

# The Efficacy of a Relationship-Based HIV/STD Prevention Program for Heterosexual Couples

Nabila El-Bassel, DSW, Susan S. Witte, PhD, Louisa Gilbert, MS, Elwin Wu, PhD, Mingway Chang, MA, Jennifer Hill, PhD, and Peter Steinglass, MD

Sustained rates of heterosexually acquired HIV infection in the United States, particularly among African American and Latina women,<sup>1</sup> have mobilized efforts to develop alternative prevention strategies, including couple-oriented prevention models.<sup>2–5</sup> Individual or group intervention efforts often fail to demonstrate increased barrier method use, particularly among women in long-term intimate relationships.<sup>6–11</sup> New methods that recognize the context of relationship dynamics and focus on couple communication patterns may enable women to initiate and sustain condom use with long-term intimate partners.<sup>10,12</sup>

Couple counseling has been found to be efficacious in promoting HIV counseling and testing, as well as condom use.<sup>13–18</sup> However, most of the studies that reached this finding were conducted outside the United States. Relationship-based risk reduction interventions encourage collaboration to address mutual needs, and these may be more effective for intimate partners than non-relationship-based interventions. Couple-based therapy literature suggests that relationship-based interventions can be provided either to 1 partner alone or to the couple together.<sup>19,20</sup> Relationship-based interventions delivered to the couple together may be more effective for several reasons. First, research suggests that individuals acting unilaterally to introduce safer sexual practices may be confronted with negative reactions, including isolation, threats to terminate the relationship, or physical violence.<sup>21–23</sup> Second, the expectation that individuals can convey new knowledge and skills to their partners assumes that they have the requisite relationship-specific communication skills. Third, the supportive environment of couple counseling may enable intimate partners to feel safer disclosing highly personal information (e.g., extradyadic relationships, sexually transmitted disease [STD] histories) to their partners

**Objectives.** This study examined the efficacy of a relationship-based HIV/sexually transmitted disease prevention program for heterosexual couples and whether it is more effective when delivered to the couple or to the woman alone.

**Methods.** Couples (n=217) were recruited and randomized to (1) 6 sessions provided to couples together (n=81), (2) the same intervention provided to the woman alone (n=73), or (3) a 1-session control condition provided to the woman alone (n=63).

**Results.** The intervention was effective in reducing the proportion of unprotected and increasing the proportion of protected sexual acts. No significant differences in effects were observed between couples receiving the intervention together and those in which the woman received it alone.

**Conclusions.** This study demonstrates the efficacy of a relationship-based prevention program for couples at risk for HIV infection. (*Am J Public Health.* 2003;93:963–969)

that will enable them to gain a more realistic appraisal of their risks for HIV/STD transmission as a couple.<sup>24</sup>

Project Connect was a randomized clinical trial designed to examine 2 aims. The primary aim was to test whether a 6-session HIV/STD relationship-based intervention would be equally, more, or less efficacious in increasing condom use, decreasing STD transmission, and reducing the number of sexual partners among heterosexual couples in comparison with a control condition consisting of a single session of HIV/STD education. The secondary aim was to examine whether the intervention would be more efficacious when the woman and her partner received the relationship-based intervention together or when the woman received it alone.

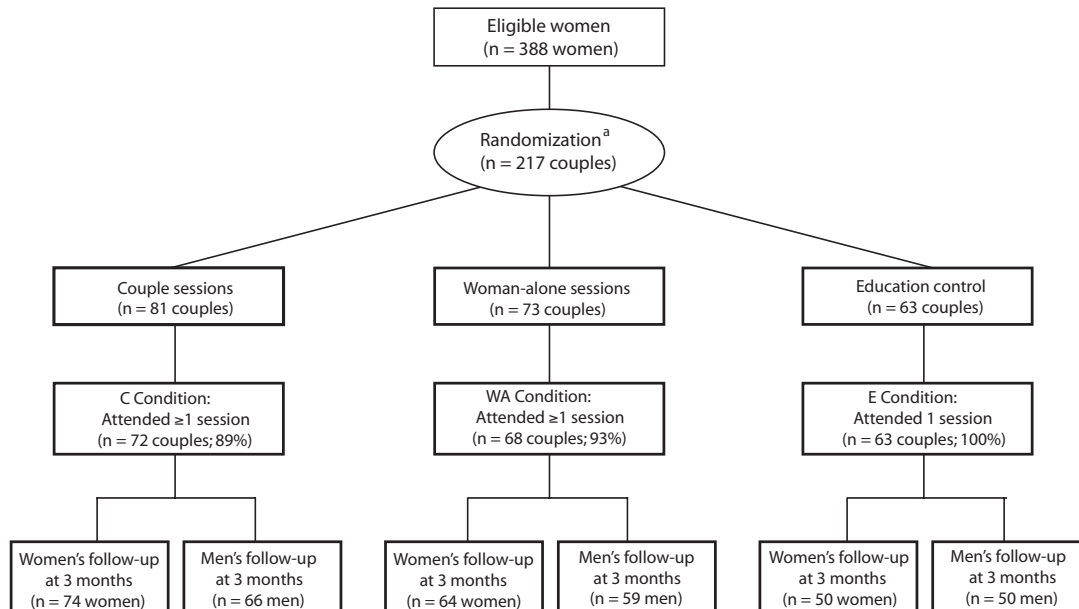
## METHODS

### Participants

The study was conducted between 1997 and 2001. Women were recruited from hospital-based outpatient clinics in Bronx, NY. Bilingual (Spanish/English) recruiters approached women in waiting rooms. Those interested completed a 10-minute face-to-face eligibility screening. Eligible women were asked to recruit their regular male sexual

partners. To gain his cooperation, the woman was given a letter describing the project that could be shared with her partner.<sup>25</sup>

A woman was eligible for Project Connect if she (1) was aged between 18 and 55 years; (2) had a regular male sexual partner whom she identified as a boyfriend, spouse, or lover; (3) was in a long-term relationship, defined as (a) involvement with this partner for the past 6 months and (b) intent to stay with him for at least 1 year; (4) had had at least 1 episode of unprotected vaginal or anal sexual relations with this partner in the past 30 days; (5) did not report any life-threatening abuse by this partner within the past 6 months<sup>26</sup>; and (6) was a patient at one of the hospital's outpatient clinics. To be eligible, a woman also had to know or suspect that her partner met at least 1 of the following HIV/STD risk criteria: (1) he had had sexual relations with other men or women in the past 90 days; (2) he had been diagnosed with or exhibited symptoms of an STD in the past 90 days; (3) he had injected drugs in the past 90 days; or (4) he was HIV positive. At the end of the screening interview, female participants were asked to give written informed consent. Before the baseline interview, the male partners also were informed about the purpose of the study and asked to give written informed consent.



Note. C = couple, WA = woman-alone, E = education.

<sup>a</sup>During a review of scientific integrity, it was determined that a few assignment envelopes had been omitted accidentally, resulting in an imbalance in the sizes of the groups assigned to each condition. Potential imbalance and resultant bias in our data analyses were explored as described in the text.

**FIGURE 1—Overview of Project Connect.**

## Design

At baseline, simultaneous but separate interviews with gender-matched interviewers took place with each partner. Couples were then randomly assigned to 1 of 3 study conditions (Figure 1): (1) the *couple condition* (C), 6 weekly relationship-based sessions in which both a woman and her partner received the intervention; (2) the *woman-alone condition* (WA), in which only the woman received the same intervention; or (3) the *education control condition* (E), in which a woman alone took part in 1 HIV/STD information session. All women and men were asked to return for follow-up assessment 3 months after the final intervention or control session.

## Assessment

Trained interviewers administered an assessment, which covered sociodemographic characteristics, HIV serostatus, and HIV/STD risk behaviors. This assessment contained several primary endpoints: within the past 90 days the self-reported number of unprotected acts of vaginal intercourse with the study partner, proportion of protected acts of vagi-

nal intercourse with the study partner, self-reported number of STD symptoms, and number of sexual partners. Participants were asked about the number of times they engaged in vaginal intercourse with their study partner and the number of times either a male or female condom was used with this partner in the past 90 days.<sup>8,27</sup> Interview staff used a 90-day calendar to stimulate participants' recollection of events during this time frame.<sup>28</sup>

## Intervention Methods

The relationship-based intervention was designed by the research team in collaboration with community consultants who provided feedback on the recruitment and intervention components during a developmental phase preceding the clinical trial.<sup>25,29</sup>

Intervention content was both theoretically and empirically based on the AIDS Risk Reduction Model<sup>30</sup> and the ecological perspective.<sup>31</sup> The AIDS Risk Reduction Model is a conceptual framework for organizing behavioral change information and skills directed at HIV risk reduction. The ecological perspec-

tive emphasizes the various factors—from ontogenetic (individual), to micro/relationship, to macro levels—that play a role in basic human development and behavior, including establishment and maintenance of protective health behaviors.<sup>32–35</sup> This perspective provides a way to conceptualize a context- and relationship-specific approach to HIV risk reduction.<sup>34</sup> The intervention also was guided by prior findings and experience with an earlier National Institute of Mental Health multisite HIV/STD prevention trial.<sup>36</sup>

For both active conditions (C and WA), the content of the sessions was the same. To aid in ensuring uniformity, a manual was designed and used by the facilitators. Weekly 2-hour intervention sessions were conducted by a female facilitator. The intervention consisted of an individual orientation session and 5 relationship-based sessions.<sup>25</sup> The purpose of the orientation session was to increase motivation for attendance, normalize the need for relationship-based prevention, and reduce misperceptions about the intervention. Sex-matched facilitators conducted orientation sessions individually for active participants in

either intervention (i.e., both the male and female partners for couples assigned to C; only the female partner for couples in WA). The intervention sessions for both C and WA centered on the woman and her recruited partner, with a strong emphasis on the relationship context, including issues of intimacy and closeness in the relationship, the meaning of monogamy and trust, and how all of these factors act as barriers to HIV/STD protection.

The intervention emphasized the importance of relationship communication, negotiation, and problem-solving skills and highlighted how relationship dynamics may be affected by gender roles and expectations. The session content emphasized each couple's contribution to enhancing the future health of ethnic communities hardest hit by HIV/AIDS. The intervention combined content related to the New York State Department of Health hierarchy of safer sexual practices<sup>37–39</sup> and prevention of HIV and other STDs, as well as joint HIV testing.

The single HIV/STD educational control session lasted 1 hour and was provided immediately after baseline interviewing and randomization. Content was standardized by the showing of a videotape<sup>40</sup> followed by a brief question-and-answer period.

To ensure the fidelity of intervention delivery, facilitators completed standardized training, used structured intervention protocols, met on a weekly basis with clinical and task supervisors, and received routine monitoring (via audiotape) and feedback from an on-site supervisor. For evaluation of quality assurance, independent raters reviewed a random sample of 10% of the sessions for each facilitator.

### Data Analysis

The analyses presented here estimate intention-to-treat effects of 2 interventions derived from the primary and secondary aims of the study, respectively: (1) the effect of assignment to the active treatment condition (C or WA) versus assignment to the educational control condition (E) and (2) within those assigned to the active treatment condition, the effect of the delivery method, C versus WA.

In these analyses, the unit of analysis was the individual. It was recognized, however,

that these individuals were members of couples; thus, reported outcomes from each partner constituting a couple were not independent. Therefore, random-effects models, which accommodate within-group correlation structures,<sup>41–44</sup> were used. In this case, the random effects were incorporated into linear regression models. These models allow responses within a couple to be correlated but assume independence across couples. Generalized least squares estimates were obtained using the Stata (Stata Corp, College Station, Tex) statistical software package.

If assignment is random, one can obtain unbiased treatment effect estimates without performing covariance adjustment. However, inclusion of pretreatment attributes for theoretically important variables related to HIV risk behavior in regression models can create estimates of treatment effects with smaller standard errors<sup>45</sup> and can illuminate associations between the outcomes and critical background characteristics. Thus, baseline measures of outcome variables were included in the regression equations because these are highly likely to be correlated with reports at follow-up. In addition, gender and HIV status were included in the regression equations because differential outcomes for HIV prevention interventions have been demonstrated by gender and HIV status.<sup>18,46,47</sup>

Intention-to-treat analyses must include all couples that were randomized, including couples unavailable for follow-up assessment. The outcome data at follow-up have missing rates that vary by condition and outcome, ranging from a low of 14% (for C, number of sexual partners) to a high of 22% (for E, number of unprotected sexual acts and proportion of protected sexual acts). In addition, a few differences at baseline were found between couples who were available for follow-up and those who were not. For subjects assigned to E, there were statistically significant differences for the following baseline characteristics: women available for follow-up were less likely to be employed, were more likely to have made more than \$5000 in the past year, were more likely to have used noninjected drugs in the past 90 days, and reported fewer instances of unprotected sexual acts and a higher proportion of protected sexual acts compared with women not available

for follow-up. Men available for follow-up reported fewer instances of unprotected sexual acts than men unavailable for follow-up. For subjects in the WA group, women who provided follow-up data were less likely to have completed high school or to have a general equivalency diploma compared with women not available for follow-up. These differences across groups further argue against using a complete-case approach to adjustment for the missing data, because such an approach requires the assumption that no such differences exist.

We used multiple imputation (MI)<sup>48,49</sup> to deal with missing data. MI uses the information that is observed or measured for a participant to predict values of variables for which that individual's information is missing. MI relies on more plausible assumptions than do ad hoc imputation methods such as complete case analysis, missing value treated as failure, or last observation carried forward.<sup>50</sup> Moreover, because MI replaces each missing value with several imputed values, it can account for uncertainty about the missing values better than single imputation (thus leading to appropriate standard errors). MI was performed with the Amelia software package.<sup>51,52</sup>

### RESULTS

Consistent with other major HIV prevention trials,<sup>53</sup> 388 of the 2416 women screened (16%) met eligibility criteria. The main exclusion criterion at screening was not having a main male partner. From the eligible couples, 217 (56%) agreed to participate. The 2 primary reasons for nonenrollment of eligible women were that (1) the male partner refused ( $n=52$ ) and (2) the woman missed 2 appointments for baseline assessment ( $n=52$ ). Eligible participating couples and eligible nonenrollers were similar in age, education, marital status, and HIV risk behaviors.<sup>36</sup> Most participating couples (90%) completed baseline interviews within 30 days of screening. Among those assigned to C, 74% attended 1 or more sessions; 81% of the participants in the WA condition attended 1 or more sessions (Figure 1). There were no significant differences between those who completed at least 1 session and those who did not with respect to background and

**TABLE 1—Sociodemographic and Risk Behavior Characteristics at Baseline: Project Connect Study, Bronx, NY, 1997–2001**

	Female			Male		
	Couples (n = 81)	Woman Alone (n = 73)	Education (n = 63)	Couples (n = 81)	Woman Alone (n = 73)	Education (n = 63)
<b>Sociodemographic characteristics</b>						
Aged <25 y, %	9.9	8.2	9.5	7.4	9.6	7.9
African American, %	54.3	54.8	54.0	48.1	61.6	55.6
Latino, %	38.3	43.8	36.5	42.0	31.5	39.7
≥ High school or GED, %	42.0	37.0	55.6	44.4 <sup>a</sup>	61.1 <sup>a</sup>	54.0 <sup>a</sup>
Never married, %	67.9	57.5	52.4	56.8	54.8	54.0
Employed, %	11.1	15.1	17.5	24.7*	45.2*	34.9*
Income <\$5000, %	64.2	72.6	68.3	56.3 <sup>b</sup>	46.6 <sup>b</sup>	47.6 <sup>b</sup>
<b>Risk behavior characteristics</b>						
> 1 partner in past 90 days, %	24.7	23.3	14.3	13.6	16.4	12.7
Ever HIV tested, %	95.1	91.8	92.1	92.6	80.8	90.5
HIV positive, %	25.9	21.9	15.9	29.6*	16.4*	11.1*
HIV unknown, %	6.2	11.0	7.9	8.6*	19.2*	9.5*
0% condom use in past 90 days, %	64.2	71.2	76.2	69.1	69.9	79.4
Non-injection drug use in past 90 days, %	60.8 <sup>c</sup>	63.8 <sup>c</sup>	44.6 <sup>c</sup>	59.2 <sup>d</sup>	67.1 <sup>d</sup>	63.9 <sup>d</sup>
Injection drug use in past 90 days, %	11.1	5.5	6.3	12.5 <sup>e</sup>	5.5 <sup>e</sup>	4.8 <sup>e</sup>
Ever had STD, %	69.1*	60.3*	47.6*	56.8	60.3	49.2
STD symptoms in past 90 days, %	50.6	57.5	42.9	11.1	2.7	11.1
No. of unprotected sexual acts, mean	27.7	24.2	23.5	28.9	24.8	25.4
Percentage of protected sexual acts, mean	18.4	12.5	11.8	16.2	19.1	12.9

Note. GED = general equivalency diploma; STD = sexually transmitted disease.

<sup>a</sup>Sample sizes are 81, 72, and 63 for couples, woman alone, and education, respectively.

<sup>b</sup>Sample sizes are 80, 73, and 63 for couples, woman alone, and education, respectively.

<sup>c</sup>Sample sizes are 79, 69, and 56 for couples, woman alone, and education, respectively.

<sup>d</sup>Sample sizes are 76, 70, and 61 for couples, woman alone, and education, respectively.

<sup>e</sup>Sample sizes are 80, 73, and 63 for couples, woman alone, and education, respectively.

\*Significant difference between conditions at the  $P \leq .05$  level, with a  $\chi^2$  test of association.

HIV risk behaviors at baseline, with 1 exception: women assigned to C who attended at least 1 session had a significantly higher rate of 0% condom use (in the previous 90 days). With respect to adherence, 54% and 64% of those assigned to C and WA, respectively, attended all sessions.

### Sociodemographic Characteristics

Background characteristics at baseline across treatment groups are presented in Table 1, broken down by gender and experimental assignment. Participants across the 3 study arms were similar in demographics, HIV risk behavior, and baseline reports of the primary outcome variables. The only significant differences were seen for the employment and HIV-status variables among the

men and for the “ever had an STD” variable among the women. We controlled for the effect of these across-group differences in the analyses used to assess treatment effects.

### Intervention Efficacy Outcomes

Table 2 presents means and standard errors for 4 primary outcome variables (number of unprotected vaginal sexual acts with the study partner, proportion of protected vaginal sexual acts with him, number of STD symptoms, and number of sexual partners, in the past 90 days) at baseline and 3-month follow-up. If a participant reported zero instances of sexual acts with a study partner, the proportion of protected sexual acts was assigned a value of 100%, consistent with the data analysis plan in the National Institute of

Mental Health multisite HIV/STD prevention study.<sup>36</sup> The proportions of participants who reported no instances of sexual acts with their study partners were 13.2%, 14.7%, and 12.2% for those assigned to C, WA, and E, respectively; their rates did not significantly differ from each other. The largest changes from baseline to follow-up in mean outcomes across treatment conditions were found for the 2 condom-use variables. For these measures, on average, the participants in C and WA exhibited the safest behaviors, and the participants in the E condition exhibited the least safe behaviors. For the mean numbers of STD symptoms at follow-up, the highest STD symptom rates appeared for the WA group and the lowest appeared for the E group. However, as noted earlier, there were significantly higher numbers of STDs among participants assigned to the C and WA condition than among those in the E condition at baseline. The changes from baseline to follow-up in means across groups for the number of STD symptoms and the number of sexual partners were small relative to the associated variability/uncertainty.

Table 3 presents results from regression analyses specifically examining the effects of assignment to intervention versus control (i.e., C and WA vs E) and modality of intervention (C vs WA) with respect to primary outcome variables. The regression analyses indicate that for condom-use variables, participants assigned to either active intervention condition reported significantly safer behaviors, on average, compared with those assigned to the control condition. Among those assigned to either active intervention condition, there were no significant differences in outcomes as a function of intervention delivery mode.

Baseline HIV serostatus was a significant predictor of the proportion of protected vaginal sexual acts and the number of STD symptoms. For these models, positive HIV status was associated with a significant increase in the percentage of protected sexual acts and the number of STD symptoms (these could, of course, reflect conditions contracted before the start of the study but discovered afterward). As expected, the measures at baseline were significantly associated with the corresponding measures at follow-up for almost all variables of interest (the exception was num-



**TABLE 2—Means and Standard Errors of Outcomes<sup>a</sup> by Condition at Baseline and at 3-Month Follow-Up: Project Connect Study, Bronx, NY, 1997–2001**

	No. of Protected Sexual Acts, Mean (SE)		Percentage of Protected Sexual Acts, Mean (SE)		No. of STD Symptoms, Mean (SE)		No. of Sexual Partners, Mean (SE)	
	Baseline	Follow-Up	Baseline	Follow-Up	Baseline	Follow-Up	Baseline	Follow-Up
Total sample (N = 434)	26 (1.5)	16 (1.4)	15 (2)	43 (2)	0.58 (0.06)	0.49 (0.05)	1.5 (0.20)	1.9 (0.28)
Couples (n = 162)	28 (2.9)	16 (2.4)	17 (2)	44* (4)	0.62 (0.10)	0.52 (0.09)	1.8 (0.52)	1.6 (0.17)
Woman alone (n = 146)	25 (2.7)	12* (2.0)	16 (2)	50* (4)	0.67 (0.11)	0.55 (0.09)	1.3 (0.07)	2.6 (0.79)
Education (n = 126)	25 (2.0)	20 (2.6)	12 (2)	33 (5)	0.41 (0.08)	0.39 (0.07)	1.2 (0.04)	1.5 (0.22)

Note. STD = sexually transmitted disease, SE = standard error.

<sup>a</sup>All outcome variables refer to self-report about the 90-day period before assessment.

\*Significant difference compared with the education condition at the  $P \leq .05$  level.

ber of sexual partners). In the STD symptoms model, adjusting for the baseline levels of this measure erased the anomalous treatment differences apparent in the unadjusted outcome means.

Several analyses also were performed that explored the sensitivity of the model formulation (results of these analyses are available upon request from the first author). The length of the relationship and interactions between gender and the treatment condition also were examined; none of these variables was significant, so they were omitted from the final analyses. For variables that differed among groups at baseline (e.g., men's employment status and women's STD history), the coefficients for these additional baseline characteristics were not significant in regression

models incorporating these variables, and the results from analyses with addition baseline characteristics did not alter our substantive conclusions. For the proportion of protected sexual acts, however, the coefficient for the intervention condition contrast (i.e., C or WA vs E) did drop slightly, concurrent with a rise in the associated standard error. Together these changes resulted in a  $P$  value of .06 rather than the original .05. This change is likely owing to the loss of degrees of freedom resulting from the inclusion of 2 nonpredictive variables in the model.

## DISCUSSION

To our knowledge, Project Connect was the first randomized clinical trial of a relationship-

based HIV/STD prevention intervention for heterosexual couples. These findings show that 6 sessions of a relationship-based HIV/STD prevention intervention were efficacious in reducing the number of unprotected sexual acts and increasing the proportion of protected sexual acts in comparison with a control condition consisting of 1 session of HIV/STD information. No significant differences in outcomes were observed between women who received the intervention together with a partner and women who received the intervention alone.

Three factors may explain the lack of differences in outcomes between the 2 active conditions. First, the content of the sessions in both active conditions targeted the intimate relationship as the focus of change. The relationship context received primary emphasis even when a woman received the intervention without her partner. All exercises in each session and homework assignments were geared toward the recruited study partners. In both active conditions, the woman was asked to practice with her partner the communication, negotiation, and condom skills that she learned in the sessions. The intervention enabled women and their intimate partners to discuss sexual issues and to explore together how they can protect themselves from HIV/STDs. Second, we speculate that couples who enrolled in the study were self-selected because of recruitment by the female partner. This may have been 1 of the reasons that the male partner in either condition was receptive to the woman's desire that they protect each other. Another explanation for the efficacy of both active conditions may be a "dose-effect"

**TABLE 3—Regression Analysis With Random Effects Estimates: Project Connect Study, Bronx, NY, 1997–2001**

	Unstandardized Regression Coefficient (SE) (P)			
	No. of Unprotected Sexual Acts	Percentage of Protected Sexual Acts	No. of STD Symptoms	No. of Sexual Partners
Intervention vs education <sup>a</sup>	-4.63* (1.86) (.01)	0.07* (0.035) (.050)	-0.02 (0.06) (.72)	0.38 (0.41) (.36)
Couples vs woman alone <sup>b</sup>	1.84 (1.50) (.22)	-0.04 (0.03) (.15)	-0.03 (0.05) (.52)	-0.48 (0.33) (.15)
Gender <sup>c</sup>	-0.69 (2.12) (.74)	-0.00 (0.04) (.99)	-0.18* (0.09) (.03)	-0.49 (.56) (.38)
HIV positive vs negative	-4.58 (3.18) (.15)	0.16* (0.06) (.01)	0.56** (0.11) (.00)	-0.27 (0.69) (.70)
HIV unknown vs negative	5.25 (4.08) (.20)	-0.03 (0.08) (.69)	0.02 (0.13) (.86)	-0.64 (0.93) (.49)
Baseline measurement	0.37** (0.04) (.00)	0.56** (0.08) (.00)	0.44** (0.04) (.00)	-0.01 (0.07) (.93)
Constant	7.17** (2.03) (.00)	0.32** (0.04) (.00)	0.22** (0.08) (.00)	2.25** (0.44) (.00)

Note. All outcome variables refer to self-report about the 90-day period before assessment. SE = standard error.

<sup>a</sup>Contrast code = 0.5, 0.5, -1.0 for conditions C, WA, E.

<sup>b</sup>Contrast code = 1.0, -1.0, 0.0 for conditions C, WA, E.

<sup>c</sup>Dummy code = 0, 1 for female, male.

\* $P \leq .05$ ; \*\* $P \leq .01$ .

consideration. Attendance among the WA condition was higher than among the C condition, and additional exposure may have facilitated a greater improvement with respect to sexual risk behavior; this differential increase in dosage may have offset any limitations to efficacy caused by delivering the relationship-based intervention to the woman alone. However, attendance is likely to be affected by aspects of the intervention itself (e.g., extent of activities focused on enhancing motivation to participate). Consequently, treatment dosage is considered a posttreatment variable. To remain consistent with intention-to-treat analysis, we did not include mediators or posttreatment variables to assess treatment effects.

A criticism of this study might be the lack of STD outcomes. We had planned to include reports of new STD diagnoses as an outcome; however, the rate of new STD diagnoses reported at follow-up was extremely low. Moreover, the study had a short follow-up period and a relatively small sample size.

The results of the study lend support to the desirability of delivering relationship-based HIV/STD interventions in primary care settings to African American and Latino couples at elevated risk for HIV/STD transmission. These study findings have considerable public health implications because they provide 2 alternative methods for an efficacious HIV/STD prevention intervention for women in long-term relationships. The public health implications are also important because reductions in numbers of unprotected sexual acts have been linked to reductions in HIV transmission<sup>15,54,55</sup> and lower levels of STD incidence.<sup>15,54,55</sup> Moreover, the study demonstrated that it is feasible to conduct a couple-based intervention among African American and Latino women and their regular male sexual partners and that these men are willing to participate in an HIV/STD intervention with their partners. To date, few heterosexual men have been invited to participate in HIV/STD intervention research with their female partners. Exner et al.<sup>56</sup> found that, as of late 1998, only 20 peer-reviewed HIV intervention studies targeted heterosexual men. The study is unique for demonstrating the willingness of heterosexual men to be part of an HIV/STD intervention study.

Recruitment and retention of couples in controlled clinical trials are formidable challenges to HIV/STD researchers. The 80% follow-up rate in Project Connect is consistent with rates found in major HIV prevention trials.<sup>53</sup> Thus, the recruitment process applied in our study provides researchers, and potentially practitioners, with new ways of increasing couple participation in clinical trials and treatment (unpublished study by some of the authors). Finally, our study demonstrates the efficacy of a theoretically and empirically driven relationship-based HIV/STD risk reduction intervention for populations of low-income African American and Latino couples at risk for HIV/STDs that may work well in primary health care settings. ■

#### About the Authors

Nabila El-Bassel, Susan S. Witte, Louisa Gilbert, Elwin Wu, Mingway Chang, and Jennifer Hill are with the Social Intervention Group, Columbia University School of Social Work, New York, NY. Peter Steinglass is with the Ackerman Institute for the Family, New York, NY.

Requests for reprints should be sent to Nabila El-Bassel, DSW, Social Intervention Group, Columbia University School of Social Work, 622 W 113th St, New York, NY 10025 (e-mail: ne5@columbia.edu).

This article was accepted July 25, 2002.

#### Contributions

N. El-Bassel, S.S. Witte, and L. Gilbert conceptualized and implemented the study. N. El-Bassel, the principal investigator, wrote the first draft of the article and participated in and supervised the revision of the article as well as participated in the planning of the data analysis. S.S. Witte, L. Gilbert, and E. Wu participated in the writing and revision of the article and the planning of the data analysis. M. Chang conducted the data analysis. J. Hill planned the data analysis, provided ongoing expertise regarding the data analysis plan, and reviewed the article. P. Steinglass provided ongoing supervision of the facilitators and was instrumental in ensuring the quality of the intervention delivery. P. Steinglass also reviewed the article and provided useful comments.

#### Acknowledgments

This study was supported by National Institute of Mental Health grant MH57145, awarded to N. El-Bassel.

#### Human Participant Protection

The protocol was reviewed and approved by the institutional review boards of Columbia University and the study site.

#### References

- Centers for Disease Control and Prevention. *HIV/AIDS Surveillance Report*. Atlanta, Ga: US Dept of Health and Human Services; 2000.
- Ehrhardt AA, Exner TM. Prevention of sexual risk

behavior for HIV infection with women. *AIDS*. 2000; 14:S53-S58.

- El-Bassel N, Gilbert L, Rajah V, Foleno A, Frye V. Social support among women in methadone treatment who experience partner violence. *Violence Against Women*. 2001;7:246-274.
- Harvey S. New kinds of data, new options for HIV prevention among women: a public health challenge. *Health Educ Behav*. 2000;27:539-565.
- Wingood GM, DiClemente RJ. Understanding the role of gender relations in HIV prevention research. *Am J Public Health*. 1995;85:592.
- O'Leary A. Women at risk for HIV from a primary partner: balancing risk and intimacy. *Annu Rev Sex Res*. 2000;11:191-234.
- O'Leary A. Preventing HIV infection in heterosexual women: what do we know? What must we learn? *Appl Prev Psychol*. 1999;8:257-263.
- El-Bassel N, Ivanoff A, Schilling R, Gilbert L, Borne D, Chen D. Preventing HIV/AIDS in drug-abusing incarcerated women through skills-building and social support enhancement: preliminary outcomes. *Soc Work Res*. 1995;19:131-141.
- Ickovics JR, Yoshikawa H. Preventive interventions to reduce heterosexual HIV risk for women: current perspectives, future directions. *AIDS*. 1998; 12(suppl A):S197-S208.
- Misovich SJ, Fisher JD, Fisher WA. Close relationships and elevated HIV risk behavior: evidence and possible underlying psychological processes. *Rev Gen Psychol*. 1997;1:72-107.
- Schilling RF, El-Bassel N, Hadden B, Gilbert L. Skills-training groups to reduce HIV transmission and drug use among methadone patients. *Soc Work*. 1995; 40:91-101.
- O'Leary A, Wingood GM. Interventions for sexually active heterosexual women. In: Peterson JL, DiClemente RJ, eds. *Handbook of HIV Prevention*. New York, NY: Plenum Publishing Corp; 2000:179-200.
- Musaba E, Morrison CS, Sunkutu MR, Wong EL. Long-term use of the female condom among couples at high risk of human immunodeficiency virus infection in Zambia. *Sex Transm Dis*. 1997;25:260-264.
- Allen S, Tice J, Van de Perre P, et al. Effect of serotesting with counselling on condom use and seroconversion among HIV discordant couples in Africa. *BMJ*. 1992;304:1605-1609.
- Padian NS, O'Brien TR, Chang YC, Glass S, Francis D. Prevention of heterosexual transmission of human immunodeficiency virus through couple counseling. *J Acquir Immune Defic Syndr*. 1993;6: 1043-1048.
- Deschamps M, Pape J, Haffner A, Hyppolite R, Johnson W. Heterosexual activity in at risk couples for HIV infection. In: *The VII International Conference on AIDS*. Florence, Italy, 1991. Abstract WC3089:1136.
- Higgins DL, Galavotti C, O'Reilly KR, et al. Evidence for the effects of HIV antibody counseling and testing on risk behaviors. *JAMA*. 1991;266: 2419-2429.
- Voluntary HIV-1 Counseling and Testing Efficacy Study Group. Efficacy of voluntary HIV-1 counseling and testing in individuals and couples in Kenya, Tanza-

- nia, and Trinidad: a randomised trial. *Lancet*. 2000; 356:103–112.
19. Weiner-Davis M. It takes one to tango. *Fam Ther Networker*. September/October 1998:46–51.
  20. Weiner-Davis M. It takes one to tango: couples therapy with individuals. In: Roberts AR, Greene GJ, eds. *Social Workers' Desk Reference*. Cambridge, Mass: Oxford University Press; 2002:277–281.
  21. Harlow L, Quina K, Morokoff P, Rose J, Grimley D. HIV risk in women: a multifaceted model. *J Appl Biobehavioral Res*. 1993;1:3–38.
  22. Kalichman S, Williams E, Cherry C, Belcher L, Nachimson D. Sexual coercion, domestic violence, and negotiating condom use among low-income African American women. *J Womens Health*. 1998;7:371–378.
  23. Wingood GM, DiClemente RJ. The influence of psychosocial factors, alcohol, drug use on African-American women's high-risk sexual behavior. *Am J Prev Med*. 1998;15:54–60.
  24. Remien R. Couples of mixed HIV status: challenges and strategies for intervention with couples. In: Wicks L, ed. *Psychotherapy and AIDS*. Washington, DC: Taylor & Francis; 1997.
  25. El-Bassel N, Witte S, Gilbert L, et al. Project Connect: HIV prevention with heterosexual couples. *Fam Syst Health*. 2001;19:379–395.
  26. Straus M, Hamby S, Boney-McCoy S, Sugarman D. The revised Conflict Tactics Scale (CTS2): development and preliminary psychometric data. *J Fam Issues*. 1996;17:283–316.
  27. El-Bassel N, Gilbert L, Ivanoff A, Schilling RF, Borne D, Safyer SF. Correlates of crack abuse among incarcerated women: psychological trauma, social support and coping behavior. *Am J Drug Alcohol Abuse*. 1996;22:41–56.
  28. NIMH Multisite HIV Prevention Trial. Quality control and quality assurance in HIV prevention research: model from a multisite HIV prevention trial. *AIDS*. 1997;11(suppl):49–53.
  29. Sormanti M, Pereira L, El-Bassel N, Witte S, Gilbert L. The role of community consultants in designing an HIV prevention intervention. *AIDS Educ Prev*. 2001;13:311–328.
  30. Catania JA, Kegeles SM, Coates TJ. Towards an understanding of risk behavior: an AIDS Risk Reduction Model (ARRM). *Health Educ Q*. 1990;17:53–72.
  31. Bronfenbrenner U. The ecology of human development. *Am Psychol*. 1979;32:513–531.
  32. Fagan JA, Wexler S. Crime at home and in the streets. *Violence Vict*. 1987;2:5–23.
  33. Rojek C, Peacock G, Collins S. *Social Work and Received Ideas*. London, England: Routledge; 1989.
  34. Moss HB, Tarter RE. Substance abuse, aggression and violence: what are the connections? *Am J Addict*. 1993;2:149–159.
  35. Reynolds J. Feminist theory and strategy in social work. In: Walmsley J, Reynolds J, Shakespeare P, Woolfe R, eds. *Health Welfare and Practice: Reflecting on Roles and Relationships*. London, England: Sage Publications; 1993:74–82.
  36. NIMH Multisite HIV Prevention Trial. NIMH Multisite HIV Prevention Trial: reducing HIV sexual risk behavior. *Science*. 1998;280:1889–1894.
  37. New York State Department of Health, AIDS Institute. *Focus on AIDS in New York State*. Albany, NY: New York State Department of Health; 1992.
  38. Stein Z, Saez H, el-Sadr W, et al. Safer sex strategies for women: the hierarchical model in methadone treatment clinics. *J Urban Health*. 1999;76:62–72.
  39. Gollub E, French P, Loundou A, Latka M, Rogers C, Stein Z. A randomized trial of hierarchical counseling in a short, clinic-based intervention to reduce the risk of sexually transmitted diseases in women. *AIDS*. 2000;14:1249–1255.
  40. *For Women Only: What Women Can Do to Protect Themselves From AIDS* [videotape available in English and Spanish]. Albany, NY: New York State Department of Health; 1997.
  41. Koepsell T, Martin D, Diehr P, et al. Data analysis and sample size issues in evaluations of community-based health promotion and disease prevention programs: a mixed-model analysis of variance approach. *J Clin Epidemiol*. 1991;44:701–713.
  42. Salonen J, Kottke T, Jacobs D Jr, Hannan P. Analysis of community-based cardiovascular disease prevention studies: evaluation issues in the North Karelia Project and the Minnesota Heart Health Program. *Int J Epidemiol*. 1986;15:176–182.
  43. Thompson D. A randomized controlled trial of in-hospital nursing support for first time myocardial infarction patients and their partners: effects on anxiety and depression. *J Adv Nurs*. 1989;14:291–297.
  44. Zhou H, Weinberg C. Potential for bias in estimating human fecundability parameters: a comparison of statistical models. *Stat Med*. 1999;18:411–422.
  45. Cochran W, Cox G. *Experimental Designs*. New York, NY: John Wiley & Sons Inc; 1992.
  46. Dolezal C, Ehrhardt A, Meyer-Bahlburg H, et al. Sexual risk behavior change among HIV+ and HIV– female injecting drug users over 4 years. *Womens Health*. 1998;27:1–17.
  47. Dolezal C, Meyer-Bahlburg H, Liu X, et al. Longitudinal changes in sexual risk behavior among HIV+ and HIV– male injecting drug users. *Am J Drug Alcohol Abuse*. 1999;25:281–303.
  48. Rubin D. *Multiple Imputation for Nonresponse in Surveys*. New York, NY: John Wiley & Sons Inc; 1987.
  49. Schafer J. *Analysis of Incomplete Multivariate Data*. London, England Chapman & Hall; 1997.
  50. Little R, Rubin D. *Statistical Analysis With Missing Data*. New York, NY: John Wiley & Sons Inc; 1987.
  51. King G, Honaker J, Scheve K. Analyzing incomplete political science data: an alternative algorithm for multiple imputation. *Am Political Sci Rev*. 2000;95: 49–70.
  52. Honaker J, Joseph A, King G, Scheve K, Singh N. *Amelia: A Program for Missing Data*. Cambridge, Mass: Harvard University, Dept of Government; 2000. Available at: <http://gking.harvard.edu/amelia>. Accessed February 14, 2003.
  53. The NIMH HIV Prevention Trial. The NIMH HIV Prevention Trial: a randomized, controlled evaluation of risk reduction interventions. *Science*. 1998;280: 1889–1894.
  54. Celentano D, Nelson K, Suprasert S, et al. Risk factors for HIV-1 seroconversion among young men in northern Thailand. *JAMA*. 1996;275:122–127.
  55. DeVincenzi I. A longitudinal study of human immunodeficiency virus transmission by heterosexual partners. *N Engl J Med*. 1994;331:341–346.
  56. Exner T, Gardos P, Seal D, Ehrhardt A. HIV sexual risk reduction interventions with heterosexual men: the forgotten group. *AIDS Behav*. 1999;3:347–358.