

Prevention for Substance-Using HIV-Positive Young People

Telephone and In-Person Delivery

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Summary: HIV risky behaviors and health practices were examined among young people living with HIV (YPLH) in Los Angeles, San Francisco, and New York over 15 months in response to receiving a preventive intervention. YPLH aged 16 to 29 years ($n = 175$; 26% black and 42% Latino; 69% gay men) were randomly assigned to a 3-module intervention totaling 18 sessions delivered by telephone, in person, or a delayed-intervention condition. Intention-to-treat analyses found that the in-person intervention resulted in a significantly higher proportion of sexual acts protected by condoms overall and with HIV-seronegative partners. Pre- and postanalyses of YPLH in the delayed-intervention condition alone found that YPLH tended to have fewer sexual partners, used fewer drugs, reported less emotional distress, and decreased their use of antiretroviral therapies. Prevention programs can be delivered in alternative formats while retaining efficacy. When YPLH are using hard drugs, drug treatment may be needed before delivery of preventive interventions.

Key Words: adolescents, intervention, HIV, HIV prevention, young people living with HIV

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Young people represent approximately 50% of all HIV infections worldwide¹ and 18% of reported HIV cases in the United States.² Nationally, approximately 110,000 young adults less than 23 years of age are living with HIV³ and 23% of HIV-infected persons are less than 30 years of age.² Because the number of sexual partners and sexual activity is highest in late adolescence and early adulthood,⁴ it is critical to ensure that transmission acts are reduced among young people living with HIV (YPLH). The goal of this article is to examine the efficacy of an intervention to reduce transmission acts.

YPLH who do not change their sexual risk acts or injection drug use may infect others and become reinfected with

new viral strains.⁵ Previous research with persons living with HIV indicates that at least one third of YPLH are likely to continue their transmission behaviors after learning their serostatus.^{6,7} The primary motivation to reduce transmission risk acts is altruism,^{8,9} although self-preservation may motivate some youth to avoid acquiring other sexually transmitted infections or to avoid becoming reinfected with drug-resistant strains of HIV. To motivate YPLH to reduce transmission for the public good, it is necessary to address the young people's need to improve their physical health and mental health, especially their adherence to health regimens.¹⁰ Adherence to medical regimens is likely to extend the quality and length of life for YPLH. With an extended lifespan, there is also a greater likelihood that YPLH may relapse into transmission behaviors.¹¹ Thus, to reduce sexual and substance use transmission acts of YPLH, an intervention that addressed the needs of the YPLH (receiving and adhering to medications and health regimens and improving mental health) and society (reducing sexual and substance use transmission acts) was evaluated.

We previously demonstrated that attending a 3-module intervention delivered in small groups, Teens Linked to Care,^{7,12} reduced unprotected sexual acts and drug use and improved physical health and mental health outcomes among YPLH—the same goals as the intervention in this study. For example, YPLH in the intervention condition reported 82% fewer unprotected sexual acts, 45% fewer sexual partners, 50% fewer HIV-negative sexual partners, and a 31% reduction in substance use compared with YPLH in a delayed condition.⁷ Health-related coping skills improved for young women living with HIV,⁷ and mental health symptoms were significantly reduced in the intervention compared with the delayed condition.¹² The intervention was cost-effective in reducing new infections (Lee MB, Leibowitz H, Rotheram-Borus MJ, unpublished data).

After demonstrating that an intervention is efficacious, researchers typically replicate the same intervention design and content and often demand fidelity to the initial intervention delivery.^{14,15} The strategy of replication with fidelity does not allow us to develop guidelines for when and how to tailor the intervention to different market segments or to improve on the initial intervention. This study deviated from the traditional

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replication strategy. Three types of adaptations were made in the current trial.

First, although there were significant improvements associated with Teens Linked to Care, 30% of YPLH did not attend even 1 intervention session.⁷ There were several significant barriers to attending groups delivered in a small group setting. First, when arriving at a group meeting for HIV-positive persons, one's serostatus is disclosed to 8 to 10 unfamiliar persons simultaneously. Fears may arise about disclosure. Second, the low rate of HIV detection among YPLH¹⁶ often led to a delay of several months organizing a group, even in urban AIDS epicenters. Third, there were so few YPLH that young gay men, women, and heterosexual men were combined within 1 group; yet, the issues were significantly different for each subpopulation. Finally, anticipating challenges related to efficacious interventions, we realized it would be necessary to tailor the delivery modalities so that persons in different life situations (ie, different market segments)¹⁵ would have an intervention acceptable to them. Therefore, we adapted our previous intervention to be delivered in modalities that are consistent with the existing case management models being implemented nationally with funding from the Ryan White CARE Act and Centers for Disease Control and Prevention.¹⁷

Most existing prevention case management services are delivered in individual 1-on-1 counseling sessions. For persons who are too ill, live in rural settings, or are homeless, telephone interventions are seen as a viable alternative delivery format.¹⁸⁻²⁰ Therefore, the Teens Linked to Care intervention,⁷ designed for small groups, was adapted to be delivered in individual sessions and on the telephone. The goals were the same (reducing sexual and substance use risk acts, improving physical health behaviors, and improving mental health), but the delivery format shifted.

Second, Teens Linked to Care was delivered in 10 to 12 sessions for each of 3 modules, reflecting each of the intervention's goals (reducing transmission, improving physical health, and improving mental health). To be more feasible for replication, we reduced the number of sessions per module from 10 to 12 to 6 sessions per module.

Third, because drug use has been consistently associated with sexual risk acts,^{4,6,7,12} we focused this study on drug-using youth. Only YPLH who had engaged in drug use at least 5 times during the previous 3 months were eligible for enrollment (criteria were set from inspection of rates of substance use in our previous trial⁷).

Behavioral changes are achieved when the desired goals are clear, consumers are motivated to change, the situations that elicit risk acts are identified, and patterns of coping with future risk situations are planned and rehearsed to proceed in a different way.^{21,22} Building on an extensive qualitative study of YPLH^{8,9,23} and our earlier interventions,^{7,12} the situations that YPLH typically encounter were identified; these situations were different for young gay men, women, young adults,

adolescents, methamphetamine users, and injecting drug users. The in-person and telephone formats allowed us to tailor the situational contexts addressed in the intervention to the YPLH's life challenges. The intervention then focused on helping YPLH to set goals; to become and remain motivated to change; and to plan and rehearse how to cope more effectively with situational challenges in sexual and substance use risk situations and medical care delivery settings and when using medications and experiencing negative emotional states. Situations in each domain were addressed for 6 sessions within each module, allowing rehearsal and planning several times in each domain.

To compare the cost-effectiveness of the in-person and telephone delivery formats with that of our previous study with YPLH in small groups,^{7,12} we monitored the costs of delivering each module of the intervention.

METHODS

Participants

Although it is estimated that there are 110,000 YPLH in the United States, fewer than 10% of these YPLH have been identified through HIV testing, and it is estimated that only 10% of the identified YPLH are linked to care.³ Therefore, recruitment is a challenge nationally for YPLH. The first strategy to recruit YPLH was via the major adolescent AIDS clinics in Los Angeles (Children's Hospital and Los Angeles Gay and Lesbian Center) and New York (Montefiore Medical Center and Kings County Medical Center). When insufficient numbers of YPLH were enrolled, we expanded to a broad range of community-based sites (eg, Los Angeles Youth Network, Gay Men's Health Crises) and sites in San Francisco, with some sites securing institutional review board approval and the remaining agreeing to comply with the University of California at Los Angeles' Institutional Review Board requirements. We then expanded recruitment procedures to include solicitation in newspapers, conferences, and community events that were likely to be attended or read by YPLH. YPLH were currently receiving medical care at the recruitment site or were linked to ongoing care at the time of enrollment into the study.

From 1999 to 2002, 253 YPLH aged 16 to 29 (median = 23) years were recruited with voluntary informed consent in Los Angeles, San Francisco, and New York. Across cities, YPLH were recruited from 17 medical providers (n = 66), 21 social service agencies (n = 121), 2 needle exchange programs (n = 6), 1 drug treatment center (n = 4), 4 other research studies (n = 5), or outreach on the street or at special events (n = 15) as well as through newspaper advertisements (n = 12) and referrals from friends (n = 19). Ten young people contacted the study from unknown sources. Many young people attended more than 1 service site concurrently, and others moved to new service sites over the course of the study; therefore, there is not only 1 site identified for each participant. Although many

youth were part of a convenience sample, a consecutive series of youth were approached from each of the medical provider sites and social service treatment settings, allowing us to document 23 refusals. There were too few youth from any 1 site to make meaningful comparisons of youth recruited from different sites.

Parental consent was obtained for nonemancipated YPLH less than 18 years of age. All YPLH received an incentive of \$20 to \$25 per assessment.

In the previous intervention trial, significant numbers of YPLH did not engage in substance use at the assessment interview or over time.⁷ Because this study aimed at reducing transmission acts among substance users, we had an eligibility criterion of using illicit drugs at least 5 times in the last 3 months. A validity study of potential screening instruments to identify HIV-seropositive persons who engaged in risky acts demonstrated low reliability and validity; thus, a full 45-minute extended interview was the criterion to identify a valid response on sexual and substance use risk acts.²⁴ Given these findings, each potential participant was initially recruited with voluntary consent for a baseline interview so as to assess eligibility. On the basis of the interview, YPLH were recruited for the intervention trial.

Eligibility rates varied across cities. In Los Angeles, 118 YPLH were recruited for the baseline assessment and 74% (n = 87) were eligible for participation. In New York, 68% (n = 68 of 100) of YPLH assessed were eligible, and 83% (n = 29 of 35) of YPLH were eligible in San Francisco. Fewer YPLH were recruited in San Francisco because this site was added a year later than the other cities. Of the 253 YPLH initially recruited, 72% (184 of 253) were eligible and 95% (176 of 184) were randomized into the trial. One baseline interview file was damaged, resulting in 175 participants.

Intervention

Similar across intervention delivery format (in-person or telephone sessions), 3 modules of 6 sessions each focused on a different target behavior: improving physical health, reducing sexual and substance use acts, and improving mental health. Module 1 focused on improving one's physical health regimen, particularly utilization and adherence to antiretrovirals (ARVs). In addition, the module addressed coping with learning one's serostatus, implementing new daily routines to stay healthy, issues of disclosure, and participation in health care decisions. Health care was addressed first to address the needs of the YPLH⁸ before asking for altruistic behaviors with sexual and drug-using partners.

Module 2 aimed to reduce unprotected sexual acts and substance use by asking YPLH to identify situations that are likely to elicit risky acts and to modify their patterns of substance use as well as increase their skills in condom use self-efficacy and negotiation skills. Disclosure of serostatus was not endorsed by the intervention; we were concerned that dis-

closing one's serostatus transferred responsibility to the informed partner to protect himself or herself. Regardless of the desire of the partner, YPLH were encouraged to use condoms if engaging in sexual acts.

Module 3 aimed to reduce emotional distress and to improve the quality of life of YPLH. The module focused on helping YPLH to anticipate situations that would raise negative emotions (eg, anxiety, depression, fear, anger). YPLH were taught a "Feeling Thermometer" to identify their affective states across difficult situations and then to self-control negative emotions through the use of relaxation, self-instruction, and meditation. Module 3 focused on helping YPLH to identify long-term life goals.

The format of each session was similar across each session and each module. Each session started with recognizing personal successes during the previous week, recognizing success in completing goals targeted during the previous session, introduction of new material (eg, strategies for remembering ARVs, proper use of condoms), rehearsal and planning for challenging situations that might arise in the next week and the future, review of the session's progress, and goal setting for the next week.

A detailed manual (available online at <http://chipts.ucla.edu/>) guided the 3 intervention modules totaling 18 sessions of 2 hours each. Each participant received \$10 for each session attended.

The in-person sessions were delivered 1-on-1 in private rooms available at collaborating sites or other community agencies. When these spaces were not available in locations accessible to a participant, arrangements were made to deliver sessions in the participant's home (if it was judged to be safe and private) or, on rare occasions, in a nearby park or coffee shop.

Telephone sessions were delivered 1-on-1 at times convenient for participants. YPLH were provided with workbooks to supplement and provide concrete prompts to complete the session content. The original design called for small group meetings in a telephone chat-room. Slower than anticipated recruitment, coupled with challenges in coordinating mutually agreeable group schedules and poor initial adherence, caused us to revise the protocol to 1-on-1 delivery during the first telephone group attempted. Follow-up and recontact efforts consisted of weekly written letters or e-mail, followed by telephone calls. Three weekly attempts were made before shifting to monthly follow-up.

Intervention facilitators held masters degrees and were licensed therapists or clinical social workers or had completed their clinical training and were accumulating hours toward licensure. Most facilitators were female. Spanish-speaking facilitators were available for monolingual Spanish-speaking participants (approximately 3% of the sample).

The facilitators were supervised biweekly and received intensive 3-day training for each module from teams of expe-

rienced cognitive-behavioral intervention researchers. The training included review of the study's theoretic orientation, the intervention manual, and videotapes of model sessions as well as practice in conducting each session of the intervention.

Quality assurance ratings were conducted from randomly selected videotapes and audiotapes of sessions. Ratings for more than 80% of the sessions exceeded criteria for content and process measures of fidelity.

Across modules, 78% (n = 94 of 120) of young people participated in at least 1 session: 87% (n = 53) attended at least 1 individual session and 69% (n = 41) participated in at least 1 session in the telephone intervention (attenders). Fewer young people completed all 18 sessions (35%): 41% of those receiving individual sessions and 29% of those receiving the telephone interventions. The mean number of sessions was 10.0 in the individual sessions and 7.5 in the telephone sessions. Attenders (n = 94) and nonattenders (n = 26) were compared on each baseline characteristic listed in Table 1. No significant differences were found between YPLH in either condition. After the 15-month assessment, young people in the delayed condition received the intervention; 56% attended the in-person intervention.

Assessments

Retention was high and similar across sites and intervention conditions as YPLH were assessed at 3 months (86%), 6 months (78%), 9 months (86%), and 15 months (82%). Young people were individually interviewed at a site convenient to them. An ethnically diverse team of trained interviewers assisted by collecting data using computerized assessments. Quality assurance ratings were conducted on 20% of interviews through audiotape reviews, and 93% met criteria on ratings of completeness, positive tone, and crisis referrals. For all assessment domains, activities reported for the previous 3 months are defined as "recent" behaviors.

The following measures were evaluated at each assessment period:

1. HIV risky behaviors

- A. Sexual risk acts. Using a structured interview protocol,²⁵ youth reported the total number of partners and sexual acts, specific sexual acts with each partner, and whether condoms were used during each of these sexual acts. A sexual partner was defined as a male or female partner with whom the youth engaged in vaginal or anal sex. A sexual act was defined as a single session of receptive or insertive vaginal or anal sex. Oral sex was reported but omitted in all calculations of risk because of its low association with HIV transmission.^{26,27} Based on extensive sexual history data obtained, we derived the following indices: (1) no recent sexual risk (abstinence or 100% condom use over the last 3 months); (2) the number of HIV-negative sexual partners or partners of unknown status; (3) the number of seroconcordant

sexual partners; and (4) the proportion of vaginal and anal sex acts protected by condoms with all partners, seroconcordant partners, and HIV-negative partners (or partners of unknown status). Disclosure of serostatus before sexual intercourse was assessed for each sexual partner. The percentage of partners YPLH disclosed was calculated for seroconcordant and HIV-negative partners or partners of unknown status.

- B. Substance use. YPLH were queried about the prevalence, frequency, and quantity of use of alcohol and a broad range of drugs (marijuana, stimulants, cocaine, crack, opiates, club drugs, and steroids). For each substance, we obtained data on the periods of most frequent drug use over the participant's lifetime, frequency of use in the last 3 months, means of use (oral, injection, or smoking), and symptoms associated with use. To evaluate dependency, we included 5 questions on the ability to limit use and physical symptoms of drug withdrawal. Based on YPLH's responses, we derived 4 indices: (1) symptoms of dependency, classified as present if 2 of 5 questions on recent dependency were endorsed (1) or not (0); (2) use of hard drugs (1) or not (0) (including stimulants, opiates, club drugs, steroids, and barbiturates); (3) injection drug use (1) or not (0); and (4) a sum of the number of different drugs used. We compared self-reported substance use with urine sample test results at baseline for 82 YPLH.²⁸ For each substance assessed, we also asked about risk during the time frame anticipated for the drug to stay active in the urine. For example, cocaine can be detected in urine samples for approximately 3 days after use, whereas marijuana can be detected for a period of at least 7 days after use. Therefore, we compared the urine screening results with the number of days since the last use as reported by participants. Percent agreement between positive test results and self-reported use is as follows: marijuana use, 84%; amphetamine or stimulant use, 83%; cocaine or crack use, 33%; and heroin use, 60%.

2. Health-related outcomes

- A. Medication adherence. At the time this study began, ARV medications were recommended for all persons living with HIV.²⁹ We assessed lifetime and recent ARV utilization and adherence, classified as present (1) or not (0). ARV adherence was based on an adapted measure.³⁰ YPLH reported the specific ARV medications they were taking; the number of times per day each medication was supposed to be taken; and how many times a dose was missed or skipped yesterday, 2 days ago, and 3 days ago. Adherence was defined as adhering to at least 90% of ARV medications that were supposed to be taken over the 3 days before the interview.
- B. Health behaviors. We assessed an index of medical adherence as the number of medical appointments missed.

TABLE 1. Baseline Characteristics of YPLH by Randomly Assigned Intervention Condition

	Telephone (n = 59) % (n)	In Person (n = 61) % (n)	Delayed (n = 55) % (n)	Total* (n = 175) % (n)
Site				
Los Angeles	49% (29)	51% (31)	47% (26)	49% (86)
New York	34% (20)	33% (20)	38% (21)	35% (61)
San Francisco	17% (10)	16% (10)	15% (8)	16% (28)
Median age (range)	23 (16–29)	23 (16–29)	22 (17–29)	23 (16–29)
Percent male	71% (42)	84% (51)	78% (43)	78% (136)
Ethnicity				
Latino	37% (22)	46% (28)	44% (24)	42% (74)
Black	29% (17)	26% (16)	24% (13)	26% (46)
White	27% (16)	21% (13)	22% (12)	23% (41)
Other ethnicities	7% (4)	7% (4)	11% (6)	8% (14)
High school graduate/GED	61% (35)	49% (30)	56% (31)	55% (96)
Percent gay, bisexual, or questioning	75% (43)	77% (47)	75% (41)	76% (131)
Bartered sex, lifetime	61% (36)	52% (32)	58% (32)	57% (100)
Have AIDS	21% (12)	21% (13)	26% (14)	23% (39)
HIV symptomatic	59% (33)	56% (34)	51% (28)	55% (95)
ARV medication use	53% (30)	51% (31)	45% (25)	50% (86)
Adherent (total n = 85, 1 missing)†	62% (18)	65% (20)	56% (14)	61% (52)
Know CD4 count	77% (44)	66% (40)	85% (46)	76% (130)
Median CD4 count (range)	487 (56–1500)	415 (0–1007)	555 (22–1128)	489 (0–1500)
Median viral load count (range)	5200 (0–750,000)	1800 (0–200,000)	2000 (0–10,000,000)	2000 (0–10,000,000)
Median number of HIV-negative partners (range)	1 (0–49)	1 (0–196)	1 (0–49)	1 (0–196)
Median percent protected sex acts (range)				
All sex partners‡	70.8 (0–100)	78.3 (0–100)	62.3 (0–100)	74.2 (0–100)
HIV-negative sex partners‡	95 (0–100)	100 (0–100)	96 (0–100)	100 (0–100)
100% condom use or abstinent	55% (31)	56% (34)	44% (24)	52% (89)
2 or more symptoms of dependency	52% (28)	53% (32)	45% (25)	50% (85)
Used hard drugs§	60% (34)	49% (30)	49% (27)	53% (91)
Injected drugs	14% (8)	13% (8)	20% (11)	16% (27)
Been in jail	57% (32)	59% (36)	61% (33)	59% (101)
Median (range)				
Number of different drugs used	2 (0–7)	1 (0–7)	1 (0–6)	1 (0–7)
Number of missed appointments	1 (0–6)	0 (0–13)	0 (0–5)	0 (0–13)
Number of positive lifestyle changes	20 (0–46)	21 (0–56)	21 (3–47)	21 (0–56)
Emotional distress	1.1 (0–3.8)	1.2 (0.1–2.5)	1 (0.1–3.6)	1 (0–3.8)

*n = 173 (n = 57 for telephone) for all measures except site, gender, ethnicity, and age.

†Defined as adhering to at least 90% of ARV medication regimens among recent ARV users.

‡P < 0.01.

§Defined as using substances other than alcohol, cigarettes, or marijuana.

In addition, we used a measure of positive health behaviors⁷ to document the frequency of engaging in 12 behaviors used to maintain health at least once a week on average: yes (1) or no (0) (eg, balanced diet, exercise, vitamins, adequate sleep).

C. Self-report health status. YPLH reported: (1) T-cell

count, (2) viral load count, (3) knowledge of T-cell count, (4) whether or not symptoms of HIV had been experienced, and (5) whether or not AIDS had been diagnosed. Self-reported CD4 and viral load counts were compared with counts from medical charts for 38 randomly chosen YPLH. Self-reported counts that

matched the most recent medical chart information were used when possible. Self-reported and medical chart information that differed by more than 6 months was not used, resulting in 33 cases being used to analyze CD4 counts and 29 cases being used to analyze viral load counts. The Pearson correlation between self-report and medical chart information was 0.80 for CD4 counts and 0.69 for viral load counts (both $P < 0.0001$).

3. Mental health outcome. The Brief Symptom Inventory (BSI),³¹ a 53-item reliable index of global severity of mental health symptoms, was administered ($\alpha = 0.97$ at baseline). Participants rated the level of severity for each symptom during the previous week on a scale from 0 (not at all) to 4 (extremely). Scores are reported as the mean response of the 53 items. The logarithm of the score is used in analyses.

Cost Data

Research staff, supervisors, and university budget leaders were monitored to calculate the resources expended for delivery of each intervention modality, including personnel, transportation, materials, food costs, overhead, and participants' opportunity costs as well as training the session facilitators. The resources were inventoried at the time that the intervention was conducted in 1999 through 2002. Monetary incentives were given for participation to reimburse participants for their time. In-person intervention and telephone intervention were assessed separately. We also excluded resources associated with the scientific evaluation of the study, for example, the assessment.

Data Analysis

Intent-to-treat analyses were conducted examining measures from the baseline assessment until 15 months. Mixed-effect regression models were used to evaluate the impact of the intervention condition on transmission-, physical health-, and mental health-related outcomes. Covariates included time since baseline assessment (months), intervention condition, ethnicity, gender, recruitment city, and a time by intervention condition interaction. A covariate for having traded sex during the lifetime of YPLH was included in models for sexual behavior outcomes, and a covariate for the amount of time since ARV initiation was included in the model for the ARV adherence outcome.

An autoregressive moving average (ARMA) covariance structure³² provided the best fit of several covariance structures we tested and was used in all longitudinal analyses. The ARMA covariance structure suggests that the correlation of outcomes between time points is dependent on the average correlation across time points and the proximity of time points. Outcomes measured closer together are more highly correlated.

Missing observations did not contribute to the fit of the model at time points where they were missing or affect how nonmissing observations were used in analyses. For the analy-

sis of 2 outcomes composed of fractions, the fraction of protected sex acts and adherence to ARVs, the analyses excluded observations with 0 denominators. For example, in the analysis of adherence, observations for participants who were not using ARVs recently were excluded.

Results are presented using relative effect size (RES) at 15 months, defined as $100 \times ([\text{outcome T1} - \text{outcome T2}]/\text{outcome T2})$. F-statistics (F), t-statistic absolute value (t), and corresponding degrees of freedom (*df*) are presented for intervention condition comparisons.

Baseline intervention condition differences of recent outcomes were tested by examining F-statistics for intervention main effects in the mixed-effect regression models; differences for demographics and other measures were tested using ANOVA; logistic regression; and Poisson regression for continuous, dichotomous, and count measures, respectively. Baseline intervention condition differences of recent outcomes were adjusted for by including an intervention condition covariate in all mixed-effect regression models.

To assess changes among YPLH in the delayed-intervention condition over time independently, we compared participants in the delayed condition on baseline and 15-month outcomes, performing a paired *t* test, McNemar test, and logistic regression, including a random effect for each pair, on continuous outcomes, dichotomous outcomes, and outcomes represented as a fraction, respectively.

All analyses were performed using SAS software, version 8.01 (SAS Institute, Cary, NC). Dichotomous and count (eg, number of protected acts) outcome measures were modeled using logistic and Poisson mixed-effect regressions, respectively, in the GLIMMIX macro, and continuous outcome measures were fit using linear mixed-effect regressions in the PROC MIXED procedure.

RESULTS

Sample

Table 1 gives characteristics of YPLH measured at baseline ($n = 175$). Most YPLH were male, gay or bisexual male (69%), and of ethnic minority heritage. About half of the YPLH were currently on ARVs and had experienced symptoms of HIV; most had used ARVs during their lifetime, had served time in jail, and had graduated from high school or received a GED certificate. Over their lifetime, YPLH had a median of 50 sexual partners; 2 YPLH reported being sexually abstinent, and 21 YPLH reported having 1000 or more sexual partners. Disclosure of serostatus and condom-protected sex seems to be higher among seroconcordant (HIV-positive) partners than among HIV-negative partners or partners of unknown status. As part of an eligibility criterion to be in the study, all YPLH had recently used substances 5 or more times. Most (78%) had used hard drugs over their lifetime.

Randomization successfully resulted in similar groups across demographic and most outcome measures, but we did

find differences at recruitment across intervention conditions for the proportion of protected sex acts across all sexual partners ($F = 9.49$, $df = 2, 155$; $P < 0.01$), among HIV-positive sexual partners ($F = 3.13$, $df = 2, 94$; $P = 0.05$), and among HIV-negative sexual partners ($F = 10.46$, $df = 2, 141$; $P < 0.01$). The in-person intervention condition had a higher proportion of protected acts across all sexual partners, among HIV-positive sexual partners, and among HIV-negative sexual partners compared with the delayed-intervention condition ($P < 0.05$). The telephone intervention condition had a higher proportion of protected acts across all sexual partners and among HIV-negative sexual partners compared with the delayed-intervention condition ($P < 0.05$). The telephone intervention condition also had a higher proportion of protected acts across all sexual partners and among HIV-negative sexual partners compared with the in-person intervention condition ($P < 0.05$).

Intent-to-Treat Analyses

Table 2 summarizes the estimated outcomes at the baseline and 15-month assessments for each intervention condition as well as for the RES. Each outcome measure reflected a linear trend over time; therefore, we have not included the mean on each measure for the intermediate time points. Significant differences for time by intervention condition effects are indicated. There was a significant difference in the proportion of protected acts between intervention conditions over time

across all partners ($F = 3.38$, $df = 2, 380$; $P = 0.03$) and among HIV-negative partners ($F = 5.18$, $df = 2, 264$; $P < 0.01$) but not among HIV-positive partners. YPLH in the in-person intervention increased their proportion of protected sexual acts across all sexual partners compared with YPLH in the delayed intervention over time ($t = 2.57$, $df = 380$; $P < 0.01$). The proportion of protected sexual acts in the telephone condition was not significantly different from that in the delayed intervention or in the in-person intervention over time. YPLH in the telephone group had a significant decrease in the proportion of protected acts among HIV-negative partners compared with YPLH in the in-person intervention over time ($t = 2.65$, $df = 264$; $P < 0.01$). The number of sexual partners and disclosure of serostatus to partners were similar over time across intervention conditions.

The proportion of YPLH using hard drugs, the proportion of injecting drug users, the proportion of YPLH with symptoms of dependency, and the number of different drugs used were similar among intervention conditions over time.

The proportion of ARV use and adherence to ARV medication were similar among intervention conditions over time. The proportion of those who changed their health behaviors (eg, exercised, ate a healthy diet, took supplements and vitamins) was similar between intervention conditions over time. On average, logs of the overall score for emotional distress on the BSI were similar between intervention conditions over time.

TABLE 2. Intervention Condition Estimated Outcomes at Baseline and 15 Months for Intent-to-Treat Analyses

Recent Outcome Measures	Telephone (n = 59)		In Person (n = 61)		Delayed (n = 55)		Relative Effect Size*	
	Baseline	15 Months	Baseline	15 Months	Baseline	15 Months	Telephone vs. Delayed	In-person vs. Delayed
Sexual behavior								
Number of HIV-negative partners	5.0	4.6	4.0	1.4	4.3	2.5	86.6	-41.5
Percent of protected acts								
All partners	59%	59%	45%	58%‡	30%	22%	172.2	169.1
HIV-negative partners	75%	65%†	53%	73%§	37%	32%	105.1	132.3
100% condom use or abstinent	57%	50%	57%	58%	46%	59%	-15.3	-1.7
Substance use								
2 or more symptoms of dependency	52%	43%	52%	40%	44%	31%	38.4	29.2
Used hard drugs	66%	47%	48%	48%	55%	49%	-3.7	-0.8
Injected drugs	15%	15%	11%	11%	21%	20%	-25.0	-45.0
Number of different drugs	1.9	1.4	1.7	1.5	1.8	1.4	1.4	10.0
Use ARVs	50%	36%	55%	43%	44%	28%	28.6	53.6
Adherent to ARV regimen	60%	54%	62%	70%	55%	74%	-27.3	-4.8
Number missed appointments	1.1	0.9	0.8	0.7	0.8	0.8	10.5	-19.1
Log emotional distress	1.0	0.8	1.0	0.9	1.0	0.9	-14.5	-0.3

*Relative effect size = $100 \times (u_1 - u_2)/u_2$, where u_1 and u_2 are estimated outcomes at 15 months.

†Telephone vs. in-person; $P < 0.01$ for time by intervention comparison.

‡In-person vs. delayed; $P < 0.05$ for time by intervention comparison.

§In-person vs. delayed; $P < 0.01$ for time by intervention comparison.

Changes in the Delayed Condition Over Time

Participants at 15 months in the delayed condition showed a trend toward having fewer sexual partners (mean decrease = 3.7, t -statistic = 1.97, $df = 42$; $P = 0.06$), using fewer different drugs (mean decrease = 0.42, t -statistic = 2.03, $df = 42$; $P = 0.05$), and having a lower mean global BSI score (mean decrease = 0.26, t -statistic = 2.06, $df = 42$; $P = 0.05$) compared with the participants at baseline. At 15 months, YPLH were also less likely to be using highly active antiretroviral therapy (HAART) compared with baseline ([McNemar test] $df = 1$; $P = 0.05$). Of YPLH using HAART at baseline, 50% (10 of 20) of participants were not using HAART at 15 months. Of participants not using HAART at baseline, 13% ($n = 3$ of 23) were using HAART at 15 months.

Cost Analysis

The total cost of the in-person intervention for the 3 modules was \$3500 per participant (approximately \$1167 per module), which was higher than the cost of \$2692 per participant for the telephone intervention (approximately \$897 per module). The excess cost of traveling time and expenses for in-person sessions accounted for this difference. Personnel accounted for most of the total costs: 65% for in-person sessions and 60% for telephone sessions. Overhead costs averaged 25% and material and instrumental costs averaged 12% of total costs across intervention conditions.

DISCUSSION

This trial aimed to test the limits of the process of tailoring and adapting an efficacious intervention. Could we change the delivery format and reduce the number of sessions and retain efficacy with drug users? Because community providers typically adapt the intervention for delivery in their particular setting and for somewhat different populations, this is a key debate in the field of prevention today. This replication of an intervention for YPLH suggests some of the pitfalls in such adaptations.

We adapted a 3-module intervention delivered in a small group setting and examined individually delivered telephone and in-person sessions as alternative formats for preventing transmission and improving physical health and mental health outcomes for YPLH. These delivery modalities are consistent with the prevention case management models for persons living with HIV. We also reduced the number of sessions by 50% to examine the influence of less lengthy interventions with YPLH.

The proportion of protected sexual risk acts, especially with seronegative partners, was significantly higher among youth randomized to the in-person intervention condition delivered in individual sessions. This is consistent with the findings of our previous intervention trial.⁷ There were significant reductions in sexual risk when YPLH were randomized to in-

dividual sessions focused on encouraging reductions in sexual transmission acts, at a cost of \$1167 per person for module 2. This finding is particularly impressive, because there was a significant difference across intervention conditions at recruitment. There was less opportunity for improvement among youth randomly assigned to the in-person condition; yet, the youth in the in-person group significantly increased their condom use compared with other groups.

Also similar to the previous intervention, approximately two thirds of YPLH attended interventions delivered in a small group format and in a telephone format in this study. At least 1 individual session was attended by 87% of youth, suggesting that a prevention case management approach may be an acceptable delivery modality for YPLH. In addition, we would anticipate that case management offers the potential to deliver the intervention over an extended period as YPLH work with their case managers. Small groups result in a lower per person cost per module (\$547 vs. \$1167) even with double the number of sessions. Yet, individual sessions have fewer concerns regarding disclosure of serostatus, and the interventions could be used in rural settings. Based on the results of this trial, an efficacious intervention for reducing sexual transmission among YPLH can be delivered in small group or in individual sessions.

One of the important implications of this trial is the need for screening among YPLH before service delivery. In reviews of a substantial number of studies with persons living with HIV³³ and in our last 2 intervention trials,^{7,12,16} we found that more than half of persons living with HIV do not demonstrate any sexual risk transmission acts over the course of the trial. Substantial resources and diminished effect sizes occur when we include those not engaging in transmission acts for delivery of preventive interventions. In this trial, we screened on substance use risk acts, which we expected to be associated with inconsistent sexual risk practices. Unlike previous researchers' findings^{4,6} and our own results in the previous intervention trial,⁷ however, hard drug users were not more likely to have unprotected sexual risk acts. Similarly, not all YPLH are in need of interventions to increase adherence to medical regimens or to improve mental health. More than half were on ARVs and adhering to more than 90% of their medication doses. Screening seems to be a key strategy for selecting YPLH in need of intervention.

The YPLH in the delayed-control condition improved over time on many outcome measures with only repeated assessments. The pre- and postanalyses among participants in the delayed condition indicated that most YPLH reduced their sexual and drug use behaviors over time, without interventions, but with repeated assessments of risk behaviors over time. Almost all participants in the control condition of every intervention trial have improved substantially.³⁴⁻³⁷ The consistent improvements associated with repeated assessments in the control conditions have led our research team to examine

repeated assessments as a cost-effective intervention strategy for persons living with HIV; this strategy is currently being evaluated (M. Lightfoot, PhD, study in progress). The benefits of repeated assessments as a strategy for improving health-related HIV behaviors may significantly reduce the costs of intervention delivery.

Reducing illicit substance use was also a primary goal of this intervention, and all youth had used drugs at least 5 times in the previous 3 months to be eligible for the trial. The effect sizes for reductions in substance use among the in-person and telephone conditions compared with the delayed condition were relatively large yet did not reach significance. Retrospective analysis suggests that we were underpowered to observe significant results within the intervention and control conditions given the substantial reductions in substance use among YPLH in the control conditions. To show a significant difference in hard drug use in the immediate intervention groups compared with the delayed-intervention group over time, we would have needed 5.4 times more participants to show significance.* Future trials with YPLH must anticipate loss of power with abstinence.

Sexual risk outcomes seem to be robust; sexual risk behaviors are significantly reduced with efficacy in in-person delivery formats despite the number of reduced sessions. The other positive outcomes were not retained, however, including improvements in mental health, adherence to medical regimens (particularly ARVs), and improvements in healthy lifestyle behaviors. It may be important to note that YPLH reported 20 positive health behaviors (eg, exercise regularly) at recruitment and emotional distress scores in the normative range. In addition to tailoring interventions to those who have deficits in a specific area, interventions for YPLH may require a greater dose of an intervention to achieve positive outcomes in medical adherence and mental health outcomes for YPLH, similar to the number of sessions in our earlier intervention.⁷ The case management services being offered and the ongoing medical care provided to persons living with HIV offer important ongoing opportunities to deliver sufficient doses of interventions in highly accessible settings. These alternatives are currently being examined.

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*This calculation is equal to $(t\text{-statistic for an } \alpha\text{-level of } 0.05/\text{observed } t\text{-statistic})^2 = (1.96/0.84)^2$, where 0.84 is the t-statistic for the time by intervention interaction parameter estimate in a mixed-effect regression model for the hard drug use outcome. The telephone and in-person interventions were combined into 1 group.

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