

**COMPOUND AUTHORIZATION AND PARENTAL PERMISSION FOR PARTICIPATION IN A
RESEARCH PROJECT
310 FR. 3 (2014-1)**

YALE UNIVERSITY SCHOOL OF MEDICINE – YALE-NEW HAVEN HOSPITAL

Study Title: “An Accessible Digital Intervention to Promote the use of school-based health centers and to empower adolescents with their sexual health”: *Randomized controlled trial*

Principal Investigator: *Lynn E. Fiellin, MD*

Funding Source: National Institute of Child Health and Human Development

Parental Permission Form for Participants Ages 14-17

Invitation to Participate and Description of Project

Your teenager is being invited to participate in a research study to help us learn more about what types of things should be included in a videogame in order to help teens make good decisions while they are playing the videogame and in real life. The study will focus on promoting healthy behaviors in adolescence and on providing strategies to assist adolescents in making decisions about the many challenges they face.

To help you decide whether or not you want your teen to participate in this research study, you should know if there are any risks and benefits to participating. This form gives you detailed information about the research study, which a member of the research team will discuss with you and your teen. Together you will go over all aspects of this research: its purpose, what will happen during the pilot testing, any risks and possible benefits. Once you understand the study, you will be asked if you agree to your teen to participating; if so, you will be asked to sign this form.

Description of Procedures

The purpose of this study is to learn more about how playing a videogame in might help teens make good decisions while they are playing the videogame and in real life. In order to participate in this study, your teen must: 1). be between the ages of 14 and 18 ; 2). be willing to sit and play on an iPad or computer for 60 minutes, one to two times per week for four weeks; 3). complete assessment questions (that take approximately 20-30 mins to complete) at different time points associated with the study (baseline, 4 weeks, 3 months, and 6 months); 4). must not have been tested for HIV in the past year; 5). have an enrollment form completed by you, for them to access their school’s health clinic if they choose to. Your teen’s participation in this research study will be voluntary and confidential.

Your teen will play a game that is designed to be fun and engaging, to promote healthy behaviors in adolescence, and to provide strategies to assist adolescents in making decisions about the many challenges they face. Your teen’s participation in this research study will be voluntary and confidential.

Your teen will be asked to play the videogame as well as complete several assessments (questionnaires) before and after they play the videogame. Your teen will also be asked to participate in a semi-structured interview after they play the videogame. The goal of the assessments is to collect data about their behaviors (what they do) and perceptions (what they think) about testing for sexually transmitted infections and HIV, risky situations they might have encountered, their knowledge and other basic questions about themselves. The goal of the semi-structured interview is to learn whether they thought playing the game was fun, boring, or interesting, and what they would they change about the game, the characters, and the storylines to make it better.

The study will last about 6 months. If you and your teenager decide that your teen will participate, here is what will happen: During their first meeting, they will be asked to complete assessment questions that will be approximately 15 to 20 minutes and will be conducted confidentially (their answers will be kept private) in a secured, private location. The questions will be completed electronically, using either an iPad or their cell phone. They will be assigned a study number, so that their answers are kept confidential. The assessment questions will be supervised by a member of the research team and will be available for help if needed. After completing the initial assessment questions, they will then play the videogame one to two times per week for 60 minutes for 4 weeks in a secured, private location. A member of the research team will be available for help if needed at all times.

After 4 weeks, your teen will be asked to complete additional assessment questions that will take approximately 15-20 minutes to complete. During the same time, they may be asked to participate in an interview about their experience playing the game. The goal of the interview is to learn whether they thought playing the game was fun, boring, or interesting, and what they would change about the game, the characters, and the storylines to make it better. Questions such as: What you thought the goal of the game was? Your favorite and least favorite moment in the game? Was the game fun? will be asked.

They will also be asked to complete follow-up assessment questions 3 months and 6 months after the beginning of the study, that will take approximately 15 to 20 minutes to complete.

Schedule of Assessments

Assessment	Baseline	Week 4	Month 3	Month 6
Participant history and demographic data: 10 items on the individual (i.e. gender, age, education, HTC history) ⁸ .	X			
School-based health centers	X	X	X	X
Information About HIV Testing	X	X	X	X
Behaviors—Youth Risk Behavior Survey (YRBS) (includes questions on sexual activity and HIV testing) ³	X	X	X	X
Knowledge/Information ¹⁰⁷ including knowledge about STIs and HIV and HTC	X	X	X	X
Beliefs About STIs and HIV	X	X	X	X
Attitudes About HIV	X	X	X	X
Attitudes about STI and HIV Testing	X	X	X	X

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Intentions Around STIs and HIV Testing	X	X	X	X
Self-Efficacy Around STI and HIV Testing	X	X	X	X
Self-Efficacy about Overall Health	X	X	X	X
Education Around STIs and HIV	X	X	X	X
Gameplay satisfaction/acceptability/feasibility, time played for each session and overall time played: 12-item Likert scale ¹⁰⁵		X		

At each of the time points listed above, the Yale research team will work with the staff at your school's health center to get information on if any study participants have come in to utilize the services of the school-based health center. The research staff will receive deidentified information (no names attached; only study numbers) from the school health center staff regarding the date and whether or not you received an STI/HIV test (result of the tests will not be shared with the research staff).

Risks and Inconveniences

There are no known risks of physical or psychological injury or inconveniences associated with this research project. If your teen becomes very tired or uncomfortable, one of the researchers would ask them if they would like a break or discontinue participation in the videogame play or completion of assessments at that time and resume it at an acceptable time for them.

Benefits

The study may help the researchers find out something that will help other teenagers later.

Economic Considerations

Your teen will receive a gift card for completing each assessment. They will receive a \$35 gift card for completing the assessments at the baseline, a \$20 gift card for the assessments completed at 4 weeks, a \$20 gift card for completing the assessments at 3 months, and a \$35 gift card for completing assessment questions at 6 months. The total possible compensation for this study is \$110 per participant.

Confidentiality and Privacy

If you decide to have your teen take part in this research study, all of the information that they give us, at all points in the study is confidential and available only to the people actually working in the study. Their name will not appear on any study materials. A study number will be used to identify such materials. The link between participant's identity and the study number is confidential and will be kept separate from all study data. Research data is kept in cabinets that are locked except when in use, and access to data stored in computers is password protected.

The Yale University Human Investigation Committee (the committee that reviews, approves, and monitors research on human subjects) may inspect study records. All published results will be group data

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without identifying any individual information. Information that will be collected during the survey interviews will be erased 12 months after the completion of the study and after review of their content has been completed.

Audiotaped interview sessions: Your teen's name will never be recorded on the tapes and the tapes will be coded by a number rather than a name in order to protect your teen's confidentiality. You may decline that your teen be taped during the study.

If there are concerns about the possibility of child abuse, this would be discussed with you and a potential referral would be made to child protective services, if indicated. In addition, information may be released if we are worried about abuse, neglect, or harm to your child or others. We will contact authorities if this is the case.

Voluntary Participation and Withdrawal

Participating in this study is voluntary, which means you are free to choose not to allow your teen to take part in this study. Refusing to allow your teen to participate will involve no penalty or loss of benefits to which your teen is otherwise entitled (such as health care outside the study, the payment for health care, and health care benefits) However, your teen will not be able to enroll in this research study and will not receive study procedures as a study participant if you do not allow use of your teen's information as part of this study. Withdrawing, meaning you no longer want your teen to be in this study, will involve no penalty or loss of benefits to which your teen is otherwise entitled. If you decide to have your teen quit the study, all you have to do is tell the person in charge. This will not harm your teen's relationship with his/her own doctors or with Yale-New Haven Hospital. The study investigators may remove your teen from the study if they believe that is in your or your teen's best interests. You do not give up any of your legal rights by signing this form.

Questions

We have used some technical terms in this form. Please feel free to ask about anything you don't understand and to consider this research and the permission form carefully – as long as you feel is necessary – before you make a decision.

Authorization and Permission

I have read (or someone has read to me) this form and have decided to allow my teenager to participate in the project described above. Its general purposes, the particulars of my teen's involvement and possible hazards and inconveniences have been explained to my satisfaction. My signature also indicates that I have received a copy of this permission form.

By signing this form, I give permission to the researchers to use [and give out] information about my teen for the purposes described in this form. By refusing to give permission, I understand that my teen will not be able to be in this research.

Name of Child: _____

Parent 1 Signature: _____

Date: _____

Signature of Person Obtaining Permission

Date

If you have further questions about this project or if you have a research-related problem, you may contact the Research Coordinator, Tyra Pendergrass, at 203-737-6101.

If after you have signed this form you have any questions about your privacy rights, please contact the Yale Privacy Officer at (203) 432-5919.

If you would like to talk with someone other than the researchers to discuss problems, concerns, and questions you may have concerning this research, or to discuss your rights as a research subject, you may contact the Yale Human Investigation Committee at (203) 785-4688.