Brief Title: Novel Prevention Intervention Program to Reduce Risky Patterns of Substance Use Among Emerging Adults (ARFP)
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RUTGERS HEALTH

CONSENT TO TAKE PART IN RESEARCH

Title of Research: DNA Discovery: Learn About Your Risk for Addiction
Principal Investigator: Danielle Dick, PhD

RESEARCH SUMMARY: This consent form is part of an informed consent process for a research study, and it will provide information that will help you decide whether you want to take part in this research. It is your choice whether to take part or not.

PURPOSE: The purpose of this research is to evaluate a new on-line program that integrates genetic, behavioral, and environmental risk factors to provide personalized risk profiles and associated resources to help reduce risk. We are interested in getting feedback on the program and studying its effects on mental health and substance use. If you take part in the research, you will be asked to complete the on-line program as well as associated research surveys. The study will take place over the course of approximately 5 months, and will involve completing an initial survey and providing a saliva sample, returning to the website to access results and review resources approximately 8 weeks later, and completing two follow-up surveys at 30 days and 3 months after receiving your results.

RISKS/BENEFITS: Possible harms or burdens of taking part in the study may be discomfort or distress while answering the questionnaires about substance use and mental health. The benefits of participating include receiving your personalized information about risk for addiction and resources that could help you adopt healthier behaviors and improve your wellbeing.

ALTERNATIVES: Your alternative to taking part in the research study is not to take part in it.

The information in this consent form will provide more details about the research and what will be asked of you if you choose to take part in it. If you have any questions now or during the research, if you choose to take part, you should feel free to ask them and should expect to be given answers you completely understand. After your questions have been answered and you wish to take part in the research, you will be asked to sign this consent form. You are not giving up any of your legal rights by agreeing to take part in this research or by signing this consent form.

Who is conducting this research?
Danielle Dick, PhD is the Principal Investigator of this research. A Principal Investigator has the overall responsibility for the conduct of the research. However, there are often other individuals who are part of the research team. Danielle Dick may be reached at danielle.m.dick@rutgers.edu or (732) 235-5607.

Sponsor of the Research: This research is sponsored by the National Institute on Drug Abuse (NIDA).

Why is this research being done?
This project seeks to evaluate a novel program that will provide young adults with information about their risk for addiction and associated resources to help reduce risk. The research will help us evaluate the program to assess participants' satisfaction, as well as any associated benefits to mental health and substance use.

Who may take part in this research and who may not?
This study is for emerging adults between 18-25 years who reside in the United States. These individuals must also be English-speaking. Participants will be excluded from the study if they are younger than 18

years old, older than 25 years old, reside outside of the United States, or if they do not provide informed consent.

Why have I been asked to take part in this research?
You are being asked to participate in this study because you are between the ages of 18-25 and expressed interest in learning about your risk for addiction.

How long will the research take and how many participants will take part?
Participation is open to 450 individuals. Participation will occur on-line across four timepoints with the following estimated duration. More information on these timepoints is available in the next section, *What will I be asked to do if I take part in this research.*

Initial timepoint (now): 30 minutes (to include completing a behavioral risk survey, sharing mailing information to receive your DNA kit, and completing a baseline research survey)

Next timepoint (approximately 8 weeks later once your risk estimates are ready): 30 minutes (to include reviewing your risk profile, completing a research survey, and receiving access to your resources)

Please note that the time it takes to engage with the resources will vary depending on the individual and assigned group.

30-day follow-up: 15 minutes (to complete a research survey)

3-month follow-up: 15 minutes (to complete a research survey).

What will I be asked to do if I take part in this research?
Once you complete this consent, you will be directed to the program website to complete an initial survey to gather data on behavioral and environmental risk factors and current substance use, and to provide mailing details for a saliva kit. After filling in this information, you will be directed to your first research survey.

You will then be mailed a saliva kit with instructions on how to easily provide and ship your saliva sample. It will take approximately 8 weeks for the lab to process your results.

Once your risk estimates are created, you will be prompted to log back into the online platform. At this point you will be randomly assigned to one of four conditions:

1. Receive risk estimates + informational materials on substance use and health
2. Receive risk estimates + personalized online modules for health promotion
3. Receive risk estimates + appointment with a genetic counselor to discuss your results
4. Receive information materials on substance use and health + receive risk estimates at the end of the study

For individuals in conditions 1-3, after receiving your risk estimates you will complete a brief research survey before returning to the program to engage with your provided resources at your leisure.

For individuals in condition 4, you will complete a brief research survey before being directed to the program to engage with your provided resources at your leisure. *You will receive your risk estimates at the end of the study.*

Two subsequent online surveys will be sent 1 month (30 days) and 3 months (90 days) later, respectively.

Upon completion of the final survey, all participants will receive access to the materials provided across all four conditions.

What are the risks of harm or discomforts I might experience if I take part in this research?
The content of the measures and feedback may produce some emotional stress. In previous studies we have found these feelings to be transitory. We believe that there is a low probability that any participant will experience more than minimal distress while taking the surveys. If you do experience emotional distress and/or concerns about your emotional health or substance use while taking part in this study, contact the 988 Suicide & Crisis Lifeline. The 988 Suicide & Crisis Lifeline provides 24/7, free and confidential support.

There is also the potential for harm if you do not understand the personalized risk information provided to you. To minimize this possibility, if you show low understanding of your risk estimates, you will receive a follow-up call from the genetic counselor involved in this study. If you report high levels of distress upon receiving your risk estimates (in our experience, less than 10% of individuals), you also will be contacted by the genetic counselor. All participants will be given the option to talk to a genetic counselor at the termination of the study.

Are there any benefits to me if I choose to take part in this research?
Participants in this study may benefit by gaining an understanding of their personalized risk factors for addiction and resources designed to help reduce risk. These resources are intended to support mental health and well-being, and help people make healthy choices surrounding substance use. All participants may benefit in the sense of having the opportunity to be involved in the research process and engage with the research team to help evaluate this personalized feedback program; some of what is learned may be enacted in programs and products designed to provide individuals with risk information about their substance use and mental health outcomes in the future. It cannot be promised, however, that all subjects will directly benefit from the assessments or feedback provided through the interventions.

What are my alternatives if I do not want to take part in this research?
Your alternative is not to take part in this research.

How will I know if new information is learned that may affect whether I am willing to stay in the study?
During the research, you will be updated about any new information that may affect whether you are willing to continue taking part in the research. If new information is learned that may affect you after the research or your follow-up is completed, you will be contacted.

Will I receive the results of the research?
While you will receive your personalized risk estimates and associated resources, you will not be provided with individual results from the research study.

Will there be any cost to me to take part in this study?
There are no costs to you for participating in this research.

Will I be paid to take part in this study?
You will receive up to $40 for taking part in this research according to the following schedule:

- $10 Amazon e-gift card for completing the post-intervention survey (after receiving risk estimates)
- $10 Amazon e-gift card for completing the 30-day follow-up
- $10 Amazon e-gift card for completing the 3-month follow-up
- $10 bonus Amazon e-gift card for completing all 3 surveys

You will also receive your personalized risk estimates as well as resources to support your wellbeing for free by the end of the study.

Who might benefit financially from this research?

This research is designed to evaluate a personalized feedback program for addiction risk. Rutgers University is licensing the intellectual property (copyright) associated with this program to Thrive Genetics, Inc. If Thrive Genetics, Inc commercializes the program, Rutgers University and the Principal Investigator leading this research, Dr. Danielle Dick, would receive a part of the profits from any eventual sales of the product. Both Dr. Dick and Rutgers University also hold equity in Thrive Genetics, Inc. This means that Dr. Dick and Rutgers University could eventually make money from the commercialization of the program being evaluated in this research.

How will information about me be kept private or confidential?
All efforts will be made to keep your personal information in your research record confidential, but total confidentiality can never be guaranteed. An ID number will be assigned to each research participant. No name will ever be placed with the research data, to include your genetic data. The only document that contains your name and ID in the same spreadsheet will be destroyed when the research is no longer ongoing. The data from the tasks and questionnaires will be stored on a password protected computer. The genetic data will be stored on the secure Amazon Web Services cloud platform with only ID numbers listed. No names or identifying information will ever be placed with your genetic data.

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

The research team may use or share your information collected or created for this research with the following people and institutions:
- The Rutgers University Institutional Review Board and Compliance Boards
- The Office for Human Research Protections in the U.S. Dept. of Health and Human Services
- The Food and Drug Administration

A description of this clinical trial will be available on 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.

What will happen to my information—data—and bio-specimens collected for this research after the research is over?

After information that could identify you has been removed, de-identified data collected for this research may be kept indefinitely to allow other scientists to verify the results. The spreadsheet that lists your ID number and name in the same sheet will be deleted when the research study is no longer ongoing.

Your DNA sample will be destroyed at the conclusion of the study and will not be shared or stored for future research.

What will happen if I do not wish to take part in the research or if I later decide not to stay in the research?
It is your choice whether to take part in the research. You may choose to take part, not to take part or you may change your mind and withdraw from the research at any time. If you do not want to enter the research or decide to stop taking part, your relationship with the research staff will not change, and you may do so without penalty and without loss of benefits to which you are otherwise entitled.

You may also withdraw your consent for the use of data already collected about you, but you must do this in writing to Danielle Dick at dnadiscoverystudy@rutgers.edu

Who can I contact if I have questions?
If you have questions, concerns, or complaints about the research, wish more information or if you feel you may have suffered a research related injury, you can contact the Principal Investigator: Danielle Dick, Department of Psychiatry, danielle.m.dick@rutgers.edu, (732) 235-5607).

If you have questions, concerns, problems, information or input about the research or would like to know your rights as a research participant, you can contact the Rutgers IRB/Human Research Protection Program via phone at (973) 972-3608 or (732) 235-9806 OR via email irboffice@research.rutgers.edu, or you can write us at 335 George Street, Liberty Plaza Suite 3200, New Brunswick, NJ 08901.

AGREEMENT TO TAKE PART IN RESEARCH

Participant Consent:

I have read this entire consent form, or it has been read to me, and I believe that I understand what has been discussed. All of my questions about this form and this research have been answered. I agree to take part in this research.

Participant Name (Print):_____

Participate Signature:_____ Date:_____