

STANFORD UNIVERSITY Research Consent Form

Protocol Director: James Lock, MD, PhD

IRB Use Only

Approval Date: March 19, 2024

Expiration Date: March 19, 2025

Protocol Title: Implementing Family-Based Treatment for Adolescent Anorexia Nervosa for Providers in Private Practice: A Feasibility Study

FOR QUESTIONS ABOUT THE STUDY, CONTACT: James Lock, MD, PhD; 401 Quarry Road, Stanford, CA, 94301; [REDACTED].

KEY INFORMATION: Your consent is being sought for this research study. However, participation in this study is entirely voluntary. The purpose of the research is to evaluate the most effective training method for Family-Based Treatment for Adolescent Anorexia Nervosa. You will be expected to be in this study for a maximum of 6 months. As a part of this study, you will be expected to participate in training and supervision; as well as to provide demographic and clinical practice information and complete periodic routine assessments. There are no risks associated with this study. Benefits to be expected include the knowledge gained from participating in training and supervision. However, there is no guarantee of any benefits from study participation.

DESCRIPTION: You are invited to participate in a research study on what method of training for Family-Based Treatment (FBT) for Adolescent Anorexia Nervosa is most effective. You will be randomly assigned (like flipping a coin) to one of two training courses, either online or webinar, for Family-Based Treatment. We are looking at both the acceptability and feasibility of providing FBT training through an online modality instead of the typical 2-day in-person trainings that is currently how training takes place. You will be asked to take surveys and answer questions regarding your experience and you will be asked to participate in a three-month training followed by expert supervision on a minimum of one and maximum of two outpatient adolescent anorexia nervosa cases over the course of three months.

In addition to participating in the training and supervision, you will be expected to provide basic demographic and clinical practice information, and complete several assessments of your progress during the study, including online questionnaires and a video assessment of your response to therapy vignettes created by the research team. You will also be expected to submit baseline data on weight gain from week 1-4 from a previously treated adolescent with AN you have treated in the last 6 months or alternatively one that you treat within 3 months of this initial screening and consent before being randomly assigned (like flipping a coin) to a training. You will be expected to submit the same information for the patient under case consultation during the supervision period.

The video assessment will be used solely for assessment purposes and will be stored in a HIPAA-compliant encrypted online server. They will only be labeled with your study ID, date, and assessment timepoint. Videos will be deleted from the server about 5 years after the end of the study. All videos will be kept strictly confidential to the extent allowed by law. **By agreeing to participate in this research, you agree to be videotaped for assessments during this study.**

We will use this information to enhance our knowledge about how to implement and improve access to evidence-based treatment trainings for community mental health providers. You were selected as a possible participant in this study because you are a therapist that has completed a

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masters or doctoral training in your field (psychology, psychiatry, family therapy, social work) seeking training in Family-based Treatment for Adolescent Anorexia Nervosa.

There is no cost to you for participating in this study, other than the basic expenses like the personal time it will take to complete all of the study procedures.

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

Identifiers might be removed from identifiable private information and, after such removal, the information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you.

Your participation in this study is entirely voluntary. If you decide to participate, you are free to withdraw your consent and discontinue participation at any time without impacting your on-going medical care. If you decide to terminate your participation in this study, you should notify Dr. Lock at [REDACTED].

Stanford University expects to enroll 140 participants in this research study. The National Institute of Health is providing financial support for this study.

PARTICIPANT'S RESPONSIBILITIES:

As a participant, your responsibilities include:

- Follow the instructions of the Protocol Director and study staff.
- 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.
- Complete your questionnaires as instructed.
- Ask questions as you think of them.
- Tell the Protocol Director or research staff if you change your mind about staying in the study.

RISKS AND BENEFITS: We do not anticipate any risks associated with participating in this study. The benefits which may reasonably be expected to result from this study include knowledge gained from participating in the training and supervision. **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 training for FBT outside of this study.

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TIME INVOLVEMENT: Following the initial baseline assessment, you will be randomized to either:

- *Online Training* which consists of 10 lectures that are self-paced with a maximum of three months to complete with each lecture bundle comprising of short didactic videos that discuss the treatment model and provide mock therapy session video clips (modeling FBT with a typical adolescent AN case), as well as supplementary readings and videotaped role-plays.
- *Webinar training* which consists of 1-hour weekly webinar lectures over three months. There will be lectures discussing the scientific evidence supporting FBT, how therapists set up treatment for FBT, main interventions used in FBT during each phase, and recorded role-plays illustrating interventions throughout the 3 phases.

Both trainings are followed by post-online expert supervision for a minimum of 1 case and a maximum of 2 cases over the course of 3 months. Your participation in this study is expected to take 6 months total.

The three online assessments (Baseline, End of Training, and End of Supervision) that you will also be required to complete, which consist of online questionnaires and a video assessment of your response to therapy vignettes created by the research team, will take you about an hour to complete each time. Your participation in this study will end when treatment has concluded.

PAYMENTS/REIMBURSEMENTS: You will receive [REDACTED] after completing each assessment amounting to a total of [REDACTED] for completing all study assessments. At the end of supervision, once you have completed a minimum of one case, then you will receive CE credit and a certificate of completion of FBT training as well.

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 social security number to receive payment.

PARTICIPANT'S RIGHTS: If you have read this form and have decided to participate in this study, please understand your participation is voluntary and you have the right to withdraw your consent or discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled.

The results of this research study may be presented at scientific or professional meetings or published in scientific journals. However, your identity will not be disclosed.

You have the right to refuse to answer particular questions.

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.

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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 authorization. If you agree to participate, 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 agreeing to participate in this study.

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 explore the what method of training for Family-Based Treatment (FBT) for Adolescent Anorexia Nervosa is most effective and the acceptability and feasibility of providing FBT training through an online or webinar modality. If your information is used for publication, any identifying information will be removed.

Do I have to agree with this authorization form?

You do not have to agree to this authorization form. But if you do not, you will not be able to participate in this research study. Agreeing to participate in this study is not a condition for receiving any medical care outside the study.

If I agree, 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: Dr. Lock at 401 Quarry Road, Stanford, CA, 94305.

What Personal Information Will Be Obtained, 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 from

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questionnaires as well as demographic information like age, sex, ethnicity, and credentials (degree).

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: Dr. James Lock
- The Stanford University Administrative Panel on Human Subjects in Medical Research and any other unit of Stanford University as necessary
- The research team, including psychologists and psychiatrists, research assistants, data analysts, and statisticians.
- The Data and Coordinating Center at Stanford University

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 study team at University California, San Francisco
- The Data and Safety Monitoring Board at Stanford University
- The sponsor of the study the National Institute of Mental Health

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 end on January 1st, 2050 or when the research project ends, whichever is earlier.

WITHDRAWAL FROM STUDY

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.
- The Protocol Director decides that continuing your participation could be harmful to you.
- The study is cancelled.
- Other administrative reasons.

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- Unanticipated circumstances.

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, James Lock, MD, PhD at [REDACTED]. You should also contact him at any time if you feel you have been hurt by being a part of this study.

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 help accessing the trainings, assessments, change your supervision appointment, or if you cannot reach the Protocol Director, please contact [REDACTED] at [REDACTED].

The Alternate Contact above, who serves as the Research Assistant on this study, will download this signed consent form and securely email you a copy for your records following its completion and the completion of the following survey.

If you agree to participate in this research, please select the AGREE option below and complete the following survey.