Trial of an urban adolescent sexual risk-reduction intervention for rural youth: a promising but imperfect fit

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Abstract

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Globally, over the past 2 decades, scores of human immunodeficiency virus (HIV) prevention interventions have been developed, targeting adolescents of differing ethnicity, race, and nationality living in geographically and culturally diverse settings [1–3]. Many of these interventions have been demonstrated through randomized trials to be effective in changing knowledge, perceptions, intentions, behaviors, or disease rates [3]. Common to these successful interventions are several characteristics, including a theoretical base; emphasis on skills training, and communication and negotiation; utilization of

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differing instructional approaches; and focus on a limited number of specific risk and protective behaviors [1,4]. Given that substantial resources are required to develop interventions, there has been increased interest in the process of replicating successful programs in new areas and in evaluating their effectiveness in these new settings [5–10]. These programs are dedicated to the identification, transfer, and implementation of effective programs at the community level [8,11].

Despite the more rapid increase in rural compared with urban rates of HIV infection [12,13] and the creation of organizations dedicated to HIV in rural areas, to date the majority of interventions, particularly those in the United States, have been developed for urban or urban-suburban settings. In general, those programs that have been developed for adolescents living in rural areas have targeted areas with high rates of HIV, both within the United States, for example, rural Georgia [14], and elsewhere in the world, for example, Namibia [15], Tanzania [16], Haiti [17], and South Africa [18].

By contrast, there has been less experience with the replication of successful interventions, which generally have been designed for urban areas with high rates of HIV, into rural settings with low rates of HIV. It can be argued that addressing a community prior to the arrival of an HIV epidemic would be the most effective prevention strategy; experience around the globe has repeatedly shown that limited time is available for effective prevention efforts once an epidemic has started to escalate. Frequently the risk behaviors that will facilitate the spread of the epidemic are already prevalent; what is missing is the virus itself [19].

However, such a replication effort may be problematic for several reasons. First, even though HIV may not yet constitute a significant public health issue in a given rural community, most of these communities, particularly economically challenged rural settings, have major health, education, and economic problems that are “real time,” requiring immediate use of resources. Therefore it may not be reasonable to expect that limited resources will be redirected from current-need areas to address probabilistic issues. For example, rural communities in the United States, with reduced access to health care [20], experience the highest rates of injury from unintentional violence [21]. Second, some of the proposed approaches run counter to local culture and beliefs; especially in the absence of an evident problem, there may be little reason to incorporate these foreign and even offensive approaches into a community [20]. Third, mechanisms established for effective and efficient intervention delivery in urban settings may not be operative in rural settings [22]. For example, adequately trained personnel may not be available to conduct the intervention training in remote settings [13]. Fourth, while the importance of the concept of covariation of risk behaviors among adolescents is widely understood, the implications of differing profiles of risk behaviors and their interactions in subsequent risk reduction or elevation have not been characterized. If the profile of risk behaviors differs significantly between sites, youth may not respond to the same prevention intervention in a similar fashion. Rural dwellers encounter different challenges, have access to different resources, and endure different experiences than urban dwellers do [23]. Finally, many of these programs have been developed over long periods, in partnership with the original communities for which they were designed [6]. This long-standing partnership may be as central to the success of the intervention as the actual content, and may be essential in a community’s decision to allow access to their children. Such partnerships may be difficult to duplicate in a replication effort.

Focus on Kids (FOK) (see “Materials and Methods”) is a theory-based HIV risk prevention intervention that has been effective in several settings with high rates of HIV around the world [15,24,25]. Developed over 2 years as part of a community-university partnership [24,26], the 8-session intervention was designed to target urban, low-income, predominately African-American youth. In the successful replications in Namibia [15] and the Bahamas [25], the target audiences were also low-income youth of African descent. Identified by the Centers for Disease Control and Prevention as one of the “Programs That Work” [7], FOK, as well as the other prevention interventions in the “Programs That Work” portfolio, have been implemented in communities around the country, including rural communities with predominately white populations. These implementation efforts have generally not been evaluated for further evidence of program effectiveness.

Accordingly, we undertook an effectiveness trial of FOK in the rural, predominately white setting of West Virginia, with an incidence of acquired immune deficiency syndrome (AIDS) of 5.4 per 100,000 population [27,28]. By contrast, the incidence in Baltimore, the home of the original FOK, was 50 per 100,000, the third highest AIDS case report rate of any major metropolitan area [27–29]. We hypothesized that the FOK intervention would positively affect behaviors and perceptions. We anticipated that, consistent with the original FOK experience in Baltimore [24], intervention effect would wane over time and would be more effective with regard to condom use than abstinence.

Material and methods

Setting

This randomized, controlled, longitudinal trial was conducted among 1,131 youth in rural West Virginia. Originally the study was to have been conducted among community settings in only 6 counties, but because of lower than anticipated enrollment the study was expanded to include youth recruited from both community (n = 422, 37%) and school (n = 709, 63%) settings in 12 of 55 counties in West Virginia. Randomization occurred at the level of the recruitment group (n = 110 groups); 870 (77%) youth were randomized to FOK, 84% of whom completed the FOK intervention, and 261 were randomized to the control condition, 88% of whom completed the control intervention. Although the full study includes 4 cells, that is, a control group and 3 variations of the FOK
intervention, for purposes of the current analyses the 3 variations of FOK are treated as a single group, because the basic components of the 3 FOK variations were comparable.

Given the mountainous, sparsely populated terrain of West Virginia [20], many of the counties were located at considerable distances, sometimes a 5-hour drive, from Morgantown, the site of the central FOK research team, and from each other, which prohibited the use of the same staff in all sites. Therefore, to conduct the interventions and deliver the assessment questionnaires, 53 interventionists and 21 interviewers were required. The interventionists and interviewers included men and women ranging in age from their mid-20s to early 60s, of white and African-American races, and employed as teachers, ministers, recreation center directors, liaison officers, faculty members, graduate students, and housewives. In each site a full day of training was conducted for the interventionists, and a half day of training for the interviewers. Training was conducted by the central FOK research team. In some of the counties, central FOK staff participated directly in intervention delivery or questionnaire collection. Spot checks were conducted by the central FOK staff, and interventionists maintained an internal monitoring form that described the activities that had been covered, to ensure comparability of intervention delivery across sites.

Participants

Youth were aged 12 to 16 years, and were identified by community facilitators and received the interventions through the school systems (n = 709) or through local community organizations (n = 422). The intervention was explained to the youth; interested youth were given materials describing the project, as well as assent and consent forms for their parents. The research was approved by the institutional review board at West Virginia University.

Guiding model of behavioral change

In as much as substantial evidence underscores the importance of designing behavioral intervention around a guiding model of behavioral change [1,3], FOK is based on a social cognitive model, protection motivation theory (PMT) [30]. As posited by PMT, environmental and personal factors combine to create a potential health threat. The perceived threat initiates 2 cognitive pathways, a Threat-Appraisal pathway and a Coping-Appraisal pathway, both of which are influenced by the larger cultural and familial environment. The Threat-Appraisal pathway evaluates the factors associated with the threat, including perceived Intrinsic and Extrinsic Rewards associated with the risky behavior, minus the perceived Severity of and Vulnerability to the threat associated with the risky behavior. The Coping-Appraisal pathway evaluates perceived ability to avert the threatened danger, including both Self Efficacy and Response Efficacy, balanced against the Response Cost. These 2 appraisal pathways combine to produce an intention of protection motivation, which, if high enough, may result in protective action. Therefore adoption of a health behavior, whether risk or protective, represents a balance between competing pathways and considerations. The PMT has been used to understand and modify behavior in numerous health domains, including diet [31], cancer screening [32], asthma adherence [33], and HIV and AIDS [15,24].

Description of intervention and control conditions

Because the FOK intervention has been described in detail elsewhere [24,26], only a brief summary is provided here. Focus on Kids is an 8-session (each approximately 1½ hours) risk-reduction intervention that emphasizes decision making, goal setting, communication, negotiating, consensual relationships, and information regarding abstinence and safer sex, drugs, alcohol, and drug selling. The intervention format includes games, discussions, homework assignments, and videos, and is delivered by a pair of interventionists to single-gender groups of 5 to 12 youths, although in several schools in the present study the number did exceed 12 youths. Focus on Kids includes a story about a hypothetical family who appears in nearly all of the sessions to contextualize decision making and choices. In West Virginia, 2 versions of FOK were used: the original version (n = 253), as developed for urban youth, with only minor “cosmetic” modifications, and, a “culturally adapted” version (n = 617) in which several changes were made specifically for West Virginia after focus group discussions and individual interviews conducted among West Virginian youth, parents, teachers, and school and community administrators [20]. By random assignment, the original version of FOK was delivered to all 253 youth through a small-group, face-to-face format, and the culturally adapted version was delivered through a small-group, face-to-face format (n = 485) or a long-distance interactive televised format (n = 132).

Modifications affecting both versions of FOK included elimination of the condom hunt, a homework assignment in which youth were supposed to obtain condoms from the store and clinics, in all communities, and elimination of the condom race, placing a condom on a cucumber, in more than 90% of sites. Both of these changes were at the request of the communities or schools. In a few counties the condom demonstration exercise was not permitted; instead, cards with pictures of condoms were used. Likewise, although the original FOK had been delivered in 8 weekly sessions of 1½ hours, given the long distances and the lack of transportation, for the community-based settings this approach was not feasible. Instead, the program was delivered in 1 day-long session or 2 half-day sessions. Warmup introductory and session closure exercises were eliminated from these compressed sessions. In most school-based set-
tings the intervention was delivered in the original 8-session format.

Additional changes were made to the culturally adapted version of FOK. The characters and the story line regarding the hypothetical family were substantially altered to reflect local culture, more factual information was added, and 2 exercises on goal setting and future planning were added.

Youth assigned to the control condition (Control) received an environmental health intervention adapted from the Council for Environmental Health curriculum “Water Education for Teachers” [34]. Of comparable length as FOK, this program was selected for the attention Control, because it does not include information on interpersonal decision making, goal setting, communication, negotiating, or consensual relationships, and does not provide information regarding abstinence and safer sex, drugs, alcohol, and drug selling. Length and recruitment strategies were comparable with the FOK format in that county. All Control classes were delivered in a face-to-face group format.

As indicated above, in the present study youth receiving any FOK variation were analyzed together, versus youth receiving the control condition.

Measures

Youth risk behaviors were assessed by youth self-report, using a modified version of the Youth Health Risk Behavior Inventory (YHRBI). Originally developed for urban African-American youth in Baltimore [35], the YHRBI was modified for West Virginia (WV-YHRBI) based on the findings from qualitative research, described previously [20]. The first section of the WV-YHRBI assesses demographic characteristics of the youth. The second section assesses youth involvement in risk or protective behaviors, including sexual intercourse or abstinence and, among sexually active youth, condom use or nonuse in the last sexual encounter and in general, as well as other sexual risk and protective behaviors. Dichotomous responses (0 = no, 1 = yes) were used for these items. In the third section, youth are queried along a 5-point Likert scale about their perceptions of risk and protective behaviors according to the 7 constructs of PMT. In this paper we report on the 2 sets of subscales assessing the PMT constructs as they apply to 2 behaviors, abstinence and condom use. Questions or items comprising each construct are listed in Table 1, along with baseline Cronbach α and adjusted α values. When fewer than 8 items were available per cluster, α values were adjusted according to the Spearman-Brown formula. Consistent with the PMT model, higher scores for perceptions of Vulnerability, Severity, Response Efficacy, Self Efficacy, Intentions, and Environment indicate increased protection, while the reverse is true for perceived Extrinsic Rewards, Intrinsic Rewards, and Response Cost. Accordingly, as indicated in Table 1, some items were reverse-coded for analysis. All but 3 of the subscale adjusted α values exceeded .69, 3 of which exceeded .90. The final section of the WV-YHRBI included 30 knowledge (true or false) questions.

Administration of questionnaires

The questionnaires were administered in 1 of 2 formats, either aurally or visually with a talking Macintosh computer (n = 391) or with a paper-and-pencil format, depending on the wishes of the local intervention site (n = 740). The talking computer method is described in greater detail elsewhere [36]. For both options, adults were available to answer any questions, and confidentiality of responses was assured. Youth completed questionnaires at baseline (prior to randomization to intervention assignment) and at 3, 6, and 9 months after intervention. The questionnaire required approximately 45 minutes to complete.

Analysis

We assessed baseline equivalence of demographic characteristics using the chi-square test and Kruskal-Wallis test. Baseline differences in behaviors, perceptions, and knowledge between FOK and Control were assessed using the general linear model. Adjusted means (or estimated marginal means) for behaviors, perceptions, and knowledge were calculated at 3, 6, and 9 months after intervention for corresponding variables at baseline.

Intervention effects on behaviors and perceptions of abstaining from or participating in sex, and among sexually active youth the use of condoms, at 3, 6, and 9 months were contrasted between FOK and Control groups. Because sexual experience may influence intervention effect [37], we also performed subanalyses among all youth who were sexually experienced at baseline and among all youth who were virgins at baseline. We also examined effect according to site of recruitment or intervention delivery (school vs community). Finally, this was an intention-to-treat model, and therefore our primary analyses were based on all 1,131 youth who were randomized to participate in the trial, independent of intervention dose. However, we also conducted secondary analyses among the 961 youth (85%), including 732 FOK (84%) and 229 Control (88%), who completed the intervention, to explore possible dose effect.

Results

Among the 1,131 youth enrolled in the study at baseline (261 Control, 870 FOK), 898 (79%) were present at 3 months (88% Control, 77% FOK; p < .001), 938 (83%) were present at 6 months (85% Control, 82% FOK; p = NS), and 904 (80%) were present at 9 months (90% Control, 77% FOK; p < .001) for the follow-up assessments.

Baseline characteristics

Baseline characteristics of the youths’ sexual experiences in the past 6 months and perceptions by intervention
Table 1
PMT constructs with α [adjusted α values] and items regarding abstinence and condom use among 1,131 West Virginia youth

### COPING APPRAISAL

**Self Efficacy (0.6324[0.7335])**
1. If I am horny I can’t control what happens.  
(1 = “Strongly agree” to 5 = “Strongly disagree”)
2. Even if all my friends were having sex, I will not feel I had to have sex.  
(5 = “Strongly agree” to 1 = “Strongly disagree”)
3. I can say no to the person going out with me if I don’t want to have sex.  
(5 = “Strongly agree” to 1 = “Strongly disagree”)
4. Sometimes sex just happens, and you really can’t control it.  
(1 = “Strongly agree” to 5 = “Strongly disagree”)
5. I can go with a person for a long time and not have sex with them.  
(5 = “Strongly agree” to 1 = “Strongly disagree”)

**Response Cost (0.3426[0.5816])**
1. If a girl says she won’t have sex, a boy would say okay.  
(1 = “Strongly agree” to 5 = “Strongly disagree”)
2. A girl and a guy can go together and not have sex.  
(1 = “Strongly agree” to 5 = “Strongly disagree”)
3. If a guy says no to having sex, a girl would say okay.  
(1 = “Strongly agree” to 5 = “Strongly disagree”)

### THREAT APPRAISAL

**Extrinsic Rewards (0.4662[0.6996])**
1. I want kids my age to think I am having sex.  
(5 = “Strongly agree” to 1 = “Strongly disagree”)
2. I want kids my age to think I am a virgin.  
(1 = “Strongly agree” to 5 = “Strongly disagree”)
3. How many of your close friends have sex?  
(5 = “Most,” 3 = “Some,” 1 = “None”)

**Intrinsic Rewards (N/A[N/A])**
1. How do you feel about having sex?  
(5 = “Very good” to 1 = “Very bad”)

**Severity (0.5588[0.7170])**
1. If one member of a couple gets an STD, they would break up.  
(5 = “Strongly agree” to 1 = “Strongly disagree”)
2. How do you feel about getting an HIV infection?  
(1 = “Very good” to 5 = “Very bad”)
3. How do you feel about getting an STD?  
(1 = “Very good” to 5 = “Very bad”)
4. How do you feel about getting pregnant or getting a girl pregnant?  
(1 = “Very good” to 5 = “Very bad”)

**Vulnerability (0.8091[0.9187])**
1. In the next 6 months, how likely is it that you will become infected with HIV?  
(1 = “Very unlikely” to 5 = “Very likely”)
2. In the next 6 months, how likely is it that you will get an STD?  
(1 = “Very unlikely” to 5 = “Very likely”)
3. In the next 6 months, how likely is it that you will become pregnant (get a girl pregnant)?  
(1 = “Very unlikely” to 5 = “Very likely”)

### OTHERS

**Environment (0.6970[0.6970])**
1. Boys think it’s important to have sex to feel like a man.  
(1 = “Strongly agree” to 5 = “Strongly disagree”)
2. Girls think it’s important to have sex to feel like a woman.  
(1 = “Strongly agree” to 5 = “Strongly disagree”)
3. Sex feels good for girls.  
(1 = “Strongly agree” to 5 = “Strongly disagree”)
4. Sex feels good for boys.  
(1 = “Strongly agree” to 5 = “Strongly disagree”)
5. A guy my age who has never had sex is probably scared.  
(1 = “Strongly agree” to 5 = “Strongly disagree”)
6. A girl my age who has never had sex is probably scared.  
(1 = “Strongly agree” to 5 = “Strongly disagree”)
7. How many boys that you know have sex?  
(1 = “Most,” 3 = “Some,” 5 = “None”)
8. How many girls that you know have sex?  
(1 = “Most,” 3 = “Some,” 5 = “None”)

**Intentions (N/A[N/A])**
1. In the next 6 months, how likely is it that you will have sex?  
(5 = “Very unlikely” to 1 = “Very likely”)

### Condom Use Constructs and Items

**COPING APPRAISAL**

**Self Efficacy (0.7168[0.7426])**
1. I could get condoms.  
(5 = “Strongly agree” to 1 = “Strongly disagree”)
2. I could put a condom on directly.  
(5 = “Strongly agree” to 1 = “Strongly disagree”)
3. I could convince my sexual partner to use a condom.  
(5 = “Strongly agree” to 1 = “Strongly disagree”)
4. I could ask for condoms in a store.  
(5 = “Strongly agree” to 1 = “Strongly disagree”)
5. I could ask for condoms in a clinic.  
(5 = “Strongly agree” to 1 = “Strongly disagree”)
6. I could ask my sex partner about her/his past sexual relationship.  
(5 = “Strongly agree” to 1 = “Strongly disagree”)
7. I could refuse sex if the other person will not use a condom.  
(5 = “Strongly agree” to 1 = “Strongly disagree”)

**Response Efficacy (0.4577[0.6280])**
1. Condoms are an important way to prevent a pregnancy.  
(5 = “Strongly agree” to 1 = “Strongly disagree”)
2. Condoms prevent you from getting an STD.  
(5 = “Strongly agree” to 1 = “Strongly disagree”)
3. Condoms break often.  
(1 = “Strongly agree” to 5 = “Strongly disagree”)
4. Condoms prevent you from getting AIDS.  
(5 = “Strongly agree” to 1 = “Strongly disagree”)

**Response Cost (0.4538[0.4864])**
1. Everyone will find out if I get a condom.  
(5 = “Strongly agree” to 1 = “Strongly disagree”)
2. If a girl carries condoms, people think she is having sex.  
(5 = “Strongly agree” to 1 = “Strongly disagree”)
3. Condoms make sex hurt for a girl.  
(5 = “Strongly agree” to 1 = “Strongly disagree”)
4. Condoms take away the feeling a guy has during sex.  
(5 = “Strongly agree” to 1 = “Strongly disagree”)

### Table 1
**Condom Use Constructs and Items**

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Table 1
Continued

5. Kids don’t want other kids to think they are using condoms. (5 = “Strongly agree” to 1 = “Strongly disagree”)
6. If my mother knew I was carrying condoms, she would be upset. (5 = “Strongly agree” to 1 = “Strongly disagree”)
7. If my father knew I was carrying condoms, he would be upset. (5 = “Strongly agree” to 1 = “Strongly disagree”)

THREAT APPRAISAL
Extrinsic Rewards (N/A[N/A])*
1. Of the boys you know who have sex, how many of them use condoms? (1 = “Most,” 3 = “Some,” 5 = “None”)
Intrinsic Rewards (N/A[N/A])*
1. Condoms make sex feel better (1 = “Strongly agree” to 5 = “Strongly disagree”)

Severity (0.5588[0.7170])* 1. If one member of a couple gets an STD, they would break up. (5 = “Strongly agree” to 1 = “Strongly disagree”)
2. How would you feel about getting an HIV infection? (1 = “Very good” to 5 = “Very bad”)
3. How would you feel about getting an STD? (1 = “Very good” to 5 = “Very bad”)
4. How would you feel about getting pregnant or getting a girl pregnant? (1 = “Very good” to 5 = “Very bad”)
Vulnerability (0.8019[0.9187])**
1. In the next 6 months, how likely is it that you will become infected with HIV? (1 = “Very unlikely” to 5 = “Very likely”)
2. In the next 6 months, how likely is it that you will get an STD? (1 = “Very unlikely” to 5 = “Very likely”)
3. In the next 6 months, how likely is it that you will become pregnant (get a girl pregnant)? (1 = “Very unlikely” to 5 = “Very likely”)

group are shown in Table 2. At baseline, approximately one fifth (21%) of the subjects had engaged in sex during the last 6 months, 80% of whom reported having used a condom at last episode of sex. Female subjects were more likely to have engaged in sex during the previous 6 months, as were older youth and youth assigned to the control group. Girls had higher knowledge of their partners’ sexual history, and higher perceptions of the efficacy of telling a partner that they did not wish to engage in sex. Boys were more likely to intend to use a condom, as were older youth, who were also more likely to intend to have sex in the next 6 months.

Besides being less likely to be sexually active than Control youth, FOK youth demonstrated greater knowledge of HIV-related and AIDS-related material, but demonstrated lower perceived Self Efficacy regarding condom use.

Intervention effect on sexual initiation or participation and condom use behaviors

After controlling for baseline differences, rates of sexual intercourse during the past 6 months increased over time, but did not differ by intervention status (Table 3). Analyses restricted to the subgroup of youth completing the intervention curriculum to which they had been assigned also demonstrated no difference. Likewise, not shown, rates of sexual initiation among baseline virgins increased over the 9-month study, but were comparable by intervention status (e.g., 17.1%, n = 28, Control youth initiated sex, vs 18.9%, n = 119, FOK youth; p = NS).

Condom-use rates declined over time in both groups. Use rates did not differ based on intervention assignment at any follow-up period overall or among youth who initiated sex or had been sexually experienced at baseline. Again, as reflected in the numbers in parentheses, condom use rates also did not differ by intervention status among the subset of youth who had completed the intervention condition to which they were assigned. Not shown in Table 3, we examined intervention effect (FOK vs control) among youth receiving the intervention in schools and among those receiving it in community-based settings, and likewise noted no significant behavioral intervention effect.

Intervention effect on perceptions

Sexual abstinence

All youth. Overall, an intervention effect was seen among all 3 subscales in the Coping Appraisal pathway regarding sexual abstinence (Table 4). In each instance, FOK intervention effects were significantly protective at 6 months post intervention. The FOK youth, compared with Control youth, demonstrated significantly higher perceptions of Self Efficacy and Response Efficacy regarding abstinence (3.60 vs 3.74, p < .01; and 4.01 vs 4.18, p < .05, respectively) and significantly lower perceived Cost of abstinence (2.47 vs 2.32, p < .01).

There were no significant differences after controlling for baseline differences in any follow-up period for subscales of the Threat Appraisal pathway, perceived Environment, or Intentions to engage in sex, based on intervention status.

Subgroup analyses. Among youth who were virgins at baseline, FOK youth compared with Control youth again demonstrated significantly higher perceptions of Self Efficacy to refuse sex (3.78 vs 3.63, p < .01) at 6 months post intervention. Likewise, their perceived Response Efficacy was marginally higher (4.20 vs 4.03, p < .10), and perceived Response Cost of abstinence was marginally lower (2.32 vs 2.43, p < .10) compared with Control youth. Perceived Vulnerability was significantly higher at both 6 months (1.37 vs 1.534, p < .05) and 9 months (1.44 vs 1.61, p < .05).

Among youth who were sexually experienced at baseline, FOK was again protective, although protective effects were limited to only 1 construct in the Coping Appraisal...
pathway, Response Cost (2.31 among FOK youth vs 2.55 among Control youth, \( p < .05 \)).

Finally, and not shown in Table 4, among all youth who completed their assigned intervention, FOK again conferred significant protection at 6 months in the realm of all 3 Coping Appraisal pathway constructs. FOK compared with Control youth had higher perceptions of Self Efficacy (3.72 vs 3.60, \( p < .05 \)) and of Response Efficacy (4.18 vs 4.01, \( p < .05 \)) and lower perceptions of perceived Response Cost (2.33 vs 2.50, \( p < .01 \)). Vulnerability was also higher at 6 months among FOK compared with Control youth (1.53 vs 1.37, \( p < .05 \)).

Condom use perceptions

All youth. The FOK intervention appeared to positively influence Coping Appraisal perceptions of condom-use (Table 5). Six months post intervention, FOK youth compared with Control youth demonstrated significantly higher perceptions of Self Efficacy to use condoms (4.36 vs 4.17, \( p < .05 \)) and lower rates of Response Cost (2.72 vs 2.92, \( p < .05 \)) at 3 months post intervention.

Among Threat Appraisal pathway constructs, there was a marginally significant effect at 6 months post intervention on Extrinsic Rewards, such that FOK youth compared with
Control youth perceived fewer Extrinsic Rewards for engaging in unprotected sex (2.08 vs 2.29, \( p < .10 \)).

Subgroup analyses. Not shown in Table 5, among youth who had completed their assigned intervention, a protective intervention effect was again seen within the Coping Appraisal. This difference was significant at 3 months for Response Cost, which was lower among FOK compared with Control youth (2.76 vs 2.93, \( p < .05 \)). At 6 months perceived Self Efficacy was marginally higher for FOK compared with Control youth (4.52 vs 4.16, \( p < .10 \)). In the Threat Appraisal pathway, perceived Extrinsic Rewards were marginally lower at 6 months for FOK compared with Control youth (2.10 vs 2.30, \( p < .10 \)).

Discussion

Consistent with the effect of FOK in other sociodemographic and geographic areas where this HIV risk-prevention intervention has been assessed, the results from this study demonstrate some protective effect on sexual risk and protective perceptions, particularly those related to the Coping Appraisal pathway. However, despite these positive effects on perceptions, and in contrast to its use in other settings, FOK was not effective in bringing about positive behavioral change in this rural, low-seroprevalence, predominantly white setting. Similar to the experience with the original FOK in Baltimore and other adolescent risk-reduction interventions [24,38], intervention effect waned over time. However, in contrast to the FOK experience in Baltimore, intervention effect was not noticeably stronger for condom use than for abstinence-related behaviors. There were no significant adverse effects of FOK on any perceptions or on any behaviors.

Improved perceptions and knowledge

The Coping Appraisal pathway demonstrated a consistent, protective intervention effect from FOK for both sexual initiation and participation, and condom use. Perceptions of enhanced Response Efficacy of sexual refusal skills and a diminished view of the costs of such measures (Response Cost) were noted among FOK participants. Likewise, increased perceptions of Self Efficacy regarding the ability to use condoms and reduced Response Cost for their use were increased among youth assigned to the FOK intervention, compared with Control youth. A somewhat weaker effect on the Threat Appraisal pathway was seen regarding condom use, such that FOK youth were somewhat less likely to perceive Extrinsic Rewards for engaging in sex without a condom.

The apparent differential effect on the Coping Appraisal pathway may be explained in part by the existence of a substantial curricular effort in the West Virginia schools regarding sexually transmitted diseases (STDs) and HIV, and pregnancy prevention. West Virginia has made important strides over the past 3 decades in lowering its teen pregnancy rate, from 72 births per 1,000 girls ages 15 to 19 (compared with a national rate of 66 births per 1,000 girls) in 1970 to 46 births (compared with a national rate of 45 births per 1,000 girls) in 2001 [39]. Thus youth have been consistently educated about the problems associated with sexual activity (e.g., the Threat Appraisal constructs of Severity and Vulnerability). These themes are included in both safer sex and abstinence curricula. By contrast, details regarding the use of condoms and discussions regarding the effects of sexual refusal are frequently not included in classroom sexual education efforts. Therefore this information may have been new for these West Virginia youth.
Possible explanations for the diminished intervention effect compared with that seen in Baltimore include the following:

1. It has been a decade since FOK was evaluated in Baltimore.
2. Compared with Baltimore, rates of HIV and STDs in West Virginia are low, but West Virginia has other significant health risks.
3. The program was developed in conjunction with the community in Baltimore over several years, whereas it was introduced to West Virginia from the outside by researchers, many of whom were not native to West Virginia.
4. Several aspects of delivery were changed to meet local conditions, including the number of sessions, the introduction of handling and manipulating condoms, the composition of the groups, and the large and widely dispersed intervention staff.
5. In an attempt to be responsive to community requests by removing activities requiring direct contact with condoms, critical intervention elements may have been eliminated.

Each of these considerations is examined in greater detail below.

First, during the decade since the original FOK was evaluated, condom use rates at last episode of intercourse have risen nationally more than 10%, from 46.2% in 1991 to 57.9% in 2001 [27]. Based on available data, changes in rates in West Virginia are comparable to those seen nationally, that is, from 50% in 1993 to 57% in 1997 [27]. Given that the rates at baseline in this study were already higher than these rates (80% condom use), it is possible that this created a “ceiling effect.”

Second, rates of HIV and other STDs in Baltimore a decade ago were among the highest in the country [29]. In West Virginia the rates of HIV and AIDS are within the lowest 10% of states in the United States. Rates of gonorrhea and HIV are within the bottom third of states [27]. By contrast, rates of obesity and tobacco use are among the highest in the nation, and continue to climb at a rate faster than the national rate [27]. Although it was never stated that HIV is not a concern among West Virginians, it can be argued that an intervention that addresses both possible problems at the same time it addresses current problems might be of more interest, and more value, to the state.

Third, much has been written about university-community partnerships in intervention development. Such a partnership existed between researchers and the Baltimore community in the original development of FOK [26]. For more than a decade we worked daily in their community, recreation centers, and schools. We engaged in multiple programs together, addressing adolescents and parents regarding sexual risk behaviors, violence prevention, and drug trafficking. We received community recognition awards, and community members became advisory board members within our institution. The depth of such a partnership did not exist in the implementation of FOK in 12 widely dispersed counties in West Virginia. In both Namibia and West Virginia we partnered with the respective central education governmental bodies. However, while in Namibia school management was highly centralized in the Ministry of Basic Education [15] and

### Table 5

Intervention effect on perception of sexual behaviors among West Virginia youth: PMT constructs for condom use (mean likert scale score)

<table>
<thead>
<tr>
<th>Follow-up</th>
<th>3-Month Adjusted</th>
<th>6-Month Adjusted</th>
<th>9-Month Adjusted</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Control</td>
<td>FOK</td>
<td>Control</td>
</tr>
<tr>
<td><strong>All youth</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Coping Appraisal</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Response Cost</td>
<td>2.916</td>
<td>2.717*</td>
<td>2.909</td>
</tr>
<tr>
<td><strong>Threat Appraisal</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Extrinsic Rewards</td>
<td>2.130</td>
<td>2.069</td>
<td>2.292</td>
</tr>
<tr>
<td>Intrinsic Rewards</td>
<td>3.872</td>
<td>3.737</td>
<td>3.842</td>
</tr>
<tr>
<td>Vulnerability</td>
<td>1.516</td>
<td>1.474</td>
<td>1.545</td>
</tr>
<tr>
<td><strong>Others</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intention</td>
<td>2.857</td>
<td>2.757</td>
<td>2.685</td>
</tr>
<tr>
<td><strong>Youth sexually experienced at baseline</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Coping Appraisal</strong></td>
<td></td>
<td></td>
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</tr>
<tr>
<td><strong>Threat Appraisal</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Extrinsic Rewards</td>
<td>2.186</td>
<td>2.085</td>
<td>2.528</td>
</tr>
<tr>
<td>Intrinsic Rewards</td>
<td>3.872</td>
<td>3.737</td>
<td>3.842</td>
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<tr>
<td>Vulnerability</td>
<td>2.234</td>
<td>2.200</td>
<td>2.292</td>
</tr>
<tr>
<td><strong>Others</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

PMT, Protection Motivation Theory; FOK, Focus on Kids.
* p < .05.
† p < .10.
Thus held great sway at the local level; in West Virginia decision making is at the county and even the school level. This difference in degree of “partnership” in intervention development and implementation may have a significant effect on an intervention program [40]. Further, much has been written about the rural reluctance to accept strangers and outsiders into rural decision making and communities [20].

Fourth, the need to develop flexible intervention delivery strategies to accommodate the widely dispersed population and the great distances is, in effect, a cultural consideration, not a geographic problem or inconvenience. This is the terrain in which West Virginians live; it is our challenge to work with them to devise intervention delivery strategies that work within this context. One adaptation strategy frequently used in West Virginia, compressing the 8 intervention sessions into 1 or 2 days rather than weekly over 2 months, has been shown in other settings to reduce intervention effect [3].

Finally, Kelly et al. [41] have suggested that risk reduction interventions may contain “core elements” that are essential to intervention effectiveness. It is possible that by removing some or a few cases, all of the activities involving direct contact with condoms, we may have eliminated such a core element of the FOK intervention.

Other findings of note

In contrast to the other studies of adolescent sexual activity in the United States [27], significantly more girls than boys were sexually active during the previous 6 months at baseline in this study. Other gender differences of interest included the higher rates of partner knowledge among female adolescents. Although these findings were also more prevalent among youth ages 15 to 16 compared with youth ages 12 to 14, age and gender were not confounded (e.g., the mean age of boys is 14.38 years and that of girls is 14.42, \( p = .572 \)).

Potential limitations of the study

This effectiveness trial has several potential limitations. First, because of the large number of differences in intervention delivery and content that occurred in the West Virginia implementation compared with its implementation in Baltimore and other sites, it is not possible to determine which factor or factors are responsible for the diminished intervention effect in this setting. Second, several of the PMT construct scales had only 1 item or low \( \alpha \) values, and therefore may or may not accurately measure the intended domain. Third, while overall retention was acceptable, attrition rates during follow-up were significantly higher among FOK youth compared with Control youth. Finally, all outcomes were measured by self-report, and thus are subject to bias.

Implications for future studies

In this intention-to-treat, effectiveness study, which sought to determine whether an efficacious program could work outside of the rarified conditions of an experimental efficacy trial, it is not possible to determine exactly which were the significant elements that resulted in the somewhat underwhelming intervention effect. But beyond these practical implementation questions, increasing numbers of researchers and adolescent health educators are questioning the notion of a “universal” or “one size fits all” approach to intervention delivery. Under some circumstances such an approach no doubt is indicated. For example, 15 to 20 years ago the adolescent HIV epidemic was newly emerging and relatively little was known about the risks and their distribution across sociodemographic and geographic niches, and the overall efficacy of behavioral intervention programs was still uncertain. But with increasing awareness, increasing rates of protective behaviors, and emerging competing problems, new strategies may be indicated. Some targeting of individuals at particular risk, both because of their continued practice of unsafe behaviors and their proximity to HIV epicenters, would be important. Continued efforts to change societal norms through mass media and through school education remain important. But approaches that broaden the message to a wider range of risk behaviors, which address new and competing health risks and which seek to target intervention approaches to individual characteristics, are called for in the next order of intervention research. Such efforts may also aid in efforts to sustain intervention effects over longer periods.

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