Thank you for your interest in this study!

On the next page you will find information about the study, including why it is being done, what you would be asked to do, benefits and potential risks, information about privacy and confidentiality, and who to contact with questions. This is called a consent form.

A member of the research team will contact you to review this information together. If you have any questions or concerns, please do not hesitate to ask.

If you decide that you want to participate in the study, you will be sent a link to electronically sign the consent form. An electronic signature is like a written signature on a paper document, but instead of using a pen and paper, you will be asked to type in your first and last name and draw your signature with a mouse, stylus, or the tracking pad of your computer/tablet/phone. If you don't have one of these devices, please let the research team know when you talk to them.

After that, you'll enter the current date (the date when you are signing the consent) and press "submit". You will be asked to confirm that you understand that your electronic signature works the same way as your written (pen-and-paper) signature. You will be able to download or email a copy of the consent form to yourself if you like.

This e-consent form is on a secure research server called *REDCap.* Like online shopping, this technology has some privacy and security risks. This risk can't be completely eliminated and we want to make you aware of this.

Please click the Submit button to continue.

Consent to Participate in a Research Study

STUDY INFORMATION

It is important that you read and understand this research consent form. This form provides the information you will need to know in order for you to determine whether you wish to participate in this study. Please ask the researcher any questions you may have, in order to ensure complete clarification on what this study entails.

Title of Research Study

Big Feelings: A Study on Children's Emotions in Therapy

Principal Investigator

Kristel Thomassin, Ph.D., C.Psych.
519-824-4120 ext. 53513
Maplewoods Centre for Family Therapy and Child Psychology
University of Guelph

Co-Investigators

Andrew Hamilton-Wright, Ph.D.
519-824-4120 ext. 53290
College of Engineering and Physical Sciences
University of Guelph

Brendan Andrade, Ph.D., C.Psych.
416-535-8501 ext. 33642
Child, Youth, and Family Service
Centre for Addiction and Mental Health

Madison Aitken, Ph.D., C.Psych.
416-535-8501 ext. 34091
Child, Youth, and Family Service
Centre for Addiction and Mental Health

Introduction: You and your child are being invited to take part in the research study named above. It is important that you understand the purpose of the study, how it may affect you and your child, the risks and benefits of participating in the research and what you and your child will be asked to do before you decide if you want to participate. This information and consent form is to help you decide if it is in your best interest to participate in this study. You do not have to participate in the study and you and your child may withdraw at any time. Participation is entirely voluntary (your choice). Services at the Maplewoods Centre will still be available to you if you decide not to participate in the research study. Please take as much time as you need to decide. If you have any questions that this form does not answer, the research coordinator or study investigators will be happy to give you further information.

Funding: This study is funded by the Canadian Institutes of Health Research, the Ministry of Colleges and Universities, and the American Psychological Foundation. This study is being hosted at the Maplewoods Centre for Family Therapy and Child Psychology at the University of Guelph and the Centre for Addiction and Mental Health. The study investigators have no conflicts of interest to report.

Purpose of the Study: You are being asked to participate in this study because you are seeking psychotherapy for your child for anxiety, depression, and/or behaviour problems. Research has shown that difficulty regulating emotions can be a risk factor for many childhood emotion and behavioural disorders. Commonly used psychotherapies often include components that help children learn to regulate their emotions. Yet, there has been very little research on emotion regulation as a mechanism of change over the course of psychotherapy. The aim of this study is to understand whether a child's ability to learn to regulate their emotions (at a physical, mental, and behavioural level) can be a marker of benefit from therapy. We will be using an evidence-based model of psychotherapy, called MATCH-ADTC (*Modular Approach to Therapy for Children with Anxiety, Depression, Trauma, or Conduct Problems*). The results of this study will allow us to better understand factors that affect children's treatment response, which may help us tailor treatments to better fit children's emotional and behavioural needs in the future.

Study Participants: Our aim is to recruit approximately 250 families (children and their parent(s)/caregiver(s)) from the Maplewoods Centre at the University of Guelph and from CAMH. Children must be between the ages of 8 – 15, and families must be seeking psychosocial treatment for a primary concern of anxiety, depression and/or disruptive behaviours. Parents and children should not be actively receiving, or due to receive, intensive psychological intervention for emotional or behavioural difficulties during the active phase of the study.

What Will Happen in the Study: If you and your child meet the inclusion criteria and decide to participate, you will be randomly assigned to one of two conditions. The first is the psychotherapy condition in which you would receive the Modular Approach to Therapy for Children with Anxiety, Depression, Trauma, or Conduct Problems (MATCH-ADTC) program, with a trained therapist. If you and your child are assigned to the MATCH-ADTC treatment condition, you will receive weekly psychotherapy in which you and your child will meet with a clinician who is trained in MATCH-ADTC to

learn new ways to think, cope with challenging feelings, and problem-solve. These sessions will be conducted in-person. Although we cannot guarantee benefits from treatment, MATCH-ADTC has been previously tested and shown benefits to other children and their parents. The clinicians may also review some of the measures that you completed as part of the study to help them best plan for treatment.

The second condition is a waiting list in which you will wait for services, as you would normally be through the Maplewoods Centre. You will have a 50/50 chance of being assigned to either condition. You will be told which condition you are assigned to. Due to clinician availability, if you are assigned to MATCH-ADTC treatment, it is possible that you will still have to wait for some time before you begin to receive treatment. If you decide not to participate in this study, you will have the same chance of receive care at the Maplewoods Centre as if you had not been offered the study. Please note that it may be that our waitlist at Maplewoods Centre is closed at that time.

MATCH-ADTC ("MATCH"). MATCH (*A Modular Approach to Therapy for Children with Anxiety, Depression, Trauma, or Conduct Problems*) is a psychotherapy program for children aged 5 years and older that primarily targets anxiety, depression, trauma, and disruptive behaviour. A clinician will assess the child for their areas of concern and begin treatment focused on the primary area. MATCH is a transdiagnostic treatment, which means it is flexible and can be used to target co-occurring problems (e.g., if children are experiencing both anxiety and behaviour problems). During these sessions, your child will wear a wristband (like a fitbit) that will allow us to observe their physiological responses (how much their heart rate changes and subtle changes in sweat activity on their skin). Some of these sessions will be audio recorded and coded to establish that treatment is conducted as planned, in a consistent and reliable manner. After completion of this study, your child's treatment will be completed. Completion of treatment does not prevent you from seeking additional services, and clinicians can make further referrals as necessary. If you are randomized to the MATCH treatment, we will share your response on the clinical measures and questionnaires you completed about yourself and your child so that the therapist can use this information to tailor their therapy approach to best fit your family. The list of questionnaires that will be share include: the Youth Self-Report (child), Top Problems Assessment (child and parent), Behavior and Feelings Survey (child and parent), Child and Adolescent Trauma Screen (parent), Child Behavior Checklist (parent), Brief Symptoms Inventory 18 (parent), and the Brief Impairment Scale (parent). Results from these measures may go in your child's clinical file at Maplewoods and would be used to best support your child's care. The therapist will share with the research team a summary of the number and dates of therapy sessions.

Waitlist. Children in the waitlist condition may receive usual treatment as soon as it is available at the clinic. Treatment available may be in the form of individual therapy or group therapy.

Study Duration: If you are assigned to the treatment condition, your child will attend weekly psychotherapy sessions for an estimated period of 4 – 6 months (16 – 24 sessions). MATCH treatment is tailored to the individual, so the treatment duration will vary depending on the needs of the child. If

you are assigned to the waitlist condition, your child will be placed on the clinic's waitlist, which is usually 4 – 6 months; however, the wait for usual treatment can be less or more than this depending on clinic volumes. If you receive usual treatment, we will conduct a follow up assessment after your child completes treatment.

Study Visits: You and your child will be asked to provide some information that will help us determine if this study will be a good fit for you. If you qualify for the study, there will be several in-person study visits. Each visit will take approximately 2 to 2.5 hours and will be conducted by a member of our research team.

Pre-Test: The pre-test study visit will take place shortly after you are enrolled into our study. At your first study visit, you will be asked to complete a series of computerized questionnaires. These questionnaires will ask about your child's behaviour, peer relationships, and emotional functioning. They will also ask about your stress, mental health, and emotional functioning. Clinicians will use some of these questionnaires for treatment planning and to tailor treatment to your child's emotional and behavioural needs. This initial study visit allows us to establish a baseline of your child's behaviour, symptoms and functioning, prior to any intervention.

Your child will be asked questions about their behaviours, symptoms, and feelings. They will also be asked to complete a series of behavioural and thinking tasks that will take approximately 25 minutes. These tasks consist of a computer piñata game, rating emotional intensity of pictures and giving a 5-minute speech. One of the tasks we will ask your child to complete will require them to view image of people and objects on the computer. For some pictures, we will ask them to look closely. For other pictures, we will ask them to imagine the picture or situation being far away. This is so that we can measure how children manage emotional content in everyday objects and situations. This task has been used with children as young as 7 years old. We want to tell you that some of the pictures might be a bit uncomfortable to look at. We will let your child know that if they feel uncomfortable, they can tell us. After this activity, we will check in with them to see how they are doing and to let them know the images are not real. Then you and your child will have a 5-minute discussion about a conflict you both experienced. The 5-minute speech and the 5-minute discussion will be video recorded. The purpose of the recording is for the research team to remember exactly what was said and done during the task, and will be coded into research data. Audio and video recordings may be shared with our collaborating researchers at CAMH. While completing these tasks, we will measure your child's physiology, which means their heart rate and how sweaty their palms are. For this, we will put some stickers with wires on them. You will have the option to apply the sticker electrodes on your child. These data will allow us to analyze physiological responses to these tasks.

Weekly Measures*:* While you are participating in MATCH treatment or on the waitlist, you and your child will be asked to complete weekly measures of your child's symptoms and emotion regulation. These measures are very brief and can be completed online.

Quarterly Study Visits: Quarterly study visits will be scheduled every 3 months while you are enrolled in MATCH treatment or on the clinic's waitlist. These visits will be the same as the first visit and will allow us to evaluate changes in your child's behaviour, symptoms, functioning, and physiology over the course of treatment, or with the passage of time.

Post-Test Study Visit: The post-test study visit will be scheduled after your child completes MATCH treatment or they are taken off the waitlist. This study visit will follow the same format as the pre-test study visit and will allow us to determine the effectiveness of the study interventions and observe any changes in your child's behaviour, symptoms, functioning, and physiology.

Voluntary Participation and Withdrawal: You and your child's participation in this study is completely voluntary and you may refuse to join the study or withdraw from it at any time. We will provide your child with an assent form that explains the study in child-friendly language and we will verbally explain what is being asked of them in this study. If your child refuses to participate in this study, we will not proceed. Your decision to accept or refuse to participate will in no way affect your services at this agency or other agencies involved in this study or your access to future services. If you withdraw from the study while on the waitlist, it will not affect your position on the waitlist. If you choose to withdraw while in treatment, you will be able to continue with the treatment program. The researchers may take you out of the study early and without your consent if they feel that the study is no longer in your or your child's best interests. If this happens, it may mean that you would not receive the study intervention for the full period described in the consent form.

You may withdraw your permission to use information that was collected about you for this study at any time by letting the study team know. However, this would also mean that you withdraw from the study. If you decide to leave the study, no more information about you will be collected. You can also ask that the information that was collected about you from before you withdrew your permission not be used for the study. Let the study investigator know if you choose this.

Risks: Some of the questionnaires will ask you about topics that may be difficult to discuss like symptoms, thoughts about death or dying, or whether anyone has hurt your child. As a result, there is potential for these questionnaires to induce stress or negative emotions. However, if you or your child become distressed in any way, a member of the research team or clinical staff will assist you. If specific questionnaires or questions make you uncomfortable, you are free to skip them, indicate that you prefer not to answer, or reschedule the study visit for another date.

Benefits: You may or may not benefit from this treatment. We hope that our treatment helps you and your child learn skills and strategies that may improve your family's functioning. Your participation in this study will increase our understanding of effective assessment and treatment for parents and children with emotional and behavioural problems. We hope that study findings will contribute further to program developments that will benefit clients seeking similar services in the future.

Confidentiality and Privacy: If you decide to participate in this study, the study team will collect only the information they need for the study. Information will be collected directly from you through tasks, interviews and questionnaires.

This study is being conducted by the Child Emotion and Mental Health Lab, located within the Maplewoods Centre at the University of Guelph. At any given time, the Child Emotion and Mental Health Lab (Director: Dr. Kristel Thomassin) is comprised of various student research assistants and volunteers. All members of the research team complete research ethics training before they can participate in research activities. Research assistants and volunteers also sign a confidentiality agreement prior to being involved in research activities. If at any time you want to know who is part of the research team, you can visit our website *(*www.childemotionlab.ca). It will also be indicated on the website if any team member also provides therapy at Maplewoods for this specific project; This includes any staff therapist providing therapy for this project. Lastly, as an investigator on this project, Dr. Kristel Thomassin may provide supervision or consultation to those delivering therapy for this project.

The study team will collect personal information (information that can identify you) including your name and initials, address, phone number, email, medical record number, and date of birth. The study team will also collect personal health information (information about your physical or mental health that could identify you) about you and your child including medical diagnoses, family history of diagnoses, sex and/or gender, socioeconomic status, education, and race/ethnicity. Researchers will also ask questions about your child's behaviour and your life experiences in general.

All efforts to maintain confidentiality will be made. Any disclosure of information you share with the research team will only be shared in special circumstances and as permitted by law. Examples of these special circumstances would be if the researcher or other members of the research team have reasonable grounds to believe that disclosing information is necessary to eliminate or reduce a significant risk of bodily harm to yourself or others, if we have reason to believe a child is being, has been, or is at risk of being abused, or where public health laws require that health professionals report a communicable disease. Should such a situation arise, the researcher will make every effort to discuss this with you.

If the results of this study are published, your and your child's identity will remain confidential. It is expected that the information collected during this study will be used in analyses and will be published/ presented to the scientific community at meetings and in journals. You can obtain results from this study through our website (www.childemotionlab.ca). You can also contact us at any time to ask about or obtain copies of published research results. De-identified aggregate group data or de-identified quotes from your participation may be made available in open access (i.e., parent and child measures, coded interaction data).

The security of information sent by e-mail cannot be guaranteed. Please do not communicate personal sensitive information by e-mail. Let the research team know if you do not want to be contacted by

e-mail. Email is not routinely monitored outside of work hours. Please do not use e-mail to communicate emergency or urgent health matters – please contact your clinician or family doctor. If it is a medical emergency, call 911. If information is to be exchanged with other mental health professionals outside of this project for case management or research needs, you will be asked to sign a separate release of information form. If you do not agree to this, information will not be released to these health professionals.

Data Sharing and Collaboration: The sharing of study data encourages collaborating between researchers and may lead to important new findings in mental health research. The researchers doing this study may use your data or samples in the future for other research projects. Coded data collected about you from this study may be combined with data collected from other people on other studies, or it may be saved in a database. The research team doesn't know what this research may be yet, but we think it will be related to future studies on mental illness. You will not be asked or told about these other studies. The results of these studies will not be shared with you. You will not directly benefit from these future studies, but it is hoped that the research may help other people in the future.

You can withdraw data up to 30 days after study participation (i.e., after the final interaction with the research team or therapy, whichever is the latest). Any personal information that could identify you will be removed or changed before the data or samples are shared with other researchers. If you withdraw your consent for future research, it may not be possible to delete de-identified data or samples that have already been shared. Your information may be shared with collaborators outside of Canada. The privacy laws outside of Canada are different and may not be as strict. To reduce the risk, study data and samples that are transferred outside of Canada will be coded (it will not contain your name or other identifying information). By signing this consent form, you agree to allow us to send your study data and samples to people or organizations located outside of Canada. There is a risk that someone could trace the information back to you. The chance that someone could do this is very small, but the risk may grow in future if people come up with new ways of tracing information back to people. Please talk to the research team if you have questions or concerns about future use of your data.

Data Storage and Retention: All collected data that is electronic in nature will be stored in folders and files saved on a secure, password-encrypted network ensuring accessibility to staff directly involved with this project. Any data that is collected as a hard-copy will be kept in locked filing cabinets. Data with identifying information (i.e., consent forms) will be stored separate of research data. Video and audio recordings will be retained on recording devices until they are transferred to a computer and coded by research team members into data. Once transferred and coded, the video and audio recordings on the devices will be deleted and only saved on secure servers at the University of Guelph and CAMH. The folder containing all video/audio recordings will only be accessible to members of the research team who have received appropriate training. Video and audio recordings files will be stored at the University and CAMH for a minimum of 10 years.

Your data will be shared with investigators participating in this research project and clinical staff not

involved in the study but who may be involved in your treatment. The study team may also contact your clinical team in the event that safety concerns or other study-related issues arise.

Information that can directly identify you will be kept in a secure place, separate from the other information collected for the study (called "study data"). Instead, study data will have a special code that we call an indirect identifier. The study team will have the list that links you to your code, and this list will also be kept separate from the study data in a secure place. Even though the likelihood that someone may identify you from the study data is very small, it can never be completely eliminated.

Incentives: If you decide to participate in this study, you will receive gift cards for each study visit. If more than one parent/caregiver would like to participate, they will also receive incentives, in gift cards, for each study visit.

	Pre-Test Visit	Weekly Surveys	Quarterly Visit(s)	Post-Test Visit
Parent	$30 questionnaires $40 in person visit	$2 each $5 bonus for every 5 completed survey	$30 questionnaires $40 in person visit	$30 questionnaires $60 in person visit
Child	$10 questionnaires $15 in person visit	$2 each $5 bonus for every 5 completed survey	$10 questionnaires $15 in person visit	$10 questionnaires $25 in person visit

Participant Rights: If the research team learns new information that may impact your decision to stay in the study, we will notify you in a timely manner. You can find out the results of this study once the entire study is complete. Please let the research team know if you would like to learn the results.

Contacts: If you have questions about this study or experience a research related injury, you can talk to the researcher who is in charge of the study at the Maplewoods Centre. That researcher would be Dr. Kristel Thomassin, who can be reached by telephone at 519-824-4120 extension 53513, or by email at Kristel.Thomassin@uoguelph.ca.

If you have questions about your rights as a participant or about ethical aspects of this study, you can speak to someone who is not involved in the study at all. That person is the Manager of the Research Ethics Board (REB) at the University of Guelph. The REB is a group of people responsible for the ethical oversight of this study. The Manager of the REB can be reached by telephone at 519-824-4120 extension 56606, or by email at reb@uoguelph.ca.

Study Title: Big Feelings: A Study on Children's Emotions in Therapy

Part 1: I have read (or had read to me) the Information Sheet for the study named "Big Feelings: A Study on Children's Emotions in Therapy". I have been informed this study aims at investigating the biobehavioural regulation of negative emotion as a mechanism of children's response to psychotherapy for anxiety, depression, and behavioural problems. I have been informed that my and my child's role as participants in this part of the study is to complete measures and tasks, participate in treatment or the control group (if I qualify) and allow investigators to use information collected for research purposes.

This study may or may not be useful in designing better ways to help children with emotional and behavioural problems. My questions, if any, have been answered to my satisfaction, so that I now have been informed of the procedures to be followed in the study, the risks to me from participation, and my right to the confidential treatment of information that is collected about me.

I consent to participate in this study. ☐

Future Research: I grant permission to be contacted by a member of the research team regarding future research opportunities or future treatment studies. Your consent can be withdrawn at any time ☐

I grant permission to the research team to use my data obtained from the present study for other research projects. Only de-identified data will be used. Your consent can be withdrawn up to 30 days after study participation. ☐

SIGNATURES

- All of my questions have been answered
- I have read each page and I understand the information within this informed consent form
- I allow access to my personal health information, medical record and research data as explained in this consent form
- I do not give up any of my legal rights by signing this consent form
- I agree to take part in this study.

_____	_____	_____
Signature of Participant	PRINTED NAME	DATE
_____	_____	_____
Signature of Person Obtaining Consent	PRINTED NAME	DATE