Children's Hospital of Philadelphia

Informed Consent and HIPAA Authorization Form

Study Title: Shifting Perspectives: Enhancing outcomes in adolescent anorexia nervosa with cognitive remediation therapy

Version Date: March 26, 2020

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Study Overview

You and your child are being asked to take part in this research study because your child has anorexia nervosa. The purpose of this study is to find out if we can improve treatment outcomes in teens with anorexia nervosa. Currently, the standard care of treatment is Family Based Treatment (FBT). We want to supplement this treatment with Cognitive Remediation Therapy (CRT), a treatment used to increase mental flexibility and our ability to think about our thinking.

In the treatment of anorexia, CRT is always combined with another treatment, like FBT. We want to see if CRT is more helpful when parents receive it or when adolescents with anorexia receive it.

If you agree to take part, your participation will last for about 6-7 months and will involve 19 visits (5 visits for assessments, one of which involves questionnaires that can be completed at home or before a therapy appointment, and 15 therapy appointments). You and your child will receive 6 months (15 sessions) of treatment for your child's eating disorder. There are differences between this study and your usual care. As a participant in the research you will:

- Be assigned one of three types of treatment (FBT alone, FBT with CRT for parents, or FBT with CRT for adolescents. Each treatment is 15 sessions.
- Have 4 to 5 research clinic visits that involve assessment of parents and the child with anorexia nervosa. There is no treatment session on these days, except for one visit which involves questionnaires that can be completed at home or before a therapy appointment)
- Be asked to complete a variety of questionnaires

The main risks of this study are from assessment. These include: discussing uncomfortable topics, fatigue from the assessments, being asked to do things that may make you nervous.

You and your child may benefit from FBT and CRT. FBT is the first line treatment for adolescents with anorexia. CRT has been shown to increase flexibility in thinking.

Participation in this study is voluntary. If you and your child do not choose to take part in this study, you both can discuss treatment options with your child's doctor.

If you and your child are interested in learning more about the study, please continue to read below.

In the sections that follow, the word "we" means the study doctor and other research staff. If you are a parent or legal guardian who is giving permission for a child, please note that the word "you" refers to your child.

What is involved in the study?

You and your parents will come to Robert's Center for Pediatric Research for your study intake and will be asked to complete a number of assessments and tasks. After that is done, you will meet with your therapist and then be assigned (randomized) one of the following treatments:

- Family Based Treatment
- Family Based Treatment + Parent Focused Cognitive Remediation Therapy
- Family Based Treatment + Adolescent Focused Cognitive Remediation Therapy

Each Family Based Treatment session is for 45-60 minutes and each Cognitive Remediation Therapy session is 45-60 minutes. If you and your parents are assigned to a FBT+CRT group, therapy appointments will be about 1.5-2 hours each week.

If you are unable to attend in-person visits at Roberts, you may be asked to complete visits remotely via video-conferencing. Remote visits will involve all tasks that do not involve physical manipulation of objects and will also not include the buffet challenge. If visits are done remotely, we may ask you to weigh your child and share this weight with the study therapist or assessor.

What are the study procedures?

Some of the procedures in this study will be repeated several times. Tests that are part of your regular, routine medical care will continue to be performed.

- **Medical Chart Review**: Study staff will review your medical record to make sure you meet the criteria of the study. During the study period, your medical chart will be reviewed periodically. You do not need to be present for this. If your medical doctor is not at Children's Hospital of Philadelphia, we will need permission to speak to your doctor (see below). One of things we will check with your doctor about is if you have any changes to medication that you may be taking.
- **Height and Weight:** Your height and weight will be measured at each study visit.
- **Questionnaires:** You and your parents will receive questionnaires to complete. They include questions about your eating habits and thoughts related to the consumption of food. Your parents will also be asked to complete a few questionnaires about themselves. These questionnaires may ask questions that make you uncomfortable or anxious.

You can complete the questionnaires either via paper and pencil or online. If you and your parents want to complete them on-line, we will send an email with a link to a secure website with all the questionnaires.

- **IQ and Neuropsychological Assessment:** You and your parents will be asked to complete several different tests that look at the ways in which your brain functions. These are like a series of games. In order to understand your brain better, we will also briefly assess you and your parents' IQ.
- **Audio and Video Recording:** While you are in this study, you will be giving us permission to audio and/or video record you and your family during some of the assessments. We will also audio/video tape your therapy sessions and the buffet challenge. This is to make sure that treatment is being delivered correctly.
- **Buffet challenge:** You will be presented with a buffet of food options to pick and choose from. You will be asked to eat what you pick. You will be given a room and your own privacy to consume the meal at your own pace. This will be videotaped.
- **Howe's Grocery:** Your parents will engage in an online simulator mimicking a grocery store. They will be tasked with selecting items they would normally choose while grocery shopping. No actual purchases will be made – this is entirely a simulation.
- **Approach Avoidance Task:** You and your parents will be asked to play a computer game that shows you pictures of various household items, including some foods. You will be asked to press various buttons on the computer when you see certain items.
- **Finger Measurement:** We will measure your index and fourth finger on your left and right hand twice. This measurement will be done once at the beginning of the study.
- **Study Intervention:** You and your parents will receive one of the following:
  - 15 sessions of Family Based Treatment
  - 15 sessions of Family Based Treatment + Parent Focused Cognitive Remediation Therapy
  - 15 sessions of Family Based Treatment + Adolescent Focused Cognitive Remediation Therapy

  Most treatment includes doing extra learning activities at home. Your therapist may ask you and/or your family to some things outside of the treatment sessions. If you or your parents receive CRT, you will be asked to practice between treatment sessions.

Visit Schedule

You will be asked to come to 15 sessions of treatment for your eating disorder over 6 months. The first 8 sessions occur every week, the next 6 sessions occur every other

week, and the last session is a month later. In addition, you and your parents will be asked to also come to CHOP for assessments. There are 5 assessments and these are separate from the 15 therapy sessions. One of these assessments is only questionnaires and can be completed at home online or the same day as your therapy session. In total, you will come to CHOP for 19 study visits.

The table below provides a brief description of the purpose and duration of each assessment visit.

Visit	Purpose	Main Procedures	Duration
Assessment 1	Baseline assessment and Clinical intake	Consent, neuropsychological assessment, height and weight, therapy session, questionnaires, Grocery store (parent), Buffet challenge (adolescent), AAT (parent and adolescent)	Up to 6 hours
Assessment 2	4 weeks post-baseline assessment (Visit 4)	Therapy session and questionnaires	Up to 2 hours
Assessment 3	9 weeks post-baseline assessment (Visit 9)	Neuropsychological assessment and questionnaires	Up to 3 hours
Assessment 4	15 weeks post-baseline assessment (Visit 13)	Neuropsychological assessment, questionnaires, Grocery store (parent), Buffet challenge (adolescent), AAT (parent and adolescent)	Up to 4 hours
Assessment 5	24-26 weeks post-baseline assessment (Visit 18)	Questionnaires, neuropsychological assessment, Grocery store (parent), Buffet challenge (adolescent), AAT (parent and adolescent)	Up to 4 hours
Assessment 6	36-37 weeks (sent online/via mail)	Questionnaires, medical chart review	Up to 30 minutes

Assessment 7	48-49 weeks (sent online/via mail)	Questionnaires, medical chart review	Up to 30 minutes

Will I receive any results from the assessments done as part of this study?

Results that could be important for your clinical care (e.g., eating disorder and other psychiatric symptoms) will be shared with you and your study therapist. We will not share other results with you as the assessments are specifically for the research question.

What are the risks of this study?

Taking part in a research study involves inconveniences and risks. The main risks of taking part in this study are discussed below.

Risks associated with interviews, assessments, and questionnaires:

There are no physical risks but you might experience momentary embarrassment or discomfort. You do not have to answer any questions that make you too uncomfortable. Due to the length of time associated with the assessments, some people may experience fatigue, anxiety, or stress. You will be allowed to take breaks and stop at any time.

Risks associated with audio/videotaping:
Some people may feel uncomfortable having the interview recorded. There is the possibility, that your video might be seen by someone outside of the study team. To prevent this the recordings will be kept on password-protected computers.

Risks associated with breach of confidentiality:

As with any study involving collection of data, there is the possibility of breach of confidentiality of data. Every precaution will be taken to secure your personal information to ensure confidentiality.

At the time of participation, you and your family will be assigned a study identification number. This number will be used on data collection forms and in the database instead of names and other private information. A separate list will be maintained that will link each your name to the study identification number for the duration of the study.

Risks associated with the Buffet Challenge:

You may feel nervous or overwhelmed when asked to serve yourself food and eat it. You may be uncomfortable being videotaped during this process.

Risk associated with Howe's Grocery:

Your parents may feel uncertainty about what foods to pick at the store.

Risks associated with the finger measurement:

You may feel uncomfortable flexing your two fingers. The measurement instrument may feel ticklish. There are, however, no physical risks in the measurement and the measurement is not invasive.

Risks associated with randomization:

Randomization means that you will get assigned to receive one of the three treatment conditions. There are no risks from randomization per se. The risks are all attributable to the risks of the various treatments.

Risks associated with having your weight and height taken:

Each visit you will have your height and weight taken. Doing this at the beginning of each therapy session is normal. It may be upsetting to see your weight and/or height each visit.

Risks associated with treatment sessions:

As part of this study you will receive Family Based Treatment and you or your parents may receive Cognitive Remediation Therapy (CRT). Sometimes in treatment you are asked to discuss things that are upsetting to you or that you do not want to talk about. Some of the tasks you may be asked to do as part of CRT may be hard at first.

Risks associated with being a participant as a CHOP employee

If you are a CHOP employee, your decision to participate will not be shared with your supervisor and will not have an effect on your performance evaluation or employment status.

Are there any benefits to taking part in this study?

You may benefit from FBT. All families receive FBT; it is the recommended treatment for adolescents with eating disorders. There may be an additional benefit if you or your parents receive CRT. However, we cannot guarantee or promise that you will be randomized into the group with additional treatment or that you will receive any direct benefit by participating in this study. The knowledge gained from this research may help doctors determine what is the appropriate treatment for adolescents with anorexia nervosa moving forward.

Do you need to give your consent in order to participate?

If you and your parents decide to participate in this study, you and your parents must sign this form. A copy will be given to you and your parents to keep as a record.

What are your responsibilities?

Please consider the study time commitments and responsibilities as a research subject when making your decision about participating in this study. You and your parents will need to follow the study doctor's instructions, keep all study appointments and do study related learning opportunities at home as directed.

What happens if you decide not to take part in this study?

Participation in this study is voluntary. You and your parents do not have to take part in order to receive care at CHOP.

If you decide not to take part or if you change your mind later there will be no penalties or loss of any benefits to which you are otherwise entitled.

Can you stop your participation in the study early?

You and your parents can stop being in the study at any time. You both do not have to give a reason.

Can the study doctor take you out of the study early?

The study doctor may take you off of the study if:

- Your condition worsens.
- The study is stopped.
- You cannot meet all the requirements of the study.
- New information suggests taking part in the study may not be in your best interests.

What about privacy, authorization for use of Personal Health Information (PHI) and confidentiality?

As part of this research, health information about you and your parents will be collected. This will include information from medical records, assessment, and interviews. Information related to your medical care at CHOP will go in your medical record. This will include your height and weight. Medical records are available to CHOP staff. Staff will view your records only when required as part of their job. Staff are required to keep you and your parents' information private. Information that could identify you and your parents will not be shared with anyone - unless you provide your written consent, or it is required or allowed by law. We will do our best to keep your personal information private and confidential. However, we cannot guarantee absolute confidentiality. You and your parents' personal information may be disclosed if required by law.

The results of this study may be shown at meetings and published in journals to inform other doctors and health professionals. We will keep your identity private in any publication or presentation.

Several people and organizations may review or receive your identifiable information. They will need this information to conduct the research, to assure the quality of the data, or to analyze the data or samples. These groups include:

- Members of the research team and other authorized staff at CHOP
- People from agencies and organizations that perform independent accreditation and/or oversight of research; such as the Department of Health and Human Services, Office for Human Research Protections.
- Groups monitoring the safety of this study
- The National Institutes of Health who is sponsoring this research

By law, CHOP is required to protect your health information. The research staff will only allow access to your health information to the groups listed above. By signing this document, you are authorizing CHOP to use and/or release your health information for this research. Some of the organizations listed above may not be required to protect your

information under Federal privacy laws. If permitted by law, they may be allowed to share it with others without your permission.

There is no set time for destroying the information that will be collected for this study.

Your permission to use and share the information and data from this study will continue until the research study ends and will not expire. Researchers continue to analyze data for many years and it is not possible to know when they will be completely done.

Certificate of Confidentiality (CoC)

A Certificate of Confidentiality (CoC) covers this research. A CoC helps protect your identifiable information and biological samples.

A CoC protects your private information from all legal proceedings. Unless you consent, information from this research study that identifies you will not be shared outside this research.

- No one can be forced to share your identifiable information or biological samples for a lawsuit.
- Your information can't be used as evidence even if there is a court subpoena.

If you consent, your data or biological samples could be shared for:

- other scientific research;

The CoC does not prevent some disclosures.

- The researchers can't refuse requests for information from those funding this research. The National Institute of Health may need information to assess this project.
- You can still share information about yourself. You can also freely discuss your involvement in this research.
- The researchers must disclose things required by law. This includes suspected child abuse and neglect, harm to self or others, or communicable diseases.

Can you change your mind about the use of personal information?

You may change your mind and withdraw your permission to use and disclose your health information at any time. To take back your permission, it is preferred that you inform the investigator in writing.

Dr. C. Alix Timko
The Children's Hospital of Philadelphia
Department of Child and Adolescent Psychiatry and Behavioral Sciences
Robert's Center for Pediatric Research, 8-212
Philadelphia, PA 19104

In the letter, state that you changed your mind and do not want any more of your health information collected. The personal information that has been collected already will be used if necessary for the research. No new information will be collected. If you withdraw

your permission to use your personal health information, you will be withdrawn from the study.

Additional Information

A Data Safety and Monitoring Board, an independent group of experts, will be reviewing the data from this research throughout the study.

You will be informed if changes to the study are needed to protect your health. You will be told about any new information that could affect your willingness to stay in the study, such as new risks, benefits or alternative treatments.

Financial Information

While you are in this study, the cost of your usual medical care – procedures, medications and doctor visits – will continue to be billed to you or your insurance. If you are a CHOP employee, the compensation you receive for this study will be considered taxable income.

Will there be any additional costs?

There will be no additional costs to you by taking part in this study.

The National Institute of Health is providing financial support and material for this study. The following research procedures and study visits will be paid by the NIH:

- Cost of parking
- Cost of FBT and CRT
- Cost of assessments
- Cost of questionnaires

Will you be paid for taking part in this study?

- Parents will be paid the following for completion of all materials at each assessment and their time and effort:
- Assessment 1: $50/parent
- Assessment 2: $10/parent
- Assessment 3: $25/parent
- Assessment 4: $35/parent
- Assessment 5: $50/parent
- Assessment 6: $5/parent
- Assessment 7: $5/parent
- Adolescents/participants will be paid the following for completion of all materials at each assessment and their time and effort:
- Assessment 1: $50/participant
- Assessment 2: $10/participant

- Assessment 3: $30/participant
- Assessment 4: $35/participant
- Assessment 5: $50/participant
- Assessment 6: $5/participant
- Assessment 7: $5/participant

If you receive payment using a bankcard, the bank will have access to identifiable information. The bank will not have access to any medical information.

Who is funding this research study?

The National Institutes of Health is providing funding for this study.

Please ask Dr. Timko if you have any questions about how this study is funded.

What if you have questions about the study?

If you have questions about this study or how your data are going to be used, call the study doctor, Dr. Timko at 267-426-5467. You may also talk to your own doctor if you have questions or concerns.

The Institutional Review Board (IRB) at The Children's Hospital of Philadelphia has reviewed and approved this study. The IRB looks at research studies like these and makes sure research subjects' rights and welfare are protected. If you have questions about your rights or if you have a complaint, you can call the IRB Office at 215-590-2830.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Sharing Data with the National Institutes of Health (NIH)

Why will my data be shared with the National Institutes of Health (NIH)?

The NIH is funding this study. The NIH's goal is to maximize the benefits that come from the research.

The NIH repository stores genetic information and phenotypic data from many studies. The NIH then shares that information with researchers. We will send the information about you and the other participants to a repository at the NIH. The information will be de-identified (no names or other direct information about you will be included). The NIH will not be able to re-identify you or any other individual.

The NIH intends to share the collected information with other researchers for future research. The researchers who receive data must promise to keep the data confidential and to use it only for the purpose approved by NIH. They must also promise to not try to re-identify anyone.

Risks Associated with Sharing Data with the NIH

There are risks associated with sharing your data with the NIH but they are very unlikely to occur. There is only a very small chance that someone could find out that the data came from you. If that happened, it's possible that someone could deny you a job or health insurance. Or you could experience stress, anxiety or embarrassment.

Benefits Associated with Sharing Data with the NIH

Sharing your information for future research will not directly benefit you. This knowledge could help others in the future.

Controlled or Unrestricted Access

The data about you will either be made available by the NIH through controlled access or unrestricted. Controlled access means the data are made available for other research only after investigators have obtained approval from NIH to use the requested data for a particular project. Data for unrestricted access are publicly available to anyone (e.g., The 1000 Genomes Project).

What will be done with my data when this study is over?

We will use and may share data for future research. They may be shared with researchers/institutions outside of CHOP. This could include for profit companies. We will not ask for your consent before using or sharing them. We will remove identifiers from your data, which means that nobody who works with them for future research will know who you are. Therefore, you will not receive any results or financial benefit from future research done on your specimens or data.

Do you need to talk to my doctor?

You are being asked to participate in this study because you have anorexia nervosa. In order to ensure that you have the most appropriate care, you must continue to see your doctor throughout this study. As part of routine clinical care, you will be asked to given us permission to talk to your doctor. If your doctor is not a CHOP doctor, he or she will need to confirm that you are medically stable and able to have outpatient treatment. We will need to ask for certain records (such as growth charts and recent medical tests) to confirm this. If your doctor is at CHOP, we will still need to communicate with him or her about your medical care. We do not need to inform your physician of your participation in a research study in order to communicate about your care.

Consent to Inform Your Doctors of Your Study Participation

Please indicate whether you would like us to inform your non-CHOP doctor(s) of your participation in this study. Please note that this only applies to non-CHOP doctors, as research results will be included in your medical record at CHOP.

_____(initials) I request that my non-CHOP doctor(s) **not** be informed of my participation in this study.

_____(initials) I request that my non-CHOP doctor(s) be informed of my participation in this study.

Consent to Take Part in this Research Study and Authorization to Use and Disclose Health Information for the Research

The research study and consent form have been explained to you by:

Person Obtaining Consent	Signature of Person Obtaining Consent
	Date

By signing this form, you are indicating that you have had your questions answered, you agree to take part and to allow your child to take part in this research study, and you are legally authorized to consent to your child's participation. You are also agreeing to let CHOP use and share the health information that will be collected for this study, as explained above. If you don't agree to the collection, use, and sharing of health information, you and your child cannot participate in this study.

NOTE: *A foster parent is not legally authorized to consent for a foster child's participation.*

Consent for Child's Participation

Name of Subject	
Name of Authorized Representative	Relation to subject: ☐ Parent ☐ Legal Guardian
Signature of Authorized Representative	Date

Consent for Parents' participation

Name of Mother

Signature of Mother

Date

Name of Father

Signature of Father

Date

Child Consent for Release of Mental Health Information:

(14 – 17 year olds only)

By signing this form, you are indicating that you have had your questions answered and you are consenting for the release of your mental health information, current mental health status, mental health records, previous diagnoses, medications and services used. If you do not agree to the collection and use and sharing of your mental health information, then you cannot participate in this study.

Name of Subject (14- 17 year olds only)

Signature of Subject

Date

Child Assent to Take Part in this Research Study (assent must be obtained from subjects 14-17 years old)

I have explained this study and the procedures involved to_____in terms he/she could understand and that he/she freely assented to take part in this study.

_____

Person Obtaining Assent

_____ _____

Signature of Person Obtaining Assent Date

This study has been explained to me and I agree to take part.

_____ _____

Signature of Subject (optional) Date

Consent for Participation for Adolescent 18 years of age:

By signing this form, you are indicating that you have had your questions answered, you agree to take part in this research study. You are also agreeing to let CHOP use and share the health information that will be collected for this study, as explained above. If you don't agree to the collection, use and sharing of health information, you cannot participate in this study.

_____

Name of Subject

_____ _____

Signature of Subject Date