Informed Consent Document

Timing Personalized Feedback after Alcohol Health Education

NCT04453007

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INFORMED CONSENT DOCUMENT
OLD DOMINION UNIVERSITY

PROJECT TITLE: Timing Personalized Feedback after Alcohol Health Education

INTRODUCTION

The purposes of this form are to give you information that may affect your decision whether to say YES or NO to participation in this research and to record the consent of those who say YES. Timing Personalized Feedback after Alcohol Health Education assesses alcohol health behaviors and related constructs over an extended period of time. The project takes place via Zoom.

RESEARCHERS

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DESCRIPTION OF RESEARCH STUDY

Several studies have been conducted looking into the subject of student health behaviors related to drinking. The current study investigates the effects of personalized feedback sent after a brief computerized education session on student drinking behaviors, over an extended period of time.

If you decide to participate, then you will join a study involving assessment of your own health behaviors. If you say YES, then you will complete a computerized survey (approximately 30 to 45 minutes) assessing your current health behaviors, including alcohol and substance use topics as well as your experiences related to the COVID-19 pandemic. This would be followed by approximately 20-30 minutes of exposure to a computerized intervention focused on alcohol and would take place via Zoom. After completing this first appointment, you may be eligible for additional assessments for monetary compensation. These assessments will focus on updated health behaviors, including alcohol and substance use. Some participants will also receive emailed feedback about their responses. If you complete this baseline procedure plus all four follow-up assessments, your total participation time for the project will be approximately 3.0 to 3.5 hours (depending on how long it takes you to complete each survey). Approximately 500 ODU students will be participating in this study.

As previously stated, the first survey should take about 30-45 minutes to complete. If it takes less than 20 minutes, it might mean that you are not reading the questions carefully enough. It is really important that you are reading carefully, so we have some questions in the survey to make sure you are not just clicking on answers. If your responses suggest you are not reading questions carefully, you will get a message about this in the survey.

EXCLUSIONARY CRITERIA

You must be between at least 18 years old but not older than 24 years old to be eligible for this study.
In addition, you must have consumed at least 1 alcoholic drink within the past 2 weeks. If you have not consumed alcohol within the past 14 days, you are not eligible for this study. Additionally, you must have consumed alcohol with others in person in the past 30 days. You must be an undergraduate student to be eligible.

RISKS AND BENEFITS

RISKS: If you decide to participate in this study, it is possible you may experience some discomfort answering questions regarding your behaviors and actions. If you would like to speak to someone at Counseling Services you may call 757-683-4401 or go to 1526 Webb Center. The research involves using a computer, so the risks involved with that are similar to typical computer use.

Additionally, identifying information will be collected from each participant. Alcohol use is illegal for individuals under 21, and so all efforts will be made to safeguard your information. Files with identifying information will be kept only on an encrypted external storage device, and that device will be kept in locked storage location when not in use. Hardcopies of signed informed consent documents will be kept in a locked filing cabinet. If you are using public computers owned and operated by ODU there may be the possibility of institutional monitoring of your responses. And, as with any research, there is some possibility that you may be subject to risks that have not yet been identified.

BENEFITS: There are no direct benefits for participating in this study. An indirect benefit to you for participating in this study is the receipt of a health education intervention. This computerized intervention targets behavior change that could potentially help improve your health (or prevent/reduce risky behaviors).

COSTS AND PAYMENTS

The researchers want your decision about participating in this study to be absolutely voluntary. Yet they recognize that your participation may pose some inconvenience and requires your time. In order to thank you for the time you spent completing the study, you will be paid $20 paid via Amazon gift card for this initial appointment. You may also be eligible for follow-up assessments online for which you would be paid $10 each (for 1, 3, 6, and 9 month assessments), also via Amazon gift card. Those who complete all follow-up assessments will receive a bonus of an additional $10 ($70 total including this first appointment and all follow-up assessments).

NEW INFORMATION

If the researchers find new information during this study that would reasonably change your decision about participating, then they will give it to you.

CONFIDENTIALITY

All information obtained about you in this study is strictly confidential. The results of this study may be used in reports, presentations and publications, but the researcher will not identify you. After data have finished being collected and analyzed, the files tying your name to your responses will be destroyed.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States federal or state government agency sponsoring the project, in this case, the National Institutes of Health, and that will be used for auditing or program evaluation of agency funded projects. You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information.

WITHDRAWAL PRIVILEGE

It is OK for you to say NO. Even if you say YES now, you are free to say NO later, and walk away or withdraw from the study at any time. The researchers reserve the right to withdraw your participation in this study, at any time, if they observe potential problems with your continued participation.

COMPENSATION FOR ILLNESS AND INJURY

If you say YES, then your consent in this document does not waive any of your legal rights. However, in the event of harm arising from this study, neither Old Dominion University nor the researchers are able to give you any money, insurance coverage, free medical care, or any other compensation for such injury. In the event that you suffer injury as a result of participation in this research project, you may contact Dr. Abby Braitman at abraitma@odu.edu or Dr. Tancy Vandecar-Burdin, the current IRB chair at 757-683-3802, or the Old Dominion University Office of Research, at 757-683-3460, who will be glad to review the matter with you.

VOLUNTARY CONSENT

By typing your name at the end of this form, you are saying several things. You are saying that you have read this form or have had it read to you, that you are satisfied that you understand this form, the research study, and its risks and benefits. If you have any questions now or in the future, please contact Dr. Abby Braitman at abraitma@odu.edu or 757-683-3708. If at any time you feel pressured to participate, or if you have any questions about your rights or this form, then you should call Dr. Tancy Vandecar-Burdin, the current IRB chair, at 757-683-3802, or the Old Dominion University Office of Research, at 757-683-3460.

And importantly, by typing your name below, you are telling the researcher YES, that you agree to participate in this study. Please print a copy of this form or take a screenshot of it for your records.

Subject's Typed Name