Adaptive Treatment for Adolescent Anorexia Nervosa
NCT Number: NCT03097874
Informed Consent Form
Date Uploaded: 10/5/23
Date of Last Approval in Document: 3/24/21

Please check one of the following:

☐ I am an adult participant in this study.

Print your name here:

_____

☐ I am the parent or guardian granting permission for a child in this study (the use of "you" refers to "your child" or "your ward.")

Print child's name here:

_____

****

Are you participating in any other research studies? _____ Yes _____No

PURPOSE OF RESEARCH

You are invited to participate in a research study of anorexia nervosa. We hope to learn which treatments are effective in treating adolescents with anorexia nervosa. You were selected as a possible participant in this study because you are between the ages of 12 and 18 and are being evaluated for anorexia nervosa. Your participation in this study is entirely voluntary. Your decision not to participate will not have any negative effect on you or your medical care. You can decide to participate now, but withdraw your consent later and stop being in the study without any loss of benefits or medical care to which you are entitled. If you decide to terminate your participation in this study, you should notify Kyra Citron at (650) 723-9182.

This research study is looking for 150 adolescents with anorexia nervosa at Stanford University and the University of California, San Francisco. Each site expects to enroll 75 research study participants.

DURATION OF STUDY INVOLVEMENT

Your participation in this research study is expected to take approximately 1 year and 9 months, consisting of nine months of treatment and one year of follow up. You will be asked to complete two follow-up sessions at 6 months and 12 months post-treatment.

All treatments will consist of up to 18 sessions, beginning at weekly visits and going to bi-weekly. Sessions will last approximately 50 to 60 minutes. Since this study includes family therapy, your parents or guardians will attend sessions with you.

PROCEDURES

If you choose to participate, Dr. James Lock and his research study staff will assess you to get further information on your diagnosis. This will include a comprehensive personal and family psychiatric history including inquiries about the duration of anorexia nervosa, age of onset, history of other eating disorders, and previous experience with treatment. We will also gather information regarding additional current or past experiences with psychiatric problems. This assessment will occur in one visit prior to beginning treatment and will involve the following measures:

- Eating Disorder Examination (EDE): The EDE is a semi-structured interview used to assess your feelings about your shape and weight as well as your eating patterns. This interview generally takes between 45 minutes to an hour to complete. It will be repeated at baseline, 3 months of treatment, end of treatment, 6-month follow-up, and 12-month follow-up
- Yale-Brown-Cornell Eating Disorder Scale (YBC-ED). The YBC-ED is another measure used to assess thoughts and behaviors commonly associated with eating disorders. This interview will take around 20 minutes to complete. This will be repeated at baseline, 3 months, end of treatment, 6-month follow-up, and 12-month follow-up.
- Children's Yale-Brown Obsessive Compulsive Scale (CY-BOCS) assesses general obsessions and compulsions and also takes around 20 minutes. This will also be administered at baseline, 3 months, end of treatment, 6-month follow-up, and 12-month follow-up.
- Kiddie Schedule for Affective Disorders and Schizophrenia for School-Aged Children, Present and Lifetime Version (K-SADS-PL): The K-SADS-PL is a widely used semi-structured interview detecting psychiatric disorders in children and adolescents. This interview will take about 1 hour and will only be administered at baseline.

You will also be asked to complete the following online questionnaires:

- Beck Depression Inventory (BDI). The BDI is a 21 question scale that asks about symptoms of depression. It will take around 5 minutes to complete. This will be administered at baseline, weeks 1-8, 3 months, end of treatment, 6-month follow-up, and 12-month follow-up.

- Beck Anxiety Inventory (BAI). The BAI is a 21 question scale that asks about symptoms of anxiety. It will take about 5 minutes to complete. This will be administered at baseline, weeks 1-8, 3 months, end of treatment, 6 month follow-up, and 12-month follow-up.
- Helping Relationship Questionnaire (HRQ). The HRQ asks your opinion about your therapist. It takes about five minutes to complete**.** This will be repeated after the first treatment session and halfway through the treatment.
- Therapy Suitability and Patient Expectancy (TSPE): The TSPE asks your opinion about the treatment you are receiving. It takes about one minute to complete. This will be given to you and your parents after the first session.
- Compulsive Exercise Test: This questionnaire is a 24 item measure that asks you questions about how you feel about exercise and how exercise makes you feel. It will take five minutes to complete. You will complete this questionnaire at baseline and at session 4 of FBT.
- Commitment to Exercise Scale: This questionnaire is 8 items and asks you questions about your feelings of the importance to exercise. It will take two minutes to complete and you will complete this questionnaire at baseline and at session 4 of FBT.

You have the right to refuse to answer individual questions from the above-mentioned questionnaires.

At the beginning of the study when you have completed all of these interviews, you and your family will begin standard Family Based Treatment. After you receive initial FBT (4 sessions) we will evaluate whether or not you have gained 2.4kg. If you have gained 2.4kg you will continue with regular Family Based Treatment. If not, your family will be randomized to either:

- Continuing the traditional Family Based Treatment as usual
- Family based treatment with an additional adaptive family therapy component (Intensive Parental Coaching – IPC) that lasts for 3 sessions.

Which treatment you receive in the clinical trial is like flipping a coin, and you will have an equal chance of being in the adaptive group or the regular treatment group. Treatment in the clinical trial will consist of up to 18 sessions of therapy spread across 9 months.

Family members living in the same household, including parents, brothers, and sisters will be expected to attend all family therapy sessions.

We would like your permission to audiotape and videotape your treatment sessions. The audio and videotapes will be used solely for the purposes of maintaining consistency and reliability in the application of the therapy treatments. All tapes will be immediately stored on a secure server after the family therapy session. They will only be labeled with your family's study ID, date, and session number. The Protocol Director and research staff may use these recordings for the purposes of evaluation, research, and training at Stanford University and University of California, San Francisco. Tapes will be erased about 5 years after the end of the study. All information on the tapes will be kept strictly confidential to the extent allowed by law.

By signing the consent form, you agree to be audiotaped during this study.

By signing the consent form, you agree to be videotaped during this study.

PARTICIPANT RESPONSIBILITIES

As a participant, your responsibilities include:

- Follow the instructions of the Protocol Director and study staff.
- Attend your treatment sessions with the therapist.
- Keep your study appointments. If it is necessary to miss an appointment, please contact the Protocol Director or research study staff to reschedule as soon as you know you will miss the appointment.
- Tell the Protocol Director or research study staff about any doctor visits, or hospitalizations that you may have.
- Complete your questionnaires as instructed.
- Ask questions as you child think of them.
- Tell the Protocol Director or research staff if you change your mind about staying in the study.

While participating in this research study, you/your child should not take part in any other research project without approval from the Protocol Directors of each study.

WITHDRAWAL FROM STUDY

If you agree to participate and then you change your mind, you are free to withdraw your consent and discontinue your participation at any time. Your decision will not affect your ability to receive medical care for your disease and you will not lose any benefits to which you would otherwise be entitled. If you decide to terminate your participation in the study, you should notify James Lock, MD at (650) 723-5473, your treating therapist, or a member of the research team.

If you withdraw from the study the following actions should be taken:

- We urge you to have one more "closing" session with your treating therapist in order to get referrals.
- You will be asked to complete an end of treatment interview, which will consist of the questionnaires and interviews as noted above.

The Protocol Director may also withdraw you from the study without your consent for one or more of the following reasons:

- Failure to follow the instructions of the Protocol Director and study staff, including but not limited to: pursuing therapy outside of the study parameters (including individual therapy, family therapy and nutritionist visits) or refusing hospitalization when study doctors prescribe such measures for medical reasons.
- The Protocol Director decides that continuing your participation could be harmful to you.
- Pregnancy
- You need treatment not allowed in the study.
- The study is cancelled.
- Other administrative reasons.
- Unanticipated circumstances.

POSSIBLE RISKS, DISCOMFORTS, AND INCONVENIENCES

There are risks, discomforts, and inconveniences associated with any research study. These deserve careful thought. You should talk with the Protocol Director if you have any questions.

Possible risks to you from being in this study may include uneasiness while sharing your feelings about your family member with anorexia nervosa and talking about ways you and the rest of your family can help her/him. The members of our research team are willing to discuss any questions you may have about these risks and discomforts. You may refuse to answer any questions if you wish to do so.

A breach of confidentiality of a family member in the context of family therapy may occur. The therapist will emphasize the importance of confidentiality at each session to reduce this risk.

There is a risk of audio/videotapes being lost. All tapes will be immediately stored on a secure server after the family therapy session. Your family name will not be on these tapes, which will be identified only by a number.

If at any time throughout the study, allegations of abuse are made or there are concerns regarding physical or psychological health, members of the research team will follow up as indicated. In addition, perpetrators of the abuse will be excluded from treatment. Exclusion from study or discontinuation from study may be based solely on allegations of abuse.

There is a degree of inconvenience involved in participation, in that you may miss work, school activities, meetings, etc.

POTENTIAL BENEFITS

A potential benefit of participating in this study and receiving therapy is possible reduction of symptoms associated with AN.

WE CANNOT AND DO NOT GUARANTEE OR PROMISE THAT YOU WILL RECEIVE ANY BENEFITS FROM THIS STUDY.

ALTERNATIVES

The alternative to participating in this study is not to participate. You may seek treatment for anorexia nervosa outside of this study.

PARTICIPANT'S RIGHTS

You should not feel obligated to agree to participate. Your questions should be answered clearly and to your satisfaction.

If you decide not to participate, tell the Protocol Director. You will still receive care for your disease and will not lose any benefits to which you would otherwise be entitled.

You will be told of any important new information that is learned during the course of this research study, which might affect your condition or your willingness to continue participation in this study.

CONFIDENTIALITY

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed except as authorized by you or as required by law. However, there is always some risk that even de-identified information might be re-identified.

Patient information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction. It is possible that, based on information gained from this study, the investigators may be required to report information (e.g., information relating to suicide, physical or sexual abuse) to the appropriate authorities.

Data from this study may be submitted to the National Institute of Mental Health Data Archive (NDA). NDA is a data repository run by the National Institute of Mental Health (NIMH) that allows researchers studying mental illness to collect and share deidentified information with each other. A data repository is a large database where information from many studies is stored and managed. Deidentified information means that all personal information about research participants such as name, address, and phone number is removed and replaced with a code number. With an easier way to share, researchers hope to learn new and important things about mental illnesses more quickly than before.

During and after the study, the researchers will send deidentified information about your health and behavior and in some cases, your genetic information, to NDA. Other researchers nationwide can then file an application with the NIMH to obtain access to your deidentified study data for research purposes. Experts at the NIMH who know how to protect health and science information will look at every request carefully to minimize risks to your privacy.

Your family may not benefit directly from allowing your information to be shared with NDA. The information provided to NDA may help researchers around the world treat future children and adults with mental illnesses so that they have better outcomes. NIMH will also report to Congress and on its web site about the different studies that researchers are conducting using NDA data. However, you will not be contacted directly about the data your family contributed to NDA.

You or your family may decide now or later that you do not want to share your information using NDA. If so, contact the researchers who conducted this study, and they will tell NDA, which can stop sharing the research information. However, NDA cannot take back information that was shared before your family changed its mind. If

you would like more information about NDA, this is available on-line at http://data-archive.nimh.gov.

The limits to confidentiality include the following:

1) If information is revealed about child abuse or neglect, elder abuse of neglect, or potentially dangerous future behavior to others or yourself, the law requires that this information be reported to the proper authorities.

2) If we have reason to believe that you intend to make an attempt to hurt or kill yourself or someone else, we will notify potential helpers or victims.

Certificate of Confidentiality

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by NIMH which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

Authorization to Use Your Health Information for Research Purposes

Because information about you and your health is personal and private, it generally cannot be used in this research study without your written authorization. If you sign this form, it will provide that authorization. The form is intended to inform you about how your health information will be used or disclosed in the study. Your information will only be used in accordance with this authorization form and the informed consent form and as required or allowed by law. Please read it carefully before signing it.

What is the purpose of this research study and how will my health information be utilized in the study?
The purpose of this study is to learn more about how to best treat adolescents with anorexia nervosa. Your health information related to this study, including, but not limited to, results of standardized questionnaires and assessments, physical health examinations (weights and vital signs) may be used or disclosed in connection with this research study.

Do I have to sign this authorization form?
You do not have to sign this authorization form. But if you do not, you will not be able to participate in this research study including receiving any research-related treatment. Signing the form is not a condition for receiving any medical care outside the study.

If I sign, can I revoke it or withdraw from the research later?
If you decide to participate, you are free to withdraw your authorization regarding the use and disclosure of your health information (and to discontinue any other participation in the study) at any time. After any revocation, your health information will no longer be used or disclosed in the study, except to the extent that the law allows us to continue using your information (e.g., necessary to maintain integrity of research). If you wish to revoke your authorization for the research use or disclosure of your health information in this study, you must write to: James Lock at 401 Quarry Rd. Stanford, CA 94305.

What Personal Information Will Be Used or Disclosed?
Your health information related to this study, may be used or disclosed in connection with this research study, including, but not limited to, results of

assessments and questionnaires and physical health (weights and vital signs) may be used or disclosed in connection with this research study.

Who May Use or Disclose the Information?
The following parties are authorized to use and/or disclose your health information in connection with this research study:

- The Protocol Director (James Lock).
- The Stanford University Administrative Panel on Human Subjects in Medical Research and any other unit of Stanford University as necessary
- Research Staff including research assistants and statisticians.

Who May Receive or Use the Information?
The parties listed in the preceding paragraph may disclose your health information to the following persons and organizations for their use in connection with this research study:

- The Office for Human Research Protections in the U.S. Department of Health and Human Services.
- The sponsor of the study the National Institute of Mental Health
- The study team at the University of California, San Francisco.
- The Data and Safety Monitoring Board at Stanford University.
- The Data and Coordinating Center at Stanford University.
- Your primary care physician, if a medical condition that needs attention is discovered, or at your request.

Your information may be re-disclosed by the recipients described above, if they are not required by law to protect the privacy of the information.

When will my authorization expire?
Your authorization for the use and/or disclosure of your health information will continue until January 1st, 2045.

Will access to my medical record be limited during the study?
To maintain the integrity of this research study, you may not have access to any health information developed as part of this study until it is completed. At that point, you would have access to such health information if it was used to make a medical or billing decision about you (e.g., if included in your official medical record).

_____ _____
Signature of Adult Participant Date

_____
Printed Name of Adult Participant

_____ _____
Signature of Legally Authorized Representative Date

_____
Printed name of Legally Authorized Representative

_____
Description of Representative's Authority to Act for Subject

FINANCIAL CONSIDERATIONS

Payment
You will be paid $50 upon completion of one-year follow-up assessments for the study. Payments may only be made to U.S. citizens, legal resident aliens, and those who have a work eligible visa. You may need to provide your social security number to receive payment.

Costs
If you participate in this study, the study will pay for those services, supplies, procedures, and care associated with the study that are not a part of your routine medical care. However, there may be additional costs to you. These include basic expenses like transportation and the personal time it will take to come to the study visits. You and/or your health insurance must pay for services, supplies, procedures, and care that are required during this study for routine medical care. You will also be responsible for any co-payments and/or deductibles as required by your insurance. Participation in this study is not a substitute for health insurance.

Sponsor
The National Institute of Mental Health is providing financial support and/or material for this study.

COMPENSATION for Research-Related Injury

All forms of medical diagnosis and treatment – whether routine or experimental – involve some risk of injury. In spite of all precautions, you might develop medical complications from participating in this study. If such complications arise, the Protocol Director and the research study staff will assist you in obtaining appropriate medical treatment. In the event that you have an injury or illness that is directly caused by your participation in this study, reimbursement for all related costs of care first will be sought from your insurer, managed care plan, or other benefits program. **You will be responsible for any associated co-payments or deductibles as required by your insurance.**

If costs of care related to such an injury are not covered by your insurer, managed care plan or other benefits program, you may be responsible for these costs. If you are unable to pay for such costs, the Protocol Director will assist you in applying for supplemental benefits and explain how to apply for patient financial assistance from the hospital. You do not waive any liability rights for personal injury by signing this form.

ClinicalTrials.gov

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.

CONTACT INFORMATION

Questions, Concerns, or Complaints: If you have any questions, concerns or complaints about this research study, its procedures, risks and benefits, or alternative courses of treatment, you should ask the Protocol Director, Dr. James Lock. You may contact him now or later at (650) 723-5473.

Injury Notification: If you feel you/your child have been hurt by being a part of this study, please contact the Protocol Director, Dr. James Lock at (650) 723-5473.

Independent Contact: If you are not satisfied with how this study is being conducted, or if you have any concerns, complaints, or general questions about the research or your rights as a participant, please contact the Stanford Institutional Review Board (IRB) to speak to someone independent of the research team at (650) 723-5244 or toll free at 1-866-680-2906. You can also write to the Stanford IRB, Stanford University, 1705 El Camino Real, Palo Alto, CA 94306.

Alternate Contact: If you need to change your appointment or if you cannot reach the Protocol Director, please contact Kyra Citron at (650) 723-9182.

IRB Use Only
Approval Date: March 24, 2020
Expiration Date: March 24, 2021

For Participant with AN

May we contact you about future studies that may be of interest to you? ☐Yes ☐ No

Signing your name means you agree to be in this study and that you will receive a copy of this signed and dated consent form.

_____ _____
Signature of Adult Participant Date

_____
Printed Name of Adult Participant

OR

_____ _____
Signature of Parent, Guardian or Conservator Date

_____ _____
Printed Name of Parent, Guardian or Conservator Authority to act for participant

_____ _____
(If available) Signature of Other Parent Date

_____ _____
Printed Name of Other Parent Authority to act for participant

The IRB determined that the permission of two parents is recommended in accordance with 45 CFR 46.408(b) unless one parent is deceased, unknown, incompetent, not reasonably available, or only one parent has legal responsibility for the care and custody of the child. *Not reasonably available* means that the other parent is not present during the consenting process, or will not be available prior to the start of research procedures.

_____ _____
Signature of Person Obtaining Consent Date

_____
Printed Name of Person Obtaining Consent