

STUDY TITLE:

TYPS: Tennessee Youth Prepared for Success

PRINCIPAL INVESTIGATOR:

Name: Jordan Nelon, Ph.D.

Department: Centerstone Research Institute

VERSION DATE:

07/06/2023

RELATED STUDIES:

N/A

Check any **applicable** boxes in the table below – you will be asked for further detail on these topics later in the protocol form:

Indicate Vulnerable Population(s) to be Enrolled	<input checked="" type="checkbox"/> Children <input type="checkbox"/> Cognitively Impaired Adults <input type="checkbox"/> Pregnant Women (IF the research activities will affect the pregnancy or the fetus) <input type="checkbox"/> Prisoners (or other detained/paroled individuals)
International Research (check this box if you will collect data from individuals located outside the United States)	<input type="checkbox"/>
Research involving external collaborators (some research activities will be carried out by individuals not employed by Northwestern or NU affiliates)	<input type="checkbox"/>
Research has U.S. Federal government funding via direct award or a sub-award (e.g., NIH, NSF, other federal agencies or departments)	<input checked="" type="checkbox"/>

1.0 Purpose and rationale of the study:

The principal objective of *Tennessee Youth Prepared for Success* is to pilot, implement, and test innovative adolescent pregnancy prevention strategies using a randomized controlled trial (RCT) to effectively educate youth on both abstinence and contraception with the goal of reducing youth pregnancies, births, and STIs/HIV/AIDS. *Tennessee Youth Prepared for Success* will address Adulthood Preparation Subjects (APS) to promote youths' successful and healthy transition to adulthood; include a Positive Youth Development (PYD) approach to engage youth and provide positive influences and skill building opportunities; and implement activities/interventions within a trauma-informed approach to account for the mental health needs of those who have experienced maltreatment, abuse, or violence. The project's goals and principal and subordinate objectives align with the PREIS program's goals/objectives and purpose, including (1) targeting high-risk youth to prevent pregnancy and STIs, including HIV/AIDS; (2) rigorously evaluating interventions using an RCT; (3) manualizing/packaging curriculum; and (4) disseminating lessons learned, best practices, and relevant findings. *Tennessee Youth Prepared for Success* will serve 1,200 youth ages 14-19 in 9 primarily rural counties in East/Middle/West Tennessee, targeting high-risk/vulnerable youth, including rural youth, those residing in counties with high teen birth rates, and/or hard-to-reach youth (e.g., systems-involved).

Tennessee Youth Prepared for Success will implement evidence-based curricula the promising curricula Be In Charge (BIC) for the treatment group, while the control group will receive the Adolescent Health Curriculum. BIC is an abstinence-based sexual health education program developed by Centerstone prevention staff in 2014 to increase a youth's sexual health knowledge and skills for responsible decision-making. It is built upon the idea of building healthy relationship skills and information to help inform responsible choices regarding sexual experiences, and it has been refined since that time with input from key stakeholders from similar target populations/geographic areas (e.g., youth, parents, school personnel). The 7 units of curriculum fit in with the theory of planned behavior where the educational components of the BiC intervention are designed to impact knowledge, attitudes, norms, and perceived control over sexual health related outcomes (i.e., sexual intercourse and contraception usage), ultimately influencing intention and behavior. The curricula is trauma-informed and integrate a PYD approach through creation of safe environments, engagement of youth through creative activities, and facilitation of progressive skill-building. *Tennessee Youth Prepared for Success* will be guided by the Sexuality Information and Education Council of the United States Guidelines for Comprehensive Sexuality Education, which assists sexual health educators in delivering comprehensive, age/culturally/developmentally- appropriate and medically accurate messages. Adulthood Preparation Subjects (APS) will be directed by ACF's Adult Preparation Subjects Resource Guide.

Primary research questions include: (1) Do behavioral intentions to delay sexual initiation vary from pre-test to 1-year follow up? To what extent does this pattern vary based on assigned treatment condition?; (2) What is the relationship between assigned treatment condition and pregnancy rates reported at 1-year follow up?; (3) How does likelihood of

abstinence and contraception use change following delivery of the intervention? To what extent does this vary based on assigned treatment condition? A series of secondary research questions seek to understand outcomes related to implementation, theoretical constructs associated with behavior, and life skill changes. The secondary questions include: (1) To what degree were facilitators/educators able to implement the intervention/BiC with fidelity?; and (2) How do sexual health knowledge (e.g., HIV/STIs, teen pregnancy), healthy relationship skills, healthy life skills, attitudes/values about adolescent development, and parent-child communication change over time for *Tennessee Youth Prepared for Success* participants? How does this effect vary by mode of intervention (i.e., Be In Charge vs. Adolescent Health Curriculum)? The proposed evaluation study seeks to establish the efficacy of a teen pregnancy prevention program tailored to the specific needs of *Tennessee Youth Prepared for Success*' population subgroups (e.g., rural youth), thus supporting efforts to address health disparities in teenage pregnancies.

In this randomized control, experimental study, participants will be randomly assigned to receive either BIC (i.e., treatment group) or the Adolescent Health Curriculum (i.e., control/comparison group). Through comparison of key program outcomes, this project seeks to establish that BIC is (1) more effective than the Adolescent Health Curriculum in decreasing pregnancy rates, delaying sexual initiation, and increasing abstinence/contraception use and (2) implemented with a higher degree of fidelity, reflective of its tailoring to current medical accuracy standards and subpopulation needs. Classrooms/community groups will be matched at the organizational level to mitigate confounding variables (e.g., geographic area, age, demographics).

2.0 Enrollment Criteria (who can be in your study and who would not be eligible to participate in your study):

Tennessee Youth Prepared for Success will serve 1,200 youth ages 14-19 in 9 Tennessee counties (Anderson, Benton, Carroll, Hardeman, Roane, Scott, Sevier, Trousdale, and Union) who are at high risk or vulnerable for adolescent pregnancy and STIs, including HIV/AIDs. Participants must: (1) be between the ages of 14-19; (2) have a signed consent form from a guardian, along with assent or consent forms from the youth, as appropriate based on age, unless deemed otherwise by the Institutional Review Board (IRB); (3) be free of debilitating intellectual, mental health, or cognitive impairment (i.e. psychosis, orientation to time/place, etc. based on screening at program entry); and (4) be willing to share their experiences with sexual health & wellbeing training. Targeted high risk/vulnerable populations include rural youth, youth residing in high teen birth rate areas, and/or hard-to-reach youth (e.g., youth in foster care). The target population is expected to include youth in grades 9-12 and mirror youth area demographics: 53% male, 47% female, 89% white, 6% Black/African American, and 2% Hispanic/Latino individuals.

3.0 Sample Size:

Tennessee Youth Prepared for Success proposes to serve a total of 1,200 unduplicated high-risk youth over the 5-year grant period (Y1: 180; Y2-Y4: 840, annually; Y5: 300). The project will study unduplicated high-risk youth in Phases I and II of the project, comprising 600 total in the control group (i.e., Y1: 90; Y2-Y4: 420) and 600 total in the treatment group (i.e., Y1: 90; Y2-Y4: 420). In Year 5, the study will have concluded, and services will continue for the 300 youth, as identified above. *Tennessee Youth Prepared for Success*' target population comprises 25,450+ youth ages 14-19 with 53% male and 47% female. To arrive at these numbers, *Tennessee Youth Prepared for Success* considered community need and access in the geographic area, Centerstone client/target area demographics, and anticipated project staff caseloads; Centerstone's independent third-party evaluator, the Centerstone Research Institute, used a power analysis to determine appropriate sample size for the rigorous evaluation, including allowances for natural attrition across the longitudinal data collection period. Participant breakout by age group, race, and ethnicity will mirror target area demographics.

The target population was selected due to the prevalence of environmental and behavioral risk factors that can make youth vulnerable to unintended pregnancy, STIs, and/or HIV/AIDS. An anticipated 48% (7,614) of area high school students will have had sexual intercourse (vs. 41% of students across the country). Of sexually active youth, an anticipated 41% (3,121) did not use a condom during their last sexual encounter, and 16% (1,218) are expected to have had 4+ sexual partners. Individual risk behaviors have resulted in poor sexual health outcomes for target population youth. Furthermore, the target population's geographical/physical composition (i.e., 1 partially rural, 8 rural counties) poses unique challenges to youth sexual risk and protective factors. Rural locales impede access to safe-sex information and pregnancy prevention services because of distance, fewer EBP- trained health professionals, and cultural factors (e.g., religious beliefs, stigma about sexual behavior/ contraception). All 9 counties' teen pregnancy rates meet or exceed that of the state (27.3/1,000).

4.0 Recruitment and Screening Methods:

All program and evaluation staff are responsible for recruitment and enrollment through either direct engagement with the target population or indirectly through support roles such as staff training and data analysis and reporting. *Tennessee Youth Prepared for Success* program and evaluation staff will devote at least 50% of their effort on activities related to recruitment, enrollment, engagement, and retention of program participants to ensure a sample size with adequate statistical power.

Tennessee Youth Prepared for Success staff have successfully managed a number of strategic partnerships, including those with county school systems, community-based organizations (e.g., Planned Parenthood), youth-serving groups, faith-based groups, youth/family resource centers, parks and recreation, local health departments, and community coalitions/action groups. Staff have fostered/maintained these relationships via frequent communications (e.g., personal visits, calls, and emails), sharing outcome data through reports, presentations, and collaborations. A formal strategy for ensuring effective

management and monitoring with partner organizations, such as county school systems, includes signed MOUs. Informal strategies include the use of e-letters; networking opportunities (e.g., conferences); on-site visits and meetings; focus groups and feedback sessions; and satisfaction surveys. During implementation, the PD/PM will maintain ongoing contact with top leadership from schools and community partners to monitor project performance and ensure effective relationships.

The Research Institute will further execute a selection of traditional and innovative, data-driven recruitment and tracking strategies appealing to the diversity of the target population. The RI utilizes Community Engagement (CE) Studios as a primary recruitment, enrollment, engagement, and retention strategy. The CE Studio is a consultative model allowing researchers to obtain meaningful, program-specific input from parents, community members, community leaders, students, and other key stakeholders. The CE Studio includes: (1) RI consultation with the PD; (2) creation of a unique panel of community experts who represent the Tennessee Youth Prepared for Success population of interest; (3) pre-meeting coaching for the PD; (4) orientation and preparation of the expert panel; (5) a face-to-face meeting where the PD makes a brief presentation and community experts provide project-specific feedback; (6) compensation of community experts; and (7) a post-meeting summary with additional feedback for the PD. The CE model is instrumental in bringing the community perspective to the forefront of the research conversation and has proven to be a particularly effective approach for engaging populations underrepresented in research, including racial and ethnic minorities, gender and sexual identity minorities, people in rural areas, and youth.

In order to be eligible for receiving *Tennessee Youth Prepared for Success* services, organizations must: (1) be located in *Tennessee Youth Prepared for Success*' service area and (2) sign a *Tennessee Youth Prepared for Success* MOU and, where applicable, have documented approval from the school board for program implementation and data collection. *Tennessee Youth Prepared for Success* has already secured third-party agreements (i.e., MOUs, LOCs) and Letters of Support from diverse state and local organizations rooted in the target population's culture and experienced in healthcare, behavioral health, trauma-informed care, and other supportive services. Schools and other youth-serving community organizations will partner with *Tennessee Youth Prepared for Success* to provide both a safe space for the provision of prevention/education services as well as access to potential participants.

Centerstone program staff will educate/train 1,200 youth, engage 2,500 parents and community members, and distribute sexual health information materials among 5,000 community members. The RI will ensure a sample size of adequate statistical power by developing a REDCap locator form, participant tracking database, and MyCap. REDCap will be used to track stakeholder engagement including which stakeholder groups and when, where, why, and how they were engaged; their level of engagement; and how challenges to engagement were overcome.

5.0 Research Locations:

Tennessee Youth Prepared for Success will serve 1,200 youth ages 14-19 in Anderson, Benton, Carroll, Hardeman, Roane, Scott, Sevier, Trousdale, and Union counties in Tennessee, targeting high-risk/vulnerable youth, including rural youth, those residing in counties with high teen birth rates, and/or hard-to-reach youth (e.g., systems-involved). BiC will be offered in primarily rural areas, including schools and non-traditional settings (e.g., Boys and Girls Club, faith-based), with hard-to-reach populations (e.g., homeless youth, foster care), and in areas of high teen birth rates. The survey platform will be administered through an online source, (i.e., Qualtrics), to collect the questionnaires or through pencil and paper administration.

6.0 Multi-site Research (research that involves external collaborating institutions and individuals):

N/A

7.0 International Research (where data collection will occur outside the United States and U.S. territories, including online activities)

N/A

8.0 Procedures Involved:

Please check the boxes for all applicable data collection procedures you plan to use:

- One-on-one interviews
- Focus Groups
- Questionnaires/surveys
- Analysis of secondary data (medical record data, educational records, government or private sector datasets, etc.)
- Ethnographic observation
- Physiological measurements (e.g., EEG, EKG, MRI)
- Biospecimen collection (saliva samples, blood draws, hair samples, etc.)
- Mobile applications/data collection devices (e.g., Fitbits, actigraphs, etc.)
- Behavioral decision making tasks (e.g., puzzles, interactive games, etc.)
- Physical activities such as walking and other forms of exercise
- Other procedures (briefly list types of procedures here if not covered by the check-boxes above): _____

Program staff (i.e., Prevention Specialist facilitators/educators) will administer pre/post surveys to *Tennessee Youth Prepared for Success* participants to assess whether the program is having its intended effects on behavior, intentions, knowledge, and risk avoidance/reduction skills. Surveys will be refined based on feedback from the pilot phase

in which participants will complete cognitive pre-testing by rating each section and survey question according to clarity, conciseness, and time required. (A subset of these pilot participants will participate in a follow-up interview, which will utilize think-aloud and verbal probing techniques to explore thoughts during survey completion, including those specific to cognitive processes involved in answering survey questions (e.g., comprehension, retrieval). RI-supported, web-based data collection tools (e.g., REDCap, Qualtrics, Smartsheet) will be used to collect all data, including participant surveys, observer- and facilitator-reported fidelity data, pilot data, program output (e.g., dissemination, referrals, partnerships) and quality data. Electronic data collection allows for real-time data quality control and availability of current data for use in program management. Prevention Specialists will also be trained to use paper-based surveys at program entry/exit with participants as an alternative in scenarios where there are barriers to technology use (e.g., limited internet connection, settings with device restrictions). Short-term (i.e., 6-month) and long-term (i.e., 12-month) follow-up survey invitations will be distributed via email, phone, and text messages, based on contact information provided by participants at program entry. Accomadations will be made for any participants who prefer to speak or wish to take the survey in Spanish. After data collection, data will be shared with ACF and the Family and Youth Service Bureau (FYSB) in accordance with grant reporting requirements.

9.0 Research with Vulnerable Populations

Recruitment will take place at community-based or school-based settings where parents may or may not be. If parents/guardians are available, we will obtain a verbal consent for the participant to join in person or on the phone. If parents/guardians are not available, pariticpants will be sent home with a permission slip with the consent form attached and will not be able to participate in the program until we receive their parent's consent form. We will also give the participants youth assent when they first take their survey to ensure they want to participate. Youth assent is based on the age of consent in Tennessee, those who are of age will receive a youth-focused consent form that is tailored to their developmental stage. Data collection will be collected in an online survey the youth can complete at home in their own time. This way the youth will not feel pressured to answer in a certain way and their privacy will be kept. If the youth does not have access to the internet, we will provide a paper copy that they can fill out with the other youth. Participants will be given a privacy paper to cover their answers as they complete the survey and will be staggered so the participants cannot view each others surveys.

10.0 Incomplete Disclosure or Deception:

N/A

11.0 Consent Process:

It is essential individuals involved in the program be properly informed of their rights, responsibilities, risks, alternative treatments, and confidentiality. Following state law, staff/partnering organization personnel will obtain parent/guardian consent prior to delivering curricula/services to participants who are minors. Participants and their legal guardians (if under age 16) will receive information (e.g., electronic & physical consent forms) about the program evaluation component and responsibilities associated with these procedures at least 30 days prior to program implementation. Consent forms will include contact information for *Tennessee Youth Prepared for Success* staff, the PI and Program Evaluator (PE), and IRB of record will be included on the consent form to ensure ample opportunity to address questions prior to program implementation. Individuals wishing to participate will be invited to sign the Consent to Participate form. Participants will be provided a copy of the consent form. All consent forms will need to be signed by a parent/guardian and/or youth before the first day of implementation, and received by *Tennessee Youth Prepared for Success* on the first day of implementation. Youth under the age of 16, who require guardian consent, will also complete an assent form to document their agreement to participate. Consent forms will cover the entire length of the study and will not reoccur throughout longitudinal follow-up. All participation is voluntary, and each participant has the right to withdraw from the study at any time, without explanation or fear of derogatory treatment. Individuals who do not consent to the collection of individually identifiable data will be allowed to participate in *Tennessee Youth Prepared for Success* services. Accommodations will be made to meet the needs of participants with disabilities, low literacy, or other factors limiting their ability to provide full informed consent.

12.0 Waiver of Participant Signature on Consent Form:

N/A

13.0 Waivers and Alterations of Consent Information:

N/A

14.0 Financial Compensation:

Participants will be compensated with an electronic gift card for the time spent on study activities. The amount, type, and timing of compensation will be structured based on participant feedback during pilot.

15.0 Audio/Video Recording/Photography

Participants will not be recorded or photographed.

16.0 Potential Benefits of this Research:

The potential benefit to science and humankind that may result from this research study is a better understanding of the effectiveness of prevention programs for youth who are at-risk for teenage pregnancy and sexually transmitted diseases. The participant may or may not benefit from being in this study.

17.0 Potential Risks to Participants:

The potential discomfort or risk of the participant in this study is expected to be low because we have taken steps to protect their privacy. In the course of any research study, however, there are potential known and unknown risks. They may feel discomfort associated with sharing personal feelings and attitudes. There also might be a slight discomfort connected with discussing your attitudes about teenage sexual activity with program staff. The time it takes to complete the survey for the study may be a slight inconvenience. In order to minimize the time, the survey will take approximately 20 minutes. Should they feel upset, they can stop taking the survey at any time. The Prevention Specialist will be present to get them in touch with someone who can help. The Research Associate and Prevention Specialist will closely follow designated procedures for protection of confidential data and materials.

18.0 Provisions to Protect Participant Privacy and Data Confidentiality:

Tennessee Youth Prepared for Success adheres to all OHRP and HIPAA privacy guidelines to fully protect confidential/sensitive participant information. Participant confidentiality will be maintained by assigning ID numbers to participants via computer algorithm.

Pre/post survey data will be stored in secure, locked, and password protected locations (e.g., REDCap, Excel, secure filing cabinet), accessible only by data collection staff. All staff involved in data collection and evaluation will maintain valid HIPAA and human subject's research certification throughout the project, and will be trained on techniques to assist participants who need individualized assistance due to cultural norms/values, literacy, disability, language barriers, etc. The data collection plan will be approved by an Institutional Review Board to ensure adequate human subjects protection, including appropriate informed consent and assent for data measuring behavioral intentions and sexual risk avoidance outcomes.

A separate encrypted file will be maintained to match ID numbers with identifying information (accessible only by evaluation staff). Documents containing individually identifiable information (e.g., consent forms) will be stored separately from data, and in confidential files accessible only to employees trained in federal and state requirements and who have signed confidentiality agreements. Once the data are uploaded to the server and verified, working data files will be deleted from local workstations in order to ensure maximum confidentiality. Files will be converted to statistical formats (e.g., SAS, SPSS) for management and analysis. Variables and datasets will be labeled using an organized

coding scheme taking into account the specific data element, sample, and time point. Codebooks will be generated to enhance capacity to organize data. All treatment and evaluation information will be maintained in accordance with guidelines for 45 CFR 46, HIPAA regulations, and Confidentiality of Alcohol and Drug Abuse Patient Records (42 CFR Part II).

19.0 Data Monitoring Plan to Ensure the Safety of Participants:

Prevention Specialists will be trained by the evaluation team to confidentially collect participant-level measures in a manner that is age-appropriate, culturally competent, and aligned with trauma-informed and *Positive Youth Development* approaches. If any participants show distress during the lesson, program staff will be trained to identify and provide support and referrals if necessary.

20.0 Long-term Data and Specimen Storage and Sharing:

N/A

21.0 Qualifications of Research Team to Conduct the Research:

Tennessee Youth Prepared for Success' prevention services team has a collective 75+ years' experience providing school- and community-based educational services, including teen pregnancy and HIV/STI prevention, as well as experience creating innovative teen pregnancy and STI prevention content. Tennessee Youth Prepared for Success' leadership team has demonstrated experience in overseeing and monitoring similarly sized projects, including adjusting services to meet changing needs and growth, and managing staff and partnerships. Each member has experience/expertise implementing evidence-based TPP programs, coordinating large-scale implementation efforts at the community level, mobilizing multiple partners and decision-makers, monitoring and providing training/technical assistance to partners, and collecting/using performance measure data.