Cluster Randomized Trial of a School-Based Program to Prevent Teen Dating Violence
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Study Protocol

Purpose of Research: The purpose of this NIH funded study is to evaluate the new and enhanced middle school version of *Fourth R*, a healthy relationships and prevention program previously shown to be effective in reducing risky behaviors and improving relationships among high school students.

Specific Aims: The primary aim is to determine whether Fourth R reduces students' teen dating violence (TDV), as indexed by less perpetration and victimization of physical, sexual, and psychological TDV, relative to students in control schools. The secondary aims are to determine whether Fourth R, relative to control, (1) improves students' emotional well-being, and increases their acquisition and use of healthy relationship skills, as indexed by improved problem-solving, communication, and conflict resolution skills and (2) ameliorates the modifiable cognitive and behavioral correlates associated with the perpetration and victimization of TDV, as indexed by fewer attitudes justifying dating violence, decreased substance use, decreased risky sexual behavior, decreased fighting and bullying, increased school connectedness, improved academic performance, and decreased psychological symptoms. Pre-specified differences by gender and ethnicity will be examined, as well as the acquisition and utilization of various program components.

Research Design: This five year study is a school-based cluster randomized trial (experimental design) of the middle school version of *Fourth R*, where students receiving the curriculum will be compared to students receiving usual health classes. Outcomes will be assessed at baseline and at 12, 24, and 36 months post intervention.

Sampling Design and Rationale: We will recruit 24 middle schools in the Houston area for the study. A cluster-randomized trial will be used to assign the 24 participating middle schools (i.e., clusters) to the intervention (n=12) or control (n=12 as usual health classes) condition. Students (N=3,000) in these schools will be the unit of analysis and will be studied prospectively to determine the program's impact by comparing intervention students with control students. Outcomes will be assessed at baseline (when students are in 7th grade), and at 12-, 24-, and 36-months post-intervention, when students are in 8th, 9th, and 10th grade, respectively. To minimize school disruption, only the 1-year follow-up survey will be conducted in schools; the 2- and 3-year follow-up will be conducted via a web-based survey. The primary hypothesis is that intervention students will have significantly lower prevalence of physical, psychological, and sexual TDV perpetration and victimization than control students. The secondary hypothesis is that intervention students will have better healthy relationship skills (problem-solving, communication, conflict resolution), higher levels of school connectedness, better decision-making with respect to substance use and risky sexual behavior, better academic performance, and better mental health and well-being than control students.

Recruitment: The research team will recruit in 7th grade health classes at participating schools. A multi-method approach will be used for recruitment and to obtain parental permission. First, with district and school approval, research staff will include parental consent forms in the beginning-of-the-semester packets that are sent home with all students and parents will be asked to review, sign, and return. All consent materials will be provided in English and Spanish. Please see enclosed letter to parents, parent permission form, and student assent form. Second, research staff will actively follow up with "non-respondents" via phone and email. Third, to reach students who do not return a parental permission form, research staff will describe the purpose, design, and enrollment criteria to 7th graders

during the first week of health class. Students will receive a $5 gift card for returning a signed consent form, regardless of whether they are permitted to participate. A stipend/gift card will be given to teachers for each class that returns parental consent forms for 90% of students, regardless of whether parents agree to allow students to participate or not. If students forget to bring back their consent forms after multiple reminders over a period of approximately 2 school weeks, trained UTMB staff will use a scripted protocol (see enclosed verbal consent protocol) to obtain verbal consent from students' parents or legal guardians via telephone. UTMB staff will work with classroom teachers to determine which students still require consent and obtain permission from principals to make phone calls from the school. UTMB staff will then use the scripted protocol when calling parents to secure their decision regarding their child's study participation via telephone. The language about the study, risks and benefits will come exactly from the consent form and will be read to parents. A parent's decision regarding their child's study participation will be documented on the consent form and a copy of the consent form will be mailed to the parent for their records.

Measures: All measures are reliable, valid, and appropriate for adolescents and have been effectively used in other school-based research, including studies involving multi-ethnic, urban dwelling public school students. For inclusion in the study, measures must be related to the components of *Fourth R* or be potential mediators/moderators (e.g., mental health, exposure to violence). All measures will be administered at baseline and at each follow-up. We expect students to experience little difficulty in finishing in a timely manner, approximately 40 minutes. Data will be collected in a way that allows for dynamic surveys (e.g., skip patterns, tailored questions). Please find the draft survey enclosed.

Implementing teachers will be asked to complete curriculum monitoring (fidelity) and attendance sheets. Research staff will follow up with teachers to ensure these are completed. The site coordinator at each school will collect forms from teachers. With district and principal approval, research staff will attend 10% of the lessons delivered by each facilitator. Standardized checklists used by *Fourth R* staff that list main points and activities of each lesson will be utilized. Other observations will include percentage of time teachers use interactive instructional techniques, student behavior, deviations from the curriculum, and class size.

Data Collection Procedures: Students will be asked to complete paper/pencil surveys or web-based surveys hosted on a secure server (paper/pencil surveys will be completed when computers are unavailable). Prior to participating in the baseline survey, students will receive information about the study, what will be asked of them over the study period, and how their confidentiality will be protected. If they choose to participate in the survey, students will complete an assent form (parental permission will have already been obtained). Baseline and the 1-year follow-up will be conducted in the schools using paper and pencil surveys or school computers for web-based surveys during regular class time (paper/pencil surveys will be completed when computers are unavailable). We will employ the services of the Survey Research Division (SRD) at the University of Washington (UW) to assist with participant retention and the follow-up assessments. A majority of students will complete the 1-year follow-up survey in school, and any remaining students will complete the survey outside of the school setting via a mixed-mode approach (web, telephone, and paper surveys). Because participants will have transitioned from middle schools to high schools, the 2- and 3-year follow-ups will be done outside of the school setting via the mixed-mode approach. Students will receive a $5 gift card for completing the baseline assessment, $10 for completing the 1-year follow-up, and $20 for the 2-year and 3-year follow-ups.

Teacher Training and Curriculum Implementation: Students in the intervention schools will receive the *Fourth R* program during their health class. Because the intervention will replace the existing health curriculum, all 7th-grade students enrolled in health class at an intervention school will be exposed to *Fourth R*. However, only students with parental consent will participate in the evaluation portion of the study. Students randomized to the control schools will receive the standard, as usual health education program. Control schools will be offered the *Fourth R* curriculum at no cost the year following matriculation of study participants to high school.

The evidence-based Fourth R program integrates the promotion of healthy relationship skills and prevention of dating violence into existing school curricula. Components are aligned with state and federal curriculum requirements in health. The program includes both a classroom-based curriculum and school-level components in which teachers receive specialized training on teaching about healthy relationships and students form safe school committees. The Fourth R classroom-level component is a 27-lesson curriculum with complete lesson plans, role-play exercises, rubrics, and handouts. The curriculum, which is delivered by existing health teachers, comprises 4 units: 1) 7 classes on personal safety and injury prevention; 2) 8 classes on substance use, addiction, and related behaviors; 3) 7 classes on growth and development; and 4) 5 classes on healthy eating. The curriculum was designed to present accurate information in an interesting and engaging format, to enhance youth motivation, and to teach skills that promote healthy relationships and reduce conflict and risk behaviors.

Research staff will work with schools to ensure that all participating health teachers have the necessary training to implement the curriculum. The 1-day teacher training incorporates strategies to increase fidelity and has been tested and refined in more than 5,000 schools in Canada. To offset any training burden, we will provide professional education credit to teachers for participating in the training and, when possible, provide training during their professional development week. Schools will be reimbursed for the cost of substitute teachers if training occurs during school hours. The first semester (fall 2017) will only involve implementation, where teachers will be provided the curriculum manual with detailed lesson plans and all necessary visual aids, observations involving discussion and feedback with members of the research team and teacher liaison, and additional individual training provided by an experienced teacher-facilitator, as necessary. Teachers will have continuous access to online training resources and will have the option of participating in an online Community of Practice, where they can share successes and challenges with other facilitators. Teachers will receive an in-person booster session after the practice year.

Follow-up, Tracking, and Retention of Participants: A high retention rate is essential for any intervention/longitudinal study to be successful. In order to maintain a high-level of participation and follow-up, we will employ SRD and use many of the strategies developed in working in school-based studies through the years. The first step in tracking participants will be to collect complete information at the time of recruitment that will facilitate subsequent follow-up of youth. Students will be asked to provide detailed tracking information, including home address, email address, phone numbers, Facebook name, and detailed contact information for relatives and close friends. With district approval, we will also obtain each participant's unique student identifier. We will maintain a confidential database with this initial information as well as any contacts and updates throughout the course of the study. This contact information will be kept in separate files from other study data.

Prior to the 1-year school-based follow-up assessment, SRD will confirm that participants are attending the school and conservatively estimate that approximately 80% will be at the same school. For the remaining 20%, as well as for the 2- and 3-year follow-up assessments, SRD will take various steps in locating and scheduling participants for the follow-up survey, including calling, texting, and

emailing. If these methods are unsuccessful, SRD will attempt to contact participants using the following methods (in successive order): call and text them at all available numbers; securely message them via social media; contact their relatives and friends, as approved by the participant; and mail them certified letters with return-to-sender envelopes. If all contact attempts fail, SRD will locate them through access to their online database and search firms. We have partnered with SRD in previous longitudinal studies with great success.

A lottery strategy will be implemented during the 2nd follow-up (9th grade) survey period and the 3rd follow-up (10th grade) survey period. This strategy has been successfully implemented on similar studies and has served to build enthusiasm among survey participants. In addition, all students who complete the survey will be offered 1 hour of high school volunteer service hours. We will send a certificate of completion to all participants who complete the survey by either mail or email and participants may present this certificate to their school for approval of volunteer service credit.

To initiate the lottery strategy, we will send a notice to all participants, including those who have already completed their survey. There are 2 versions of the notice: (A1) tells those who have completed the survey that their name will be entered in the drawing, and they need to do nothing else to qualify for this opportunity; (A2) informs those who have not yet completed the survey that their name will be entered into the drawing if they complete their survey by the specified lottery deadline. The deadline is to be determined based on approval and will give participants sufficient notice and time to complete the survey. The notices will be either mailed or emailed to participants, depending on the best contact method we have for each participant. Study participants who have completed their survey by the deadline will be entered into a drawing for a $100 e-gift card. There will be 10 participants chosen to each win a $100 e-gift card. Winners will be chosen at random from all completed surveys by the lottery deadline. The drawing will be held within 2 business days after the deadline and e-gift cards for the winners will be emailed within 5 business days of the deadline. Winning participants will be notified by phone. A lottery conclusion notice will be emailed/mailed to all lottery participants once winners are randomly selected.

Implementing the lottery is an important participant retention strategy in that these last two survey follow-ups are completely web-based and given this unprecedented Coronavirus (COVID-19) pandemic it is even more important to implement innovative ideas in retaining participants. Our hope is that this strategy will encourage those participants who are slow to respond and will enhance the likelihood for more web survey completions to improve study response rates, which is critical for the success of the study.

Data Analysis: The primary objective of the data analysis is to evaluate the effectiveness of the *Fourth R* intervention in reducing TDV perpetration and victimization among a 7th–10th-grade population. Data analysis will be conducted in 5 phases: (1) preliminary analysis, (2) confirmatory analysis, (3) exploratory analysis, (4) attrition analysis, and (5) cost-effectiveness analysis. Preliminary analysis will be conducted using baseline data to produce a profile of the sample with regard to demographics and baseline outcome characteristics. This analysis will consist of descriptive statistics, such as frequencies, means, cross tabulations, and graphical representations of the data. The results from this analysis will provide information on imbalances between study groups that should be accounted for in the confirmatory analysis. Confirmatory analysis will be conducted to test the proposed hypotheses, which have been stated a priori, within the context of the study design. Linear and generalized linear regression models will be used to test for intervention effects while controlling for baseline differences through the use of covariates. The study design is composed of data collected on students within schools. Data from students within the same school are anticipated to be correlated to varying degrees.

Two-level multilevel models will be used to assess the impact of the intervention in the presence of this correlation where level-1 is the student measurement and level-2 is the school unit. Application of traditional regression estimation techniques, which assume independence between observations, to correlated data can lead to an underestimation of the standard error, resulting in an increased probability of Type I error. Results from this analysis will be used to answer the primary research questions. Analyses will also be conducted to assess the impact of the intervention on the secondary outcome measures and to investigate the nature of their relationship to changes in TDV behavior. Exploratory analysis will be conducted after all primary and secondary research questions have been addressed. The purpose of this analysis is to identify relationships and patterns in the data that may not have been anticipated in the onset of the study. All results from this analysis will be labeled as exploratory in nature and will be used for the purpose of yielding evidence that is suggestive of hypotheses to be considered in subsequent studies. Attrition analyses will be conducted at all follow-up time points to assess patterns of missingness. These patterns will be quantified and documented as to their potential impact on the generalizability of findings. In the event that these analyses reveal nonrandom missing patterns that may impact program generalizability, imputation techniques will be employed. Additionally, will measure cost-effectiveness of the program relative to standard instruction. Specifically, we will examine the (1) cost-effectiveness of Fourth R in decreasing the number of students who are victims or perpetrators of TDV, (2) cost–benefit of Fourth R in preventing cases of injury due to TDV, and (3) cost-utility of Fourth R in increasing the quality-adjusted life years (QUALYs) saved by estimating the cost per QUALY saved. Finally, we will conduct a cost analysis of Fourth R from the school-district perspective to inform administrators and decision-makers about the costs and benefits that a school is likely to incur by adopting Fourth R. In this analysis, only school-related costs and benefits will be included. Program costs will include materials paid for by the school and personnel time costs. Benefits will include school costs averted because of the program.

Protection against Risk: The potential risks are related to the sensitive information pertaining to TDV and sexual risk behaviors that are obtained from the study participants, specifically for research purposes. These potential risks are loss of confidentiality and anonymity. It is also possible that students may feel some discomfort as a result of participating in the survey or the intervention. Several mechanisms, however, described below will be in place to minimize these risks.

In order to protect sensitive information, we will obtain a certificate of confidentiality from the Department of Health and Human Services (DHHS) in accordance with Section 301(d) of the Public Health Service Act (42 U.S.C. 242m). In addition, all data collection staff will receive intensive training related to confidentiality issues prior to data collection. They will also sign confidentiality agreements and will receive on-going training and supervision during data collection. In order to protect the confidentiality of the participants, all records will be filed in locked cabinets and password protected computers systems for use by authorized personnel only. All participants' records will be given a unique study identification number for data entry and data management purposes. No names will be kept on the computer where the study data is collected or stored. No participants, schools, or school district will be identified in data analysis files or in reports.

The sensitive nature of the intervention and assessments may elicit negative thoughts and feelings in the participants. Although we have not had any adverse events associated with intervention or assessment activities in previous studies, the PI will regularly consult with his collaborators. In addition, as a licensed clinical psychologist, Dr. Temple is trained to manage any clinical issues that may arise. Although we anticipate that, in most cases, any negative thoughts and feelings will be mild and manageable, we have developed a clinical protocol to manage more severe cases. With respect to the assessments, we will emphasize to research staff (including SRD staff, who are leaders in survey

data collection) that if a student becomes upset, they should offer them the option of discontinuing the survey without penalty (i.e., still receiving gift card) or continuing at a later time. Furthermore, the tailored survey administration limits student exposure to potentially sensitive items: students without a history of dating are not exposed to TDV questions; similarly, students who have not engaged in sexual behavior are not exposed to more-detailed questions about number of sexual partners or condom use. All students will also be instructed that they may skip any item that makes them feel uncomfortable. In the event of any emotional distress, research staff will remain with the student until he or she is no longer distressed. Dr. Temple will be available at all times to provide immediate supervision or to counsel students. Students who wish to pursue additional therapy will be given a referral list specifically tailored to his or her request. We will have prepared referral lists for TDV perpetration and victimization, as well as for other psychological problems. At the end of each assessment, all students will be offered a list of referrals and a teen safety plan designed specifically for adolescents in violent relationships. Of note, we have established connections with local organizations that will be available to provide counseling to participants if needed. We will not be asking about suicide as part of the program, so it is unlikely that we will have to deal with this issue. However, anyone having direct involvement with the students will be fully trained by Dr. Temple in procedures for assessing and intervening in cases where suicidal ideation is expressed. Research staff will be instructed to immediately contact Dr. Temple and the project director if suicidal ideation is expressed. Appropriate clinical action will be taken in these circumstances, including hospitalization and/or referral to another level of clinical care.

We will work closely with school counselors/social workers, so that teachers have an outlet to refer students in need of additional mental health services. School counselors/social workers will be involved in certain aspects of the intervention training, so that they develop a relationship with the teachers and acquire knowledge of the various aspects of the TDV intervention. Teachers and school counselors/social workers will also be provided with an extensive referral list, as well as teen safety plan to review with affected students. Dr. Temple and our teacher liaison will be available to provide additional support for the teachers and school counselors/social workers as needed. Middle school teachers will also receive information on confidentiality and disclosure issues. At the beginning of the intervention, the teacher will inform students about restrictions on his or her ability to keep certain information confidential, i.e., by law, if the student discloses intentions to hurt themselves or others, or if they disclose past or present physical, sexual, or emotional abuse or neglect, he or she will be required to report this information to Child Protective Services; the latter has not been necessary in any of our past intervention studies, including in our pilot study of Fourth R. Any adverse event must also be reported to the UTMB IRB.

Potential Benefits to Subjects and Others: Participants in the intervention group will receive information and skills to help them prevent or reduce their experience of TDV. Participants in the control condition will not receive the intervention; however, previous experience in adolescent health promotion studies indicates that participants who do not receive the intervention usually enjoy participating in evaluation surveys about their knowledge, attitudes, and beliefs, and are comfortable answering questions about related behaviors. Findings from the study will help other urban youth to prevent or reduce TDV and its serious physical and mental health consequences. Control schools will be offered Fourth R free of charge once study students have graduated from middle school.

Importance of the Knowledge to Be Gained: By implementing and evaluating this intervention, the study will be contributing significantly towards the development of health promotion programs to prevent or reduce TDV among urban youth populations.