A Randomized Controlled Trial of a Game-Based Intervention to Reduce Alcohol Use among Sexual and Gender Minority Youth

Protocol Number: STUDY23030071

National Clinical Trial (NCT) Identified Number: NCT06215664

Principal Investigator: Robert W.S. Coulter and James E. Egan

Sponsor: University of Pittsburgh

Grant Title: A Randomized Controlled Trial of a Game-Based Intervention to Reduce Alcohol Use among Sexual and Gender Minority Youth

Grant Number: R01AA030017

Funded by: National Institute on Alcohol Abuse and Alcoholism (NIAAA)

9/27/2024

ASSENT/CONSENT TO ACT AS A PARTICIPANT IN A RESEARCH STUDY

Study Title

A Randomized Controlled Trial of a Game-Based Intervention to Reduce Alcohol Use among Sexual and Gender Minority Youth

Principal Investigators

Robert Coulter, PhD, MPH, University of Pittsburgh School of Public Health, robert.ws.coulter@pitt.edu; Phone: 412-624-0647

James Egan, PhD, MPH, University of Pittsburgh School of Public Health, jameserinegan@pitt.edu; Phone: 412-624-2255

Questions about the study

You can contact the study investigator if you have any questions about the study, concerns or complaints. Contact Principal Investigator, Dr. Coulter at robert.ws.coulter@pitt.edu or by phone at 412-624-0647.

Sources of Support

This study is funded by the National Institutes of Health and the National Institute on Alcohol Abuse and Alcoholism (R01AA030017).

Research Assent/Consent Summary

The primary purpose of this study is to understand how well a game-based intervention reduces alcohol harms and improves other health behaviors among sexual and gender minority youth. Participation in this study includes completing surveys, playing an online game, reading information online, responding to discussion board questions, and completing an interview. Your study participation will be about 1.25 years long.

Introduction

Before volunteering to participate in this research study, it is important that you understand what it is about. We are conducting this research study to learn about how playing a web-based game may improve your health. We would like to invite you to volunteer to participate in this study because you have told us that you identify as a sexual or gender minority young person. When we say sexual and gender minority youth, we are referring to lesbian, gay, bisexual, transgender, queer, and non-binary (LGBTQ+) youth. The study will be ongoing for 14 months with up to 1,992 individuals. The primary purpose of this study is to understand how well a game and web-based intervention reduces alcohol harm and improves other health behaviors among sexual and gender minority youth.

Research Activities

If you agree to volunteer for the study, you will be asked to do the following activities:

1. We will send you a link and ask you to complete an online survey. This survey should only take about 30-45 minutes to complete. The survey asks questions

about your life and experiences. We may also ask you to Zoom to get to know you better. You will be asked to turn on your video camera. This will be recorded and take 5-15 minutes to complete.

2. After finishing the survey, you will be randomly assigned to one of two groups. Each group will receive a link to play a game on your device, read information online, and respond to discussion board questions. Everyone will receive a link the other game and information at the end of the study.
3. You'll be asked to play a game as much as you want and read information online over the course of one month.
4. In about 3 months from today, you will be sent a link to complete another survey. This should also take about 30-45 minutes to complete.
5. In about 6 months from today, you will be sent a link to complete the final survey. This should take about 30-45 minutes to complete.
6. In about 1 year from today, you will be sent a link to complete the final survey. This should take about 30-45 minutes to complete.
7. In about 1 year from today, we may ask you to take part in a Zoom-based interview. We will ask questions about your experience playing the game, alcohol use, and other life experiences.
8. In about 1.25 years from today, a link to play the other game will be sent to you.

Study Risks

You may find some of the questions on the survey to be personal. It is also possible that you may be outed if someone were to see you playing a game with LGBTQ+ content or some of the questions on the survey. For example, we will ask about your LGBTQ+ identities, experiences of being bullied, mental health issues, and drug/alcohol use. You may skip any question that makes you feel too uncomfortable. You may also stop the survey at any time. A list of resources will be provided at the end of each survey to you. To protect you, the game has login procedures. To protect yourself, you should be aware of where you are and who may see you while playing the game, answering the surveys, and being interviewed. We may text message you. Text messages may not be encrypted or secure during their transmission or storage. It is possible they could be intercepted and used by others not associated with this study.

Study Benefits

There will be no direct benefit to you from participating in this study. However, playing the game may be helpful to you.

New Information

We will tell you about any new information that we learn that may cause you to change your mind about staying in the study.

Confidentiality

Participation in research may involve a loss of privacy; however, the information you share with us will be handled as confidentially as possible to protect your privacy and keep your participation confidential. Your personal information will be stored on a secure, password-protected online server. Your responses to the survey questions will

be recorded in a manner that only the study staff will have access to. Your contact information will not be stored with your responses to the interview questions. To make sure you are located within the study area, we will collect your IP address as well as your browser's time zone. This information will be kept confidential. Only the study investigators will have access to these files. However, authorized representatives of the University of Pittsburgh Office of Research Protections or the Department of Health and Human Services may review your identifiable research information for the purpose of ensuring the appropriate conduct of this research study. No personally identifying information will be used in any reports or publications that may result from this study. At some point, your identifiers might be removed from your private information. This de-identified information may be used by other researchers for future research studies. If this happens, we will not contact you for additional assent/consent. In unusual cases, the investigators may be required to release identifiable information related to your participation in this research study in response to an order from a court of law. If the investigators learn that you or someone with whom you are involved is in danger or potential harm, they will need to inform, as required by Pennsylvania law, the appropriate agencies. According to University of Pittsburgh policy, all research records must be maintained until all study participants reach the age of 25. However, study data may be kept indefinitely.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena. There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state, or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations. Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

Costs

There will be no costs to you for taking part in this study.

Payments

In return for your time and effort, you will be given a re-loadable debit card which will be added to for each survey and interview you complete. You will receive $10 for the initial

survey, $30 for the first follow up, and $40 for the second follow up, $50 for the final survey, and $50 for the interview. You may receive up to $180 total. Payment is contingent upon validation of your eligibility.

Compensation for Injury

If you believe that the research procedures have resulted in an injury to you, immediately contact one of the Principal Investigators who are listed on the first page of this form. At this time, there is no plan for any additional financial compensation. You do not waive any rights by signing this form.

Withdrawal From Study Participation

You can withdraw from this research study at any time. It is possible that you may be removed from the research study by the researchers if circumstances arise which warrant doing so, for example, you are determined to be ineligible. Any identifiable research information obtained as part of this study prior to the date that you withdrew your assent/consent will continue to be used by the investigators for the purposes described above. If you want to withdraw, notify the study team. Your decision to withdraw will have no effect on your current or future relationship with the University of Pittsburgh.

Questions about Participation

Do you have any questions about this study?

1. No [participant will move on to the assent/consent to participate section]
2. Yes [participant will be asked to text, email, or call the Principal Investigator or Study coordinator with their question; they will also be provided an open-ended text box where they can specify their questions and our team will follow-up with them]

[here we will use skip logic (based on the screener survey) and branching to make sure that people < 18 receive assent and people 18 and older receive consent]

Assent To Participate (Complete this if you are under 18)

The above information has been explained to me and all my current questions have been answered. I understand that I am encouraged to ask questions, voice concerns or complaints about any part of this research study during this study. Any future questions, concerns or complaints will be answered by a qualified individual or by the investigators listed on the first page of this consent document at the telephone numbers and emails given. I understand that I may always request that my questions, concerns or complaints be addressed by a listed investigator. I understand that I may contact the Human Subjects Protection Advocate of the Human Research Protection office, University of Pittsburgh (1-866-212-2668) to discuss problems, concerns, and questions; obtain information; offer input; or discuss situations that occurred during my participation. By signing this form, I assent to participate in this research study. Please print a copy of this form for your records.

_____ _____

Printed Name of Participant Date

_____

Signature of Participant

Consent To Participate (Complete this if you are 18)

The above information has been explained to me and all my current questions have been answered. I understand that I am encouraged to ask questions, voice concerns or complaints about any part of this research study during this study. Any future questions, concerns or complaints will be answered by a qualified individual or by the investigators listed on the first page of this document at the telephone numbers and emails given. I understand that I may always request that my questions, concerns or complaints be addressed by a listed investigator. I understand that I may contact the Human Subjects Protection Advocate of the Human Research Protection office, University of Pittsburgh (1-866-212-2668) to discuss problems, concerns, and questions; obtain information; offer input; or discuss situations that occurred during my participation. By signing this form, I consent to participate in this research study. Please print a copy of this form for your records.

_____ _____

Printed Name of Participant Date

_____

Signature of Participant

Investigator Certification

I certify that I have explained the nature and purpose of this research study to the above-named individual, and I have discussed the potential benefits and possible risks of study participation. Any questions the individual have about this study have been answered, and we will always be available to address future questions, concerns or complaints as they arise. I further certify that no research component of this protocol was started until after this form was signed.

_____ _____

_____

Printed Name of Person Obtaining Assent/Consent Role in Research Study

_____ _____

Signature of Person Obtaining Assent/Consent Date