
Study Title for Participants: Brains, Emotion, and Sleep Together (BEST) study

Formal Study Title: Studies of anxiety and sleep in youth

Lead Researcher: Dr. Ned Kalin, (608) 263-6079, 6001 Research Park Blvd, Madison, WI, 53719

Institution: *University of Wisconsin-Madison*

Key Information

The information in this section is to help you decide whether or not you would like to be a part of this study. You can find more detailed information later on in this form.

Why are researchers doing this study?

This research is being done to help us learn why some children develop bothersome anxiety symptoms, and how this relates to sleep. This study may help develop new ideas about how to help people with these problems. You are being invited to be part of this study because you are a female between ages 8-11 who is safe for magnetic resonance imaging (MRI) brain scan.

What will I do in this study?

You will visit our research lab up to 6 study time. Study sessions will involve an interview and questionnaires about your thoughts, mood, feelings and health, practice in an MRI brain scanner, an MRI brain scan, samples of your saliva and cheek cells, and sleep studies at home and in the laboratory. We expect that you will be in this research study for about 3 months to complete all 6 visits, but it may be longer to make scheduling easier.

You can find detailed information about the study procedures in the section called **If I take part in the study, what will I do?**

What are some reasons I might – or might not – want to be in this study?

You may want to be in this study if you and are:	You may NOT want to be in this study if you:
<ul style="list-style-type: none">• Comfortable having researchers ask questions about your thoughts, mood, feelings and health• Willing to complete an MRI brain scan.	<ul style="list-style-type: none">• Want to be in a study that might help improve your own health.• Are not comfortable having researchers ask questions about your thoughts, mood, feelings and health.

<ul style="list-style-type: none">• Willing to collect sleep and mood information for a 2-week period.• Willing to give saliva and cheek cell samples for research tests.• Willing to sleep in the laboratory overnight – your parent will come with you.• Interested in helping with this study even though it won't help or benefit you.	<ul style="list-style-type: none">• Do not want to complete the MRI or sleep study sessions.
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Do I have to be in the study?

No, you do not have to be in this study. Taking part in research is your choice. You can stop the study at any time – nothing bad will happen and no one will be mad at you. You and your family can ask all the questions you want before you decide if you want to be in the study.

Detailed Information

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

Who can I talk to about this study?

The researcher at your session will answer any questions you may have about the study. In addition, you may call Dr. Kalin at (608) 263-6079 or Dr. Williams at (608) 262-2430 with any later questions or comments you may have about the study. You can also send an email with any questions or comments about the study to our study team at beststudy@psychiatry.wisc.edu.

If I take part in the study, what will I do?

You may be asked to participate in up to six study sessions, as well as the collection of sleep data at home, which are described below.

Study Visit 1: Interview

During Study Visit 1 a researcher will review the study with you and your parent to explain all the parts of the study and answer your questions. Your parent will be asked to sign a form to give their permission for you to participate, and the researcher will also you if you

want to be part of the study. If you say yes, we will move to the next part of the visit. If you say no, that will be the end of the study.

If you say yes to being in the study, you and your parent will both talk to a researcher and answer a lot of questions about you. This session may take place in our lab space, or it may take place on the computer as a video interview. Some of the questions are about your mood and feelings. You can choose not to answer a question if it makes you uncomfortable. We may make a recording of your discussion with the researcher to make sure we did everything correctly. We may also share the recording with researchers from the National Institute of Health, (outside UW Madison), but we will get rid of it after one year, and do our best to make sure your identity is kept secret. You will also complete some questionnaires on a computer about your mood and feelings. You can choose not to answer a question if it makes you uncomfortable.

Study Visit 2: Computer Task

You will complete some activities with study team members about words and patterns. We may place a couple of small sensors on your forehead and hands to measure the activity of the muscles around your eye while you look at pictures. You may also listen to some sounds over headphones. Some of the sounds over the headphones may be loud, startling, or a little unpleasant, like a scream noise. You will also answer some questions on a computer about your mood, feelings, experience, and your body. You can choose not to answer a question if it makes you uncomfortable.

Between Study Visits 2 and 3: Home Sleep Recording

Between study Visit 2 and Study Visit 3, you will wear a device that looks like a headband while sleeping at home up to five nights a week for up to two weeks. This headband will record your brain waves while you're asleep, and this will tell us how deeply you sleep and for how long. The headband is made of fabric and will fit in a circle around your head. Here is a picture of the headband for you to see. The strap of the headband can be adjusted to fit on your head. You will also wear a watch on your wrist to record your heart-rate during the day and while wearing the headband at night. When you go to sleep you will turn the headband on so it can record the information while you are asleep. In the morning, you will turn it off. We will show you how to do all of this, and your parent will also help you. This would all



Picture of the sleep headband

be done at home and you will be given a number to call if you have any problems. Before we start the study, you and your parent will have a training visit where you will get all of the things you need to run the study at home. While you are collecting this sleep data at home, we will also ask you questions about your mood throughout the day on a personal electronic device (e.g. phone or tablet) that we provide to you. You are only allowed to perform study-related procedures on the laptop and phone/tablet, no other use is allowed. All of the equipment will be returned to the study team when data collection is done. In the evening and in the morning, you will also answer some questions about mood and

sleep. We may also ask you to spit in a tube during the day when you answer the mood questions.

Study Visit 3: Computer Task and Practice MRI Scan

Similar to Visit 2, we will attach sensors to your forehead and hands and then have you view some pictures and listen to sounds over headphones. You will also complete a fake or practice MRI. This means that you will get to practice having an MRI scan in a pretend MRI scanner. This helps you get used to being in an MRI machine and lets you practice keeping your head still. It is REALLY important that you keep your head still so we don't get blurry pictures. The fake MRI scan will last about 30 minutes. The fake MRI looks a lot like the real MRI scanner, but it cannot actually take pictures of your brain. While you are in the fake scanner, we will ask you questions to make sure you are comfortable. You may also see some practice pictures like the ones you might see when you have your real MRI, so you can get used to what you will do in the real scanner.

Study Visit 4: MRI Scan and Samples

At Study Visit 4 you will have some more fake scans for practice before having the real MRI. You will also wear earplugs and headphones to help block out some of the sounds from the scanner. A covering will be placed on one of your fingers to record your heartbeat, and two small sensors will be taped on two of your fingers record sweat level. For some of the MRI scans you can rest. For others, you might see pictures projected above you. You may see pictures of faces, shapes, or other images that may be pleasant or unpleasant. Your scan session will be about 90 minutes and you can take a break during the session if you want to. You will be able to talk to and hear the person running the scanner.

While the MRI machine takes pictures of your brain it makes loud tapping and pinging noises. The earplugs and headphones you wear will block out some of these noises. During the entire MRI scan you will have to lie still trying not move your head or body. Sometimes some people have said they felt tingling in different parts of their body during the scan. This does not hurt and will not cause you any harm. We will do everything we can to make sure you are comfortable during your MRI. You will be able to stop being a part of the study at any time.

We will also ask you to give us samples of your spit up to 2 times during your visit to measure chemicals related to stress and development. We will also use a small brush to scrape the inside of your cheek to collect cells. This does not hurt and will be used to understand how your genes may contribute to what we find out from studying how your brain works.

Study Visit 5 and Study Visit 6: Laboratory Sleep Studies

Study Visit 5 and Study Visit 6 are overnight sleep studies in our laboratory. During these visits you will wear an EEG net on your head that looks like a hat covered with tiny cups called electrodes. In addition to the net on your head, we will add a few other things like stickers around your eyes, on your chin, behind your ears, and a few on your legs. We will also place a sensor on your finger, along with a belt around your chest and stomach

and a sensor below your nose to monitor your breathing. These additional sensors will allow us to see if you are sleeping normally throughout the night. With these additional sensors, and the electrodes still on your head, you will go to sleep. While you are sleeping, we will be recording you using a camera and microphone. This also helps us to see if your sleep is normal. Your parent will stay with you overnight, either in the same room, or in a room next door. For a few days before these sleep nights, we will also ask you to report some mood information like you did during the home sleep studies.

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

You can leave the research at any time. Nothing bad will happen and no one will be upset with you if you leave the study. If you do leave the study, we will use the information we have already collected from you.

Will being in this study help me in any way?

Being in this study will not help you directly. There is a possible benefit to other people. For example, if we learn something about the causes of anxiety and how it impacts sleep, we may be able to better help people with anxiety in the future.

What are the study risks?

When you talk with the researcher about your mood and feelings you will be asked some personal questions, which may make you uncomfortable. Most of the information you share will be kept private, but if the researcher thinks your safety is at risk, for example you are having thoughts about hurting yourself or someone else, they will share this with your parents. Also, if you share information about something bad that has happened to you such as being hurt physically or sexually, we may share this with your parents and/or appropriate supports and services to help keep you safe.

Some people should not have MRI studies. We will ask your parents lots of questions to make sure that you are okay to have an MRI. Some people don't like being in the scanner because they feel closed in and have to hold still. Some people also get tired or bored during the study. If you are uncomfortable in the scanner you can stop at any time. The MRI scanner makes loud tapping sounds when it is running, but you will be wearing earplugs and headphones to help block out the noise. People who are pregnant should not have MRI's. If you think you might be pregnant, you should tell your parent or one of the researchers that you do not want to be in the study. If you have started your period, you will take a pregnancy test before the MRI scan to make sure you are not pregnant. You will pee in a cup and your pee will be tested by someone on our study team. If you are pregnant, a doctor will talk with you and your parents about it.

You might not like wearing the headband or head-net for the sleep studies. You may find it uncomfortable. If it makes it hard to sleep or you don't like it, let your parent and us know and you can stop the study at any time. You may feel uncomfortable or nervous sleep in the laboratory – your parent will be with you for that visit.

What happens to the information collected for the research?

The results may be included in presentations to other researchers, but your name will never be used. We may also share the information we collect from you with other researchers. However, all the information we get about you will be kept secret and data we share will be labeled with a number instead of your name.

What else do I need to know?

Will I receive anything for participating?

If you agree to take part in this research study, we will pay you for your time and effort as follows:

- Visit's 1, 2, and 3 - \$50 each
- Home Sleep Data Collection - \$25/day for each day complete + a \$50 bonus for completing at least 8 of 10 possible days
- Visit 4 - \$100
- Visits 5 and 6 - \$100 each night, plus \$25 for the 3 days of data collection before each night of laboratory sleep.

If you decide to stop at any time you will still receive payment for the sessions that you finished.

How many people will be in this study?

We expect about 275 people will be in this research study.