The Ohio State University Consent to Participate in Research

Study Title: Optimizing residential treatment gains for adolescents through tailored behavioral parent training: An RCT

Protocol Number: 2022B0315

Researcher: Kayla Herbell, Ph.D., RN

Sponsor: National Institute of Mental Health

This is a consent form for research participation. It contains important information about this study and what to expect if you decide to participate.

Your participation is voluntary. Please consider the information carefully. Feel free to ask questions before deciding whether or not to participate. If you decide to participate, you will be asked to sign this form and will receive a copy of the form.

Purpose: This study aims to test the outcomes of a web-based parent training program and discussion groups to support parenting and child behavior for parents of children admitted to residential treatment. We are interested in understanding how the program supports parents and children, especially during the transition from residential treatment to the community.

This study is open to any caregiver who cares for a child admitted to residential treatment. This includes grandparents, step-parents, adult siblings, foster parents, etc. If more than one parent of the child is interested in participating, we will separately consent each parent. However, for data collection and analysis purposes, each family will designate one parent as the "primary" parent. Data will be collected from the primary parent only, and the primary parent will be designated using a survey.

If you have multiple children in residential treatment that meet eligibility criteria, we will randomly select one of the children and you will answer questions about that child.

If you choose to participate in this study and you are the primary parent, you will:

Read this consent form and agree to participate. Complete all survey measures on a device with internet access. The research team will email you a link to access the surveys and be available to answer any questions you have regarding the surveys. The first visit (baseline) is at the time of enrollment and you will be asked to respond to survey questions about parenting and child behavior. The second set of questionnaires is six weeks after baseline and the third is six months after baseline. It will take approximately 1 hour each time you fill outthe surveys. Any data collected as part of the eligibility screening collected before you provided consent will be used for research purposes.

After completion of the baseline surveys, primary parents will be randomized into one of two groups: (1) intervention group or (2) the usual care group. If you are in the usual care group, you will continue the treatments and programming you normally engage in. For example, this may include regularly scheduled family therapy, case management, or other programming. If you are in the intervention group you will complete an online program and attend virtual parent groups. Activities will include completing two modules in a web-based program (takes approximately 20 minutes) and attending 90-minute discussion groups over Zoom. The research assistant will provide training on the assigned web-based program (e.g., logging in, how to begin using the program, and technical assistance). You will receive reminder text messages and phone calls throughout the 6-month study period. The study team will

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monitor how much you use the program. For example, we will collect whether you complete modules, how long modules take, and quiz scores.

If you participate in this study and are the non-primary parent you will:

Read this consent form and agree to participate. Complete a short set of questions about your background. Receive instruction regarding the primary parent intervention group assignment. If the primary parent is assigned to the usual care group, you will continue the treatments and programming you normally engage in. For example, this may include regularly scheduled family therapy, case management, or other programming. If the primary parent is assigned to the intervention group, the research assistant will provide standardized training on the assigned web-based intervention (e.g., logging in, how to begin using the program, and technical assistance). Surveys will be completed by the primary parent only. For parents attending group, the primary parent must attend (although you may participate). Both parents will have individual access to the assigned program content, and web-based program usage data will be collected from both parents.

Duration: The study lasts six months and the total time required for participating in the study varies depending on which group you are assigned. The total time commitment for parents in the intervention group is about 12.5 hours, while the total time commitment for parents in the usual care group is about 3.5 hours.

You may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with The Ohio State University.

Risks and Benefits: There are no known physical risks associated with participation in the proposed study or receiving the web-based program, parent groups, or the usual care conditions. There are no alternative treatments or procedures.

Study staff are committed to minimizing risks even when though risks are minimal. Potential risks related to the proposed study include coercion, the actual or perceived loss of confidentiality, participant burden, and discomfortwith data collection in that participants may feel uncomfortable being recorded or answering some of the questionsasked, or their responses may reveal problems in child behavior or parenting. If you do not wish to answer a question, you may skip it and go to the next question.

Your participation is voluntary and you can leave the study at any time.

Portions of this study are recorded. For example, the parent groups will be recorded to ensure we follow the study protocol. Further, the parent groups have other parents in them, and while we ask others in the group to keep the discussion content confidential, we cannot guarantee this. Please remember this when choosing what to share in the group setting.

In any study that collects information, there is a risk that information, or data, would be seen by someone outsidethe study team who should not have access to the information. We will take several actions to keep your information safe and confidential. Although we will have records that will allow your name and identifying information to be associated with your data and recordings, your survey responses or other online data we collect will be kept secure and associated with your unique ID number. Your data will be stored in a password-protected database, and only approved research team members will have access to it. When storing your data, we will use a unique identification code

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to identify you whenever possible. In this way, your name or other identifying information will onlybe connected through a separate file that links your name and the code. Given all of these actions, it is unlikely that your information would be seen by someone not authorized to see it.

We are required by the agency funding this research to assess for suicidal ideation using a questionnaire. If you endorse suicidal intent, we will help you to seek further assistance through resources such as a warm line or the National Suicide Hotline. Per state law, all research team members are required to report child abuse or neglect as well as significantsafety concerns related to wanting to harm yourself or others.

There are no direct benefits to individual participants.

Confidentiality: We will work to make sure that no one sees your online responses without approval. But, because weare using the internet, there is a chance that someone could access your online responses without permission. In some cases, this information could be used to identify you. Your data will be protected with a code to reduce the riskthat other people can view the responses.

Again, participation is voluntary.

There may be circumstances where this information must be released. For example, personal informationregarding your participation in this study may be disclosed if required by state law. Also, your records may be reviewed by the following groups (as applicable to the research):

Office for Human Research Protections or other federal, state, or international regulatory agencies; The Ohio StateUniversity Institutional Review Board or Office of Responsible Research Practices; The Sponsor, the National Instituteof Mental Health (NIMH), supporting the study.

Certificate of Confidentiality:
The NIH has issued a Certificate of Confidentiality for this study. This Certificate provides extra protection for you and your study information, documents, or samples (blood, tissue, etc.). The Certificates are issued so that we cannot be required to disclose any identifiable, sensitive information collected about you as a part of this study in a lawsuit or legal proceeding. We are also prevented from releasing your study information without your consent. This is a layer of protection over and above the already existing protections in place for you and your information, documents, or samples.

However, these protections do not apply in some situations. For example, we may have to release your information if a law requires us to do so, the Agency that is funding this study requests the information, or if the FDA tells us to release this information. We may also use your information to conduct other scientific research as allowed by federal regulations.

Study information that has health implications may be placed in your medical record where authorized employees may see the information. Further, authorized requests for your records (medical record release for continuity of care) may result in research-related information being released.

Please talk to the study team, or contact the Office of Responsible Research Practices at 614-688-8641, if you have questions.

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You may also visit the NIH website at https://grants.nih.gov/policy/humansubjects/coc.htm to learn more.

Clinical Trials: A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Will my de-identified information be used or shared for future research? Data from this study can be submitted to the National Institute of Mental Health Data Archive (NDA) at the National Institutes of Health (NIH). NDA is a large database that stores and manages de-identified study data from many NIH studies. Sharing your de-identified study data helps researchers learn new and important things more quickly than before.

De-identified study data means that all personal information about you (such as name, address, birthdate and phone number) is removed and replaced with a code number. The study researchers will have to collect your personal information to make that code number. The code number cannot be used to identify you, and the researchers will never send your personal information to NDA.

It is possible that you will participate in more than one study that sends data to NDA. NDA can connect your data from different studies by matching the code number on your de-identified data from each study. This data matching helps researchers who use NDA data to count you only once. It also helps researchers who use NDA to better understand your health and behavior without knowing who you are.

During and after the study, the researchers will send de-identified study data about your health and behavior to the NDA. Other researchers worldwide can request your de-identified study data for different research projects. Every researcher (and the institution to which they belong) who requests your de-identified study data must promise to keep your data safe and promise not to try to learn your identity. Experts at the NIH who know how to keep your data safe will review each request carefully to reduce risks to your privacy. Sharing your study data does have some risks, although these risks are rare. Your study data could be accidentally shared with an unauthorized person who may attempt to learn your identity. The study researchers will make every attempt to protect your identity.

You may not benefit directly from allowing your study data to be shared with NDA. The study data provided to NDA may help researchers worldwide learn more about how to better support families of children with mental illness. NIMH will also report to Congress and on its website about the different studies using NDA data. You will not be contacted directly about the study data you contributed to NDA.

Do you consent to having your data deposited in the National Institute of Mental Health Data Archive? You may decide now or later that whether you want your study data added to NDA. You can still participate in this research study even if you decide that you do not want your data to be added to NDA. If you know now that you do not want your data in NDA, please tell the researcher before the end of the appointment. If you decide any time after today that you do not want your data to be added to NDA, call or email the study staff, and they will tell NDA to stop sharing your study data. Once your data is part of NDA, the study researchers cannot take back the data that was shared before they were notified that you changed your mind. If you would like more information about NDA, it is available online at http://nda.nih.gov

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1, Yes, I consent to depositing my de-identified data into the National Institute of Mental Health Data Archive (NDA) at the National Institutes of Health.

2, No, I do not consent to depositing my de-identified data into the National Institute of Mental Health Data Archive (NDA) at the National Institutes of Health.

Incentives: Only the primary parent in the study will receive incentives. The primary parent will receive a $20 gift card at the first data collection appointment and $20 at the completion of surveys at the second and third time points. The total gift card amount is $60. If you choose to skip some questions because you are uncomfortable responding, you will still receive the incentive. By law, payments to participants are considered taxable income.

Participant Rights: You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status.

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights you may have as a participant in this study. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with The Ohio State University.

An Institutional Review Board responsible for human subjects research at The Ohio State University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of research participants.

Contacts and Questions: For questions, concerns, or complaints about the study, or if you feel you have been harmed as a result of study participation, you may contact Kayla Herbell, Ph.D., RN, 614-688-0959, herbell.3@osu.edu

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact the Office of Responsible Research Practices at 1-800-678-6251.

Will you be contacted about participating in future research? If you agree, we may contact you after your participation in this study about participating in future research. Please check one of the following options.
1, Yes, I agree to be contacted about future research.
2, No, I do NOT agree to be contacted about future

As a condition of participation in this study, primary parents must be able to have contact with their child who is in residential treatment. This means primary parents can freely speak to their child and/or visit their child. This also means that there are no orders from child protective services or other parties that say that you may not have contact with your child. By clicking “I agree” you certify that you are allowed contact with your child and there are no orders in place that restrict your contact.
1, I agree

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Providing consent

I have read (or someone has read to me) this page and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study. I am not giving up any legal rights by agreeing to participate.

To print or save a copy of this page, select the print button on your web browser.

Printed name of participant:

Signature of participant:

Date:

Time:

Investigator/Research Staff

I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

Printed name of person obtaining consent:

Signature of person obtaining consent:

Date:

Time:

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