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It's Your Game: Keep It Real: Delaying Sexual Behavior with an Effective Middle School Program

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Purpose: This study tested the effects of a theory-based, middle-school human immunodeficiency virus, STI, and pregnancy prevention program, *It's Your Game: Keep it Real (IYG)*, in delaying sexual behavior. We hypothesized that the *IYG* intervention would decrease the number of adolescents who initiated sexual activity by the ninth grade compared with those in the comparison schools.

Methods: The target population consisted of English-speaking middle school students from a large, urban, predominantly African-American and Hispanic school district in Southeast Texas. Ten middle schools were randomly assigned either to receive the intervention or to the comparison condition. Seventh-grade students were recruited and followed through ninth grade. The *IYG* intervention comprises 12 seventh-grade and 12 eighth-grade lessons that integrate group-based classroom activities with computer-based instruction and personal journaling. Ninth-grade follow-up surveys were completed by 907 students (92% of the defined cohort). The primary hypothesis tested was that the intervention would decrease the number of adolescents who initiated sexual activity by the ninth grade compared with those in the comparison schools.

Results: Almost one-third (29.9%, n = 509) of the students in the comparison condition initiated sex by ninth grade compared with almost one-quarter (23.4%, n = 308) of those in the intervention condition. After adjusting for covariates, students in the comparison condition were 1.29 times more likely to initiate sex by the ninth grade than those in the intervention condition.

Conclusions: A theory-driven, multi-component, curriculum-based intervention can delay sexual initiation up to 24 months; can have impact on specific types of sexual behavior such as initiation of oral and anal sex; and may be especially effective with females. Future research must explore the generalizability of these results. © 2009 Society for Adolescent Medicine. All rights reserved.

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The United States has made little progress in the last three decades in protecting its young people against teen pregnancies and human immunodeficiency virus (HIV) and other sexually transmitted infections (STIs) [1–3]. Youth are

becoming sexually experienced early (10% of 6th graders, age 11) [4], and the proportion increases steadily through high school: more than two-thirds of high school seniors have had sex [5]. Moreover, almost 40% of US teens who are sexually active reported not using a condom during their last intercourse [5].

Evidence suggests that HIV is disproportionately concentrated among young people under the age of 25 and among African-American and Hispanic populations [1,2,6,7], and primary prevention efforts still fall short of what is needed to curtail this epidemic. Programs have been developed for

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these populations; however, more effective primary prevention programs targeting sexual behaviors at earlier ages are needed.

In Kirby's review [8], only two curriculum-based sex education programs were found to have positive effects among middle-school students [9,10], and no studies examined whether interventions had impact on the prevalence of oral or anal sex, particularly high-risk behaviors for STIs [11,12]. The present study tested the effects of an HIV, STI, and pregnancy prevention program, *It's Your Game: Keep it Real (IYG)*, on sexual behavior among urban, low-income, middle-school youth. The primary hypothesis tested was that the *IYG* intervention would decrease the number of adolescents who initiated sexual activity by the ninth grade relative to those in the comparison schools.

Methods

Study design

IYG was evaluated using a randomized controlled trial design conducted in 10 Texas urban middle schools serving a low-income, urban population. The study was approved by the University of Texas institutional review board and the school district's Office of Research and Accountability. The researchers and school district worked together to identify 13 representative middle schools in seven feeder patterns, across the school district, that might participate. One was ineligible because of its small student population (<500). Twelve middle schools were asked in Spring 2004 to participate in the study; two declined to participate. The remaining 10 middle schools were randomly assigned to intervention or comparison using a multi-attribute randomization protocol, taking into account the size and racial/ethnic composition of the student body (African-American and Hispanic) and the geographic location of the school [13]. All schools had a high percentage (>90%) of students who received free or reduced-cost lunch, an indicator of low socio-economic status, which was therefore not considered as a separate factor in the randomization process. Intervention students received the *IYG* intervention, delivered in the seventh and eighth grades; comparison students received their regular health classes, which varied by school.

Study participants

Students were offered a \$5 incentive for returning the parental consent form; student assent was obtained at the time of the baseline survey. There was no significant difference in the consent rate between the intervention and comparison conditions (Figure 1). The sample size imbalance between the intervention and comparison conditions was not associated with recruitment or consent procedures; these were performed before randomization occurred.

Of the consenting students, 90% completed the baseline survey in the fall of 2004, for which they received a \$5 incentive. Seventh- and eighth-grade follow-up surveys were

conducted in spring 2005 and 2006, respectively: students received a \$10 incentive for participating in each. Seventh-grade surveys were completed by 1,193 students (91% of baseline, 83% of consented); eighth-grade surveys were completed by 981 students (75% of baseline, 68% of consented). This attrition reflects the high mobility and student withdrawal rates in the school district.

Because the intervention program was multiyear and school wide, the study cohort for follow-up was defined *a priori* as those students who had completed a baseline survey and who were still enrolled in their original, randomized school at the time of the eighth grade survey. Those in the study cohort (n = 981) compared with those who left their assigned school after completing the baseline survey or declined to participate (n = 326) were slightly more likely to be female (59% vs. 52%), to report achieving As and Bs (51% vs. 30%), to live with both biological parents (36% vs. 20%), and to have never had sex (90% vs. 80%) (data not shown). For the ninth-grade follow-up surveys, conducted during the 2006/2007 school year, students were tracked and located in more than 50 different high schools in several school districts.

Intervention

The *IYG* curriculum was developed using a systematic instructional design process, Intervention Mapping (IM) [14], to ground its content in social cognitive theory, social influence models, and the theory of triadic influence [15–17]. Extensive qualitative work and participatory methods with all stakeholders including a teen advisory board provided formative guidance in developing the curriculum and community support for the study.

IYG consists of 12 seventh-grade and 12 eighth-grade, 45-minute lessons delivered by trained facilitators. The program integrates group-based classroom activities with personal journaling and individual activities delivered on laptop computers. A life skills decision-making paradigm (*Select, Detect, Protect*) teaches students to *select* personal limits regarding risk behaviors, to *detect* signs or situations that might challenge these limits, and to use refusal skills and other tactics to *protect* these limits. Specific topics covered in the seventh grade include characteristics of healthy friendships; setting personal limits and practicing refusal skills in a general context (e.g., regarding alcohol and drug use, skipping school, cheating); information about puberty, reproduction and STIs; and setting personal limits and practicing refusal skills related to sexual behavior. The eighth-grade curriculum reviews these topics and also covers the following: the characteristics of healthy dating relationships; the importance of HIV, STI, and pregnancy testing if a person is sexually active; and skills training regarding condom and contraceptive use.

The curriculum also includes six parent-child homework activities at each grade level, designed to facilitate dialogue on such topics as friendship qualities, dating, and sexual behavior. The computer component includes a virtual world

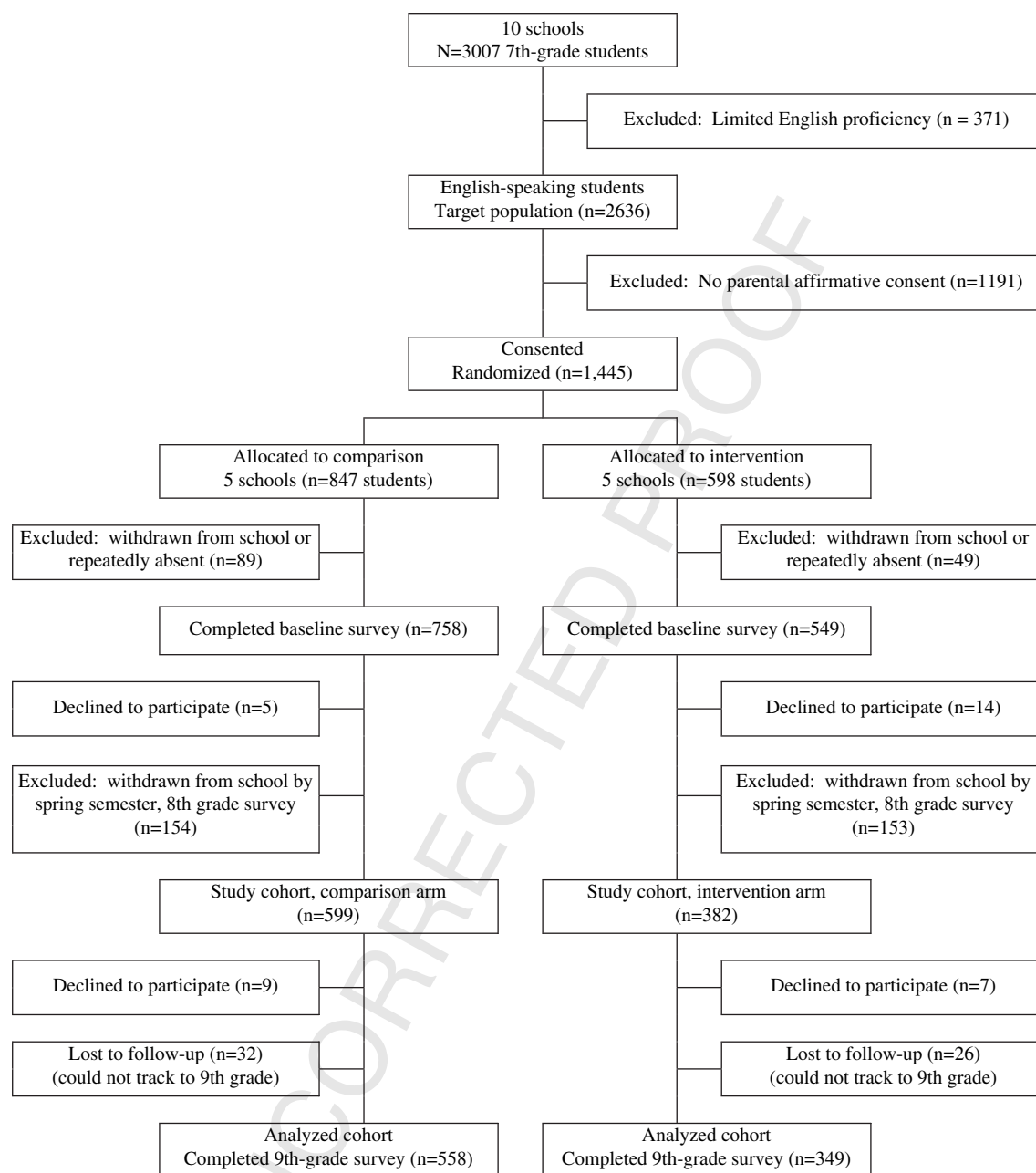


Figure 1. Flow of study participants.

interface, educational activities (quizzes, animations, peer video, and fact sheets) that target determinants of sexual risk-taking and are tailored to gender and sexual experience, and “real world”-style teen serials with on-line student feedback that allows for real-time group discussion in the classroom. Journaling allows students to express their own opinions and feelings on sensitive topics in a confidential setting.

Data collection

Survey data were collected using laptop computers via an audio-computer-assisted self-interview (ACASI) [18,19]. Automatic skip patterns decreased student burden and

exposure to sensitive questions. Student data collection was facilitated by trained data collectors who assured participants of their anonymity and of their ability to refuse to answer questions. Data collectors were unaware of study condition. Most data collection was performed in groups at schools except for the ninth-grade follow-up, when some data collection was done individually at other public locations (e.g., libraries).

Process evaluation

We collected process data to monitor dose and fidelity of intervention implementation. Student attendance sheets and

Reported sexual behaviors	Comparison		Intervention		Total	
	n	%	n	%	n	%
Ever had sex	46	8.3	37	10.6	83	9.2
Sex in past 3 months	27	4.8	22	6.3	49	5.4
Type of sex						
Oral sex ^d						
Ever had oral sex	23	4.3	15	4.4	38	4.3
Oral sex in past 3 months	13	2.4	10	2.9	23	2.6
Vaginal sex ^e						
Ever had vaginal sex	37	6.9	31	9.1	68	7.7
Vaginal sex in past 3 months	23	4.1	17	4.9	40	4.6
Condom at last vaginal sex	32	5.7	26	7.4	58	6.6
Unprotected vaginal sex in past 3 months	9	1.6	4	1.1	13	1.5
Unprotected vaginal sex with one or more partners in past 3 months	8	1.4	4	1.1	12	1.4
Anal sex ^f						
Ever had anal sex	22	4.1	11	3.3	33	3.8
Anal sex in past 3 months	11	2.0	7	2.1	18	2.1
Unprotected anal sex in past 3 months	5	.9	3	.9	8	.9

* $p < .05$.^a All psychosocial variables are coded as protective factors except for perceived friends' sexual behavior, exposure to risky situations, reasons for having sex, oral intent, and vaginal intent.^b Although these knowledge scales had low alphas, they were retained as scales, since items reflected salient points covered in the IYG curriculum.^c Score reflects number of reasons chosen.^d Oral sex was defined as "when someone puts his or her mouth on their partner's penis, vagina, or anus/butt or lets their partner put his or her mouth on their penis, vagina, or anus/butt."^e Vaginal sex was defined as "when a boy puts his penis inside a girl's vagina; some people call this 'making love' or 'doing it.'"^f Anal sex was defined as "when a boy puts his penis in his partner's anus or butt."

facilitator activity logs were used to assess exposure to both classroom and computer-based curricula. Two-thirds (66.19%, $n = 231$) of students in the analysis cohort attended at least 20 of the 24 lessons from the combined seventh and eighth grade curricula (data not shown).

Primary outcome measure

The effect of the intervention on delayed sexual initiation at the ninth grade follow-up for those students who reported no lifetime sexual activity at baseline was assessed as the primary outcome. The primary hypothesis tested was that the intervention would decrease the number of adolescents who initiated sexual activity by the ninth grade relative to those in the comparison schools. Sexual activity was defined as participation in vaginal, oral, or anal sex. Sexual activity questions were defined in advance and were worded in a gender-neutral manner to illicit responses for same and opposite-sex partners.

Secondary outcome measures

Sexual behaviors. Secondary outcome measures examined the impact of the intervention on (1) delayed initiation of specific types of sex (oral, vaginal, anal); (2) delayed sexual initiation by gender and racial/ethnicity; and (3) reduced risk behavior at the ninth-grade follow-up for those who reported being sexually active in the last 3 months. Additional endpoints were assessed for sexually active students. All sexual behavior measures were adapted from existing surveys and extensively pilot tested among urban middle school populations [20–23].

Psychosocial measures. Psychosocial variables based on social cognitive theories were also assessed, using measures adapted from existing surveys and extensively pilot tested [9,20,21,24,25]. These variables measure the determinants that the intervention addressed and have been found in many studies to affect behavior change [6].

Analysis approach

The analysis examined the impact of the intervention from baseline to ninth grade follow-up (approximately 24 months). Descriptive analyses were conducted on the analyzed cohort to test for differences between intervention ($n = 349$) and comparison groups ($n = 558$) at baseline using t tests and chi-square tests looking for any differences in the outcome measures, both behavioral and psychosocial at baseline. The following demographic measures were also compared between the treatment conditions: gender, age, ethnicity, parental education, school grades, and language spoken at home. Differences were used as potential confounders in the initial phase of modeling. If a variable was both significantly related to the dependent variable using a more conservative significance level ($p = .10$) and differentially distributed between treatment conditions, it was retained in

the final model. Because of the second criteria, relationship to the dependent variable, the set of covariates included in each model varied from outcome to outcome. This was done, rather than keeping all covariates in all models, to minimize data loss caused by missingness in the demographic measures as well as to fit the most parsimonious model needed to correctly make a comparison between the two treatment conditions.

Subjects were removed from an analysis only when they had missing data on the variables included in that analysis; missing data were not imputed. Observations from students within the same school could not be assumed to be independent (ICC ranged from 0 to .03); therefore, multi-level models were used. Each model contained baseline measures of the dependent variable, where appropriate, as well as any other covariate judged to be a potential confounder. A dichotomous variable indicating treatment condition was entered into each model. The regression coefficient from this measure was then used to test for intervention effectiveness. The Wald statistic, ratio of the regression parameter to its standard error, was used to test for statistical significance. For all dichotomous outcomes, a multilevel regression model for binary outcomes with a log link function was used, resulting in a relative risk ratio as the effect size. For continuous outcomes, a linear multilevel model was used resulting in an estimate of the difference in the adjusted means as the effect size. All analyses were conducted using two-tailed tests, and no adjustments were made for multiple tests of significance. The primary and secondary hypotheses were stated *a priori*. Statistical significance was set at $p \leq .05$.

Three sample groups were used in the analysis. The psychosocial variables were analyzed on the entire analyzed cohort ($n = 907$). Sexual initiation variables were analyzed only on those students who had not engaged in the behavior at the baseline measure. For sexual behavior measures other than the initiation measure, only students who reported sexual activity within the last 3 months were included in the analysis. Attrition analyses were conducted to determine differences in those retained for the analyzed cohort ($n = 907$) and those who were not retained in the study cohort ($n = 74$) and also if they were differential between intervention and control groups.

Results

Sample characteristics for the analyzed cohort

Table 1 describes the demographic characteristics of the analyzed cohort at baseline. No significant differences by intervention and comparison conditions were observed at baseline for sexual behavior, although some differences in the distribution of age, ethnic status and in a few psychosocial variables were found.

Attrition

The analyzed cohort consists of those completing the ninth-grade follow-up survey (Figure 1). No differences

were observed in baseline demographic or behavioral variables for participants retained in the trial versus those not retained except for age: those lost to follow-up were slightly older than those retained (mean age 13.2 vs. 13.0 years; data not shown). In addition, we examined differences by intervention and comparison status for those not in the defined cohort (those who dropped out before the eighth-grade survey), and found no differences in demographic variables or sexual behaviors except for lifetime vaginal sex (21% comparison vs. 15% intervention; $p = .04$).

Attrition in the defined cohort was nondifferential between the intervention and comparison condition (data not shown).

Effects of the HIV, STI, and pregnancy intervention

Almost 30% of students in the comparison condition initiated sex by ninth grade, compared with 23% of those in the intervention condition: students in the comparison condition were 30% more likely to initiate sex by the ninth grade than were students in the intervention condition.

A greater percentage of students in the comparison condition initiated oral, vaginal, or anal sex by the ninth-grade follow-up compared with students in the intervention condition (Table 2). Even after adjusting for covariates, students in the comparison condition had a 1.76 times greater risk of initiating oral sex and a 2.67 times greater risk of initiating

anal sex by ninth grade than those in the intervention condition.

More than one-quarter of Hispanic students in the comparison condition initiated sex compared with 17.4% of Hispanic students in the intervention condition (Table 2). After adjusting for covariates, Hispanic students in the comparison condition were 64% more likely to initiate sex than Hispanic students in the intervention condition. Among African-American and male students, there were no statistical differences in initiation of sex between conditions. Among females, 26.1% of those in the comparison group initiated sex by the ninth grade compared with 18.5% of those in the intervention group. After adjusting for covariates, females allocated to the comparison condition had a 1.42 times greater risk of initiating sex by ninth grade than did females in the intervention condition.

The prevalence of initiation of oral sex by ninth grade was significantly higher among students in the comparison condition who were African-American or female than among those in the intervention condition. The subgroup analysis showed significant differences between intervention and comparison groups for initiation of vaginal sex only among Hispanic students and for initiation of anal sex among African-Americans, male, and female students.

Students who reported being sexually active at the ninth-grade follow-up and who were in the comparison condition

Table 2

Risk of the comparison condition for initiating sexual behavior among those who reported no experience at seventh-grade baseline but reported having initiated at ninth-grade follow-up, in the analyzed cohort, by gender and race/ethnicity

	Total ^a responses n	Comparison % yes	Intervention % yes	ARR	(95% CI)
Initiated sex	817/823	29.9% (n = 509)	23.4% (n = 308)	1.29 *	(1.02, 1.64)
Hispanic ^b	381	27.8	17.4	1.64 *	(1.09, 2.47)
African-American ^b	324	33.7	30.6	1.07	(.78, 1.46)
Males	307	35.7	32.4	1.12	(.80, 1.56)
Females	510	26.1	18.5	1.42 *	(1.01, 2.01)
Initiated specific types of sex					
Oral	831 of 837	17.6% (n = 512)	10.0% (n = 319)	1.76 **	(1.21, 2.56)
Hispanic ^b	375	17.0	10.0	1.71	(.97, 3.03)
African-American ^b	340	17.7	9.5	1.84 *	(1.04, 3.25)
Males	319	25.0	17.6	1.53	(.96, 2.44)
Females	512	12.8	5.5	2.14 *	(1.12, 4.09)
Vaginal	804 of 810	26.9% (n = 499)	22.3% (n = 305)	1.26	(.98, 1.61)
Hispanic ^b	379	24.1	14.8	1.67 *	(1.06, 2.62)
African-American ^b	319	32.8	30.1	1.09	(.78, 1.50)
Males	307	30.8	29.4	1.12	(.79, 1.60)
Females	497	24.3	18.4	1.36	(.95, 1.93)
Anal	835 of 842	9.9% (n = 514)	3.7% (n = 321)	2.67 **	(1.45, 4.94)
Hispanic ^b	372	9.4	4.4	2.19	(.91, 5.26)
African-American ^b	345	11.9	3.3	3.12 *	(1.21, 8.06)
Males	322	16.3	7.5	2.31 *	(1.13, 4.72)
Females	513	5.8	1.5	3.90 *	(1.16, 13.13)

Note: All models adjusted for age, gender, and race/ethnicity.

* $p < .05$.

** $p < .01$.

^a For initiated sex and the three specific types of sex (oral, vaginal, anal), Total Responses are the number of students answering the question at the ninth-grade follow-up of those who had reported no sexual experience (initiated sex) or no experience with that specific type of sex at baseline.

^b Because of the small sample sizes, the racial/ethnic comparison did not include the “other” subgroup.

Table 3
Risk of the comparison condition for engaging in the behavior among students reporting specific sexual behaviors in the last 3 months at ninth-grade follow-up^a

	n ^b	Comparison	Intervention
Oral sex in last 3 months	85	58	27
Vaginal sex in last 3 months	166	103	63
Anal sex in last 3 months	37	30	7
Vaginal, oral, or anal sex in last 3 months	197	124	73
Condom at last sex (for vaginal sex only)	n ^b 166	ARR 1.04	95% CI (.87,1.25)
Number of times having sex in the last 3 months: 2 or more versus 1			
Oral	85	.93	(.69, 1.28)
Vaginal	165	1.30*	(1.02, 1.66)
Anal ^c	37	27.14	(.10, 7693)
Number of times having sex in the last 3 months with drug/alcohol: 1 or more versus 0			
Oral	83	1.24	(.59, 2.60)
Vaginal	164	.69	(.35, 1.35)
Anal ^c	33	.57	(.09, 3.77)
Number of times having sex in the last 3 months without a condom: 1 or more versus 0			
Vaginal	166	.92	(.71, 1.19)
Anal ^c	34	1.12	(.38, 3.35)
Number of lifetime partners: 2 or more versus 1			
Oral	84	1.17	(.82, 1.68)
Vaginal	160	1.05	(.89, 1.24)
Anal ^c	35	.89	(.16, 4.81)
Number of partners in the last 3 months: 2 or more versus 1			
Vaginal	158	1.31	(.83, 2.07)
Anal ^c	37	Unable to estimate	
Number of partners in the last 3 months without a condom: 1 or more versus 0			
Vaginal	165	.86	(.63, 1.18)
Number of times having sex in the last 3 months without effective pregnancy prevention ^d	162	.83	(.51, 1.35)

** $p < .01$.

* $p < .05$.

^a All models adjusted for age, gender, ethnicity, and baseline score.

^b Sample sizes vary because of missing data.

^c Analyses had little precision and power because of small sample sizes.

^d Effective pregnancy prevention was defined for the student in the survey by listing effective pregnancy prevention methods.

had a higher frequency of vaginal sex during the last 3 months relative to the intervention condition (Table 3). No intervention effects were observed for the number of times that students had sex under the influence of alcohol or used condoms or for number of partners.

At the time of the eighth-grade post-intervention survey, students in the intervention condition, relative to students in the comparison condition, had more positive beliefs about abstinence until marriage, perceived their friends as having more positive beliefs about waiting to have sex, had greater confidence in refusing sex and using condoms, had greater knowledge about HIV and STI signs and symptoms and about using condoms to prevent them, reported being exposed to fewer risky situations, and cited more reasons for not having sex (Table 4). They also reported fewer intentions to have oral sex in the next year and greater intentions to remain abstinent through high school when compared with students in the comparison condition. Some intervention

effects on psychosocial variables were sustained through ninth grade.

Discussion

This study is the first trial, to our knowledge, demonstrating that a middle school-based HIV-, STI-, and pregnancy prevention intervention can delay overall sexual behavior (defined as oral, vaginal, and anal sex) and can have an impact on specific sexual behaviors such as oral and anal sex. Subgroup analysis revealed differential effects by gender and race/ethnicity. In particular, the intervention delayed overall sexual behavior as well as oral and anal sex among females. *IYG* also had sustained positive effects on such psychosocial variables as more positive beliefs about abstinence and being involved in fewer risky situations.

Students who were sexually active at baseline (9%), in the fall of seventh grade, represent particularly high-risk

Table 4
It's Your Game psychosocial outcomes, eighth and ninth Grade, among the analyzed cohort (n = 907)^a

Outcome ^c	Eighth grade					Ninth grade						
	n ^b	Difference in adjusted mean	Intervention Mean	SD	Comparison Mean	SD	n ^b	Difference in adjusted mean	Intervention Mean	SD	Comparison Mean	SD
General beliefs about waiting to have sex	869	.01	2.86	.57	2.89	.66	874	.03	2.81	.59	2.82	.62
Beliefs about abstinence until marriage	862	.17**	2.78	.70	2.63	.74	864	.12**	2.75	.69	2.65	.73
Perceived friends' beliefs about waiting to have sex	875	.17**	2.47	.71	2.35	.69	873	.06	2.32	.71	2.29	.65
Perceived friends' sexual behavior	830	-.05	1.58	.71	1.62	.70	832	-.09*	1.77	.74	1.83	.69
Self-efficacy to refuse sex	853	.11*	3.07	.85	2.97	.86	856	.08	3.07	.87	3.01	.83
Condom knowledge	896	.53**	2.58	.71	2.04	1.01	893	.16**	2.41	.79	2.25	.95
Perceived friends' beliefs about condoms	861	.06	3.36	.68	3.30	.67	869	.12**	3.32	.64	3.21	.68
Self-efficacy to use condoms	827	.12**	2.51	.39	2.37	.44	833	.02	2.46	.44	2.41	.44
Exposure to risky situations	862	-.10*	.75	.65	.82	.69	868	-.12*	.86	.86	.96	.91
STI signs/symptoms knowledge	870	.10**	.83	.24	.78	.26	869	.10**	.82	.18	.76	.20
HIV/STI knowledge	888	.17**	.82	.21	.65	.29	894	.10**	.80	.24	.70	.29
Reasons to have sex	839	.08	1.62	1.78	1.48	1.49	844	.05	1.50	1.52	1.44	1.47
Reasons not to have sex	892	.71**	4.87	2.45	4.29	2.49	890	.17	4.32	2.38	4.25	2.43
Intention: oral sex in next year	883	-.24**	1.97	1.26	2.14	1.24	881	-.12	2.10	1.27	2.15	1.26
Intention: vaginal sex in next year	877	-.06	2.26	1.32	2.31	1.30	876	-.03	2.51	1.38	2.54	1.37
Intention: abstinent through high school	875	-.31**	3.16	1.44	2.89	1.41	876	.03	2.85	1.37	2.85	1.40
Intention: abstinent until marriage	877	.16	2.67	1.40	2.48	1.33	873	.11	2.54	1.31	2.41	1.30

* $p < .05$.

** $p < .01$.

^a All models adjusted for age, gender, race/ethnicity and baseline score.

^b Sample sizes vary because of missing data.

^c All psychosocial variables are coded as protective factors except for perceived friends' sexual behavior, exposure to risky situations, reasons for having sex, oral sex intent, and vaginal sex intent.

populations with respect to health outcomes [26] and may need more intensive interventions. An intervention effect on the frequency of vaginal sex and anal sex during the prior 3 months was observed in this study, despite reduced analytic power to detect impact on specific types of sexual behavior among those sexually active. Only one other middle-school curriculum-based study published to date has reported significant reductions in frequency of sexual activity [9].

Exposure to oral and anal sex appears to be increasing among teens and young adults [27]; however, no middle-school-age programs, to our knowledge, have directly addressed or evaluated anal and oral sex outcomes. Research suggests that adolescents perceive oral sex as having fewer health consequences than vaginal sex [28–31], and results from the entire baseline sample indicate that as many as 7.9% of seventh graders report lifetime oral sex and 6.9% report lifetime anal sex [32], an extremely high-risk behavior for HIV transmission [11,12]. It is unknown, however, whether these results can be generalized to other populations, as few studies have measured anal and oral sex among middle-school populations.

An important finding was the magnitude of the behavioral impact of *IYG* when compared with similar programs. For example, students in the comparison group were 29% greater risk of initiating sex by the ninth grade than those who were not be exposed to *IYG*. Furthermore, the program was associated with a significant reduction (by 23%) in the number of students having vaginal sex two or more times in the past 3 months. These results compare with other effective

programs published to date that tended to be associated with a lowering of the prevalence of adolescents in engaging such risk behaviors by about one-third [8].

National data emphasize the need to implement intervention programs as early as possible: 11% of 6th graders, 15% of seventh graders, 18% of eighth graders, and 33% of ninth graders have reported lifetime sexual activity [4,5]. This rapid acquisition of sexual behavior is cause for concern and clearly demonstrates that early comprehensive sex education such as *IYG* is imperative. However, in the United States, most students are not receiving comprehensive sex education or are receiving it too late [33].

The efficacy of *IYG* may be partly attributable to the innovative multi-modal application of computer-based gaming technology, interactive computer-based activities, and small-group classroom interaction that does not currently exist in middle-school HIV/STI- and pregnancy-prevention curricula [34]. Its capability to provide interactive and individual tailored experiences that are also confidential is particularly salient when considering the sensitive nature of these topics.

Methodological strengths of the study include a well-conducted randomized controlled trial design, the ACASI interview for greater self-report validity, and our high level of retention among students in our defined cohort, and use of previously established measures [9,20–25]. Moreover, no other intervention trial has assessed the impact of the intervention of specific types of sexual behaviors. Most studies examine the impact on sexual intercourse, which may be interpreted in many ways by the respondent.

This study has some limitations: self-reported outcome measures; unknown generalizability to other populations; a small sample of sexually active youth in seventh grade, leaving little statistical power among these youth; a higher proportion of female participants; and the study participation rate, albeit similar to many school-based studies [9,35]. School-based studies such as this one may not be able to reach extremely high-risk youth who are highly mobile or who drop out early. Studies should be conducted to examine how to track and intervene in such populations.

Another potential limitation was the attrition and our inability to conduct an intention to treat analysis of those who were lost to follow-up. A decision was made *a priori* to define the study cohort as those students who were enrolled in the eighth grade at the completion of the spring semester because of the lack of resources to follow up the entire cohort enrolled at baseline and also to ensure that those enrolled in comparison and intervention conditions were followed up in the same manner.

Although costly, a much larger sample is needed to evaluate results among sexually active middle-school youth and to conduct subgroup analysis among ethnic and gender groups. It is important to understand the reason that our program and other programs have differential impacts for ethnic and gender groups because of disparities in risk; however few studies have enough power to examine subgroup differences. Further, the program included multiple components that were tested together; the efficacy of the individual components is therefore unknown. Future studies should test the efficacy of the intervention among different populations and should test the efficacy of the computer intervention alone.

In conclusion, the study results indicate that the *It's Your Game* curriculum was effective among low-income, urban, African-American and Hispanic middle-school students. This provides evidence that school-based sexual health interventions can be implemented early and can delay initiation of sexual activity. This has important implications for implementing policy and for dissemination of evidence-based interventions.

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