UNIVERSITY OF OREGON

Informed Consent for Research Participation Form

Title: Integration of DBT Skills and Parent Training for Parents with a History of Substance Abuse
Sponsor: Center on Parenting and Opioids (CPO); National Institute of Drug Abuse (NIDA)
Protocol Number: STUDY00000041
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You are being asked to participate in a research study. The box below highlights key information about this research for you to consider when making a decision whether or not to participate. Carefully consider this information and the more detailed information provided below the box. Please ask questions about any of the information you do not understand before you decide whether to participate.

Key Information for You to Consider

- **Voluntary Consent**. You are being asked to volunteer for a research study. You may choose not to participate or to discontinue participation at any point in the study.
- **Purpose**. The purpose of this research is to test a new integrated and remote telehealth version of evidence-based group therapy and see how much it helps parents who have emotional difficulties and a history of substance use improve their own mental health and learn skills for parenting.
- **Duration.** The full study will last approximately 7 months following your consent to participate and your participation will be approximately 70 hours over the course of those 7 months.
- **Procedures and Activities.** There are 5 parts of the study: 1) You will participate in a clinical intake to see if you are eligible to participate in the full study. 2) You will complete a set of online questionnaires prior to the start of the group therapy. 3) You will participate in a weekly group therapy program for parents that lasts for 20 weeks (approximately 5 months). Sessions will take place remotely on [day of week] from [time] over Zoom, a HIPAA compliant video-conferencing software. 4) You will complete a set of online questionnaires at the end of the group therapy. 5) You will participate in a post-intervention exit interview.
- **Risks**. Some of the screening and survey questions will ask you about your emotions and personal experiences. This can sometimes be distressing and/or emotionally intense. Participation in group

therapy can also bring about intense feelings. There is a slight chance that confidentiality could be broken. If you report being a danger to yourself, others, and/or if it is suspected that your child has been or is being abused, we may need to contact authorities. Staff is trained at conducting risk assessments so that confidentiality is only breached when absolutely necessary.

- **Benefits**. If you are eligible to participate in the full study, then you will receive evidence-based treatment, which may or may not be of direct benefit to you. You may experience improvements in your mental health and parenting skills.

- **Alternatives.** Participation is voluntary and the only alternative is to not participate.

Who is conducting this research?
Yoel Everett is the Principal Investigator (PI) for this study and Dr. Christina Gamache Martin is a Co-Investigator (Co-I) on this study. Dr. Maureen Zalewski is the Principal Investigator of the UO START Lab and serves as a faculty advisor for this study.

This study is one of many studies in a large research project on parenting and substance use. The large project is organized by the Center on Parenting and Opioids (CPO). CPO involves researchers at both the University of Oregon (UO) and the Oregon Health & Sciences University (OHSU).

Why is this research being done?
We want to help parents who have a history of substance use and experience difficulties with mental health and managing emotions. We have created a group therapy for parents that combines several evidence-based treatments, which we anticipate will improve parents' mental health and provide parents with new skills for parenting. Up to 12 parents will participate in the study. We are doing this study to see how well this new group therapy works.

How long will I be in this research?
The full study has 5 phases that will take place over the course of about 7 months:
1) *Clinical intake*. This is a screening that will last 3-6 hours. We will meet for 3 hours today, and if we need more time, we will schedule another appointment. If you are eligible for the study, then you will complete the other 4 parts of the study. If not, then your participation will be complete.
2) *Pre-intervention assessment*. You will complete a set of online questionnaires about yourself, your child and your parenting. The questionnaires take approximately 1 hour to complete.
3) *Group therapy*. You will participate in a 20-week group therapy program for parents that takes place remotely on [day of week] from [time] over Zoom, a HIPAA compliant video-conferencing software. Each weekly session will last approximately 2.5 hours. You will also be asked to complete weekly online questionnaires before each session and this will take approximately 30 minutes.
4) *Post-intervention assessment*. Following the group therapy program, you will complete another set of online questionnaires about yourself, your child and your parenting. This will take approximately 1 hour to complete.
5) You will also be asked to participate in a 1 hour exit interview over Zoom.

What happens if I agree to participate in this research?

1) Clinical intake screening. A trained clinician who is a member of our research team will ask you questions about your mental health. You will complete a brief survey asking about your family's demographic information. You will do a short task about your vocabulary. We will discuss the results of the screening with you. If needed, you will receive recommendations for services separate from this study. The information we collect during this screening will help us determine if you are eligible to participate in the full study.

2) *Pre-intervention assessment*. If you are eligible for the study and choose to participate, then you will complete a set of online questionnaires about yourself, your child, and your parenting.

3) Group Therapy. You will meet remotely via Zoom, a HIPAA compliant video-conferencing software in a group setting with approximately 5 other parents for group therapy. The group therapy combines an evidence-based treatment program for improving mental health (Dialectical Behavior Therapy Skills; DBT) with evidence-based parent training programs for improving parenting quality and reducing children's emotional and behavior difficulties. The group will meet weekly for 20 weeks on [day of week] from [time]. Each session will be led by two co-leaders, who are clinical psychology PhD students working under the supervision of a licensed psychologist. Sessions will last approximately 2.5 hours. Prior to each session, you will fill out online questionnaires about yourself and your child and this will take approximately 30 minutes. At times, as part of standard clinical case management, we will ask to conduct a brief individual check in with you over the phone or on Zoom.

During each session, you will learn DBT Skills (mindfulness, distress tolerance, emotion regulation, and interpersonal effectiveness) and parenting skills (such as managing children's disruptive behavior and helping children to cope with difficult emotions). At home, in between each session, you will fill out a worksheet that takes about 10-20 minutes to complete. We hope you will also practice the skills you are learning. This should fit into your everyday activities without taking up extra time.

You must attend the group therapy regularly. We understand that you may need to miss a session if you are sick or have a serious emergency, and in such cases, we ask that you notify the group co-leaders. If you miss four (4) sessions in a row, then you may no longer be able to continue in the group therapy. You will be invited to complete the post-intervention assessment and exit interview no matter how many group therapy sessions you attend.

4) Post-intervention assessment. You will complete a set of online questionnaires about yourself, your child, and your parenting.

5) *Exit interview*. You will complete a 1 hour exit interview via Zoom where a trained clinician who is a member of our research team will ask about your mental health and about your thoughts and experiences from the group therapy.

The clinical intake and therapy sessions are video recorded for the purpose of clinical supervision, to enhance the therapists' skills, train therapists and further refine the development of the group therapy. The exit interview is video recorded so we can collect data on your experience in the group therapy.

What happens to the information collected for this research?

We will use the information we collect during this study to evaluate how well the integrated group therapy worked. Trained members of our research team will enter your responses on the questionnaires to a digital form. They will also watch and make digital notes about the video recordings of the exit interview.

The information collected will be combined with the information collected from other therapy group members. Trained members of our research team will then analyze the data to see how parents' mental health, children's mental health and behaviors, and parents' parenting changed during the study. We will report some findings at a group level (summarized across all participants) and some findings at an individual level. We will never include your name or your child's name in how we store your data or in any of the future reports about this research (see next section for more information about how we protect the confidentiality of your family's information). We may share the findings from this study in psychological and educational presentations, books, and articles.

We will destroy the video recordings and digital questionnaire data 3 years after our findings have been published.

We will create a digital file that includes scored data from each participant, with only each participant's codes ("de-identified data"). We will store this file on a password-protected server and keep it indefinitely. This de-identified data will be used for future research without obtaining additional consent.

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 Web site at any time.

Who will have access to my data?

Only trained members of our research team will have access to all of your study data. Please note that specific regulatory agencies may review the research records. Examples of these agencies include the University of Oregon Institutional Review Board (UO IRB) and federal funding agencies (e.g., National Institutes of Health; National Institute of Drug Abuse).

De-identified data from this study will also be shared to the CPO Data Repository (CPO-DR). "De-identified" means that all personal information about you (such as name, address, birthdate and phone number) is removed. The CPO-DR is a library for data. It stores data from many research studies. Researchers can use the data in the CPO-DR for research and teaching. Since we will not link your name or other personal information to the data in the CPO-DR, there will be no way for us to remove your data after we have shared it. You will not be contacted directly by other researchers about the study data you contributed to the CPO-DR. Sharing data from multiple studies helps researchers learn new and important things about mental health and substance use.

Data in the CPO-DR will be preserved indefinitely. Other researchers across the world can ask for access to the data in CPO-DR. Only researchers who have agreed to protect the confidentiality of participants and the privacy of the data will be authorized to access the CPO-DR. CPO staff will be responsible for determining which researchers have access to the data.

It is possible that data in the CPO-DR could be accidentally shared with an unauthorized person who may attempt to learn your identity. We will not share any of your personal information from our study to the CPO-DR. So, the risk of someone learning your identity by accessing CPO-DR data is small. We, along with the CPO staff, will make every attempt to protect your identity.

How will my privacy and data confidentiality be protected?

Because your honest answers are so valuable to us, we will do everything we can to keep the information you share about yourself and your child confidential (e.g. completely private) and secure. Here is how we will protect your privacy:

1. We train all members of the research team and any staff members from our entire lab with whom you may come in contact to protect your privacy. Research team members complete research training, in which confidentiality is reviewed. Additionally, only a select group of key staff members will have access to every component of the study. It is important to note that because this is a study on the development of an intervention, the group therapy co-leaders will be involved in research aspects of the study and will have access to the data collected during the study.
2. In all cases, your name and your child's name will not be stored directly with your research or treatment data. All such data we collect on you will be assigned a random ID number. This ID number will be used instead of your name. There will be one digital file in which we will store your ID number, your name, your and your child's birthdates, address, phone number(s), your emergency contact information, and your dates of participation for intake and each assessment. No other data will be stored in this highly

confidential digital file. Instead, we will store all other data collected during the study separately, according to our approved research procedures.

3. All video recorded interactions are recorded using a HIPAA compliant videoconferencing platform (Zoom). Video recordings are initially stored on safe and secure servers of the University of Oregon and later transferred to secure, online cloud storage with extra security features to encrypt and protect the data. We also label the video recordings with a random code number and not your name or other identifying information.
4. We will not write/type identifying information on any document that contains your random ID number that we use in working with you, with exception to child abuse report forms (if applicable) and/or suicide assessments (if applicable). If you participate in the group therapy, we may use your name on some of the documents related to clinical case management during your participation in the therapy group. We ask that you do not write/type your name on any of the documents you fill out that contain your random ID number. Other forms that you will be asked to sign (that do not list your random ID number) include consent forms.
5. Group therapy meetings will be conducted remotely over a HIPAA compliant version of Zoom. The weekly sessions will be video recorded and the group leader or co-leader may write session notes on the sessions. In an effort to improve the group therapy and ensure group leaders are adhering to the treatment model, your group leaders, who are clinical psychology PhD students, participate regularly in consultation team meetings with their supervisor, who is a licensed psychologist. All consultation team members are trained to protect privacy and confidentiality. Data collected during treatment will be stored on a password protected secure server. Therapy group data that may be collected from the session notes include the number of sessions you attend and information on the number and types of DBT and parenting skills you use each week. We will also document any clinically relevant aspects of your participation. In a separate file, we will store other information regarding your emergency contacts and any release of information forms to contact other providers (which you would authorize), or other relevant forms that are standard for maintaining a client file.
6. When scheduling your intake, you may also have given permission to communicate via phone, text message and/or email. Phone and text communication with the research team may be conducted using Google Voice. Your name will not be saved in a contact list connected to the Google Voice account. Your phone number will be used to search for the message thread. All messages will be permanently deleted from the device once your participation in the study is complete. Emails will also only be sent and viewed using a password protected device, and via an encrypted email service called Hushmail.
7. We will write papers and make presentations using the information from this project for scientific purposes only, and we will never use names that could identify anyone in the study. Information you share in the group therapy is private and will not be reported in any publication or presentation.
8. This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This Certificate allows our research team to legally refuse to disclose information that may identify you in any federal, state, or local legal proceedings. This includes civil, criminal, administrative, legislative proceedings, for example. We would use the Certificate to resist any demands for information that would identify you. This Certificate also applies to the staff and researchers at the Center on Parenting and Opioids. We explain exceptions to using this Certificate in the “Limitations of Confidentiality” section below. Information or documents protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects. The Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities of child abuse and neglect, or harm to self or others. It will also not be used to prevent an audit by the Institutional Review Board (IRB). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your

involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

Limitations of Confidentiality

We protect your information from disclosure to others to the extent required by law. We cannot promise complete secrecy. You should understand that the researcher is not prevented from taking steps, including reporting to authorities, to prevent serious harm of yourself or others in the case of an "exception to confidentiality". The research team includes individuals who are mandatory reporters. If the research team has reasonable cause to suspect abuse or neglect of a child or adult, a report may be required under Oregon State Law. In such a case, the research team may be obligated to breach confidentiality and may be required to disclose personal information.

While there are no questions in the intake that ask about whether your child has been abused and the group therapy does not explicitly focus on child abuse, participation in the therapy group will involve sharing and discussing different parenting situations. Should you volunteer information today, at the assessments or over the course of participation in the therapy group that leads us to suspect that your child (or another child) has experienced or is experiencing abuse, we will ask you additional questions to clarify the risk and current safety of your child. Depending on what we learn, we may be obligated to contact a child welfare agency and will try to include you in this process.

We will also take precautions to determine your safety and the safety of your child or others if we hear that you or s/he plans to hurt your/him/herself or someone else. This may mean notifying others. During the clinical intake, we will ask you if you've engaged in or thought about self-harm or have had thoughts about death or harming others. During treatment, you may disclose that you are having thoughts or urges related to self-harm or have thoughts about death. We will ask some follow-up questions to learn if these are recent and if the behavior is highly dangerous. If we believe these behaviors are life threatening, we will take necessary actions to prevent this from happening, such as creating a safety plan, and/or calling a local mobile crisis unit that operates through the police station to assist you. The online assessment questionnaires also ask if you've experienced thoughts about self-harm or have had thoughts about death or harming others. Group co-leaders do not provide emergency or on-call services to group members, and do not review responses to the online assessment questionnaires immediately, but if you endorse or indicate an increase in such thoughts they will check in with you individually during the next group session to ask follow-up questions to determine your or others' safety. We want to emphasize that telling us you engage in self-harm or have had recent thoughts about death will not automatically result in our breaching confidentiality. In addition, if you reveal at any point that you engage in self-harm or dangerous behaviors in the presence of your child (ex. drinking and driving with child), we will be required to contact authorities.

There are other times we may share information with others but this will only be done with your consent. For example, if you have another provider that we should contact to discuss treatment, we will have you complete a standard release of information form. This is not considered part of your group therapy data. In addition, we will have you complete a form of emergency contacts. We would only use these contacts if we lost contact with you while you were part of treatment and were concerned about your well-being.

Confidentiality of information provided by group therapy members is very important to us. During the group orientation, a group therapist will review confidentiality with each group member. As a group member, you are expected to protect your fellow participants' privacy. This means that you should not talk about anything that happens in the group or identify fellow participants outside of group. While it is the policy and expectation that group members will maintain confidentiality, it's important to remember that we cannot guarantee it.

What are the risks if I participate in this research?

The risks or discomforts of participating in this research include being asked questions about your emotions and experiences, which can sometimes be distressing. It's possible you may experience intense emotions during the intake or in following assessments. Furthermore, participation in treatment can also bring about intense feelings. While treatment can be beneficial, it is possible to experience unimproved or worsening symptoms even when you are engaged in treatment.

The other risk to the study is 'exceptions to confidentiality' and the possibility that if you report being a danger to yourself, others, or if it is suspected that your child has been or is being abused, we may need to contact authorities. Staff is trained at conducting risk assessments so that confidentiality is only breached when absolutely necessary.

The risks to confidentiality pertaining to remote (i.e., videoconference and electronic data collection) are like those of in-person participation. There are some additional risks for confidentiality when telehealth services are used, however. First, there is no way to guarantee that the telehealth software is completely secure. As with any technology, there is a chance of a security breach that would affect the privacy of personal and/or mental health information. Second, since participants will be completing sessions in their own homes, we cannot guarantee the same level of privacy we could provide in our lab or clinic. This means that you are responsible for making sure that you are in a private area where disruptions (e.g., others coming into the room or hearing what you say in another room) are minimized as much as possible.

In order to reduce risks to confidentiality, we suggest that all sessions occur in a private room within one's home, with no one else present, and that you wear headphones to limit the possibility of other people overhearing confidential information. Please see "Informed Consent to Telehealth Services" below for more information regarding the risks of participating in telehealth services.

What are the benefits of participating in this research?

We cannot promise any benefits to you or others from your participation in this research. However, possible benefits to you include benefits associated with participation in evidence-based mental health treatment and parenting programs, such as improvement in your mental health, your child's emotional and behavior difficulties or your parenting skills. Additionally, some people may find it interesting to be a part of a research project. Finally, the information we learn from this project may benefit society through the development of a new integrated treatment.

What if I want to stop participating in this research?

Taking part in this research study is your decision. Your participation in this study is voluntary. You do not have to take part in this study, but if you do, you can stop at any time. You have the right to choose not to participate in any study activity or completely withdraw from continued participation at any point in this study without penalty or loss of benefits to which you are otherwise entitled. Your decision whether or not to participate will not affect your relationship with the researchers or the University of Oregon.

If you decline to participate today, and do not wish to reschedule this clinical intake for a later day, you will not be eligible to participate in the remainder of this study. If for any reason, you are unable to or do not wish to participate in all of the assessments or treatment, you have the right to do this. There will be no penalty, except that you will no longer be able to participate in the group treatment. In this event we would refer you to other services if necessary. In the event that you choose to stop participating, we will store the data collected on you and use it in analyses where possible, unless you explicitly request your data to be destroyed.

Will I ever be asked to stop participating?

As previously stated, if you miss four (4) sessions in a row, then you will no longer be able to continue in the group therapy, but will be invited to complete the post-intervention assessment. You may also be removed from the group if you violate the telehealth agreements on confidentiality (see Informed Consent to Telehealth Services below). Additionally, if we are concerned about the severity of your mental health symptoms or the appropriateness of this treatment for your symptoms, then in the interest of your well-being, we may ask you to stop participating in the group therapy and provide you with referrals for more appropriate care.

Will it cost me money to take part in this research?
Taking part in this research may lead to additional costs to you, such as needing to arrange childcare during assessments and weekly group sessions.

Will I be paid for participating in this research?
For taking part in this research, you may be paid up to a total of $360 which will be paid via check payments that will be mailed to you or via a reloadable debit card that will be provided to you. Payments will be made after you complete each phase of the study and are broken down as follows: $60 after the intake, $30 after the pre-intervention assessment, $10 after each weekly measure you complete during the 20 weeks of treatment, $30 after the post-intervention assessment, and $40 after the exit interview.

Please be aware, compensation for participation in research may be considered taxable income. The University requires tracking for compensation that is paid to you; this may include your name and contact information. This information is stored confidentially and separate from research data. If you receive $600 or more in a calendar year, you may be contacted to provide additional information (e.g. Social Security Number) for tax reporting purposes.

Who can answer my questions about this research?
If you have questions, concerns, or have experienced a research related injury, contact the research team at:

Yoel Everett – yeverett@uoregon.edu
Christina Gamache Martin – gamachem@uoregon.edu
Maureen Zalewski – zalewski@uoregon.edu
UO START Lab – (541) 346-7054

An Institutional Review Board ("IRB") is overseeing this research. An IRB is a group of people who perform independent review of research studies to ensure the rights and welfare of participants are protected. UO Research Compliance Services is the office that supports the IRB. If you have questions about your rights or wish to speak with someone other than the research team, you may contact:

Research Compliance Services
5237 University of Oregon
Eugene, OR 97403-5237
(541) 346-2510
researchcompliance@uoregon.edu

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Informed Consent to Telehealth Services

Telehealth service is the delivery of healthcare services when the therapist and client are not in the same physical location/site through the use of various technology. This could include video sessions via telehealth software on a computer, tablet, or smart phone, or phone sessions. We will be using the video conferencing platform Zoom. To invite you to participate in the online platform, we will send a link to your email address. Telehealth sessions will be digitally recorded.

Risks/Benefits of Telehealth Sessions

Generally speaking, the risks and benefits of telehealth are similar to those of in-person sessions. There are additional risks, however. First, there is no way to guarantee that the telehealth software is completely secure. As with any technology, there is a chance of a security breach that would affect the privacy of personal and/or medical information. Second, since you will be completing sessions in your own home, we cannot guarantee the same level of privacy that you have when you are in our clinic. This means that you are responsible for making sure that you are in a private area where disruptions (e.g., others coming into the room or hearing what you say in another room) are minimized as much as possible. Third, in the event of group sessions conducted via video, it is possible that your confidentiality could be breached if others in the group are not in a confidential setting.
In order to reduce risks to confidentiality, we require that all video or telephone sessions occur in a private room within one's home, with no one else present, and if needed, that you wear headphones to limit the possibility of other people overhearing confidential information.

Since this may be different than the type of sessions with which you are familiar, it is important that you understand, acknowledge, and agree to the following statements:

- You understand that you have undertaken to engage in a telehealth encounter for yourself that will contain personal identifying information as well as protected health information.
- You understand that the therapist(s) will be at a different location from you.
- You have been informed of and accept the potential risks associated with telehealth, such as failure of security protocols that may cause a breach of privacy of personal and/or medical information.
- You understand that the laws that protect privacy and the confidentiality of medical information also apply to telehealth, and that no information obtained in the use of telehealth which identifies you will be disclosed to other entities without your consent or as may be allowed by law.
- To protect privacy of all group members, we expect that you will avoid recording of any kind during the session.
- To protect privacy of all group members, we expect that you will avoid photography of any kind during the session.
- To protect privacy, you may want to consider using your first name only in your Zoom setting. We can help you with this.
- As a safety measure, we will ask you your location and confirm that you are in a private setting at the beginning of each zoom session.
- As a safety measure, we will ask you for two updated emergency contacts.
- You have been given the opportunity to ask your provider questions relative to your Telehealth encounter, security practices, technical specifications, and other related risks.
- You understand that group members may be removed from the group if they violate telehealth agreements on confidentiality.

By signing this form, you certify:

- That you have read or had read and/or had this form explained to you;
- That you fully understand its contents including the risks and benefits of telehealth services;
- That you agree to participate in video-group sessions in a private location;

- That you agree for us to send you the link to the online platform through your email

STATEMENT OF CONSENT

I have had the opportunity to read and consider the information in this form. I have asked any questions necessary to make a decision about my participation. I understand that I can ask additional questions throughout my participation.
I understand that by signing below, I volunteer to participate in this research. I understand that I am not waiving any legal rights for myself. I have been provided with a copy of this consent form. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

Consenting to participate in this study means that you consent to being video recorded throughout all phases of the research study, as described above. Recordings will be used for data analysis and for treatment purposes.

I consent to participate in this study.

Name of Adult Participant	Signature of Adult Participant	Date

Researcher Signatures (to be completed at time of informed consent)
I have explained the research to the participant and answered all of his/her questions. I believe that he/she understands the information described in this consent form and freely consents to participate.

Name of Research Team Member	Signature of Research Team Member	Date