Consent Form for Participation in a Research Study

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Study Title: PACER Study

Overview of the Research

You are being asked to provide consent to participate in a research study funded by the National Institutes of Health (NIH). Participation is voluntary. You can say yes or no. If you say yes now you can still change your mind later. Your participation in this study will not affect any proceedings related to your Student Code violation/alcohol infraction (if you have one). Your participation will not affect your right to UConn Student Health and Wellness services. Some key points to consider are summarized in this overview, but you should consider all of the information in this document carefully before making your decision.

Goal of the research: This research is being done to better understand what interventions are most effective at helping college students manage their stress better. We want to look at the impact of three different interventions: 1) a yoga class, 2) training in a psychological approach known as distress tolerance (DTT), and 3) no intervention.

Duration of participation: Participation will involve approximately 2-14 hours of your time over the next 8 months.

What you will do: You will be randomly assigned to a group, which may or may not involve approximately 8 weeks of participation in a group intervention. You will be asked to complete three surveys throughout the study. The surveys will ask about your background and demographics, your drinking, how you deal with your emotions, how you've been feeling recently, and your trauma history. You will receive a $20 electronic gift card for each survey that you complete.

You will also have the opportunity to provide three hair samples and/or participate in a focus group if you want. You will receive a $20 electronic gift card for each hair sample you provide and a $20 electronic gift card for participating in the focus group. These are both optional. You can still be in the study even if you do not want to provide a hair sample or participate in the focus group.

Possible risks or inconveniences: There is a small risk of injury for participants who are assigned to the yoga intervention group. Additionally, some of the survey questions you answer might cause you to feel uneasy. There are also small risks for participants who decide to provide a hair sample and participate in the focus group.

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Possible benefits: You may develop skills to improve your general stress management. Other possible benefits include increased relaxation and concentration as well as reduced alcohol abuse. Your participation in this research study will help us better understand how colleges and universities can help students manage their stress better.

A more detailed description of this research follows.

Introduction

You are invited to participate in a research study to determine what interventions are effective at helping college students manage their stress better. You are being asked to participate because you are a student at UConn and your scores on the screener measures indicate you may benefit from the interventions we are offering.

Why is this study being done?

The purpose of this research study is to find out what interventions are effective at helping college students manage their stress better. We also want to see if it is feasible to implement this study on a larger scale.

What are the study procedures? What will I be asked to do?

Required study procedures for all participants:

If you agree to participate, you will be asked to complete a baseline survey. This survey will ask you about your background and demographics, including questions about your previous treatment and trauma histories. Questions in the survey set will also ask about how you deal with your emotions, how you've been feeling recently, and your drinking.

Following the baseline survey, you will have an equal chance of being assigned to one of three groups, described below. Your assignment into a group is done randomly, by chance because we don't know if one study group will help students more than another.

1) One group of students will participate in a **yoga class**:
   - Led by a trained facilitator, the yoga class will meet (virtually through a secure video conferencing software) for 60 minutes, once or twice a week, for approximately 8 weeks. The class will involve meditation, standard yoga poses, breathing exercises, and relaxation.
2) One group of students will participate in a training in a psychological approach known as **distress tolerance training (DTT)**:
   - Led by a trained facilitator, the DTT will meet (virtually through a secure video conferencing software) for 60 minutes, once or twice a week, for approximately 8 weeks. The DTT curriculum we use is called PRISM and includes the skills used in cognitive behavioral approaches to build coping skills. These participants will learn and practice skills to maintain control of your emotions in uncomfortable or distressing situations.

3) One group of students will not be assigned to an intervention. These students will have the opportunity to participate in four free PRISM or yoga sessions after all assessments are complete.

After 8 weeks, you will be contacted to complete a post-test survey. This survey is the same as the baseline survey, but excludes questions about your background and demographics.

Six months after you complete the post-test survey, you will be contacted to complete the 6-month follow-up survey. This survey is the same as the post-test survey, but will include additional questions about factors that affected your attendance and participation in your group. We may want to follow up with you long-term, years after the study is complete. This will help us understand if the interventions used in this study affect your ability to manage your stress years later. At the end of this form, we will ask you if this is ok with you. If you say yes, we will ask for some additional contact information that we can use to reach you in the future. If you say no, you can still participate in this study.

Unless you choose to participate in the "additional procedures" described below and/or give us permission to contact you long-term, your participation is finished after you complete the 6-month follow-up survey.

All surveys will be completed online, using a unique link that will be emailed to you. All surveys are expected to take about 35-50 minutes. After you complete each survey, you will be emailed a $20 gift card as a "Thank You" for your time. You are eligible for the $20 gift card if you complete 90% or more of the survey.

Additional procedures only for participants who are interested:

The procedures below are optional. You do not need to agree to the assessments described below in order to participate in this study. You will be paid for your participation in these procedures. The opportunity to provide a hair sample will be limited to the first 30 students from each intervention group to consent to participation in this assessment. Participation in the focus group will be limited to the first six students from each of group to consent to participation in the focus group.

Hair sample:

After your baseline survey, you may be emailed to ask if you would like to provide a hair sample. We will use a hair sample to test for recent heavy alcohol use. This test can detect past alcohol use for up to 90 days. We will not test your hair for use of any substances other than alcohol.

Providing a hair sample is expected to take you about 10 minutes. You will take the hair sample yourself, in the comfort of your home. We will ask you to cut about 200 strands of your hair (about the size of a #2 pencil) close to your scalp. We will also ask you to complete a brief questionnaire about your hair care. These questions will be used to determine how reliable the hair sample is. We will ask you to mail the hair sample and questionnaire to us. We will mail you all the materials you will need to take the hair

sample and mail it to us at no cost to you. You will be given access to an instructional video explaining how to take the hair sample.

Just like the surveys, you will have the opportunity to provide a hair sample at three points in the study: baseline, post-test, and 6-month follow-up. You will be paid a $20 electronic gift card for each time point you provide a hair sample. At the end of this form, we will ask you if you would like to provide a hair sample. If you say yes, we will ask for your mailing address that we will use to mail you hair test collection supplies and questionnaire.

Focus group:

Around the time of your 6-month follow-up survey, you may be emailed to ask if you would like to participate in a focus group with other students who have participated in this study. The focus group will be led by a facilitator using a guide containing questions about your experience participating in the study. The discussion should last about an hour. It will be audiotaped using a digital recorder.

What are the risks or inconveniences of the study?

As with other forms of exercise, yoga carries a risk of injury. The most common injuries associated with yoga are sprains and strains. Although you will be encouraged to challenge yourself, you will be reminded frequently to listen to your own body and only perform exercises that feel right to you. Modifications of all poses as well as blocks and straps for support will be provided.

The survey will include questions about your substance use. Some of the survey questions might cause you to feel embarrassed or uneasy. If you feel upset by any of the questions, you can do any of the following: You can choose not to answer any question. You can take a break and continue later. You can choose to stop the survey at any time. If you are negatively affected by the survey, you should let someone from Student Health and Wellness know so you can be referred for counseling. Immediately after you finish the survey, you will be emailed a copy of the Informed Consent along with a list of national and local resources and their contact information. It may be helpful for you to reach out to these resources if you are feeling upset at any point during or after the survey. If you are negatively affected by the survey, you should contact a principal investigator (Crystal Park: (860) 486-3520; Beth Russell: (203) 236-9874; Michael Fendrich: (959) 200-3612).

If you choose to provide a hair sample: There is a small risk you may be able to notice the spot where the hair was taken and not like how that looks. The instructional video shows you how to take the hair sample from a spot that will not be very noticeable. If you do not want to give a hair sample for any reason, you can choose not to participate in this part of the study.

If you choose to participate in the focus group: Other students who participate in the focus group will be aware of your answers. We ask that you and others not share information discussed in the focus group outside of the group. We will ask participants to try not to use any names during the focus group in order to protect your confidentiality. Once the study is complete, the audio recordings will be destroyed.

A possible inconvenience of this study is the time it takes to participate in the groups (yoga or DTT), complete the surveys, and (for those who are interested) provide the hair samples and participate in the focus group. The yoga and DTT intervention groups and the focus group will occur virtually, through a secure video conferencing software. You will be able to provide the hair sample from the comfort of your home. The surveys can be completed at a time and place that is convenient for you, on your personal device (phone, computer, or tablet).

What are the benefits of the study?

Participants who participate in yoga or DTT may develop skills to improve their general stress management. Other possible benefits for these participants include increased relaxation and concentration as well as reduced alcohol abuse. Your participation in this research study will help us better understand how colleges and universities can help students manage their stress better. Your participation will also help us determine if it is feasible to implement this study on a larger scale.

Will I receive payment for participation? Are there costs to participate?

There are no costs to be in this study. You will be paid a $20 electronic gift card after each survey is 90% or more complete. Altogether, you could make up to $60 for the surveys. If you choose to provide hair samples, you will be paid a $20 electronic gift card after you submit each hair sample. Altogether, you could make up to $60 for the hair samples. If you choose to participate in the focus group, you will be paid a $20 electronic gift card after the focus group is complete.

The gift cards will be emailed to you at an email address you specify.

How will my personal information be protected?

Surveys will be conducted using your personal computer, cell phone, or tablet.

All electronic data will be collected and stored on secure severs supported by the University of Connecticut Information Technology Services (UITS); UITS servers are backed up daily. The computing facilities where data and software will be hosted include the latest technologies and secure environments for conducting data collection for research. The computing facilities were designed with policies and rules that meet or exceed HIPAA and other Federal information security regulations. Only authorized members of the research team will have access to data through individual user IDs and passwords.

The research team will keep any information you give us confidential, and will not share it with anyone outside of the research team, including program providers, with certain exceptions. To help keep information about you private and confidential, we have obtained a Certificate of Confidentiality from the National Institutes of Health (NIH). This Certificate does not imply that the NIH approves or disapproves of the project. This Certificate will protect the researchers from being forced to give information about you to others, even under a court order or subpoena. Even with a

Certificate of Confidentiality, we are required to report to the police or other appropriate authority if you disclose information that you may cause immediate harm to yourself or another person.

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.

Study records including identifiable information will be kept in REDCap for three years from the end of the study period (September 2022). Thereafter, de-identified datasets will be downloaded from the University server and stored on the lead researcher's University-issued, password protected computer. The project will be deleted and scrubbed from University servers. De-identified datasets will be kept indefinitely.

The following procedures will be used to protect the confidentiality of your data. The researchers will keep all study records (including any codes to your data) locked in a secure location or stored in a secure drive. Research records will be labeled with a code. A master key that links names and codes will be maintained in a separate and secure location in a secure drive. The master key and any other files containing identifying information will be destroyed after 3 years. All electronic files (e.g., database, spreadsheet, etc.) containing identifiable information will be password protected. Any computer hosting such files will also have password protection to prevent access by unauthorized users. Only the members of the research staff will have access to the passwords. Data that will be shared with others will be coded as described above to help protect your identity.

At the conclusion of this study, the researchers may publish their findings. Information will be presented in summary format and you will not be identified in any publications or presentations.

We will do our best to protect the confidentiality of the information we gather from you but we cannot guarantee 100% confidentiality. Your confidentiality will be maintained to the degree permitted by the technology used. Specifically, no guarantees can be made regarding the interception of data sent via the Internet by any third parties.

You should also know that the UConn Institutional Review Board (IRB) and Research Compliance Services may inspect study records as part of its auditing program, but these reviews will only focus on the researchers and not on your responses or involvement. The IRB is a group of people who review research studies to protect the rights and welfare of research participants.

What happens if I am injured because I took part in the study?

In the event you become injured during the course of the research study, immediately notify the principal investigator or a member of the research team. If you require medical care for such injury, your care will be billed to you or to your insurance company in the same manner as your other medical needs are addressed.

However, if you believe that your illness or injury directly resulted from the research procedures of this study, you may be eligible to file a claim with the State of Connecticut Office of Claims

Commissioner. For a description of this process, contact Research Compliance Services at the University of Connecticut at 860-486-8802.

Can I stop being in the study and what are my rights?

You do not have to be in this study if you do not want to. If you agree to be in the study, but later change your mind, you may drop out at any time for any reason. There are no penalties or consequences of any kind if you decide that you do not want to participate. You do not have to answer any question that you do not want to answer.

You may or may not have been referred to BASICS because of a Student Code violation/alcohol infraction. Your decision to participate or not participate in the study will not affect any proceedings related to this Student Code violation (if you have one). Your decision to participate or not participate in the study will not affect your right to UConn Student Health and Wellness services in any way.

You will be notified of all significant new findings during the course of the study that may affect your willingness to continue.

At any time, you can email the researchers to withdraw your information from the study at crystal.park@uconn.edu., beth.russell@uconn.edu, or michael.fendrich@uconn.edu.

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

Take as long as you like before you make a decision. We will be happy to answer any question you have about this study. If you have further questions about this study or if you have a research-related problem, you may contact any of the principal investigators:

- Crystal Park at 860-486-3520/crystal.park@uconn.edu
- Beth Russell at 860-221-8414/beth.russell@uconn.edu
- Michael Fendrich at 959-200-3612/michael.fendrich@uconn.edu

If you have any questions concerning your rights as a research participant, you may contact the University of Connecticut Institutional Review Board (IRB) at 860-486-8802.

Documentation of Consent to Participate:

We are asking for your consent to participate in the main study procedures. By indicating yes, you are agreeing to participate in the group assignment, eight sessions (if assigned to yoga or DTT), and a survey that will occur three different times.

Do you agree to participate in the main study procedures?
○ No
○ Yes

My signature indicates I have read this form and decided that I will participate in the project described above. Its general purposes, the particulars of involvement, and possible risks and

inconveniences have been explained to my satisfaction. I understand that I can withdraw at any time. My signature also indicates that I understand I will receive a copy of this consent form by email.

_____	_____	_____
Participant Signature:	Print Name:	Date:

We are asking for your consent to provide a hair sample. You will be asked to provide a hair sample three different times. You do not have to say yes to providing a hair sample in order to participate in the study. You can say yes and change your mind later.

Do you agree to provide a hair sample?
○ No
○ Yes
○ I'm not sure

_____	_____	_____
Participant Signature:	Print Name:	Date:

We are asking for your consent to participate in a focus group. The focus group will occur once at the end of the study. You do not have to say yes to the focus group in order to participate in the study. You can say yes and change your mind later.

Do you agree to participate in an audio-recorded focus group about your experience in this study?
○ No
○ Yes
○ I'm not sure

_____	_____	_____
Participant Signature:	Print Name:	Date:

We may want to follow up with you long-term, to see if the intervention had an effect on your ability to manage stress years after your participation in this study is complete. If this is ok with you, we will ask you to provide some information that will make it easier to contact you in the future. Do you agree to allow us to contact you long-term?

○ No
○ Yes

_____	_____	_____
Participant Signature:	Print Name:	Date: