EVALUATION ABSTRACT:
THE EVALUATION OF PRACTICE SELF-REGULATION IN CALIFORNIA, MAINE, MICHIGAN, NEW MEXICO, AND LOUISIANA

Grantee

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Intervention Name

Practice Self-Regulation (PS-R)

Intervention Description

PS-R is a manualized therapy intervention that is trauma-focused and performed one-on-one with youth ages 14 to 19 years old who are receiving individual outpatient counseling services. The intervention aims to decrease risky sex behaviors by increasing knowledge of sexual health and the impact of trauma on sexual decision making, readiness to change risky sexual behavior, ability to manage impulsive behavior, confidence in ability to negotiate safe sex, and intentions to practice safe sex. It also enables participants to explore the effect of previous trauma on their behavior more generally.

The intervention has three key components: (1) intensive four-day facilitator training provided by the developer, using the Trauma Outcome Process Workbook for Sexual Health Facilitator's Guide; (2) the Trauma Outcome Process Workbook for Sexual Health, which the youth works through on their own between sessions; and (3) ten one-on-one therapy-education sessions led by a trained facilitator, in which the facilitator covers sexual health education and facilitates a discussion of the workbook chapter the youth has completed. The content of the intervention reflects the seven essential topics outlined in the National Sexuality Education Standards (anatomy and physiology, puberty and adolescent development, identity, pregnancy and reproduction, sexually transmitted infections and human immunodeficiency virus (HIV), healthy relationships, and personal safety). The workbook contains self-directed activities that help simplify the complex concepts associated with trauma to help youth easily understand and apply effective coping strategies for self-regulation and optimal sexual decision making. In addition to providing these core components of sexual health education, this intervention provides a setting for discussion between the youth and facilitator about the effect of trauma, personal goals, beliefs, values, and choices that affect a person's sexual health and well-being. The intervention also uses components of expressive therapy, such as multisensory activities, to enhance the therapeutic experience for the youth and enable them to envision pathways toward reducing personal risk.

The intervention should be delivered in a private space (for example, a clinician's office) ideally over 10 consecutive weeks (one session each week), however, it might take longer depending on a youth's mental health needs and scheduling (for example, vacations or missed appointments). For the purposes of the study, the intervention window has been defined as an 18-week period. During the intervention window, intervention participants are expected to receive all 10 sessions of PS-R in place of their regularly scheduled counseling sessions with their therapist. However, at the therapists' discretion, the PS-R sessions can temporarily halt to address pressing or acute needs of the study participants. Although there are no explicit educational requirements for PS-R facilitators, to participate in the study, facilitators must be: (1) clinicians with advanced degrees (for example, a master of social work) and an active clinical license; (2) trained in study procedures by a PRG research analyst; and (3) participate in a four-day PS-R training, conducted by Joann Schladale.

Comparison Condition

Business as usual

Comparison Condition Description

The comparison condition will be business as usual; that is the typical therapy or counseling that participants would receive from facilitators. There will be no alternative program or additional activities offered to the participants assigned to the comparison group. The comparison condition is referred to as Therapy Practice Group for the purposes of the study.

Therapy models typically used by facilitators will vary, but it is likely that other trauma-informed interventions or therapies will be used with control participants (e.g., Trauma Focused Cognitive Behavioral Therapy). Facilitators have been instructed they can answer specific questions related to sexual health in therapy sessions, however, they are to provide information only and referrals for additional services when necessary as they would under typical circumstances. Partner agency representatives and participating private practitioners have confirmed that

no other curriculum-based teen pregnancy prevention programs or similar therapy-based sexual education programs will occur during the study period.

Behavioral Outcomes

Condom use and number of sexual partners

Non-behavioral Outcomes

Sexual health knowledge (related to pregnancy, HIV and sexually transmitted infection transmission, and methods of protection), intention to engage in sex and safe sex behaviors, sexual attitudes (related the value or importance of engaging in sex and safe sex behaviors, self-efficacy to practice safe sex (use condoms or contraceptives, negotiate condom use, make healthy and safe sexual decisions), affect regulation beliefs and attitudes (related to the malleability of emotions and value of affect regulation), self-efficacy to regulate affect, self-esteem, self-regulation tendencies (related to rational and impulsive decision making), practice of affect regulation (related to frequency and consistency with which youth regulate their emotions)

Sample and Setting

The study is being conducted in California, New Mexico, Michigan, Maine, and Louisiana. Staff will screen all youth receiving treatment or counseling services from study agencies or clinics and partnering private practitioners' offices for eligibility. The intent-to-treat sample will be comprised of eligible youth who are enrolled into the study during the two-year implementation period (July 1, 2016 to June 30, 2018). To be eligible, participants must (1) consent or assent to participate; (2) be at least 14 years old, but no older than 19 years old; (3) be appropriate for the study as deemed by agency staff; and (4) be receiving individual outpatient counseling services at one of the study's implementation sites. The exclusion criteria are: (1) previous participation in the Teen Health Study; (2) previous use of the Trauma Outcome Process workbook; (3) self-report of previous participation in other teen pregnancy prevention-funded programs; or (4) self-report of roommate who participated in the Teen Health Study. The evaluation plans to enroll 600 eligible youth over the course of the study period.

Research Design and Data Collection

The study is an individual randomized controlled trial in which evaluators randomly assign eligible, consenting participants to intervention or comparison conditions at a one-to-one ratio. Random assignment occurs after participants' evaluation consent or assent and before the provision of any programming or collection of baseline data.

Randomization is blocked at the regional (state) level, which does not guarantee in each site that facilitators will deliver both the PS-R and comparison conditions; however, the expectation is that over the course of the implementation period facilitators will likely deliver both. Although this minimizes potential therapist-related confounds, it increases the risk of comparison group contamination. To reduce contamination risk, facilitators will train on the expectations of the study; following each session with comparison group participants, they will be asked to self-report the type of therapy provided and whether core components of PS-R were covered in the session. In addition, every therapist will be instructed to video record two randomly selected comparison condition sessions for each participant who gives permission to video record; a team of observers picked by the intervention developer will review these sessions to assess whether comparison youth are exposed to the intervention.

Participants in both the intervention and comparison groups will be surveyed at baseline (before the first intervention session), 18-week follow-up (post-baseline) survey, and 9-month follow-up (post-18-week follow-up). Participants will complete questionnaires (available in English and Spanish) electronically on a computer in a private room; however, paper questionnaires will be available if participants require them. The preferred mode for all data points is in-person data collection, but evaluators will collect data online, by mail, or over the phone in an interview format with difficult-to-reach participants at 18-week and 9-month follow-ups. Data collection windows for both follow-up questionnaires will be four months. The evaluators will track when participants respond and sensitivity analyses will examine whether outcomes differ for participants who responded on time (within the first month of the data collection window) and late (in the second, third, or fourth months of the window).

For the implementation evaluation, the evaluators will collect data on fidelity, attendance, and quality. Evaluators will collect these data through attendance logs and therapist reports (updated and completed after every session), as well as video observation reports (completed for 10 percent of all intervention and comparison participant sessions).

Schedule/Timeline

Sample enrollment and baseline data collection began July 2016 and will end June 2018. Not all youth enrolled in the period will be eligible to complete follow-up surveys during the grant due to the shortened project period. The 18-week post-baseline data collection began November 2016 and will end June 2018, and the 9-month follow-up data collection began August 2017 and will end June 2018.

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