NCT # NCT04861636

Teen Weight Control (HealthTRAC)

Documents:

1) Consent Form (version date: 5/5/23)
2) Assent Form (version date: 5/5/23)

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Research Consent Form and Authorization Form

Rhode Island Hospital, The Miriam Hospital, EP Bradley Hospital,
Newport Hospital, and Gateway HealthCare

Name of Study Participant: _____

Principal Investigator: **Lifespan/Weight Control & Diabetes Research Center:** Elissa Jelalian, PhD
University of Oregon/Prevention Sciences Institute: Wendy Hadley, PhD
OHSU/Doernbecher Children's Hospital: Alex Foster, MD, MPH

Title of Research Study: HealthTRAC
Stage 2

Study Key Information

Your child is being asked to take part in a research study. A research study helps scientists and doctors learn new information to improve medical practice and patient care. This form contains information that will help you decide whether participating in this study is the best decision for your child. Taking part in this study is completely voluntary. Even if you decide to allow your child to take part in the study, you and your child are free to leave at any time if you change your minds. The researcher will explain the study to you and your child and answer any questions you may have. We encourage you to discuss this study with others (your family, friends or other doctors) before you agree to have your child participate in the research.

If you decide to allow your child to be in the study, you will be asked to sign this consent which states that the study has been explained, that your questions have been answered, and that you agree to have your child participate. If your child is 8 years or older, the "assent" (agreement) of your child will be obtained by the researcher before your child may participate in this study. Your child must sign the assent form. You will be given a copy of the signed consent form to keep.

A. What is the purpose of the research?

The purpose of this research study is to evaluate two weight loss programs aimed at helping teenagers who are overweight and are interested in losing weight. Teenagers and one parent/caregiver will be asked to participate. In this research study we want to learn more about the best strategies for weight loss interventions for teenagers.

This research study is being conducted at three locations:

1) **Lifespan**/Weight Control & Diabetes Research Center in Providence RI
2) **University of Oregon (UO**)/Prevention Sciences Institute in Portland, Oregon
3) **Oregon Health and Sciences University (OHSU)**/Doernbecher Children's Hospital in Portland, Oregon

Participants will be recruited and enrolled at all three locations. If you and your child enroll in the study, you will participate in group treatment sessions at either the Lifespan (Rhode Island) or UO/OHSU (Oregon) site.

B. What is experimental/new in this study?

There are two groups in the study. Some participants in this study will learn different strategies to regulate their emotions in addition to learning strategies to lose weight.

C. What do I have to do in this research?

If you and your child decide to join this research study, you and your child will be asked to complete several questionnaires. Your child will be randomly assigned, "randomized," into one of two different treatment groups which will be explained thoroughly in the following form. Randomization means that your child is put into a group by chance. It is like flipping a coin. Which group your child is put in is done by a computer. Neither you nor the researcher can choose what group your child will be in. Your child will have an equal chance of being placed in any group. Your child will be asked to attend one treatment session per week for 12 consecutive weeks followed by two biweekly sessions for a total of 14 sessions over 16 weeks. Your child will also be asked to attend eight monthly maintenance sessions over a 12-month period. The first fourteen sessions will be held in person. The maintenance sessions will be held online using Zoom or Microsoft Teams, with the exception of the final session, which will be held in person. All group sessions will last 75 minutes. You will be asked to attend 7 sessions over the 22-teenager group session time period. Three sessions will occur during the first 14 teenager sessions and the additional four sessions will occur at 6-, 8-, 10-, and 12-months. The 6-, 8-, and 10-month sessions will be held remotely, in conjunction with the teenager sessions. Parent/Caregiver sessions will be focused on learning about diet and activity recommendations for teens and strategies to help with your child's weight loss efforts.

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As part of this study, your child will be asked to follow a dietary plan, increase exercise up to 60 minutes per day six days per week by the end of the program, and complete brief homework assignments throughout the group meetings. Your child will also be asked to keep a record of all food eaten and physical activity done each day for most of the time they are in the study. No matter which group your child is assigned to, they will be asked to complete these activities.

It will take you and your child about 18 months to complete this study. During this time, we will ask your child to make 26 study visits and for you to make 11 study visits.

D. What could go wrong?

All assessment measures have been widely used with other teenagers, with no negative reactions reported. However, if your child experiences any emotional discomfort in discussing their weight or other issues, they will have the opportunity to speak to an investigator about this discomfort. They will be assured that they do not have to answer any questions that they do not feel comfortable with.

E. What are the benefits?

Your child may or may not benefit from this study, but it may help them to manage their weight, eat well, and exercise. This study may help us learn more about the best ways to help teens lose weight.

F. Other things I should know about this research?

If we find out about new information from this research that may affect your child's health, safety or willingness to stay in this research, we will let you know as soon as possible.

G. If I don't want to take part in this research what are my other choices?

Your child has the option of having a referral to a nutritionist if you and your child choose not to participate in the HealthTRAC program. You may choose this option at any time.

You and your child do not have to be in this research study to be treated for excess weight. Your healthcare provider can discuss with you what clinical treatment options are and which clinical treatment(s) might be right for your child considering their medical history. These clinical treatment options include receiving at least 26 contact hours with professional(s) focusing on behavioral weight management. Each of the clinical treatment options has known rates of being effective, known risks, as well as possible drawbacks.

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- **Please carefully read this form, additional detail about each item just described is found below**
- **Please listen to the study team explain the study and this form to you**
- **Please ask questions about anything that is not clear**

1. Nature and Purpose of the Study

You and your child are being asked to take part in a research project because your child is a teenager who is interested in participating in a behavioral weight loss program. In this study we are trying to learn more about the best ways to help teens lose weight and follow national health guidelines such as engaging in physical activity and eating a healthy diet.

This research study is being conducted at three locations:

1) **Lifespan**/Weight Control & Diabetes Research Center in Providence RI
2) **University of Oregon (UO**)/Prevention Sciences Institute in Portland, Oregon
3) **Oregon Health and Sciences University (OHSU)**/Doernbecher Children's Hospital in Portland, Oregon

Participants will be recruited and enrolled at all three locations. If you and your child enroll in the study, you will participate in group treatment sessions at either the Lifespan (Rhode Island) or UO/OHSU (Oregon) site.

We expect to enroll approximately 200 parent/caregiver and teenager pairs into this study. We expect to enroll 100 pairs at Lifespan (Providence, Rhode Island) and 100 pairs total across the UO and OHSU sites in Portland, Oregon. The study is sponsored by the National Institute of Health.

2. Explanation of Procedures:

Prior to beginning the group sessions, you and your child will be asked to complete several questionnaires about your child's eating habits, screen time, and emotions. Your child will be asked to wear a wrist-worn device that tracks their physical activity for 1 week. Your child will then be randomly assigned (i.e., "randomized") into one of the intervention groups described below. Randomization means that your child will be assigned to a group by chance. It is like flipping a coin. Which group your child is put in is done by a computer. Neither you nor the researcher can choose what group your child will be in. Your child will

have an equal chance of being placed in any group. All teens in the HealthTRAC study will receive one of two health-based interventions. These interventions are described in further detail below.

The two study groups within the HealthTRAC study are: (1) the Standard Behavioral Weight Control Group (SBWC) and (2) the Standard Behavioral Weight Control + Emotion Regulation training group (SBWC+ER). One hundred teen/parent or caregiver pairs will be assigned to each group.

1. The SBWC group involves a dietary plan that will include a reduced calorie diet (1400-1600 kilocalories per day) along with education and activities about physical activity and behavioral weight control strategies (e.g. portion control, healthy snacking). Parents/Caregivers will learn about ways to support their child's weight loss efforts.
2. The SBWC+ER intervention combines the aspects of SBWC and also provides training for your child in how to recognize their feelings and ways to cope with these feelings in order to improve their abilities to make healthier diet and physical activity choices.

Your child will be asked to attend one group treatment session per week for 12 weeks and two additional bi-weekly sessions after the initial 12 for a total of 14 sessions. Your child will also be asked to attend eight monthly maintenance sessions. The first fourteen sessions will be held in person. The maintenance sessions will be held online using Zoom, with the exception of the final session, which will be held in person. Each of these sessions will last approximately 75 minutes and will focus on behavioral weight control strategies and, if assigned to the SBWC+ER group, how to handle feelings. You will be asked to attend 7 sessions over the year, including 4 maintenance sessions, three of which will be remote. The parent/caregiver sessions are specifically focused on providing information about the diet and physical activity plan recommended for your child and behavioral strategies to help with your child's weight loss efforts.

All group sessions will be videotaped. These recordings will allow the research team to review a sample of treatment sessions and make sure the program is being delivered the same way across sites. The video files will be stored at the Lifespan site on a password protected server (computer network) and only accessible by study staff. If you and your child are a participant at an Oregon site, the videos will be securely sent to the Lifespan site for review and storage. The videos will be destroyed two years after completion of the study.

As part of this study, your child will be asked to follow a dietary plan, increase exercise up to 60 minutes per day six days per week by the end of the program, and complete brief homework assignments throughout the group meetings. Your child will also be asked to keep a record of

all food eaten and physical activity done each day for the majority of their time in this study. No matter which group they are randomized to, your child will be asked to complete these activities.

Your child will be asked to share their food record with their group leader. They can track their food and diet on paper, using notebooks provided by the study, or electronically by using the MyFitnessPal app. If they would like to use the app, the study team will set up an account for you. Only you, your child, and the group leader(s) will have access to your account. It will be password protected. The account will not contain any information that would identify your child, such as their photo, name, or contact information.

Your child will have the opportunity to earn points for meeting goals while participating in the intervention sessions. Your child can earn up to 3 points per session for turning in food logs, meeting an individual goal, and for keeping your weight exactly the same or for losing weight Your child will have the opportunity to earn a total of 63 points across the 22 sessions. For every 5 points they earn, your child can redeem these points for a $5 gift card. In total your child will have the opportunity to earn up to $60 (in gift cards) for meeting group session goals.

Individual point totals will be posted for the group to see. No names will be posted. Your child will be assigned a number that that only they and the researchers will know so that your child can track their points compared to others.

There will be no cost to you or your insurance company to participate in this study. Given the recent increases in gas prices, we recognize that the cost of transportation can be a burden for families. This study can provide $10 cash compensation to caregivers to offset the cost of gas for each session attended during the first 14 sessions of the program (months 1-4, up to $140 when all sessions attended). During the baseline assessment for the study, you will be asked to complete a survey question that asks if you would like to opt in and receive funds to offset the cost of travel for the first 14 sessions of the program. You and your child will also be asked to complete assessment measures that include questions about your child's screen time, eating habits, and emotions. Your child will be asked to wear a wrist device that measures their physical activity at four time points: prior to the start of the program, and at 4-months, 12-months, and 18-months after the first session. The first assessment should take about 2 hours to complete and all following assessments should take about 90 minutes to complete. You and your child will be separately compensated for completion of each visit.

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Your child will receive $30 for completion of the baseline and 4-month visits. They will receive an additional $20 for completing specific procedures after the assessment visits. These post-visit procedures include wearing the wrist device for 7 days and completing two interviews about what they ate and drank over the past 24 hours. These procedures must be completed within three weeks of the visit to receive the additional $20. While these procedures are voluntary, if they are not completed, you and your child would not be able to participate in the study. The reason is because we would not have any data on your child prior to them starting the program and thus would not know whether the program affected their eating and activity behaviors.

At the 12- and 18- month visits, your child will receive $50 for completing each visit, and $25 for completing the post-visit procedures within three weeks of the visit. At each assessment, your child will also have an opportunity to earn up to an additional $5 for completion of a game, depending on their score. Therefore, your child can earn up to $55 for the baseline and for the 4-month assessment, and up to $80 for the 12-month and 18-month assessments, for a maximum total of $270.

You will also be compensated $30 for completion of each assessment visit (Baseline, 4-month, 12-month, and 18-month), for a total amount of $120. The table below explains the program and compensation. If you do not complete all the assessments, you will receive payment for those that you did complete.

<table>
<tr><th colspan="4">Session and Assessments Timeline</th></tr>
<tr><th>Week</th><th>Session/Assessment</th><th>Teen Compensation</th><th>Parent/Caregiver Compensation</th></tr>
<tr><td colspan="2">Baseline</td><td>$30+ $20 for completing post-visit procedures within 2 weeks + up to $5 for completing game</td><td>$30</td></tr>
<tr><td colspan="4">In Person Sessions (14 total)</td></tr>
<tr><td>Week 1</td><td>Session 1- Caregivers also attend</td><td>No points this week</td><td></td></tr>
<tr><td>Week 2</td><td>Session 2</td><td rowspan="7">(3 points available to earn each session)</td><td rowspan="7"></td></tr>
<tr><td>Week 3</td><td>Session 3</td></tr>
<tr><td>Week 4</td><td>Session 4</td></tr>
<tr><td>Week 5</td><td>Session 5</td></tr>
<tr><td>Week 6</td><td>Session 6</td></tr>
<tr><td>Week 7</td><td>Session 7</td></tr>
<tr><td>Week 8</td><td>Session 8 - Caregivers also attend</td></tr>
</table>

Session and Assessments Timeline			
Week	**Session/Assessment**	**Teen Compensation**	**Parent/Caregiver Compensation**
Week 9	Session 9	(3 points available to earn each session)	
Week 10	Session 10		
Week 11	Session 11		
Week 12	Session 12		
Break	Break between 12 & 13		
Week 14	Session 13		
Break	Break between 13 & 14		
Week 16	Session 14 - Caregivers also attend		
	4- month follow-up assessment	$30+ $20 for completing post-visit procedures within 2 weeks + up to $5 for completing game	$30
Remote Sessions (7 total)			
Month 5	Session 15	(3 points available to earn each session)	
Month 6	Session 16 - Caregivers also attend		
Month 7	Session 17		
Month 8	Session 18 - Caregivers also attend		
Month 9	Session 19		
Month 10	Session 20 - Caregivers also attend		
Month 11	Session 21		
Final Session – In person			
Month 12	Session 22 - Caregivers also attend		
	12-month follow-up assessment	$50+ $25 for completing post-visit procedures within 2 weeks + up to $5 for completing game	$30
18 Month Assessment			
Month 18	18-month follow-up assessment	$50+ $25 for completing post-visit procedures within 2 weeks + up to $5 for completing game	$30

1. Height, Weight, and Waist Circumference. Weight will be obtained on a digital scale and height will be obtained using a stadiometer. We will also measure waist circumference (the distance around your child's waist). This information will be obtained in a private space by a member of the investigative team.

2. Demographics. At the initial assessment only, you will be asked some basic information about your family, such as age, gender, ethnicity and level of education.
3. Dieting and Eating Patterns. To look at previous weight loss attempts, as well as current patterns, your child will be asked about episodes of overeating and other unhealthy eating habits, and to maintain weekly food records. Your child will also be asked to complete a 3-day dietary recall with a nutritionist.
4. Physical Activity. Before the start of the program and at each of the follow up assessments, your child will be asked to wear a wrist-worn physical activity monitor for 7 days, which will allow us to determine how physically active they are.
5. Access to Resources. We will also ask about your family's access to food and housing resources. We will also ask about neighborhood safety and access to recreational resources.
6. Screen Time. Your child will be asked to complete questions regarding the amount of time spent on screen-time activities during three 24-hour periods. These types of activities include video chats, videogaming, television, movies, and social media usage.
7. Other Measures. Additionally, your child will be asked about how they manage stress and their emotions, and will be asked to complete a computerized activity. They will also be asked questions about their ability to plan and follow through with activities. You will be asked questions about how you think your child handles their emotions.

For the seven days following each assessment visit, we will text a survey to your child's cell phone at 9pm each night. The survey will have five questions about how your child's emotions affected their desire to eat over the course of the day. We will use a program called Qualtrics to send these surveys; this ensures that your child's information is kept confidential and that only the research team can access their responses.

If you and your child decide to join the research study, some screening tests will be done first to see if your child is eligible to participate. These will occur during the first assessment session. If the screening tests show that your child meets all study requirements, then we will be able to assign your child to a study group. If the screening tests show that your child does not meet all the study requirements and cannot be in the research study, the research investigator will discuss other options with you.

All data will be stored at the Lifespan site on a password protected server (computer network) that is only accessible by study staff. If you are a participant at one of the Oregon sites, your research data, without your name or other information that would identify you (such as your

address or telephone number) will be electronically sent by secure methods to Lifespan and stored on this secure server. This ensures all the data is in one place and can be analyzed together.

You and your child's identifiable private information may be stripped of identifiers and used for future research studies or distributed to another researcher for future research studies without additional informed consent.

Text Messaging:

Text messaging is part of this research study. This may include you receiving text messages from research staff and/or you sending text messages to research staff. Lifespan takes your confidentiality seriously and will take steps to protect the information contained in the text messages to the degree permitted by the technology being used. Depending on the nature of the study, some of the following steps may be taken: encrypting the data during transmission, eliminating sensitive health care information from the texts, and storing all data gathered on secure servers

In this study, research staff will text you and your child about your appointments. We will also send your child a survey by text, each day, for 7 days following each of your assessment visits. We will not include any sensitive information, such as information about your child's health, in the text messages. If you have health information to share with the study, please call a study staff member. Contact information will be provided to you upon study enrollment.

However, Lifespan can make no guarantees about the secure transmission of texts you send to us, nor can Lifespan guarantee security after you receive the text message from Lifespan. For example, text messages that display on your phone screen may be seen by someone close by or by someone you have allowed to use your phone. Also, if you do not password protect your phone and it is lost or stolen, anyone who finds it might view the information in the texts about your health or other topics. To try to lessen these risks, you should make sure your phone is password protected, only open and view messages where no one will be able to view the screen and delete messages as soon as possible after reading them. Additionally, when you trade in your phone, remember the SIM card (memory card used in cell phones) should be cleared.

Finally, it is also possible that the mobile phone company that transmits the text messages may keep copies of ALL your texts (those from the study, and your other texts) even after the study is ended. Lifespan has no control over these companies and cannot make any guarantees about their conduct.

Contact Information: You can call us with any concerns or questions about the research.

- ***If you are a participant at the Lifespan site, call:***
  Elissa Jelalian, PhD
  401-793-9716
  Available during typical business hours (9am – 5pm)

- ***If you are a participant and receiving treatment at the UO site, call:***
  Wendy Hadley, PhD
  541-346-2185
  Available during typical business hours (9am – 5pm)

- ***If you were enrolled at OHSU and have general questions about the study:***
  Alex Foster, MD, MPH
  503-494-8495
  Available during typical business hours (9am – 5pm)

3. Discomforts and Risks

All assessment measures have been widely used with other teenagers, with no negative reactions reported. However, if your child experiences any emotional discomfort in discussing their weight or other issues, they will have the opportunity to speak to an investigator about this discomfort. They also will be assured that they do not have to answer any questions that they do not feel comfortable with

4. Benefits

Your child may or may not benefit from this study, but it may help your child to manage their weight, eat well, and exercise. This study may help us learn more about the best ways to help teens lose weight.

5. Alternative Therapies

You and your child have the option of having a referral to a nutritionist if you choose not to participate in the HealthTRAC program. You may choose this option at any time.

6. Refusal/Withdrawal

It is up to you whether you and your child want to be in the study. You and your child are not required to enroll or participate. If you and your child decide to participate, you and your child can always change your mind and quit at any time. If you decide not to be in the study, or if you quit later, you and your child will still be able to get the health care services you normally get. If you join, but later the researcher or your doctor feels being in the study is no longer good for your child, they may choose to take you and your child out of the study before it is over. If new information becomes available that might change your mind about whether you want to stay in the study, the researcher will share this information with you as soon as possible.

Reasons the researchers would take you out of the study even if you wanted to stay in:

- The researcher believes that it is not in your best interest to stay in the study.
- You become ineligible to participate.
- Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- You do not follow instructions from the researchers.
- The study is suspended or canceled.

Follow-up after Withdrawal of Consent

If you remove your child from the study, it would still be useful for us to know how your child do over the next 18-months, which is the duration of this study. We would appreciate if you would permit us to get follow-up information about your child's health from their doctor and/or their medical record.

_____ If I withdraw my child from the study, you have my permission to collect information about my child's health from their doctor or medical record

_____ I do not give my permission for you to continue to collect information about my child if I withdraw my child from the study.

_____ _____

Signature of study Parent/Caregiver or guardian Date

You have the right to change your mind at any time regarding follow-up after withdrawal. If you decide to have your child quit the study, please tell the head researcher Elissa Jelalian, PhD (401-793-9716).

7. Medical Treatment/Payment in Case of Injury

A research injury is any physical or mental injury or illness caused by being in the study. If your child is injured by a medical treatment or procedure they would have received even if they were not in the study, that is not a research injury. To help avoid research injury and added medical expenses, it is very important to follow all study directions carefully. If your child does experience a research injury, Lifespan or the study doctor can arrange medical treatment for your child. Such treatment will be paid for as described below.

If your child has insurance and has a research injury that is not covered by the study, it is possible that some or all the cost of treating your child could be billed to their insurer. If their health insurance will not cover such costs, it is possible you would have to pay out of pocket. In some cases, Lifespan might be able to help you pay if you qualify for free care under Lifespan policy. However, Lifespan has no policy to cover payment for such things as lost wages, expenses other than medical care, or pain and suffering.

For OHSU subjects:

If you believe you have been injured or harmed as a result of participating in this research and require treatment, contact Alex Foster, MD, MPH at 503 494-8495.

If you are injured or harmed by the behavioral counseling, you will be treated. OHSU and the NIH not offer any financial compensation or payment for the cost of treatment if you are injured or harmed as a result of participating in this research. Therefore, any medical treatment you need may be billed to you or your insurance. However, you are not prevented from seeking to collect compensation for injury related to negligence on the part of those involved in the research. Oregon law (Oregon Tort Claims Act (ORS 30.260 through 30.300)) may limit the dollar amount that you may recover from OHSU or its caregivers and researchers for a claim relating to care or research at OHSU, and the time you have to bring a claim.

If you have questions on this subject, please call the OHSU Research Integrity Office at (503) 494-7887.

This federally funded study also does not have the ability to provide compensation for research-related injury. If you are injured or become ill from taking part in this study, it is important to tell your study doctor. Emergency treatment may be available but you or your insurance company will be charged for this treatment.

8. Rights and Complaints

Signing this form does not take away any of your lawful rights. If you or your child have any complaints about this study or would like more facts about the rules for research studies, or the rights of people who take part in research studies, you may contact the Director of the Lifespan Office of Research Administration, at (401) 444-6246 or for OHSU participants, you may talk to the IRB at (503) 494-7887 or irb@ohsu.edu.

9. Confidentiality and Research Authorization for Use and Disclosure of Your Health Care Information.

Your child's research records will be treated as private health care records and will be protected according to Lifespan privacy practices and policies that are based on state and federal law. Federal law requires us to get your permission to use or disclose (release your child's information to someone outside of Lifespan) their health information for research purposes. If you sign this form you agree to have your child be in this research study and you permit the use and disclosure of your child's health information for the purpose of conducting the research, providing treatment, collecting payment and running the business of the hospital. This permission has no expiration date. You may withdraw your child from the study at any time. However, if you do not want the researchers to use or disclose any further information in this study you must cancel permission in writing and may do so at any time. If you cancel your permission, your child will stop taking part in the study and no new information will be collected about them. However, if you cancel your permission, it will not apply to actions already taken or information already collected about your child by the hospital or the researchers before you canceled your permission.

- ***If you are a participant at the Lifespan site, write to:***
  Dr. Elissa Jelalian, PhD
  Weight Control and Diabetes Research Center
  196 Richmond Street, Providence, RI 02903

- ***If you are a participant at the University of Oregon site, write to:***
  Dr. Wendy Hadley, PhD
  University of Oregon
  Prevention Science Institute
  1600 Millrace Drive,Eugene, OR 97403

For subjects enrolling at OHSU, OHSU personnel will be the ones accessing your child's health information and research data.

Generally, the entire research record and any medical records held by the hospital may be used and released research purposes. The following people or businesses/companies might use, release, or receive such information:

- The researcher and their support staff;
- The study sponsor, National Institute of Diabetes and Digestive and Kidney Diseases
- Doctors, nurses, laboratories and others who provide services to your child or the sponsor in connection with this study;
- The company or section of the U.S. government that is paying for the study and others they hire to oversee, administer, or conduct the research;
- The United States Food and Drug Administration, the Department of Health and Human Services, the Office of Inspector General, the Office of Civil Rights, European Medicines Agency
- People who volunteer to be patient advocates or research volunteer protectors;
- Members of the hospital's administrative staff responsible for reviewing, approving and administering clinical trials and other healthcare or research activities. This would include OHSU entities in case of a local audit.
- Accrediting Organizations

There are times when the law might require or permit Lifespan to release your child's health information without your permission. For example, Rhode Island law requires researchers and health care workers to report abuse or neglect of children to the Department of Children, Youth and Families (DCYF) and to report abuse or neglect of people age 60 and older to the Department of Elderly Affairs.

All researchers and health care providers are required to protect the privacy of your child's health care information. Other people and businesses/organizations that are not health

care providers are not required by law to do that, so it is possible they might re-release your child's information.

You have the right to refuse to sign this form and not allow your child to participate in the research. Your refusal would have no effect on your treatment, charges billed to you, or benefits at any Lifespan health care site. If you do not sign, your child will not be able to enroll in the research study and will not receive treatment as a study participant.

If you decide to have your child quit the study after signing this form (as described in Section 6), no new information will be collected about your child unless you gave us permission to do so. However, the hospital or the researchers may continue to use information that was collected before you removed your child from the study to complete analysis and reports of this research.

You will not be allowed to see or copy the information about your child's participation described in this form if the research study is open. You may see and copy the information when the study is completed.

A description of this clinical trial will be available on *http://www.ClinicalTrials.gov*, as required by U.S. law. This Website will not include information that can identify your child. At most, the Website will include a summary of the results. You can search this Website at any time.

The National Institutes of Health has issued a Certificate of Confidentiality for this research. This adds special protection for the research information and specimens that may identify your child. The researchers may not disclose information that may identify your child, even under a court order or subpoena, unless you give your permission to release this information about your child. However, a Certificate of Confidentiality does not prevent researchers from disclosing information about your child if required by law (such as to report child abuse, communicable diseases or harm to self or others); if you have consented to the disclosure (such as for your child's medical treatment); or if it is used for other research as allowed by law. In addition, the Certificate cannot be used to refuse a request if a governmental agency sponsoring the project wants to audit the research. Any research information that is placed in your child's medical record would not be covered under this Certificate. The Certificate will not be used to prevent disclosure for any purpose you have consented your child to in this informed consent document. The Certificate does not stop

you or your child from voluntarily releasing information about themselves or your child's involvement in this research. If others obtain your written consent to receive research information about your child, then the researchers may not use the Certificate to withhold that information.

Contact for Future Studies:

Your child's participation in **any research** is completely voluntary and you/ your child should feel no pressure to have them participate in another research study.

Please check and initial one of the options below regarding future contact about other research done by us or other researchers we are working with (collaborators).

_____ ☐ Yes, I may be contacted about my child participating in other research projects studying weight management. I give permission for my contact information (name and mailing address and/or phone number) to be given to other researchers working with the study investigator.

_____ ☐ No, I do not want to be contacted about my child participating in other research projects. **Do not** give my contact information to the staff of any other research studies.

Lifespan IRB 1
IRBNet ID: 1662468-33
Use on or after: May 24, 2023
Expiration:
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IRB#: _____

MED. REC. NO. _____

NAME _____

BIRTHDATE _____

SIGNATURE

I have read this informed consent and authorization form. ALL OF MY QUESTIONS HAVE BEEN ANSWERED, AND I WANT MY CHILD TO TAKE PART IN THIS RESEARCH STUDY.

By signing below, I give my permission for my child to participate in this research study and for the described uses and releases of information. *I also confirm that I have been now or previously given a copy of the Lifespan Privacy Notice.*

This informed consent document is approved for use with a valid IRB stamp at the top of each page. The document expires for use on the date listed within the IRB stamp. DO NOT sign this document after this expiration date.

If the expiration date is blank, this document does not expire.

The Researcher is required to provide a copy of this consent to you.

Signature of Parent/Caregiver/Guardian	Date (MM/DD/YEAR)	Time when signed
Printed Name of Parent/Caregiver/Guardian		
Print name of Child participant		
Signature of researcher or designate	Date (MM/DD/YEAR)	Time when signed

☐ **A copy of this complete (note total number of pages in footer) signed consent form has been given to the participant.**

Child Assent Form

Rhode Island Hospital, The Miriam Hospital, EP Bradley Hospital,
Newport Hospital, and Gateway HealthCare

Name of Study Participant: _____

Principal Investigator: **Lifespan/Weight Control & Diabetes Research Center:** Elissa Jelalian, PhD
University of Oregon/Prevention Sciences Institute: Wendy Hadley, PhD
OHSU/Doernbecher Children's Hospital: Alex Foster, MD, MPH

Title of Research Study: HealthTRAC

We want to tell you about a research study we are doing. A research study is a way to learn more about something. We would like to find out more about how to help teens lose weight. Both you and your parent/caregiver will be part of this study.

If you agree to join this study, you will be asked to answer questionnaires about things like your eating habits, screen time, and emotions. You will be asked to wear a wrist-worn device that measures your physical activity; you will be asked to wear this device for 1 week at each assessment point of the study (baseline, 4-month follow up, 12-month follow up, and 18-month follow up).

You will be randomly assigned, "randomized", into one of the two study groups described below. Randomization means that you are put into a group by chance. It is like flipping a coin. Which group you are put in is done by a computer. Neither you nor the researcher can choose what group you will be in. You will have an equal chance of being placed in any group. Both groups focus on helping teens lose weight, but they are slightly different. One hundred teens (and their parents/caregivers) will be in each group.

The two study groups within the HealthTRAC study are the Standard Behavioral Weight Control Group (SBWC) and the Standard Behavioral Weight Control + Emotion Regulation training group (SBWC+ER). The SBWC group involves a dietary plan that will include a reduced calorie diet (1400-1600 kilocalories per day) along with education and activities about physical activity and behavioral weight control strategies (e.g. portion control, healthy snacking). In addition, your parent/caregiver will receive information about how they can help you in your weight loss efforts.

The other group will also have education and activities about diet and physical activities but will also include training in how to recognize your feelings and how they affect your diet and ways to cope with these feelings in order to improve your ability to make healthier diet and physical activity choices. This group is called the SBWC+ER intervention group.

You will be asked to attend one group treatment session per week for 12 weeks and two bi-weekly sessions in the next month (14 total). You'll then be asked to attend 8 monthly maintenance sessions. The first fourteen sessions will be held in person. The maintenance sessions will be held online using Zoom or Microsoft Teams, with the exception of the final session, which will be held in person. Each of these sessions will last approximately 75 minutes and will focus on behavioral weight control strategies and, if you are assigned to the SBWC+ER group, you will also receive information on how to handle feelings. Your parent/caregiver will be asked to attend 7 sessions over the year, including 4 maintenance sessions, three of which will be held remotely. The parent/caregiver sessions are specifically focused on providing information about the diet and physical activity plan recommended for you and behavioral strategies to help with your weight control.

Before each session, the group leader will meet with you one-on-one in a private room to collect your weight and ask you how you have been since the last session.

All group sessions will be videotaped. These recordings will allow the research team to review a sample of treatment sessions and make sure the program is being delivered the same way across sites. The video recordings will be saved by our research team for 2 years and then we will destroy them. No one will listen to or watch these recordings except the researchers.

As part of this study, you will be asked to follow a dietary plan, increase exercise up to 60 minutes per day six days per week by the end of the program, and complete brief homework assignments throughout the group meetings. You will also be asked to keep a record of all food eaten and physical activity done each day for a year. No matter which group you are assigned to, you will be asked to complete these activities.

You will be asked to share your food record with your group leader. You can track your food and diet on paper, using notebooks provided by the study, or electronically by using the MyFitnessPal app. If you would like to use the app, the study team will set up an account for you. Only you, your caregiver, and the group leader(s) will have access to your account. It will be password protected. Your account will be just for you, but it will not contain any information that would identify you such as your photo, name, or contact information.

You will have the opportunity to earn points for meeting goals while participating in the intervention sessions. You can earn up to 3 points per session for turning in food logs, meeting an individual goal, and for keeping your weight exactly the same or for losing weight. You have the opportunity to earn a total of 63 points across the 22 sessions. For every 5 points you earn, you can redeem these points for a $5 gift card. In total you have the opportunity to earn up to $60 (in gift cards) for meeting group session goals.

Individual point totals will be posted for the group to see. No names will be posted. You will be assigned a number that that only you and the researchers will know so that you can track your points compared to others.

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You and your parent/caregiver will also be asked to complete assessment measures that include questions about your screen time, eating habits, and emotions as well as wear a wrist device that measures your physical activity at four time points: prior to the start of the program, at the end of treatment (at month 4), and then at 12- and 18-months after you are assigned to your study group. At each assessment visit, a research staff member will meet with you one-on-one in a private room to collect your height, weight, and distance around your waist.

The first assessment should take about 2 hours to complete, and the other three assessments should take about 90 minutes each to complete. You will be asked to complete questionnaires. You will receive $30 for completion of the baseline and 4-month visits. You will receive an additional $20 for completing specific procedures after the assessment visits. These procedures include wearing a wrist device for 7 days and completing two interviews about what you ate and drank over the past 24 hours. These procedures must be completed within three weeks of the visit to receive the additional $20. While these procedures are voluntary, if they are not completed, you and your parent/caregiver would not be able to participate in the study. The reason is because we would not have data to help determine whether the program affected eating and activity behaviors.

At the 12- and 18- month visits, you will receive $50 for completing each visit, and $25 for completing the post-visit procedures three weeks of the visit. At every assessment (Baseline, 4-month, 12-month, and 18-month), you will also be asked to complete a game, where you can earn a cash prize depending on the score. You can earn up to $5 at each assessment depending on your score. Therefore, you can earn up to $55 for the baseline and for the 4-month assessment, and up to $80 for the 12-month and 18-month assessments, for a maximum total of $270.

Your parent/caregiver will be compensated $30 for completing each assessment visit (Baseline, 4-month, 12-month, and 18-month), for a total amount of $120. The table below explains the program and compensation. If you do not complete all the assessments, you will receive payment for those that you did complete.

For the seven days following each assessment visit, we will text a survey to your cell phone at 9pm each night. The survey will have five questions about how your emotions affected your desire to eat over the course of the day. We will use a program called Qualtrics to send the surveys; this ensures that your information is kept confidential and that only the research team can access your responses.

Session and Assessments Timeline			
Week	**Session/Assessment**	**Teen Compensation**	**Parent/Caregiver Compensation**
Baseline		$30+ $20 for completing post-visit procedures within 2 weeks + up to $5 for completing game	$30
In Person Sessions (14 total)			
Week 1	Session 1 – Caregivers also attend	No points this week	
Week 2	Session 2	(3 points available to earn each session)	
Week 3	Session 3		
Week 4	Session 4		
Week 5	Session 5		
Week 6	Session 6	(3 points available to earn each session)	
Week 7	Session 7		
Week 8	Session 8 – Caregivers also attend		
Week 9	Session 9		
Week 10	Session 10		
Week 11	Session 11		
Week 12	Session 12		
Break	Break between 12 & 13		
Week 14	Session 13		
Break	Break between 13 & 14		
Week 16	Session 14 – Caregivers also attend		
	4- month follow-up assessment	$30+ $20 for completing post-visit procedures within 2 weeks + up to $5 for completing game	$30
Remote Sessions (7 total)			
Month 5	Session 15	(3 points available to earn each session)	
Month 6	Session 16 – Caregivers also attend		
Month 7	Session 17		
Month 8	Session 18 – Caregivers also attend		
Month 9	Session 19		
Month 10	Session 20 – Caregivers also attend		
Month 11	Session 21		
Final Session – In person			
Month 12	Session 22 – Caregivers also attend		
	12-month follow-up assessment	$50+ $25 for completing post-visit procedures within 2 weeks + up to $5 for completing game	$30
18 Month Assessment			
Month 18	18-month follow-up assessment	$50+ $25 for completing post-visit procedures within 2 weeks + up to $5 for completing game	$30

Discomforts and Risks

All assessment measures have been widely used with other teenagers, with no negative reactions reported. However, if you experience any emotional discomfort in discussing your weight or other issues, you will have the opportunity to speak to an investigator about this discomfort. You do not have to answer any questions that you do not feel comfortable with

You may or may not benefit from this study, but it may help you to manage your weight, eat well, and exercise. This study may help us learn more about the best ways to help teens lose weight.

The research team may talk about this study with your doctor, but not with anyone else unless your parent/caregiver, your guardian, and you say it's okay. However, if you report you are suicidal, want to hurt someone, or have been sexually abused, we will tell your parent/caregiver and get you help.

You do not have to join this study. It is up to you. You can say okay now and change your mind later. All you must do is tell us you want to stop. No one will be mad at you if you don't want to be in the study or if you join the study and change your mind later and stop.

Before you say **yes or no** to being in this study, we will answer any questions you have. If you join the study, you can ask questions at any time. Just tell the researcher that you have a question. We will discuss this study with your parent/caregiver or your guardian and ask them if it is okay for you to be in the study.

If you have any questions about this study, you can ask us:

- If you are in Rhode Island, call: Elissa Jelalian, PhD at 401-793-9716
- If you are in Oregon, call: Wendy Hadley, PhD at 541-346-2185 or Alex Foster, MD, MPH at 503-494-8495

SIGNATURE

Child/Adolescent Assent

Signature of **Child/Adolescent Subject** Date (MM/DD/YEAR) Time when signed

Child/Adolescent Age