Study Title: Chompions! A Treatment Study for Childhood Avoidant/Restrictive Food Intake Disorder (ARFID)

NCT#: NCT05105308

IRB Reference Date: 11/21/2023

Duke University Health System

Consent to Participate in a Research Study
Chompions!: A treatment study of childhood Avoidant/Restrictive Food Intake Disorder

CONCISE SUMMARY
Avoidant Restrictive Food Intake Disorder (ARFID) is a disorder that affects toddlers, children, adolescents, and adults. Individuals with ARFID are not able to consume an adequate amount or variety of food to a degree that it affects their mental and/or physical health. ARFID often begins in early childhood so it is important to treat children in early in life as possible to prevent any negative consequences of poor nutrition. There are currently no treatments for young children with ARFID. We have developed two different study programs and the purpose of this study is to test them out and see if they help children with ARFID and to learn more about how these study programs work. Your family will be assigned to one of these study programs.

Your child may experience a direct medical benefit as a result of participating in this study. The goal of this study program is to improve the quality of your child's nutrition, mental health, and well-being.

The greatest risks of this study include the possibility of distress in response to presentation with unfamiliar foods and loss of confidentiality.

If you are interested in learning more about this study, please continue to read below.

Your child is being asked to take part in this research study because your child may have Avoidant Restrictive Food Intake Disorder (ARFID). Research studies are voluntary and include only people who choose to take part. Please read this consent form carefully and take your time making your decision. As your study doctor or study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below.

Please tell the study doctor or study staff if your child is taking part in another research study.

A grant from the National Institutes of Mental Health (NIH) will sponsor this study. Portions of ***Dr. Nancy Zucker*** and her research team's salaries will be paid by this grant.

WHO WILL BE MY DOCTOR ON THIS STUDY?
If you decide to have your child participate, ***Dr. Nancy Zucker*** will be your child's doctor for the study and will be in contact with your child's regular health care provider throughout the time that your child is in the study and afterwards, if needed.

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WHY IS THIS STUDY BEING DONE?

The purpose of this study is to our primary objective is to determine whether two experimental study programs Feeling and Body Investigators-ARFID Division (FBI-ARFID) or Family-Assisted Diet (FAD) can improve symptoms of ARFID.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

Approximately 168 parent-child pairs will take part in this study. The study will include both boys and girls between the ages of 5 to 9 and their parents.

WHAT IS INVOLVED IN THE STUDY?

Participation in this study is entirely voluntary. If you agree to allow your child to be in this study, you will be asked to sign and date this consent form. Participation in this study program involves a number of activities. The activities that you will complete

Pre-Study Program Assessment

To better understand the nature of your child's eating issues, we will interview the parent about the history of their child's eating problems. This interview will be conducted over a video conference call. This interview will be recorded. This interview is used to determine if your child is diagnosed with ARFID and/or other mental health problems. We will discuss together following this interview whether this study is the right fit for your family. If so, we will invite your family to participate in the remaining activities of the study. We will get the contact information of your child's doctor and communicate with your doctor throughout the study to inform them of your child's progress throughout the study.

Video Recorded Food Adventure. We will also ask that your child complete a lab in which we will assess their food consumption and behavior as your child is presented with several foods. Your child will then rate their views on the food and their mood using an emoticon scale.

These recordings will be kept in your child's secure research folder for six years after the study is completed or until your child reaches the age of 21, whichever is longer.

Questionnaires. You and your child will also be asked to complete a questionnaire battery at various points throughout the study, including during the Pre-Program Assessment. These help us measure your child's progress during the study program and also to understand more about your child. We will also ask you to complete questionnaires about yourself.

Your Child's Daily Intake. You will have three 24-hour dietary recalls in which you will keep track of everything your child eats and drinks on three separate days (two weekdays and one weekend day). You will have three phone calls in which you report your child's intake to a member of the study team.

Study program

As part of this study you and your child will be randomly assigned (like the flip of a coin) to a study program arm, receiving either ***('Family Assisted Diet (FAD)' study program arm or 'Feeling and Body Investigator:***

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ARFID Division' study program arm).
You and your child will receive one of two behavioral study programs for ARFID which are both between 20 to 30 sessions. Each study program involves both parent and child and will work to assist the child in trying new foods, eating more food if that is needed, and introducing new foods into their regular eating. Throughout both study programs, you will do food practices at home that we teach you and ask you to record.

Post-Study Program Assessment
Following the study program, you will repeat the assessments that you completed prior to the study program so we can look at any changes that occurred with study program. This includes the diagnostic interviews, questionnaires, the eating lab task for your child, and the 3-day dietary recalls of what your child eats.

You will have three 24-hour dietary recalls in which you will keep track of everything your child eats and drinks on three separate days (two weekdays and one weekend day). You will have three phone calls in which you report your child's intake to a member of the study team.

- You will have the same diagnostic interview conducted again over a video conference call to reassess your child's eating difficulties and mental health. This interview will be recorded.
- Your child will again complete a lab in which we will assess their food consumption and behavior as your child is presented with several foods. Your child will then rate their views on the food and their mood using an emoticon scale.

You and your child will also be asked to complete a questionnaire battery

3 Month Follow-Up
3 months following the completion of the study program, we will ask you and your child to again complete the interview about your child's eating symptoms, video recorded food adventure, and a questionnaire battery so we can examine how your child is doing after the study program ends.

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Timeline

As a part of the study, families will be asked to complete study activities in timely manner in accordance with our study timeline described below:

Timeframe	Item
<u>Start of Study</u>	
Within **Two Weeks** of Study Start	Complete 3 dietary recalls where you go over your child's intake during a 24 hour period
Within **Four Weeks** of Study Start	Complete an interview about your child's eating symptoms
Within **Seven Weeks** of Study Start	*If eligible for treatment,* complete: 1) Questionnaires 2) Parent Mental Health Interview about Child 3) Child Interview about their thoughts & attitudes around food (ages 7+) 4) Video Recorded Food Adventure
<u>Post-Treatment</u>	
Within **Two Weeks** Post Treatment	Complete: 1) Interview about your child's eating symptoms 2) Exit Interview on your treatment experience
Within **Four Weeks** Post Treatment	Complete 3 dietary recalls where you go over your child's intake during a 24 hour period
Within **Six Weeks** Post Treatment	Complete: 1) Questionnaires 2) Parent Mental Health Interview about Child
<u>3-Month Follow Up</u>	
Within **Four Weeks** of 3-month Follow Up Start	Complete: 1) Interview about your child's eating symptoms 2) 3 Month Follow Up Interview 3) Video Recorded Food Adventure 4) Questionnaire on Eating Symptoms

We are currently working within an accelerated timeline with our grant coming to an end, as well as to gather more accurate insights into treatment outcomes. Please note that we will be adhering to strictly to these time constraints. We understand that this may not align with the schedules of some families. If this timeline is something that is not feasible for your family, please let us know and we will be happy to introduce you to other alternatives for accessing treatment, such as parent support groups.

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Individuals at Duke University and our research partners, approved by the Duke University Health System Institutional Review Board, will analyze the data collected under this study. Data storage and analysis will follow the standard privacy and confidentiality policies described in this document.

Some of the data collected in this study are personally identifiable, such as video recordings of your child trying new foods, or recordings of interviews. Other data can be de-identified, such as your responses to questionnaires. This means it is possible to remove personal identifiers (such as name, address, birthdate and phone number) from the data.

HOW LONG WILL I BE IN THIS STUDY?

Your participation will begin with the diagnostic interview and will end once you complete the study activities, typically about 4 to 6 months of the study program with a 3 month follow up, if you participate in all parts of the study. You and your child can choose to stop participating at any time without penalty or loss of any benefits to which you are entitled. However, if you and your child decide to stop participating in the study, we encourage you to talk to your child's doctor first.

WHAT ARE THE RISKS OF THE STUDY?

There are no known physical risks associated with participation in this study. There is, however, the potential risk of loss of confidentiality. Every effort will be made to keep your and your child's information confidential, however, this cannot be guaranteed. To minimize this risk, you and your child will be assigned a unique code number. The key to this code will be kept in a locked file cabinet in the locked office of the principal investigator of this study. There is a potential risk that participants will feel uncomfortable answering questions in some of the questionnaires or interviews. To minimize this discomfort, you are not required to answer any question that makes you feel uncomfortable. You may stop your participation in this study at any time.

It is possible that your child may be distressed by trying unfamiliar foods. There may also be risks, discomforts, or side effects that are not yet known.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

If you agree to allow your child to take part in this study, there may be direct medical benefit to your child. A possible benefit is that your child's symptoms of ARFID may improve including improvements in the quality of their physical and emotional health. However, such benefits cannot be guaranteed. We hope that in the future the information learned from this study will benefit other families that have children with ARFID.

WILL MY CHILD'S INFORMATION BE KEPT CONFIDENTIAL?

Participation in research involves some loss of privacy. We will do our best to make sure that information about your child is kept confidential, but we cannot guarantee total confidentiality. Your child's personal information may be viewed by individuals involved in this research and may be seen by people including those collaborating, funding, and regulating the study. We will share only the minimum necessary information in order to conduct the research. Your child's personal information may also be given out if required by law.

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Study records that identify you or your child will be kept confidential as required by law. Federal Privacy Regulations provide safeguards for privacy, security, and authorized access. Except when required by law, you and your child will not be identified by name, social security number, address, telephone number, or any other direct personal identifier in study records disclosed outside of Duke University Health System (DUHS). For records disclosed outside of DUHS, you and your child will be assigned a unique code number. The key to the code will be kept in a locked file in Dr. Zucker's office.

Your information will be stored in a secure electronic database.

We will use a third-party web-based application from KSADS-COMP to administer and score the responses for the diagnostic assessments in this study. The KSADS-COMP is used to administer the diagnostic interview, the Schedule for Affective Disorders and Schizophrenia for School-Aged Children. To properly score assessments, information including the child's gender, age, race/ethnicity, and their study ID number will be entered along with assessment responses. The minimal amount of information will be submitted to the KSADS-COMP for purposes of administering and accurately scoring the assessments. Data is encrypted using industry-standard SSL technology. The information provided to the KSADS-COMP is subject to its terms of use. Use of the KSADS-COMP has been approved by Duke. As with any website platform or software, there may be potential security risks and Duke cannot guarantee that the website is free of risk. If the data are further disclosed by the KSADS-COMP they are no longer covered by the Duke privacy protections.

Your child's records may be reviewed in the future, in order to meet federal or state regulations. Reviewers may include representatives of the National Institutes of Health and the Duke University Health System Institutional Review Board. If any of these groups review your child's research record, they may also need to review your child's entire medical record if your child is a Duke University Health System patient. If this information is disclosed to outside reviewers for audit purposes, it may be further disclosed by them and may not be covered by the federal privacy regulations.

The Department of Health and Human Services (HHS) has issued a Certificate of Confidentiality to further protect your privacy. With this Certificate, the investigators may not disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings, unless you have consented for this use. Research information protected by this Certificate cannot be disclosed to anyone else who is not connected with the research unless:

1) there is a law that requires disclosure (such as to report child abuse or communicable diseases but not for legal proceedings);

2) you have consented to the disclosure, including for your medical treatment; or

3) the research information is used for other scientific research, as allowed by federal regulations protecting research subjects.

Parent/Guardian Initials _____

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Disclosure is required, however, for audit or program evaluation requested by the agency that is funding this project.

You should understand that a Confidentiality Certificate does not prevent you or a member of your family 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. This means that you and your family must also actively protect your own privacy.

Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

The study results will be retained in your child's research record for six years after the study is completed or until your child reaches the age of 21, whichever is longer. At that time either the research information not already in your child's medical record will be destroyed or information identifying your child will be removed from such study results at DUHS. Any research information in your child's medical record will be kept indefinitely.

This information may be further disclosed by the sponsor of this study. If disclosed by the sponsor, the information is no longer covered by federal privacy regulations. If this information is disclosed to outside reviewers for audit purposes, it may be further disclosed by them and may not be covered by federal privacy regulations.

While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your child's name or other personal information will not be revealed.

Some people or groups who receive your child's health information might not have to follow the same privacy rules. Once your child's information is shared outside of DUHS, we cannot guarantee that it will remain private. If you decide to share your child's private information with anyone not involved in the study, the federal law designed to protect your child's health information privacy may no longer apply to the information you have shared. Other laws may or may not protect sharing of private health information.

WHAT ARE THE COSTS TO YOU?
There are no costs to you, or your child associated with participating in this study.

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WHAT ABOUT COMPENSATION?

You will be reimbursed up to $600 for your participation in this study. You will receive compensation at each assessment time point (baseline, post-study program, 3 months) for each activity that you have completed (3-day dietary recalls; a diagnostic interview; and the video recorded food approach and consumption lab). The table below illustrates how you will be compensated.

Time Point	Compensation for completing 3-day dietary recalls	Compensation for completing interview about your child's eating symptoms	Compensation for completing video recorded food adventure	Total Compensation
Baseline	$50	$50	$50	$150
[redacted]	Compensation for completing 3-day dietary recalls	Compensation for completing interview about your child's eating symptoms	Compensation for completing video recorded food adventure	[redacted]
Post-study Program	$75	$75	$75	$225
[redacted]	Compensation for completing weekly symptom measure survey	Compensation for completing interview about your child's eating symptoms	Compensation for completing video recorded food adventure	[redacted]
3-Month Follow Up	$75	$75	$75	$225
Final Total of Study Compensation				**$600**

Your child will also be receiving a small toy after each of the three lab assessment sessions and toys throughout the study program sessions. You will not receive compensation for the 20 investigational study program sessions.

In order to receive payment for your participation in this study, you will be asked to provide your social security number and home address on a Payment Verification Form. This form will be collected separately from your consent form and will not be linked to any information you provide. If you don't want to provide your social security number, you can still be in the study, but you will not receive payment.

Payment received as compensation for participation in research is considered taxable income to the research subject. If payment to an individual totals $600 or more in any one calendar year, Duke University is required to report this information to the Internal Revenue Service (IRS). Research subject payments to a non-employee of Duke University adding up to $600 or more during any calendar year will result in a 1099 (Miscellaneous Income) form being issued to the individual and a copy sent to the IRS.

WHAT ABOUT RESEARCH RELATED INJURIES?

Immediate necessary medical care is available at Duke University Medical Center in the event that your child is injured as a result of his/her participation in this research study. However, there is no commitment by Duke University, Duke University Health System, Inc., or your child's Duke physicians to provide monetary compensation or free medical care to your child in the event of a study-related injury. For questions about the study or research-related injury, contact Dr. Zucker at 919-308-9140 during regular business hours and after hours and on weekends and holidays.

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WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?
You may choose not to allow your child to be in the study, or, if you agree to allow your child to be in the study, you may withdraw from the study at any time. If you withdraw your child from the study, no new data about your child will be collected for study purposes other than data needed to keep track of your child's withdrawal. All data that have already been collected for study purposes will be sent to the study sponsor.

Your decision not to allow your child to participate or to withdraw your child from the study will not involve any penalty or loss of benefits to which your child is entitled, and will not affect your child's access to health care at Duke. If you do not sign this consent form, you will continue to receive care, but not as a part of this study. If you do decide to withdraw your child, we ask that you contact Dr. Zucker in writing and let her know that your child is withdrawing from the study. Her email address is nancy.zucker@duke.edu.

We will tell you and your child about new information that may affect your child's health, welfare, or willingness to stay in this study.

Your child's data may be stored and shared for future research without additional informed consent if identifiable private information, such as your child's name and medical record number, are removed. If your child's identifying information is removed from their samples or data, we will no longer be able to identify and destroy them. The use of your child's data may result in commercial profit. You and your child will not be compensated for the use of the data and samples other than what is described in this consent form.

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

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?
For questions about the study or a research-related injury, or if you or your child have problems, concerns, questions or suggestions about the research, contact Dr. Zucker at 919-308-9140 during regular business hours and after hours and on weekends and holidays.

For questions about your child's rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, contact the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111.

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STATEMENT OF CONSENT
"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. ***(Or for studies involving children over age 6 –*** to my child and me.) I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree for my child to be in this study, with the understanding that I may withdraw my child at any time. [***For studies involving children over age 6*** – We have discussed the study with my child, who agrees to be in the study.]) I have been told that I will be given a signed and dated copy of this consent form."

_____	_____	_____
Signature of Parent/Guardian	Date	Time
_____	_____	_____
Signature of Child Giving Assent	Date	Time
_____	_____	_____
Signature of Person Obtaining Consent	Date	Time

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You are being asked to sign this consent addendum because you are participating in a research study at Duke entitled "Chompions". Dr. Zucker is your study doctor.

Please read this consent addendum carefully and take your time making your decision. As your study doctor or study staff discusses this addendum with you, please ask him/her to explain any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to sign this consent addendum.

You do not have to sign this addendum to remain in the study.

PURPOSE OF THIS ADDENDUM

Some of the data collected in this study are personally identifiable, such as video recordings of your child trying new foods, or recordings of interviews. Other data can be deidentified, such as your responses to questionnaires. This means it is possible to remove personal identifiers (such as name, address, birthdate and phone number) from the data.

If you give us permission to do so, the study researchers will submit your deidentified data from this study to the National Institute of Mental Health Data Archive (NDA) at the National Institutes of Health (NIH). NDA is a large database where deidentified study data from many National Institute of Mental Health (NIMH) studies is stored and managed. Deidentified study data means that all personal information about you (such as name, address, birthdate and phone number) is removed and replaced with a code number. The goal of the NDA is to allow researchers to combine data from many studies, allowing each study to have a greater impact on our learning about health. Sharing your deidentified study data helps researchers learn new and important things about mental health and substance use more quickly than before.

During and after the study, the study researchers will send deidentified study data about your health and behavior to the NDA. The study researchers will not send identifiable study data (such as videos or personal identifiers) to the NDA. Other researchers across the world can then request your deidentified study data for other research. Every researcher (and institutions to which they belong) who requests your deidentified study data must promise to keep your data safe and promise not to try to learn your identity. Experts at the NIH who know how to keep your data safe will review each request carefully to reduce risks to your privacy. Sharing your study data does have some risks, although these risks are rare. Your study data could be accidentally shared with an unauthorized person who may attempt to learn your identity. The study researchers will make every attempt to protect your identity.

You will not benefit from allowing your study data to be shared with NDA. The study data

provided to NDA may help researchers around the world learn more about mental health and substance use and how to help others who have problems with mental health and substance use. NIMH will also report to Congress and on its website about the different studies using NDA data.
You will not be contacted directly about the study data you contributed to NDA.

You may decide now or later that you do not want your study data to be added to the NDA. You can still participate in this research study even if you decide that you do not want your data to be added to the NDA. If you know now that you do not want your data in the NDA, please tell the study researcher today. If you decide any time after today that you do not want your data to be added to the NDA, call or email the study staff who conducted this study, and they will tell NDA to stop sharing your study data. Once your data is part of the NDA, the study researchers cannot take back the study data that was shared before they were notified that you changed your mind. If you would like more information about NDA, this is available on-line at http://nda.nih.gov.

Except for the activities described in this addendum, the terms of your original consent form remain in full effect.

QUESTIONS REGARDING THIS ADDENDUM

If you have any questions, concerns or complaints concerning this consent addendum, please contact Dr. Nancy Zucker, at (919) 308-9140 during regular business hours and at (919) 308-9140 after hours and on weekends and holidays.

For questions about your rights as a research participant, or to discuss questions, concerns or suggestions related to the research or this consent addendum, or to obtain information or offer input about the research, please contact the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111.

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STATEMENT OF CONSENT

"The purpose of this consent addendum has been explained to me. (Or for studies involving children over age 6 – to my child and me.) I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research or this addendum, or to obtain information or offer input about the research. I have read this addendum and agree to the choices I have indicated above, with the understanding that I may withdraw my child at any time. (For studies involving children over age 6 – we have discussed the study with my child, who agrees to be in the study.) I have been told that I will be given a signed and dated copy of this addendum."

_____	_____	_____
Signature of Parent or Guardian	Date	Time
_____	_____	_____
Signature of Person Obtaining Consent	Date	Time