The Intersection Between Loss of Control Eating and Obesity: The Role of Restriction and Food Reinforcement

NCT05177705

November 7th, 2022

Parent Permission for a Child to Participate in a Research Study

Title of research study: ***Food-ittude Study***

Version Date: ***November 7, 2022***

Investigator: ***Katherine Balantekin, PhD, RD***

Key Information: The following is a short summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form.

Why am I being invited to take part in a research study?

You are being invited to take part in a research study because your child is 8-11 years of age, has reported liking most of the study foods, has no known food allergies to the study foods, and has a willingness to consume food provided by our laboratory. They have also expressed a willingness to answer questionnaires on each visit, and to participate in a game to earn food rewards during appointments. You will complete questionnaires and your child will participate in other study tasks, detailed below.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?

The purpose of the study is to help understand the relationship between eating behavior and the development of overweight and obesity in children. There is no direct benefit to the participant, however, participants get the opportunity to learn about scientific research.

How long will the research last and what will I need to do?

We expect that your child will be in this research study for 7 visits over the next year.

You will be asked to complete surveys about yourself and your child. Your child will be asked to come in for 7 study visits. At these visits, they will answer questionnaires, complete a computer task to earn portions of food and/or activity time, and eat buffet meals.

More detailed information about the study procedures can be found under ***"What happens if I say yes, I want to be in this research?"***

Is there any way being in this study could be bad for me?

There are no significant risks associated with these procedures. The child will be alone in the study room during the buffet meal on Visits 2,3, 4, and 6, which creates some slight risks. For safety reasons, we will monitor your child during this task via video, but will not be recording the task.

More detailed information about the risks of this study can be found under ***"Is there any way being in this study could be bad for me? (Detailed Risks)"***

Will being in this study help me in any way?

There are no benefits to you from your taking part in this research. We cannot promise any benefits to others from your taking part in this research.

What happens if I do not want to be in this research?

Participation in research is completely voluntary. You may choose not to enroll in this study

Your alternative to participating in this research study is to not participate.

Detailed Information: The following is more detailed information about this study in addition to the information listed above.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at (716) 829-5820 or at foodittudeub@gmail.com**.** You may also contact the research participant advocate at 716-888-4845 or researchadvocate@buffalo.edu.

This research has been reviewed and approved by an Institutional Review Board ("IRB"). An IRB is a committee that provides ethical and regulatory oversight of research that involves human subjects. You may talk to them at (716) 888-4888 or email ub-irb@buffalo.edu if:

- You have questions about your rights as a participant in this research
- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You want to get information or provide input about this research.

How many people will be studied?

We expect about 110 children and their parent/guardian to participate in this research study.

What happens if I say yes, I want to be in this research?

At each visit you and your child will interact with a trained research assistant. All research will be conducted in the Nutrition and Exercise Department at UB South Campus, in rooms Farber 24 and Sherman 10/12.

Visit 1 (2 hours)-TODAY:

The Parent will:

- Complete a consent form
- Have their own height and weight measured
- Help their child complete a 24 hour food recall based on everything consumed the previous day
- Fill out additional questionnaires

The Child will:

- Be asked not to eat or drink anything other than water for 2 hours prior to the appointment
- Complete an assent form
- Have their own height and weight measured
- Complete a 24-hour food recall based on everything consumed the previous day
- Fill out additional questionnaires
- Complete computer tasks

Visit 2 (1 hour):

The Parent will:

- **Be instructed how to fill out the checklist for the restricted or non-restricted period**

The Child will:

- Be asked not to eat or drink anything other than water for 2 hours prior to the appointment
- Complete a 24 hour food recall based on everything consumed the previous day
- Fill out a pre-meal survey
- Eat a buffet meal
- Fill out a post-meal survey

In between Visit 2 and 3, the participant will have two weeks of either a restricted period (the parent will be asked to restrict intake of their child's preferred food and related foods) or an unrestricted period (the parent will be provided servings of the child's preferred food to distribute throughout the week to consume at home).

Visit 3 (1 hour):

The Parent will:

- Be instructed how to fill out the checklist for the restricted or non-restricted period (the opposite period from the previous visit)

The Child will:

- Be asked not to eat or drink anything other than water for 2 hours prior to the appointment
- Have their weight measured
- Complete a 24 hour food recall based on everything consumed the previous day
- Fill out a pre-meal survey
- Eat a buffet meal
- Fill out a post-meal survey

In between Visit 3 and 4, the participant will have whichever of the following conditions they did not experience between Visits 2 and 3: two weeks of either a restricted period (the parent will be asked to restrict intake of their child's preferred food and related foods) or an unrestricted period (the parent will be provided servings of the child's preferred food to distribute throughout the weeks to consume at home).

Visit 4 (1 hr):

The Parent will:

- Get paid

The Child will:

- Be asked not to eat or drink anything other than water for 2 hours prior to the appointment
- Complete a 24 hour food recall based on everything consumed the previous day
- Fill out a pre-meal survey
- Eat a buffet meal
- Fill out a post-meal survey
- Be paid

Visit 5 (70 minutes) – 6 months from today:

The Parent will:

- Have their height and weight taken
- Fill out more questionnaires

The Child will:

- Be asked not eat or drink anything besides water for 2 hours before the appointment
- Have their height and weight taken
- Tell us what they had to eat and drink yesterday
- Fill out more questionnaires
- Play computer games

Visit 6 (1 hour):

The parent will:

- Get paid

The child will:

- Not to eat or drink anything besides water for 2 hours before the appointment
- Tell us what they had to eat and drink yesterday
- Fill out a survey before eating

- Eat a buffet meal
- Fill out a survey after eating
- Get paid

Visit 7 (70 minutes) – One year from today:

The parent will:

- Have their height and weight taken
- Fill out more questionnaires
- Get paid

The child will:

- Be asked not to eat or drink anything besides water for 2 hours before the appointment
- Have their height and weight taken
- Tell us what they had to eat and drink yesterday
- Fill out more questionnaires
- Play computer games
- Get paid

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible for: ensuring that your child attends the scheduled appointments. In addition, we ask that you encourage your child to comply with all study procedures.

What happens if I say yes, but I change my mind later?

You and your child can leave the research at any time it will not be held against you.

Is there any way being in this study could be bad for me? (Detailed Risks)

There are no significant risks associated with these procedures. The child will be alone in the study room during the buffet meal on Visits 2,3, 4, and 6, which creates some slight risks. For safety reasons, we will monitor your child during this task via video (to ensure that no problems arise during eating) but will not be recording the task. There is also a risk of breach of confidentiality.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical or education records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this organization.

Your study information will not be used for future studies, even if information that identifies you is removed.

During the study, participant responses/data will be stored in REDCap (an online password-protected database) separate from information that identifies them, such as name. This identifying information will be stored under lock and key.

Can I be removed from the research without my OK?

The principal investigator of the study can remove you from the research study without your approval. Possible reasons for removal include frequently missed appointments or lack of adherence to study procedures. After the screening visit your child may be withdrawn from the study due to a variety of factors (such as ineligible weight status, health status, etc) and they will not be eligible for the remainder of the study, but they will be paid $25 for child and $10 for the parent for completion of the first visit.

What else do I need to know?

Who is paying for this research?

This research is being funded by the National Institutes of Health.

Will I get paid for my participation in this research?

If you agree to take part in this research study, we will pay you a total of $70 for your time and effort. You will receive $40 after visit 4, $20 after visit 6, and $10 at the conclusion of the seventh visit (the end of the study). You child will receive $25 per visit, with a $25 bonus if they complete all 7 visits. If, for any reason and at any point, your child decides to withdraw his/her participation in the study, he/she will be compensated for each visit they have completed.

The Study Card Program Group, under The University at Buffalo's Office of Financial Management, in conjunction with U.S. Bank, will manage study compensation by providing a Reloadable Focus Blue Card, which is a prepaid debit card. On visits 4, 6, and 7, the amount outlined in the Informed Consent Form will be automatically approved and applied to your U.S. Bank Focus Blue Card balance. If you receive your bank card at the study visit, your payment will be available no later than the next business day. The Study staff will provide you with additional information about how the bank card works. In order for U.S. Bank to be able to reimburse you using the Focus Blue Card, only your first and last name (required), physical address (required), and birth date (required) will be shared with U.S. Bank. The Study Card Program Group, under The University at Buffalo Office of Financial Management, will also have access to this information and UB affiliated Researchers and staff, within the same university department as the Investigator of this study, may also have access to this information. By agreeing to use the U.S. Bank Card service, you are authorizing the release of this information to U.S. Bank and authorizing access to this information to Study Card Program Group, under The University at Buffalo Office of Financial Management and other UB affiliated Researchers and staff. No protected health information will be shared with the U.S. Bank or the Study Card Program Group.

Please note that a fee of $2 per month will be deducted from your card balance after 365 days of card inactivity. Your card will be considered activated as of today's date.

Please also note that U.S. Bank may use your personal contact information to market the bank's other products and services to you. You may limit U.S. Bank's direct marketing to you by visiting U.S. Bank online at http://www.usbank.com/privacy.

If you receive a single gift card or debit card deposit of $100 or greater, you will be asked to complete an IRS Form W-9. This form will be held confidentially by the research team and those responsible for administering research funds.

Payments that you receive for your participation in this research are considered taxable income. If the amount of payment that you receive reaches or exceeds $600.00 in a calendar year, you will be issued a form 1099.

What are my alternatives to participating in this research study?

Instead of being in this research study, you may choose not to participate in this study.

Signature Block for Capable Adult

Your signature documents your permission to take part in this research. By signing this form you are not waiving any of your legal rights, including the right to seek compensation for injury related to negligence or misconduct of those involved in the research.

Signature of subject	Date
Printed name of subject	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	

[Check the below box and obtain the signature of the witness if a witness will observe the consent process, e.g. illiterate subjects or short form of consent documentation. *Note: you must have prior IRB approval to utilize the short form of consent* documentation.]

☐ My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject, and that consent was freely given by the subject.

Signature of witness to consent process	Date
Printed name of person witnessing consent process	

Permission to Take Part in a Human Research Study

Signature Block for Parental Permission

Your signature documents your permission for the named child to take part in this research. By signing this form you are not waiving any of your legal rights, including the right to seek compensation for injury related to negligence or misconduct of those involved in the research.

Printed name of child

Signature of parent or individual legally authorized to consent to the child's general medical care

Date

Printed name of parent or individual legally authorized to consent to the child's general medical care

- ❑ Parent
- ❑ Individual legally authorized to consent to the child's general medical care (See note below)

Note: Investigators are to ensure that individuals who are not parents can demonstrate their legal authority to consent to the child's general medical care. Contact legal counsel if any questions arise.

Assent

- ❑ Obtained
- ❑ Not obtained because the capability of the child is so limited that the child cannot reasonably be consulted.

Signature of person obtaining consent

Date

Printed name of person obtaining consent