Study Protocol

Reducing HIV Risk Among Adolescents: Evaluating HEART for Teens

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2 INTRODUCTION AND STUDY RATIONALE

As few as half of sexually active youth used a condom the last time they had sex, and 14% did not use any form of contraception at last intercourse (Kann et al., 2018). This risky behavior can have lasting consequences. As many as one in four sexually active girls has a sexually transmitted disease (STD; Centers for Disease Control and Prevention [CDC], 2018c; Forhan et al., 2009), which can increase the risk of HIV and infertility (CDC, 2018b). Further, adolescent boys, particularly young men who have sex with men, are at heightened risk of HIV and other STDs, with recent data showing that 17% of new HIV infections occur among young boys and men under the age of 24 (CDC, 2018a).

New approaches are needed to engage youth in HIV prevention to curb the spread of HIV/STDs. Online, technology-based sexual health programs, also known as eHealth, mHealth, and digital health programs, are one promising tool that can be used (Lightfoot, 2012; Rapoff, 2013). Technology use is now ubiquitous among youth: 95% of U.S. teens have access to a smartphone and nearly half of these youth report they are online “almost constantly” (Smith & Anderson, 2018). Thus, online sexual health programs may be a particularly relevant way to offer information and teach skills to youth in a way that is readily available, familiar, non-threatening, and intuitive.

The number of online sexual health programs targeting youth has been steadily increasing for the past decade (for reviews, see Chavez et al., 2014; Swanton et al., 2015; Widman, Nesi, et al., 2018). Yet to our knowledge, there are no brief online interventions that provide evidence-based sex education and are tested and found effective for diverse samples of both boys and girls. Such a program, particularly one shown to be efficacious among such diverse samples, could be of significant interest to schools or community programs that would benefit from a general program that is appropriate for a wide audience of youth with diverse identities.

The purpose of this study is to provide an initial evaluation of one such program, called Health Education and Relationship Training for Teens (HEART for Teens). This brief online program was adapted from a program we originally developed for adolescent girls, called HEART for Girls (Widman, Golin, Noar, Massey, & Prinstein, 2016).

3 STUDY AIMS

Aim 1: Evaluate the feasibility and acceptability of the HEART for Teens program.

Aims 2: Evaluate the preliminary efficacy of the HEART for Teens program in a randomized controlled trial of youth from a rural school district in the southeastern U.S.

4 STUDY DESIGN

4.1 Randomized Controlled Trial

A two-arm randomized controlled trial. Arm 1: HEART intervention; Arm 2: attention-matched controlled program, called Growing Minds (Burnette et al., 2018). Participants will be assessed at pre-test and immediate-post test.

4.2 Study Population

All 10th and 11th grade students from a school district in the southeastern U.S. will be recruited to participation in this study (*n* recruited = 754).

4.2.1 Inclusion Criteria

1. Must be a 10th or 11th grade student
2. Must speak English
3. Provide written parental consent
4. Provide written student assent

4.2.2 Exclusion Criteria

1. Unable to speak fluent English
2. Unwilling or unable to provide parent consent or student assent

5 QUALTRICS DATA COLLECTION

All data collected will be directly entered and stored in the web-based Qualtics research electronic data system. This Qualtics database will be stored, maintained, and monitored by the NC State Office of Information Technology and the study personnel. The Qualtircs system is a secure, web-based application designed to support survey and data collection. NC State has a license to host the Qualtrics system. Access to the Qualtrics database will be carefully restricted to authorized research team members as needed to perform their job functions, pursuant to Federal regulations.

6 RECRUITMENT

Potential study participants will be recruited via in-class announcements at their high school. Students will be provided with an informed consent document to take home to their parent/guardian. Parents are asked to sign and return the form to indicate whether child is approved to participate in the study. All students in the 10th and 11th grades will be recruited.

7 INFORMED CONSENT

Written informed consent from parents will be collected via an IRB-approved informed consent document. Once parental consent is collected, study staff will explain the study to students and also provide them with a written assent form approved by the NC State IRB. Students will be allowed sufficient time to ask questions about the study and express understanding. Only students who have received parental consent and have signed an assent document will be allowed to participate in the study. Written consent/assent documentation will be stored in a secure physical or electronic server location according to standard operations approved by the NC State IRB.

8 DATA COLLECTION PROCEDURES

After parental consent and student assent are obtained, pre-test data will be collected using computerized Qualtrics surveys in a small group classroom setting. Participants will then be randomly assigned to either the HEART for Teens online program or to an attention-matched control program focused on cultivating academic growth mindsets, called Growing Minds (Burnette, Russell, Hoyt, Orvidas, & Widman, 2017). Random assignment to study condition will be conducted using random sampling and allocation procedures in SPSS version 24. Participants will be stratified based on sexual activity status (ever sexually active versus never sexually active). Approximately one week after pre-test, participants will complete the online intervention on a study-provided netbook computer as well as a computerized Qualtics post-test survey in a small group classroom setting. Participants will use headphones to listen to program content and to control for any outside noise.

9 PARTICIPANT REIMBURSEMENT

Participants will be compensated with a $10 gift card for the pre-test assessment and a $10 gift card for the intervention and immediate post-test assessment.

10 MEASURES

10.1 ***Participant Characteristics.*** Demographic data will be collected on participant gender, age, race/ethnicity, sexual orientation, and receipt of free or reduced-price lunch (a proxy for socioeconomic status). Sexual activity status will be assessed with two items: one that inquired if participants had ever engaged in any sexual activity, including sexual touching, oral sex, and/or intercourse; and a second, if they answered "yes" to the first question, that inquired if participants had ever engaged in sexual intercourse. Additionally, among those who reported sexual intercourse, information was gathered about condom use at last sex.

10.2 ***Program Acceptability.*** Program acceptability will be assessed through a questionnaire that was adapted from prior acceptability surveys (Bauermeister et al., 2015; Widman et al., 2017). Specifically, six items will be included to assess six aspects of acceptability: 1) how much participants liked the program; 2) how much they learned from the program; 3) how much they felt the program kept their attention; 4) whether they would use information from the program in the future; 5) whether the program would be useful for girls their age; and 6) whether the program would be useful for boys their age. Items are rated on a four-point Likert scale ranging from 0 (*not at all*) to 3 (*a lot*).

10.2 ***Intentions.*** Intentions to discuss sexual health and to use condoms will be assessed with two items. The first asks how likely teens are to discuss sexual health issues, including pregnancy and STDs, with their partner(s) prior to sexual activity (communication intentions). The other item asks how likely teens are to use condoms the next time they have sex (condom intentions). Participants will be prompted to answer these questions whether or not they had engaged in sexual activity before. Response options range from 0 (*not at all likely*) to 4 (*very likely*).

10.2 ***Sexual Self-Efficacy.*** The Self-Efficacy for HIV Prevention Scale (Brown et al., 2014) will be used to assess self-efficacy about communication and condom use. Six items assess confidence communicating about sexual topics (e.g., "How sure are you that you could talk to your partner about safer sex?"). Two items assess confidence obtaining and using condoms (e.g., "How sure are you that you could have condoms available when you need them?"). Participants responded from 1 (*Couldn't do it*) to 4 (*Very Sure*), with higher scores indicating greater sexual self-efficacy.

10.3 ***Knowledge.*** HIV/STD knowledge will be assessed with 9 items (e.g., "STDs usually have noticeable symptoms, like itching or burning"). Participants rate each item as *True*, *False*, or *Don't Know.* Responses are recoded as 0 (*Incorrect* or *Don't Know*) or 1 (*Correct*). Scores are summed to reflect the total number of correct HIV/STD knowledge questions (possible range=0-9).

10.4 ***Condom Attitudes.*** Participants' attitudes about condoms will be assessed with the 3-item effect on sexual experiences subscale of the Condom Attitudes Scale Adolescent Version (St. Lawrence et al., 1994). An example item includes, "Condoms take away the pleasure of sex." Responses are on a scale from 1 (*Strongly Disagree*) to 5 (*Strongly Agree*).

10.5 ***Condom Norms***. The 3-item condom norm subscale from the Sexual Risk Behavior Beliefs and Self-Efficacy Scale for adolescents (Basen-Engquist et al., 1999) will be used to assess participants' perceptions of their peers' views of condom use. Participants respond from 1 (*Strongly Disagree*) to 5 (*Strongly Agree*) to items such as, "Most teenagers believe condoms should always be used if a person my age has sex".

10.6 *Sexual Assertiveness*. Self-reported sexual assertiveness will be assessed with 3-items from the Multidimensional Sexual Self-Concept Scale (Snell, 1998). Items such as, "I'm very assertive about the sexual aspects of my life," are rated on a scale from 1 (*Strongly Disagree*) to 5 (*Strongly Agree*).

11 STATISTICAL ANALYSIS STRATEGY

11.1 Analysis Plan

First, descriptive statistics will be utilized to summarize sociodemographic variables and pre-test levels of each outcome variable. To establish pre-test equivalence, differences between groups will be assessed using *t*-tests for continuous variables and χ_2-tests for categorical variables. Second, to assess the efficacy of the HEART intervention from pre-test to immediate post-test, linear regression analyses will be utilized to compute adjusted means and mean differences between intervention and control groups. For each outcome, the corresponding pre-test measure will be included as a covariate. Third, moderation analyses will be conducted to examine if intervention effects are moderated by gender or sexual orientation. Cohen's *d* value will be calculated as an indication of effect size. Analyses will be completed using SPSS Version 24.

11.2 Sample Size Considerations

For this preliminary assessment, the final sample size will be determined by the number of students and parents who granted consent.

12 STUDY CONDUCT

12.1 Ethics

This study will be conducted in accordance with Good Clinical Practice (GCP), as defined by the International Conference on Harmonization (ICH) and in accordance with the ethical principles underlying European Union Directive 2001/20/EC and the United States Code of Federal Regulations, Title 21, Part 50 (21CFR50).

The study will be conducted in compliance with this protocol. The protocol and any amendments and the subject informed consent will receive Institutional Review Board (IRB) approval prior to initiation of the study.

Any serious breach to the study protocol or principles of GCP in connection with the study or the protocol which are likely to affect the physical or mental safety of study participants or the integrity of the study will be reported to the NC State IRB.

Personnel involved in conducting this study will be qualified by education, training, and experience to perform their respective tasks.

12.2 Responsibilities within the Study

The study shall be conducted as described in this approved protocol and research staff will not implement any deviation or change to the protocol without prior approval from the NC State IRB and sponsor.

12.3 Reports and Publications

The confidentiality of records that could identify participants within the database will be protected, respecting the privacy and confidentiality rules in accordance with the applicable regulatory requirement(s). The data collected during this study are confidential and proprietary to NC State.

12.4 Database Retention and Archiving

The database and supporting documentation will be maintained by the PI and research staff in electronic files on a secure server accessed only by authorized personnel. The database and study records will be maintained for at least 5 years after study completion.

13 DATA SAFETY MONITORING BOARD (DSMB)

No DSMB was established.

14 DATA AND STUDY MONITORING PLAN (DSMP)

The research team will meet weekly or as often as necessary to review and monitor all aspects of the study: recruitment, data collection, completeness, data quality, protocol deviations, and any reported study-related adverse events. Study staff will be responsible for database integrity checks, data retrieval and export.

15 PATIENT SAFETY AND MONITORING PLAN (PSMP)

15.1 Risks of Study Participation

The psychological risks directly posed by participating in this study are judged to be minimal and rare (<1%). One risk of participating in this study is that participants may feel uncomfortable answering sensitive questions about their attitudes or private/illegal behaviors (e.g., sexual activity). To reduce this risk, we will inform students that they do not have to answer any questions that they do not want to answer. They will be told that they can skip any items that make them uncomfortable or stop their participation at any time. Participants can also speak with members of the research team if they become upset, and/or the research team can provide students with referrals if they would like to speak with someone about any of the information they receives as part of this program.

Another risk of participating is that the data we are collecting is sensitive and must be carefully protected to ensure confidentiality. Several steps will be taken to protect participant survey data and academic records. This includes deidentifying all data by using only a participant ID number, and not the participant's name. We will also store data in password-protected files on our secure server. The spreadsheet linking participant names with ID numbers will be stored in a separate file from participant data and secured with a separate password. Only the PI, Co-Investigator, and Project Manager will have access to this spreadsheet.

15.2 Handling of Non-Study Related Harms or Adverse Events

Non-study related issues will not be reportable to the NC State IRB. For instance, the research team may become aware of a patient’s medical or psychiatric issue during the survey assessment even though unsolicited. The research staff will explain to the student that research is a separate activity from clinical care and will encourage the student to notify their physician of their concern. In the event that a student expresses an urgent matter or a crisis (e.g., suicidality), the research team will be trained to use good clinical judgement and the standard operating procedure (SOP) which has been developed for staff.

15.3 Handling of Study-related harms or unanticipated adverse events

Adverse events (AEs) directly related to answering survey questions is expected to be extremely rare (<1%). Nonetheless, should an unanticipated study-related adverse even occur that is judged by the PI to be partially or fully related to study participation, the event will be reported to the NC State IRB within 72 hours.

Unanticipated study-related AE's may be physical, psychological, social, or legal in nature. Study-related harms or unanticipated AE's will be tracked by research staff and included in a final progress report to the sponsor.