California State University, Northridge
CONSENT TO ACT AS A HUMAN RESEARCH PARTICIPANT

MATAspire Substance Misuse Prevention and Mental Health Promotion Study

You are being asked to participate in a research study. Participation in this study is completely voluntary. Please read the information below and ask questions about anything that you do not understand before deciding if you want to participate. A researcher listed below will be available to answer your questions.

RESEARCH TEAM
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KEY ELEMENTS

- **Purpose**: This study is for enrolled CSUN students 18 and older (with an active CSUN email for at least 10 weeks) to test the effectiveness of a web-app for substance misuse prevention, coping, mental health and wellness promotion.
- **Procedures:** You will complete an online survey, then be randomized into an intervention group or a control group.
  (1)The intervention group will complete 6 weekly web-app modules about coping & substance use and three online surveys. (Total time commitment: 3 hours across 4 months.)
  (2) The control group will not complete any web-app modules, you will complete one additional survey 30 days after randomization and another 90 days later. (Total time commitment: 1 hour across 4 months).
- **Risks and discomforts**: the surveys deal with sensitive issues such as abuse, traumatic incidents, and substance use that may cause psychological/emotional distress or discomfort, social discomfort, and/or economic/legal risks if you report illegal substance use, and minor risk of your private information being breached.
- **Benefits**: participants in the intervention group will learn about coping skills and substance misuse prevention. Control group participants have no subject benefits.
- **Compensation and cost**: (1) Intervention group participants will earn up to $105 in gift cards of their choice via Tangocard.com, and (2) control group participants will earn up to $90.
- **Confidentiality of Data**: identifiable information will be replaced with a random participant ID in the data (de-identified); identifiable information will be kept separate from your responses; access will be limited to project personnel; identifiable information will be destroyed 3 years after the study ends; de-identified data will be kept indefinitely for future research.
- **Mandated reporting**: Researchers are required to report abuse or neglect of a child, dependent adult or elder.

PURPOSE OF STUDY

The purpose of this research study is to learn more about CSUN student substance use and mental health, and test the effectiveness of an online web-application substance misuse prevention and mental health promotion program. This study is part of a comprehensive SAMHSA-funded grant program, MATAspire, under the direction of Dr. Bethany Rainisch, Program Director and Professor in the Department of Health Sciences at CSUN.

SUBJECTS

Inclusion Requirements

You are eligible to participate in this study if you are a CSUN student age 18 and over with active CSUN login credentials for at least 10 weeks after study enrollment. You may only participate in this study once.

Exclusion Requirements

You are not eligible to participate in this study if you are under 18, are not an enrolled CSUN student, or if you have previously participated in this study.

Time Commitment

You will be randomized into one of two study groups, with different time commitment:

GROUP 1 - intervention: This study will involve approximately 2 ½ hours of your time over the course of five weeks and 15-minute follow-up survey 90 days later.
GROUP 2 - control: This study will involve approximately 30 to 45 minutes of your time over the course of five weeks and 15-minute follow-up survey 90 days later.

PROCEDURES

The following procedures will occur:

Both groups:

All elements of this study are web-based, intended to be used on a computer or mobile/tablet device.

a) You are being asked to read and sign this informed consent electronically, and to provide your CSUN email address so we can: (1) verify that you are a CSUN student; (2) send you study surveys; (3) send you reminders and study-related emails; and (4) email you redemption links to Tangocard.com that may be exchanged for gift cards of your choice to compensate you for your time as a participant.
b) After completing the informed consent, you will be asked to answer a 25 to 30-minute baseline survey in Qualtrics on topics related to demographics, mental health and wellbeing, substance use, attitudes, and perceptions. All participants will receive a Tangocard.com reward link for $30 via their CSUN email after completing the baseline survey and first login to the web-app for randomization.

Within a day or two after completing the baseline survey, you will receive an email with information on how to log in to the web-application. The web-application (which does NOT collect any research data in the modules) utilizes the CSUN IT identification management system (username/password) for logging in.

The first time you log-in, you will be randomized in to one of two study groups:

GROUP 1 (intervention):
You will complete six weekly modules in the interactive MATAspire web-application. Each module will last approximately 15 minutes, and contains information about coping skills and a substance: (Module 1) coping skills, (2) alcohol, (3) cannabis, (4) nicotine, (5) opioids, and (Module 6) reinforcement. Each module will be released 6 days after the prior one is completed and the last module no sooner than 31 days after first login. You will have **7 days** to complete each module after it is released. If a module is not completed within 7 days, you will not be compensated and may be dropped from the study.
None of the replies you input as part of interactive activities in the module will be collected or stored as part of this research. No quiz responses or self-reporting is stored by the web-app after leaving each page. In order to be compensated, the research team will only collect information regarding which group you were randomized into, and when you have completed a module.

After completing the third module, you will receive a short 5-minute survey via email about your coping skills, and after the final module (#6), you will receive a 15 to 20-minute Exit survey via email. Ninety (90) days following the Exit survey, MATAspire will send you a follow-up survey. You have 6 days to complete the survey sent upon completion of module 3, two weeks to complete the Exit survey, and two weeks to complete the Follow-up survey. You will receive up to three reminders per survey. If the surveys are not completed within that time, participants will not be compensated and may be dropped from the study.

GROUP 2 (control group):
You will not complete any modules. However, 30 days after completing the Baseline Survey and being randomized into the control group, you will receive a 15 to 20-minute Exit survey. Ninety (90) days following the Exit survey, MATAspire will send you a similar follow-up survey via email. You have two weeks to complete the Exit survey, and two weeks to complete the Follow-up survey. You will receive at least three reminders per survey. If the exit and follow-up surveys are not completed within two weeks, participants will not be compensated and may be dropped from the study.

RISKS AND DISCOMFORTS
The possible risks and/or discomforts associated with the procedures described in this study include:

Psychological: You will be asked to answer questions about highly sensitive topics, including experiences of violence, sexual abuse, self-reported and family substance use behavior and self-reported mental health issues. These questions may upset you, or cause emotional distress or discomfort, especially if you have pre-existing emotional vulnerabilities.

Social: You may feel judged by others if believed to be participating in this study. You can choose where you want to participate with your mobile device, in order to manage such social risk.

Economic/legal: This study asks you to provide potentially highly sensitive, personal information (i.e., illegal substance use). Though extremely unlikely, if certain individuals not part of the approved research team learn this information, you could potentially experience adverse economic or legal reactions. However, this study has obtained a Certificate of Confidentiality, which provides special protection of your identifiable information; and protects the researcher from being forced to release information, even if subpoenaed by a court order (see full disclosure about the Certificate of Confidentiality under "Confidentiality").

Privacy: there is always a small risk that private information provided through the internet can be breached. Your information is kept as safe as possible through use of secure, password-protected, and encryption-based systems.

If you should feel any discomfort or risk during or after participating in this study, free counseling is available on campus. You may call University Counseling Services at (818)677-2366, and select option 1 to make an appointment. Short-term care is provided to students at UCS at no cost (up to 8 sessions), with referral to more long-term services. To get more information about substance abuse and resources, you can also call the national FREE SAMHSA 24-hour substance use hotline number 1-800-662-HELP (4357), or TTY: 1-800-487-4889. See the end of this consent form for more resources.

BENEFITS

Subject Benefits

The possible benefits you may experience from the procedures described in this study, should you be randomized into the intervention web-app group, include: learning about substances and their effect on your health; how you can prevent substance misuse; ways to use substances responsibly to prevent risky behavior and the negative consequences associated with substance misuse. You will also learn how substance misuse and mental health problems are related, different coping skills and stress-reduction techniques, and alternatives to substance use to increase your health and wellness. There are no subject benefits to participants randomized to the control group.

Benefits to Others or Society

Your participation may help improve strategies and services for substance misuse prevention and mental health promotion through a web-application on a college campus for young adults such as yourself.

ALTERNATIVES TO PARTICIPATION

The only alternative to this study is to not participate. However, all students can visit our website (csun.edu/MATAspire/resources) for information related to substance misuse prevention, coping skills, and other mental health services; and programs offered by the University Counseling Services, such as individual therapy (including counseling for alcohol and other drug use), workshops, groups, and online information. The website also links you to other CSUN health and wellness resources featured in the MATAspire app, and to the online eCHECKUP to go programs for alcohol and marijuana awareness, and wellness coaching.

COMPENSATION, COSTS AND REIMBURSEMENT

Compensation for Participation

You will be randomized into one of two groups. Compensation will vary between the groups, and will be distributed after you complete electronic surveys throughout the study. Gift cards of your choice are provided via Tangocard.com reward links, which you will receive to your CSUN email.

GROUP 1 - Intervention (four surveys):

You will receive $30 after completing the baseline survey and first login to the web-app for randomization; $15 after completing a short survey about your coping skills after module 3; $30 after completing the Exit survey, sent to you after module 6, and $30 after completing the 90-day follow-up survey.

Total compensation if you complete all components is **$105.**

GROUP 2 - Control (three surveys):
You will receive $30 after completing the baseline survey and first login to the web-app for randomization; $30 after completing the Exit survey; and $30 after completing the 90-day follow-up survey.
Total compensation if you complete all components is **$90.**

If you decide to withdraw from the study or are withdrawn by the research team, you will only receive compensation for the surveys that you have completed on time.

Costs
There is no cost to you for participation in this study.

WITHDRAWAL OR TERMINATION FROM THE STUDY AND CONSEQUENCES
You are free to withdraw from this study at any time. **If you decide to withdraw from this study, you should notify the research team immediately**. The research team may also end your participation in this study if you do not complete surveys and/or scheduled web-app modules within the requested timeframe. You will be notified via email if the research team ends your participation.

CONFIDENTIALITY
Subject Identifiable Data
All data collected is confidential. The informed consent and the survey data (baseline, coping survey, exit, and 90-day follow-up), which includes your name and email address, will be collected and stored in the HIPAA secure server of CSUN Qualtrics as part of this research. Every year, all survey data is downloaded and purged from Qualtrics. This consent form containing your name and email address will be kept by the PI on her password-protected computer. All identifiable survey data (e.g., name and email address) that will be collected about you will be removed and replaced with a participant code (i.e., de-identified). Once de-identified, a separate master list linking the coded research data and your identifiable information will be stored on a password-protected, encrypted USB flash drive kept in a locked cabinet in the Program Manager's (PM) office, only accessible to the PM and PI. Your email will also be kept in a separate tracking sheet to monitor gift cards and study progress accessible to the study team on the password-protected myCSUNbox, as an additionally password-protected file.

To help keep information about you confidential, this research is covered by a Certificate of Confidentiality from the Department of Health and Human Services (HHS). This means that the researchers cannot be forced, even under a court order or subpoena, to release information that could identify you. There are some important things that you need to know: The Certificate DOES NOT stop researchers from reporting issues required by federal, state or local laws, such as child or elder abuse, some communicable diseases, and threats to harm yourself or others. Also, because this research is sponsored by HHS, staff from HHS may review records that identify you during an audit. This Certificate does not imply that the Secretary, HHS, approves or disapproves of the project.

Data Storage
All research data will be collected electronically within the HIPAA-certified, password-protected and encrypted Qualtrics account accessible to the study team members listed on page 1. Every year, data will be downloaded to the secure password-protected CSUN server (myCSUNbox). All identifiable information that will be collected about you will be removed and replaced with a code. The master list linking the research data to your identifiable information will be stored digitally on a password-protected, encrypted USB flash drive in a locked cabinet in the PM's office, only accessible to the

PM and PI. The de-identified research data is stored on the myCSUNbox account separately and accessible to the research team. For compensation and study tracking purposes, your email address will also be kept in a separate, password-protected gift card tracking file on myCSUNbox accessible to the DA, PI, Program Manager, and one graduate research student. At the end of the study, the master list linking your identifiable information to your research data will be kept by the PI in a locked box in her office; the consent forms will be kept on the PIs computer; and the password-protected tracking list will be retained on the PI's myCSUNbox account for 3 years after the completion of the study, after which they will be deleted. The de-identified research data will be retained indefinitely for future research.

Data Access
Only the researchers named on the first page of this informed consent can access the complete confidential data on Qualtrics to manage administration of compensation, and track participant progress. The researchers named on the first page of this informed consent will have access to the data collected in this study once it has been de-identified. Other researchers will be able to request access to de-identified data for future research. Any information derived from this research project that personally identifies you will not be voluntarily released or disclosed without your separate consent, except as specifically required by law. Publications and/or presentations that result from this study will not include identifiable information about you.

Data Retention
The consent forms, master list linking the research data to your identifiable information, and the compensation tracking list, which includes your name and email, will be kept by the PI separately for 3 years after the study ends. At that time, all identifiable data will be destroyed. The researchers intend to keep the de-identified research data on the secure CSUN server indefinitely.

Mandated Reporting
Under California law, the researchers are required to report known or reasonably suspected incidents of abuse or neglect of a child, dependent adult or elder, including, but not limited to, physical, sexual, emotional, and financial abuse or neglect. If any researcher has or is given such information in the course of conducting this study, they may be required to report it to the authorities.

IF YOU HAVE QUESTIONS
If you have any comments, concerns, or questions regarding the conduct of this research please contact the research team listed on the first page of this form.

If you have concerns or complaints about the research study, research team, or questions about your rights as a research participant, please contact the Research and Sponsored Programs office, 18111 Nordhoff Street, California State University, Northridge, Northridge, CA 91330-8232, by phone at (818) 677-2901 or email at irb@csun.edu.

VOLUNTARY PARTICIPATION STATEMENT
You should not sign this form unless you have read it and been given a copy of it to keep.
Participation in this study is voluntary. You may refuse to answer any question or discontinue your involvement at any time without penalty or loss of benefits to which you might otherwise be entitled. Your decision will not affect your relationship with California State University, Northridge. Your signature below indicates that you have read the information in this consent form and have had a chance to ask any questions that you have about the study.

If you would like to speak to a researcher before you decide to participate, you may email the PI at Bethany.rainisch@csun.edu, the evaluator at Myriam.forster@csun.edu, or the program manager at linn.dahlman@csun.edu.

Participation, please check one:

□ I agree to participate in the study.

□ I do NOT agree to participate in the study.

Please sign your name to consent to participate

Name: _____

Please input your CSUN student email address so we can send you study-related communications and compensate you for your participation. Failure to provide a valid CSUN email address will result in loss of compensation.

_____

CONTACT INFORMATION AND RESOURCES

SAMHSA's National Substance Abuse Helpline: 1-800-662-HELP (4357), or TTY: 1-800-487-4889 (confidential, free, 24-hour-a-day, 365-day-a-year, information service, in English and Spanish, for individuals and family members facing mental and/or substance use disorders).

University Counseling Services (UCS) [https://www.csun.edu/counseling/appointments]. To make an appointment, call (818)677-2366, and select option 1.

Making your first appointment is easy. Any regularly enrolled CSUN student who is interested in accessing mental health services may contact UCS during regular business hours, between 8 a.m. and 5 p.m., Monday through Friday.

UCS After-hours urgent care assistance: If you are in crisis or have an urgent concern *after regular business hours*, please call our main line at (818) 677-2366 and select option 3.

UCS Alcohol and Other Drug Counseling Dr. Steve Silver, Psychologist and Alcohol and Other Drugs Counselor, UCS (818) 677-2366

UCS CSUN's list of resources: https://www.csun.edu/sites/default/files/UCS-Referral-List.pdf

Visit the MATAspire resources list for more [https://www.csun.edu/MATAspire/resources]