Official Title:	Increasing physical activity among breast cancer survivors: Use of the ORBIT Model to refine and test a novel approach to exercise promotion based on affect-regulation
NCT number:	NCT04903249
Document Type:	Informed Consent Form
Date of the Document:	10/22/21

Title of research study: *The "PHIT" (Physical activity, Hedonically-Informed Training) for Breast Cancer Recovery Study*

(Study Consent Form Part 1)

Investigator: ***Courtney Stevens, PhD***

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

Why am I being invited to take part in a research study?

We invite you to take part in a research study because you are ≥18 years old, you are within 5-yrs of completing primary cancer treatment for Stage 0-III breast cancer, you own an Android or iPhone smartphone and are willing to use it to complete app-based surveys for the duration of the study, and you do not exercise regularly (and have not exercised regularly for the past 6-months or more).

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?

This research is being done to better understand how to support individuals who have completed treatment for breast cancer in becoming more physically active. You estimated that you spend fewer than 60 minutes per week participating in moderate-vigorous physical activity (in a typical week). In this qualification portion of the research study, we are verifying your activity levels so that you can enter into the intervention study. You should go about your daily routine as you usually do. At this time, we are NOT asking you to make any changes to your activity levels.

How long will the research last and what will I need to do?

This first part of the study lasts 10 days.

You will be asked to complete a survey on the computer. This survey will ask you about yourself, your health, and your overall thoughts about activity. You are free to skip any question that you would prefer not to answer. You will be given an activity monitor to wear on your hip for 10 days. During the same 10 days you will be asked to download an app to answer brief smartphone surveys on your phone.

More detailed information about the study procedures can be found under ***"What happens if I say yes, I want to be in this research?"***

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

The likelihood and amount of harm or discomfort you may feel as a result of your participation in this study is not expected to be greater than the likelihood and amount of harm or discomfort you experience as you go about your daily life. There are some risks of participation in this research that you should be aware of. Detailed information about the risks of this study can be found under ***"Is there any way being in this study could be bad for me? (Detailed Risks)."***

Will being in this study help me in any way?

There are no benefits to you from your taking part in this research. We cannot promise any benefits to others from your taking part in this research. However, there are benefits of this research for others. The data collected for this study will be used to inform future efforts to create personalized interventions to support physical activity participation among survivors of breast cancer.

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

Participation in research is completely voluntary. You can decide to participate or not to participate without penalty.

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

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, contact the research team. You may call the Principle Investigator, Dr. Courtney Stevens at 603-650-9643.

An emergency contact number is (603) 650-5000, the main hospital number

This research has been reviewed and approved by an Institutional Review Board ("IRB"). You may talk to them at (603) 650-1846 or irb@hitchcock.org if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

How many people will be in this study?

We expect about 30 people will be in this research study.

What happens if I say yes, I want to be in this research study?

Study timepoint	**What you will do**
Study enrollment	We will review this consent form and you will be asked to sign your name if you wish to participate.
Time 1 REDCap survey	You will be emailed a secure link to complete an electronic survey (you will fill this out on your own).
Baseline	You will be asked to download a mobile application called "RealLife Exp" to your smartphone. We will provide you with instructions for downloading and using the RealLife Exp mobile app.

	We will mail you an activity monitor and provide you with instructions about how to use it. You will be asked to wear an activity monitor on your waist for 10 days during all waking hours and your wrist while you sleep. We will use the data collected to determine the amount of moderate-vigorous intensity physical activity and rest time that you get in a typical week. You will be asked to respond to brief surveys on your smartphone using the RealLife Exp mobile app during the same 10 days that you will wear the activity monitor on your waist (and wrist to sleep). You will complete these check-in surveys three times each day (Morning, afternoon, and evening); you will have 2 hours to answer each check-in. The surveys will ask you questions about how you are feeling, your physical activity, and other behaviors (such as how much time you spend sitting). Each check-in will take 2 minutes or fewer to complete. You will also be asked to use the RealLife Exp mobile app to let us know if you are currently exercising and answer questions about how you're feeling during exercise at the start, middle, and end of the workout. **<u>However, for these first 10 days, you should only do this if such an exercise session is something you would typically do during an average week. We are not asking you to increase your physical activity levels at this time.</u>** You will be asked to return the activity monitor to the study team using after you have worn it for the 10-day assessment period. We will provide you a pre-paid mailing envelope that you should use to send it back to us.

- The study team may contact you to see if you would like to participate in other research studies in the future.
- There are no procedures involved with this study that are part of regular medical care that would not be done even if you did not take part in the research.

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

<u>Your responsibilities as a person taking part in this study:</u>

(1) Be aware it is important for your safety that the research team knows about your medical history and any changes in your health that may come up during your participation.
(2) Notify the research team in advance if you plan to undergo any new medical treatment during this study or are taking or plan to start taking any new medications.
(3) Notify the research team immediately if you suffer any injury or unexpected reactions to the study procedures.
(4) Make reasonable efforts to follow the instructions of the research team.

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

You can leave the research at any time it will not be held against you.

Is there a possibility being in this study could be bad for me or harm me? (Detailed Risks)

There is always a risk of injury (e.g., fall, strains) during physical activity. The activity monitor is worn at the waist and secured with an elastic belt, it may cause discomfort or feelings of self-consciousness when wearing it. There may be some mild discomfort associated with answering questions about yourself in the questionnaires or interview. You have the right to refuse to answer questions that you find too uncomfortable. There is a risk of loss of confidentiality if your information or your identity is obtained by someone other than the investigators, but precautions will be taken to prevent this from happening.

This study is federally funded by the National Cancer Institute and compensation for a research-related injury or illness is not provided by federal law.

If you are injured or become ill as a result of research procedures, you will be provided with medical treatment but the following organizations do not plan to pay for this treatment.

- Mary Hitchcock Memorial Hospital
- Dartmouth-Hitchcock Clinic
- Dartmouth-Hitchcock Medical Center
- Trustees of Dartmouth College
- Federal funding agency

If you have any questions or concerns about the legal responsibility of these organizations, please call the Mary Hitchcock Memorial Hospital Office of Risk Management at (603) 653-1250 during normal business hours.

If you agree to take part in this study and you sign this consent form, you are not giving up any of your legal rights.

What happens to the information collected for the research?

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

The data collected for this study will be maintained indefinitely (for a minimum of 6 years). We are careful to protect the identities of the people in this study. We also keep the information collected for this study secure and confidential. All information collected about you will be recorded using a number and not your name. Information is kept within the locked offices of the research team and upon password-protected computer systems.

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this organization.

The information collected for this study may be used by researchers or officials of the following institutions.

- Dartmouth College
- Mary Hitchcock Memorial Hospital
- Dartmouth-Hitchcock Clinic

- Dartmouth-Hitchcock Medical Center
- The Dartmouth-Hitchcock Health Institutional Review Board (D-HH IRB)
- The National Cancer Institute (NCI)

In order to conduct this study, researchers need to use your health care information. We will access your medical record to determine your cancer diagnosis, treatment regimen, and comorbidities. This data is called Protected Health Information ("PHI"). PHI is protected by federal privacy laws (HIPAA). By signing this consent form, you give your permission to have your PHI collected, used and disclosed for purposes of this study. There is no intention to disclose your PHI to others outside of the study. There are protections in place to keep your PHI and research data confidential. However, HIPAA requires notification so you are aware that if your PHI is disclosed to others, it may no longer be protected by federal privacy laws.

We may publish the results of this research. However, we will keep your name and other identifying information confidential. No publication or public presentation about the research described above will reveal your identity without another authorization from you.

Identifiable data collected for this study will be used for research purposes which are determined to be reasonable and in line with expectations by a review committee. Only members of the research team will be allowed to see this information and know which number is connected to which participant.

Once data collected for this research study is no longer identifiable, the data may be used or disclosed for other purposes. For instance, data could be used in future research studies or distributed to another investigator for future research studies without your additional informed consent.

Your permission to use your health information for this study will not end until the study is completed. During this study, you and others who take part in the study may not have access to the study data. You may ask for study data once the study is over. You have a right to receive a copy of the information in your medical record at any time.

Your name, address, and social security number may be given to an office at DHMC that arranges for payments and reports payments to the IRS.

Can I be removed from the research without my OK?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include not wearing the activity monitor to measure your physical activity levels.

What else do I need to know?

This research is being funded by the National Cancer Institute (NCI).

If you agree to take part in this research study, we will pay you up to $50 for your time and effort. Specifically, you will be paid $20 for completing the Time 1 REDCap survey. Additionally, you will earn $1 for each of the 3 surveys we send you per day using the RealLife Exp mobile app during the 10-day assessment period. You will only be paid for the app-based surveys that you complete (thus, you can earn up to $30 for completing these app-based assessments).

We will ask you to return the study-issued activity monitor (i.e., accelerometer device) at the end of the 10-days; we will provide you a pre-paid envelope and ask that you follow instructions to mail the activity monitor back to us at your earliest convenience.

If you decide to terminate your participation in the research study at any time before the 10-day period is over, you will receive prorated compensation based on the assessments that you do complete following the successful return of the activity monitor (i.e., accelerometer device).

Instead of being in this research study, you may choose to not participate. National physical activity guidelines recommend that all survivors of cancer avoid inactivity. You can speak with your oncology providers about other opportunities to help you increase your weekly physical activity.

You will have the option to receive a plain language summary of the results of this research at the conclusion of all data collection and cleaning.

Signature Block for Capable Adult

Your signature documents your permission to take part in this research.

Signature of subject	Date
Printed name of subject	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	IRB Approval Date

Title of research study: *The "PHIT" (Physical activity, Hedonically-Informed Training) for Breast Cancer Recovery Study* ***(Study Consent Form Part 2)***

Investigator: ***Courtney Stevens, PhD***

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

Why am I being invited to take part in a research study?

We invite you to take part in a research study because you are ≥18 years old, you are within 5-yrs of completing primary cancer treatment for Stage 0-III breast cancer, you own an Android or iPhone smartphone and are willing to use it to complete app-based surveys for the duration of the study, and you do not exercise regularly (and have not exercised regularly for the past 6-months or more).

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?

This research is being done to better understand how to support individuals who have completed treatment for breast cancer in becoming more physically active. There is good evidence that physical activity is safe and important for the health and well-being of survivors of cancer; however, increasing physical activity following treatment is challenging for many survivors of breast cancer. This research will be used to inform future programs to support physical activity among survivors of breast cancer.

How long will the research last and what will I need to do?

We expect that you will be in this research study for 12 weeks.

You will be given an activity monitor to wear on your hip (and wrist to sleep) and a Fitbit wrist-worn tracker. We will give you an exercise prescription that we will ask you to follow for 12 weeks. For 10-day periods at the 2-, 6, and 12-week follow-up assessment timepoints we will send you brief surveys to complete on your phone using an app called RealLife Exp. At the end of the study you will complete a longer survey on a computer and have a phone meeting with a member of the research team to discuss your experience participating.

More detailed information about the study procedures can be found under ***"What happens if I say yes, I want to be in this research?"***

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

The likelihood and amount of harm or discomfort you may feel as a result of your participation in this study is not expected to be greater than the likelihood and amount of harm or discomfort you

experience as you go about your daily life. There are some risks of participation in this research that you should be aware of. Detailed information about the risks of this study can be found under ***"Is there any way being in this study could be bad for me? (Detailed Risks)."***

Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research. However, you may realize health benefits (e.g., less fatigue, stress reduction, increased sleep quality) due to increased physical activity over the study period.

There are benefits of this research for others. The data collected for this study will be used to inform future efforts to create personalized interventions to support physical activity participation among survivors of breast cancer.

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

Participation in research is completely voluntary. You can decide to participate or not to participate without penalty.

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

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, contact the research team. You may call the Principle Investigator, Dr. Courtney Stevens at 603-650-9643.

An emergency contact number is (603) 650-5000, the main hospital number

This research has been reviewed and approved by an Institutional Review Board ("IRB"). You may talk to them at (603) 650-1846 or irb@hitchcock.org if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

How many people will be in this study?

We expect about 30 people will be in this research study.

What happens if I say yes, I want to be in this research study?

Study timepoint	**What you will do**
Tele-Visit 1	This phone call is expected to take 45 minutes of your time (approximately). We will review this consent form and you will be asked to sign your name if you wish to participate. We will explain the exercise prescription we would like you to follow over the next 12-weeks of the study. We will also discuss guidelines for safety, strategies for overcoming barriers to exercise, and answer any questions you may have.

	We will provide you with a Fitbit watch to help you track your activity while you participate in the study (you are not required to wear the Fitbit in order to participate in the study).
2-weeks follow-up 6-weeks follow-up 12-weeks follow-up	You will be asked to wear an activity monitor on your waist for 10 days during all waking hours and your wrist while you sleep. We will use the data collected to determine the amount of moderate-vigorous intensity physical activity and rest time that you get in a typical week. This will be just like what you did previously during the baseline assessment for this study. You will be asked to respond to brief surveys on your smartphone using the RealLife Exp mobile application during the same 10 days that you will wear the activity monitor on your waist (and wrist to sleep). You will complete these check-in surveys three times each day (Morning, afternoon, and evening); you will have 2 hours to answer each check-in. The surveys will ask you questions about how you are feeling, your physical activity, and other behaviors (such as how much time you spend sitting). Each check-in will take 2 minutes or fewer to complete. You will also be asked to use the RealLife Exp mobile app to let us know if you are currently exercising and answer questions about how you're feeling during exercise at the start, middle, and end of the workout. You will be asked to return the activity monitor to the study team using after you have worn it for the 10-day assessment period. We will provide you a pre-paid mailing envelope that you should use to send it back to us.
Time 2 REDCap survey	You will be emailed a secure link to complete an electronic survey (you will fill this out on your own).
Tele-Visit 2	You will complete a phone meeting with a member of the research team. This phone call is expected to take 45 minutes of your time (approximately). As part of this meeting we will ask you some questions about your experience as a participant. We will audio record this portion of the phone call and we will ask your permission before we start recording.

- The study team may contact you to see if you would like to participate in other research studies in the future.
- There are no procedures involved with this study that are part of regular medical care that would not be done even if you did not take part in the research.

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

Your responsibilities as a person taking part in this study:

(1) Be aware it is important for your safety that the research team knows about your medical history and any changes in your health that may come up during your participation.
(2) Notify the research team in advance if you plan to undergo any new medical treatment during this study or are taking or plan to start taking any new medications.
(3) Notify the research team immediately if you suffer any injury or unexpected reactions to the study procedures.
(4) Make reasonable efforts to follow the instructions of the research team.

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

You can leave the research at any time it will not be held against you.

Is there a possibility being in this study could be bad for me or harm me? (Detailed Risks)

You may experience some mild soreness or pain as a result of increasing your physical activity. Additionally, there is always a risk of injury (e.g., fall, strains) during physical activity. The activity monitor is worn at the waist and secured with an elastic belt, it may cause discomfort or feelings of self-consciousness when wearing it. There may be some mild discomfort associated with answering questions about yourself in the questionnaires or interview. You have the right to refuse to answer questions that you find too uncomfortable. There is a risk of loss of confidentiality if your information or your identity is obtained by someone other than the investigators, but precautions will be taken to prevent this from happening.

This study is federally funded by the National Cancer Institute and compensation for a research-related injury or illness is not provided by federal law.

If you are injured or become ill as a result of research procedures, you will be provided with medical treatment but the following organizations do not plan to pay for this treatment.

- Mary Hitchcock Memorial Hospital
- Dartmouth-Hitchcock Clinic
- Dartmouth-Hitchcock Medical Center
- Trustees of Dartmouth College
- Federal funding agency

If you have any questions or concerns about the legal responsibility of these organizations, please call the Mary Hitchcock Memorial Hospital Office of Risk Management at (603) 653-1250 during normal business hours.

If you agree to take part in this study and you sign this consent form, you are not giving up any of your legal rights.

What happens to the information collected for the research?

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

The data collected for this study will be maintained indefinitely (for a minimum of 6 years). We are careful to protect the identities of the people in this study. We also keep the information collected for this study secure and confidential. All information collected about you will be recorded using a number and not your name. Information is kept within the locked offices of the research team and upon password-protected computer systems.

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this organization.

The information collected for this study may be used by researchers or officials of the following institutions.

- Dartmouth College
- Mary Hitchcock Memorial Hospital
- Dartmouth-Hitchcock Clinic
- Dartmouth-Hitchcock Medical Center
- The Dartmouth-Hitchcock Health Institutional Review Board (D-HH IRB)
- The National Cancer Institute (NCI)

In order to conduct this study, researchers need to use your health care information. We will access your medical record to determine your cancer diagnosis, treatment regimen, and comorbidities. This data is called Protected Health Information ("PHI"). PHI is protected by federal privacy laws (HIPAA). By signing this consent form, you give your permission to have your PHI collected, used and disclosed for purposes of this study. There is no intention to disclose your PHI to others outside of the study. There are protections in place to keep your PHI and research data confidential. However, HIPAA requires notification so you are aware that if your PHI is disclosed to others, it may no longer be protected by federal privacy laws.

We may publish the results of this research. However, we will keep your name and other identifying information confidential. No publication or public presentation about the research described above will reveal your identity without another authorization from you.

Identifiable data collected for this study will be used for research purposes which are determined to be reasonable and in line with expectations by a review committee. Only members of the research team will be allowed to see this information and know which number is connected to which participant.

Once data collected for this research study is no longer identifiable, the data may be used or disclosed for other purposes. For instance, data could be used in future research studies or distributed to another investigator for future research studies without your additional informed consent.

Your permission to use your health information for this study will not end until the study is completed. During this study, you and others who take part in the study may not have access to the study data. You may ask for study data once the study is over. You have a right to receive a copy of the information in your medical record at any time.

Your name, address, and social security number may be given to an office at DHMC that arranges for payments and reports payments to the IRS.

Can I be removed from the research without my OK?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. For example, the study team may need to remove you without your approval if you experience a medical event (e.g., heart attack) after enrollment that would make it unsafe for you to continue to participate in an unsupervised exercise intervention.

What else do I need to know?

This research is being funded by the National Cancer Institute (NCI).

If you agree to take part in this research study, we will pay you up to $110 for your time and effort. Specifically, you will earn $1 for each of the 3 surveys we send you per day using the RealLife Exp mobile app during the 10-day assessment periods at 2-, 6-, and 12-weeks follow-up. You will only be paid for the app-based surveys that you complete (thus, you can earn up to $90 for completing these

app-based assessments). Additionally, you will be paid $20 for completing the Time 2 REDCap survey.

We will ask you to return the study-issued activity monitor (i.e., accelerometer device) after each assessment period (i.e., baseline, 2-, 6-, and 12-weeks follow-up); we will provide you a pre-paid envelope and ask that you follow instructions to mail the activity monitor back to us at your earliest convenience once the assessment period is complete.

If you decide to terminate your participation in the study early (before the week 12 follow-up assessment), we will ask that you return the Fitbit monitor given to you at the Tele-Visit 1 appointment. In this case, we would provide you a pre-paid envelope and ask that you follow instructions to mail the Fitbit back to us at your earliest convenience. If you do not terminate your participation in the study early, the Fitbit is yours to keep.

Instead of being in this research study, you may choose to not participate. National physical activity guidelines recommend that all survivors of cancer avoid inactivity. You can speak with your oncology providers about other opportunities to help you increase your weekly physical activity.

You will have the option to receive a plain language summary of the results of this research at the conclusion of all data collection and cleaning.

Signature Block for Capable Adult

Your signature documents your permission to take part in this research.

Signature of subject	Date
Printed name of subject	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	IRB Approval Date