



## The Evaluation of the Safer Sex Program in New Orleans, Louisiana

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| Intervention Name            | Safer Sex   |
| Intervention Description     | <p>The Staying Mature and Responsible Towards Sex (SMARTS) study is implementing Safer Sex, an in-person, individual-level, clinic-based intervention that aims to reduce risky sexual behaviors among sexually active adolescent females. In addition to providing participants with factual information that might be typical in clinical programming, the program aims to motivate behavioral change teaching participants social and self-regulative skills and helping them to evaluate social norms. The intervention consists of four one-on-one sessions where a health educator, who is trained in motivational interviewing and the intervention, meets with participants over the course of six months. The initial intervention session is 30 minutes long and delivered in a private setting. The first session aims to capture the participant's attention; impart information; and promote motivational, attitudinal, and ultimately behavioral changes. After the initial session, there are three booster sessions where the health educator meets with the participant in-person for 10 to 15 minutes at one, three, and six months. These booster sessions are intended to sustain that behavioral change.</p> <p>The program is intended to be delivered within a clinical setting by a female health educator trained in the intervention. Health educators are expected to motivate behavioral change by using individual-focused interviewing techniques to assess the participant's context. In addition to providing the participant with relevant facts, it is hypothesized that motivation to reduce risky behavior will result from the provision of social and self-regulative skills; resulting self-efficacies; and attitudinal and belief change that can result from the deliberation of risks, expectations, and modifications of perceived social norms.</p> |
| Counterfactual               | Female Sexual Health  |
| Counterfactual Description   | <p>Female Sexual Health is an individual-level, information-only sex education program that aims to increase participants' knowledge about how sexually transmitted infections (STIs) are contracted, the consequences of contracting STIs, and how to prevent them. The content and objectives are related only to knowledge acquisition and do not aim to modify or promote motivational and attitudinal changes that are theoretically expected to precede behavioral change. A female health educator uses a Microsoft PowerPoint presentation to provide information about reproductive anatomy and STIs, including chlamydia, gonorrhea, trichomoniasis, herpes, human papillomavirus (HPV), syphilis, and HIV/AIDS. Female Sexual Health is intended to be implemented in one 30-minute session and does not have any booster sessions.</p> <p>Female Sexual Health includes the information-only component of the first session of Safer Sex and time spent with a health educator. By design, Female Sexual Health provides the same factual information and equivalent baseline exposure to a health educator. This is to better ensure that any observed impacts are due to the intervention itself and not simply a result of the provision of factual information or exposure to a health educator. Therefore, the evaluation is testing effects of an interpersonal intervention that aims to provide participants with skills and social motivational incentives in addition to factual information.</p>   |
| Primary Research Question(s) | What is the impact of the offer to participate in Safer Sex relative to the offer to participate in Female Sexual Health on participants' reported consistent use of condoms six months after the end of intervention?  |

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| Additional Outcomes     | Frequency of sexual activity; knowledge of safe sex practices, STIs, and condom use; belief of risk of HIV infection, STI infection, and pregnancy associated with sexual activity; belief of control associated with condom use and sexual activity; attitudes supportive of condom use; attitudes supportive of delayed initiation; condom use self-efficacy; communicative and assertive self-efficacy; beliefs of normative behaviors; intentions to engage in sex; intentions to use condoms.   |
| Sample                  | <p>Clinics in the New Orleans area that served young women between the ages of 14 and 19 were identified as potential clinics. The intervention and evaluation were explained to clinics and memoranda of understanding was developed before a clinic was identified as a participating clinic. Potential participants were referred to the SMARTS study from a number of possible sources. At participating clinics, clinicians and clinic staff referred female patients ages 14 to 19 to the SMARTS research assistant/health educator, who then conducted a full eligibility screening. Additionally, staff from other clinics (not participating in the study) could have also referred females ages 14 to 19 to a health educator to learn more about the study. Study participants could also have referred their friends and family to the program.</p> <p>To be enrolled, the referred adolescent had to meet with a SMARTS health educator at a participating study clinic, respond to eligibility screening questions and meet study eligibility criteria, and provide consent/assent. To be eligible, a participant had to be a female age 14 to 19 years at baseline, provide consent/assent to participate, report having engaged in sex with a male at least once in the past three months, express a willingness to return for planned follow-up assessments, and screened by the clinician for physical and mental health. In addition, to be eligible the potential participant must not knowingly have been pregnant or trying to get pregnant, or have previously participated in a specified list of prevention programs. The projected sample size was 330 youth.</p>  |
| Setting                 | The study took place in five health clinics in the New Orleans, Louisiana, area.   |
| Research Design         | <p>The study is an individual randomized controlled trial. Health educators randomly assigned eligible, consenting participants to intervention or control conditions on a rolling basis after consent/assent was obtained and before the provision of any programming or collection of baseline data. Random assignment was conducted at each site. Before random assignment, the evaluator placed a piece of paper in an envelope indicating an experimental condition (i.e., Safer Sex or Female Sexual Health), randomly shuffled the envelopes, and recorded a study ID on the outside of each envelope. Before giving the envelopes to the sites, the evaluator recorded each envelope's ID number and condition to enable confirmation of the assignment process. After each study participant provided consent, the health educator opened the next envelope in the stack, which would both randomize the participant into a condition and provide her with a study ID number. There was no difference in the consent or assignment processes for the intervention or control groups.</p> <p>Baseline, outcome, and covariate data were collected via self-administered questionnaires that were scheduled at the following times for both groups: baseline (before the first program session); 1-month interim (1 month after baseline and, for intervention-assigned participants, ideally before the 1-month booster session); 6-month interim (6 months after the baseline and, for intervention-assigned participants, ideally before the 6-month booster session); 6-month follow-up (12 months after baseline and, for intervention-assigned participants, 6 months after the final booster session); and 12-month follow-up (18 months after baseline and, for intervention-assigned participants, 12 months after the final booster session).</p> |
| Impact Findings         | To be determined when data collection and analysis are complete.   |
| Implementation Findings | To be determined when data collection and analysis are complete.   |
| Schedule/Timeline       | Young women were recruited and enrolled in the study from February 2012 through May 2014. Data are collected on a rolling basis through May 2015. A final report, which focuses on six month follow-up data, will be available to the Office of Adolescent Health in 2015-2016.  |