STUDY TITLE: **Emotion Coaching Skills as an Augmentation to Family Based Therapy for Adolescents with Anorexia Nervosa or Atypical Anorexia Nervosa**

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CINCINNATI CHILDREN'S HOSPITAL MEDICAL CENTER

PARENTAL PERMISSION AND CONSENT FORM
FOR PARTICIPATION IN A RESEARCH STUDY

STUDY TITLE: Emotion Coaching Skills as an Augmentation to Family Based Therapy for Adolescents with Anorexia Nervosa or Atypical Anorexia Nervosa

INVESTIGATOR INFORMATION:

Claire M. Peterson Ph.D. 513-803-7459

KEY INFORMATION

INTRODUCTION:

You have been asked to participate in a research study. You are also being asked to give permission for your teen to participate in a research study. Before agreeing to participate in this study, it is important that you read and understand the following explanation. It describes, in words that can be understood by a lay person, the purpose, procedures, benefits, risks and discomforts of the study and the precautions that will be taken. It also describes the alternatives available and the right to withdraw your teen from the study at any time. No guarantee or assurance can be made as to the results of the study. Also, participation in the research study is completely voluntary. Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled. You may withdraw your teen from the study at any time without penalty.

WHO IS CONDUCTING THE RESEARCH STUDY?

This study is directed by Dr. Claire Peterson a researcher at Cincinnati Children's Hospital. Dr. Claire Peterson is responsible for the supervision of this research.

WHY IS THIS RESEARCH BEING DONE?

The purpose of this study is to see how well an emotion coaching intervention works for parents of teenagers with anorexia nervosa (AN) or atypical anorexia nervosa (AAN). Emotion coaching refers to showing your teenager that you are listening and understanding their feelings.

WHY HAVE YOU AND YOUR TEEN BEEN ASKED TO TAKE PART IN THIS RESEARCH STUDY?

You and your teen are being asked to take part in this research study because your teen has anorexia nervosa (AN) or atypical anorexia nervosa (AAN).

WHO SHOULD NOT BE IN THE RESEARCH STUDY?
You and your teen should not be in this study if your teen: 1) is younger than 13 years old or older than 17 years old, 2) has other chronic diseases affecting appetite (such as diabetes) 3) has a major developmental disorder (e.g., autism), or (4) you or your teen do not speak English. You should also not be in this study if you spend less than 50% time with your teen at meal times (e.g., you see your teen on weekends only).

HOW LONG WILL YOU AND YOUR TEEN BE IN THE RESEARCH STUDY?
If you qualify, you and your teen will be in the research study for about 6 months.

The researcher may decide to end your teen's participation in this research study at any time, without you or your teen's permission, for any of the following reasons: the study doctor determines that it is in your teen's medical best interest, the study ended early for any reason, or new information becomes available. You may terminate you and your teen's study enrollment at any time. This consent, unless you choose to withdraw it, shall remain in effect until the end of the research study.

HOW MANY PEOPLE WILL TAKE PART IN THE RESEARCH STUDY?
This study will be conducted at Cincinnati Children's Hospital Medical Center (CCHMC). A maximum of 50 families will participate in this research study.

WHAT IS INVOLVED IN THE RESEARCH STUDY?
If you agree to allow your teen to participate, you will participate in an additional 10 –session emotion coaching group intervention for parents to help improve communication skills. This will be in addition to standard treatment that you and your teen receive for AN or AAN. These groups will be held via Zoom for Healthcare given the recent limitations on social meeting due to COVID-19. Zoom for Healthcare is HIPAA compliant and will allow for audio and video access for all group sessions.

You and your teen will be asked to complete four visits via Zoom for Healthcare: a baseline visit, a 1-month visit, an end of treatment visit, and a follow up visit. Prior to your baseline visit, you and your teen will complete some questionnaires online. These questionnaires will ask about you and your teen's background, mood, eating disorder symptoms, emotions, ways of coping with emotions, and parenting stress. At the baseline study visit, scheduled at your convenience, you and your teen will complete interviews and a family meal video, and you will be scheduled for the 10-session parent group. The audio and video recordings will be shared confidentially with study collaborators at the University of Georgia for coding purposes.

All participants will be randomized to either the treatment condition or the control conditions. In the treatment condition you would participate in an additional 10 –session emotion coaching group intervention for parents to help improve communication skills. The 10 sessions will cover several topics including parent emotion awareness, active listening, emotion support skills, and emotion coaching skills. Each week, you will have homework which will involve recording a conversation with your teen. These will be used in the next group and you will get feedback on your use of new skills. You can audio record homework on a device you have or we will give you an audio recorder. It is important that you are also attending weekly family- based treatment as part of the standard of care for your teen's eating disorder.

In the control condition, you would participate in a 10-session educational support group. In the control condition, the 10 sessions will cover several topics such as causes of AN and AAN, treatment, medical issues, medications, and how to talk to family members.

You will be asked to complete questionnaires at the 1-month visit. You will be asked to complete the same questionnaires at the 3-month visit. You will be asked to complete the same questionnaires online at the end of the 10- session emotion coaching group for parents followed by a post-treatment study visit where you will complete the same interviews and family meal video. We will also ask about your thoughts on the intervention.

After the 10th treatment session is completed, you and your teen will continue with the remainder 10 sessions of family- based treatment for your teen's eating disorder.

WHAT ARE THE RISKS AND DISCOMFORTS OF THE RESEARCH STUDY?
There are minimal risks to teen or adult participants in this study. All forms and interviews, as well as the intervention homework recordings have been used in research without any reported negative effects. You and your teen can refuse to answer questions for any reason. You might be slightly inconvenienced by participating in intervention sessions; but every effort will be made to schedule these at times that are convenient for you and your family.

If problems should occur, you will be encouraged to discontinue any of the procedures that cause you to feel uncomfortable in any way. Dr. Peterson will meet with you to discuss your concerns, and if appropriate, assist in making clinical referrals. Another risk may be loss of confidentiality. Please see the section of this consent form entitled How Will Information About You and Your Teen Be Kept Private and Confidential to learn steps that will be taken to reduce the risk of loss of confidentiality. Finally, there may be unknown or unforeseen risks associated with study participation.

ARE THERE DIRECT BENEFITS TO TAKING PART IN THE RESEARCH STUDY?
If you and your teen agree to take part in the study, your teen may receive a direct benefit of improved communication skills. Your teen may also benefit from improved eating disorder symptoms. It is also possible that the intervention will not help your teen.

The information that researchers get from this study will allow health care providers and other caregivers and patients to have a better understanding of how to improve communication skills in parents of teens with anorexia nervosa and if this in turn improves teen's symptoms of anorexia nervosa. It is through you and your teen's participation that researchers hope to influence the way health professionals work with families to provide the best possible care.

WHAT OTHER CHOICES ARE THERE?
You or your teen may choose not to participate in the study, and this will not affect your teen's care at Cincinnati Children's Hospital Medical Center.

HOW WILL INFORMATION ABOUT YOUR TEEN BE KEPT PRIVATE AND CONFIDENTIAL?
Cincinnati Children's Hospital Medical Center, the Primary Investigator, and all Co-investigators collaborating on the study will take the following precautionary measures to protect you and your teen's privacy and confidentiality of you and your teen's research and/or medical records. All participants' data will remain strictly confidential as all information is coded with a unique number, rather than you or your teen's name or other identifying information. These files are

stored in password-protected computer files. All study documents will be stored in a locked cabinet in Dr. Peterson's secure lab area and only research staff working on the project will have access to these secured files. All sessions will be audio recorded to ensure treatment fidelity. However, these will be erased following review of the session. Audio recordings of homework as part of the intervention will be deleted after used in session.

The hospital IRB will have access to individual data in case of adverse events or as necessary to ensure the safety and protection of the patients.

By signing this consent form you are giving permission for representatives of CCHMC, Dr. Peterson and CCHMC employees involved with the research, the Institutional Review Board and the Office for Research Compliance and Regulatory Affairs, and the National Institutes of Health, to be allowed to inspect sections of your medical and research records related to this study. The information from the research study may be published; however, you will not be identified in such publication. The publication will not contain information about you that would enable someone to determine your identity as a research participant without your authorization. Because this research study involves payment for participation, we are required by Internal Revenue Service (IRS) rules to collect and use your social security number (SSN) or taxpayer identification number (TIN) in order to track the amount of money that we pay you. Unless you have given specific permission for another use of your SSN or TIN related to this research study, we will only use your SSN or TIN to keep track of how much money we pay you and your SSN or TIN will not be used as part of this research study.

There is one exception to this confidentiality. If you or your teen provide information about something that might put you, your teen, or another person in danger, we are obligated by our concern for you and your family, and by laws in the state of Ohio, to get you the appropriate help you need to deal with this danger.

You and your teen's rights as research participants will be monitored by Dr. Peterson, research staff working on this project, as well as CCHMC's Institutional Review Board, which reviews all research involving human subjects. A copy of this consent form will be included in your teen's medical research record at CCHMC. Your teen will also be registered in the CCHMC's computer system as a research subject, which may be beneficial for future clinical care.

WILL THE RESULTS OF MY TEEN'S RESEARCH-RELATED TESTS BE AVAILABLE?
If you have questions or are interested in receiving more information about the study or study results, you may contact **Dr. Peterson at (513) 803-7459**.

WHAT IF NEW INFORMATION BECOMES AVAILABLE DURING THE RESEARCH?
The investigator will tell you and your teen about new information from this or other studies that may affect your teen's health, welfare, or willingness to stay in this study.

WHAT ARE YOUR COSTS TO BE IN THIS STUDY?
Aside from your time, there are no costs for participating in this research study. You will be responsible for the usual costs of your teen's medical care, but you will not be charged any additional costs for study participation.

WILL YOU/YOUR TEEN BE PAID TO PARTICIPATE IN THIS RESEARCH STUDY?
You will receive payment for the time associated with you and your teen's participation in the research study if you qualify to participate. We will give you your payment in the form of a

reloadable debit card (ClinCard) and you will receive a handout that will explain how to use the card. We will provide you with a card and we will load money onto your card after each visit that you complete based on the schedule listed below. For the entire study period, families can be compensated up to $200 in total ($100 for the caregiver, $100 for the teen).

Session Number	Teen Incentive	Caregiver Incentive
Baseline Visit	$25	$25
1-Month Visit	$25	$25
3-Month Visit	$25	$25
End of Treatment Visit	$25	$25
Total	$100	$100

WHAT ARE YOUR RIGHTS AS A PARTICIPANT?

You and your teen's participation in this study is completely **voluntary**. You or your teen may choose either to take part or not to take part in this research study. You and your teen's decisions whether to participate will not result in any penalty or loss of benefits to you or your teen and the standard medical care for your teen's condition will remain available to him/her.

If you decide to allow your teen to take part in the research study, you are **free to withdraw** your consents and discontinue you and your teen's participation in this research study at any time. Leaving the study will not result in any penalty or loss of benefits to your teen.

If you or your teen has questions about the study, you will have a chance to talk to one of the study staff, the Principal Investigator, or your regular doctor. Do not sign this form unless you have had the chance to ask questions and have received satisfactory answers.

Nothing in this consent form waives any legal rights you or your teen may have, nor does it release the investigator, the sponsor, the institution, or its agents from liability for negligence.

ABILITY TO CONDITION TREATMENT ON PARTICIPATION IN THIS STUDY

You have a right to refuse to sign this parental permission form and Authorization to use/disclose your teen's Protected Health Information for research purposes.

If you refuse to sign this consent, you and your teen's rights concerning treatment, payment for services, and enrollment in a health plan or eligibility for benefits will not be affected.

WHO DO YOU CALL IF YOU HAVE QUESTIONS OR PROBLEMS?

For questions, concerns, or complaints about this research study or to report a research-related injury, you can contact the researcher Dr. Claire Peterson at 513-803-7459, 3333 Burnet Ave, Cincinnati, OH 45229. Researchers are available to answer any questions you may have about the research at any time.

If you have general questions about you and your teen's rights as research participants in this research study, or questions, concerns, or complaints about the research, you can call the Cincinnati Children's Hospital Medical Center Institutional Review Board at 513-636-8039. You can also call this number if the research staff could not be reached, or if you wish to talk to someone other than the research staff.

HIPAA AUTHORIZATION FOR USE/DISCLOSURE OR PROTECTED HEALTH INFORMATION FOR RESEARCH

To be in this research study you must also give your permission (or authorization) to use and disclose (or share) your and your teen's "protected health information" (called PHI for short).

WHAT PROTECTED HEALTH INFORMATION WILL BE USED AND SHARED DURING THIS STUDY?

CCHMC will need to use and share your PHI as part of this study. This PHI will come from:

- Your CCHMC medical records
- Your research records

The types of information that will be used and shared from these records include:

- Laboratory test results, diagnosis, and medications
- Reports and notes from clinical and research observations
- Imaging (like CT scans, MRI scans, x-rays, etc.) studies and reports
- If applicable, information concerning HIV testing or the treatment of AIDS or AIDS-related conditions, drug or alcohol abuse, drug-related conditions, alcoholism, and/or psychiatric/psychological conditions (but not psychotherapy notes).

WHO WILL SHARE, RECEIVE AND/OR USE YOUR PROTECTED HEALTH INFORMATION IN THIS STUDY?

This form authorizes the following to disclose, use, and receive your PHI:

- Staff at all the research study sites (including CCHMC)
- Personnel who provide services to you as part of this study
- Other individuals and organizations that need to use your PHI in connection with the research, including people at the sponsor and organizations that the sponsor may use to oversee or conduct the study.
- The members of the CCHMC Institutional Review Board and staff of the Office of Research Compliance and Regulatory Affairs.

HOW WILL YOU KNOW THAT YOUR PHI IS NOT MISUSED?

People that receive your PHI as part of the research are generally limited in how they can use your PHI. In addition, most people who receive your PHI are also required by federal privacy laws to protect your PHI. However, some people that may receive your PHI may not be required to protect it and may share the information with others without your permission, if permitted by the laws that apply to them.

CAN YOU CHANGE YOUR MIND?

You may choose to withdraw your permission at any time. A withdrawal of your permission to use and share your PHI would also include a withdrawal from participation in the research study. If you wish to withdraw your permission to use and share PHI you need to notify the study doctor, listed on the first page of this document, in writing. Your request will be effective immediately and no new PHI about you will be used or shared. The only exceptions are (1) any use or sharing of PHI that has already occurred or was in process prior to you withdrawing your permission and (2) any use or sharing that is needed to maintain the integrity of the research.

WILL THIS PERMISSION EXPIRE?

Your permission will expire at the end of the study. If the study involves the creation or maintenance of a research database repository, this authorization will not expire.

WILL YOUR OTHER MEDICAL CARE BE IMPACTED?
By signing this document, you are agreeing to participate in this research study and give permission to CCHMC to use and share your PHI for the purpose of this research study. If you refuse to sign this document, you will not be able to participate in the study. However, your rights concerning treatment not related to this study, payment for services, enrollment in a health plan or eligibility of benefits will not be affected.

SIGNATURES FOR THE PARENT PERMISSION AND INFORMED CONSENT FORM:

I have read the information given above. The investigator or his/her designee have personally discussed with me the research study and have answered my questions. I am aware that, like in any research, the investigators cannot always predict what may happen or possibly go wrong. I have been given sufficient time to consider if I and my teen should participate in this study. I hereby give my permission for both myself and my teen to take part in this study as research study participants.

I will receive a copy of this signed form for my records.

_____ Date:_____
Signature of Participant's Parent or
Legally Authorized Representative*

* If signed by a legally authorized representative, a description of such representative's authority must be provided:
_____

_____ Date: _____
Signature of individual obtaining permission