Activating and Connecting Teens (ACT) Study

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UNIVERSITY OF WASHINGTON
CONSENT FORM
Activating and Connecting Teens (ACT) Study

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If there is an emergency, you can call Children's Hospital at 206-987-2000, and ask to speak to the psychiatrist on-call.

Researcher's statement
We are asking you and your child to be in a research study. The purpose of this consent form is to give you information to help you decide whether to be in the study or not. Please read the form carefully. You may ask questions about the purpose of the research, what we will ask you to do, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions, you can decide if you want to be in the study or not. This is called "informed consent." We will give you a copy of this form for your records.

COVID-19 Study Changes

While COVID-19 social distancing recommendations are in place, all study procedures, including assessments, tasks, and therapy, will occur via telephone or HIPAA compliant, secure teleconference video visits. All telephone or teleconference video platform accounts are managed by either the University of Washington or Seattle Children's Hospital. To eliminate in-person interactions, we will not be conducting the Magnetic Resonance Imaging (MRI) portion of the study, so payment for this portion of the study will not be applicable ($75 per MRI scan). The wearable fitness trackers will be mailed to you once we determine study eligibility after Visit 1, so we will collect your address in order to mail the devices. Payments will now occur electronically, such as receiving a gift card or direct account payment. All other parts of the study will remain the same as outlined below.

PURPOSE OF THE STUDY

We want to learn how a form of "talk" therapy, called Behavioral Activation (BA), works for depressed teens who have experienced significant stressful events in their past. This therapy has been shown to help depressed teens feel better, but we do not know *why* this therapy works. The purpose of this study is to understand how this therapy changes behavior and brain regions involved in positive emotions and experiences. We also want to learn how changes in behavior and the brain improve depression over time.

STUDY PROCEDURES

This is a 24-week study that involves two in-person visits before treatment, weekly treatment visits for 12 weeks, two in-person visits after treatment and a follow-up 12 weeks after treatment has ended. An app will be downloaded to your child's smartphone. This app will measure behavior daily as well as prompt your child to answer questions about his or her mood twice weekly across the first 12 weeks of the study. The in-person visits will each take about 2-3 hours each, the treatment visits will take about 60 minutes each, the 24-week follow-up will take about 30 minutes, and the smartphone survey measures will take about 30 minutes or less per week.

What your child will be asked to do

Assessment Visits Weeks 0 and 12: During the assessment visit in Weeks 0 and 12, we will ask you and your child to fill out surveys about your child's mental and physical health, life experiences, and family dynamics. For example, you and your child will answer questions about his or her mood, stressful experiences like arguments with friends, and how well your child gets along with family. You and your child will be asked to complete some surveys and interviews that ask about sensitive topics. For example, you and your child will be asked to report about traumatic events he or she might have experienced as a child (e.g., being harmed by an adult), thoughts of suicide, and use of tobacco, drugs, and alcohol. Your child will also be asked to fill out a survey about their sexual orientation as well as their level of pubertal development that includes pictures to help answer accurately. Some children might feel embarrassed by these questions. If you would like to see the pubertal assessment survey, or any other survey, before we administer it to your child, please let us know. In addition to answering questions about your child, you will be asked about your own mental health, such as questions about your mood, including thoughts of suicide. You or your child do not have to answer any items that you do not feel comfortable answering.

Once the interviews and surveys are complete, we will describe the main MRI tasks to your child and ask if he or she wants to continue with the study. If he or she agrees, we will ask your child to practice these tasks that have to do with emotion and reward learning. The tasks involve looking at pictures of people and objects (some positive, some negative, and some neutral) and responding to them in various ways. Your child may practice being in the MRI by scheduling a time in a mock scanner beforehand.

MRI Visits Weeks 0 and 12: During the MRI visits in Weeks 0 and 12, your child will complete a brain scan while doing some of the tasks he or she practiced in the previous study session. The session will last about 2 hours in total, but the time in the scanner will be shorter, about one hour. This session is taking place at the Diagnostic Imaging Sciences Center/Integrated Brain Imaging Center located in the basement of the RR wing in the Department of Radiology, University of Washington Medical Center.

In the study visit, we will perform magnetic resonance imaging (MRI). The MRI machine uses a strong magnet and radio waves to make images of the inside of the body. The scanning procedure is very much like an x-ray or CT scan but it does not involve radiation. Your child will lie on a long narrow bed for about 60-75 minutes while the machine gathers data and makes

pictures of his or her brain. At the beginning of the visit, we will show you and your child the MRI machine so you can see how it works and so you know what to expect. The MRI exposes your child to a magnetic field, which your child will not feel. Your child will, however, hear a lot of tapping noises from the MRI scanner. We will give your child earplugs or ear phones to wear to reduce the sounds of the MRI scanner. The space in the large magnet where your child lies is somewhat confined. But, we have taken many steps to help the "claustrophobic" feeling. MRI scanning is commonly used, even with young children and adolescents.

Before the MRI scan, we will ask you and your child to fill out a few confidential surveys asking about the presence of metal in your child's body. Because the MRI scanner is a large magnet, we must be sure that your child does not have any metal when he or she enters the magnet room. If we think that it will make the MRI scan easier for your child, we will ask them to practice the tasks that he or she will do in the MRI scanner during a "practice" scan. The practice scan will be in a machine that looks like the MRI scanner but does not actually take any pictures. Because there are unknown risks from having an MRI for females who are pregnant, pregnant females cannot have an MRI. To make sure that no pregnant females have an MRI, all females will be given a pregnancy test. The results of this test will be given to your child and it will be up to her whether she wants to tell you or not. If you do not want your child to have a pregnancy test, she cannot have an MRI. However, she may still participate in the first study visit.

We will be able to contact your child at any time during the testing session. We will stop the scan session if your child feels that he or she does not wish to participate anymore.

After the introduction to the MRI machine, we will remind your child about the tasks he or she practiced during the previous session ask if he or she wants to continue with the study. We will then ask if he or she would like to practice being in the scanner to get more comfortable with it.

We will use two tasks in the fMRI session that will last between 10 and 20 minutes each. Each of the tasks involves looking at shapes or of people feeling different emotions. In some of the tasks, we will ask your child to only look at the pictures and press a button when a certain kind of picture appears. In one of the tasks, your child will have a chance to win an additional monetary reward based on how well your child does in the task.

While your child is in the scanner, we will also collect images of the structure of your child's brain. While we collect those images, your child will be watching a video of their choice (either a cartoon, sports game or dance video) to feel more comfortable and enjoy the scan more.

Finally, your child will receive a wearable fitness tracker and apps will be downloaded on your child's smartphone to measure things like physical activity, sleep quality, heart rate, time spent on the phone and number of texts/calls. The data pulled from your child's smart phone will be sent once daily to a secure encrypted server in a secure location, using secure methods. No information will be collected on where your child is spending time or who he or she calls or texts or what he or she is typing or saying on the phone. All data will be de-identified, meaning the phone numbers will be removed before storing other data elements.

The total session will last about two hours.

Smartphone Surveys: During the time in between the Week 0 and 12 study visits your child will be asked to respond to some questions via his or her smartphone about feelings and behaviors. This will happen two days per week with the smartphone app prompting him or her to answer questions three times during the day. This will take about 2 to 3 minutes each time. If your child is unable to answer the questions when they appear, your child can delay answering for up to two hours or can ignore the survey if he or she is unable to complete it within the two hour period. If your child is unable to respond to the questions at one time, he or she will still be able to answer questions in the next series. When downloading the app, we will turn on an option on your child's phone that only allows the app to work when connected to WiFi so there will be no data charges.

Importantly, answers to smartphone questions will not be monitored by study staff on a regular basis. Therefore, responses to smartphone questions can not be used to contact study staff. We provide local mental health and 24-hour crisis line referrals as part of participation in the study in case you or your child need mental health services or help during a crisis. Your child can continue with the rest of the study procedures even if he or she decides to not participate in the smartphone questions.

Treatment: If your child is eligible, he or she will be asked to participate in BA treatment. Your child will be asked to take part in 12-weeks therapy with one 50-minute session each week. Most sessions will only involve your child and the therapist. There are a few sessions, however, where the session will be split in two parts. During these sessions, your therapist will work with your child alone for part of the time, and with you and your child for the rest of the time. The focus of sessions will be on ways to help your child understand and cope with feelings of sadness and depression.

If we feel that your child might need extra help with his or her depression by taking medication, we will let you know. We can help you find a doctor to help make this decision. If you have questions about this, please let us know.

Follow-up Week 24: About 12 weeks after your child has completed treatment, we ask your child to complete follow-up surveys about mood, mental health, and life experiences since we last met either by phone or in-person.

Study Withdrawal: You and your child may be withdrawn from the study if your child misses 3 consecutive therapy sessions, develops exclusionary criteria (e.g., substance abuse, psychosis, mania) that would require a different mental health intervention (e.g., different type of therapy or certain psychiatric medications), requires a higher level of mental health care (e.g., inpatient mental health care), or is unable to complete the MRI scan (e.g., has metal in body, becomes pregnant) during the course of the study. If a different or higher level of care is required, we will work closely with you and your child to find appropriate mental health care. If withdrawn from treatment, we will ask for your permission to contact you and your child for a final assessment visit.

Recording of Study Procedures: Interviews and therapy sessions will be audio-recorded, and this is required as part of the study to make sure the interviewing and therapy is being done the same across all participants. We would also like to use the audio-recordings to train future therapists and research staff, and you have the chance to decide whether you are okay with the audio-recordings being used to teach others. You can change your mind about whether you are okay with the audio-recordings being used for teaching purposes at any time.

RISKS, STRESS, OR DISCOMFORT

Assessment Visits: There are no physical risks to the Week 0 and 12 assessment visits. Your child might feel some mild brief negative emotion associated with answering sensitive questions or viewing the pictures from the practice tasks. If your child experiences a strong emotional reaction to the study materials, you can be put into immediate contact with the primary investigator, Dr. Jessica Jenness. If you or your child experience any type of research-related harm, including emotional distress, you may contact the principal investigator of this study at (206) 616-7967. If your child decides he or she does not want to do the study any more, you or your child may stop at any time.

Breach of confidentiality is a risk to being in the study, for example if you're and/or your child's information was accidentally given to or was taken by someone who should not have it.

MRI Visits: The MRI is generally considered a harmless imaging technique because it does not involve exposure to ionizing radiation such as x-rays. There are, however, some risks with MRI that are easy to avoid but which you should be aware of. These potential risks very rarely cause harm when MRI is performed within established guidelines by people who are trained.

MRI uses a powerful magnet to make images. Therefore, persons with metal implants, such as certain types of surgical clips or pacemakers should not have an MRI. Other metal objects such as keys, pocketknives, or some types of jewelry must be removed prior to entrance to the magnet room. These objects can be pulled towards the magnet at very high speeds and can cause serious injury. Your child will be screened for such objects to make sure this does not happen.

In addition to a large magnet, the MRI scanner also uses radio frequency waves that can, on rare occasions, cause a mild warming sensation similar to what you feel on a warm day at the beach. The MRI scanner makes loud banging noises during the scanning session. During the MRI study your child will be given with earplugs to reduce the noise heard from the scanner. It is also possible that the magnetic fields in the scanner can cause mild nerve and muscle twitching in the arms and legs. Such effects are extremely rare, however. Some people simply find it uncomfortable and/or claustrophobic to lie in the confined space of the MRI scanner. If during the MRI your child gets nervous or upset, the procedure will be stopped. Although there are no known long-term harmful effects from having an MRI scan performed, it is always possible that there are long-term effects that are not presently known.

IF YOUR CHILD FEELS DISCOMFORT AT ANY TIME, HE/SHE CAN TELL THE OPERATOR AND HE/SHE CAN STOP THE EXAM.

The brain scans for this study are for research purposes only. They are not meant to be used for medical diagnosis. They are not meant to find medical problems or conditions. The investigators for this study are not trained to identify medical diagnoses. The investigators and the University of Washington are not responsible for failure to find existing medical conditions with these MRI scans. The scan will not be reviewed by the investigators for the purpose of detecting medical conditions or changes. There is a risk that the scans will reveal a brain medical condition in your child that you did not know about. If the investigators find something that might be a medical condition in your child, you will be told and, if you wish, we will send the scan information to your child's doctor. Any decisions about its significance and any medical care needed as a result of the information will be made by you and your doctor.

Treatment Visits: We hope the treatment offered to you will be helpful. It is possible that you will not find it helpful. Especially in the beginning of the research study, it is possible that your child's mood will feel no different and maybe even worse, before it begins to feel better. Some teens have serious problems, like feeling they want to hurt themselves or someone else. If your child feels like hurting him or herself, or hurting someone else, your child's therapist will evaluate your child's risk of harm and will make a safety plan with you and your child.

You should know that there are other treatments for teens that are sad and depressed. Some treatments involve taking antidepressant medications. Some treatments involve other forms of "talk" therapy, such as Cognitive-Behavioral Therapy. Some teens take antidepressant medications and participate in "talk" therapy. If your child prefers to get another treatment, you and your child do not have to participate in this study. We can help you find an alternative treatment.

You should also know that we cannot enroll participants currently taking medications for depression. Once enrolled, we will talk with you and your child about treatment with medicines if we think it is needed or if your child decides to take medication for depression, and we will offer referrals for that treatment. Whether or not your child takes medicines is a decision that you and your child would make.

CONFIDENTIALITY OF RESEARCH INFORMATION

As you and your child will be participating in a treatment study, it is important for us to open a medical record here at Seattle Children's Hospital (if your child does not already have one) and keep very general notes regarding your child's participation in treatment. More detailed notes of your child's progress in treatment will be kept in a separate, confidential, research chart.

We will make every effort to keep your child and your family's personal information confidential and private. We will only share what we learn about your child's depression with you and your child. If either you or your child want us to keep things we talk about confidential from each other, we will do so. There may be some information that we feel is important for both you and your child to know. If this is the case, we will talk with the person asking us to keep the information confidential. We will decide on a plan of action together.

Because your child's answers to the surveys in this study are confidential, we cannot share his or her answers with you. We will have safeguards to make sure all the information that we collect

from your session is kept confidential. The surveys and data will be identified only with a study ID number. We will store the records in a separate secure locked cabinet or password protected file on a secure research server, and only the study ID number will be used to identify your records in our data analysis. Your name, your child's name, and your identifying information will not be used in any reports of the research.

We will keep a link between your child's study ID number and you and your child's identity and study data until the end of the study visits. At the end of the first study visit, you will be asked about whether you are interested in being contacted for future studies. If you and your child agree to be contacted for future studies, we will keep the link between your child's study ID number and you and your child's identity and study data.

All information that may identify you or your child (e.g., your name and contact information) will be stored in a password-protected file on a secure research server, separate from the data collected during the study. Your and your child's name will not be directly connected to the study data for any reason other than deciding eligibility for future studies. This password-protected file will be the only link between your child's study ID number and you and your child's identifying information. The data from your child's smart phone will be stored on a secure encrypted server and stored in a de-identified way (i.e., his or her phone number will not be stored with the data), which means that this data will also be identified only by the study ID number. If your child turns 18 before the end of the study, we will need to get consent from your child as an adult to continue in the study and to collect and store smartphone data and responses. We will contact your child as soon as he or she turns 18 by phone to get verbal consent to continue to collect and store smartphone data and responses until we are able to get written consent for all study procedures at the next scheduled session.

All data collected in the course of this study will be made available to other researchers for future data analyses after the study is completed. We will share data with other investigators within and outside the University of Washington upon submission of a written request. If the request is approved, the data released will be "anonymized" which means we will remove information that would identify individual subjects (e.g., name, birthdate, address, contact information).

The MRI Screening Form includes your child's name, date of birth, sex, age, height and weight. We will assign a unique study code that will also be on the MRI Screening Form. All information collected from your child during the study (including the brain images) will be labeled with this code instead of your child's name or other information that can identify him or her directly. The MRI Screening Form will be kept separate from all other data at the Diagnostic Imaging Sciences Center/Integrated Brain Imaging Center. The signed Consent and Assent Forms will be kept separate from all other data in a locked cabinet in a locked room in our lab or in a password-protected file on a secure research server.

There are two exceptions to confidentiality. First, if we learn that you might harm yourself or your child might harm him or herself, we must report that information to the proper authorities. If we learn that your child might harm him or herself we will inform you and work with you to

make sure that a safety plan is in place. Second, if we learn that your child is being actively abused or neglected or has been abused or neglected in the past, we must report this information to the Department of Social and Health Services (DSHS). We will try to inform you and your child before we report this information to DSHS, but no matter what we would report within 48 hours. Study materials might be court ordered for use in custody or other court hearing. The researcher will make every reasonable effort to protect the confidentiality of the information, though it is possible that a civil or criminal court might demand the release of the material collected.

We have a Certificate of Confidentiality from the federal National Institutes of Health. This helps us protect your privacy. The Certificate means that we do not have to give out identifying information about you even if we are asked to by a court of law. We will use the Certificate to resist any demands for identifying information.

We can't use the Certificate to withhold your research information if you give your written consent to give it to an insurer, employer, or other person. Also, you or a member of your family can share information about yourself or your part in this research if you wish.
There are some limits to this protection. We will voluntarily provide the information to:

- a member of the federal government who needs it in order to audit or evaluate the research;
- individuals at the University of Washington, the funding agency, and other groups involved in the research, if they need the information to make sure the research is being done correctly;
- the federal Food and Drug Administration (FDA), if required by the FDA;
- state or local authorities, if we learn of child abuse, elder abuse, or the intent to harm yourself or others.

BENEFITS OF THE STUDY

Your child will be provided with evidence-based treatment for depression as part of this study. Neither you nor your insurance company will be charged for taking part in this study. The sponsor of this research, The National Institute of Mental Health will pay for the costs of the study. This includes the cost of therapy sessions each week.

SOURCE OF FUNDING

The study team and/or the University of Washington is receiving financial support for this research from the National Institutes of Health.

OTHER INFORMATION

Please understand that your and your child's participation in the research is voluntary and that you and your child are free to withdraw your consent and stop participation in the research at any time without any penalties or loss of benefits to which you are otherwise entitled. Some children may not be eligible to participate in the study or might only be eligible to participate in the first session. A description of this clinical trial will be available on http://www.clinicaltrials.gov, as

required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Website at any time

Your child will be paid $395 if all study procedures are completed ($50 each for the first and final study assessment visits, a total of $150 if both MRI visits are completed, a total of $120 if all smartphone surveys are completed, and $25 for the 24-week follow-up). You will be paid $60 if all study procedures are completed ($30 for the first and final study assessment visits) and reimbursed for parking during all visits.

Printed name of study staff obtaining consent Signature Date

Subject's statement

This study has been explained to me and my child. I volunteer myself and my child to take part in this research. I have had a chance to ask questions. If I have questions later about the research, I can ask one of the researchers listed above. If I have questions about my rights as a research subject or I or my child has been harmed by the study, I can call the Human Subjects Division at (206) 543-0098. I will receive a copy of this consent form.

Printed name of subject Signature of subject Date

Audiotape Consent:

I know that I have a choice in deciding whether my/my child's audio tapes can be used by the researchers in the future to teach other therapists how to conduct therapy with depressed teens. My preference is:

☐ I want my/my child's audiotapes to be used to teach other therapists how to do therapy.

☐ I do not want my/my child's audiotapes to be used to teach other therapists how to do therapy.

_____ _____

Signature of Teen Participant Date

_____ _____

Signature of Parent/Guardian Date