in the two conditions were quite different. SISTA participants were at lower risk for HIV: only 53% of

Table 4 | Weighted analysis

	β	95% CI	<i>p</i>
All HIV-negative WSM (N = 1,190)			
<i>Had had unprotected vaginal or anal intercourse</i>			
Time	-0.44	(-0.61, -0.28)	<.001***
Condition	-0.10	(-0.34, 0.15)	.45
Time × Condition	0.24	(-0.02, 0.50)	.07
<i>Instances of unprotected vaginal intercourse</i>			
Time	-0.11	(-0.30, 0.08)	.25
Condition	-0.12	(-0.51, 0.28)	.57
Time × Condition	-0.04	(-0.44, 0.36)	.84
<i>Number of partners</i>			
Time	-0.12	(-0.41, 0.18)	.43
Condition	-0.23	(-0.62, 0.16)	.24
Time × Condition	0.05	(-0.50, 0.60)	.86
<i>Number of unprotected partners</i>			
Time	-0.40	(-0.66, -0.14)	.002**
Condition	-0.14	(-0.64, 0.37)	.60
Time × Condition	0.02	(-0.54, 0.57)	.95
HIV-negative WSM who had sex in previous 90 days at baseline (N = 736)			
<i>Had had unprotected vaginal or anal intercourse</i>			
Time	-1.20	(-1.45, -0.94)	<.001***
Condition	-0.20	(-0.58, 0.17)	.29
Time × Condition	0.41	(-0.01, 0.82)	.06
<i>Instances of unprotected vaginal intercourse</i>			
Time	-0.22	(-0.42, -0.03)	.03*
Condition	-0.25	(-0.60, 0.09)	.14
Time × Condition	-0.08	(-0.45, 0.28)	.66
<i>Number of partners</i>			
Time	-0.37	(-0.62, -0.12)	.004**
Condition	-0.14	(-0.46, 0.18)	.39
Time × Condition	-0.10	(-0.51, 0.31)	.62
<i>Number of unprotected partners</i>			
Time	-0.64	(-0.80, -0.48)	<.001***
Condition	-0.05	(-0.53, 0.44)	.86
Time × Condition	0.05	(-0.48, 0.58)	.85

For Condition, reference category = CTR; For Time, reference category = Baseline.

* $p < .05$, ** $p < .01$, *** $p < .001$.

them were sexually active at baseline (compared to 69% of CTR women). Only 40% had unprotected sex at baseline (compared to 54% in CTR). Moreover, based on the study design, it was possible that women could have participated in the SISTA intervention without enrolling in the research study. Therefore, the final study sample of SISTA participants may not completely reflect the actual population that completed SISTA at each site. We did not collect information about how women were recruited, which would have provided context regarding potential confounding variables by recruitment method.

Additionally, participants were not randomized to participate in SISTA or receive CTR, which introduces the possibility of self-selection bias. In the final study design, women in the CTR served as a contemporaneous comparison group. Comparing SISTA to

a standard of care (CTR) allowed us to control for secular effects, and provide guidance to service providers, CDC, and local and state health departments regarding the effectiveness of SISTA versus CTR. From an effectiveness evaluation standpoint, this cannot reasonably be considered a bias. Women who are motivated to attend a five-session intervention no doubt differ from women who are not so motivated. Such self-selection is a real-world phenomenon and as such should be reflected in the results of an effectiveness trial, not artificially masked.

Finally, this study does not account for all potential implementation barriers to SISTA, which may have decreased its effectiveness. Financial support for SISTA (or lack thereof) has major implications for the program's implementation and sustainability. Lack of fidelity to the original intervention and attrition or

insufficient exposure or dosage of the intervention could also contribute to decreased SISTA effectiveness [26–29]. Although implementation fidelity is outside the scope of this paper, we video recorded SISTA sessions at each agency and determined through a fidelity checklist that providers implemented the intervention with fidelity to the SISTA manual. Moreover, each agency had internal monitoring processes to ensure implementation fidelity, including the completion of fidelity checklists and observation by supervisors. However, recruitment of women outside of the original eligibility criteria of the study that studied SISTA's efficacy (18 and 29 years old African American women only) could be considered lack of fidelity. Regarding attrition and dosage, we tracked SISTA attendance by participants through self-report on the follow-up surveys. Attendance at each of the five sessions was between 81% and 92%, and 76% of SISTA participants attended all five sessions. Only 12% of the SISTA sample attended one or two sessions. Although no studies have been conducted to determine how many sessions or what percent of core elements are necessary in order for the benefits of SISTA to be achieved, the majority of the SISTA sample as a whole received the entire program.

This study was designed with the assumption that both SISTA participants and CTR recipients would have similar levels of HIV risk. The results did not support this assumption but highlight that these two intervention strategies can be highly complementary. In our study, participants self-selected which intervention to receive. As we have argued elsewhere [22], programs such as SISTA are seen as offering participants other benefits such as enhanced sense of self-worth and belonging, in addition to HIV prevention, and provide an opportunity for agencies to connect clients to other services and programs. Other studies have demonstrated that SISTA *can* reduce HIV risk among participants' who are determined to be at high risk for contracting HIV or transmitting it to others [30].

CONCLUSION

Community-based agencies face significant and often competing pressures—from funders, collaborators, clients, and potential clients—and as a result may not always strictly adhere to the same eligibility criteria as in the original efficacy trials. Offering a diversity of HIV related services that draw on different approaches (e.g., individualized counseling, small group programs) can allow these agencies to balance these demands. Single-session interventions such as CTR may play a valuable role in HIV prevention efforts because there is no risk of attrition, which may be important for certain populations and situations (e.g., unstable, highly mobile, or hard-to-reach groups). Considering resource intensity (staff, time, money) of running multisession group, more targeted recruitment may be beneficial to offer

maximum impact of similar programs. In addition, to maximize benefits of participating in SISTA, implementing agencies can use SISTA as a vehicle for linking at-risk women to other services. Policy makers and researchers must diligently and continually assess the extent to which these interventions—after disseminated and implemented “in the field”—continue to have the desired impact. Finally, the CDC's decision to no longer support some HIV prevention programs through the DEBI program underscores that the development of evidence-informed policy is an on-going process that should not end with the identification of interventions based on research trials, and continued research is needed to evaluate evidence-based interventions in real-world contexts.

Acknowledgments: We would like to thank Cassandra Wright for the work she did as the project coordinator for this study. We also thank our agency partners for their generosity of time, resources, and personnel throughout the course of this study. Finally, Steve Pinkerton also assisted in the conceptualization of the study.

Declarations: The content of this article represents original work. It has neither been published nor is simultaneously being considered for publication elsewhere.

Funding: Funding for this study was provided by the National Institute of Mental Health (R01MH089828).

Compliance With Ethical Standards

Ethics Approval: The study described in this manuscript was approved by the Institutional Review Board at the Medical College of Wisconsin. All participants provided written informed consent. No animals were involved in this study.

Conflicts of Interests: We have no financial, consultative, or institutional interests that might lead to bias or conflict of interest.

Data: The authors have full control of all primary data and agree to allow Translational Behavioral Medicine to review the data if requested.

Authors' Contributions: J.O. conceptualized the study and was a major contributor in writing the manuscript. M.B. analyzed and interpreted the data and was a major contributor in writing the manuscript. S.T. assisted with data analysis and interpretation. All authors read and approved the final manuscript.

References

1. Sagerian MJ, Huedo-Medina TB, Pellowski JA, Eaton LA, Johnson BT. Single-session behavioral interventions for sexual risk reduction: a meta-analysis. *Ann Behav Med*. 2016;50(6):920–934.
2. Herbst JH, Sherba RT, Crepaz N, et al.; HIV/AIDS Prevention Research Synthesis Team. A meta-analytic review of HIV behavioral interventions for reducing sexual risk behavior of men who have sex with men. *J Acquir Immune Defic Syndr*. 2005;39(2):228–241. http://journals.lww.com/jaids/Fulltext/2005/06010/A_Meta_Analytic_Review_of_HIV_Behavioral.16.aspx.
3. Crepaz N, Tungol-Ashmon MV, Vosburgh HW, Baack BN, Mullins MM. Are couple-based interventions more effective than interventions delivered to individuals in promoting HIV protective behaviors? A meta-analysis. *AIDS Care*. 2015;27(11):1361–1366.
4. Covey J, Rosenthal-Stott HE, Howell SJ. A synthesis of meta-analytic evidence of behavioral interventions to reduce HIV/STIs. *J Behav Med*. 2016;39(3):371–385.
5. Collins C, Harshbarger C, Sawyer R, Hamdallah M. The diffusion of effective behavioral interventions project: development, implementation, and lessons learned. *AIDS Educ Prev*. 2006;18(4 Suppl A):5–20.

6. Thomas CW, Smith BD, Wright-DeAgüero L. The Program Evaluation and Monitoring System: a key source of data for monitoring evidence-based HIV prevention program processes and outcomes. *AIDS Educ Prev*. 2006;18(4 Suppl A):74–80.
7. Lyles CM, Crepaz N, Herbst JH, Kay LS; HIV/AIDS Prevention Research Synthesis Team. Evidence-based HIV behavioral prevention from the perspective of the CDC's HIV/AIDS prevention research synthesis team. *AIDS Educ Prev*. 2006;18(4 Suppl A):21–31.
8. Cunningham SD, Card JJ. Realities of replication: implementation of evidence-based interventions for HIV prevention in real-world settings. *Implement Sci*. 2014;9:5.
9. Margaret Dolcini M, Gandelman AA, Vogan SA, et al. Translating HIV interventions into practice: community-based organizations' experiences with the diffusion of effective behavioral interventions (DEBIs). *Soc Sci Med*. 2010;71(10):1839–1846.
10. Jemmott JB 3rd, Jemmott LS, Fong GT, Morales KH. Effectiveness of an HIV/STD risk-reduction intervention for adolescents when implemented by community-based organizations: a cluster-randomized controlled trial. *Am J Public Health*. 2010;100(4):720–726.
11. Glasgow RE, Eckstein ET, Elzarrad MK. Implementation science perspectives and opportunities for HIV/AIDS research: integrating science, practice, and policy. *J Acquir Immune Defic Syndr*. 2013;63(Suppl 1):S26–S31.
12. Proctor EK, Landsverk J, Aarons G, Chambers D, Glisson C, Mittman B. Implementation research in mental health services: an emerging science with conceptual, methodological, and training challenges. *Adm Policy Ment Health*. 2009;36(1):24–34.
13. Glasgow RE, Lichtenstein E, Marcus AC. Why don't we see more translation of health promotion research to practice? Rethinking the efficacy-to-effectiveness transition. *Am J Public Health*. 2003;93(8):1261–1267.
14. Curran GM, Bauer M, Mittman B, Pyne JM, Stetler C. Effectiveness-implementation hybrid designs: combining elements of clinical effectiveness and implementation research to enhance public health impact. *Med Care*. 2012;50(3):217–226.
15. DiClemente RJ, Wingood GM. A randomized controlled trial of an HIV sexual risk-reduction intervention for young African-American women. *JAMA*. 1995;274(16):1271–1276.
16. *Implementing HIV Testing in Nonclinical Settings: A Guide for HIV Testing Providers*. 2016. <https://www.cdc.gov/hiv/testing/nonclinical/>.
17. Lyles CM, Kay LS, Crepaz N, et al.; HIV/AIDS Prevention Research Synthesis Team. Best-evidence interventions: findings from a systematic review of HIV behavioral interventions for US populations at high risk, 2000–2004. *Am J Public Health*. 2007;97(1):133–143.
18. Dworkin SL, Pinto RM, Hunter J, Rapkin B, Remien RH. Keeping the spirit of community partnerships alive in the scale up of HIV/AIDS prevention: critical reflections on the roll out of DEBI (Diffusion of Effective Behavioral Interventions). *Am J Community Psychol*. 2008;42(1–2):51–59.
19. Rosen L, Manor O, Engelhard D, Zucker D. In defense of the randomized controlled trial for health promotion research. *Am J Public Health*. 2006;96(7):1181–1186.
20. Sanson-Fisher RW, Bonevski B, Green LW, D'Este C. Limitations of the randomized controlled trial in evaluating population-based health interventions. *Am J Prev Med*. 2007;33(2):155–161.
21. Hogben M, McNally T, McPheeters M, Hutchinson AB. The effectiveness of HIV partner counseling and referral services in increasing identification of HIV-positive individuals: a systematic review. *Am J Prev Med*. 2007;33(2 Suppl):S89–100.
22. Owczarzak J, Broaddus M, Pinkerton S. Fidelity and adaptation of an evidence-based HIV prevention intervention delivered in community contexts. *Health Education Research*. 2016; doi:10.1093/her/cyw012.
23. Dolcini MM, Catania JA, Gandelman A, Ozer EM. Implementing a brief evidence-based HIV intervention: a mixed methods examination of compliance fidelity. *Transl Behav Med*. 2014;4(4):424–433.
24. Nguyen VT, Nguyen HT, Nguyen QC, Duong PT, West G. Expenditure analysis of HIV testing and counseling services using the cascade framework in Vietnam. *PLoS One*. 2015;10(5):e0126659.
25. World Health Organization. *Guide for Monitoring and Evaluating National HIV Testing and Counselling (HTC) Programmes: Field-Test Version*. Geneva, Switzerland; 2011.
26. Dusenbury L, Brannigan R, Falco M, Hansen WB. A review of research on fidelity of implementation: implications for drug abuse prevention in school settings. *Health Educ Res*. 2003;18(2):237–256.
27. Rohrbach LA, Dent CW, Skara S, Sun P, Sussman S. Fidelity of implementation in Project Towards No Drug Abuse (TND): a comparison of classroom teachers and program specialists. *Prev Sci*. 2007;8(2):125–132.
28. Durlak JA, DuPre EP. Implementation matters: a review of research on the influence of implementation on program outcomes and the factors affecting implementation. *Am J Community Psychol*. 2008;41(3–4):327–350. <https://login.proxy.lib.mcu.edu/login?url=http://proquest.umi.com/pqdweb?did=1468396441&Fmt=7&clientId=26832&RQT=309&VName=PQD>.
29. Aarons GA, Sommerfeld DH, Hecht DB, Silovsky JF, Chaffin MJ. The impact of evidence-based practice implementation and fidelity monitoring on staff turnover: evidence for a protective effect. *J Consult Clin Psychol*. 2009;77(2):270–280.
30. Sapieno TN, Moore A, Kalayil EJ, et al. Evaluation of an HIV prevention intervention designed for African American Women: results from the SISTA Community-based organization behavioral outcomes project. *AIDS Behav*. 2013;17(3):1052–1067.
31. Lukwago SN, Kreuter MW, Bucholtz DC, Holt CL, Clark EM. Development and validation of brief scales to measure collectivism, religiosity, racial pride, and time orientation in urban African American women. *Fam Community Health*. 2001;24(3):63–71. <http://www.ncbi.nlm.nih.gov/pubmed/11563945>.
32. Rosenberg M. *Society and the Adolescent Self-Image*. Princeton, NJ: Princeton University Press; 1965.
33. Catania JA, Dolcini MM, Coates TJ, et al. Predictors of condom use and multiple partnered sex among sexually-active adolescent women: implications for AIDS-related health interventions. *J Sex Res*. 1989;26(4):514–524.
34. Amaro H. Love, sex, and power. Considering women's realities in HIV prevention. *Am Psychol*. 1995;50(6):437–447.
35. St Lawrence JS, Chapdelaine AP, Devieux JG, O'Bannon RE 3rd, Brasfield TL, Eldridge GD. Measuring perceived barriers to condom use: psychometric evaluation of the Condom Barriers Scale. *Assessment*. 1999;6(4):391–404.