COMPOUND AUTHORIZATION AND CONSENT FOR PARTICIPATION IN A RESEARCH STUDY

YALE UNIVERSITY SCHOOL OF MEDICINE

Study Title: Development and Initial Efficacy Testing of a Cognitive-Behavioral Intervention to Treat Adolescent Binge Eating (Treatment Study Consent)
Principal Investigator (the person who is responsible for this research): Janet Lydecker, Ph.D.
Phone Number: 203-737-4299
Funding: *National Institute of Diabetes and Digestive and Kidney Diseases*

Research Study Summary:

- We are asking you to join a research study and allow your child to join a research study.
- The purpose of this research study is to look at the effects of two approaches to address binge eating and weight.
- This study may happen in-person or may happen online. During the COVID-19 pandemic, all "visits" are happening online.
- Study procedures will include: an interview with a research clinician at the beginning and end of treatment that will ask questions about your child's health, eating behaviors, and any psychological or physical problems. Your child will complete interviews and fill out surveys; you will fill out surveys. There will also be weekly material for your child for four months. There will also be monthly check-ins with you and your child when you will both fill out surveys. There will also be a follow-up visit when you and your child both fill out surveys. We will also ask you to measure your and your child's height and weight at all visits.
- You and your child will be assigned to receive (randomly, like flipping a coin) either cognitive-behavioral therapy *or* healthy eating information for four months.
- **Up to 18** visits are required for your child: 1 before treatment, and 16 treatment sessions (*if you and your child are assigned to cognitive-behavioral therapy)* or 4 treatment session plus weekly mailed materials (*if you and your child are assigned to healthy eating information)*. Monthly check-ins and the end-of-treatment visit will occur on the same days as program sessions. You will attend the visits before and after treatment, monthly check-ins, and the follow-up visit.
- These visits will take **up to 21** hours total, spread over at least 7 months.
- There are no physical risks associated with this study. The treatment in this study ("talk therapy" or healthy eating information) does not involve many risks, but you or your child may feel uncomfortable when thinking about or discussing eating and weight. There is the possible risk of loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed. There is a chance that your child's binge eating or obesity may not improve or may worsen during the study. Your child will be withdrawn from the study if the clinical condition becomes significantly worse.
- The study may have no direct benefit to you or your child from your participation or your child's participation in this study. The cognitive-behavioral treatment is known to be helpful to some adults with binge-eating disorder and obesity, but we do not know if it will be help teens with binge eating. We anticipate that some of the knowledge from this study will be used to improve treatments for adolescents and to increase our understanding of binge eating.

- There are other choices available to you outside of this research. Healthy eating information is similar to what you could get from a nutritionist or from reading federal websites with information about children's nutrition. Lifestyle treatments to prevent gaining more weight are available without enrolling in the study. These types of programs do not generally talk about binge eating. Interpersonal psychotherapy is a "talk therapy" that may help treat binge eating among youth but does not generally reduce weight. If you choose not to participate in this study, we can give you referrals for alternative treatments.
- Taking part in this study is your choice. You can choose to take part, or you can choose not to take part in this study. You can also change your mind at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.
- If you are interested in learning more about the study, please continue reading, or have someone read to you, the rest of this document. Take as much time as you need before you make your decision. Ask the study staff questions about anything you do not understand. Once you understand the study, we will ask you if you wish to participate and allow your child to participate; if so, you will have to sign this form.

Why is this study being offered to me?

We are asking you and your child to take part in a research study because your child experiences binge eating, is above the 85th percentile on the growth chart, and is between 12 and 17 years old. We are looking for 5 teens to participate in the first part of this study, and 50 teens to participate in the second part of this study (which is the part of the study that you are invited to participate in).

Who is paying for the study?

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) is paying for this study.

Who is providing other support for the study?

No one else is providing support for the study.

What is the study about?

The purpose of this study is to look at how well a new treatment works on binge eating and weight compared to receiving information on healthy eating. Cognitive-behavioral therapy is sometimes known as talk therapy. Cognitive-behavioral therapy is known to work with adults, but how well it works with teens with binge eating is not known.

What are you asking me to do and how long will it take?

If you agree to take part in this study and allow your child to take part, this is what will happen:

1. **Intake Appointment**: For the first appointment, you and your child will meet with a research clinician. During this visit, we will ask questions about your child's health, eating behaviors, any alcohol or drug use, and any other psychological and physical problems that you may have now or may have had in the past. We will also ask you to measure your weight and height and your child's weight and height. We will also ask you and your child to do surveys. This visit will take approximately 2 hours and may be divided into separate meetings if that is easier for your child.

2. **Treatment**: If your child is eligible and you decide to participate, you and your child will be assigned to receive (randomly, like flipping a coin) cognitive-behavioral therapy *or* healthy eating information for 4 months. You and your child will be assigned randomly (by chance), not because of any special characteristics or problems you or your child might have.

Cognitive Behavioral Therapy: Your child will meet with a clinician weekly during this therapy and you will join them for therapy once a month. Each session will take approximately 1 hour. This therapy will focus on eating regularly, decreasing binge eating, building coping skills, and changing some things about how your child thinks about binge eating and about weight/shape. We will also ask you to measure your and your child's weight during these sessions using the scale we send you.

Healthy Eating Program: You and your child will meet with a clinician monthly during this program. Each session will take approximately 30 minutes. Your child will also get information and handouts in the mail every week. This information will focus on nutrition, having a healthy lifestyle, and problematic eating.

3. **Monthly Check-ins**: While your child is in treatment, we will check on how things are going once a month. We will ask you and your child to fill out surveys. We will also ask you and your child to measure your weight during these check-ins using the scale we send you. We will also ask you and your child questions about what you liked or did not like about treatment so far, and whether you think it is or is not helping your child with eating and weight. These check-ins will happen during scheduled treatment sessions.

4. **End of Treatment Interview**: At the end of treatment, you and your child will meet with a research clinician again who will ask your child questions about their health, eating behaviors, and what they thought about treatment. We will also ask you and your child to measure your and your child's weight and height. We will also ask you and your child to answer some questions on surveys. This visit will take approximately 2 hours.

5. **Follow-up**: Three months after treatment ends, we will ask you and your child to fill out surveys to see how you are doing. We will also ask you and your child to measure your height and weight. This visit will take approximately 1 hour.

	Intake	Month 1	Month 2	Month 3	Post	Follow-Up (3 mo)
ADOLESCENT						
Interviews	*				*	
Surveys	*	*	*	*	*	*
Height and weight	*	*	*	*	*	*
Treatment credibility	*					
Ratings of session content		*	*	*	*	
PARENT						
Surveys	*	*	*	*	*	*
Weight (height: at intake only)	*	*	*	*	*	*

Treatment credibility	*					
Ratings of session content		*	*	*	*	

FitBit Scale: If your adolescent is determined to be eligible and chooses to participate, you and your adolescent will be given one FitBit scale. This is a “smart” scale that displays weight on a screen and also syncs weight data with a FitBit account. The scale uses Bluetooth and/or Wi-fi technology to sync with the account.

We will create an account for your use during the study (from the time you receive the scale until the 3-month follow-up visit is completed) that uses your study ID rather than your personal information. FitBit offers different levels of privacy and we will select the most private options. After the study is over, you are welcome to keep the scale and you are encouraged to change your log-in information or switch to using a personal account. We will only access your weight data during the study and will not access your account after the study is done.

If you choose not to use receive the FitBit scale, you will have the option of a non-smart scale or to use a home scale to tell your clinician your weight at the different timepoints during treatment and follow-up when we are tracking progress.

What are the risks and discomforts of participating?

There are no physical risks associated with this study. The treatments in this study (“talk therapy” or healthy eating information) does not involve many risks, but you or your child may feel uncomfortable when thinking about or discussing eating and weight.

There is the possible risk of loss of confidentiality. Every effort will be made to keep your and your child’s information confidential; however, this cannot be guaranteed.

There is a chance that your child’s binge eating or weight may not improve or may worsen during the study. Your child will be withdrawn from the study if his or her clinical condition becomes significantly worse. If this happens, we will offer you referrals.

How will I know about new risks or important information about the study?

We will tell you and your child if we learn any new information that could change your mind about taking part in this study.

How will this study benefit me/my child?

There may be no direct benefit to you or your child from your participation in this study. The cognitive-behavioral treatment is known to be helpful to some adults with binge-eating disorder and obesity, but we do not know if it will help teens with binge eating. We cannot determine ahead of time whether your child will personally benefit or how much your child will benefit.

How can the study possibly benefit other people?

The benefits to science and other people may include a better understanding of binge eating and excess weight among teens, as well as how to treat binge eating for teens. This study may lead to new treatments.

Are there any costs to participation?

You will not have to pay for taking part in this study. The only costs include transportation and your time coming to the study visits. If there are any findings about medical or psychological conditions, we may recommend that your child see his or her doctor or therapist. If you choose to do this, you or your health insurance must pay for services, supplies, procedures, and care that are not part of this study.

Will I be paid for participation?

You will be paid for taking part in this study. You will be paid for each monthly check-in and for the interview at the end of treatment. You will get $25 at each monthly check-in, $50 for the interview at the end of treatment, and $25 for the follow-up. Your child will be paid separately-- $25 at each monthly check-in, $50 for the end-of-treatment interview and $25 for the follow-up-- for their participation. The treatment and evaluations will be free of charge. You are responsible for paying state, federal, or other taxes for the payments you receive for being in this study. Taxes are not withheld from your payments.

What are my choices if I decide not to take part in this study?

Instead of participating in this study, you have some other choices.
You could:

- Get treatment for your child without being in a study. There are certain available treatments for overweight and obesity, and other available treatments for binge eating. Weight: Healthy eating information is similar to what you could get from a nutritionist or from reading federal websites with information about children's nutrition. Lifestyle treatments to prevent gaining more weight are available without enrolling in the study. These types of programs do not generally talk about binge eating. Eating: Interpersonal psychotherapy is a "talk therapy" that may help treat binge eating among youth but does not generally reduce weight. If you choose not to participate in this study, we can give you referrals for alternative treatments for your child.
- Take part in another study.

How will you keep my and my child's data safe and private?

We will keep information we collect about you confidential. We will share it with others if you agree to it or when we have to do it because U.S. or State law requires it. For example, if you or your child tell us about plans to hurt yourself or someone else, or if you or your child know of a child or an elderly person being abused.

When we publish the results of the research or talk about it in conferences, we will not use your name. If we want to use your name, we would ask you for your permission.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The Certificate protects the researchers from being forced to tell people outside of the study about your or your child's participation in the study, for example, if there is a court subpoena, unless you or your child allow us to do so. However, *the protection offered by the Certificate does not stop us from voluntarily reporting information about suspected or known sexual, physical, or other abuse of a child or older person, or a participant's threats of violence to self or others. If any member of the research team is given such information, he or she will make a report to the appropriate authorities as required by federal, state, or local law.*

Even when a Certificate is in place, you and your family members must still continue to actively protect your child's privacy. If you voluntarily give your written consent for anyone to receive information about your child's participation in the research, then we may not use the Certificate to withhold this information.

We understand that information about your child obtained in connection with your child's health is personal, and we are committed to protecting the privacy of that information. If you decide to be in this study, the research team will get information that identifies you and your personal health information. This may include information that might directly identify your child, such as your name, address, telephone number, email address, and date of birth. This information will be de-identified at the earliest reasonable time after we receive it, meaning we will replace your child's identifying information with a code that does not directly identify you. The principal investigator will keep a link that identifies you and your child to your coded information, and this link will be kept secure and available only to the PI or selected members of the research team. Any information that can identify will remain confidential. All records will be kept in locked cabinets separate from any identifying information, and all computer records will be password-protected. The research team will only give this coded information to others to carry out this research study. The link to your personal information will be kept for 7 years, after which time the link will be destroyed and the data will become anonymous. The data will be kept in this anonymous form indefinitely.

If you sign this form, you are giving permission for the use and/or disclosure of your health information for this research study. You do not have to give this permission. However, if you do not give permission, you will not be able to take part in the study.

This authorization to use and disclose your and your child's health information collected during your participation in this study will never expire.

You do not give up any of your or your child's legal rights by signing this form.

We will also share information about you with other researchers for future research, but we will not use your name or other identifiers. We will not ask you for any additional permission.

Audio-Recording

If you are willing, the interviews and treatment sessions will be recorded. This is not required for you to participate. We will not use your or your child's name during the recording. If you are willing and agree to the recording, we will ask you to sign a separate section below. If you do agree to recording, all audio records will be erased after the completion of this study (five years) or at any time at your request.

What Information Will You Collect About Me and My Child in this Study?

The information we are asking to use and share is called "Protected Health Information." It is protected by a federal law called the Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA). In general, we cannot use or share your health information for research without your permission. If you want, we can give you more information about the Privacy Rule. Also, if you have any questions about the Privacy Rule and your rights, you can speak to Yale Privacy Officer at 203-432-5919.

The specific information about you and your health that we will collect, use, and share includes:

- Research study records
- Medical records of only those services provided in connection with this study.
- Records about phone calls made as part of this research
- Records about your study visits
- Information obtained during this research regarding
    - Diaries and questionnaires
    - The diagnosis and treatment of a mental health condition
    - Use of illegal drugs or the study of illegal behavior

You cannot have access to any of the research information, including surveys, interviews, and treatment information that your child provides. If your child reports any information to us about abuse or plans to hurt himself or herself or someone else, we will be required to report this information to the appropriate authorities. If your child tells us he or she is a danger to himself or herself or others, we may need to tell you to make sure your child is safe.

How will you use and share my and my child's information?

We will use your and your child's information to conduct the study described in this consent form.

We may share your information with:

- The U.S. Department of Health and Human Services (DHHS) agencies
- Representatives from Yale University, the Yale Human Research Protection Program and the Institutional Review Board (the committee that reviews, approves, and monitors research on human participants), who are responsible for ensuring research compliance. These individuals are required to keep all information confidential.
- Those individuals at Yale who are responsible for the financial oversight of research including billings and payments
- The Principal Investigator (Dr. Janet Lydecker)
- Members of the Research Team
- Study Safety Monitor and others authorized to monitor the conduct of the Study (Dr. Mona Sharifi)

We will do our best to make sure your information stays private. But, if we share information with people who do not have to follow the Privacy Rule, your information will no longer be protected by the Privacy Rule. Let us know if you have questions about this. However, to better protect your health information, agreements are in place with these individuals and/or companies that require that they keep your information confidential.

Why must I sign this document?

By signing this form, you will allow researchers to use and disclose your and your child's information described above for this research study. This is to ensure that the information related to this research is available to all parties who may need it for research purposes.

What if I change my mind?

The authorization to use and disclose your and your child's health information collected during your participation in this study will never expire. However, you may withdraw or take away your permission at any time. You may withdraw your permission by telling the study staff or by writing to Dr. Janet Lydecker, 301 Cedar Street at the Yale University, New Haven, CT 06520.

If you withdraw your permission, you and your child will not be able to stay in this study but the care you get from your doctor and your child's doctor outside this study will not change. No new health information identifying you will be gathered after the date you withdraw. Information that has already been collected may still be used and given to others until the end of the research study to insure the integrity of the study and/or study oversight.

What if I want to refuse or end participation before the study is over?

Taking part in this study is your choice. You can choose to allow your child to take part, or you can choose not to allow your child to take part in this study. You also can change your mind at any time. Whatever choice you make, you will not lose access to your or your child's medical care or give up any legal rights or benefits.

At your request, we would refer you to a clinic or doctor who can offer treatment. Not participating or withdrawing later will not harm your relationship with your own doctors, your child's doctors, or with this institution.

To withdraw from the study, you can write to the principle investigator at any time and tell them that you no longer want to take part.

The researchers may withdraw you from participating in the research if necessary. For example, if you were to start other treatments for eating or weight, if your symptoms worsen, or if you are not attending study appointments (for example, if you move).

What will happen with my data if my child stops participating?

If you and your child are no longer participating, information that has already been collected may still be used and given to others. Your and your child's identities will not be attached to the data.

Who should I contact if I have questions?

Please feel free to ask about anything you don't understand.

If you have questions later or if you have a research-related problem, you can call the Principal Investigator at **203-737-4299.**

If you have questions about your rights as a research participant, or you have complaints about this research, you call the Yale Institutional Review Boards at (203) 785-4688 or email hrpp@yale.edu.

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.

Authorization and Permission

Your signature below indicates that you have read this consent document and that you agree to be in this study and allow your child to be in this study.

We will give you a copy of this form.

____
Child's Name

Parent Printed Name	Parent Signature	Date
Person Obtaining Consent Printed Name	Person Obtaining Consent Signature	Date

Consent to Audio-Record Interviews/Sessions:

Your signature below indicates that you agree to allow audio recording for you and your child.

Signature: ________________________________

Date: ____________________________________

____ ______________________
Signature of Person Obtaining Consent Date