Informed Consent

Study Title: Project MiCRIM: Sleep and Stress

Intervention Date: March 8th, 2022

Permission to Take Part in a Human Research Study

Title of research study: Project MiCRIM

Investigator: Scott M. Pickett, PhD

Key Information: The following is a short summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form.

Why am I being invited to take part in a research study?

We invite you to take part in a research study because you are an adult, between 18 and 24 years old, that is a criminology or criminal justice major.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?

The purpose of this research is to test a brief online mindfulness-based intervention that incorporates informational elements about mindfulness, thoughts, emotions, and acceptance. The data from this study may inform future studies examining the benefits of mindfulness practices on stress and rumination, which are often associated with short sleep and/or sleep complaints. If the study intervention proves to be effective, it could help fund future studies on possible interventions.

How long will the research last and what will I need to do?

We expect that you will be in this research study for 4 weeks, while completing a daily sleep questionnaire and a guided mindfulness-based meditation online (about 30 minutes) at least 5 days per week. Additionally, you will complete a set of questionnaires before and after the 4 weeks.

You will be asked to complete a set of questionnaires about sleep patterns and your emotions before coming in to your first session. During your first session, you will be giving a saliva sample collected from your mouth after fasting (only consuming water and/or black coffee) for 12 hours prior to the session and will be provided with instructions about wearing an Actiwatch (sleep tracking device) and completing a sleep diary for the next 4 weeks. In addition to this, you will be instructed to complete a brief mindfulness-based meditation practice online paired with supplemental information about mindfulness, thoughts, emotions, acceptance, and (optional) sleep improvement methods for at least 5 days each week. You will answer a 3-question survey related to the mindfulness practice and sleep improvement methods each time. After 4 weeks, you will be asked to come back to the laboratory in order to provide a saliva sample collected from your mouth after fasting (only consuming water and/or black coffee) for 12 hours prior to the session. Additionally, your Actiwatch and sleep diary data will be reviewed and you will be asked to complete a final set of questionnaires.

More detailed information about the study procedures can be found under ***"What happens if I say yes, I want to be in this research?"***

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Is there any way being in this study could be bad for me?

The risks associated with this study are minimal. You may experience distress answering some of the questions about your emotions. Additionally, there are less than minimal risks associated with wearing the Actiwatch device may feel uncomfortable and/or there may be the possibility of minor skin irritation. It is highly unlikely that you will experience these risks. There are less than minimal risks associated with providing a saliva sample.

More detailed information about the risks of this study can be found under ***"Is there any way being in this study could be bad for me? (Detailed Risks)"***

Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include possible improvements in sleep, stress, and/or rumination related to the intervention and/or learning new strategies to cope with daily stress.

What happens if I do not want to be in this research?

Participation in research is completely voluntary. You can decide to participate or not to participate.

Your alternative to participating in this research study is to not participate.

Detailed Information: The following is more detailed information about this study in addition to the information listed above.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at through the PI (Scott M. Pickett, PhD) at Scott.Pickett@med.fsu.edu or the study coordinator (Andrea Cheshure, M.S.) at acheshure@fsu.edu .

This research has been reviewed and approved by an Institutional Review Board ("IRB"). You may talk to them at 850-644-7900 or humansubjects@fsu.edu if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

How many people will be studied?

We expect about 40 people here will be in this research in the entire study nationally.

What happens if I say "yes" to being in this research?

If you choose to participate in this research, you will be asked to complete the following procedures:

- Session 1: you will read and sign the consent form on a computer at the research facilities/lab. Then, you will complete a set of questionnaires about sleep and emotions on the same computer.
- Upon completing the questionnaires, you will receive instructions on the following:
    1. How to wear a device called an Actiwatch (sleep tracking device) and sign a contract stating that you will care for and return the device as instructed
    2. How to complete a daily sleep diary, which will entail questions about before going to bed and after waking up
    3. How to follow a brief mindfulness-based meditation practice by following an online link. This will be paired with informational materials on mindfulness, thoughts, emotions, and acceptance; each of these topics will be covered each week, respectively. Additionally, there will be an optional sleep improvement methods module available to you, but not required to read through or engage in any sleep improvement methods. Finally, you will be instructed to complete a 3-question survey online based on the guided mindfulness-based meditation and sleep improvement methods.
- Session 2: Prior to coming in, you will be asked to fast for approximately 12 hours before your second scheduled appointment. You will return to the research facilities/lab, then your Actiwatch and sleep diary data will be reviewed for high quality data. If you provide at least 15 days of high quality Actiwatch and sleep diary data, you will be asked to complete a second set of questionnaires, similar to the first session. Then, you will be asked to provide a saliva sample in a plastic tube via the passive drool collection protocol (similar to the procedure you completed in Project BioSleep). At this time, all procedures have been completed and you will receive a debriefing document and monetary compensation for your time and effort.

- Below is a timeline of the study procedures.

Session 1	4-week intervention	Session 2
Provide saliva sample. Receive Actiwatch device and further instructions.	Follow an online link to a guided mindfulness-based meditation practice. Complete this at least 5 days/week. Answer a 3-question survey based on the guided mindfulness-based meditation practice and sleep improvement methods. Complete daily sleep diary questionnaires. Wear Actiwatch daily.	Return Actiwatch device to lab. Provide Actiwatch and sleep diary data to be analyzed by study personnel. Provide saliva sample. Receive debriefing document and compensation.

What happens if I say "yes," but I change my mind later?

You can leave the research at any time it will not be held against you.

If you choose to drop out of the study, data collection will stop immediately and no further data will be collected from you. Arrangements will be made in order for you to return the Actiwatch device to the research facilities/lab.

Is there any way being in this study could be bad for me? (Detailed Risks)

The risks associated with this study are minimal. You may experience distress answering some of the questions about your emotions. Additionally, wearing the Actiwatch device may feel uncomfortable and/or there may be the possibility of minor skin irritation. This device is similar to a wrist watch and any annoyance or irritation should likely resolve after the device is removed. If wearing the device results in annoyance or irritation such that you cannot continue in the study, you may remove the device at any time. It is highly unlikely that you will experience these risks.

There are less than minimal risks associated with providing a saliva sample.

Taking part in this research study may lead to added costs to you related to transportation to and from study locations in the local area (FSU facilities).

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this organization.

Any electronic data collected will contain participant ID numbers and responses to self-report measures. Any identifying information will be detached from stored electronic data. Electronic data will be stored without identifiers on a password protected computer in a locked office in the College of Medicine. Consent forms will be stored for 12 months after study conclusion. Saliva samples will be stored in a locked freezer in the same facility. De-identified data will be stored indefinitely. Authorized

research personnel at Florida State University's College of Medicine will have access to the data via a password-protected drive.

Your information or samples that are collected as part of this research may be used or distributed for future research studies, but all of your identifiers are removed.

We may publish the results of this research. However, we will keep your name and other identifying information confidential to the extent allowed by law.

Can I be removed from the research without my OK?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include refusal to participate in study activities.

What else do I need to know?

If you agree to take part in this research study, we will pay you $50.00 for answering the questionnaires provided, following the mindfulness practice procedures, providing at least 15 days of complete sleep data (use of Actiwatch and sleep questionnaires), and providing a saliva sample.

Permission to Take Part in a Human Research Study

Signature Block for Capable Adult

Your signature documents your permission to take part in this research.

Signature of subject	Date
Printed name of subject	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	