Official Title:	**D12030: A Randomized, Controlled Trial to Determine the Effects of an Exercise Intervention on Physical Activity during Chemotherapy for Patients with Early Stage Breast Cancer**
NCT number:	02159157
Document Type:	Informed Consent Form Main
Date of the Document:	3/17/2016

CONSENT TO TAKE PART IN RESEARCH

Dartmouth-Hitchcock Medical Center

Study title:	**D12030: A Randomized, Controlled Trial to Determine the Effects of an Exercise Intervention on Physical Activity during Chemotherapy for Patients with Early Stage Breast Cancer**
Principal Investigator:	**Mary Chamberlin, MD** **Norris Cotton Cancer Center** **Dartmouth-Hitchcock Medical Center** **One Medical Center Dr.** **Lebanon, NH 03756** **Telephone: 603-653-6181**
Sponsors:	**Sullivan Fund of the Norris Cotton Cancer Center** **American Cancer Society**

Introduction: You are being asked to take part in a scientific research study. Taking part in research is voluntary.

You are being asked to take part in this study because you have breast cancer that is confined to your breast, your doctor has recommended chemotherapy and/or radiation and you exercise for less than 5 hours per week.

Your decision whether or not to take part will have no effect on the quality of your medical care. Please ask questions if there is anything about this study you do not understand.

Background Information

Scientists have been looking at the connection between physical activity and breast cancer for many years. They believe regular exercise may improve the chance of surviving breast cancer. However, the reason for the improvement is not well

understood. Also, it has been observed that some people exercise less during chemotherapy.

What is the purpose of this study?

The purpose of the study is to learn whether it is possible to use motivational phone calls to increase physical activity levels in adults undergoing chemotherapy. The study would also like to find out whether increased physical activity affects how well a patient gets through chemotherapy. The researchers will use a combination of questionnaires, body measurements, and blood tests to look for changes that may be a result of changes in physical activity.

Half the people in this study will receive general physical activity guidelines and phone calls to help maintain their existing activity levels. The other half will receive customized physical activity guidelines and phone calls to encourage them to increase their physical activity.

There are no drugs involved in this study. However, while you take part in this study you will be treated with chemotherapy drugs and/or radiation as recommended by your oncologist.

Will you benefit from taking part in this study?

You might or might not personally benefit from being in this research study.
We hope to gather information that may help people in the future.

What does this study involve?

Your participation in this study may last about 8 months. If the screening process shows you are able to take part in this study, we will ask you to return to the clinic for a "baseline" visit. After these two visits, there will be no extra visits other than the clinic visits you will have for your standard cancer care. However, each clinic visit will be longer because you are taking part in this study. In addition, you will need to make time for a phone call from a member of the study team every week for 24 weeks and then once a month for 2 months.

If you are getting chemotherapy before having surgery, your participation in this study will be interrupted for approximately 4-12 weeks to allow you to recover from surgery and to return to the level of activity you had before surgery. This interruption will not count toward the total number of weeks in the study.

The recommended exercise for everyone who takes part in this study is walking at a brisk pace. A brisk pace is defined as walking about 3,000 steps in 30 minutes. If you take part in this study, you will be given a device called a pedometer to keep track of how many steps you take each day.

We will ask everyone to fill out some surveys about what you eat, how much energy you have, how you are exercising, and how you feel about exercising. Some of these surveys may be done either at the clinic or at home.

You cannot take part in any weight loss programs while you are in this study. You may take part in other exercise classes or programs.

Screening:

Before you can take part in this study, we will go over this consent form with you. You need to sign this consent form if you want to take part in the study.

You will also take part in the following activities and have some tests to see if you are able to be in this study. Some of the tests are routine and would be done whether or not you took part in this study. Some of these tests may not need to be repeated if they were done recently.

- Physical exam and review of your medical history, including some routine blood tests to learn about the health of your organs. The blood tests might be done at the Baseline Visit.
- Complete *Physical Activity Readiness Questionnaire (PAR-Q)*
- Complete *Leisure Time Exercise Questionnaire (LTEQ)*
- Pregnancy test if you are a women who is able to have a child
- Review activity log book

We will give you a pedometer and an activity log to track how much you walk for no fewer than 3 days. If you are not able to use the pedometer or record your walking for a week, you will not be able to stay in the study.

You may need to get approval from your regular doctor or treating oncologist to be in this study. We will ask for approval if you are over 69 years old or answer "yes" to any of the questions on the *PAR-Q*.

Baseline Visit:

If you are eligible and agree to be in the study after the screening, you will be assigned by chance (like the flip of a coin) to one of the following groups:

Group A – has an appointment with a physical therapist (PT) and receives educational materials. This group will receive phone calls to help you **maintain** your pre-study level of physical activity.

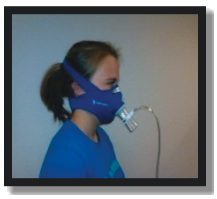
Group B – has an appointment with a physical therapist (PT) and receives educational materials. This group will receive phone calls to help you **increase** your physical activity level.

The phone calls for both groups will happen weekly for the first 24 weeks and then once more in week 28. We will try to call at the time that is the most convenient for you.

Neither you nor your doctor can control which group you will be assigned to. You will not be able to change your group assignment once it is made. You may also decide at this time that you do not want to be in the study.

Both groups will take part in the following activities and have some tests as part of the Baseline Visit. It may take two visits to the clinic to complete all of these:

- Weight, waist, hip and height measurements
- Body composition analysis (BCA) using a device called a "bio-impedance spectrum analyzer". This machines sends low level electrical currents through contacts at your wrists/hands and feet/ankles to measure the amount of your muscle and fat.
- Resting metabolic rate (RMR) will determine how much energy your body utilizes while at rest. You will be asked to sit quietly for 25 minutes in a dimly lit room. You may read or listen to relaxing music. After 30 minutes, we will attach a recording device to your head. This consists of a stretchable face mask with a breathing tube. Please see the picture to the left. You will wear the mask, while resting, for about 20 minutes. You will be breathing in room air at all times.



- Review of routine safety blood tests done as part of your cancer treatment.

- Blood will be drawn for study blood tests.
- Review of how well you are able to perform routine daily activities.
- Complete FACIT-F questionnaire about how your cancer is affecting your physical and emotional well-being.
- Receive instructions in how to rate your exercise and your feelings about exercising.
- Review how to use pedometer and activity log book.

Weeks 1-28

You will receive a phone call every week from a research team member for the first 24 weeks of the study. We will try to have the same person call you every time. She or he will go over your activity log, the questionnaire titled *Borg Rating of Perceived Exertion Scale,* ask how you feel, and ask how you are doing with your exercise goal. Participants in Group B will also get help setting exercise goals for the next week.

To check the quality of the interviews, 10 telephone calls from participants will be randomly selected to be audio-recorded. Your calls may or may not be selected. The person who is calling will ask for your permission to turn on the tape recorder at the start of each recorded call. ***You do not have to agree to be recorded to take part in this study.*** The recording will be erased after the review is completed, and no transcripts will be made of these audio-recordings.

There will be no calls in weeks 25-27. You will be called during week 28.

If you miss more than 4 (four) phone calls in a row or do not fill in your activity log for 4 (four) weeks in a row, you will be removed from the study.

We will collect information from the routine blood work being done as part of your cancer treatment.

End-of-Study Visit (about week 32)

We will repeat some of the tests and procedures that were done at the Baseline and Screening visits:

- Weight, waist, hip and height measurements
- BCA will be done using a bio-impedance spectrum analyzer
- Resting metabolic rate measurement
- Review of routine safety blood tests done as part of your cancer treatment
- Blood will be drawn for study blood tests
- Review of how well you are able to perform routine daily activities
- Complete FACIT-F questionnaire
- Complete *LTEQ*

What are the options if you do not want to take part in this study?

Instead of being in this study you have the following options:

- Continuing the standard or common cancer treatment for someone in your situation without the additional exercise
- Exercising on your own after checking with your oncologist
- Taking part in another research study.

These other options have their own risks and benefits. Please discuss them with your doctor.

You do not have to take part in this study to receive medical care or treatment.

The educational materials used in this study are available to you whether or not you take part in the study.

If you take part in this study, what activities will be done only for research purposes?

If you take part in this study, the following activities will be done only for research purposes:

- Study-specified blood tests
- Using a pedometer and writing down how much you walk
- Completing surveys
- Regular contact by phone with a research team member
- BCA using a bio-impedance spectrum analyzer
- Measurement of resting metabolic rate (RMR)

What are the risks involved with taking part in this study?

There are few risks to taking part in walking programs. As with any exercise program, there is a risk of injury such as pulled or strained muscles when the proper technique is not used. It is also possible that some individuals will experience muscle soreness when starting the exercise program.

RMR test: you may feel uncomfortable while wearing the face mask.

If you develop severe muscle soreness or other problems, contact the study director: Dr. Chamberlin at 603-653-6181.

There may be risks to your privacy. Information about your privacy is provided under the section titled *How will your privacy be protected?* and *Who may use or see your health information?*

Reproductive Risks and Risks to Pregnant Women:

Women who are pregnant or nursing may not take part in this research study. If you are able to have a child, we will ask you to use birth control while you are on this study. Talk to the study team about what form of birth control is appropriate for you.

If you get pregnant, you should let us know right away by calling Dr. Chamberlin at 603-653-6181. If you get pregnant, you will be withdrawn from the study.

Other important items you should know:

- **Leaving the study:** You may choose to stop taking part in this study at any time for any reason. If you decide to stop taking part, it will have no effect on the quality of medical care you receive.

The study doctor or sponsor may end your participation in this study:

- if staying in the study would be harmful to you
- if you get pregnant
- if you need treatment not allowed in this study
- if the sponsor decides to stop the study early
- if the study is stopped by a government regulatory agency

If you leave the study before it is over, you will be asked to have all procedures that are listed in the "End-of-Study Visit" section of this consent form.

- **New Information:** If new information related to this research becomes available during the study that may affect your decision to stay in this study, it will be made known to you.

- **Funding:** The Norris Cotton Cancer Center and the American Cancer Society are providing the funding for this research.

- A description of this clinical trial will be available on 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.

- **Number of people in this study:** We expect between 96 and 120 people to enroll in this study. This study is only being done at Dartmouth Hitchcock Medical Center (DHMC).

How will your privacy be protected?

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.

The information collected as data for this study includes:

- Personal information that identifies you such as your name and your birth date
- Health information from your past and present medical records
- Information collected for research purposes
- Records about your research study visits
- Information from your physical exams
- Laboratory and other test results
- Study survey results, activity logs

As stated earlier in this form, 10 telephone calls will be randomly selected from among all study participants. These calls will be audio-recorded for review to make sure the research nurse is conducting the interviews properly. Your calls may or may not be selected. We cannot rule out the possibility that some identifying information will be recorded on the tape (such as the use of your full name). The recording will be erased after the review is completed and no longer than two weeks after it is recorded. The nurse will ask for your permission to turn on the tape recorder at the start of each

recorded call. You do not have to agree to be recorded to take part in the study. A transcript will not be made of audio-recordings.

Electronic information will be kept in a secure, password-protected research database indefinitely. Paper records will be kept in locked offices or locked filing cabinets. After the study is completed, research information is stored in Dartmouth College Records Management off-site storage. Documents are shredded on site after 50 years.

The information collected for this study will be used only for the purposes of research as stated earlier in this form.

The results of this research may be published or presented at meetings, but will not include your name or reveal your identity.

Who may use or see your health information?

By signing this form, you allow the research team to use your health information and give it to others involved in the research. The research team includes the study director plus others working on this study at Dartmouth-Hitchcock Medical Center and elsewhere. You also permit any health care provider holding health information needed for this study to give copies of your information to the research team.

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

- Authorized representatives of the Department of Health and Human Services (DHHS) and other government health authorities
- Dartmouth College
- Mary Hitchcock Memorial Hospital
- Dartmouth-Hitchcock Clinic
- Dartmouth-Hitchcock Medical Center
- The Committee for the Protection of Human Subjects at Dartmouth College, an institutional review board

During this study, information that identifies you may be given to some organizations that may not have a legal duty to protect it. These organizations may also use and disclose your information for other purposes.

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.

It is possible for a court or government official to order the release of study data including information about you.

What if you decide not to give permission to use and share your personal health information?

If you do not allow use of your health information for this study, you may not take part in this study.

If you choose to stop taking part in this study, you may cancel permission for the use of your health information. You should let the researcher know if you want to cancel your permission. The study team will assist you in putting your wishes in writing. Information collected for the study before your permission is cancelled will continue to be used in the research.

Whom should you call about this study?

If you have questions about this study the research director for this study: Dr. Chamberlin at 603-653-6181 during normal business hours.

If Dr. Chamberlin is not available, other members of the section of Hematology/Oncology will be available to answer your questions during normal business hours.

If you have questions, concerns, or suggestions about human research at Dartmouth, you may call the Office of the Committee for the Protection of Human Subjects at Dartmouth College 603-646-6482 during normal business hours.

What about the costs of this study?

The pedometer along with the activity log will be given to you free of charge. You may keep the pedometer after the study is over.

Most of the medical care that you will receive during this study is the usual care a doctor would recommend for your condition. You or your insurance plan are expected to pay for the costs of this usual medical care.

All *additional* tests/visits/procedures as described in the *"If you take part in this study, what activities will be done only for research purposes?"* section will be paid for by the sponsor. Insurance plans are billed only for study procedures that are the usual care for your condition.

For assistance in determining your coverage, please call the billing specialist in DHMC Patient Financial Services at 603-653-1047 or 800-368-4783. Please provide the billing specialist with the protocol number, D12030.

Will you be paid to take part in this study?
No, you will not be paid for taking part in this study.

CONSENT
I have read the above information about ***A Randomized, Controlled Trial to Determine the Effects of an Exercise Intervention on Physical Activity during Chemotherapy for Patients with Early Stage Breast Cancer*** and have been given time to ask questions. I agree to take part in this study, and I will be given a copy of this signed consent form.

Participant's Signature	Date	PRINTED NAME
Researcher or Designee Signature	Date	PRINTED NAME