HIC #: 2000031180
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COMPOUND AUTHORIZATION FOR PARTICIPATION IN A RESEARCH PROJECT

YALE UNIVERSITY SCHOOL OF MEDICINE

=Study Title: A digital game targeting suicide prevention in adolescents who report substance misuse (Formative Work and Pilot Study)

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Pilot study Consent Form for Participants 18+

Research Study Summary

We are asking you to join a research study.

- The purpose of this research study is to learn about your thoughts on the usability, acceptability, and feasibility of delivering a digital game intervention focused on warning signs, coping strategies, and help-seeking behaviors. Study activities will include: 1) playing an iPad a prototype of the game developed by Dr. Fernandes and her team, 2) answering questions about your experience playing the game, and your thoughts, attitudes, and knowledge around prevention.
- Your involvement will require: 1) 90-120-minute session (1.5-2 hours) of your time, in person after school, (for one session in total); 2) reliable transportation home or to the next location after school. In certain cases where transportation is not available by family or school, we will provide a bus pass.
- All COVID-19 protocols and procedures that are in place for your school will be followed.
- The potential risks associated with this study have to do with the maintenance of the confidentiality of the identities of the participants enrolled in the study and information relating to them. As with all of our studies, we will train study researchers in maintaining confidentiality. Prior to the start of each session, researchers will discuss potential risks including breach of confidentiality.
- The study may have no benefits to you. The study may help the researchers find out something that will help other teenagers later.
- Taking part in this study is your choice. You can choose to take part, or you can choose not to take part in this study. You can also change their mind at any time. Whatever choice you make will not have any effect on your relationship with their school or the research staff.
- If you are interested in learning more about the study, please continue reading or have someone read to you the rest of this document. Ask the study staff questions about anything you do not understand. Once you understand the study, we will ask you if you wish to participate; if so, you will have to sign this form.

Invitation to Participate and Description of Project

The purpose of this research study is to learn about your thoughts on the usability, acceptability, and feasibility of delivering a digital game intervention focused on warning signs, coping strategies, and help-seeking behaviors. The study will focus on preventing risk and promoting prosocial behaviors in adolescence by providing strategies to assist adolescents in identifying warning signs, coping strategies, and help-seeking behaviors.

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To help you decide whether or not you participate in this study, you should know if there are any risks (problems that you might have as a result of the study) and benefits (how the study might help you or other adolescents and young adults) to participating. This form gives you detailed information about the research study, which a member of the research team will discuss with you. We will go over all aspects of this research: its purpose (the reason we are doing the study), what will happen during the study, any risks, and possible benefits. Once you understand the study, you will be asked if you agree to participate. If so, you will be asked to sign this form.

Description of Procedures

The purpose of this research study is to learn about your thoughts on the usability, acceptability, and feasibility of delivering a digital game intervention focused on warning signs, coping strategies and help-seeking behaviors.

In order to participate in this study, you must: 1) attend a high school with a school-based provider; 2) be between the ages of 13 and 17 (signing adult consent if 18 or 19); 3) be willing to sit at a computer or play an iPad for approximately 90-120 minute session during a one-time session after school; 4) complete behavioral and psychological assessment questions (that take approximately 45 mins to complete) at two different time points associated with the study (baseline and 3 months) to be used to assess the game's usability, acceptability, and feasibility and the ability of the game to assist adolescents in identifying warning signs, coping strategies, and resources for support; and 5) have the consent of your parent/legal guardian to participate if you are under 18 years of age.

You will play a game that is designed to be fun and engaging, while promoting healthy behaviors in adolescence, and providing strategies to assist adolescents in making decisions about the many challenges they face. Your participation in this research study is voluntary and we have procedures in place to keep it confidential. The study team will keep your answers private and confidential, however, if there are concerns that you will harm yourself or others, the study team will make your school-based provider aware to ensure your safety. Your school will not have access to your assessment responses, but they will only be informed if help is required for specific issues related to your safety (e.g., suicidality, depression).

You will be asked to play a videogame as well as answer questions about your gameplay experience in a group, after you play the videogame. The questions you will answer about your experience with the game will be audiotaped. You may choose not to be audiotaped and still participate in study. The goal of these questions is to learn whether you thought playing the game was fun, boring, or interesting, and what you would change about the game, the characters, and the storylines to make it better.

The study will require one session 90-120 minutes (1.5-2 hours) in-person after school (for one session in total and one follow-up assessment). If you decide that you will participate, here is what will happen:

During the first session, you will be asked to sign this consent form and complete assessment questions that will take approximately 45 minutes and will be conducted confidentially (your answers will be kept private) in a secured, private location. You will be assigned a study number which will be used in place of your name, so that your answers will be kept confidential. The assessment questions will be supervised by a member of the research team and will be available to help if needed. You will then begin the gameplay portion of the project, where you will play a videogame on an iPad. A member of the research team will be available for help if needed at all times. After you complete the gameplay portion, you will be asked to participate in a brief focus group about your playing experience. Questions such as: What did you think the goal of the game was? Your favorite and least favorite moment in the game? Was the game fun? Has any aspect of the game been confusing

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or unclear? will be asked. We will also ask questions like: Did you feel that the questions were in-depth enough to elicit a detailed response? Would you add any questions to the questionnaire? Did you feel like any of the questions from the questionnaire used biased language that may have influenced a response? **Your participation in this research study will be voluntary and confidential.**

Risks and Inconveniences

There are no known risks of physical or psychological injury or inconveniences associated with this research project. Your teen may be asked sensitive questions that reveal information about their mental health to the study team. If the study team is concerned about your teen's responses, they will connect your teen to resources for support. If you become very tired or uncomfortable, one of the researchers would ask you if you 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 you.

However, there is a slight risk regarding the confidentiality of your participation in this study, if information about you becomes known to persons outside this study. The researchers are required to keep your study information confidential; however, so the risk of breach of confidentiality is very low.

Benefits

You may not benefit from the study directly, but the study may help the researchers find out something that will help other teens later.

Economic Considerations

You will receive gift cards for participating in this study. You will receive a $25 gift card as compensation at each time point. The total possible compensation for this study is $50 per participant.

Confidentiality and Privacy

If you decide to take part in this research study, all of the information that you give us, at all points in the study is confidential and available only to the people actually working in the study. Your 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 Institutional Review Boards (the committee that reviews, approves, and monitors research on human subjects) may inspect study records. All published results will be group data without identifying any individual information. Information that will be collected during the assessments and interviews will be erased 12 months after the completion of the study and after review of their content has been completed.

Audiotaped sessions about gameplay experience: Your name will never be recorded on the tapes and the tapes will be coded by a number rather than a name to protect your privacy. It is possible someone may recognize your voice. You may decline to have your voice audiotaped during questions about your gameplay experience.

If we are worried by something we hear from you such as you are being harmed, we will let you know and we will discuss this with you. In addition, information may be released if we are worried about abuse, neglect, or harm to yourself or others. We will contact your school-based provider if this is the case.

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All members of the research team have completed mandatory reporter training; this includes mandatory reporting for abuse and neglect to appropriate officials via Careline at 1-800-842-2288. Suicidal risk will be reported to school official as well as parent/guardian. In extreme cases, 9-1-1 will be called.

Data may be shared by the following additional groups:

- Department of Health and Human Services-National Institute on Drug Abuse (Study sponsor)
- Co-Investigators and other investigators
- Study Coordinator and Members of the Research Team

By signing this form, you let us use the information in the way we described above for this research study. This authorization to use and disclose information collected during your participation in this study will never expire.

The research staff at the Yale School of Medicine has to obey the privacy laws and make sure that your information stays confidential. Some of the people or agencies listed above may not have to obey those laws, which means that they do not have to protect the data in the same way we do. They could use or share your information in ways not mentioned in this form. However, to better protect your health information, agreements are in place with these individuals and/or companies that require that they keep your information confidential.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the National Institute on Drug Abuse which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent your from voluntarily releasing information about themselves or their involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of child abuse and neglect, or harm to self or others.

What Information Will We Collect About You in this Study?

The information we are asking to use and share is called “Protected Health Information.” It is protected by a federal law called the Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA). In general, we cannot use or share your health information for research without your permission. If you want, we

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can give you more information about the Privacy Rule. Also, if you have any questions about the Privacy Rule and your rights, you can speak to the Yale Privacy Officer at 203-432-5919.

The specific information about your health that we will collect, use, and share includes:

- Names, telephone numbers, email addresses, parent/guardian names, parent/guardian phone numbers, and parent/guardian email addresses
- Your school-based provider's name and email
- Research study records
- The entire research record held by the **Yale School of Medicine** created from 3/01/2022 to 3/01/2024.
- Records about phone calls made as part of this research
- Records about your study visits
- Information obtained during this research regarding
    - Field notes and questionnaires
    - Records about the study device

Voluntary Participation and Withdrawal

Participating in this study is voluntary, which means you are free to choose not take part in this study. Refusing to participate will involve no penalty or loss of benefits to which you are otherwise entitled (such as health care outside the study, the payment for health care, and health care benefits). However, you 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 information as part of this study.

Withdrawing, meaning you no longer want to be in this study, will involve no penalty or loss of benefits to which you are otherwise entitled. If you decide to quit the study, all you have to do is tell the person in charge. This will not harm your relationship with your doctors or with Yale-New Haven Hospital. The study investigators may remove you from the study if they believe that is in your 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. We encourage you to talk to your family about your decision as well. If you come up with questions after reading this form, contact the Principal Investigator, Dr. Claudia-Santi F. Fernandes, at claudiasanti.fernandes@yale.edu.

Authorization and Permission

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

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

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☐ YES: Participant gives permission to be audiotaped.

☐ No: Participant does not give permission to be audiotaped.

_____	_____	_____
Participant Printed Name	Participant Signature	Date

Name of School-Based Provider: _____

School-Based Provider Email Address: _____

OR

School-Based Provider Phone Number: _____

FOR YALE UNIVERSITY ONLY

_____	_____
Printed Name of Person Obtaining Consent	Date
_____	_____
Signature of Person Obtaining Consent	Date

If you have further questions about this project or if you have a research-related problem, you may contact the Principal Investigator, Dr. Claudia-Santi Fernandes, at claudiasanti.fernandes@yale.edu.

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 Research Protection Program at (203) 785-4688.

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