Addressing Weight Bias Internalization to

Improve Adolescent Weight Management Outcomes

(NCT06389656)

Principal Investigator: Dr. Katherine Darling, PhD

Research Consent Form

(Document Approval Date: April 8, 2024)

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Research Consent and Authorization Form

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

Name of Study Participant: _____

Principal Investigator: Katherine Darling, Ph.D.

Title of Research Study: SWIFT Open Trial

If you are a parent or legal guardian who is giving permission for a child (<18 years old), please note that the word "you" in this document refers to your child.

Please check one of the following:

_____ You are the parent or guardian granting permission for a child in this study.

__X___ You are the parent or guardian granting permission for yourself and your child to participate in this study.

Study Key Information

You are 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 to take part in the research. Taking part in this study is completely voluntary. Even if you decide to take part in the study, you are free to leave at any time if you change your mind. The researcher will explain the study to you 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 participate in the research. If you agree that you would like to participate in this research study, you will be asked to review and sign this consent. A copy will be given to you.

A. What is the purpose of the research?

The purpose of this research is to test a program for teenagers focused on feeling better about their weight, improving healthy habits (such as physical activity, eating, and sleep), and losing weight. We would like to learn about how easy and engaging this program is for teenagers, by having them participate in the program and provide feedback on session content, examples used, and improving the fit of the program to teenagers.

B. What is experimental/new in this study?

Participants in this study will learn different strategies to cope with weight stigma and internalized weight bias in addition to learning strategies to lose weight.

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

If you decide to join this research study, you will be asked to complete several questionnaires about things like your health behaviors, such as eating and physical activity, and experience with weight stigma. You will also be asked to attend one treatment session per week for 20 weeks for 75 minutes per session. Parents/caregivers will be asked to attend 4 of these sessions. Sessions will focus on ways to decrease negative feelings associated with weight, cope with experiences of weight stigma and bias, and changing diet and physical activity behaviors to improve weight-related health outcomes.

It will take you about 5 months to complete this study. During this time, we will ask you to make 22 study visits and for your parent/caregiver to make 5 study visits. This includes 20 program sessions for teens, in addition to two assessments. For caregivers, this is 4 program sessions and 1 assessment.

D. What could go wrong?

It is possible that you may experience some emotional discomfort in discussing your weight or other issues. You do not have to answer any questions that you do not feel comfortable with. In any research study, there is a small possibility that your personal information could be made public. The study will take precautions to minimize this risk

E. What are the benefits?

You may or may not benefit from this study, but it may help you to manage your weight, eat well, exercise, and feel better about yourself. This study may help us learn more about how to improve teens' mental and physical health outcomes.

F. Other things I should know about this research?

If we find out about new information from this research that may affect your 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?

You have the option of having a referral to a nutritionist if you choose not to participate in the SWIFT program. You may choose this option at any time. You do not have to be in this research study. Your healthcare provider can discuss with you what your clinical treatment options are and which clinical treatment(s) might be right for you considering your medical history.

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Use on or after: April 8, 2024
Expiration: February 19, 2025
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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 are being asked to take part in a research project because you are a teenager who is interested in a healthy lifestyle program, focused on improving weight bias internalization and health behaviors. In this study, we are trying to learn more about the best ways to improve teen's perception of themselves, while following national health guidelines (e.g., physical activity and healthy diet) to lose weight. We expect to enroll approximately 24 pairs of teens and caregivers into this study. This study is sponsored by the National Institutes of Health.

2. Explanation of Procedures:

Prior to beginning the group sessions, you will be asked to complete several questionnaires about your experiences with weight stigma and health behaviors, such as eating and physical activity. You will also be asked to track your physical activity, eating behaviors, and experiences with weight bias each day for 1 week after the initial assessment.

The intervention involves learning about ways to identify and decrease negative feelings associated with weight, coping with experiences of weight stigma and bias, and making changes to diet and physical activity levels. The first four weeks of the program will focus on addressing weight bias and coping with stigma. The following 16 weeks involve integrating knowledge about weight stigma into an evidence-based adolescent weight management program. 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 weight loss efforts while decreasing weight stigma and bias.

You will be asked to attend one group treatment session per week for 20 weeks. Groups will be comprised of approximately 6-8 teenagers total. You will be with the same groups of teens for all of your sessions. The sessions will be held in person at the Weight Control and Diabetes Research Center. Each of these sessions will last approximately 75 minutes and will focus on coping with weight bias and stigma along with learning about behavioral weight control strategies. Your parent/caregiver will be asked to attend 4 in person sessions over the 20-week intervention. The parent/caregiver sessions are specifically focused on providing information about weight stigma in the home and how to have weight-related conversations along with supporting you with nutrition and physical activity goals while decreasing weight bias.

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As part of this study, you will be asked to follow a nutrition plan with a focus on improving diet quality, increase exercise up to 60 minutes per day six days per week by the end of the program, decrease screen time to < 2 hours per day and complete brief homework assignments throughout the group meetings. You will also be asked to complete brief nightly diary entries about eating behaviors, emotions, and daily experiences with weight stigma during the study.

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 an 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 also 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 attending the session and meeting weekly individual and program goals. You have the opportunity to earn a total of 60 points across the 20 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. There will be no cost to you or your insurance company to participate in this study.

You will also be asked to complete assessment measures that include questions about background and demographic information, experiences with weight stigma and bias, and health behaviors. The baseline assessment should take about 90 minutes to complete, and the post-treatment follow up assessment should take about 2 hours to complete. You will be compensated $40 for completion of the baseline assessment. If, during the assessment, the results indicate you are ineligible to participate in the program, the visit will end early, and you will be compensated $20 for your time.

You will receive $60 for completion of the post-treatment assessment. The post-treatment assessment will include an interview about your experiences and thoughts on the program.

1. Height, Weight, and Waist Circumference. Weight will be obtained on a digital scale and height will be obtained using a stadiometer. 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. At both of the assessments we will ask about your current diet intake and diet quality, as well as ask about episodes of overeating and other unhealthy eating habits, to understand your current behaviors regarding dietary intake and eating behaviors.

4. Physical Activity. Before the start of the program and at the follow up assessment, you will be asked to complete a questionnaire to assess physical activity, which will allow us to determine how physically active you are.
5. Access to Resources. We will also ask about your family's access to food and housing resources.
6. Weight Bias and Stigma. We will ask you questions about how you view yourself and your weight, as well as situations in which you may have experienced stigma or bias because of your weight status to assess internalized weight bias and experiences of weight stigma.
7. Acceptability. At the end of each group session, as well as at the end of the program, we will ask you about how helpful each session was to you and how much you liked each session. During the final assessment, we will also conduct an individual interview where we learn more about your experiences in the program and how to make the program a better fit for other teenagers. These interviews will be audio recorded so that the researchers can accurately capture the conversation. The audiotapes, notes and transcriptions of the tapes will be stored in the secure Lifespan server and will only be accessible by authorized study team personnel or HIPAA-compliant transcription company. These tapes will be kept for no longer than two years. The transcriptions will be stripped of identifying information and will undergo analysis to identify themes for future program development. Non-identifying quotes may be used to illustrate these themes.
8. At Home Measures. For the seven days following each assessment visit, we will text a survey to your cell phone at 8:30pm each night. The survey will have questions about your eating habits and experiences of weight stigma over the course of the day. If you do not have a cell phone, there are other ways to complete this nightly survey. For example, we can text it to your caregiver's cell phone, or email it to you or your caregiver.

All data will be stored at the Lifespan site on a password protected server (computer network) that is only accessible by study staff.

Your 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

We will send you 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 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 has 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.

Katherine Darling, PhD
401-793-8688, kdarling1@lifespan.org
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 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. In any research study, there is a small possibility that your personal information could be made public. The study will take precautions to minimize any potential risk in a data breach. We will protect your records so that your name, address, phone number, and other personal information will be kept private. Confidential material will be stored in locked files and electronic files will reside on secure servers in password protected datasets. Therefore, the chance that this information will be made public is very small.

There is a risk that other group members may share your name or information they learn about you with other people outside of the group setting. We require all participants in this study to protect one another's privacy by not sharing the information about group members with anyone else. To further protect privacy, we use first names during group, and participants are encouraged to share as little or as much information as they feel comfortable to do so. In addition, other group members will not see your personal records, including the information you share during private check ins. Despite these protections, it is possible that another group member may share your information outside of group. If that happens, our study staff will take corrective action with that participant. It important that we protect one another's confidentiality such that we have a safe and respectful group environment through which all group members can learn and share.

4. Benefits

You may or may not benefit from this study, but it may help you to feel better about yourself, manage your 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 have the option of having a referral to a nutritionist if you choose not to participate in the SWIFT program. You may choose this option at any time.

6. Refusal/Withdrawal

It is up to you whether you want to be in the study. You are not required to enroll or participate. If you decide to participate, you 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 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 you, they may choose to take you 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.

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- You do not follow instructions from the researchers.
- The study is suspended or canceled.

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 you are injured by a medical treatment or procedure you would have received even if you 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 you do experience a research injury, Lifespan or the study doctor can arrange medical treatment for you. Such treatment will be paid for as described below.

If you have insurance and have a research injury that is not covered by the study, it is possible that some or all the cost of treating you could be billed to your insurer. If your 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.

8. Rights and Complaints

Signing this form does not take away any of your lawful rights. If you 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, Research Protection Office in Lifespan Office of Research, at (401) 444-6246.

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

Your 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 information to someone outside of Lifespan) your health information for research purposes. If you sign this form, you agree to be in this research study and you permit the use and disclosure of your 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 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, you will stop taking part in the study and no new information will be collected about you. However, if you cancel your permission, it will not apply to actions already taken or information already collected about you by the hospital or the

researchers before you canceled your permission. To do this, write to: Dr. Katherine Darling, PhD, WCDRC, 196 Richmond Street, Providence, RI 02903.

Generally, the entire research record and any medical records held by the hospital may be used and released for 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 you 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.
- Accrediting Organizations

There are times when the law might require or permit Lifespan to release your 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 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 information.
You have the right to refuse to sign this form and not 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, you will not be able to enroll in the research study and will not receive treatment as a study participant.

If you decide to quit the study after signing this form (as described in Section 6: Refusal/Withdrawal), no new information will be collected about you unless you gave us

permission to do so. However, the hospital or the researchers may continue to use information that was collected before you quit the study to complete analysis and reports of this research. You will not be allowed to see or copy the information described in this form if the research 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 you. 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 you. The researchers may not disclose information that may identify you, even under a court order or subpoena, unless you give permission. However, a Certificate of Confidentiality does not prevent researchers from disclosing information about you 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 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 medical record would not be covered under this Certificate. The Certificate will not be used to prevent disclosure for any purpose you have consented to in this informed consent document. The Certificate does not stop you from voluntarily releasing information about yourself or your involvement in this research. If others obtain your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

10. Contact for Future Studies:

Your participation in **any research** is completely voluntary and you should feel no pressure to participate if you are contacted about 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 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 other research projects. **Do not** give my contact information to the staff of any other research studies.

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Signature Page for Child Participants

Parent/Guardian Signature(s)

- I have read this informed consent and authorization form. ALL OF MY QUESTIONS HAVE BEEN ANSWERED, AND I WANT 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 (HIPAA). *I also confirm that I have been now or previously given a copy of the Lifespan Privacy Notice.*
- **The Researcher is required to provide a copy of this consent to you.**

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.

Print name of child participant		
Signature of Parent/Guardian	Date (MM/DD/YEAR)	Time when signed
Print name of Parent/Guardian	Relationship to child	

Research Investigator /or Designee's Statement & Signature

- I have fully explained the research described above, including the possible risks and benefits, to all involved parties (participant /parents/legal guardian as applicable).
- I have answered and will answer all questions to the best of my ability.
- I will inform all involved parties of any changes (if applicable) to the research procedures or the risks and benefits during or after the course of the research.
- I have provided a copy of the consent form signed by the participant/parent/guardian and a copy of the hospital's privacy notification (if requested).

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.**