Pilot Study on Mindfulness Meditation and Behavioral Flexibility Among Emerging Adults

NCT number NCT05560425
Document Date 10/10/2023

University of North Carolina at Chapel Hill
Consent to Participate in a Research Study
Adult Participants

Consent Form Version Date: October 10th, 2023
IRB Study # 21-1486
Title of Study: Training skills to support emerging adults navigate college life.
Principal Investigator: Charlotte Boettiger
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Funding Source and/or Sponsor: NIH National Institute on Alcohol Abuse and Alcoholism (NIAAA)

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The purpose of this research study is to train emerging adults skills in navigating college and measure sensitivity to reward conditioning. This study will include screening procedures to ensure eligibility, questionnaires that will be completed in-person and on a computer, learning skills to navigate college, performing a computerized task while recording eye movement, and providing a blood sample by finger prick. This study requires two in-person visits (1.75 hours each) and four virtual visits (1.5 hours each). Participants will be compensated for their time and have a chance to receive bonuses. There are no significant risks associated with participation in this study.

What are some general things you should know about research studies?
You are being asked to take part in a research study. To join the study is voluntary. You may choose not to participate, or you may withdraw your consent to be in the study, for any reason, without penalty.

Research studies are designed to obtain new knowledge. This new information may help people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies. Deciding not to be in the study or leaving the study before it is done will not affect your relationship with the researcher, your health care provider, or the University of North Carolina-Chapel Hill. If you are a patient with an illness, you do not have to be in the research study in order to receive health care.

Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study.

You will be given a copy of this consent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this study?
The purpose of this research study is to train emerging adults skills in navigating college life and measure sensitivity to reward conditioning.

Are there any reasons you should not be in this study?
You should not be in this study if you are under 18 or over 19, are not college enrolled, have any known neurological or psychiatric disorders, use any psychoactive medications (e.g. antidepressants or narcotic pain relievers), use any anti-inflammatory medication, do not speak English fluently, or do not have a high school diploma or equivalent.

How many people will take part in this study?

There will be approximately 18 people in this research study.

How long will your part in this study last?
Participation in this study will involve 6 visits; 4 virtual training visits and 2 in-person visits, all on separate days for a total of 10 hours. If you decide at any point that you do not wish to continue, you may leave with no negative consequences. The blood sample collected will be destroyed at the end of the study, and if you choose to leave the study your blood sample will not be analyzed.

What will happen if you take part in the study?
Participation in this study will involve 6 visits, which will occur on separate days, for a total of 9.5 hours. We will send you some questionnaires (online) to complete one month after the last visit.

If you agree to participate, first you will be seated comfortably in a quiet room in the Boettiger laboratory on the UNC campus. You will then need to complete the screening procedures listed below to make sure that you can participate in the rest of the study.

Visit 1 (Davie Hall)	Visits 2-5 (Zoom)	Visit 6 (Davie Hall)
Consent Form	Consent Form	Consent Form
Drug & Alcohol screen	Questionnaires	Drug & Alcohol screen
Health Screening	Skill training in either mindfulness meditation or transitioning to college life	Reward-Driven Attentional Bias Task
Neuropsychiatric Interview		Blood sample (by finger prick)
Reward-Driven Attentional Bias Task		Questionnaires
Blood sample (by finger prick)		
Complete questionnaires (prior to visit 2)		

Screening Procedures: (10-15 minutes)

- Fill out the Health Screening Sheet. This sheet screens for psychoactive medications, psychiatric or neurological illness, and major health problems, especially liver disease. It also screens for conditions incompatible with this study, including lack of English proficiency.
- Breathalyzer test, to detect alcohol in your system.
- Urine test for amphetamine/methamphetamine/MDMA ("ecstasy"), cocaine, opiates, THC, and PCP.
- After the on-site screening procedures described above, addiction and other psychiatric history will be assessed using a standard neuropsychiatric interview in a private testing room.

If the screening procedure determines that you can participate in the rest of the study and you choose to continue, this is what will happen next:

Testing Procedures:

- We will then explain the Reward-Driven Attentional Bias computerized task that we will ask you to complete while having your head resting on a chin rest so your visual attention can be tracked with an eye tracker. This task will ask you to pay attention to the images displayed and to respond according to the instructions by pressing a button. You will be given more detailed instructions and a practice visit before you begin (~2-3 minutes).
- You will complete the training and testing portions of the computerized task (~35 minutes).
- You will be asked to provide a blood sample (by finger prick) that will be used to test whether a specific inflammatory marker is associated with individual behavioral differences in the task you will perform.

Testing of the sample will take place in a UNC laboratory. The sample will not be used for additional tests, and any unused samples will be destroyed at the end of the study by the Boettiger Lab. (~5 minutes)

- You will be randomized to either a mindfulness meditation or transition to college life training group.
- You will be asked to fill out some questionnaires to quantify personality measures, mood states, personal alcohol and drug use, and family history of alcohol use. You do not have to answer any questions you do not wish to answer, for any reason. (Prior to visit 2).
- During visits 2-5, you will complete a few online questionnaires before virtually joining the training group you were randomized to at the end of visit 1 (mindfulness meditation or transition to college life training group).
- In-between Zoom visits you will either practice mindfulness skills or journal about college life skills for 10 min/day.
- During visit 6, we will collect another blood sample (~5 minutes), have you fill out some additional questionnaires (~20 minutes), and complete the computerized task again (~35 minutes). The Health Screening Sheet will be reviewed for any changes since visit 1.

What are the possible benefits from being in this study?

Research is designed to benefit society by gaining new knowledge. However, due to previously reported effects of Koru mindfulness training among emerging adults, you may experience a decrease in perceived stress and sleep problems if randomized to the mindfulness meditation training group.

What are the possible risks or discomforts involved from being in this study?

Answering the questionnaires may cause you emotional discomfort or distress. You may choose not to answer any question, and you may quit at any time during all tasks.

There are no risks for injury expected to occur with virtual discussion and training of mindfulness and meditation or college life skills. Potential risks include boredom or fatigue, but discomfort will be minimized by having all videos (aside from the instructor's) turned off throughout training. Additional discomfort may arise during mindfulness practice for subjects who have previously experienced trauma or are currently experiencing high stress. Participants will be followed up with and provided trauma resources if necessary.

Participants will be asked questions regarding use of illegal substances and involvement in activities such as driving while under the influence of drugs and/or alcohol. To minimize risk, participants may choose not to answer any question and they may terminate participation at any time during all tasks. Participant's data will only be identified using an ID assigned to them at the beginning of the study. Any paperwork that includes participants' names or other personal information will be kept separate from study documents with their ID number and will be stored in a locked file cabinet in the locked lab. All data will be archived without personal identifiers, using only ID numbers.

There are no known risks for injury associated with the behavioral components of these cognitive studies. Other possible risks include frustration, boredom, or fatigue. Moreover, participating in computerized cognitive tasks with use of eye-tracking technology may make subjects anxious or uncomfortable. Based on our previous experience, it is unlikely that participants will find these potential psychological risks extreme enough to end their participation.

There may be uncommon or previously unknown risks. You should report any problems to the researcher.

What if we learn about new findings or information during the study?

You will be given any new information gained during the course of the study that might affect your willingness to continue your participation.

How will information about you be protected?
Information collected for the purpose of this research study will be kept confidential as required by law. All copies of test records and results will be kept in locked filing cabinets, in locked offices, or in computer files that require a password to get to. All information will be accessible only to authorized study personnel. Codes will be used on all data sheets in place of your name. All outgoing emails will be encrypted; however, text messages about appointment reminders will be unencrypted.

Participants will not be identified in any report or publication about this study. Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, UNC-Chapel Hill will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this research study could be reviewed by representatives of the University, research sponsors, or government agencies (for example, the FDA) for purposes such as quality control or safety. We may use de-identified data and/or specimens from this study in future research without additional consent.

What is a Certificate of Confidentiality?
To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. 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 Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law, such as mandatory reporting requirements for child abuse or neglect, disabled adult abuse or neglect, communicable diseases, injuries caused by suspected criminal violence, cancer diagnosis or benign brain or central nervous system tumors or other mandatory reporting requirement under applicable law. The Certificate of Confidentiality will not be used if disclosure is for other scientific research, as allowed by federal regulations protecting research subjects or for any purpose you have consented to in this informed consent document.

You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

Will you receive results from research involving your specimens?
Most research with your specimens is not expected to yield new information that would be meaningful to share with you personally. There are no plans to re-contact you or other subjects with information about research results.

What will happen if you are injured by this research?
All research involves a chance that something bad might happen to you. If you are hurt, become sick, or develop a reaction from something that was done as part of this study, the researcher will help you get medical care, but the University of North Carolina at Chapel Hill has not set aside funds to pay you for any such injuries, illnesses or reactions, or for the related medical care. Any costs for medical expenses will be billed to you or your insurance company. You may be responsible for any co-payments and your insurance may not cover the costs of study related injuries.

If you think you have been injured from taking part in this study, call the Principal Investigator at the phone number provided on this consent form. They will let you know what you should do.

By signing this form, you do not give up your right to seek payment or other rights if you are harmed as a result of being in this study.

What if you want to stop before your part in the study is complete?
You can withdraw from this study at any time, without penalty. The investigators also have the right to stop your participation at any time. This could be because you have had an unexpected reaction, or have failed to follow instructions, or because the entire study has been stopped.

Will you receive anything for being in this study?
Study participants will receive either 6.0 class credits or monetary compensation for their participation and either consistent training of meditation skills or journaling about college life skills. Participants will also have opportunities to receive gift card bonuses based on computerized task performance. After visit 1, participants will be sent the study questionnaires/surveys (on REDCap) via email to complete prior to their second visit. They will be compensated with a $15 gift card for completing these surveys. During visits 1 and 6, participants can receive bonuses for accuracy performance during the Reward-AB task, but at a minimum be compensated at $12/hour. At the beginning of visits 3-6, participants will be given a $10 gift card if they practiced or journaled about skills learned during the previous week ≥3 days, or a $20 gift card if ≥5 days. Participants will be given a $10 gift card for completing online questionnaires one month after visit 6. Participants will be reimbursed for any parking costs and/or ride share options for visits 1 and 6.
If you withdraw from the study, you will receive class credits or compensation according to the time you have participated. Participants will receive 1 credit for completion of visit 1, 3 credits for completion of visits 1-5, and 6 credits for completion of all study visits (visits 1-6; excluding follow-up email) and procedures.

Your name, address, and social security number (SSN) are required to process payments and/or to report taxable income to the IRS. You will be asked to sign a separate Social Security Number Collection form. If you do not provide your SSN (or ITIN), we cannot issue you a payment for participation. However, you may still choose to participate in this study.

Will it cost you anything to be in this study?
It will not cost you anything to be in this study.

Who is sponsoring this study?
This research is funded by the National Institutes of Health, National Institute on Alcohol Abuse and Alcoholism (NIAAA). This means that the research team is being paid by the sponsor for doing the study. The researchers do not, however, have a direct financial interest with the sponsor or in the final results of the study.

If you withdraw or are withdrawn from this study all data collected up until the point of withdrawal will be retained, however no additional information will be collected unless you provide additional written permission for further data collection at the time of your withdrawal.

What if you are a UNC student?
You may choose not to be in the study or to stop being in the study before it is over at any time. This will not affect your class standing or grades at UNC-Chapel Hill. You will not be offered or receive any special consideration if you take part in this research.

What if you have questions about this study?
You have the right to ask, and have answered, any questions you may have about this research. If you have

questions about the study (including payments), complaints, concerns, or if a research-related injury occurs, you should contact the researchers listed on the first page of this form.

What if you have questions about your rights as a research participant?
All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject, or if you would like to obtain information or offer input, you may contact the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

Participant's Agreement:

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate in this research study.

_____ _____
Signature of Research Participant Date

_____
Printed Name of Research Participant

_____ _____
Signature of Research Team Member Obtaining Consent Date

_____
Printed Name of Research Team Member Obtaining Consent