The Evaluation of SpeakOut in Public Clinics Throughout California

Grantee
Grantee Name: Regents - University of California (University of California, San Francisco)
Project Lead: Christine Dehlendorf, M.D. M.A.S. Principal Investigator
Email address: christine.dehlendorf@ucsf.edu

Evaluator
Evaluator's Organization: University of California, Davis
Evaluator Lead: Eleanor Bimla Schwarz, M.D., MS. Co-Investigator
Email address: ebschwarz@ucdavis.edu

Intervention Name
SpeakOut

Intervention Description
SpeakOut is a multipronged intervention, designed for easy implementation by health providers and health educators in a wide range of clinical settings. The goal of SpeakOut is to encourage teen users of Long-Acting Reversible Contraceptive (LARC) methods, specifically intrauterine devices (IUDs) and implants, to discuss their birth control experiences and disseminate evidence-based information about their LARC method with peers. SpeakOut is available in both English and Spanish and consists of four core components: (1) one-on-one communication coaching, (2) method-specific printed materials for participants to keep or share with friends, (3) method-specific websites with information and resources, and (4) method-specific text messages.

During an adolescent's visit to a health clinic, trained staff deliver an educational script in a one-on-one setting, reviewing effective communication strategies and encouraging the adolescent to share information about her contraceptive method of choice with her peers, to the extent she would feel comfortable doing so. The trained staff member then provides printed materials, reviews a method-specific website with the participant, and invites them to sign up for weekly text messages. This in-person intervention component is expected to take about 10 to 15 minutes total. Participants who decline to enroll in texts during the initial meeting are shown how to sign up for texts through the website if they want to at a later time. Participants receive one text per week with information about the participants' contraceptive method and about how to share their experience, for the eight weeks following sign-up.

The SpeakOut intervention is delivered to adolescents (primary participants), and the expectation is that these adolescents will disseminate what they have learned to their peers (secondary participants).

Comparison Condition
PartyWise

Comparison Condition Description
Adolescents in the comparison condition also receive an intervention composed of the same four components: (1) one-on-one education, (2) printed materials, (3) a website, and (4) text messages. Comparison participants receive a 10 to 15 minute, one-on-one educational intervention focused on safe alcohol consumption, exploring current usage, and motivators to reduce potentially harmful levels of consumption. The facilitator offers educational handouts on the effects of alcohol consumption for women and adolescent girls and introduces the participant to the PartyWise website, containing additional information and resources related to safe consumption of alcohol. Participants are invited to sign up to receive one text message per week for eight weeks containing tips on safe alcohol consumption and interesting facts about alcohol's effects on the body.

Similar to the SpeakOut program, the PartyWise intervention is delivered to the adolescents (primary participants), who are encouraged to disseminate what they have learned to their peers (secondary participants). However, the content that the PartyWise primary participants are expected to share focuses on safe alcohol consumption, rather than effective contraception options.

Behavioral Outcomes
Initiation or continuation of a LARC method (among sexually active secondary participants, assessed according to whether secondary participant is using LARC at baseline), use of other forms of
contraception and condom use at last sex (for both primary and secondary participants)

**Non-behavioral Outcomes**

Quality and fidelity of the delivery of SpeakOut and the comparison interventions and initiation of conversations about LARC with peers (primary participants); receipt of positive social communication about LARC (secondary participants); positive attitudes related to LARC methods and increased knowledge about LARC (primary and secondary participants)

**Sample and Setting**

The evaluation will enroll participants from eight public family planning clinic sites located throughout California. Each clinic will notify study staff of scheduled appointments for patients ages 15 to 19 who are using or are planning to initiate LARC or are already using LARC. Research staff will approach patients in the clinic before or after their appointment and invite them to be screened for eligibility for the study. All recruitment, consent, and baseline activities can occur before or after appointments in accordance with clinic flow. Each primary participant recruited through the clinic will be asked to identify up to five social contacts with whom they feel comfortable talking about personal issues. These friends and family members will make up the pool of secondary participants who will be recruited for the evaluation. The evaluation plans to enroll 432 adolescent LARC users as primary participants and 1,728 social contacts as secondary participants.

To be eligible, primary participants must: (1) be female, (2) be ages 15 to 19, (3) be able to speak and read English or Spanish, (4) be a resident of California, (5) be a user of an IUD or implant for birth control (or plan to initiate use on the day of enrollment), (6) be comfortable with close friends knowing that they use an IUD or implant, and (7) be able to think of at least one adolescent friend or family member under 20 years old they would be comfortable asking to join a study about health topics such as birth control and alcohol. Primary participants cannot be pregnant at baseline or previously enrolled as primary or secondary participants.

Secondary participants must: (1) be female, (2) be ages 15 to 19, (3) be able to speak and read English or Spanish, (4) be a resident of California, and (5) be listed as a social contact by a primary participant at enrollment. Secondary participants cannot be pregnant or previously enrolled as primary participants.

**Research Design and Data Collection**

Evaluators will randomly assign primary participants to receive either SpeakOut or the comparison intervention, PartyWise, immediately before intervention delivery. Therefore, all analyses of primary participant outcomes will be considered as resulting from an individual-level randomized controlled trial. However, the main focus of this study is on the outcomes among the peers of the primary participant (that is, the secondary participants). Because these peers are effectively nested within the primary participant at the time of random assignment, the analysis of outcomes about secondary participants can be considered as resulting from a cluster randomized controlled trial.

Primary participants in both the intervention and comparison groups will receive a baseline survey, a 3-month follow-up survey, and a 9-month follow-up survey. Two to four weeks after enrollment, research staff will reach out to the secondary participants listed as contacts by the primary participants and invite them to enroll. Secondary participants complete a baseline survey, a 3-month follow-up survey, and a 9-month follow-up survey, measured from the day of enrollment of the primary participant in each cluster.

For the implementation evaluation, the evaluators will collect data on fidelity and quality of the one-on-one educational coaching sessions. With consent of the participant, these sessions will be audio recorded. After each session, facilitators will complete a fidelity checklist. The evaluation team will randomly select 20 percent of all sessions to conduct a quality and fidelity observation using the audio recordings. In addition, the webhost will record website hits and statistics, and the text messaging service will record the number of text messages sent and received, as measures of dosage of these core components.

**Schedule/Timeline**

Sample enrollment and baseline data collection began in November 2016 and will continue through October 2018. Follow-up data collection will begin in February 2017 and end in August 2019.