Evaluation Abstract: Evaluation of It’s Your Game…Keep It Real in South Carolina

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Intervention Name
It’s Your Game…Keep It Real

Intervention Description
It’s Your Game…Keep It Real (IYG) is an evidence-based program identified by the Office of Adolescent Health in its Teen Pregnancy Prevention (TPP) Resource Center. The two-year intervention, grounded in social cognitive theories and the theory of planned behavior, consists of 12 50-minute lessons delivered in 7th grade and 12 50-minute lessons delivered in 8th grade, implemented within the participating middle school. In each grade, the program integrates group-based classroom activities with personalized journaling and individual, tailored, computer-based activities. A life skills decision-making paradigm (Select, Detect, Protect) underlies the activities, teaching 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. IYG educates students on how to make good decisions and identify their personal rules about a variety of risk behaviors, including drugs, alcohol, and sexual behaviors. Students are taught to avoid a risky situation by either using a clear “no” statement or alternative action (for example, “My parent is calling me, I have to go.”). These avoidance strategies are reiterated in the curriculum activities (such as role plays and journaling activities) and computer activities. The classroom curriculum also includes three parent-child homework activities at each grade level designed to facilitate dialogue on topics including friendship qualities, dating, and sexual behavior.

The program lessons are intended to be delivered in a variety of classroom instructional settings (for example, physical education, health course, or social studies). In this study, facilitators were drawn from school and district personnel and were required to complete a two-day training conducted by the curriculum developers before implementation. The lessons were to be delivered during regular classroom time according to the schedule that works best for the participating school (for example, twice a week, once a week, or every day, and during fall and/or spring semester) with no more than two weeks between lessons. Because classrooms often vary in size (from 15 to 40 students), the group size was allowed to vary depending on the number of students enrolled in the classroom. The IYG program addresses all eight of South Carolina’s health standards and meets the standards of the state’s Comprehensive Health Education Act (CHEA), which mandated teaching comprehensive reproductive health education in public schools. IYG was to serve as the primary reproductive health content and substitute for any prior reproductive health education taught in the school.

Counterfactual
Standard of care (i.e., business as usual)

Counterfactual Description
No systematic alternative program was offered in the comparison schools, including any evidence-based or promising TPP program. The CHEA requires public middle schools in South Carolina to cover certain topics, including reproductive health education and sexually transmitted infection (STI) prevention. Specifically, in grades 6 through 8, this law mandates that health education must include reproductive health education and information on STIs. At its core, the state’s CHEA, which guides all sexuality education instruction, emphasizes local control of content; thus, school districts have the authority to implement it with varying levels of fidelity.
Each school in the comparison condition provided its usual health and sex education program, which varied by district. However, schools were not considered eligible for participation in the research study if an evidence-based TPP program was being or was planned to be implemented in the middle school so that the research design would not be compromised by competing programs. For schools in the comparison condition, the usual health and sex education would be defined as a varying level of activities that addressed some or all of the following: puberty-reproductive health, healthy relationships, decision making (general health), decision making (sexual health), communicating values about sex, identifying and avoiding risky situations, teen pregnancy, HIV/AIDS/STIs, abstinence, condoms and contraception, media influences, and dating violence. The evaluation collected data from the comparison school health teachers about the lessons that were conducted. One school covered all topics using the Sex Can Wait curriculum. All other schools addressed some but not all topics using typical 7th and 8th grade health education materials (for example, Holt).

**Primary Research Question**

What is the impact of the IYG program relative to the standard of care on initiation of vaginal sex by the end of 9th grade (12-18 months post-program) on students reporting they never had sex at baseline?

**Secondary Behavioral Outcomes**

(1) What is the impact of the IYG program relative to the standard of care on the initiation of vaginal sex by the end of 8th grade (0-6 months post-program) on students reporting they never had sex at baseline? (2) What is the impact of the IYG program relative to the standard of care on having vaginal sex in the past 3 months as measured at the 9th grade follow-up? (3) What is the impact of the IYG program relative to standard of care on having vaginal sex without using an effective method of birth control in the past 3 months as measured at the 9th grade follow-up?

**Sample**

This study involved working with selected school districts and schools throughout South Carolina. Participating schools had to meet the following criteria: (1) be a mainstream school (not an alternative or special school) in a public school district; (2) include 7th and 8th grades; (3) have at least 20 7th graders; (4) be willing to participate and agree to the conditions of the study at the school and district levels; (5) provide the SC Campaign with school-level statistics needed for the randomization process, if not available on the SC Department of Education website; (6) not be involved in another federally funded project with the SC Campaign; (7) not currently be using an evidence-based teen pregnancy prevention program in 7th or 8th grades; and (8) not be intending to begin implementing an evidence-based teen pregnancy prevention program in 7th or 8th grades in the next three years.

A total of 15 school districts representing 45 schools were screened. Screening criteria included approval of the curriculum, IYG, at the district level through the mandated approval process (that is, Comprehensive Health Education Committee approval, school improvement council approval, and school board approval). Of the 15 school districts representing 45 schools that were screened, 13 school districts representing 30 eligible schools agreed to participate in the study. Of the 13 school districts, the SC Campaign accepted memoranda of understanding (MOUs) from the first 24 schools (representing 11 school districts, 2 of which merged a year into the study). Because the SC Campaign met with multiple districts over the same period, MOUs were finalized concurrently with many districts. When 24 schools were successfully recruited, the SC Campaign closed recruitment.

Of the 24 recruited schools, 12 were randomly assigned to the intervention condition and 12 to the comparison condition. After random assignment of schools, two criteria were used to screen students in schools: (1) enrolled in the 7th grade in fall 2011 and (2) not be special education students with limited abilities to complete the survey and/or engage in the intervention.

The final enrolled sample size was n=3,143 students for whom parental consent and student assent were obtained.
**Setting**

The 24 study schools were rural middle schools across South Carolina with total enrollment sizes ranging from 213 to 1,486 students. Most study schools (n=16) were defined as teaching only 6th through 8th grades; the remaining participating schools were defined as K through 8th grades (n=2 schools), 5th through 8th grades (n=3 schools), 7th and 8th grades (n=1 school) or 7th through 12th grades (n=2 schools).

In 2011, 23.6% of South Carolinian school-aged children (5-17 years) lived in poverty, whereas the average percent across participating school districts was 31.5% (range=22.4% - 42.7%). Further, the average percent of students who qualified for free lunch across the 24 participating schools was 62.6%, ranging from 34.2% to 90.5%. The state of South Carolina, although racially diverse, is predominately white (67%). In the evaluation sample, 11 of the 24 schools had more than 50% white students and 10 of the 24 schools had more than 50% black students (with 7 of those 10 having more than 70% black students). The remaining schools were mixed between white, black, Latino, and other races/ethnicities.

**Research Design**

This evaluation employed a group-randomized controlled trial design, with randomization at the school level. District was used as a stratification variable, so that school assignments to the intervention and comparison arm were balanced within districts. The randomization procedure involved identification of all possible combinations of two equal-size groups of schools and identification of the combination for which the groups were most similar to each other in terms of aggregate characteristics shown in literature to be related to the outcomes of interest (for example, racial composition, poverty indicators, academic performance indices, and urbanicity). One of these two groups was then randomly assigned to intervention and one to comparison. In other words, assignment was conducted with the goal of minimizing observable differences between the intervention and comparison conditions. Schools were randomly assigned to intervention condition in June 2011. Active parental consent for the study was obtained at the start of the 2011–2012 school year (early August to early October) across all 24 schools and then again in January 2012 for 6 of the 12 comparison schools that had low parental consent return rates in the fall. Students completed the baseline survey shortly after parental consent was obtained; student assent was obtained immediately prior to administering the survey.

Only select district administration staff, select school administration staff, school project site coordinators, and IYG facilitators at intervention schools knew their schools’ condition before obtaining active parental consent and the administration of the baseline survey. (IYG facilitators knew because they were trained to implement IYG in August 2011.) District and school staff were explicitly asked to not share intervention condition with anyone. To further minimize the likelihood that students or parents would learn their intervention condition, exactly the same evaluation parental consent form was used at all 24 schools, and schools were instructed to keep the distribution processes separate from program consent for their reproductive health programming. In addition to consenting to the evaluation, parents received consent forms for programming. The programming consent forms slightly differed between the intervention and comparison conditions but were similar to diminish the likelihood that parents or students at intervention schools would associate the IYG program with the study. In intervention schools, explicit directions were provided to not tell students and teachers that IYG was being evaluated. To the evaluator’s knowledge, no parent or other school staff asked or learned about their school’s intervention condition during the consent process.

The intervention was implemented either in fall or spring of 7th and 8th grade and follow-up surveys were administered in spring of 8th and 9th grades. Surveys were administered on tablets in schools. For students who were absent or no longer in school, surveys were administered online (the majority of cases), via a mailed paper-and-pencil survey, or via an abbreviated telephone survey including just the primary outcomes.
Method

The analytic sample for the primary outcome included all students who were not sexually active at baseline and who provided responses for the outcome at follow-up as well as for all covariates included in the analysis model. The analytic sample for secondary outcomes included students who provided responses for the outcomes of interest at baseline and follow-up, whose responses to the “Ever had sex” question were logical over time (e.g., a “Yes” was not followed by a “No”), and who provided responses for all covariates included in the analysis models.

Due to the nested nature of the study design (students within schools), multilevel regression analysis was used to account for the potential correlation between students within schools. Specifically, logistic regression models were used because the behavioral outcomes were dichotomous. Each model included the following variables: (1) an indicator denoting intervention condition; (2) the baseline outcome variable (when applicable); (3) age, gender and race/ethnicity; (4) a set of a priori identified outcome-related covariates that differed at $p<.15$ between the conditions when adjusted for clustering in the sample of students who completed a baseline and corresponding follow-up survey; (5) an indicator representing when the student completed their baseline survey (fall 2011 or February 2012); (6) design variables used in the randomization process (school enrollment, school configuration, and potential exposure to an evidence based program in 9th grade); and 7) a school-level covariate representing the percent of students reporting they ever had vaginal sex at baseline (excluding those students who completed baseline surveys in February). The last was included to control for potential environmental or normative influences that may have resulted from the observed imbalance in rates of reported vaginal sex in the study’s sample of students taking a baseline survey in fall (7.4% and 9.0% in the intervention and comparison conditions, respectively).

Two sets of sensitivity analyses were conducted to understand (1) the influence of including the school-level covariate representing the percent of students reporting they ever had sex at baseline, and (2) the influence of including the students who completed the baseline survey 4 months after the main sample. Attrition analyses were conducted to assess whether any sample characteristics were associated with students not completing follow-up surveys and whether the association(s) differed by condition.

Impact Findings

The behavioral results indicate that there were no statistically significant differences in rates of sexual initiation at the end of 8th grade between students who received IYG relative to those receiving the usual sexual health education programming in the comparison schools. By the end of 9th grade, study data showed that students receiving the usual sexual health education programming had lower rates of sexual initiation than those receiving IYG and the difference was statistically significant. The 9th grade findings also showed that there were no statistically significant differences between the two conditions on vaginal sex in the past 3 months and vaginal sex without effective birth control in the past 3 months. The study design differed from the original IYG studies in a number of important ways, such as implementing in a rural versus urban setting, testing the intervention with school-based versus outside facilitators, timing of intervention exposure, and the definition of the primary outcome variable (vaginal sex only versus a combination of vaginal, oral, or anal). Additionally, imbalances in sexual risk behavior at baseline, a strong counterfactual sexual health education, and an imbalance in exposure to an evidence-based program (EBP) in 9th grade before the final study survey affect interpretation of the study findings.

Implementation Findings

Results of implementation analyses indicate that IYG was delivered with high fidelity to the original curriculum across both years. During 7th and 8th grade, SC facilitators delivered all lessons and an average of 98% of the IYG activities with no major unplanned adaptations. At the student level, 7th graders attended 94% of the 12 lessons, on average; 8th graders attended an average of 84% of the lessons. All facilitators completed training in IYG prior to teaching it; facilitators also received strong and timely technical support throughout the study period. Observer ratings of implementation quality were high during both years of program delivery. Implementation data from the comparison schools indicate
most of the comparison schools implemented sexual health education programming. Further, the average number of minutes provided for students in the comparison schools that taught sexual health education equaled approximately 7 hours per year versus 10 hours per year for IYG. In 9th grade, students in both conditions were exposed to an evidence-based high school program (Safer Choices); however, a greater proportion of the students from the comparison schools received Safer Choices in 9th grade than did students from the intervention condition.

**Schedule/Timeline**

Baseline data collection ended in February 2012. The first follow-up survey, conducted at the end of the sample’s 8th grade year, was completed in August 2013. The final follow-up survey, conducted at the end of the sample’s 9th grade year, was completed in August 2014.