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Safer choices 2: Rationale, design issues, and baseline results in evaluating school-based health promotion for alternative school students ☆

Susan R. Tortolero [a,*], Christine M. Markham [a], Robert C. Addy [a], Elizabeth R. Baumler [a], Soledad Liliana Escobar-Chaves [a], Karen M. Basen-Engquist [b], Nicole K. McKirahan [a], Guy S. Parcel [a]

[a] *Center for Health Promotion and Prevention Research, School of Public Health, University of Texas Health Science Center at Houston, United States*
[b] *School of Public Health, University of Texas Health Science Center at Houston, United States*

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Abstract

Background: Students attending 'alternative' high schools form relatively small, highly mobile high-risk populations, presenting challenges for the design and implementation of HIV-, other STI-, and pregnancy-prevention interventions. This paper describes the rationale, study design, and baseline results for the *Safer Choices* 2 program.
Study design: Modified group-randomized intervention trial with cross-over of schools but not of students. The study cohort was defined *a priori* as those who completed the baseline measures and were still enrolled at the time of first follow-up.
Design results: Of 940 students initially enrolled in the study, 711 (76%) formed the study cohort. There were significant demographic differences between those included and those excluded from the study cohort in sex, age, sexual experience, experience with pregnancy, drug use, and some psychosocial measures. There were no significant differences between the intervention and control groups within the study cohort. The only significant difference between those students excluded from the intervention group and those excluded from the control group was reported age at first intercourse.
Baseline data results: Students ($n=940$) enrolled were predominately African-American (29.7%) and Hispanic (61.3%); 57.3% were female; 66% had ever had sex; and reported drug use in the previous 30 days ran from 4.3% (cocaine) to 26.9% (marijuana). Of the 627 sexually experienced, 41.8% reported their age at first intercourse as 13 years or younger; 28.5% reported ever being or having gotten someone pregnant; 74% reported sex in the past 3 months. Of the 464 sexually active in the last 3 months, 55.4% reported unprotected intercourse and 31.3% reported using drugs beforehand.
Conclusion: The cross-over design will provide a rigorous test of the intervention; however, loss to follow-up of this population can result in some selection bias. Students attending dropout prevention and recovery schools are at high risk for HIV, STIs, and pregnancy, and are in need of interventions.

Keywords: Randomized controlled trial; Group randomized trial; Adolescent; Sexual behavior; HIV infections/prevention and control; Sexually transmitted diseases/prevention and control; Pregnancy in adolescence/prevention and control; Sex education; African-Americans; Hispanic-Americans; Unsafe sex

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* Corresponding author. Tel.: +1 713 500 9634.
E-mail address: Susan.Tortolero@uth.tmc.edu (S.R. Tortolero).

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1. Introduction and background

HIV, other sexually transmitted infections (STIs), and teen pregnancy are major public health problems for adolescents. In the US, nearly one-half of all STIs occur in young people under the age of 25, with an estimated 9.1 million new STI cases in that age group in 2000. [1] Minority youth are at particularly high risk for STIs, HIV, and pregnancy [2–4]: In 2003, of reported AIDS cases among 13- to 19-year-olds, 87% were among Black and Hispanic youth [5].

While a number of research studies have developed and tested interventions to address these problems in mainstream school settings [6–12], this approach often fails to reach students who run the greatest risk of HIV infection [6]. One possible way of reaching a higher-risk population of students is through implementing programs in alternative schools. Nationally, these schools had an enrollment of 612,900 students (1.3% of all public school students) as of October 1, 2000. Students may be assigned to attend alternative schools for a variety of reasons, including behavioral problems, truancy, excessive absenteeism, poor grades, or pregnancy. Students in alternative schools are more likely to engage in behaviors that put them at high risk of contracting HIV [13–16]. The 1998 national Alternative High School Youth Risk Behavior Survey (ALT-YRBS) found that 87.8% of students reported having had sexual intercourse during their lifetime [13], compared to 49.9% of students in regular high schools in 1999 [17]. Alternative school students were also more likely to have initiated sexual intercourse at an early age, less likely to report using condoms at last sexual intercourse, and almost twice as likely to report using alcohol or drugs at last sexual intercourse [13,16,17].

While alternative schools provide a point of access to high-risk adolescents, they also give the researcher several challenges in designing and evaluating health promotion programs using a randomized trial design. This paper addresses some of the design and methodological issues in conducting a school-based intervention trial in alternative schools, in the context of a description of the rationale, study design, and baseline results of a particular intervention. The discussion may also be useful for those designing intervention trials to evaluate programs for other settings, such as clinics or community groups, where a small number of groups are available for randomization and populations are both high-risk and highly mobile.

2. Study design

Safer Choices 2 is a 5-year research study to adapt, implement, and evaluate a theoretically based, multi-component HIV-, STI-, and pregnancy-prevention program, Safer Choices [7], for use in alternative schools. The adaptation process and program content of Safer Choices 2 is described elsewhere [18]. The adapted program consists of 15 lessons, a video, and journaling activities delivered in a classroom setting by a trained facilitator over an 8-week period. The intervention is based on social cognitive theories [19] and includes skill-based and experiential activities. The overall goal of the Safer Choices 2 intervention trial was to evaluate experimentally the impact of the Safer Choices 2 program in reducing levels of unprotected sexual intercourse relative to those in the comparison condition.

2.1. Cross-over and randomization

The goal of any comparative trial is to provide the basis for valid inference that the intervention as implemented caused the result as observed [20]. Currently, the most well-accepted study design for assessing the efficacy of school-based interventions is the group-randomized trial, whereby schools are the unit of randomization and students are nested within schools [20]. This usual type of design has methodological as well as practical advantages for conducting school-based research, particularly when examining both individual and school effects from the intervention.

The first challenge a researcher faces when using alternative schools as research sites is that the number of alternative schools available to randomize is usually limited. Moreover, there is greater variation among alternative schools in size of the student population, ethnic and racial composition, and enrollment criteria: different alternative schools may serve significantly different populations (e.g., adjudicated youth, pregnant and parenting youth, or youth who have failed academically). It can therefore be difficult to identify enough schools with similar characteristics for randomization into comparable groups. The limited number of alternative schools in any one geographic location and