TITLE OF THE STUDY: Learning Observation in Kids (LOKI)

LEAD RESEARCHER: Ryan Herringa, M.D., Ph.D.; (608) 263-6068

INVESTIGATORS: Ryan Herringa, M.D., Ph.D., Assistant Professor, Department of Psychiatry; Josh Cisler, Ph.D., Assistant Professor Department of Psychiatry

Why is this research being done?
A research study is a way for us to learn new things. We are doing this study to learn about how some kids may be or act different after something very bad or sad happens to them and why some of these kids may feel sad, empty, stressed, or worried while others do not. We want to learn about this by looking at the relationship with your caregiver and the way you can learn new things by watching them do something. You are being asked to be in our research study because you are between the age of 10 and 14 years old. You can decide whether or not you want to be in this study, and you can stop being in it if you want to.

How long will the study last?
You will come to the clinic five different times within one or two months. Each time you come to the clinic, you will stay for 2 to 4 hours. You may also do some of these study visits over video chat. Six months after these study visits, we will also ask to answer some questions at home.

What will happen during the study?
There are six parts to this study. You’ll visit our clinic up to five times and will do an online survey at home 6 months after you visit the clinic.

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 a similar table that moves into the special tube. There are some sounds we will listen to that will sound like a real MRI scanner. 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 will invite you back to finish the research.
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, third, and fourth visits, we can practice again in the MRI simulator if you want to. Then, we’ll go into the MRI control room and talk to the MRI technicians, the people running the scan, 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. We will also place a couple of stickers on your other hand, and that is where you will feel a buzzing or tingling sensation. While you will get to choose how strong this buzzing will feel, we want it be annoying but not painful. When you choose the level that you want, we will use that for all of the scan days. 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 a learning game. During the game on all three days, you will just look at a lot of pictures. Sometimes you may feel that buzzing or tingling sensation on your fingers. You will also watch a video of your caregiver playing the game while you are in the scanner.

The MRI techs will check on you with an intercom throughout all of the scans to make sure you are OK. You’ll also be given a “stop everything!” squeeze ball in case you suddenly feel sick or very scared in the scanner. At the end of each day, someone on our study will ask you a few questions about what you remember about the task.

While you are doing the MRI scans, your caregiver will play the same learning game in a different room. They will have similar stickers placed on them as you do and will feel the same buzzing or tingling sensation on their fingers.

We will also get some spit samples and cut tiny pieces of your hair. We’ll do this carefully so you won’t notice the missing hair. We’ll also ask you to pee in a cup. We’ll test your spit, pee, 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.

Your spit from the tubes will be used to test your DNA. DNA is a part of your body that helps choose 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 to see how it might relate to your feelings and behaviors. The DNA we collect will be used both by researchers here and may be shared with researchers outside of Wisconsin.

In the fifth visit, you and your caregiver will come back to play a couple more games outside of the MRI scanner. These games will be about people’s facial expressions. While you play all of these computer games, you and your caregiver will have some stickers and a belt placed on you to see how your body is working when you’re playing the games, similar to the stickers and belt you wore during your scans. Both you and your caregiver will play some games that look at vocabulary and ways of thinking, and you 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 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 tired and wanted to finish early).

**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

We may offer you and your caregiver to complete the first and/or fifth visit 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.

About six months after you finish all of these study days, you will get an email with a link to some final online surveys. It will ask similar things to the other online surveys about your feelings, thoughts, and things that have happened to you.

It is really important that you do not talk about what you see or do in the study with your caregiver until after all three MRI scans are done. This helps us make sure that you and your caregiver are not changing your answers because of what the other person said.

If you are in another study for the Herrinaga 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.

**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.

**Will I be given anything for being in this study?**

You may have already gotten a $10 gift card for doing the online survey. You will get up to $500 more for doing everything else in the study. You will get:

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Day 1</td>
<td>$75</td>
</tr>
<tr>
<td>Day 2</td>
<td>$100</td>
</tr>
<tr>
<td>Day 3</td>
<td>$100</td>
</tr>
<tr>
<td>Day 4</td>
<td>$150</td>
</tr>
<tr>
<td>Day 5</td>
<td>$50</td>
</tr>
<tr>
<td>Extra Surveys</td>
<td>$25</td>
</tr>
</tbody>
</table>
The money will be given to your caregiver to take care of for you. After the MRI, you may also get a picture of your brain to take home with you.

**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 in order to keep your answers a secret.
- 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.
- 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.

**Will anything bad happen to me if I am in this 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. You may not like the feeling of the stimulation or may not want to continue to feel it. 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 this study?**
If you are feeling sad or worried or stressed or something bad or sad has happened to you, we may be able to tell your parent or someone like a counselor so they can figure out what is going on and can help you feel better. Otherwise, we do not think that being in the study will help you. You may learn something new about your caregiver and feel good knowing that what we find out from this study could help other people someday.

**Are there other things I could do instead?**
You don’t have to be in this study for doctors to take care of you. You can decide not to be in this study, and no one will be mad at you.

**Who can I talk to about this 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. During the three scan days, we will ask that you
don’t talk to your caregiver about what you did or saw during the task. However, you can always talk to them about the study as a whole or any worries or questions you have.

Finally, you can always contact someone on our research team. You can call us at 608-265-3610, email us at braveyouthlab@psychiatry.wisc.edu, or talk to one of us while you are at the clinic.
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 will get to keep a copy of this paper.

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

First Name: ____________________________ Last Name: ____________________________  
(please print)

Child’s Signature or Initials: ____________________________ Date: ______________

For administrative use on day of scan:
Initials: __________ Date: ___/___/___

Person Obtaining Assent/Consent:
I have discussed this clinical 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: ______________