ELECTRONIC CONSENT

The Ohio State University Combined Consent to Participate in Research and HIPAA Research Authorization

Study Title:
Episodic Future Thinking: An Interventional Pilot Study to Promote Weight Loss in Breast Cancer Survivors

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Sponsor: Alliance for Clinical Trials in Oncology

- **This is a consent form for research participation.** It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate.
- **Your participation is voluntary.** You may refuse to participate in this study. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with The Ohio State University. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status.
- **You may or may not benefit as a result of participating in this study.** In addition, as explained below, your participation may result in unintended or harmful effects for you that may be minor or may be serious depending on the nature of the research.
- **You will be provided with any new information that develops during the study that may affect your decision whether or not to continue to participate.** If you decide to participate, you will be asked to sign this form and will receive a copy of the form. You are being asked to consider participating in this study for the reasons explained below.

Key Information about This Study

The following is a short summary to help you decide whether to be a part of this study. The information in this section is intended to be an introduction to the study only. Information that is more detailed is listed later in this form. If you are considering participation in the study,

the entire document should be discussed with you before you make your final decision. You can ask questions about the study now and at any time in the future.

Increased weight is known to be associated with many negative health effects in survivors of breast cancer. This includes a higher risk of breast cancer recurrence, a decreased quality of life, and an increased risk of other medical conditions such as heart disease and diabetes. The goal of this study is to encourage healthy lifestyle choices that are known to promote weight loss such as a healthy diet and regular exercise. The aim is to promote a long-lasting reduction in weight. The purpose of this research is to study the effectiveness of engaging in certain thought exercises in order to promote weight loss in women who are survivors of breast cancer. We will also study decision-making surrounding maintaining a healthy weight.

You have been asked to be in this study because you:

- Are greater than or equal to 18 years old
- Have a Body Mass Index (BMI), which is a measure of body fat, of greater than or equal to 25 kg/m^2
- Are motivated to lose weight
- Have access to a smartphone, and
- Have been diagnosed and treated for ductal carcinoma in situ (DCIS) or stage 1 to stage 3 breast cancer.

This study will investigate a new behavioral intervention that works through a web application delivered to your smartphone. All subjects in this study will receive access to an effective weight loss program. We are also comparing the effectiveness of two possible additions to this program. Both of these additions include thought exercises. You will be assigned to one of two groups that experience one or the other. The group you are assigned to will be chosen by chance, like flipping a coin. You will not be told which treatment you are getting. However, some of the researchers will know.

Regardless of which arm you are randomized to, you will be trained to develop cues, which are vivid, detailed, and personal to you. A cue is delivered by the web application to your smartphone 3 times a day. During each of these 3 times, you will read the cue for 30-60 seconds in a quiet location. Your adherence to the web-based application will be tracked. The total study duration is 24 weeks. Three visits related to the study are planned and your weight will be checked at each visit. Every effort will be made to match the timing of your study visits with office visits for your usual cancer care. A blood draw to measure markers of metabolism and inflammation is needed during the beginning of the study and at 12 weeks. All questionnaires and surveys can be completed online remotely. You will continue receiving routine care from your cancer team.

Risks associated with participation are minimal and may include the time required to complete the behavioral tasks and questionnaires as well as a small potential risk of

psychologic distress related to completion of the behavioral intervention. There are no costs associated with being in the study. Subjects can choose to withdraw from the study at any point.

1. Why is this study being done?

Being overweight or obese is a risk for cancer recurrence, diabetes, heart disease, and poor quality of life in people who have had breast cancer. There is a critical need to find an approach that can help breast cancer survivors lose weight and maintain that weight loss. This study is being done to evaluate the effectiveness of a behavioral intervention on promoting weight loss and healthy lifestyle choices.

2. How many people will take part in this study?

Approximately 80 participants will be included in the study.

3. What will happen if I take part in this study?

Before you begin the study:

- You will complete a questionnaire to ensure you are motivated to lose weight
- Your doctor will review your medical and cancer history to confirm eligibility for the study
- You will complete counseling on healthy nutrition and physical activity recommended for all cancer survivors. You will also have the option to complete a visit with a dietitian.
- You will create a MyFitnessPal account. Through this smartphone application, you will be able to log and receive daily feedback about your calorie and activity goals, throughout the study duration. We also suggest recording your weight at least monthly in MyFitnessPal; this can be measured on any weight scale that is available to you. Your adherence to MyFitnessPal will be tracked and logged.

If you can participate in the study, and you choose to take part:

- You will complete 3 clinic visits (at enrollment before starting the study, 12 weeks and 24 weeks). Study visits and routine cancer care visits will be in the same clinic. Every effort will be made to match the timing of your study visits with office visits for your usual cancer care. Participants can continue to receive any cancer care as appropriate by their cancer treatment team. You may receive telephone calls by the research team throughout the study.
- You will be "randomized" into one of 2 study groups. Randomization means that you are put into a group by chance. A computer program will place you in one of the two study groups. Neither you nor your study doctor can choose the group in which you will be placed. You will have a 1 in 2 chance of being in ‘Group 1’, and a 1 in 2 chance of being in ‘Group 2’.

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- Regardless of the group you are assigned to, you will be trained to develop cues, which are vivid, detailed, and personal to you. These cues serve as thought exercises, which you will engage in by using a web application on your smartphone. Specifically, you will participate in a guided interview at the start of this study in which you're asked to think vividly about positive life events and trained to generate cues that will then serve as text message prompts with the goal to promote weight loss.

- These cues will be delivered as a link to your smartphone three times a day; you will be asked to read and vividly imagine the event for a period of 30-60 seconds in a quiet location during each of these times. You will regenerate these cues every 2-4 weeks.

- The total study duration will be 24 weeks. You will receive cues for a total of 12 weeks and subsequently have the option to continue these cues for another 12 weeks. Your adherence and participation will be tracked by the web-based application.

- Online tasks to measure behavior and decision-making will be completed every 4 weeks throughout the 24 weeks.

- An online dietary questionnaire and quality of life/symptom questionnaire will be completed at enrollment and 12 weeks.

- You will complete a blood draw (to measure markers of metabolism and inflammation) at enrollment and at 12 weeks.

- Your weight will be measured at each clinic visit

- We also need your permission to review your medical records to confirm details about your diagnosis. All information from your medical records will be kept confidential. Throughout the study, we may stop your participation if you do not or are unable to complete any of the study procedures.

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Study calendar

Data/Event	Enrollment	4 weeks	8 weeks	12 weeks	16 weeks	20 weeks	24 weeks
Clinic Visits	X			X			X
Nutrition and physical activity Counseling by provider. Nutrition and physical activity handouts provided.	X						
Sign up for MyFitnessPal	X						
Motivation to Lose Weight Survey	X						
Training to develop behavioral cues	X						
Regenerate behavioral cues		X	X	X	X	X	X
Online behavioral tasks and surveys	X	X	X	X	X	X	X
Demographic and medical history questionnaire	X						
Online Food Questionnaire	X			X			
Blood draw and fasting blood sugar	X			X			
Weight measured in clinic	X			X			X
Quality of life and symptoms survey	X			X			

4. How long will I be in the study?

You will be in the study for 24 weeks.

5. Can I stop being in the study?

You may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with The Ohio State University.

6. What risks, side effects or discomforts can I expect from being in the study?

We anticipate that this study will entail minimal risks. One possible risk is the time required to complete the online behavioral tasks and surveys. You may get tired when we are asking you questions or you are completing questionnaires. You do not have to answer any question you do not want to answer. You may experience hunger from changes in eating patterns and possible discomfort related to changes in physical activity (e.g, muscle soreness).

There is a small theoretical risk of psychological distress associated with completion of the behavioral tasks. You may refuse to answer any questions that make you uncomfortable and may stop being in the study for any reason, at any time. There is also minimal risk associated with a standard blood collection, including potential pain and a small risk of infection or bruising at the venipuncture site. There may be side effects and discomforts that are not yet known. You will be told about any new risks that become known during this research study.

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Additionally, with any research project, the potential for loss of privacy exists. This will be mitigated by maintaining all patient data on the Ohio State University Medical Center's secure network. We will make all reasonable efforts to limit the use and disclosure of your personal information only to people who have a need to see it. You can learn more about how we plan to protect your information in the section below on confidentiality.

7. What benefits can I expect from being in the study?

You may or may not benefit from being in this study. It is possible this behavioral intervention will promote weight loss and improve healthy lifestyle choices related to diet and exercise. If the behavioral intervention works, you may therefore have some benefit. If it does not work, you may not benefit. If you take part in this study, you may help others in the future as information discovered in this research may provide data for weight loss in other breast cancer patients.

8. What other choices do I have if I do not take part in the study?

Sometimes new information comes out that may affect your health, welfare, or willingness to stay in a study. You may choose not to participate without penalty or loss of benefits to which you are otherwise entitled.

If you decide not to join this study, other options are available. You do not have to join this study to get treatment. You can receive the usual treatment for your cancer and for weight loss without being in the study. If you do not join, your care at Ohio State will not be affected.

9. What are the costs of taking part in this study?

Participation in this study is at no cost to you, other than transportation costs to and from the breast center. All procedures, tests and devices that are part of this research will be paid for by the study.

10. Will I be paid for taking part in this study?

You will not be paid to participate in this study.

11. What happens if I am injured because I took part in this study?

If you suffer an injury from participating in this study, you should notify the researcher or study doctor immediately, who will determine if you should obtain medical treatment at The Ohio State University Wexner Medical Center. The cost for this treatment will be billed to you or your medical or hospital insurance. The Ohio State University has no funds set aside for the payment of health care expenses for this study.

12. What are my rights if I take part in this study?

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights you may have as a participant in this study.

You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

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You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled. This study involves research tests that may produce information that could be useful for your clinical care. We will share this information with you.

An Institutional Review Board responsible for human subjects research at The Ohio State University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of research participants.

13. Will my de-identified information and bio-specimens be used or shared for future research?

No.

14. Will my study-related information be kept confidential?

Efforts will be made to keep your study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law.

In addition, your records may be reviewed by the following groups (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies;
- U.S. Food and Drug Administration;
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices;
- The sponsor supporting the study, their agents or study monitors; and
- Your insurance company (if charges are billed to insurance).

Internet/Email Data Collection

- We will work to make sure that no one sees your survey responses without approval. However, because we are using the Internet, there is a chance that someone could access your online responses without permission. In some cases, this information could be used to identify you.
- Your data will be protected with a code to reduce the risk that other people can view the responses.

A description of this clinical trial is 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 the website at any time.

During this study, you will not have access to certain medical information and test results collected for study purposes. If an emergency occurs while you are in the study, medical information needed for your treatment can be made available to your study doctor and other physicians who treat you. When the study is completed, all the information in your medical record will be available to you.

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The NIH has issued a Certificate of Confidentiality for this study. This Certificate provides extra protection for you and your study information, documents, or samples (blood, tissue, etc.). The Certificates are issued so that we cannot be required to disclose any identifiable, sensitive information collected about you as a part of this study in a lawsuit or legal proceeding. We are also prevented from releasing your study information without your consent. This is a layer of protection over and above the already existing protections in place for you and your information, documents, or samples.

However, these protections do not apply in some situations. For example, we may have to release your information if a law requires us to do so, the Agency that is funding this study requests the information, or if the FDA tells us to release this information. We may also use your information to conduct other scientific research as allowed by federal regulations.

Study information that has health implications may be placed in your medical record where authorized employees may see the information. Further, authorized requests for your records (medical record release for continuity of care) may result in research-related information being released.

Please talk to your study team, or contact the Office of Responsible Research Practices at 614-688-8641, if you have questions.

You may also visit the NIH website at *https://grants.nih.gov/policy/humansubjects/coc.htm* to learn more.

15. HIPAA AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

I. What information may be used and given to others?

- Past and present medical records;
- Research records;
- Records about phone calls made as part of this research;
- Records about your study visits;
- Information that includes personal identifiers, such as your name, or a number associated with you as an individual;
- Information gathered for this research about:
  - Physical exams
  - Laboratory, x-ray, and other test results
  - Diaries and questionnaires
  - Current and past medications or therapies
  - The diagnosis and treatment of a mental health condition
  - Surveys and questionnaires
- Records about any study drug you received;
- Records about the study device

II. Who may use and give out information about you?

Researchers and study staff.

III. Who might get this information?

- The sponsor of this research. "Sponsor" means any persons or companies that are:
  - working for or with the sponsor; or
  - Owned by the sponsor.
- Authorized Ohio State University staff not involved in the study may be aware that you are participating in a research study and have access to your information;
- If this study is related to your medical care, your study-related information may be placed in your permanent hospital, clinic, or physician's office record;

IV. Your information may be given to:

- The U.S. Food and Drug Administration (FDA), Department of Health and Human Services (DHHS) agencies, and other federal and state entities;
- Governmental agencies in other countries;
- Governmental agencies to whom certain diseases (reportable diseases) must be reported; and
- The Ohio State University units involved in managing and approving the research study including the Office of Research and the Office of Responsible Research Practices.

V. Why will this information be used and/or given to others?

- To do the research;
- To study the results; and
- To make sure that the research was done right.

VI. When will my permission end?

There is no date at which your permission ends. Your information will be used indefinitely. This is because the information used and created during the study may be analyzed for many years, and it is not possible to know when this will be complete.

VII. May I withdraw or revoke (cancel) my permission?

Yes. Your authorization will be good for the time period indicated above unless you change your mind and revoke it in writing. You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the researchers. If you withdraw your permission, you will not be able to stay in this study. When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

VIII. What if I decide not to give permission to use and give out my health information?

Then you will not be able to be in this research study and receive research-related treatment. However, if you are being treated as a patient here, you will still be able to receive care.

IX. Is my health information protected after it has been given to others?

There is a risk that your information will be given to others without your permission. Any information that is shared may no longer be protected by federal privacy rules.

X. May I review or copy my information?

Signing this authorization also means that you may not be able to see or copy your study-related information until the study is completed.

16. Who can answer my questions about the study?

- For questions, concerns, or complaints about the study, or if you feel you have been harmed because of study participation, you may contact or Dr. Sagar Sardesai (phone: 614-293-6401, email: sagar.sardesai@osumc.edu).
- For questions related to your privacy rights under HIPAA or related to this research authorization, please contact **HIPAA Privacy Officer at 614-293-4477 or suite E2140, 600 Ackerman Road, Columbus, Ohio 43201**.
- For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact the Office of Responsible Research Practices at 1-800-678-6251.
- If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact Dr. Sagar Sardesai (phone: 614-293-6401, email: sagar.sardesai@osumc.edu).

Signing the consent form

I have read (or someone has read to me) this form and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this combined consent and HIPAA research authorization form**.**

Printed name of participant	**Signature of participant**
	AM/PM
	Date and time
Printed name of person authorized to consent for participant (when applicable)	**Signature of person authorized to consent for participant (when applicable)**
	AM/PM
Relationship to the participant	**Date and time**

Investigator/Research Staff

I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

Printed name of person obtaining consent	**Signature of person obtaining consent**
	AM/PM
	Date and time

Witness(es) - *May be left blank if not required by the IRB*

Printed name of witness	**Signature of witness**
	AM/PM
	Date and time
Printed name of witness	**Signature of witness**
	AM/PM
	Date and time