

Title: Personalized Feedback Programs for College Students

NCT #: NCT04975191

Document date: 10/18/2021

Document Type: Informed Consent Form

STUDY TITLE: Personalized Feedback Programs for College Students

VCU INVESTIGATOR: Danielle Dick, Ph.D. & Joshua Langberg, Ph.D.

SPONSOR: National Institutes of Health, NIAAA

You are being invited to participate in the research study: **Personalized Feedback Programs for College Students**

This consent form is meant to assist you in thinking about whether or not you want to be a part of this research. Please ask the investigator or the study staff to explain any information in this consent document that is not clear to you. Study staff can be reached at pfpstudy@vcu.edu.

Purpose of study

The purpose of this research study is to evaluate the effectiveness of different forms of personalized feedback intended to help students make their best personal choices to support their health and well-being in college.

Your participation is voluntary. You may decide not to participate in this study. If you do choose to participate, you may withdraw from the study at any time. Your decision not to take part or to withdraw will involve no penalty or loss of benefits to which you are otherwise entitled.

Study Procedures

If you entered this study through Spit for Science: The VCU Student Survey and consent to participate, then your responses to Spit for Science: The VCU Student Survey will be shared with this study and matched with the data collected in these procedures for data analysis. As a reminder, the Spit for Science survey collected information about your demographics, personality, mental health, substance use, and related factors.

If you entered this study through Psychology SONA and consent to participate, then your responses to the Personalized Feedback Programs for College Students SONA Survey will be matched with the data collected in these procedures for data analysis. As a reminder, the SONA survey collected information about your demographics, personality, mental health, substance use, and related factors.

There are two personalized feedback programs and one resources program that all students will have the opportunity to complete over the course of the study. When you complete each of the programs will vary across the three time points for different participants.

At the first time point (today), you will be randomly selected into one of the four following conditions. All conditions involve answering questions and receiving resources and information on-line. You have an equal chance of being assigned to any one of the conditions.

- 1) A condition providing a list of resources available to you at VCU that are intended to support your success
- 2) A condition in which you will complete an on-line, interactive program answering questions and receiving information about your personality-related traits along with personalized recommendations for success
- 3) A condition in which you will complete an on-line, interactive program answering questions and receiving information about your current substance use patterns along with personalized recommendations for success
- 4) A condition in which you will complete an on-line, interactive 2-part program, first answering questions and receiving information about your personality-related traits followed by your current substance use patterns to make personalized recommendations for success

Should you consent to participate in this study at this time, you will be automatically redirected into the content of your condition. Individuals in groups 2-4 will go through their assigned program(s) before returning to REDCap to answer questions regarding their experiences with their program(s) and future intentions regarding campus resource use and substance use. Those in group 1 will receive a list of VCU resources before answering the questions pertaining to future intentions regarding campus resource use and substance use.

The expected time commitment at Time Point 1 will vary slightly by group. The expected durations for each group are as follows:

- (1) 10 minutes
- (2) 20-30 minutes
- (3) 20-30 minutes
- (4) 40-50 minutes

At the following two time points (approximately 30 days from today and 3 months from today) all participants, regardless of the group you were initially randomized into, will be asked to complete an on-line survey about your mental health and wellbeing, substance use, and utilization of campus resources. All responses to these surveys will be kept strictly confidential. The investigators who will be analyzing the data from the survey responses will not have access to your email address or any other identifying information. The expected time commitment at the two follow-up time points will be 15-20 minutes each.

After the final survey, all participants, regardless of their initial group, will be invited to receive all of the personalized feedback components available across all conditions.

Risk and Benefits

As for any research study, there are risks and benefits for participation. Here are a the risks and benefits of this study:

Risks and Discomforts:

- There are no more than minimal risks involved in this study, however all research participation might involve loss of privacy or confidentiality. Standard practices will be used to protect participant confidentiality and personal information, including removing identifiers from all survey and program data collected, using only numbers to identify participant data, and keeping all data files securely stored.
- *You* can also help protect your information by choosing locations to complete the surveys that you are comfortable in, and, when possible, avoiding the use of shared emails and computers or other devices to complete surveys as well as making sure to close your browser when you are done with a survey.
- There is a small chance that you will experience emotional distress and/or concerns about your emotional health or substance use while completing one of the surveys and/or the different programs offering personalized feedback. If you are experiencing any challenges in these areas, you can contact University Counseling Services at 828-6200. There is someone on call all day, every day, all year long.

Benefits to You and Others:

The potential benefit to you from participating in this project is you will receive personalized feedback that may help you make choices to get the most out of your college experience, and to support your health and well-being. You will get personalized recommendations and resources, which may help you. You will also help with assessing the value of receiving personalized feedback to your college experience, which may be of use to other students in the future.

Compensation

To compensate you for your time and to show our appreciation, you will receive the following for your participation in this study:

- A \$25 Amazon e-gift card after completion of your assigned condition and the initial brief REDCap survey
- a \$20 Amazon e-gift card after completion of the 30-day follow-up REDCap survey
- A \$20 Amazon e-gift card after completion of the 3-month follow-up REDCap survey
- To further thank those who participate at all timepoints of the study, **all participants who complete all 3 surveys will receive an additional \$20 Amazon bonus e-gift card at the conclusion of their participation**

As a reminder, you may be asked to go through a personalized feedback program before completing a brief survey. Only those that complete the post-program survey will receive compensation so it is important that you pay attention to the prompts and instructions related to returning to the survey after going through a personalized feedback program.

How will information about me be protected?

VCU and the VCU Health System have established secure research databases and computer systems to store information and to help with monitoring and oversight of research. Your information may be kept in these databases but are only accessible to individuals working on this study or authorized individuals who have access for specific research related tasks.

Identifiable information in these databases are not released outside VCU unless stated in this consent or required by law. Although results of this research may be presented at meetings or in publications, identifiable personal information about participants will not be disclosed.

Personal information about you might be shared with or copied by authorized representatives from the following organizations for the purposes of managing, monitoring and overseeing this study:

- The study Sponsor, representatives of the sponsor and other collaborating organizations
- Representatives of VCU and the VCU Health System
- Officials of the Department of Health and Human Services

In the future, identifiers might be removed from the information you provide in this study, and after that removal, the information could be used for other research studies by this study team or another researcher without asking you for additional consent.

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Certificate of Confidentiality

To help us protect your privacy, we have been issued a Certificate of Confidentiality (CoC) from the National Institutes of Health. A Certificate of Confidentiality helps the researchers keep your information private and protects researchers from being compelled to disclose information that would identify the subjects in this study. For example, researchers can refuse to give out your information in a court case. Researchers may have to give your information if the study is audited, or if the information is required by the Food and Drug Administration (FDA).

The researchers cannot prevent you or others, for example a member of your family, from sharing information about you or your involvement in this research. If you give an insurer, employer, or other person permission to receive research information, then the researchers may not use the Certificate to withhold that information.

Whom should I contact if I have questions about the study?

For general questions about the study, please contact the study coordinator, Emily Balcke, at pfpstudy@vcu.edu.

The principal investigator named below is the best person to contact if you have any questions, complaints, or concerns about your participation in this research:

Danielle Dick, Ph.D.
8 N Harrison Street
Richmond, VA 23220
(804) 827-0061; ddick@vcu.edu

If you have general questions about your rights as a participant in this or any other research, or if you wish to discuss problems, concerns or questions, to obtain information, or to offer input about research, you may contact:

Virginia Commonwealth University Office of Research
800 East Leigh Street, Suite 3000, Box 980568, Richmond, VA 23298
(804) 827-2157; <https://research.vcu.edu/human-research/>

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

If you have any questions, please contact the study team before taking the survey.

Statement of Consent

I have been provided with an opportunity to read the consent form carefully. All of the questions that I wish to raise concerning this study have been answered.

By participating in this survey, you acknowledge that:

- You are 18 years of age or older.
- You are a full-time freshman student at Virginia Commonwealth University

Please enter your VCU email address:

Do you consent to participate in this research study?
Yes- Yes, I understand the study and want to participate
No- I want to withdraw from the study