camh

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.

camh

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

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

Co-Investigators

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

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

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

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 CAMH 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 Centre for Addiction and Mental Health and the Maplewoods Centre for Family Therapy and Child Psychology at the University of Guelph. 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 CAMH and the Maplewoods Centre at the University of Guelph.

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 they would normally be through CAMH. 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 likely 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 still be able to receive treatment from the Child, Youth, and Emerging Adult Program at CAMH.

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 FitBit wristband that will allow us to observe their physiological responses (how much their heart rate changes during these sessionsSome 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.

Waitlist. Children in the waitlist condition will 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-ADTC 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. If you receive MATCH-ADTC treatment, we will conduct a follow up assessment 1-year after your child completes treatment. Overall, you and your child will be involved in this study for approximately 1 year to 1.5 years.

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 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 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 and rating emotional intensity of pictures using a software called Inquisit. Your child will be asked to give a 5-minute speech and then you both will have a 5-minute discussion about a conflict you both experienced. The speech and discussion will be video recorded, for the research team to remember exactly what was said and done during the task. Video recordings are mandatory for participation in this study. Audio and video recordings may be shared with our collaborating researchers at the University of Guelph.
`

While completing these tasks, your child will be asked to wear some physiology equipment that measures their physiological responses. The data will be collected using a BIOPAC mobile testing unit; a widely used, non-invasive, unit that is worn like a bracelet and two belts. You and your child can try out the equipment, including the electrodes, to see if you are comfortable with the equipment. This 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 sent to you and your child via email or text. If your child is not able to complete these measures independently, a researcher can call them to complete the measures over the phone.

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 very similar to the initial study visit. At each quarterly visit, you will be asked to complete some of the computerized questionnaires that you completed at your initial study visit and your child will be asked questions about their behaviour, symptoms, and feelings. Your child will be asked to wear the physio equipment and you will both be asked to complete the same tasks as previous study visits. These study visits 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. You will be asked to complete the same series of computerized questionnaires that you

completed at your pre-test study visit and your child will be asked questions about their behaviour, symptoms, and feelings. Your child will be asked to wear the physio equipment and you will both be asked to complete the same tasks as previous study visits. This study visit will allow us to determine the effectiveness of the study interventions and observe any changes in your child's behaviour, symptoms, functioning, and physiology.

Follow Up Study Visit: If your child was in the waitlist condition and received usual care, the follow up study visit will be scheduled shortly after they complete treatment. If your child received MATCH treatment, their follow up visit will be scheduled for 1-year after they complete treatment. The follow up visits follow the same format as the pre-treatment and post-treatment study visits. You will be asked to complete the same series of computerized questionnaires and your child will be asked about their behaviour, symptoms, and feelings. Your child will be asked to wear the physio equipment and you will both be asked to complete the same tasks as previous study visits. These follow up visits allow us to compare how helpful usual care is with MATCH treatment, and to evaluate changes in the long-term.

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. Information about your participation in this study and a copy of the consent form will be added to your CAMH medical record.

Risks: Some of the questionnaires will ask you about topics that may be difficult to discuss. 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. While wearing physio equipment, children may also feel discomfort from the electrodes attached to the skin, taking the electrodes off may feel like taking off a "Band-Aid" which might be uncomfortable for some children.

Your child will be asked to try the electrodes on by placing it on the back of their hand or on their arm to see how it feels prior to outfitting them with the equipment. If either yourself or your child are not comfortable with the equipment and electrodes, your child can choose to remove it at any time.

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.

You may have completed questionnaires in previous studies or at clinical appointments at CAMH that are also being used in this study. To decrease the amount of times you provide the same information, and shorten the study visit, you can choose to share this information with the study. The study team will only collect relevant information which would be gathered routinely through the research study. You will be given the option to consent to this at the end of the consent form.

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.

Your participation in this study will be recorded in your medical record at CAMH. This is for clinical safety purposes. If you participate in this study, information about you from this project may be stored in your hospital file and in the hospital computer system. CAMH shares patient information stored in our electronic health record with other hospitals and healthcare providers in Ontario so they can access the information if it is needed for your clinical care. The study team can tell you what information about you will be stored electronically and may be shared outside of CAMH. If you have concerns about this, or have any questions, please contact the Information and Privacy Office at 416-535-8501 ext. 33314 or by email at privacy@camh.ca

Representatives of CAMH, including the CAMH Research Ethics Board and Quality Assurance team, may look at your medical/study records (including personal information and personal health information) at CAMH to check that the information collected for the study is correct and follows proper laws and guidelines.

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.

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 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. They may share your data with other researchers at CAMH or with collaborators around the world. 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.

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 password-encrypted folders and files saved on a secure, protected 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 CAMH and the University of Guelph. 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 Guelph and CAMH for 10 years, after which they will be destroyed.

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. 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.

Compensation: 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 compensation, in gift cards, for each study visit.

	Pre-Test Visit	Quarterly Visit(s)	Post-Test Visit	Follow Up Visit
Parent	$40	$40	$60	$70
Child	$15	$15	$25	$35

If you suffer an injury or side effects from participation in this study, medical care should be provided by your doctor or you will be referred for appropriate medical care. The costs of your medical treatment will be paid for by the provincial medical plan or by seeking reimbursement from your private medical insurer (if any) to the extent that such coverage is available. You have not waived any of your rights to legal recourse in the event of research-related injury.

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 CAMH. Those people are Brendan Andrade, who can be reached at 416-535-8501 extension 33642, and Madison Aitken, who can be reached at 416-535-8501 extension 34091.

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 Chair of the Research Ethics Board (REB). The REB is a group of people responsible for the ethical oversight of this study. The Chair of the REB can be reached by telephone at 416-535-8501 ext. 34020.

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, participate in treatment or the control group (if I qualify) and allow investigators to use information collected for research purposes. I have been informed that audio and video recordings are required for my participation in this study.

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 at any time ☐

Previous Research: I grant permission to the research team to use my data obtained from previous studies or from regular clinical appointments at CAMH for this research project. Only de-identified data will be used. ☐

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 understand that my family doctor/health care provider may be informed of my participation in this study.
- By signing this consent form, I consent for myself and my child to be video and audio recorded.
- I agree to take part in this study.

_____	_____	_____
Signature of Participant	PRINTED NAME	DATE

_____	_____	_____
Signature of Person Obtaining Consent	PRINTED NAME	DATE