Parental Consent and Permission Form

Title of Research Study: ***Piloting a Family-Based Intervention of Time-Restricted Eating to Treat Obesity***

Investigator Team Contact Information:

For questions about research appointments, the research study, research results, or other concerns, call the study team at:

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Supported By: This research is supported by the Clinical and Translational Science Institute at the University of Minnesota.

Key Information About This Research Study

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

What is research?

Doctors and investigators are committed to your care and safety. There are important differences between research and treatment plans:

- The goal of research is to learn new things in order to help groups of people in the future. Investigators learn things by following the same plan with a number of participants, so they do not usually make changes to the plan for individual research participants. You, as an individual, may or may not be helped by volunteering for a research study.
- The goal of clinical care is to help you get better or to improve your quality of life. Doctors can make changes to your clinical care plan as needed.

Why are my child and I being asked to take part in this research study?

We are asking you and your child to take part in this research study because you both struggle with maintaining a healthy weight.

What should I know about a research study?

- Someone will explain this research study to you and your child.
- Whether or not you and your child decide to 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 or your child.
- You and your child can ask all the questions you want before you decide.

Why is this research being done?

Obesity affects over 40% of adults and over 25% of children in the United States and is associated with several physical and psychological issues such as high blood pressure, heart disease, type 2 diabetes and reduced quality of life. Obesity can be hereditary, which means that if a parent is obese, the children in the family have a 40-75% likelihood of also becoming obese due to environmental and genetic factors. Treatments for obesity that apply to the whole family unit might be one way of addressing concerns about obesity and the child and adult level.

Typical obesity treatment focuses on restricting calories. In adults with obesity, behavior-based weight loss programs result in weight reduction of 1-4 kg over one year. In children, behavior-based therapy typically results in weight stabilization. Family-based obesity treatment also focuses on intentional caloric restriction through reduced consumption of energy dense foods as well as increased consumption of low energy density foods, increased physical activity and implementation of strategic parenting practices.

A different way to approach weight loss may involve time-restricted eating (TRE), which restricts the eating window while allowing intake of any kind of food intake during the eating window. This approach to eating allows individuals to select foods that alight with their needs and preferences. Researchers hope that a reduced eating window will also lessen the number of eating occasions which leads to reduced calorie intake.

This study will enroll a parent and child as a group (called a dyad). Dyads will be randomized (chosen by chance, like the toss of a coin) to one of the following treatments:

- Having lifestyle sessions with a dietician and being asked to reduce your calorie intake
- Having sessions with a dietician and restricting eating to a 10-12 hour window each day

How long will the research last?

We expect that you and your child will be in this research study for up to 12 weeks and you will be asked to complete an online satisfaction survey four weeks after the visit at week 12. There will be two in-person visits for the study, 8 virtual visits with a dietician and six phone calls where you are asked to recall what you and your child ate over the past 24 hours.

What will my child and I need to do to participate?

You and your child will be asked to do the following if you decide to participate in the study:

- Provide demographic information about your family (contact information, education level, income level) one time
- Provide information about your medical history and medication history and information about your child's medical history and medication history
- You and your child will have your height and weight measured in the research unit (two times)
- Fill out questionnaires about appetite, what your child has been eating and quality of life (two times)
- Be contacted by phone and asked about what you and your child have eaten in the past 24 hours (six times)
- Be asked to fill out a survey about your satisfaction with the study (two times)
- Log into a website each day to keep track of what time your child started eating in the morning and the last time that your child ate (for 12 weeks)
- Use a Bluetooth scale to measure your weight and the weight of your child at home. You will be provided with the scale and instructed on how it is to be used. You will use this scale once per week while you are in the study (12 times).
- Brush your teeth with a Bluetooth toothbrush twice per day. If you and your child are assigned to the time-restricted eating group, you should brush your teeth in the evening within 30 minutes of finishing the evening meal. If you and your child are assigned to the lifestyle session group, you are not required to use the Bluetooth toothbrushes, but they will be provided to you if you would like to use them (twice daily for 12 weeks).

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

Many of the activities that you will be asked to do during this study pose no additional risk to you than being at a routine doctor visit, such as answering questions about your health and the medicines you have been taking and how you have been feeling, and having your height and weight measured. The dietary treatment sessions pose little risk and would be done if you or your child elected to enroll in treatment for your obesity. The questionnaires and phone calls to discuss what you and your child have eaten over the past 24 hours might make you feel uncomfortable because they will ask about your eating habits and your quality of life.

The Bluetooth scale and Bluetooth toothbrushes will collect information about your weight and about the times that you brush your teeth and how long you brush your teeth for. You will be asked to download an app onto your Smartphone that will collect this information and you will be asked to share this information with the study team. The applications that you download will collect identifying information such as your email address and your phone number in order to allow the application to install. There is a risk that this information could be hacked and the weights of you and your child as well as the toothbrush use information could be exposed.

Will being in this study help me in any way?

We cannot promise any benefits to you or your child from your taking part in this research. However, possible benefits include weight loss, learning to make better food choices and how to increase your activity levels. We hope that the information from this study might benefit others in the future.

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

You and your child do not have to participate in this research study if you do not want to. You and your child can elect to have other obesity treatments that could include lifestyle therapy, calorie counting and using medications to help control your weight.

Detailed Information About This Research Study

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

How many people will be studied?

We expect about 40 people (20 groups consisting of a parent and child) will enroll in this study at the University of Minnesota.

What happens if I say "*Yes, I want to be in this research*"?

If you and your child would like to be in the study, this is what will happen at each visit:

Prescreening/Consent:

- You will have a virtual session and will speak to the study team about the study. You and your child can ask any questions that you might have. If you want to be in the study, you will be asked to review and sign this form and a signed copy will be provided to you. If your child is over 8 years old, your child will be asked to review and sign an assent form to note that they want to participate in the study.
- You will be asked to provide information about yourself and your child including your email address and telephone number, as well as height and weight of you and your child.
- You will be contacted three times within the next two weeks and will be asked to recall all of the foods that you and your child ate within the past 24 hours.

Screening/Week 0:

- You will come to the research unit and will speak to the study team about the study.
- You and your child will have your height and weight measured.
- You will be asked to complete questionnaires about your appetite, the eating habits of you and your child, and your quality of life.
- You will be randomized (chosen by chance, like the toss of a coin) to be in the lifestyle group or the time-restricted eating group.
- You will be provided with a Bluetooth scale to take home and you will be taught how to

use it. You will download an app to your phone and the app will weight information for you and your child. You will be asked to share this information with the study team.

- You will be provided with Bluetooth toothbrushes to take home with you. You will download an app to your phone that will record information on the toothbrushing habits of you and your child. If you and your child were randomized to the time-restricted eating group, you will be asked to brush your teeth with the toothbrush in the morning and in the evening within 30 minutes of finishing your evening meal. You will be asked to share this information with the study team.
- You and your child will meet with a dietician to learn about your treatment plans, which involve food choices.
- You will be asked to complete a periodic time log by logging into a website. Information about what time you and your child started eating each day and what time you stopped eating each day. You will receive an email that reminds you to log into the website to complete this information.

Week 1, Week 2, Week 3 and Week 4, Week 6, Week 8 and Week 10:

- You and your child will be asked to weigh yourselves on the Bluetooth scale and make certain that the information is uploaded to the app on your phone.
- You will be sent periodic email reminders to complete the daily time log.
- You (but not your child) will have a phone or Zoom meeting with the study dietician to discuss treatment strategies and progress. The dietician will ask you to share your time logs, Bluetooth scale data and toothbrush data.

Week 5, Week 7, Week 9 and Week 11:

- You will be sent periodic email reminders to complete the daily time log.
- You will be asked to weigh yourself and your child on the Bluetooth scale and make sure that the information uploads to the app on your phone
- You will be asked to keep using the Bluetooth toothbrushes according to your treatment protocol.

Week 12:

- You will return to the research clinic. You and your child will have your height and weight measured.
- You will be asked to complete questionnaires about your appetite, the eating habits of you and your child, and your quality of life. You will also be asked to complete a questionnaire about your experience with the study.
- You and your child will meet with the dietician for a dietary session. The dietician will also review your Bluetooth scale data, your Bluetooth toothbrush data and your time log.
- You will be contacted three times during the week and be asked to recall all of the foods that you and your child ate within the past 24 hours.

Follow-up:

- You will receive an email asking you to complete a questionnaire about your experience with the study at 1, 3, and 6 months after the end of treatment.

The experimental treatment you and your child will receive will be chosen by chance, like flipping a coin. Neither you nor the study doctor will choose what experimental treatment you get. You will have an equal chance of being given either experimental treatment.

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

If you decide that you and your child should take part in the study, you will be responsible for attending the in-person and the phone/Zoom visits each week and carrying out the strategies discussed with you for you and your child. You will be responsible for weighing yourself and your child once per week on the Bluetooth scale. You will also be responsible for completing the periodic time logs and completing the phone visits where the food that you and your child ate during the past 24 hours is collected. If you are randomized to be in the time-restricted eating group, you will be responsible for using the Bluetooth toothbrushes and brushing your teeth twice per day and within 30 minutes of the evening meal.

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

If you and your child take part in this research study, and want to leave, you should tell us. Your choice not to be in this study will not negatively affect your or your child's right to any present or future medical care.

If you decide to stop the participation of you and your child, any data that had been collected before you notified us of your decision to withdraw will remain in the study database. New information will not be collected.

Will it cost me anything to participate in this research study?

Taking part in this research study will not lead to any costs to you.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information as well as your child's personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete confidentiality. Organizations that may inspect and copy your information include the Institutional Review Board (IRB), the committee that provides ethical and regulatory oversight of research, and other representatives of this institution, including those that have responsibilities for monitoring or ensuring compliance (such as the Quality Assurance Program of the Human Research Protection Program (HRPP)).

Additional sharing of your information for mandatory reporting

If we learn about any of the following, we may be required or permitted by law or policy to report this information to authorities:

- Current or ongoing child or vulnerable adult abuse or neglect;
- Communicable, infectious or other diseases required to be reported under Minnesota's Reportable Disease Rule;
- Certain wounds or conditions required to be reported under other state or federal law; or
- Excessive use of alcohol or use of controlled substances for non-medical reasons during pregnancy.

Will anyone besides the study team be at my consent meeting?

You may be asked by the study team for your permission for an auditor to observe the consent meeting with you and your child. Observing the consent meeting is one way that the University of Minnesota makes sure that your rights as a research participant are protected. The auditor is there to observe the consent meeting, which will be carried out by the people on the study team. The auditor will not document any personal (e.g., name, date of birth) or confidential information about you or your child. The auditor will not observe your consent meeting without your permission ahead of time.

Whom do I contact if I have questions, concerns or feedback about my experience?

This research has been reviewed and approved by an IRB within the Human Research Protections Program (HRPP). To share feedback privately with the HRPP about your research experience, call the Research Participants' Advocate Line at 612-625-1650 (Toll Free: 1-888-224-8636) or go to z.umn.edu/participants. You are encouraged to contact the HRPP if:

- 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 have questions about your rights as a research participant.
- You want to get information or provide input about this research.

Will I have a chance to provide feedback after the study is over?

The HRPP may ask you to complete a survey that asks about your experience as a research participant. You do not have to complete the survey if you do not want to. If you do choose to complete the survey, your responses will be anonymous.

If you are not asked to complete a survey, but you would like to share feedback, please contact the study team or the HRPP. See the "Investigator Contact Information" of this form for study team contact information and "Whom do I contact if I have questions, concerns or feedback about my experience?" of this form for HRPP contact information.

Can I be removed from the research?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include not attending the study visits or not completing the daily time log and using the Bluetooth scale or the Bluetooth toothbrushes (if you and your child were randomized to the time-restricted eating arm).

What happens if I am injured while participating in this research?

In the event that this research activity results in an injury, treatment will be available, including first aid, emergency treatment and follow-up care as needed. Care for such injuries will be billed in the ordinary manner, to you or your insurance company. If you think that you have suffered a research related injury let the study physicians know right away.

Will I be compensated for my participation?

If you agree to take part in this research study, we will pay for your time and effort. This is what you will receive for each visit:

- Baseline/Week 0: $35
- Week 1: $15
- Week 2: $15
- Week 3: $15
- Week 4: $15
- Week 6: $15
- Week 8: $15
- Week 10: $15
- Week 12: $35

If you complete all of the visits in the study, your family will earn a total of $175. Payment will be made using a pre-paid debit card called Greenphire ClinCard. It works like a bank debit card. We will give you a debit card and each time you receive a payment for participation in this study, the money will be added to the card after each completed visit.

You may use this card at any store that accepts MasterCard or you can use a bank machine to remove cash. However, there may be fees drawn against the balance of the card for cash withdrawals (ATM use) and inactivity (no use for 3 months). We will give you the ClinCard Frequently Asked Questions information sheet that answers common questions about the debit card. You will also receive letters with additional information on how you can use this card and who to call if you have any questions. Be sure to read these letters, including the cardholder agreement, for details about fees.

The debit card system is administered by an outside company. The company, Greenphire, will be given your name and social security number. They will use this information only as part of the payment system. Your information will not be used for any other purposes and will not be given or sold to any other company. Greenphire will not receive any information about your health status or the study in which you are participating.

Use of Identifiable Health Information

We are committed to respect your privacy and to keep the personal information of you and your child confidential. When choosing to take part in this study, you are giving us the permission to use your personal health information that includes health information in your medical records and information that can identify you or your child. For example, personal health information may include your/your child's name, address, phone number or social security numbers. Those persons who get your health information may not be required by

Federal privacy laws (such as the 1099 Rule) to protect it. Some of those persons may be able to share your information with others without your separate permission. Please read the HIPAA Authorization form that we have provided and discussed.

How will information about me and my child be used in publications and presentations?

We may publish the results of this research in scientific, medical, academic or other journals or reports, or present the results at conferences. Information that makes it easy to identify you or your child (such as names and contact information, SSN and medical records numbers) will not be part of any publication or presentation. If you or your child have extremely unique or rare conditions that are not shared by many others, it is possible that some people may be able to determine you or your child's identity even without these identifiers.

Optional Elements:

Yes, **I agree**	**No,** **I disagree**	
_____	_____	The investigator may contact me in the future to see whether I am interested in having my child participate in other research studies by the Center for Pediatric Obesity Medicine.

Signature Block for Capable Adult:

Your signature documents your permission for you and your child to take part in this research. You will be provided a copy of this signed document.

_____ _____
Printed Name of Child Relationship

_____
Printed Name of Participant

_____ _____
Signature of Participant Date

_____ _____
Signature of Person Obtaining Consent Date

_____
Printed Name of Person Obtaining Consent