CEDA Child Assent (Ages 10-14)

University of Wisconsin-Madison
Child Assent Form

Title of the Study: Cognitive-Emotional Development in Adolescents (CEDA)
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What is this study about?
A research study is a way to find out about something. We are doing this study to learn why some youth have sad or empty, worried or stressed a lot, while other kids hardly ever feel these things. You are being asked if you want to be in this research study because you are between the age of 10 and 16 years old.

What will I need to do if I am in this study?
There are three parts to this study. You’ll visit our clinic for three visits every year for two years. You’ll do the same things each year so that we can learn what about you changes or stays the same each year. You may also do some of these study visits over video chat.

In the first visit, we will ask you and your caregiver questions about your health, thoughts, and feelings. This talk could take a while, but you can take breaks whenever you need them. Then, we’ll also have you practice being in an MRI by using our simulator, which is not a real scanner, but it has the table that moves into the special tube. There are some sounds we will listen to and some games that we will play. The games are about how we can change how we look at a picture to feel differently about it, and how well we remember faces and places shown to us. Some of the pictures you see could give you strong feelings and/or make you uncomfortable. This practice MRI is used so kids can get a feel for what a real MRI is like. If everything goes OK in the simulator, and you are a good fit for our study, we’ll invite you back to finish the research. You’ll also be given a kit to collect your poop at home. We’ll have your parent send the kit to a lab on campus, so please don’t bring it in.

After we are done with this visit, our research team can write up a summary paper about how you’re doing. We can send this to your mental health provider so they better know how to take care of you. We will also send you an email and ask you to fill out some questionnaires online. You may repeat this visit if we couldn’t schedule your MRI scans in time.

In the second visit, we will practice one more time in the MRI simulator. This is to get you as ready as can be for the real MRI. After this practice session, we’ll have you use the bathroom. Then, we’ll go into the MRI control room and talk to the technologists while we put a few stickers on your face and hands. The stickers are used to measure things like muscles in your face and your sweat levels. Before the MRI starts, we will also give you some ear plugs, since the MRI is very loud. Once you are all set up, we will take pictures of your brain using the MRI machine while you rest or play simple games. The MRI techs will check on you with an intercom throughout the scan to make sure you are OK. You’ll also be given a “stop everything!” squeeze ball in case you suddenly feel sick or really scared in the scanner.

During the scan, your caregiver will have similar stickers placed on them, and they will play the same games and another game asking them to react to emotional pictures in different ways.

After the MRI, we will also get some spit samples and cut tiny pieces of your hair. We’ll do this in a way so it’s hard to notice the missing hair. We’ll also ask you to pee in a cup. We’ll test your spit, pee, poop, and hair to see
what is going on inside of your body. It may help us answer some questions about how your feelings can affect your body, or how your body affects your feelings. The saliva sample you provide will be used to test your DNA. DNA is a part of your body that helps determine things like what color your eyes are or if you have allergies. Every person has DNA and every person’s DNA is a little different. We will look at your DNA and see how it might relate to mental health. The DNA we collect will be used both by researchers here and may be shared with researchers outside of Wisconsin.

In the third visit, you will come back to play a couple of more games outside of the MRI scanner. Both you and your caregiver will play some games that look at vocabulary and ways of thinking, and will answer some questions, on an iPad. Last, you will work together with your caregiver to draw some pictures using an Etch-a-Sketch. You will be video recorded during this task. We will also use this this visit to finish up anything from the first or second visits that didn’t get done for any reason (like we ran out of time, or you maybe got too tired).

**ETCH-A-SKETCH GAME**

Like we told you earlier, one of the games you will play will be recorded by us using a video camera. We are the only ones who will get to watch them, they won’t show your name, and we will keep the video as safe as we can. Please let us know if you want to play this game.

**Youth Initials:**

_____ Yes. I, the Youth Participant, would like to participate in this task and **agree to be recorded** for study purposes

_____ No. I, the Youth Participant, **do not want to be included** in this task, and I **will not be recorded** for this task

If you are in another study for the Herringa lab, there may be some study activities you would usually do for both studies that you will only have to do once. The study team and your caregiver can tell you more about this.

We may offer you and your caregiver to complete some of these visits online. This means that you and your caregiver will do some or all of the activities at home during an online video chat with us. This includes the MRI practice session, you may complete this practice during a video chat or come in for a short additional visit to practice in person.

**Can I stop being in the study?**
You may stop being in the study at any time without penalty.

**Will anything bad happen to me if I am in the study?**
You may feel embarrassed or sad when we ask you questions about your feelings. You may feel scared when we ask you to lie still in the MRI machine. There’s also a small chance someone outside of the study could see your information.

**What good things might happen to me if I am in the study?**
If you are having lots of stress feelings we may be able to help your parent or your counselor or doctor figure out what’s going on so they can help you. Otherwise we do not think being in this study will help you. You may feel good knowing that what we find out from this study may help other people someday.
Will I be given anything for being in this study?
You may have already received a $10 gift card for doing the online screening and phone screening. You will get up to $640 for doing everything else for the study. You’ll get $75 for the first visits each year, $165 for the scan day each year, and $50 each third visit each year. You will also get a $50 bonus for repeating all three visits the next year. This money will be paid to your parent or guardian to take care of for you. After the MRI, you may also get a picture of your brain to take home.

Will anyone know I am in the study?
- Your being in the study will be kept secret. What we learn about you will be kept in a safe spot in the research lab.
- Your name will not be written anywhere on the sheet that you will write your answers on.
- We will be working together with other researchers to learn as much as we possibly can. The other researchers will not know you were in the study because all of your information is secretly coded.
- Researchers at the National Institute of Mental Health will also have some of the secretly coded information listed above.
- When we are finished with this study we will write a report about what was learned. This report will not include your name or that you were in the study.
- We will tell your parents or guardian and counselor about your answers if we think they need to know something you have told us. We would tell them if you are feeling really sad or are not feeling well. We may also tell them if we think there is a chance you could be pregnant. We are doing this so you can get better, and get the care that you need.
- We’ll be letting your doctor(s) know about how you’re doing so they can do their best to take care of you.
- To help protect your privacy, we have a Certificate of Confidentiality from the government that says we don’t have to tell other people what you tell us, even if a judge asks us. But you should know if you tell us that you or someone else might be in danger, we will take steps to get help.

Who can I talk to about the study?
If you have any questions about the study or any problems, you can talk to your parents, guardian or anyone on the research team. You can contact the research team at 608-265-3610 or brave@psychiatry.wisc.edu.

What if I do not want to do this?
You don’t have to be in this study. It is up to you. You can decide whether or not you want to be in this study, and you can stop being in it if you want to. If you say okay now, but change your mind later, that’s okay too. Just tell one of us.

Future Studies:
We would like to keep your contact information (like your name and phone number) so that we can reach you to be in future possible studies. If you and your caregiver agree to this, and you turn 18, we will contact you again at that time to make sure it is still ok to keep your contact information.
Child Authorization

Your mom or dad (or guardian) has to give permission for you to be in this study if you decide you want to participate.

I have been told about the study and what I will need to do if I agree to be a part of it. I agree to be in this study. I have been told that I can stop at any time. If I have any questions, at any time, they will be answered. I can keep a copy of this paper.

If you would like to be in the study, please fill out the lines below.

Child’s Name (Please print)

First: ______________________________ Last: ______________________________

Child’s Signature or Initials: ______________________________ Date: _____________________

Principal Investigator or Person Obtaining Assent/Consent:
I have discussed this research study with the child using language that is understandable and appropriate. I believe I have fully informed the participant of the nature of the study and its possible risks and benefits. I believe the participant understood this explanation and assented to participate in this study.

Name of Person Obtaining Assent/Consent: ______________________________

Signature: ______________________________ Date: ______________

You should receive a copy of this form after signing it.