UNIVERSITY OF OREGON

Informed Consent for Research Participation Form

Title: Development of DBT/Parent Training group intervention
Sponsor: Office of the Vice President for Research and Innovation, University of Oregon
Researcher(s): Yoel Everett, Graduate Student, UO START Lab, University of Oregon
Maureen Zalewski, Faculty, UO START Lab PI, University of Oregon

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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 out a new integrated version of evidence-based group therapy and see how much it helps parents who have emotional difficulties improve their own mental health and learn skills for parenting a child who has emotional and/or behavior difficulties.
- **Duration.** The full study will last approximately 8 months following your consent to participate.
- **Procedures and Activities.** There are 4 parts of the study: 1) You have already participated in a clinical intake to see if your family is eligible to participate in the full study. 2) You will complete 2 sets 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 24 weeks (i.e., 6 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 final post-intervention assessment.
- **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.

  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 your family is eligible to participate in the full study, then your family will receive evidence-based treatment. We expect this may improve your family's mental health and provide you with parenting skills. You will also be paid for your participation.
- **Alternatives.** Participation is voluntary and the only alternative is to not participate.

Why is this research being done?

We want to help families with parents and children who have difficulties with mental health and managing emotions. We have created a group therapy for parents that combines several evidence-based treatments, which

we hope will improve parents' and children's mental health and provide parents with new skills for parenting. 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 4 phases that will take place over the course of about 8 months:
1) Clinical intake. You have previously completed this phase of the study and are eligible to participate in the following 3 phases.

2) Pre-intervention assessments. You will complete 2 sets of online questionnaires about yourself, your child and your parenting. Each set of questionnaires takes approximately 1 hour to complete.

3) Group therapy. You will participate in a 24-week group therapy program for parents that takes place remotely on [day of week] from [time] over Zoom, a HIPAA compliant video-conferencing software. You will also be asked to complete weekly questionnaires before each session. Each weekly session will last approximately 3 hours.

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. You will also be asked to participate in a remotely conducted, 30-minute exit interview over Zoom.

What happens if I agree to participate in this research?
1) Clinical intake screening (already previously completed). 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 your family is eligible to participate in the full study.

2) Pre-intervention assessments. If you are eligible for the study and choose to participate, then you will complete several online questionnaires about yourself, your child, and your parenting. Two to three weeks prior to beginning the group therapy, you will complete one set of questionnaires, and then you will be asked to complete the same set of questionnaires again, shortly before the first group therapy session.

3) Group Therapy. You will meet remotely via Zoom, a HIPAA compliant video-conferencing software in a group setting with 3 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 24 weeks on [day of week] from [time]. Each session will be led by two (2) co-leaders. Sessions will last approximately 3 hours. Prior to each session, you will fill out questionnaires about yourself and your child. 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. If you miss four (4) sessions in a row, then you will no longer be able to continue in the group therapy. You will be invited to complete the post-intervention assessment no matter how many group therapy sessions you attend.

4) Post-intervention assessment. You will complete several online questionnaires about yourself, your child, and your parenting. You will also complete a 30-minute exit interview via Zoom to hear about your thoughts and experiences from the group therapy.
All phases of the study will be video recorded. The clinical intake and therapy sessions are 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 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 (across all participating families) and some findings at an individual family level. We will never include your name or your child's name in how we store your family's 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 family, with only each family's codes (and no names or other personally identifying information). We will keep this file indefinitely. We will store this file on a password-protected server maintained by the UO Psychology department.

How will my privacy and data confidentiality be protected?

We will take many measures to protect the security of all your family's personally identifiable information, but we can never fully guarantee confidentiality of all study information.

Here are the steps we will take to protect your family's privacy and data confidentiality:

We will store the digital and video data on a password-protected secure server. Any paper forms used will be stored in a locked filing cabinet in a locked room, accessible only by trained members of the research team. The data collected from your family will be available only to trained members of the research team and to specific organizations that may inspect or copy research data for quality assurance, such as the UO Institutional Review Board or its designees or the Office for Human Research Protections (OHRP, in the U.S. Department of Health and Human Services).

Your family's data will be identified by a code (e.g., a string of numbers and/or letters). Your family's data will not be labeled with your name or your child's name. During the course of the research, your family's personally identifying information is only accessible to trained members of the research team.

We will store your family ID number, your and your child's name, your birthdates, address, phone number(s), your emergency contact information, and your dates of participation for intake and each assessment in a separate digital file. 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.

Because your honest answers are so valuable to us, we will do everything we can to keep everything about your child and you confidential (e.g. completely private) and secure. Despite taking steps to protect your privacy and secure your personal information, we can never fully guarantee your privacy and confidentiality will be protected. We will take the following measures to protect your privacy and secure your personal information:

1) Clinical intake data is being collected inside the UO Psychology Clinic. Your data will be stored such that no person who is not part of the research team will have access to your data. Your data will be coded into a digital form and stored on a protected secure server.

2) In all cases, your name and your child's name will not be stored directly with your research or treatment data. All data we collect on you will be assigned a random ID number. This ID number will be used instead of your names.

3) We will not write identifying information on any form 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 your name on any of the forms 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 and incentive receipts.

All paper documents that link IDs and identifiable information are stored in a locked filing cabinet and are only accessible by lab project coordinators and trained members of the research team.

4) We train all members of the research team 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 may have access to the data collected during the study.

5) Videos that are recorded are stored on safe and secure servers and are only accessible by the research team.

6) Group therapy meetings will be conducted remotely over 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 participate regularly in consultation team meetings with their supervisor, Dr. Zalewski. All consultation team members are trained to protect privacy and confidentiality. Data collected during treatment will be stored on a protected secure server.

7) Group therapy co-leaders will complete weekly session notes on your group participation. Therapy group data that may be collected from the 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.

8) 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.

9) This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or

proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use.

Information, documents, or biospecimens 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, see below); 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.

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 likely ask you if you’ve ever engaged in or thought about self-harm or have ever had thoughts about death. Additionally, 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. 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.

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 family 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 childcare expenses 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. Your compensation will be broken down as follows: $40 for the clinical intake (already completed and compensated); $40 for completing two sets of online questionnaires pre-intervention, $10 for completing each set of weekly questionnaires throughout the following 23 weeks of treatment, $50 for completing the post-intervention questionnaires and a 30 minute exit-interview. Moreover, the treatment is provided at no cost to you. Payments will be made via check and mailed to you.

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
Maureen Zalewski – zalewski@uoregon.edu
UO START Lab – (541) 346-7053

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

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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 a HIPAA compliant version of 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

A researcher will complete this section after you complete your participation.
For administrative use only:

- ☐ The family was ineligible after completing the clinical intake (Assessment 1, Treatment Initiation, and Assessment 2 were not completed).
- ☐ The family stopped participating in the study after completing both the clinical intake and Assessment 1 (Treatment Initiation, and Assessment 2 were not completed).
- ☐ The family stopped participating in the study after completing the clinical intake, Assessment 1, and the Treatment Initiation (Assessment 2 was not completed).