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Couple-Focused Human Immunodeficiency Virus Prevention for Young Latino Parents

Randomized Clinical Trial of Efficacy and Sustainability

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Objective: To evaluate the efficacy and sustainability of a couple-focused human immunodeficiency virus (HIV) prevention intervention in reducing unprotected sex and increasing intent to use condoms and knowledge about AIDS.

Design: Randomized controlled trial.

Setting: Urban community settings in Southern California.

Participants: Primarily Latino couples (168 couples; 336 individuals) who were aged 14 to 25 years, English or Spanish speaking, and coparenting a child at least 3 months of age.

Intervention: A 12-hour theory-based, couple-focused HIV prevention program culturally tailored for young Latino parents, with emphasis on family protection, skill building, and issues related to gender and power. The 1½-hour control condition provided basic HIV-AIDS information.

Main Outcome Measures: Primary outcome measures included self-report of condom use during the past

3 months; secondary, intent to use condoms and knowledge about AIDS.

Results: The HIV prevention intervention reduced the proportion of unprotected sex episodes (odds ratio, 0.87 per month from baseline to 6 months; 95% confidence interval [CI], 0.82-0.93) and increased intent to use condoms (slope increase, 0.20; 95% CI, 0.04-0.37) at the 6-month follow-up; however, these effects were not sustained at 12 months. Knowledge about AIDS was increased in both groups from baseline to 6 months (slope estimate, 0.57; 95% CI, 0.47-0.67) and was maintained in the intervention group only through 12 months. Female participants in both groups had higher intent to use condoms and knowledge about AIDS than male participants ($P \leq .01$).

Conclusions: The couple-focused HIV prevention intervention reduced risky sexual behaviors and improved intent to use condoms among young Latino parents at the 6-month evaluation. A maintenance program is needed to improve the sustainability of effects over time.

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ADOLESCENT PARENTS OF ethnic/racial minority background are at high risk for sexually transmitted infections, including human immunodeficiency virus (HIV). Behaviors leading to early pregnancy and continued high-risk sexual behaviors after childbirth¹⁻⁴ make these youth vulnerable to disease transmission. The adolescent birth rate in the United States, now rising after more than a

Most HIV prevention programs for adolescents are designed to reduce sexually risky behaviors (hereinafter referred to as risk behaviors) among general populations of youth and are attended by individuals rather than couples. Participants are predominantly African American

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decade of declining rates,⁵ is highest among Latina women.⁶ Thus, greater efforts must be directed toward prevention of teen pregnancy, sexually transmitted infections, and HIV among young parents, especially Latinos.

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youth⁷⁻¹³ or represent mixed ethnic/racial groups.¹⁴⁻²¹ We found only 2 randomized controlled trials involving entirely Latino samples of young adolescents among US studies.^{22,23}

Although results support the effectiveness of theory-based HIV prevention interventions for adolescents,^{7,10,12,14,23-26} findings

are inconsistent, and the length of follow-up varies. Treatment effects may wane to insignificant levels over time^{14,19} or be delayed up to 2 years.^{10,27} Some interventions have been ineffective in improving condom use and decreasing risk behaviors.²⁸

The efficacy of an HIV prevention program for pregnant and parenting adolescents was demonstrated in one randomized clinical trial involving Latina and African American girls attending alternative schools.²⁹ At the 6-month follow-up, participants reported fewer sexual partners, higher intent to use condoms, and greater knowledge about AIDS. Similarly, integrating HIV prevention into prenatal care increases condom use and decreases unprotected sex in African American samples.^{30,31}

In one of the few clinical trials involving couples, condom use and unprotected sex did not significantly differ between women (18-25 years) and their male partners receiving the couple-focused HIV prevention intervention and a comparison condition. Consistency of condom use increased significantly in both groups at the 3-month (women and men) and 6-month (women only) follow-up visits.^{32,33} A relationship-based intervention provided individually to adult heterosexual couples and the same intervention provided to the women alone were equally efficacious in reducing unprotected sex.^{34,35} Significant reductions in HIV/sexually transmitted infection risk behaviors were reported in a multisite randomized clinical trial involving serodiscordant African American couples.³⁶

Preliminary evaluation of the couple-focused HIV prevention intervention, conducted before the larger clinical trial reported herein, revealed significant reductions in unprotected sex and an increase in intent to use condoms among young Latino child-rearing couples at the 6-month follow-up.³⁷ Unlike earlier work, this study examines the efficacy and sustainability of the intervention, which addresses relational dynamics affecting sexual behavior within the context of romantic partnerships. This report is in compliance with the Consort 2010 recommendation for reporting of clinical trials.^{38,39}

METHODS

PARTICIPANTS

One hundred sixty-eight couples (including 336 young mothers and fathers) were recruited from Women, Infants, and Children programs; alternative schools; community-based service organizations; and clinics in Southern California from August 1, 2001, through September 30, 2004. We initially recruited couples through the mothers via small-group presentations and individual contacts; follow-up telephone calls confirmed the eligibility of the mothers and their male partners. The lengthy recruitment period and large number of sites were the result of complexities associated with identifying teenaged parents in a romantic relationship and willing to attend an HIV prevention program with their partners.

PROCEDURES

The institutional review board of the University of California, Los Angeles, approved the study, waiving the requirement for parental consent for participants younger than 18 years. Couples aged

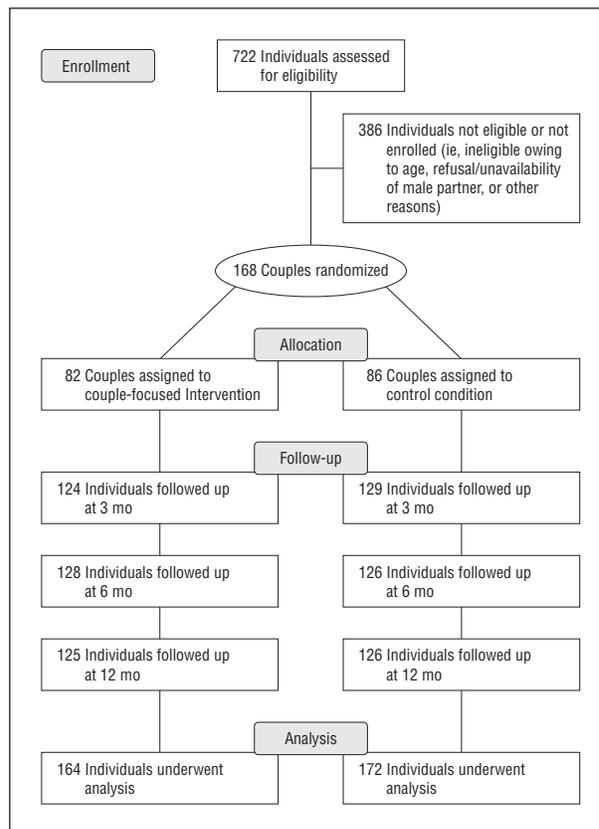


Figure. Cohort table displaying progress of participants throughout the study.

14 to 25 years and coparenting a child at least 3 months of age were eligible if they spoke English and/or Spanish. The broad age range is consistent with the current belief that young adults have developmental and health needs similar to those of adolescents⁴⁰ and may participate jointly in HIV prevention programs.³¹

Couples were randomized to the experimental or control condition with a 1:1 allocation within strata defined by geographic area. The sequence was created by the team's statistician using commercially available software (Stata 7; StatCorp, College Station, Texas) and with a block size of 4. Group assignment was revealed to participants after completion of the baseline questionnaire. The **Figure** shows the number assigned to each condition.

The intervention was delivered in small groups of 1 to 5 couples (average, 2 couples). Eight intervention and 3 control series were conducted in Spanish and the remainder in English. Community-based service organizations and a hospital provided space for program implementation. Participants received \$15 for each class attended, with child care and transportation provided.

EXPERIMENTAL AND CONTROL CONDITION

Couple-Focused HIV Prevention Program

The 6-session (12-hour), couple-focused HIV prevention program (Respecting and Protecting Our Relationships) was developed through a community-academic partnership formed to design a culturally appropriate and innovative HIV prevention intervention for young Latino parents. Details on this collaboration and pilot testing have been previously reported.^{3,37} The intervention was based on principles from social cognitive theory,⁴¹ the theory of reasoned action,^{42,43} the theory of

gender and power,⁴⁴⁻⁴⁶ and a theoretical framework derived from extensive clinical work with Latino youth.⁴⁷ The highly structured curriculum emphasized protecting the family to promote safer sexual behaviors. Pairs of male and female facilitators involved participants in small-group discussions about HIV prevention (eg, transmission modes and vulnerability) and attitudes and beliefs about HIV and “safer” sex. Unique features included facilitated discussions (“talking circles”) in which issues of gender norms and power were discussed in terms of effect on partner relationships and healthy sexual decision making. Discussions integrated cultural teachings to enhance positive aspects of relational norms and motivate reduction of risky sexual behaviors. Interactive activities (eg, games), writing exercises, and skill-building activities (eg, condom use and sexual negotiation) were incorporated throughout the curriculum. In separate groups, male and female participants explored issues related to sexuality, gender roles, and relationship violence. In 1 session, young parents identified people who made up their “Palabra Circle” (circle of relationships) and how others would be affected if they became infected with HIV; then a young mother who was seropositive for HIV shared her experiences living with HIV and how her health affected her family, friends, and life plans.

Control Condition

The 1½-hour (1 session) control condition, modeled after the usual care standard used in National Institute of Mental Health trials,⁴⁸ presented basic information (lecture format) to couples on HIV/AIDS transmission, signs and symptoms, and methods of prevention, including a brief demonstration of condom use.⁴⁸ The session was conducted by specially trained facilitators not involved in delivery of the HIV prevention program.

Facilitators and Facilitator Training

The facilitators of the couple-focused HIV prevention program were 4 men and 3 women, all Latino except 1 bilingual African American facilitator, with backgrounds in community health and social services involving high-risk Latino youth. About 40 hours of didactic and experiential training prepared facilitators to act as role models, nurturers, and teachers/guides, using their own experience whenever possible. The facilitation was based on a process known as *espejo* (mirror) teaching, using strategies such as storytelling, reflection, and guidance.

OUTCOMES

Participants completed questionnaires before and after the intervention and at 3-, 6-, and 12-month follow-up visits; only 5.0% chose to complete these in Spanish. At the baseline evaluation, a research assistant read each item aloud to small groups as they recorded their responses. Follow-up evaluations were generally performed in the home via individual interviews (60 minutes) conducted with female and male partners separately but concurrently. Participants received \$25 for each questionnaire.

Questionnaires were pilot tested for cultural relevance and readability and to ensure acceptable psychometric characteristics. Sociodemographic variables were assessed at baseline only. All questionnaires evaluated sexual behavior, intent to use condoms, and knowledge about AIDS.

The primary outcome was sexual behavior measured by the reported number of vaginal sex episodes with and without condoms during the past 3 months. Condom use was evaluated in relation to vaginal sex only, because reports of anal sex were low (17.3% among male and 15.5% among female partici-

pants). Secondary outcomes were evaluated by a 30-item questionnaire on knowledge about AIDS and a 4-item assessment of intent to use condoms. Other variables included multiple sexual partners, history of physical and sexual abuse, and substance use.

Data collectors, who received 16 hours of training, were blinded to participants' group assignment. Several steps were taken to maximize reliability and validity of the self-report measures on sexual behavior, as recommended and practiced by other researchers.^{11,49} Standard and familiar sex terms were used, with clear definitions provided. Participants were asked to report sexual behavior during a relatively short time frame to increase the validity of self-reported sexual data.^{11,23,50} Data collectors assisted recall of behavior by providing anchor dates (eg, school breaks and holidays) and calendars for reference.

SAMPLE SIZE AND STATISTICAL ANALYSIS

An intention-to-treat model was used to evaluate intervention effects. All randomized participants were included in the analysis. To minimize potential bias resulting from missing data, we used multiple imputation, creating 20 imputed data sets. This technique corrects for the underestimation of variance that occurs with a single imputation. The data sets were analyzed separately, and the results were combined to calculate the estimates, significance levels, and confidence intervals.⁵¹

The data consisted of linked measurements on the female-male dyads and of repeated measurements taken longitudinally on these dyads. This meant that, in the data analysis, the correlations between the partners in the dyad and those among the repeated measurements over time on the same couple had to be taken into account. To this end, we used hierarchical models with fixed and random effects.⁵² We assessed the effect of the intervention by testing for a group \times time interaction. Because of the potential for different effects during the 12-month follow-up, we fit piecewise linear models to the data with a single knot at 6 months. This allowed us to estimate separately and to compare effects of the intervention over the 2 time periods: baseline to 6 months and 6 to 12 months. For continuous outcomes, mixed models with normally distributed errors were used. To model the probability of unprotected sex and the effect of the intervention on this outcome, each sexual episode in the preceding 3 months was considered as a Bernoulli random variable with probability p of no condom use. A logit link was used to relate p to individual and/or couple characteristics, including group \times time interactions, and random effects were included on the logit scale. We used commercially available software for data imputations and mixed model analyses (SAS, version 9.1.3; SAS Institute, Inc, Cary, North Carolina) and descriptive analyses (SPSS, version 17; SPSS, Inc, Chicago, Illinois).

RESULTS

SAMPLE CHARACTERISTICS

Table 1⁵³ provides participant characteristics at baseline. The mean age of mothers was 18.5 (SD, 1.7) years; male partners were slightly older (20.4 [SD, 2.2] years). The large majority self-identified as Latino. Most had 1 child and shared biological parenthood, with the exception of 11 male participants, who nonetheless reported being actively engaged in coparenting. The mean length of relationship was 35.2 (range, 3-120) months. Child-

Table 1. Sociodemographic Characteristics of Female and Male Participants at Baseline by Intervention Condition^a

Characteristic	Intervention Group		Control Group		Total Sample	
	Female (n=82)	Male (n=82)	Female (n=86)	Male (n=86)	Female (n=168)	Male (n=168)
Age, mean (SD), y	18.5 (1.5)	20.3 (2.2)	18.6 (1.8)	20.4 (2.2)	18.5 (1.7)	20.4 (2.2)
Education, mean (SD), y	11.0 (1.5)	11.4 (1.8)	11.4 (1.4)	11.4 (1.0)	11.2 (1.4)	11.4 (1.4)
Acculturation (Latinos only) ^b	3.6 (1.0)	3.4 (1.0)	3.7 (0.9)	3.5 (0.9)	3.7 (1.0)	3.4 (1.0)
Length of relationship, mean (SD), mo	33.1 (15.5)	33.8 (17.6)	36.3 (20.9)	37.3 (21.7)	34.7 (18.5)	35.6 (19.8)
Age at first sexual encounter, mean (SD), y	15.0 (1.5)	14.6 (2.0)	14.6 (1.8)	14.7 (2.2)	14.8 (1.7)	14.6 (2.1)
No. of lifetime sex partners, mean (SD)	3.1 (3.4)	6.0 (8.0)	2.9 (2.8)	6.3 (7.7)	3.0 (3.1)	6.1 (7.8)
Ethnicity						
Latino ^c	73 (89.0)	69 (84.1)	78 (90.7)	77 (89.5)	151 (89.9)	146 (86.9)
African American	4 (4.9)	8 (9.8)	5 (5.8)	4 (4.7)	9 (5.4)	12 (7.1)
Other	5 (6.1)	5 (6.1)	3 (3.5)	5 (5.8)	8 (4.8)	10 (6.0)
Lifetime history of STI	11 (13.4)	5 (6.1)	14 (16.3)	10 (11.6)	25 (14.9)	15 (8.9)
History of abuse						
Physical	24 (29.3)	23 (28.0)	22 (25.6)	23 (26.7)	46 (27.5)	46 (27.4)
Sexual	30 (36.6)	11 (13.4)	28 (32.6)	10 (11.6)	58 (34.5)	21 (12.5)
Reporting concurrent sexual partners	4 (5.0)	6 (7.6)	2 (2.3)	2 (2.4)	6 (3.6)	8 (4.9)
Alcohol use in past mo	31 (37.8)	53 (64.6)	32 (37.2)	60 (69.8)	63 (37.5)	113 (67.3)
Methamphetamine use in past mo	5 (6.1)	12 (14.6)	2 (2.3)	7 (8.1)	7 (4.2)	19 (11.3)
Marijuana use in past mo	15 (18.5)	30 (36.6)	11 (12.8)	36 (41.9)	26 (15.6)	66 (39.3)
Proportion having unprotected sex ^d	71.7	73.3	68.2	75.6	69.9	74.6

Abbreviation: STI, sexually transmitted infection.

^aUnless otherwise indicated, data are expressed as number (percentage) of participants. Percentages are based on the number of participants answering each item.

^bMeasured by the Marín & Marín Short Acculturation Scale,⁵³ with possible scores ranging from 1 (low) to 5 (high).

^cIncludes participants identified as Latino and Latino/mixed.

^dDefined as weighted average of the individual proportions, with weights proportional to number of exposures.

hood history of abuse was common. Most participants reported that they were in a monogamous relationship. No significant differences were found in baseline characteristics between the experimental and control groups (Table 1).

INTERVENTION ATTENDANCE AND FOLLOW-UP RETENTION

Most participants (90.3%) attended at least 8 hours of the intervention; 70.1% received the full 12 hours. The Figure displays the number completing questionnaires at each data collection point. Data are presented for individuals to avoid excluding those with a partner having missing data. Of the original sample, 74.7% completed the 12-month evaluation.

EFFECTS ON PRIMARY OUTCOME

Table 2 presents estimates of the parameters from fitting a logit model for the probability of unprotected sex in the past 3 months. A number of different models were evaluated to test the effect of gender on the outcome and to test for potential effect modification by gender. The best-fitting model included gender only as a main effect and had terms for group (control=0; intervention=1), time₁ (baseline to 6 months), time₂ (6-12 months), and group × time interactions. The effect of the intervention is measured through these latter terms, with a significant group × time term indicating that the intervention participants modified their behavior at a faster (or slower) rate compared with

Table 2. Logit Models for Intervention Effect on Probability of Unprotected Sex

	Estimate (SE)	P Value	OR (95% CI) ^a
Intervention group	0.499 (0.376)	.18	1.65 (0.79-3.44)
Time ₁ (0-6 mo)	-0.018 (0.029)	.54	0.98 (0.92-1.04)
Group × time ₁	-0.135 (0.033)	<.001	0.87 (0.82-0.93)
Time ₂ (6-12 mo)	0.041 (0.039)	.31	1.04 (0.96-1.13)
Group × time ₂	0.102 (0.045)	.03	1.11 (1.01-1.22)
Female gender	-0.114 (0.204)	.58	0.89 (0.60-1.33)

Abbreviations: CI, confidence interval; OR, odds ratio.

^aIn this model, the control condition is the reference group; time₁ and time₂ represent the slopes for the reference group. The estimated ORs for time and for group × time are per month; thus, for group × time₁ and for group × time₂, the 6-month ORs are calculated from estimates to the power of 6: (0.87)⁶ = 0.44 and (1.11)⁶ = 1.84, respectively. Multiplying the OR at the beginning of each time by these numbers will give the OR at the end of each period, and hence these ORs represent the intervention effects for 0 to 6 months and for 6 to 12 months.

the controls. Because parameter estimates on a logit scale are difficult to interpret, odds ratios and 95% confidence intervals are also presented in Table 2. The odds ratio, 0.87 per month, for the group × time₁ interaction is significant ($P < .001$), showing a sharper decline in unprotected sex from baseline to 6 months in the intervention group. This effect was reversed in the 6- to 12-month period, with the intervention group increasing unprotected sex ($P = .03$) at a more rapid rate. The slopes for the control group were near zero and nonsignificant over both time periods ($P = .54$ and $P = .31$), suggesting no changes over time. Gender, even as a main effect, was not significant.

Table 3. Linear Models for Intent to Use Condoms and Knowledge About AIDS

Outcome	Estimate (SE) ^a	P Value	95% CI
Intent to use condoms			
Intervention group	-0.355 (0.466)	.45	-1.27 to 0.56
Time ₁ (0-6 mo)	-0.028 (0.058)	.63	-0.14 to 0.09
Group × time ₁	0.202 (0.085)	.02	0.04 to 0.37
Time ₂ (6-12 mo)	-0.028 (0.059)	.64	-0.14 to 0.09
Group × time ₂	-0.122 (0.084)	.15	-0.29 to 0.04
Female gender	0.724 (0.279)	.01	0.18 to 1.27
Knowledge about AIDS			
Intervention group	0.140 (0.496)	.78	-0.83 to 1.11
Time ₁ (0-6 mo)	0.571 (0.049)	<.001	0.47 to 0.67
Group × time ₁	0.004 (0.071)	.95	-0.14 to 0.14
Time ₂ (6-12 mo)	-0.152 (0.051)	<.01	-0.25 to -0.05
Group × time ₂	0.149 (0.069)	.03	0.01 to 0.29
Female gender	0.649 (0.312)	.04	0.04 to 1.26

Abbreviation: CI, confidence interval.

^aThe estimates for time and for group × time are per month.

EFFECTS ON SECONDARY OUTCOMES

Table 3 presents the estimates, significances, and confidence intervals for the linear models for intent to use condoms and knowledge about AIDS. No interactions of gender with treatment were found. Thus, the predictors in these models are exactly the same as in Table 2. For both secondary outcomes, gender was significant as a main effect, with female participants having higher values across the entire study for intent to use condoms (0.724 higher; $P = .01$) and knowledge about AIDS (0.649 higher; $P = .04$). There was a significant group × time₁ interaction for intent to use condoms ($P = .02$) with a higher slope for the intervention group in the baseline to 6-month period. The slopes for the control group were near zero and nonsignificant during both times, implying little or no change. Knowledge about AIDS increased in the intervention and control groups from baseline to 6 months ($P < .001$), with no significant difference in the slopes for the 2 groups ($P = .95$). From 6 to 12 months, the control group significantly declined in knowledge ($P = .003$), whereas the intervention group did not. A test for the difference between the intervention and control groups during this period showed a significant difference in slopes ($P = .03$), further confirming that knowledge in the intervention group remained constant during this interval.

COMMENT

The 6-month results indicate that the couple-focused HIV prevention program was efficacious in reducing unprotected vaginal sex acts and increasing intent to use condoms and knowledge about AIDS among young Latino parents. Participants receiving the intervention showed a sharp decrease in unprotected sex acts between baseline and the 6-month evaluation; however, this pattern was followed by an almost equal increase between 6 and 12 months. No significant changes in unprotected sex or intent to use condoms were observed for couples receiving the control condition. These findings on con-

dom use at the 6-month follow-up support our earlier work.³⁷ The odds ratio for risk behavior between the 2 groups was reduced by more than 50% during the first 6 months. This decrease in unprotected sex was somewhat larger than the pooled odds ratio estimate of 0.75 reported in a meta-analysis of behavioral interventions to reduce HIV risk in Hispanics.⁵⁴ Other interventions measuring condom use show similar reductions in risk behavior for Latino youth²³ and African American couples.³⁶

Knowledge about AIDS significantly increased for participants in both groups through the 6-month evaluation. Within the 6- to 12-month interval, knowledge was maintained by participants in the couple-focused HIV program, whereas knowledge scores decreased for those receiving standard information. Gender differences were significant as main effects only for intent to use condoms and knowledge about AIDS; female participants scored higher in both groups.

Our findings support the need for an intervention maintenance program to help sustain behavior change. Maintenance, tailored to the original intervention, should be implemented approximately 6 months after completion of the sessions. The efficacy of maintenance programs in HIV prevention studies is being tested, with some positive effects reported.¹¹

An important issue raised by these results concerns whether programs with 6 months or less of follow-up should be disseminated for replication as evidence-based models of intervention. Although establishment of intervention efficacy is essential, sustainability of program effects cannot be assumed on the basis of short-term outcomes.

Several challenges existed in conducting this clinical trial. Enormous efforts were required to recruit male partners and to retain couples for long-term evaluation, using computer-based tracking systems, frequent telephone calls, and incentives. Because we recruited through young mothers, women had to convince their partners to participate, and some young men changed their minds before enrollment. Most couples had a lengthy relationship, raising the possibility that stability of the relationship or partner commitment influenced recruitment efforts. Delivery of the intervention required extensive time and resources. Including a cost analysis in future studies will enhance understanding about resources needed for this type of research. Despite these challenges, addressing relationship issues within the context of an HIV prevention intervention was more effective than traditional education. Our results suggest that extending this approach to other age groups and non-child-rearing populations may be advantageous. In future research, we recommend that recruitment efforts be directed toward the couple rather than facilitated through women, as this approach may increase enrollment of individuals in less committed relationships. Strategies for dyadic outreach should focus on how the intervention may improve couple communication and negotiation of condom use and build healthy relationships in which sharing of personal information is safe.

The limitations of this trial warrant consideration. The design of the study does not allow us to determine how

various intervention components contributed to the outcomes. Sexual behaviors were based on self-report data, which may be influenced by memory recall and social desirability. Responses of male and female partners, particularly concerning the number of protected and unprotected sexual episodes, may be inconsistent. At baseline, we found moderate concordance between partners' reports about whether condoms were used during the last sex episode; if one partner reported that condoms were not used, the probability that the other partner agreed was substantial.² Reports of frequency of sex and condom use between partners in another couple intervention were often found to be inconsistent.³⁶ Our findings may not be representative of other groups of youth because the participants were predominantly young Latino parents.

Despite these limitations, this randomized clinical trial is important, as it represents the first long-term evaluation of a couple-focused HIV prevention program for Latino childbearing teenagers and young adults. Additional research is needed to examine whether promoting condom use as the key prevention strategy in couple-focused HIV intervention programs is the best approach for young parents who report being in committed and monogamous relationships. Promoting self-protective behaviors in relationships may require alternative strategies (eg, continued monogamy with HIV testing) not tested in this trial.

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