Effects of a Behavioral Intervention to Reduce Risk of Transmission Among People Living With HIV

The Healthy Living Project Randomized Controlled Study

The Healthy Living Project Team

Context: The US Centers for Disease Control and Prevention (CDC) strongly recommend comprehensive risk counceling and services for people living with HIV (PLH); yet, there are no evidence-based counseling protocols.

Objective: To examine the effect of a 15-session, individually delivered, cognitive behavioral intervention on a diverse sample of PLH at risk of transmitting to others.

Design: This was a multisite, 2-group, randomized, controlled trial.

Participants: Nine hundred thirty-six HIV-infected participants considered to be at risk of transmitting HIV of 3818 persons screened were randomized into the trial. Participants were recruited in Los Angeles, Milwaukee, New York, and San Francisco.

Intervention: Fifteen 90-minute individually delivered intervention sessions were divided into 3 modules: stress, coping, and adjustment; safer behaviors; and health behaviors. The control group received no intervention until the trial was completed. Both groups completed follow-up assessments at 5, 10, 15, 20, and 25 months after randomization.

Main Outcome Measure: Transmission risk, as measured by the number of unprotected sexual risk acts with persons of HIV-negative or unknown status, was the main outcome measure.

Results: Overall, a significance difference in mean transmission risk acts was shown between the intervention and control arms over 5 to 25 months (χ^2 = 16.0, degrees of freedom = 5; P = 0.007). The greatest reduction occurred at the 20-month follow-up, with a 36% reduction in the intervention group compared with the control group.

Conclusion: Cognitive behavioral intervention programs can effectively reduce the potential of HIV transmission to others among PLH who report significant transmission risk behavior.

Key Words: behavioral trial, prevention case management, prevention with positives

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People living with HIV (PLH) are now living longer and more sexually active lives, leading the US Centers for Disease Control and Prevention (CDC) to place a new focus on "prevention with positives".[1,2] Until recently, prevention planning shied away from targeting PLH because of concerns about stigmatization.[3] Because the virus is transmitted from one person to another, however, this failure is a missed opportunity to avert new infections.[1,4,5]

Decreasing the number of unprotected acts of vaginal or anal intercourse between PLH and persons of unknown or HIV-negative serostatus is the most targeted method of reducing sexual transmission of HIV.[6] Many PLH make and maintain changes in their sexual behavior to avoid transmitting HIV.[7–9] Nevertheless, some continue to engage in unprotected sex acts after learning of their serostatus.[7,9–13] The CDC has recommended prevention case management (PCM) or comprehensive risk counceling and services for individual PLH at risk of transmitting HIV.[2,5,13a] This approach combines assistance with medical and social services with HIV prevention counseling. To help develop effective HIV prevention counseling for PLH, the National Institute of Mental Health (NIMH) sponsored the Healthy Living Project (refer to Appendix I for members of Healthy Living Project Team). Building on previous successes in reducing sexual transmission among PLH,[14,15] the intervention focuses on helping people to cope with the challenges of living with HIV,[16] particularly not transmitting the virus. The intervention involved 15 90-minute structured sessions divided into 3 modules of 5 sessions each. Sessions were tailored to individuals within a structure that used problem-solving and goal-setting techniques. An overarching goal related to personal striving provided continuity throughout sessions. The intervention is based on social action theory,[17] in which behaviors such as risky sexual activity are framed as the result

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of 3 interactive domains: (1) the environmental context, including sociodemographic variables; (2) responses to internal affective states such as depression and anxiety; and (3) the self-regulation capacities of the individual, including outcome expectancies and self-efficacy for protective behaviors.[17] Three modules of 5 sessions each addressed these domains in the context of stress and coping (module 1); sexual risk behaviors (module 2); and HIV-specific health behaviors, including provider relationships and medication adherence (module 3).

The study was designed as a multisite, 2-group, randomized, controlled trial to test the effect of this individually delivered cognitive behavioral intervention. Such a theoretically derived model of behavior change is essential to implementing effective PCM with PLH. The intervention was developed for PLH with a sexual risk of transmitting HIV to others, and recruitment selected such individuals. In this article, we report on the primary study outcome of the Healthy Living Project.

METHODS

This study was conducted in four US cities: Los Angeles, CA; Milwaukee, WI; New York, NY; and San Francisco, CA. Details of the baseline methods[18,19] and intervention[20] have been published elsewhere. The study protocol, and assessment measures are available on the study web site (available at: http://chipts.ucla.edu/projects/chipts/hlp.asp). The institutional review boards at each of the participating institutions approved all study procedures. Voluntary written informed consent was obtained from all participants.

Study Population

Between April 2000 and January 2002, HIV-infected individuals in the 4 study cities were recruited from community agencies and medical clinics for a baseline interview. The assessment was used to screen participants for eligibility in the randomized intervention trial. Potential participants were required to be at least 18 years of age, to provide written informed consent and medical documentation of their HIV infection, to be free of severe neuropsychologic impairment or psychosis, and not to be currently involved in another behavioral intervention study related to HIV. Severe neuropsychologic impairment and psychosis were assessed on a case-by-case basis by interviewers in consultation with senior project personnel, including the clinical supervisor at the involved institution.

With regard to sexual risk, participants were eligible if reporting at least 1 act of unprotected vaginal or anal intercourse in the previous 3 months with any partner of HIV-negative or unknown serostatus, which was the main trial outcome measure of transmission risk acts. In addition, individuals were eligible if reporting unprotected intercourse with at least 1 HIV-infected partner other than a primary relationship (eg, a 1-time partner). Although this was not part of the primary trial outcome, it allowed us to assess the effect of the intervention on individuals who might be putting themselves at risk of other sexually transmitted infections. Among the 27% of the total sample who only reported sexual risk limited to contacts with other HIV-positive persons, the proportion of subjects randomized to each arm was evenly distributed (n = 125 in each arm; $P = 1.0$). The study did not have a separate randomization stratum for these participants.

The trial was initially designed to study the intervention in the context of 3 priority risk groups: men who have sex with men (MSM), women, and injection drug users (IDUs). In the first 6 months of recruitment for the trial, we noted a substantial number of HIV-infected heterosexual men who met sexual risk eligibility but were being excluded based on the a priori risk categories established for the trial. To respond to this trend in the epidemic, we began enrolling heterosexual men who met all other criteria.

Design and Procedures

Using laptop computers, interviews were conducted in private settings in research offices, community-based organizations, and clinics.[18,19] Procedures involved a combination of audio computer-assisted self-interviewing (ACASI) and computer-assisted personal interviewing (CAPI) using the Questionnaire Development System (Nova Research Company, Bethesda, MD). ACASI has been shown to be an effective method of decreasing social desirability bias, and thereby enhancing veracity of self-report of sensitive behaviors, including sexual and substance use risk acts.[21,22] Participants received $50 for completing the baseline interview.

Extensive sexual history information was obtained, including number of partners over the 3 months before interview and, for each of the 5 most recent partners of each gender, partner serostatus; total counts of oral, vaginal, and anal sex acts; and frequencies of these acts in which condom protection was used, from which the number of unprotected sex acts was calculated. To avoid unacceptable respondent burden, sexual risk behaviors with more than 5 partners of either gender were assessed cumulatively as total counts of each type of sex act, frequencies in which they were condom protected, and number of additional partners of each serostatus.

Randomization

Sexual risk eligibility criteria for the trial were programmed into the computerized assessment interview. PLH determined to be eligible were asked to participate and then randomized. In New York and San Francisco, randomization was done at a second appointment after the baseline interview. In Milwaukee, randomization was done immediately after completion of the baseline interview and establishment of eligibility, without a separate appointment. In Los Angeles, randomization was initially done at a separate appointment; however, the protocol was changed around June 2001 to randomize immediately after completion of the baseline interview and establishment of eligibility, without a separate appointment.

Simple randomization was implemented using computer-generated random numbers stored in a randomization table on a server computer housed at the Los Angeles study site. The randomization web site was accessible to each site using a unique log-on identification number and password. At the time of randomization for a participant, a project staff

member logged onto the randomization web site and entered the participant's identification number, birth date, and a behavioral risk categorization to retrieve the next randomized assignment from the randomization table. Reported problems with the web site or the server were addressed as they arose.

Intervention Condition

The Healthy Living Project experimental intervention was designed on the basis of qualitative studies.[20] It consisted of 15 90-minute individual counseling sessions grouped into 3 modules, each consisting of 5 sessions. Module 1 (stress, coping, and adjustment) addressed quality of life, psychologic coping, and achieving positive affect and supportive social relationships. Module 2 (safer behaviors) addressed self-regulatory issues, such as avoiding sexual and drug-related risk of HIV transmission or acquisition of additional sexually transmitted diseases, and disclosure of HIV status to potential partners. Module 3 (health behaviors) addressed accessing health services, adherence, and active participation in medical care decision making. Intervention sessions followed a standard structure and set of activities but were individually tailored to participants' specific life contexts, stressors, and goals. Participants received $10, $15, and $20 for attending each session of modules 1, 2, and 3, respectively. Participants in the control condition received no active psychosocial interventions during the 25 months of the trial.

Facilitators were trained centrally in cognitive-behavioral intervention strategies and were "certified" if supervisors' observations and quality assurance ratings indicated skilled implementation. All intervention sessions were audiotaped, and 10% were rated at a central site to ensure replication with fidelity.

Follow-up assessment interviews were scheduled every 5 months for the intervention and control groups. At the 10-, 15-, and 25-month visits, blood samples were collected from consenting participants for CD4 cell counts, viral load assays, and serum banking. Participants received $30 for completing each assessment interview at 10, 15, and 20 months and $60 for the 25-month interview.

Figure 1 summarizes the flow of participants over the course of the study and attendance rates for the intervention sessions and assessment interviews.

Statistical Analysis

Our primary endpoint was transmission risk acts: the number of unprotected sex acts during the last 3 months with partners whose HIV serostatus was negative or unknown to the participant. An unprotected sex act was defined as any act of insertive or receptive anal or vaginal intercourse in which neither party used a condom. Sample size for the trial was determined by using effect sizes and treatment effect variances from 2 previous related longitudinal behavioral intervention studies assuming a power of 0.80 and a type I error rate of 0.05.[8,14]

Calculating Transmission Risk Acts

The number of transmission risk acts could be determined directly for 87% of participants who reported 5 or fewer most recent partners of each gender at all time points or, if they had more than 5 partners, reported partners of only 1 HIV serostatus (positive or negative/unknown). The remaining participants (13%) reported having engaged in unprotected sex with more than 5 partners of HIV-positive and HIV-negative/unknown serostatus at 1 or more time points; thus, the transmission risk for some of their sex acts could not be determined. This uncertainty occurred for 201 (4%) of 4697 observations across all time points. For these observations, the number of unprotected sex acts with partners of each HIV serostatus was imputed by first estimating the longitudinal random effects binomial regression model for the most recent 5 (or 10) partners and then applying the person-specific model estimate to impute missing HIV serostatus-specific data on unprotected sex acts for the additional partners (refer to Appendix II for details).

Analytic Approach

Counts of transmission risk acts were compared between participants in the intervention and control groups, using a random effects Poisson regression model in an intention-to-treat analysis.[23] The Poisson rates were modeled as an unstructured mean model, using 5 indicator variables to represent time points. Group differences were allowed at the baseline. Intervention group differences at 5 to 25 months were allowed by including the interactions of intervention group and time. Participants were considered random, treating the participant-specific baseline intercept as normally distributed.

Although participants were randomized, comparison of transmission risk acts at baseline revealed an imbalance between the intervention and control groups (see Results section), indicating an ineffective randomization process. To adjust for the imbalance and to obtain an unbiased estimate of treatment effects, propensity score analysis was performed.[24–26] The propensity score was derived by fitting a logistic regression of the conditional probability of being in the intervention group given 16 baseline covariates, including the 3 that were found to be imbalanced at baseline: transmission risk acts, number of unprotected sex acts, and race/ethnicity. Analysis based on classifying participants into 5 groups, each with similar propensity scores, can remove 90% or more of the bias present in unadjusted comparison.[25,26] Adequacy of the derived propensity score in achieving balance within the stratum was evaluated by comparing the 16 baseline covariates between treatment groups. Missing observations for 15 (1.6%) of 936 subjects were imputed before estimating the propensity scores. Details of the propensity score analysis are given in Appendix II. Treatment effects were then estimated by using the propensity scores to adjust for observed baseline differences.

Participants were stratified into 5 quintiles defined by propensity scores. Poisson regression analysis was conducted within each quintile stratum. The parameter estimates were then averaged across the 5 strata. To account for uncertainty in imputation, 4 sets of multiply imputed data containing the imputed transmission risk acts and propensity score-related variables were generated, for which separate analyses were performed. The results were combined using multiple imputation inference procedures.[26,27]

Combining the averaged unstructured mean models from propensity score analysis across multiply imputed data

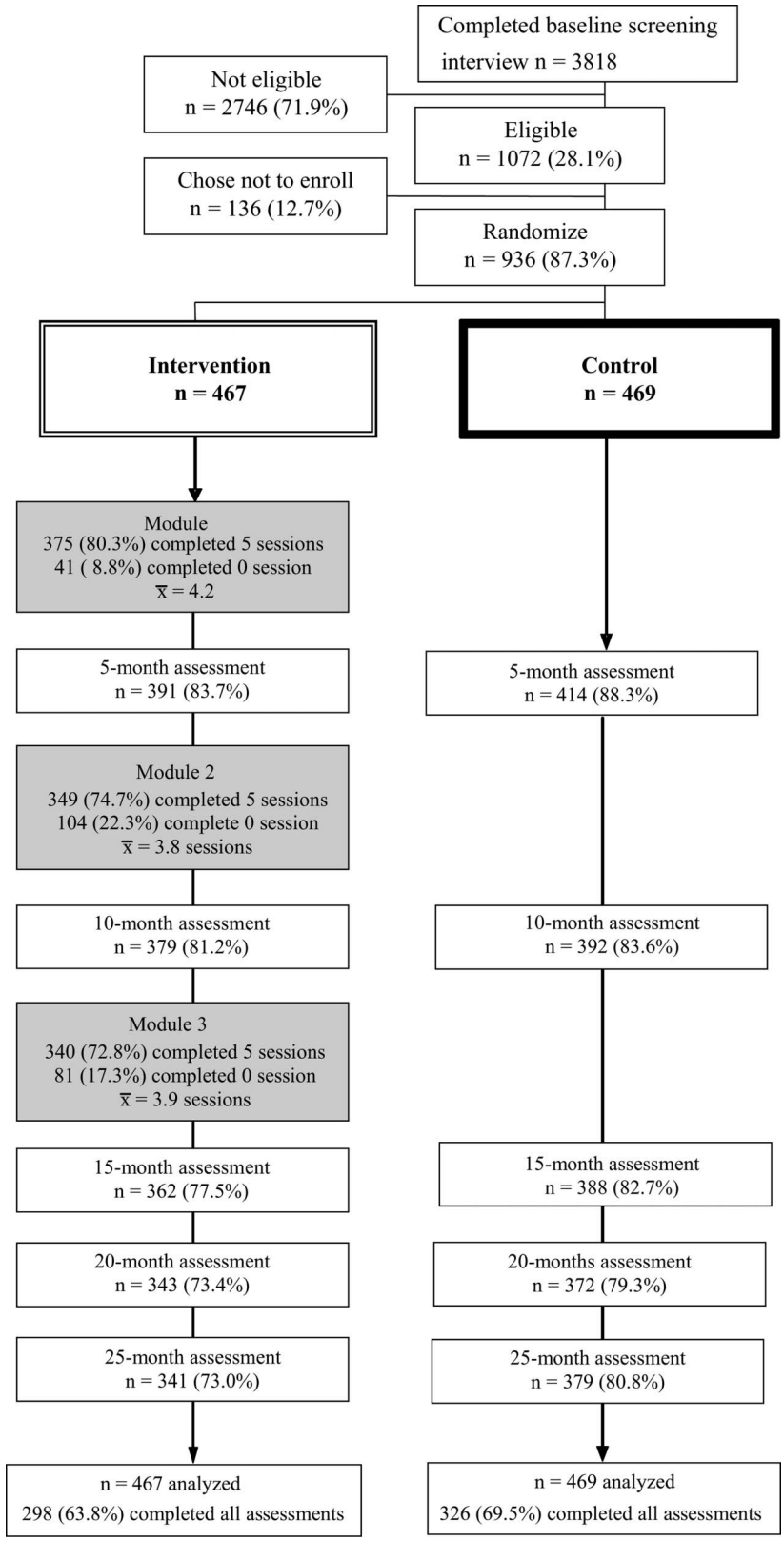

FIGURE 1. Flow chart of participants in trial.

sets, the overall between-group significance of the intervention effects at the 5 follow-up times was tested simultaneously using a 5-degrees of freedom (*df*) χ^2 test. We tested for group difference at each time point separately using a 1-*df* χ^2 test. Analysis without propensity score adjustment was also conducted for comparison. Treatment group differences at baseline were compared by the *t* test for continuous outcomes and by the χ^2 contingency table method for frequencies.

We used the SAS GLIMMIX[28] macro (SAS Institute, Cary, NC) to fit the random effects models, PROC LOGISTIC (SAS Institute, Cary, NC) to estimate propensity scores, and PROC MIANALYZE (SAS Institute, Cary, NC) to compute the significance levels combined across the 4 imputed data sets.

RESULTS

Of 3818 PLH screened for the intervention study, 1072 were eligible and 936 (87%) of those eligible agreed to participate and were randomly assigned to the intervention or control arm of the trial (see Fig. 1). All randomized participants were included in the final analysis.

Sample Characteristics

At baseline, the mean age of the participants was 39.8 years (range: 19–67 years). Most participants were male (79%), of whom 72% were MSM. Thirty-two percent of participants were white, 45% were African American, 15% were Hispanic, and 8% were other. Eighty-one percent had education less than a college degree. Participants reported a median of 2 sex partners in the past 3 months; 33% reported more than 5 partners. Seventy-three percent reported unprotected vaginal or anal intercourse with an HIV-negative or unknown status partner; the remaining 27% reported unprotected vaginal or anal intercourse with an HIV-infected secondary partner. Six ineligible individuals who were inadvertently randomized were included in sample based on the intention-to-treat principle. Twelve percent reported injection drug use in the past 3 months, and 70% reported noninjection drug use. Sixty-nine percent were on antiretroviral therapy, the mean CD4 count was 425 cells/μL, and 15% reported an HIV-1 RNA load <50 copies/mL. Table 1 presents participants' demographic characteristics, health status, and drug use.

Baseline characteristics were well balanced between the randomized intervention and control arms, with 3 exceptions (see Table 1): transmission risk acts in the last 3 months, unprotected sex acts in the last 3 months, and race/ethnicity. At baseline, individuals randomized to the intervention group reported more transmission risk acts than individuals randomized to the control group (mean of 11.4 vs. 7.2; $P = 0.045$), although the median number of transmission risk acts was not significantly different between groups (median of 3 vs. 2; $P = 0.41$, rank sum test). The intervention group also reported more unprotected sex acts (mean of 20.7 vs. 12.8; $P = 0.009$). Compared with the control group, the intervention group had more African Americans (49% vs. 40%) and fewer Latino/Hispanics (13% vs. 17%) ($P = 0.033$ overall). Applying the propensity score stratification in analysis successfully eliminated the imbalance, because comparison of these variables and others at baseline in each stratum showed no

TABLE 1. Baseline Characteristics and Risk Behaviors of Study Participants in a Preventive Intervention for PLH

	Intervention (n = 467)	Control (n = 469)	Total (n = 936)	*P*
City, n (%)				0.91
Los Angeles	163 (35)	170 (36)	333 (36)	
Milwaukee	43 (9)	44 (9)	87 (9)	
New York	127 (27)	118 (25)	245 (26)	
San Francisco	134 (29)	137 (29)	271 (29)	
Mean age (y), (SD)	39.6 (7.2)	40.1 (7.7)	39.8 (7.4)	0.27
19–35, n (%)	125 (27)	122 (26)	247 (26)	0.30
36–40, n (%)	143 (31)	131 (28)	274 (29)	
41–45, n (%)	104 (22)	119 (25)	223 (24)	
46–50, n (%)	65 (14)	54 (12)	119 (13)	
>50, n (%)	30 (6)	43 (9)	73 (8)	
Race/ethnicity, n (%)				0.033
White	142 (30)	157 (33)	299 (32)	
African American	231 (49)	190 (40)	421 (45)	
Latino/Hispanic	61 (13)	82 (17)	143 (15)	
Other	32 (7)	40 (8)	72 (8)	
Gender				0.40
Male, n (%)	364 (78)	376 (80)	740 (79)	
Female, n (%)	103 (22)	93 (20)	196 (21)	
Education, n (%)				0.18
High school or less	88 (188)	97 (21)	185 (20)	
High school graduate	126 (27)	99 (21)	225 (24)	
Some college	176 (38)	183 (39)	359 (38)	
College or more	77 (16)	90 (19)	176 (19)	
Currently a student, n (%)				0.30
Yes	56 (12)	67 (14)	123 (13)	
No	411 (88)	402 (86)	813 (87)	
Employment status				0.20
Employed	180 (38)	161 (34)	341 (36)	
Unemployed	287 (62)	306 (66)	593 (63)	
Mean no. partners in past 3 months (SD)	9.1 (23.4)	7.2 (13.8)	8.1 (19.2)	0.14
1, n (%)	114 (24)	111 (24)	225 (24)	0.96
2–5, n (%)	202 (43)	203 (43)	405 (43)	
≥6, n (%)	151 (32)	155 (33)	306 (33)	
Mean no. unprotected sex acts in past 3 months	20.7 (61.1)	12.8 (21.5)	16.8 (46.0)	0.009
Mean no. transmission risk acts in past 3 months (SD)	11.4 (42.8)	7.2 (16.5)	9.3 (32.5)	0.045
0, n (%)	125 (27)	125 (27)	250 (27)	0.49
1–2, n (%)	106 (23)	125 (27)	231 (25)	
3–10, n (%)	154 (33)	144 (31)	298 (32)	
>10, n (%)	81 (17)	72 (15)	153 (16)	
Alcohol/drug use, past 3 months, n (%)				
Injection drug	62 (13)	50 (11)	112 (12)	0.22
Daily hard drug use	35 (8)	40 (9)	75 (8)	0.56
Marijuana, alcohol only	17 (4)	27 (6)	44 (5)	0.13
Mean no. years since learning HIV^+ (SD)	8.3 (4.6)	8.2 (4.8)	8.2 (4.7)	0.83
CD4 count, cells/μL (SD)	417 (264)	433 (288)	425 (277)	0.39
Viral load (<50 copies/mL)	64 (14)	78 (17)	142 (15)	0.21

statistically significant difference and the group difference at baseline for the averaged model for the transmission risk acts was not significant ($P = 0.13$).

Retention and Completion Rates

Completion of intervention sessions was 70% or greater for all modules (see Fig. 1), with 3% of enrolled participants completing 1 to 4 sessions. Sixty-four percent of intervention participants and 69% of controls completed all 6 study assessments. Follow-up was significantly lower among the intervention group than the control group at 15 months (78% vs. 83%; $P = 0.03$) and at 25 months (73% vs. 81%; $P = 0.01$). Adherence to session protocols was 95% for module 1, 86% for module 2, and 85% for module 3. For competence in conducting specific session elements, there was less variability by module, with 97% of module 1 sessions and 96% each of module 2 and module 3 sessions rated as satisfactory. No serious intervention-related adverse events were reported.

Intervention Effect

Figure 2 depicts the main trial outcome for transmission risk acts across 6 time points for the intervention and control arms based on the estimated model averaged over the 5 propensity score strata and the 4 multiply imputed data sets. Overall, a significance difference in mean transmission risk acts was shown between the intervention and control arms over 5 to 25 months ($\chi^2 = 16.0$, $df = 5$; $P = 0.007$), with reduction (suggestive or evident) at 10, 15, and 20 months of follow-up ($P = 0.066$, $P = 0.080$, and $P = 0.007$, respectively). The amounts of reduction in the intervention group relative to the control levels were 22%, 23%, and 36% at respective time points. There were no differences at 5 months ($P = 0.41$) and 25 months ($P = 0.57$). Analyses without the propensity score adjustment showed similar results, with significant intervention effects over 5 to 25 months ($\chi^2 = 27.8$, $df = 5$; $P < 0.0001$), and trends similar to those shown in Figure 2: the mean transmission risk acts was lower in the intervention arm compared with the control arm at 15 months ($P = 0.0016$) and 20 months ($P = 0.0014$), but the differences were not significant at 5 months ($P = 0.18$), 10 months ($P = 0.10$), and 25 months ($P = 0.48$). A significant reduction in the number of transmission risk acts from baseline was observed for both groups ($P < 0.0001$ for both).

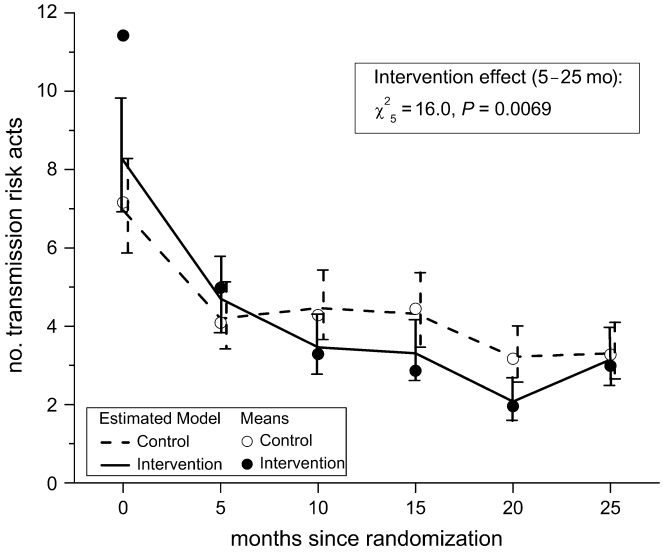

FIGURE 2. Transmission risk acts across 6 time points for the intervention and control arms.

DISCUSSION

The Healthy Living Project intervention was successful in helping PLH reduce unprotected sexual intercourse with HIV-negative or unknown status partners. At the 20-month assessment, or 5 months after completion of the intervention, the intervention group had reduced transmission risk acts by an average of 36% compared with the control group. Although the early part of the intervention, which addressed general coping skills, did not establish a significant treatment effect at the 5-month point, a positive intervention effect was seen around the time of the module applying coping effectiveness skills to specific sexual situations involving potential for HIV transmission at 10 months. This intervention effect increased over time, as seen in the 15- and 20-month assessments.

Unfortunately, the treatment effect in terms of a reduction of HIV transmission risk acts was not maintained at 25 months. Nonetheless, significant reductions in transmission risk acts from baseline levels were observed for the intervention and control groups at 25 months. The attenuation of the intervention effect over time in this study is consistent with results from other randomized controlled trials of behavioral interventions.[29,30] This finding highlights how HIV is now more like a chronic disease, requiring ongoing case management over time as HIV-positive persons enter new relationships or new life challenges. A "booster" model seems warranted.

It is important to note that the number of transmission risk acts was reduced in the lagged control and the intervention arms of the study. First, because sexual risk is variable over time and subjects were selected based on having some risk behaviors (as opposed to none), a statistical phenomenon know as "regression-to-the-mean" occurred, whereby overall group average decreases would be expected to occur in both groups from baseline. Second, even though the control arm did not receive the specific theory-guided intervention, the effect of repeat assessments of sexual behavior (just asking about unprotected sex) may serve as a cue for risk reduction for subjects. This effect has been seen in other behavioral HIV prevention trials.[31]

Although some might argue that the results of this study are limited because of the nature of the self-report primary outcome measure, a biologic outcome in this study was not feasible. The most logical biologic outcome would have been to track sexual partners and assess the number of new infections attributable to trial participants. This would obviously be impractical. Alternatively, change in the incidence of sexually transmitted diseases could be measured as a surrogate for sexual risk. The prevalence of sexually transmitted infections at recruitment in this study population was low (1.4%, 12 cases of *Chlamydia* and 1 of gonorrhea), however. Given substantial

attention to quality assurance and previous reports on the validity of self-report measures,[31a,32] the findings seem substantial.

One of the challenges in interpreting the outcomes of this trial was the observed imbalance in transmission risk acts between the intervention and control groups at baseline. We do not know if this was attributable to systematic errors in the implementation of trial randomization procedures, which we investigated extensively. We tested the randomness of the random numbers generated for the randomization table and the actual assignments for the trial participants, using a run test for autocorrelation and logistic regression for sequence order effect. The null hypothesis of randomness was accepted for both sets of tests.

We also conducted an extensive review of the randomized data and identified 84 mismatches between the original randomization table and actual assignments. Many of these mismatches are likely attributable to problems in implementation of the randomization procedure when the eligibility criteria were expanded to include heterosexual men. Because of limitations in the documentation, we cannot ascertain the full extent to which such explanations are applicable to the mismatches observed.

Importantly, the overall trial efficacy was significant whether or not we adjusted for the baseline difference. Although this trial demonstrated a significant effect of the intervention in reducing the number of transmission risk acts for the overall study population, there is, of course, interest in the relative effectiveness of the intervention for specific behavioral risk subgroups. Although this trial was not designed to detect significant differences in effectiveness between such subgroups, more detailed examination of the intervention effect within populations of special interest is planned and will be presented in subsequent publications.

Although this intervention was delivered as 15 sessions for research purposes, the same content was adapted to 8 sessions when delivered to the lagged control participants. The intervention is intensive and would only be feasible for complex cases in which less intense provider-based or group interventions do not seem to be sufficient for reducing transmission risk. Perhaps the most appropriate adaptation of the intervention would be in the context of comprehensive risk counseling and services such as PCM, where significant resources are already being directed to specific clients.[2,5] Thus, the theory-based tools in this intervention would be used to improve the effectiveness of services already being delivered.

In the US national HIV prevention plan,[1,33] prevention with positives emerged as the top priority, because even small behavior change among infected individuals can have a significant impact on the epidemic. The Healthy Living Project is an evidence-based PCM approach that meets the CDC's directives. The utilization of the Healthy Living Project intervention suggests a protocol for PCM that can be effective in reducing the number of new HIV infections.

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APPENDIX I

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APPENDIX II

Statistics

Imputation of the Transmission Risk Acts

The primary outcome was the count of transmission risk acts, that is, unprotected sex acts with partners who were HIV-seronegative or of unknown status. Of the total counts of anal and/or vaginal sex acts reported by each participant, only those

involving the most recent 5 male and 5 female partners could be distinguished with respect to HIV serostatus, because their data were obtained on individual basis. For participants with additional partners, data on the additional partners' serostatus and sex acts were obtained collectively, as the total number of additional partners, the number of additional partners with HIV-negative or unknown serostatus, and the count of protected sex acts and of unprotected sex acts with additional partners, without cross-classification. Thirteen percent of participants had at least 1 observation such as this, accounting for 201 (4.3%) of the total 4697 observations for which the primary outcome could not be determined directly. These observations occurred most frequently at baseline, and the frequency decreased with time.

We addressed this issue with multiple imputation.[27] We fit a longitudinal random effects binomial model to the reported count of unprotected sex acts with HIV-negative or status unknown partners (numerator) of the total count of unprotected sex acts that participants had with the most recent 5 (or 10) partners for whom individual data were available (denominator). Data from all time points were used. Each participant was modeled with a subject-specific normal random effect. We included study site, behavioral risk group, ethnicity, age, education, and the significant first-order interactions, along with time, as covariates. We assumed that the subject- and time-specific estimates of the probability of transmission risk acts obtained for the most recent individual partners applied to the additional partners, multiplying them by the collective count of unprotected sex acts of the additional partners to impute the number of transmission risk acts for each time point. This estimate was then totaled with the count of transmission risk acts for the most recent individual partners to obtain the grand total for each participant.

To account for uncertainty in imputation, 4 sets of randomly generated estimates of transmission risk probabilities were obtained for each participant. Analyses described in the main text were performed separately for each complete data set, and the results were combined according to multiple imputation procedure.[34,35]

Propensity Score Analysis

To adjust for the imbalance seen at baseline between the intervention and control arms and to obtain an unbiased estimate of treatment effects, propensity score analysis was performed.[24,25] The propensity score was calculated by fitting a logistic regression of the conditional probability of being in the intervention group given 16 baseline covariates. The 16 covariates used were age, ethnicity, number of antiretroviral therapy drugs taken, log of total number of partners, log of total number of unprotected sex acts, log of transmission risk acts (1 of 4 multiply imputed values), total number of oral sex acts, total number of oral sex acts with HIV-negative or unknown partners (1 of 4 multiply imputed values), square root of the Beck Depression Inventory sum score, Positive State of Mind scale score, State Trait Anxiety scale score, ever had a sexually transmitted infection or not, antiretroviral therapy user or not, study site (city), education, and risk group classification. The propensity score was then used in multivariate modeling to adjust for the observed baseline differences between the 2 study arms.