Social–Cognitive Theory Mediators of Behavior Change in the National Institute of Mental Health Multisite HIV Prevention Trial

The National Institute of Mental Health Multisite HIV Prevention Trial Group

The National Institute of Mental Health Multisite HIV Prevention Trial was a trial of an intervention to reduce sexual HIV risk behaviors among 3,706 low-income at-risk men and women at 7 U.S. research sites. The intervention, based on social–cognitive theory and designed to influence behavior change by improving expected outcomes of condom use and increasing knowledge, skills, and self-efficacy to execute safer sex behaviors, was effective relative to a control condition in reducing sexual risk behavior. At 3 months after completion of the intervention, measures of these potential mediators were higher in the intervention than in the control condition. Although the effect of the intervention on sexual risk behavior was significantly reduced when the variables were controlled statistically, supporting the hypothesis of their mediation of the intervention effect, most of the effect remained unexplained, indicating the influence of unmeasured factors on outcome.

Key words: HIV prevention intervention, social–cognitive theory, mediation analysis

Developing effective interventions that assist persons in changing high-risk sexual behavior practices requires the identification of factors that contribute to risk. Social–cognitive theory (SCT; Bandura, 1986, 1997) has identified the importance of skills and of confidence in those skills (i.e., self-efficacy) in effecting behavior change. Additionally, the expected outcomes of a behavior are posited to influence motivation to adopt that behavior, and behavioral intervention can also alter expected outcomes. In any behavioral domain, it is important to identify the specific expected outcomes and skills necessary to carry out the behavior of interest. In persons with HIV, skills and self-efficacy for negotiating condom use with partners (LoConte, O'Leary, & Labouvie, 1997; Marin, Gomez, Tschann, & Gregorich, 1997), sexual self-control (e.g., when condoms are not available; O'Leary, 1992), expectations about the hedonistic effects of condom use (Jemmott, Jemmott, Spears, Hewitt, & Cruz-Collins, 1992), and expected partner reactions and self-evaluative outcomes (O'Leary, Maibach, Ambrose, Jemmott, & Celentano, 2000) have been found to be associated with behavior in cross-sectional analyses (see Bandura, 1994, for a comprehensive review of the application of SCT to HIV prevention).

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We recently reported the outcomes from a large-scale national study of an HIV risk reduction intervention for disadvantaged men and women at high risk for infection (The NIMH Multisite HIV Prevention Trial Group, 1998). Study participants were randomized to receive either an intensive small-group intervention or an informational program. The small-group intervention, designed to affect behavior change using the principles of SCT, provided risk sensitization and information combined with skill building for antecedent management, condom use, and condom-use negotiation (see The NIMH Multisite HIV Prevention Trial Group, 1997, chap. 4, for a detailed description of the intervention). Results indicated significant reductions in self-reported sexual risk for intervention recipients relative to controls and, for men, a 50% reduction in incidence of gonorrhea.

Although the trial described above was the first large-scale Phase 3 trial of a behavioral HIV risk reduction intervention for low-income individuals primarily at heterosexual risk for infection, a number of smaller trials have also been conducted (comprehensively reviewed in Peterson & DiClemente, 2000). Many of these have been based on SCT and cognitive–behavioral therapeutic techniques, although other theoretical frameworks, such as the health belief model (Rosenstock, Strecher, & Becker, 1994) and the theory of reasoned action (Fishbein, Middlestadt, & Hitchcock, 1994), have also been used. However, the evaluations of these interventions, regardless of the theoretical basis of the intervention strategies, have focused almost exclusively on behavior change assessment and have not attempted to verify that the intervention components designed to produce the behavior change were in fact responsible for it. Understanding the influence of mediators is critical, given the likelihood that of the elements that produce the behavior change observed in a given intervention, only some are independent active ingredients whereas others may be superfluous. Most effective interventions have targeted multiple potential mechanisms for achieving this behavior change, including factors suggested by each study's theoretical framework; like the NIMH multisite study, these studies have evaluated the multicomponent intervention against a single control treatment (Kamb et al., 1998; Kelly et al., 1994; Shain et al., 1998). These interventions typically have been delivered in multiple-session, multicomponent formats. An ideal approach to identifying the effective elements of interventions is to randomize participants to conditions that provide single components or limited sets of components (O'Leary, DiClemente, & Aral, 1997). For example, Kalichman, Rompa, and Coley (1996) randomized low-income women to receive one of four interventions: (a) sexual communication skills training, (b) self-management skills training, (c) a combination of (a) and (b), and (d) HIV education and risk sensitization. Results indicated the superior effectiveness, relative to the other treatments, of the combined-skills intervention in producing behavioral risk reduction at follow-up.

Although such efforts to identify effective intervention components are laudable and necessary as the HIV prevention field refines prevention technologies, such approaches require considerable statistical power and, accordingly, substantial expense. Mediation analysis represents an alternative strategy that can be feasibly incorporated into simpler experimental designs. Mediation analysis permits the identification of intervention components that are associated with, and that at least partly account for, behavior change effects of a single intervention with multiple components.

This is achieved by including measures operationalizing the mediators in the assessment of the intervention and then establishing the relationships of the mediators to the behavior changes observed in connection with the intervention.

It should be noted that a number of studies have reported the first step of mediation: that putative mediators have been shown to change in response to the intervention. For example, some studies have assessed behavioral skills and have shown them to increase among intervention recipients (Kelly et al., 1994; St. Lawrence, Crosby, Belcher, Yazdani, & Brasfield, 1999; St. Lawrence et al., 1997). Hobfoll and colleagues (1994) showed that women receiving an intervention used condom credit cards to obtain condoms, another likely mediator.

The NIMH Multisite HIV Prevention Trial (The NIMH Multisite HIV Prevention Trial Group, 1997, 1998) afforded an opportunity to test an intervention that was designed to reduce HIV risk behavior by influencing SCT factors in a large group of participants from across the county who were predominantly minority and disadvantaged men and women highly vulnerable to HIV infection and AIDS. The purpose of the present report is to describe findings of mediation analyses (Baron & Kenny, 1986) for this intervention trial. These analyses can determine the extent to which the SCT factors addressed in the intervention actually served as the active ingredients producing its effects and can provide important empirical evidence of the utility of SCT in HIV-prevention intervention.

Our specific hypotheses were that each of the seven SCT factors addressed in the intervention—(a) self-efficacy; (b) hedonistic, (c) partner reaction, and (d) self-evaluative outcome expectancies; (e) safer sex and (f) condom-use knowledge (condom mechanics and other sexual activities); and (g) condom-use skills—would mediate the intervention effectiveness as demonstrated by (a) being higher postintervention in the treatment arm than in the comparison arm and (b) attenuating the effect of treatment condition on sexual risk outcome when included in the model, compared with the model without the mediator(s). However, failure of any factor to demonstrate mediation was viewed as potentially valuable information because it might suggest the inclusion of superfluous intervention material that could be deleted in subsequently developed interventions.

Method

Participants

Study staff recruited participants in this study between January 1994 and February 1996 from the waiting rooms of sexually transmitted disease (STD) clinics ($n = 1,564$ men; $n = 862$ women) and health service organizations (HSOs; women only, $n = 1,280$) that serve low-income populations in inner-city neighborhoods in 37 clinics at seven sites across the United States. These research sites were located in (a) the Bronx and Harlem, New York City; (b) lower Manhattan, Brooklyn, and Northern New Jersey; (c) Baltimore, Maryland; (d) Atlanta, Georgia; (e) Milwaukee, Wisconsin; (f) Los Angeles, California; and (g) Orange and San Bernardino Counties, California. To be eligible for the study, participants had to be clients at the recruitment settings and at least 20 years old (STD clinics) or 18 years old (HSOs; participants from the HSOs were also all women). In addition, they had to report having had unprotected sexual intercourse in the previous 90 days and had to meet at least one of the following HIV risk criteria (without specifying which): having had sex with one or more new

sexual partners, having more than one sexual partner, having had an STD, having had sex with someone known to have other sex partners, or having had sex with someone they knew injected drugs or was infected with HIV. Of 11,189 persons found to be eligible, 6,575 (59%) returned and completed a baseline interview. A total of 3,706 participants (56% of those completing the baseline interview) were randomized and received at least one intervention session. Most participants were of African American (68%) or Hispanic (20%) ethnicity; detailed demographic and risk characteristics of the sample have been reported elsewhere (The NIMH Multisite HIV Prevention Trial Group, 1997, chap. 3).

Trial Design Overview

Screening and recruitment were conducted in person in clinic waiting rooms. Those found to be eligible were invited to undergo a baseline interview on a subsequent day. Informed consent was given prior to the baseline interview. This interview elicited information concerning sociodemographic characteristics, sexual behavior, alcohol and other drug use, STD symptoms, and HIV testing. Participants were paid for these interviews. When a sufficient number of individuals had been interviewed to form two groups of at least 4 participants each, all were invited to attend a small-group intervention session. Participants were randomly assigned to one of two conditions at this time. In the control condition, participants received a 1-hr HIV education session in which they viewed an HIV informational videotape; this was followed by a brief question-and-answer period. Participants assigned to the intervention condition, called Project LIGHT (Living in Good Health Together), were asked to attend seven 90- to 120-min small-group HIV risk reduction sessions, scheduled twice weekly. Project LIGHT was based on social–cognitive behavior change principles and emphasized the development, practice, and personal application of risk reduction strategies. This intervention provided information about outcomes to expect regarding condom use and nonuse as well as modeling, individualized practice, and goal setting with feedback. Skill-building activities focused on condom use, condom negotiation, and sexual self-control. The intervention is described in detail elsewhere (The NIMH Multisite HIV Prevention Trial Group, 1997, chap. 4). Attendance at the intervention sessions was generally quite good; the average number of intervention sessions attended was five, and 63% of the participants assigned to the intervention group attended six or all seven sessions.

Follow-up interviews were conducted at 3, 6, and 12 months following the intervention. Most of the information collected at baseline was also collected at each follow-up time point. Social–cognitive mediators were assessed at the 3-month interview. Although assessing mediators prior to randomization (i.e., at baseline) enables more reliable evaluation of the effect of the intervention on those factors, in the present study mediator assessment was delayed until postintervention because of concern that a baseline assessment that included mediators might be reactive (see O'Leary et al., 1998, for a report of pilot work conducted prior to the present study). However, the similarity of the participants randomized to the two conditions (The NIMH Multisite HIV Prevention Trial Group, 1998) lends confidence to our presumption of equivalence for the SCT variables at baseline. Completion rates for follow-up interviews were 82% or greater for participants in both the intervention and control conditions across all follow-up assessment points. This relatively high rate of retention was due in part to the fact that participants were not randomized until they had presented for an intervention session.

Measures

Sexual Risk Behavior

Participants reported their sexual behavior for the 3 months prior to each assessment point. Participants were first asked how many people they had had sex with during the past 90 days. If the number was five or fewer, specific information was collected about the characteristics of each partner

(if six or more partners were reported, information was collected for the five most recent partners). Then, focusing on specific partners, one at a time, participants were asked whether, and how many times, they had had vaginal and anal intercourse with that partner during the reference period. In addition, for those indicating they had had either kind of sex, the participant was asked for each instance whether a condom was used. Summing over instances and partners, the variables used in outcome analyses included (a) consistent (100%) condom use or abstinence, reflecting optimal risk reduction; (b) proportion of intercourse acts during which a condom was used; and (c) number of unprotected intercourse acts.

Social–Cognitive Mediators

Safer sex self-efficacy. A large empirical literature suggests a causal relationship between self-efficacy—a person's confidence that she or he can accomplish a specific task—and a variety of health risk behaviors, including condom use and contraception. Correlations between self-efficacy and behavior are strongest when the self-efficacy measures are tailored not only to specific risk behaviors but also to situational factors likely to be associated with those risk behaviors for the population of interest. Therefore, qualitative interviews were conducted with several dozen men and women from the target populations to ascertain situational factors associated with their last instance of unsafe sex. Data were analyzed separately for men and women, and four dominant situational factors were identified for each gender. The self-efficacy items are conceptually equivalent for men and women, but the four situations differed. Items reflecting four dimensions of self-efficacy were developed, and, for each scene, participants were asked whether they had confidence that they could (a) "bring up the issue of condoms or safe sex in conversation," (b) "convince this partner that the two of you should use a condom or have safe sex, even if s/he says 'I hate those things,'" (c) "convince your partner that the two of you should use a condom or have safe sex even if you both prefer doing it with the feel of bare skin," and (d) "refuse to have sex or leave the situation if s/he won't allow use of a condom or have safe sex." As a result, four self-efficacy items were rated on an 11-point scale ranging from 0 (*not at all confident*) to 10 (*completely confident*) in each of the four identified situations. We created separate scales reflecting the four dimensions by averaging across scenes as well as a total scale that averaged across dimensions and scenes. Thus, five indices of self-efficacy were derived from these items—an overall index (.92/.91) that represents the average over all 16 items (4 scenarios × 4 questions per scenario) and four subscales that each represented the average over the questions measuring the four self-efficacy dimensions as follows: for conversation, coefficient $\alpha s = .71/.69$; for overcoming partner resistance, coefficient $\alpha s = .80/.73$; for overcoming hedonistic resistance, coefficient $\alpha s = .76/.75$; and for leaving the situation, coefficient $\alpha s = .80/.73$. Because these subscales were highly intercorrelated ($r = .57–.81$), the overall index was used for the present analyses.

Condom-use outcome expectancy. A growing empirical literature indicates that outcome expectations (OEs) are also an important influence on motivation to engage in health-protective practices. OEs are beliefs about the likelihood of outcomes occurring as a result of engaging in a behavior. Social–cognitive theory clearly delineates three domains of relevant OEs: physical, social, and self-evaluative (Bandura, 1986; O'Leary, 1992). All three were assessed based on experience with the pilot data. Physical (hedonistic) OEs are expectations regarding physical pleasure (or lack thereof) associated with condom use. Social OEs are expectations regarding the sexual partner's potential positive and negative reactions to the suggestion of condom use. Self-evaluative OEs are anticipated positive or negative feelings about self as a result of using (or not using) condoms. These three OE dimensions were assessed using scales comprising several items scored on 5-point Likert scales, selected on the basis of psychometric analyses of pilot data. Hedonistic OEs were assessed with four items (coefficient $\alpha = .81$); an example item is "Condoms ruin the mood." Seven items assessed partner reaction OEs (coefficient $\alpha = .73$); an example is

"My sex partner would get mad if I said we had to use a condom." Self-approval OEs were assessed with three items (coefficient α = .63); an example is "I would feel more responsible if we used a condom." The 5-point scale used to rate the items ranged from *strongly disagree* to *strongly agree*. Higher scores on the scales indicate more positive OEs.

Safer sex knowledge. The most basic personal determinant in the social–cognitive theoretical framework is knowledge, which is a necessary but not sufficient condition for behavior change. Data from pilot studies with the target populations indicated very high levels of knowledge about routes of HIV transmission but lower levels of knowledge regarding recommended HIV prevention practices. Therefore, the pilot data were used to develop a scale comprising eight dichotomous (safe sex–not safe sex) items to assess knowledge of safer sex practices. Analyses of these items on the basis of item response theory (Thissen, Steinberg, & Wainer, 1993) indicated unignorable multidimensionality. Results from factor analysis were similar. Because the scale items are dichotomous, a tetrachoric correlation matrix was formed prior to performing both a principal-components and a maximum-likelihood factor analysis. Using the Kaiser-Guttman rule based on eigenvalues greater than one (Guttman, 1954) and judging from the scree plot, both factor methods indicated that two factors were present. Thus, the Safer Sex Knowledge scale was split into the two subscales used here: Condom Mechanics (knowing how to use condoms properly; five items; coefficient α = .53) and Other Sexual Activities (three items; coefficient α = .36). The correlation between these two subscales was quite low (.07). An example of a Condom Mechanics item is "having sex with a condom with an oil-based lubricant." The three items on the Other Sexual Activities scale were "having two partners and always using condoms with both," "mutually masturbating," and "having anal sex with a latex condom." Participants received one point for each item answered correctly (i.e., answers describing safe behavior) and no points for items answered incorrectly (i.e., answers describing unsafe behavior). Each scale score represents the proportion of items that the participant answered correctly times 100.

Condom-use skills assessment. Because condom use is central to prevention of the spread of HIV infection, we included a behavioral assessment of participants' condom-use skills. Interviewers asked participants to demonstrate the use of a condom by performing the following actions while interviewers observed and recorded their responses: selecting a water-based (not an oil-based) lubricant, selecting a latex (not natural) condom, applying a condom to a penis model (pinching the tip and unrolling in the correct direction all the way to the base), removing the condom from the model, and other relevant components of condom use. We created an eight-item scale (coefficient α = .62) on which each item was scored 0 if the participant did not demonstrate the skill and 1 if he or she did. Because the total scale score is the sum of the items scored 1 divided by the number of items, the total score represents the proportion of the component skills the participant demonstrated correctly. Analyses guided by item response theory suggested that these items make up a single scale.

Statistical Analyses

Mediation analysis attempts to demonstrate that the active ingredients thought and designed to produce the intended effect are in fact related to that effect. In the case of the present study, the SCT factors of expected outcomes of condom use, skills, confidence in those skills (self-efficacy), and relevant knowledge domains were designed to be enhanced by the intervention and expected to mediate behavior change in response to it. Specifically, the mediators of interest were the self-efficacy summary variable, the three condom-use OE variables (partner reaction, self-approval, and hedonistic), the two Safer Sex Knowledge subscales (Condom Mechanics and Other Sexual Activities), and the condom-use skills assessment measure.

To address the question of mediation, two steps are required (Baron & Kenny, 1986): (a) Determine whether the intervention is related to each

hypothesized mediator, and (b) determine whether the intervention effect is reduced when the hypothesized mediators are included in a model looking at the intervention effect on a behavioral endpoint. All three sexual risk variables were initially used for the second step of the analysis. However, because results were very similar for all three variables, only results based on consistent condom use or abstinence are reported here. Consistent condom use or abstinence was examined as the focal outcome because it is the only measure of complete risk reduction. Partial risk reduction (as evidenced by a reduction of unprotected sex acts) is of unknown importance, particularly in the absence of detailed information regarding self and partner serostatus and other partner characteristics. (The correlations among these endpoints at each follow up were very high, ranging in absolute values from .84 to .87.) In the first step, linear regression models were used to determine whether intervention assignment predicted mediator score. Models were fit one at a time to the value of each continuous mediator scale score measured at the 3-month follow-up interview, and, in addition to an indicator for group assignment (intervention or control), each model included effects for study population and study site.

In the second step, logistic regression repeated-measures models were fit to the dichotomous outcome (1 if 100% condom use or abstinence, 0 if not). Like the other behavioral endpoints, this outcome was measured at each of the three follow-up interviews. Through the use of repeated-measures models, the effects of the intervention and the mediators were considered in relation to the outcome at all three time points at once. The logistic regression models were fit using generalized estimating equations methodology, which accounts for the correlation of measures on the same participant and assumes missing data are missing at random (Diggle, Liang, & Zeger, 1994).[1] The logistic regression models were implemented using the statistical software package SUDAAN (Shah, Barnwell, & Bieler, 1996). Thus, participants with data from one to all three follow-up visits were included. First, a model that did not include the mediators was fit to consistent condom use or abstinence to estimate the intervention effect unadjusted for the mediator effect. Next, a model was fit that included the 3-month values of all seven mediator variables. In addition to group assignment, both models included effects for study population, site, age (continuous), race/ethnicity (four categories: Hispanic, not Black; Hispanic, Black; not Hispanic, not Black; not Hispanic, Black), high school degree (yes or no), and time (assessment point). The parameter estimates for the group assignment indicator from the models with and without the mediators were subtracted and the statistical significance of the reduction in the intervention effect was determined using methods reported by Freedman, Graubard, and Schatzkin (1992). All parameter estimates reported are nonstandardized regression coefficients (B).

Results

Effect of Treatment on Sexual Behavior

As presented in the major outcome article (The NIMH Multisite HIV Prevention Trial Group, 1998), the intervention was signifi-

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[1] The assumption that data were missing at random is justified for several reasons. First, attrition was equivalent for the treatment groups at the assessment points, being one percentage point apart at all three time points. Second, participants with high risk behavior at baseline—including commercial sex work, drug use, and past sexual abuse—were no more likely to be lost to the study (miss a visit and not come back) than others. It should also be noted that we checked the impact of missing data on the intervention effect (not, of course, the topic of the present report) using a number of different imputation methods (described in The NIMH Multisite HIV Prevention Trial Group, 1998), which would be expected to produce more conservative results (e.g., imputing baseline risk values), and we continued to find an intervention effect.

cantly associated with increases in consistent condom use or abstinence. At the 3-month follow-up, 27% of control participants and 42% of intervention participants were consistently safe. The corresponding figures at 6 months were 33% and 44%, and at 12 months, 34% and 43% (all $ps < .0001$).

Correlational Analyses of Mediator Variables

Table 1 shows the intercorrelations of the mediators, assessed at the 3-month follow-up interview. For the most part, correlations are low to moderate, indicating that they represent relatively distinct constructs and reducing concerns about multicollinearity. Separate analyses of intervention and control group correlations indicated stronger associations for the intervention group but again low-to-moderate correlations (between −.01 and .33).

Mediation Analyses

The mediation analysis steps outlined above were performed in order. Participants who had a baseline interview, who were eligible and randomized, and who had a 3-month interview made up the population that could be included in the analysis. Of the 3,706 participants who had a baseline interview and were randomized, 2,970 (80%) also had a 3-month interview. Of these, 1,811 were women. Despite their completion of the 3-month interview, variables of interest were missing for some individuals because of missing responses for the relevant questionnaire items. Exclusions from the 2,970 are noted below.

Effects of the Intervention on Mediator Variables

In the first step of the analysis, models were fit to each mediator as the outcome to determine whether the intervention affected the mediator—that is, did participants in the intervention have higher scores on the hypothesized mediating variables than those assigned to the control condition? Between one and all seven mediator values were missing for 104 people. Depending on the mediator considered, data from between 2,908 and 2,931 participants were included in each model.

Unadjusted means for each mediator by treatment group are given in Table 2. All seven mediators were significantly higher among intervention condition participants than among control condition participants (all $ps < .0001$) after adjusting for study population and site in a linear regression model. Thus, the first condition for the establishment of mediation was satisfied.

Table 2
Level of SCT Factors at 3 Months by Treatment Group

Mediator	Intervention (n = 1,518)		Control (n = 1,415)	
	M	SE	M	SE
Self-efficacy (0–10)	7.4	.05	7.1	.06
Hedonistic OE (1–5)	3.5	.02	3.2	.03
Partner reaction OE (1–5)	3.5	.02	3.3	.02
Self-approval OE (1–5)	3.4	.03	3.1	.03
SSK—Condom Mechanics (0–100)	80.0	.006	69.0	.007
SSK—Other Sexual Activities (0–100)	80.0	.007	70.0	.008
Condom-use skills (0–100)	86.0	.004	74.0	.005

Note. All seven scale scores were missing for 35 participants, and between one and five scale scores were missing for an additional 69 participants. ns used in the calculation of each mean ranged from 1,512 to 1,518 in the intervention group and from 1,396 to 1,415 in the control group, depending on which scale mean was being calculated. All differences were statistically significant, $p < .0001$. SCT = social–cognitive theory; OE = outcome expectancy; SSK = Safer Sex Knowledge Scale.

Attenuation of Intervention Effect Using Statistical Adjustment of Mediators

In the second step, repeated logistic regression models were fit to the dichotomous outcome consistent condom use or abstinence measured at the 3-, 6-, and 12-month assessments. Participants included in this analysis must have had at least one follow-up interview in which the outcome was measured and had nonmissing values of all of the 3-month mediators. A majority of the 2,968 participants included (80%) had all three assessment interviews. Of the total participants, 2,846 were included at 3 months, 2,716 at 6 months, and 2,574 at 12 months.

First, the model was fit without the mediators to estimate the intervention effect unadjusted for the mediator effect. Next, the seven hypothesized mediator variables were added and the model refit. After adjusting for study population site, age, race/ethnicity, and education (high school degree or not), group assignment was highly significant ($p < .0001$). Intervention participants were more likely than control participants to report consistent condom use or abstinence (odds ratio [OR] = 1.68; 95% confidence interval [CI] = 1.49–1.90). The nonstandardized regression coefficient for the intervention effect in this model was .52 (SE = .06). After the seven mediators were added to the model, presented in Table 3,

Table 1
Intercorrelations of Multisite Trial Social–Cognitive Constructs

Construct	1	2	3	4	5	6	7
1. Self-efficacy	—	.23	.32	.15	.11	.03	.15
2. Hedonistic OE		—	.32	.02	.16	.05	.14
3. Partner reaction OE			—	.12	.05	.01	.14
4. Self-approval OE				—	.08	.04	.09
5. SSK—Condom Mechanics					—	.07	.38
6. SSK—Other Sexual Activities						—	.19
7. Condom-use skills							—

Note. All correlation coefficients are significantly different from 0 except .03 in row 1, .02 in row 2, and .01 in row 3. OE = outcome expectancy; SSK = Safer Sex Knowledge Scale.

Table 3

Logistic Regression Model Fit to Consistent Condom Use or Abstinence With Mediators Included

Variable	Model with all mediators at once[a]				Model with a single mediator[b]	
	B^c	SE	OR	95% CI	Intervention B	Mediator B
Intervention	.33	.07[d]	1.39	1.21–1.59		
Self-efficacy	.08	.02	1.08	1.04–1.12	.48	.18
Hedonistic OE	.15	.04	1.16	1.08–1.25	.45	.32
Partner reaction OE	.50	.05	1.65	1.51–1.81	.44	.65
Self-approval OE	.30	.03	1.35	1.27–1.43	.45	.35
SSK—Condom Mechanics	.13	.15	1.14	0.85–1.52	.47	.44
SSK—Other Sexual Activities	−.34	.12	0.71	0.57–0.90	.56	−.28
Condom-use skills	.32	.20	1.38	0.93–2.06	.43	.78

Note. OR = odds ratio; CI = confidence interval; OE = outcome expectancy; SSK = Safer Sex Knowledge Scale.
[a] Nonstandardized regression coefficients (B) and ORs for variables shown from a logistic regression model, which included group assignment indicator (intervention) and all seven mediators at once as well as effects for study population, study site, age, race/ethnicity, and education (high school degree or not). [b] Intervention and mediator nonstandardized regression coefficients from each of seven logistic regression models, which included group assignment and the single mediator indicated as well as effects for background covariates as above. Each mediator was significantly related to outcome ($p < .01$ for each) when included without the other mediators. [c] B for intervention effect with no mediators = .52. [d] Intervention effect still significant, $p < .001$.

the intervention parameter estimate was reduced to .33 ($SE = .07$), which was still highly significant ($p < .0001$; OR = 1.39; 95% CI = 1.21–1.59).

Thus, addition of mediator variables designed to assess components of the intervention program reduced the intervention effect by approximately 36% (a significant reduction; $p < .0001$), suggesting that the success of the intervention was at least partially due to changes in the SCT elements measured. After adjustment for the others, each mediator, except for knowledge of condom mechanics and condom-use skills, was significantly related to consistent condom use or abstinence. Additionally, we assessed the possibility that the mediators might predict the outcome differentially across treatment groups and examined the Intervention × Mediator interactions. The model was refit with the usual variables plus the seven interactions. No significant interactions were detected (*ps* ranged from .1 to .9), indicating that the effect of each mediator did not vary by treatment group.

Table 3 also presents parameter estimates for the intervention effect that resulted when each individual mediator alone was used to adjust the intervention effect, an indication of the contribution of each mediating factor to the overall attenuation of intervention effect. When considered individually, a statistically significant relationship was found between each of the seven mediators and consistent condom use or abstinence (all *ps* ≤ .01). With one exception, each variable contributed somewhat to the mediation effect as seen by the reduction of the intervention regression coefficients from .52 to between .43 and .48, depending on the mediator. The variable that deviated from this pattern was knowledge about other sexual activities. Adjusting for this latter mediator alone resulted in an enhancement rather than reduction of the intervention effect. In the single-mediator model as well as in the model with all mediators included at once, knowledge of sexual activities was associated with a decrease in the probability of consistent condom use or abstinence rather than an increase as was seen with the other mediators. We performed the same analysis

with each of the three items in the scale separately to determine whether one item might account for the effect. Although all three items produced negative betas, only "mutually masturbating" was statistically significant ($\beta = -.17$, $p = .04$).

Significant mediation by variables designed to assess the various components of the program suggests that the success of the intervention was at least partially due to changes in self-efficacy, skills, OEs, and knowledge. Of interest, the SCT factors did not account for intervention effectiveness completely, at least as operationalized and assessed in this study. Thus, other unmeasured factors also contributed to the intervention's impact on sexual risk reduction. Furthermore, the loss of statistical significance for condom-use knowledge and skills after adjustment for the other mediators may suggest that although these factors are necessary, they are not sufficient for consistent condom use and that it is important to include intervention components aimed at the other areas.

Although not of primary importance to the present article, a number of secondary issues were also of interest. Because it has frequently been argued that women are less able to respond to HIV risk reduction interventions than men (e.g., O'Leary, 2000), we were interested in testing for moderation by gender. The interaction of Gender × Treatment Condition on the sex behavior outcome was not significant, indicating that men and women were not differentially responsive to the intervention. We also wished to explore the possibility that results may have varied by ethnic group. In our model fit to the outcome consistent condom use (with all covariates included except the mediators), we found no evidence that the intervention effect varied by ethnic group (nonsignificant Ethnicity × Intervention interaction, $p = .5$). That is, intervention participants were more likely to report consistent condom use than control participants regardless of ethnicity. Ethnicity × Mediator interactions were then tested in the model, which additionally included the mediators. No significant interactions were detected, implying that the effect of each mediator did

not vary by ethnic group (ps ranged from .2 to .9). Finally, a series of models without and then with all mediators included were fit among participants of each ethnic group separately. In all groups, we saw the same general pattern as in the population as a whole: There was a significant intervention effect before addition of the mediators, which was reduced after the mediators were added.

Discussion

The present analyses provide evidence that the Project LIGHT intervention worked in part for the reasons it was designed to. The SCT factors of expected outcomes regarding hedonistic effects of condom use, partner reaction, self-approval, self-efficacy, and condom mechanics all demonstrated mediation effects. It is noteworthy, though, that some of the effects of the intervention on mediators (such as self-efficacy) were quite small.

Most of the social–cognitive constructs behaved as mediators: They were increased by the intervention and at least partially accounted for its behavior change effects. However, knowledge about other safer sex techniques militated against mediation (i.e., enhanced, rather than reduced, the intervention effect when included in the model). These items included mutual masturbation (safe), using latex condoms for anal sex (safe), and using condoms with multiple partners (safe). It is possible that individuals with particularly sophisticated knowledge about the transmission of HIV responded to the intervention with strategies more complex than those used here, such as engaging in HIV antibody testing and "negotiated safety" (Kippax et al., 1997; O'Leary, 1999), using withdrawal, or using complex partner selection strategies (Wolitski & Branson, in press).

In the present study, expected outcomes, such as expected partner reaction and self-evaluative outcomes, were stronger mediators than self-efficacy. This might be due in part to the fact that the intervention's skill-building components were weakened by the group format of the intervention. Skill building is most effective when it is tailored to the individual's specific life circumstances. In the Project LIGHT intervention, skill building took place in groups half the size of the overall group (each facilitator worked with half of the participants), and facilitators tried to work with each individual, but time limitations precluded intensive work. This view is supported by the relatively small effect of the intervention on self-efficacy (see Table 2). To be maximally effective, skill building should include self-monitoring (not done in Project LIGHT because of low literacy levels of participants) and antecedent identification and management (done, but as just described, not intensively).

One possible function of intervention mediation analysis could be to identify superfluous intervention components that appear not to account for intervention effectiveness. This would permit streamlining of the intervention and possibly increasing its cost-effectiveness by reducing its delivery time. An obvious candidate for this streamlining would be intervention components conveying alternatives to consistent condom use because they may have been responsible for the "knowledge of other safer sex techniques" finding. For example, the intervention included recommendations for achieving safer pregnancy by engaging in joint HIV antibody testing and establishing seroconcordance prior to engaging in unprotected sex. It is possible that some participants generalized this strategy into generalized negotiated safety agreements with

partners. It might be argued, however, that this is not an undesirable consequence of an HIV risk reduction intervention and that more sophisticated assessment strategies should be used to measure it more effectively.

The other potential mediators all appear to have contributed to the intervention effect, each reducing the regression coefficient into the .40s, with the cumulative mediation effect a combination of the mediation effects of the mediators. This finding suggests that the intervention components addressing each of these mediators are useful and enhance the effectiveness of the intervention.

Although the social–cognitive constructs accounted for a substantial portion of variance in behavior change, they did not account for all or even most of it. This could be because we failed to adequately assess all of the relevant social–cognitive mediators or because of measurement error; however, it is clear that other factors were additionally influential. It is possible that the intervention had unintended positive effects, such as improving participants' sense of self-worth, enhancing social support, or improving community norms for condom use, and that these changes in turn facilitated behavior change. It is also possible that socially desirable responding due to experimental demand characteristics accounts for some of this unaccounted-for self-reported behavior change. It should be noted that our study's comparison condition controlled for demand but not for attention.

How much support for SCT can be ascribed to the present results? Our study design does not permit strong inference in that it fails to compare two theories. Other theoretical models commonly used in health behavior interventions, such as the health belief model (Rosenstock et al., 1994) and the theory of reasoned action (Fishbein et al., 1994; later "theory of planned behavior," Ajzen, 1988) share common elements with SCT, notably in their cost-benefit aspects. SCT goes beyond these in its inclusion of a focus on skills and self-efficacy as well as on self-evaluative outcomes. However, future work in this area should attempt to account for variance in intervention effectiveness not accounted for by the present theoretical model and its instantiation and should compare different theoretical models for effectiveness.

Tests of mediation for the sorts of theory-driven strategies used in this study have seldom been reported. To conduct informative mediation analyses in the context of intervention evaluation research, it is vital that the theoretical constructs addressed in the intervention also be well-assessed in evaluation components of a study. This can be achieved regardless of whether the theoretical causes of behavior change derive from established health behavior theories, as here, or whether they are based on previously untested approaches. Only careful analyses of the processes of behavior change can refine intervention approaches to be as effective, focused, and cost-effective as possible.

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