

# Project STYLE: A Multisite RCT for HIV Prevention Among Youths in Mental Health Treatment

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**Objective:** The study examined the efficacy of family-based and adolescent-only HIV prevention programs in decreasing HIV risk and improving parental monitoring and sexual communication among youths in mental health treatment. **Methods:** A randomized controlled trial (RCT) with 721 adolescents (ages 13–18 years) and their caregivers from mental health settings in three U.S. cities were randomly assigned to one of three theory-based, structured group interventions: family-based HIV prevention, adolescent-only HIV prevention, and adolescent-only health promotion. Interventions were delivered during an all-day workshop. Assessments were completed at baseline and three months postintervention. **Results:** Compared with those in the health intervention, adolescents in the HIV prevention interventions reported fewer unsafe sex acts (adjusted rate ratio=.49,  $p=.01$ ), greater condom use (adjusted relative change=59%,  $p=.01$ ), and greater likelihood of avoiding sex (adjusted odds ratio=1.44,  $p=.05$ ). They also showed improved HIV knowledge ( $p<.01$ ) and self-efficacy ( $p<.05$ ). The family-based intervention, compared with the other interventions, produced significant improvements in parent-teen sexual communication ( $p<.01$ ), parental monitoring ( $p<.01$ ), and parental permissiveness ( $p=.05$ ). **Conclusions:** This RCT found that the HIV prevention interventions reduced sexual risk behavior over three months in a large, diverse sample of youths in mental health treatment and that the family-based intervention improved parental monitoring and communication with teens about sex. These interventions show promise. (*Psychiatric Services* 65:338–344, 2014; doi: 10.1176/appi.ps.201300095)

Compared with peers without mental illness, adolescents with psychiatric disorders engage more frequently in behavior that increases HIV risk (1,2). For example,

prior research has found that 40%–50% of youths with a mental disorder reported having sex before age 13 (3,4) compared with only 6% of a nationally representative sample (5).

Likewise, youths with psychiatric disorders are less likely to use condoms (55%) and more likely to use substances during sex (49%) compared with youths in the general population (40% and 22%, respectively) (5,6). Given the increased risk of HIV infection among these youths, HIV prevention programs targeted toward this population are important.

Although adolescents with mental health problems may engage in behavior that elevates HIV risk, only three studies have targeted this population (7–9) and only one study demonstrated a significant behavioral impact (7). These previous evaluations had a number of significant limitations, including a lack of the following: a comprehensive assessment of risk behavior (8,9), a time- and attention-matched comparison condition (7–9), random group assignment of participants (7–9), and participants with racial, ethnic, and geographic diversity (7,8). These interventions all addressed individual-level factors, such as knowledge, personal motivation, and safer sex skills, but did not target broader social factors related to HIV risk. Parents can affect teen risk behavior through their parenting practices, such as monitoring, permissiveness, and parent-adolescent communication about sex (10). A number of studies have demonstrated improvements in communication and parental monitoring, although the impact on adolescent sexual risk behavior has been variable (11–16). Given

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the influence of parenting behaviors and family dynamics on youths in mental health treatment, improving these factors may reduce HIV risk (17). Because no previous study had developed or tested a family-based HIV prevention intervention for youths in mental health treatment, Project STYLE (Strengthening Today's Youth Life Experiences) developed one (18).

This study examined the impact, after three months, of a family-based HIV intervention and an adolescent-only HIV intervention (7), compared with an adolescent-only general health condition, in reducing HIV risk behaviors and improving parental monitoring and sexual communication among adolescents in mental health treatment. The choice of analyzing the three-month postintervention data from the trial is consistent with the Centers for Disease Control's criteria for identifying efficacious programs. The HIV prevention interventions (either family-based or adolescent-only intervention) shared several similar targets, so we hypothesized that they would be significantly more efficacious than the general health condition at three months in decreasing risky behavior among youths and in enhancing adolescent HIV-related knowledge and self-efficacy. Intervention targets specific to the family-based intervention (parental HIV knowledge, sexual communication, and monitoring) were hypothesized to improve more in the family-based relative to the adolescent-only interventions.

## Methods

### *Participants*

Participants (adolescents ages 13 to 18) were recruited from inpatient and outpatient mental health settings between 2003 and 2008 (19). The study was conducted at Rhode Island Hospital in Providence, Emory University in Atlanta, and the University of Illinois at Chicago. Project recruiters worked closely with clinicians, discharge coordinators, and office staff (including administrative support staff and intake coordinators) to identify all eligible adolescents, thus reducing bias due to "preselection" by site personnel. Referrals from clinicians and discharge coordinators accounted for 97% of the sample. Passive recruitment via

project posters and flyers accounted for the remainder.

Eligible youths were in mental health treatment and living with a primary caregiver for the past three months. Both the participating parent and the teen spoke English. Adolescents who self-reported HIV infection, pregnancy, or sexual aggression were excluded because the intervention was not designed to address important issues relevant for those youths (such as disclosure of HIV, support during pregnancy, and legal charges). If more than one caregiver was present in the home, the family selected the primary caregiver to participate in the study with the adolescent. Of those referred, 74% were able to be contacted, and 36% were ineligible or refused participation. [A CONSORT diagram showing the flow of participants in the study is available online as a data supplement to this article.] Of the remaining eligible families, 80% were enrolled, for a final analytic sample of 721 adolescents. Reasons for nonenrollment included lack of interest in a research program, not having enough time, and a current crisis due to recent adolescent hospitalization (19). Study protocols were reviewed and approved by sites' institutional review boards, and all participants completed written informed consent or assent. Randomization was conducted at each site on the morning of the intervention.

### *Interventions*

The interventions, matched by time and attention (group size), were delivered during an eight-hour workshop at each site in groups of four to eight participants and led by trained facilitators (master's- or doctoral-level clinician and research assistant). All three interventions served as a supplement to the ongoing mental health treatment of adolescents enrolled in the program. Interventions included engaging didactics, interactive exercises, videos, and in-depth discussions. Each intervention focused on knowledge, attitudes, and self-efficacy in regard to the intervention's health targets and addressed the interaction between psychiatric disorders and health behaviors.

The family-based intervention (N=227 adolescents) included content to improve parental communication with

teens, as well as monitoring and supervision of them, and content to improve the adolescent skills found in the adolescent-only HIV intervention. The family-based intervention was based on the Social-Personal Framework (17), which proposes that adolescent HIV risk taking is a function of the interplay of adolescent psychopathology (including substance use) and parenting styles (monitoring and communication), as well as personal, peer, and community factors. In this intervention, both parents and teens attended group sessions separately and then came together to practice skills learned in their respective groups, including improved parent-adolescent general and sexual communication. The family-based intervention was developed through an iterative process of qualitative work, feasibility and acceptability testing, and pilot trials in all three cities over one year (18,19).

The adolescent-only HIV intervention (N=259) emphasized sexual decision making, refusal of sex, abstinence, and condom use and was based on a previously developed efficacious group intervention for adolescents in mental health treatment (7). The adolescent-only general health intervention was based on school health programs, and it targeted exercise, nutrition, sleep, smoking, and information about HIV. In the adolescent-only HIV (N=259) and general health (N=235) interventions, only the adolescents attended the group sessions. All participants completed a risk reduction plan and received practice assignments to review in an individual session with a facilitator two weeks later.

### *Training and quality assurance*

Centralized training of the intervention protocol was conducted annually for all facilitators. Training consisted of presentation of factual information regarding HIV, adolescent psychosexual development, group dynamics, and behavior management. Facilitators practiced all material under supervision. In all three conditions, adherence to a training manual and competence of delivery were rated as having been done "well" to "very well" more than 90% of the time (ratings given at more than 20% of sessions).

### **Data collection**

Parents and adolescents completed audio computer-assisted structured interview (ACASI) assessments before randomization (baseline) and three months postintervention. Assessments lasted approximately 90 minutes, and parents and adolescents were each compensated \$50. Demographic data collected included age, gender, ethnicity, race, household income, and parent education.

### **Psychiatric measures**

The Columbia Impairment Scale (CIS) (20), a 13-item scale administered to both parent ( $\alpha=.83$ ) and adolescent ( $\alpha=.78$ ), provides a global measure of adolescent impairment. It assesses interpersonal relations, broad psychopathological domains, functioning in job or schoolwork, and use of leisure time, with higher scores indicating greater impairment (range 0–52). The Diagnostic Interview Schedule for Children (C-DISC) (21) is a structured computer-assisted diagnostic interview that generates DSM diagnoses (22,23). The following disorders were assessed: major depressive disorder, generalized anxiety disorder, posttraumatic stress disorder, mania, hypomania, oppositional defiant disorder, conduct disorder, and attention-deficit hyperactivity disorder. Disorders were counted if the screening threshold was exceeded by either parent or adolescent reports on the C-DISC, consistent with other studies (24,25).

### **Measures of risk behavior**

The primary outcome measure was adolescent self-reported unprotected episodes of vaginal sex, anal sex, or both during the past 90 days. Youths completed the AIDS Risk Behavior Assessment (6,26,27), a structured interview designed specifically for use with adolescents to assess sexual and other HIV risk behaviors, such as alcohol and marijuana use. The measure assessed history of sexual behavior and condom use during each sexual event in the past 90 days. Both the number of unprotected sexual episodes and the proportion of times that condoms were used in the past 90 days were calculated. Secondary outcomes were the proportion of youths reporting any sex, avoidance of sex, number of partners in

the past 90 days, and use of alcohol or marijuana in the past 30 days.

### **Measures of knowledge, attitudes, and parental behaviors**

For all measures used, higher scale scores indicate greater knowledge, self-efficacy, open communication, monitoring, or permissiveness.

The HIV Knowledge Scale (28) surveys participants' knowledge of routes of HIV transmission and general information, with 27 true-false items for adolescents ( $\alpha=.97$ ) and parents ( $\alpha=.99$ ) summed to create a total knowledge index. The Self-Efficacy for HIV Prevention Scale (29) was administered to adolescents and assesses perceived ability to engage in specific HIV-preventive behaviors, such as discussion of safe-sex measures with partners ( $\alpha=.89$ ; range 12–48). The Parent-Adolescent Sexual Communication Scale (30) assesses the openness of sexual communication (range 6–42); youths ( $\alpha=.79$ ) and parents ( $\alpha=.61$ ) completed separate versions. The Parenting Style Questionnaire (31) measures the degree of parental monitoring ( $\alpha=.69$ ; range 1–20) and permissiveness ( $\alpha=.75$ ; range 1–20) as perceived by the adolescent.

### **Data analyses**

Across the three arms of the trial, retention at three months was 91% ( $N=654$ ), and there were no differences in attrition between treatment arms ( $\chi^2=2.52$ ,  $df=2$ ,  $p=.28$ ). In order to address potential bias introduced by attrition, multiple imputations by chained equations were used to address missing data and account for differences in distributional assumptions (32).

Study hypotheses were tested with generalized linear models. Negative binomial distributions were used for behavioral counts. All models controlled for the baseline assessment of the respective measure. Adolescent sexual risk, substance use, knowledge, and self-efficacy were compared between both HIV interventions (family-based and adolescent-only) and the adolescent-only health intervention. Parental measures were compared between family-based and the adolescent-only HIV and health interventions.

At both assessments, most of the individuals in the sample reported no

unprotected sex acts and were recorded as having contributed a zero for the variable “unprotected sex acts in the past 90 days,” which resulted in a zero-inflated distribution. Those who contributed a zero were in one of three categories: those who had never had sex, those who had not had sex in the past 90 days, or those who had not had any unprotected sex in the past 90 days. To address the zero inflation and help distinguish between the three categories, we first compared among the trial arms the number of participants who had ever had sex. Then, for those who reported by the three-month assessment ever having had sex, we evaluated differences among arms in the number of youths engaged in any sexual activity during the past 90 days. Finally, for participants who reported sexual activity during the past 90 days, we used a negative binomial model to evaluate the number of unprotected acts. Imputations were generated with the use of IVEware (33). Analyses were run on each of ten imputed data sets with SAS Proc Genmod, and results were concatenated across imputations with SAS Proc MIanalyze (34).

## **Results**

### **Sample characteristics and comparisons between conditions**

The mean  $\pm$  SD age of adolescent participants was  $14.85 \pm 1.59$  years, and 57% ( $N=410$ ) were female. Racially, 60% ( $N=429$ ) were African American, 33% ( $N=238$ ) were Caucasian, 7% ( $N=54$ ) were other races. Ethnically, 11% ( $N=78$ ) were Latino. Mean income was \$31,947. All youths were in mental health treatment at the time of enrollment, 51% ( $N=368$ ) had received psychotropic medications in the past three months, and 43% ( $N=310$ ) had been psychiatrically hospitalized in the past 90 days, with a stay of  $15.49 \pm 13.32$  days. Nearly half (42%,  $N=303$ ) of youths met C-DISC threshold screening criteria for at least one mental disorder by either their own or their parent's report, and 22% ( $N=159$ ) met criteria for more than one disorder. Participants met criteria for the following: oppositional defiant disorder (23%,  $N=166$ ), conduct disorder (20%,  $N=144$ ), major depressive disorder (11%,  $N=79$ ),

**Table 1**Risk behaviors reported by adolescents before and after a one-day intervention program<sup>a</sup>

Behavior	Baseline (N=721)				3 months postintervention (N=654)				HIV prevention versus control		
	HIV prevention (N= 486)		Control (N=235)		HIV prevention (N=446)		Control (N=208)				
	N	%	N	%	N	%	N	%	OR <sup>b</sup>	95% CI	p
Ever had vaginal or anal sex	257	53	130	56	303	65	140	63	1.88	.91–3.92	.09
Avoid sex past 90 days	164	35	72	33	154	36	50	26	1.44	1.00–2.08	.05
Vaginal or anal sex, past 90 days <sup>c</sup>	157	53	71	52	160	61	73	60	1.06	.68–1.66	.79
100% condom use, past 90 days <sup>d</sup>	66	46	36	54	78	53	29	45	2.37	1.05–5.38	.04
Alcohol use, past 30 days	104	22	45	19	98	23	43	21	1.07	.68–1.69	.77
Marijuana use, past 30 days	116	24	49	21	108	25	42	20	1.22	.78–1.93	.38

<sup>a</sup> HIV prevention included an intervention for adolescents only or for parent and teen; the control condition was a general health intervention for adolescents only. Percentages are based on the number of valid cases for each measure.

<sup>b</sup> Adjusted for baseline measurements

<sup>c</sup> Reported for adolescents who were sexually active by the 3-month assessment

<sup>d</sup> Reported for adolescents who reported sexual activity during the past 90 days

generalized anxiety disorder (8%, N=57), posttraumatic stress disorder (5%, N=36), hypomania (5%, N=36), attention-deficit hyperactivity disorder (4%, N=29), and mania (3%, N=22). Parental reports on the CIS revealed significant functional impairment for 62% (N=447) of the teens. There were no significant baseline differences across intervention conditions on demographic characteristics, impairment, or risk behaviors.

### Risk outcomes

**Sexual risk.** Consistent with hypotheses, youths in the family-based and adolescent-only interventions, compared with youths in the general health intervention, reported a significantly greater increase in condom use

100% of the time and more avoidance of sexual encounters during the past 90 days (Table 1). Likewise, youths in the HIV interventions reported a significant decrease in unprotected sexual acts and an increase in the proportion of protected sexual acts (Table 2).

**Substance use.** There were no significant differences in alcohol or marijuana use among participants in the general health intervention and the two HIV interventions (Table 1).

### Knowledge, attitude, and parenting behaviors

Compared with youths in the general health intervention, those in the family-based and adolescent-only HIV interventions reported significantly more HIV prevention self-efficacy (adjusted

relative change=3.75%; 95% confidence interval [CI]=.16–6.86,  $p=.04$ ) and more HIV knowledge (adjusted relative change=18.85%; CI=8.89–27.21,  $p<.01$ ) at three months. As expected, youths in the family-based intervention, compared with those in adolescent-only HIV and general health interventions, reported significantly more sexual communication with parents, more parental monitoring, and less parental permissiveness (Table 3). Parents in the family-based HIV prevention intervention also had a significantly greater increase in HIV knowledge.

### Discussion

This study revealed promising short-term efficacy of Project STYLE, an HIV prevention program for families

**Table 2**Risk incidence reported by adolescents before and after a one-day intervention program<sup>a</sup>

Behavior <sup>b</sup>	Baseline				3 months postintervention				HIV prevention versus control		
	HIV prevention (N=157)		Control (N=71)		HIV prevention (N=160)		Control (N=73)				
	M	SD	M	SD	M	SD	M	SD	RR <sup>c</sup>	95% CI	p
Partners past 90 days	2.11	1.79	2.04	1.83	2.69	4.01	2.26	2.53	1.32	.91–1.90	.14
Unprotected sex acts	5.58	13.54	5.88	13.60	3.53	7.10	9.32	19.80	.49	.28–.86	.01
Percentage of protected sex acts	63.51	41.51	65.85	42.22	72.02	37.23	63.02	41.03	59.04	16.50–82.23	.01

<sup>a</sup> HIV prevention included an intervention for adolescents only or for parent and teen; the control condition was a general health intervention for adolescents only.

<sup>b</sup> Sexual risk outcomes were reported for those who reported sexual activity during the past 90 days.

<sup>c</sup> Rate ratio, adjusted for baseline measurements



**Table 3**

Family scale scores after the family intervention and other interventions (adolescent only and general health promotion)

Measure	Baseline (N=721)				3 months postintervention (N=654)				HIV prevention versus control		
	Family (N=227)		Other (N=494)		Family (N=206)		Other (N=448)				
	M	SD	M	SD	M	SD	M	SD	Relative change (%) <sup>a</sup>	95% CI	p
Adolescent report											
Communication <sup>b</sup>	27.15	9.48	26.32	9.82	28.14	8.40	25.02	9.28	17.98	7.62 to 30.70	<.01
Monitoring <sup>c</sup>	15.21	3.89	15.44	3.83	15.75	3.89	14.86	4.39	11.41	3.60 to 21.62	<.01
Permissiveness <sup>c</sup>	10.22	4.00	9.99	3.89	10.44	4.00	10.90	4.21	-12.15	-21.86 to .05	.05
Parent report											
Communication <sup>b</sup>	34.34	6.52	33.63	6.02	34.76	5.99	34.28	5.91	.24	-6.42 to 5.38	.94
Parent HIV knowledge <sup>d</sup>	67.31	15.74	65.75	15.90	74.90	15.40	67.90	16.87	24.19	11.59 to 44.05	<.01

<sup>a</sup> (Adjusted mean difference/adjusted comparison condition mean) × 100%. Relative change scores were adjusted for baseline measurements.

<sup>b</sup> Possible scores range from 6 to 42, with higher scores indicating greater communication.

<sup>c</sup> Possible scores range from 1 to 20, with higher scores indicating greater perceived parental monitoring or permissiveness.

<sup>d</sup> Possible scores range from 1 to 27, with higher scores indicating greater perceived knowledge about HIV.

and youths with mental health problems. Findings indicated that youths who received the HIV prevention programs reported significantly fewer unsafe sex acts, a greater proportion of consistent condom use, and greater likelihood of avoiding sex three months after the interventions than youths in the attention- and time-matched general health intervention. The magnitude of the impact is similar to other effective prevention programs (11,14–16). For youths in the HIV prevention programs, unsafe sex acts decreased by nearly half, whereas they increased over time by nearly half among adolescents in the general health intervention. Similarly, the proportion of youths consistently using condoms increased by 15% in the HIV interventions and decreased by 17% among those in general health condition.

These results are significant in several ways. First, youths in mental health treatment are at increased vulnerability for HIV and other sexually transmitted infections relative to their peers, and this study yielded positive changes in this high-risk population. Second, the study extends previous HIV prevention trials by revealing change in behavioral outcomes (that is, sexual behavior), including a time- and attention-matched comparison condition, random assignment

of individuals, and enrollment of a diverse population (by race, ethnicity, and location). Third, the methodological strengths of this study provide greater confidence that HIV prevention, either for adolescents or for adolescents and their parents, can have a short-term impact on safer sexual behavior. An important finding was that the interventions did not result in increased sexual activity or substance use, despite parental concerns that explicit discussion will increase teen risky behavior. In fact, youths in the HIV prevention interventions reported greater likelihood of avoiding sexual encounters.

The study found improvements in most factors hypothesized to account for the interventions' impact. The HIV interventions were associated with increased adolescent HIV knowledge and self-efficacy for HIV prevention skills. Similarly, the family intervention, which targeted parenting behaviors, produced significant improvement in parental HIV knowledge and, by adolescent report, increased parent-teen communication about sex, more parental monitoring, and less parental permissiveness. It is possible that these improvements, which change the family dynamics, will manifest themselves in safer adolescent behavior over a longer follow-up period (16).

Most HIV prevention programs for adolescents have been lengthy multisession interventions, but these data suggest that a single-day workshop can produce change, even for troubled families. The extent of mental health treatment received by the sample (43% had been hospitalized in the past three months, and 51% had received psychiatric medications) suggests that the adolescents and families faced numerous psychosocial stresses. Despite the diverse, urgent symptoms that brought the adolescent to treatment (such as suicidal behavior or aggression), families participated in a full-day workshop, were retained at follow-up, and demonstrated significant positive impact from a one-day workshop. For such distressed families, multisession interventions are unlikely to be feasible, and thus, by fitting STYLE to the needs of families (a one-day workshop), the intervention was ecologically valid and effective.

This randomized controlled trial (RCT) had several strengths, including a diverse multisite sample of youths whose HIV risk behavior has been infrequently studied (those in mental health treatment), manualized interventions based on accepted theoretical constructs, rigorous attention to fidelity and monitoring of the intervention, excellent retention, and

both adolescent and parent assessments. Nevertheless, there were limitations. The sample comprised families agreeable to participation in a trial, and so the results may not generalize to all families in mental health treatment. The outcome assessments were by self-report, so social desirability bias is possible. However, evidence suggests that ACASI methods increase validity when sensitive behaviors are being reported (26).

## Conclusions

This multisite RCT found that theory-based HIV prevention interventions tailored for youths in mental health treatment reduced sexual risk behavior. The family intervention targeted sexual communication and parental monitoring—topics relevant to general functioning—as well as adolescent sexual risk. It is possible that techniques used to improve family communication and parental monitoring of children could be adapted for use with teens' other problematic behaviors. The one-day HIV interventions with one brief follow-up visit had a behavioral impact and were effectively delivered in either groups with only adolescents or with parents and adolescents together. This feasibility and efficacy suggest that STYLE may be worthy of future dissemination. Not all approached families were able to commit to a full-day weekend workshop. Treatment centers might be able to provide more options in offering the interventions and thus extend their reach. It will be important to replicate and extend these findings. If replicated, effective approaches for implementing these interventions in mental health care settings can be determined.

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## ***Psychiatric Services* Invites Short Descriptions of Novel Programs**

*Psychiatric Services* invites contributions for Frontline Reports, a column featuring short descriptions of novel approaches to mental health problems or creative applications of established concepts in different settings.

Text should be 350 to 750 words. A maximum of three authors, including the contact person, can be listed; one author is preferred. References, tables, and figures are not used. Any statements about program effectiveness must be accompanied by supporting data within the text.

Material to be considered for Frontline Reports should be sent to one of the column editors: Francine Cournos, M.D., New York State Psychiatric Institute, 1051 Riverside Dr., Unit 112, New York, NY 10032 (e-mail: fc15@columbia.edu), or Stephen M. Goldfinger, M.D., Department of Psychiatry, SUNY Downstate Medical Center, Box 1203, 450 Clarkson Ave., Brooklyn, NY 11203 (e-mail: smgoldfingermd@aol.com).