Confirming the Efficacy/Mechanism of Family Therapy for Children With Low Weight Avoidant/Restrictive Food Intake Disorder (ARFID)

Informed Consent Form

NCT04450771

February 28, 2025

☐ 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

Your consent is being sought for participation in an eating disorders treatment research study. This is an intervention that attempts to reduce eating disorder symptoms associated with Avoidant Restrictive Food Intake Disorder. Participation in the research study will include attending one-hour telehealth therapy sessions that will take place over the course of 14 weeks. You will also complete assessment interviews (for surveys and measurement) over the course of the study: one interview at the beginning of the study; one interview 1 month into treatment; one interview 2 months into treatment; one interview following treatment; and one interview 6 months after the end of treatment. As part of this research study, you will complete structured interviews with trained research assistants, complete psychological questionnaires, and engage in a variety of treatment-specific activities, including but not limited to verbal, written, and behavioral exercises about eating habits.

Your participation in this study is completely voluntary. Some possible risks and inconveniences of the study include psychological discomfort during interviews and treatment sessions, and the inconvenience of potentially missing work, school activities, meetings, etc. Some possible benefits of participating in this research are an improvement in eating disorder symptoms.

PURPOSE OF RESEARCH

You are invited to participate in a research study of ARFID, Avoidant Restrictive Food Intake Disorder. We hope to learn which treatments are effective in treating children with ARFID. You were selected as a possible participant in this study because you are between the ages of 6 and 12 and are being evaluated for ARFID. 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 [redacted] at [redacted].

This research study is looking for 100 children with Stanford University.

VOLUNTARY PARTICIPATION

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.

DURATION OF STUDY INVOLVEMENT

Your participation in this research study is expected to take approximately 10 months, consisting of four months of treatment and 6 months of follow up. You will be asked to complete one follow-up session at 6 months post-treatment. Treatment may consist of up to 14 weekly telehealth sessions depending on the type of treatment you are assigned to. Sessions will be up to an hour long. Since this study includes family therapy, you will attend sessions with your family.

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 ARFID, 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. It is possible that, based on information gained from this study, the researchers may be required to report information (e.g., information relating to suicide, physical or sexual abuse) to the appropriate authorities. This assessment will occur in one visit, prior to the beginning of treatment.

You will also be asked to complete the following questionnaires:

- Center for Epidemiological Studies Depression Scale for Children (CES-DC): This is a validated measure of child depression and will be completed by children at all major assessment points.
- Revised Children's Manifest Anxiety Scale, Second Edition (RCMAS-2): This is a validated measure of childhood anxiety and will be completed by children at all major assessment points.

Additionally, if your child is 8 years old or older, they will be asked to complete the following tasks and questionnaires as well:

- Heartbeat Tracking Task: Children ages 8+ will be asked to complete this 10-minute task with a trained assessor at baseline and after sessions 2, 4, 6, and 8. For this task, children will be asked to guess their heart rate over time windows of 25, 30, 35, 40, 45, and 50 seconds. Heart rate will be tracked using a Finger Pulse Oximeter (a non-invasive cap that can be placed on the finger) that will be mailed to families ahead of time. Immediately following each trial, children will be asked to rate their confidence in their guess. This task will be used as a measure of interoceptive sensibility.
- Color-Word Interference Test (D-KEFS): Children ages 8+ will be asked to complete this 5-7-minute subtest of the D-KEFS (Delis-Kaplan Executive Function System) with a trained assessor at baseline and after sessions 2, 4, 6, and 8. This test will be used to measure set-shifting and cognitive flexibility, and involves asking children to name and read the names of colors.
- MAIA-Y (Multidimensional Assessment of Interoceptive Awareness for Youth): Children ages 8+ will be asked to complete this 10-15-minute questionnaire about interoceptive sensibility at baseline and after sessions 2, 4, 6, and 8.

You have the right to refuse to answer particular questions.

At the beginning of the study, once you have completed all of these interviews, you and your family will be randomized to either:

- Family-Based Treatment for ARFID (FBT-ARFID) with medical management
  - FBT-ARFID consists of 14 1-hour telehealth sessions that will be conducted approximately weekly over a 4-month period. It is a manualized treatment based on the model of FBT that employs the same interventions as standard FBT for AN and BN: externalization, agnosticism, parental empowerment, a behavioral focus on changing eating behavior. Early sessions focus on inciting parents to make changes and includes a family meal that allows therapists to observe and consult directly to mealtime behaviors. FBT-ARFID for children 12 and under is manualized and consists of 2 phases. The first phase is focused on parents taking charge and changing the eating behaviors of their child that are maintaining ARFID. The second phase focuses on the child taking up in an age-appropriate way managing their eating consistent with the changes the parents have employed in phase 1.
- Manualized Non-Specific Care (NSC) with medical management
  - Manualized Non-Specific Usual Care for ARFID (NSC): This treatment is a manualized non-specific psycho-educational and motivational

enhancement approach that is based on a supportive non-directive psychotherapy model that has been used in other RCTs with eating disorders as a comparison. NSC consists of 9 sessions with the child alone and 5 parent-only meetings. Sessions are 1 hour and telehealth. NSC matches FBT-ARFID for time and therapist attention. The focus of the NSC intervention is psychoeducation about health and social impacts of restrictive eating and supporting parent and child exploration of motivation to change eating patterns and choices they make about changes to eating. However, the therapist does not initiate behavioral or cognitive interventions. Feelings about eating and making changes are explored in both the child and parent sessions. There is no overlap with FBT-ARFID because there are no family sessions, no discussions about weight or behavioral strategies, no monitoring of behavioral or weight progress, no family meal, and no empowerment of parents to manage the restrictive eating.

Which treatment you receive in the clinical trial is like flipping a coin, and you will have an 50% chance of being in the FBT-ARFID group or the Manualized Non-Specific Care group. Treatment in the clinical trial will consist of up to 14 sessions of therapy spread across 4 months. After randomization, you will start the appropriate course of treatment.

Family members living in the same household, including parents, brothers, and sisters will be expected to attend all family therapy sessions. The time commitment for the FBT-ARFID treatment will be the same for all family members as all 14 sessions are family sessions. The time commitment for family members differs in the NSC treatment arm. The patient will have to attend 9 child-only sessions and parents will need to attend 5 parent-only sessions in the NSC treatment. Siblings will not have to attend sessions if your family is randomized to this treatment.

We would like your permission to audiotape and videotape your treatment sessions. The audio and video tapes will be used solely for the purposes of maintaining consistency and reliability in the application of the therapy treatments. Additionally, if your child is 8 years old or older, we would like your permission to audiotape and videotape the Color-Word Interference Test. These audio and videotapes will be used solely for the purposes of scoring the test. 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 use of video-recordings by Protocol Director and research staff will be limited to evaluation of treatment consistency, research, and training of project staff at Stanford. If your information is used for publication, any identifying information will be removed. 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 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 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 [redacted].

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 related to ARFID or family therapy), or refusing hospitalization when study doctors prescribe such measures for medical reasons.
- The Protocol Director decides that continuing your participation could be harmful.
- 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 ARFID and talking about ways the rest of your family can help you. 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 after the family therapy session on a secure server. Your family name will not be on these tapes, which will be identified only by a number.

There is a risk of the videoconferencing platform failing to perform optimally. In such a case, the therapist would call you via telephone to troubleshoot and work out an optimal solution.

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. The researchers may be required to report information (e.g., information relating to suicide, physical or sexual abuse) to the appropriate authorities as well. In addition, referral for Psychiatric evaluation will be provided for suicidal risk.

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 ARFID.

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 ARFID 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 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.

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.

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.

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. 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.

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 of 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 specimens 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 specimens 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

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 children with avoidant restrictive food intake disorder. 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 Obtained, Used or Disclosed?

Your health information, including personal identifiers, related to this study, may be used or disclosed in connection with this research study, including, but not limited to, name, date of birth, telephone number and address for payment, results of assessments and questionnaires, physical health (weights and vital signs), blood tests, and recorded therapy sessions may be used or disclosed in connection with this research study. If your information is used for publication, any identifying information will be removed.

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 Health
- Your primary care physician, if a medical condition that needs attention is discovered, or at your request.
- The Data and Safety Monitoring Board at Stanford University.
- The Data and Coordinating Center at Stanford University.

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 Legally Authorized Representative (LAR) Date
(e.g., parent, guardian or conservator)

_____
Printed Name of LAR

_____
LAR's Authority to Act for Participant
(e.g., parent, guardian or conservator)

FINANCIAL CONSIDERATIONS

Payment
You will be paid [redacted] upon completion of end of treatment and follow-up 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. 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 NIH 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.

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 [redacted].

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 [redacted].

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.

Alternative Contact: If you need to change your appointment or if you cannot reach the Protocol Director, please contact [redacted] at [redacted].

EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

As a research participant you have the following rights. These rights include but are not limited to the participant's right to:

- be informed of the nature and purpose of the experiment;
- be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized;
- be given a description of any attendant discomforts and risks reasonably to be expected;
- be given an explanation of any benefits to the subject reasonably to be expected, if applicable;
- be given a disclosure of any appropriate alternatives, drugs or devices that might be advantageous to the subject, their relative risks and benefits;
- be informed of the avenues of medical treatment, if any available to the subject after the experiment if complications should arise;
- be given an opportunity to ask questions concerning the experiment or the procedures involved;
- be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation without prejudice;
- be given a copy of the signed and dated consent form; and

- be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion or undue influence on the subject's decision.

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 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