Research Consent Form
Dana-Farber/ Harvard Cancer Center
BIDMC/BCH/BWH/DFCI/MGH/Partners Network Affiliates

OHRS 11.01.2018b

Protocol Title:

A pilot study to assess the Haymakers for Hope fitness program in cancer survivors.

DF/HCC Principal Research Doctor / Institution:
Elizabeth O'Donnell, MD: MGH

Main Consent

INTRODUCTION AND KEY INFORMATION

All research is voluntary. It is your choice whether you take part in this research or not. If you decide to participate, please sign and date at the end of this form. We will give you a copy and you can refer to this consent form at any time.

The following is a short summary of this research study to help you decide whether you would like to be a part of this study. More detailed information is provided later in this form.

For purposes of this research, you will be referred to as a "participant."

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

You are invited to take part in in this research study, because you have a history of cancer.

2. Why is this research being done?

There is evidence to suggest that patients who have cancer or who have a history of cancer feel better and have better cancer outcomes when they exercise. Studies have shown that cancer survivors who exercise after a cancer diagnosis feel better, lose weight, increase fitness levels and lean muscle mass, decrease body fat, and experience favorable changes in blood biomarkers linked to cancer recurrence compared to survivors who do not exercise. Much of research around exercise if observational and there exists a critical unmet need for evidence-based exercise and well-being interventions that are accessible to all cancer patients who may benefit. The goal of this research is to offer and study the Haymakers for Hope 16-week exercise program.

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3. Who is supporting this research?

Haymakers for Hope (H4H) is supporting this research study by providing the funding and programming for the 16-week exercise program.

4. What does this research study involve and how long will it last?

This research study involves the following:

Participants will attend the 16-week program of boxing conditioning. This 16-week will include supervised exercises designed to improve strength, flexibility, balance and cardiopulmonary fitness. Outcome measures will be measure at baseline and repeated at the completion of the 16 weeks. There will be 4 sessions of 1 hour each week for each of the 10 participants. The program will be conducted at gymnasiums contracted with the H4H program and outcomes assessments at MGH and the gymnasiums.

The research study procedures include*:*

- Screening for eligibility and study treatment including evaluations and follow up visits.
- Blood testing at the beginning and end of the study
- Body composition assessment using dual-energy x-ray absorptiometry (DXA) **(an imaging test that measures the amounts of fat, bone, water, and muscle that your body is made of)** at the beginning and end of study
- Cardiopulmonary fitness testing (measures how efficiently your heart and lungs are working during exercise) at the beginning and end of study
- Blood testing at the beginning and end of study
- Questionnaires to assess quality of life, fatigue, activity levels, purpose in life, and mood at the beginning and end of study

You will be in this research study for up to 16 weeks.

It is expected that about 10 people will take part in this research study.

Information about you and your health is personal and private. Generally, it cannot be obtained without your written permission. By signing this form, you are providing that permission and your information may be obtained and used in accordance with this informed consent and as required or allowed by law. This means that researchers may obtain information regarding your past medical history, as well as specimens and samples from previous health care providers such as hospitals and labs.

5. What are the risks to participating in this study?
There are risks to taking part in any research study. We want to make sure you know about a few key risks right now.

Exercise Program
The major risks of participating in this supervised exercise program offered by trained Haymakers for Hope include fatigue, muscle soreness, and possible joint or skeletal injury. These risks will be reduced by proper warm-up/cool down periods, conservative and individual exercise prescriptions and progression, and careful monitoring by the exercise trainer. Any exercise program is associated with a somewhat increased risk of having a sudden heart attack. However, this risk is greatly reduced by having a trainer work with the participant.

Blood Draw
There is a small risk of bleeding, bruising, infection, inflammation, phlebitis, blood clot or discomfort at the site of the blood collection. Attention will be taken to apply pressure following the procedure to reduce bleeding. Participants may feel dizzy or faint when blood is being withdrawn. We will ask that they lie down for a few minutes until any dizziness passes.

DXA Scan
A DXA scan x-ray involves exposure to radiation. Although it can vary from person to person, the whole-body radiation exposure from each scan will be about 2.5 mrem (i.e., about ¼ radiation from a chest x-ray). The total exposure to radiation for the DXA scans will be a small fraction of the average annual exposure a person in the United States receives from natural background radiation. The risk of harm from this amount of radiation is low and no harmful health effects are expected.

Major known risks to participating in this research study include:

- Disclosure of sensitive personal information may result is a loss of privacy
- Possible emotional distress due to personal questions
- Significant amount of time required to complete questionnaires (online and/or in person)
- Significant amount of time required to attend study visits

6. Will being in this study benefit me in any way?

We do not know if taking part in this study will benefit you. This study may help researchers learn information that could help people in the future.

7. What are my options?

Instead of being in this research study, you have other options which may include the following:

- Decide not to participate in this research study.
- Participate in another research study.
- Receive standard treatment including physical therapy.
- Receive no exercise therapy.

If you choose not to participate, are not eligible to participate, or withdraw from this research study, this will not affect your present or future care and will not cause any penalty or loss of benefits to which you are otherwise entitled.

We encourage you to take some time to think this over, to discuss it with other people and your primary doctor, and to ask questions at any time.

A. WHY IS THIS RESEARCH STUDY BEING DONE?

This research study is a Pilot Study, which is the first-time investigators are examining this exercise intervention

In this research study, we are:

- Studying the Haymakers for Hope 16-week program of boxing condition
- We will be assessing the effect of this program on:
  - Cardiopulmonary fitness, strength, and levels of physical activity
  - Quality of life and purpose in life
  - Energy
  - Sleep quality
  - Mood
  - Body composition
- We believe that this exercise program will improve all these areas of assessment

B. WHAT IS INVOLVED IN THE RESEARCH STUDY?

Before the research starts (screening):
After signing this consent form, you will be asked to undergo some screening tests or procedures to find out if you can be in the research study. Many of these tests and procedures are likely to be part of regular cancer care and may be done even if it turns out that you do not take part in the research study. If you have had some of these tests or procedures recently, they may or may not have to be repeated.

- **A medical history,** which includes questions about your health, current medications, and any allergies.
- **Performance status**, which evaluates how you are able to carry on with your usual activities.
- **Blood tests**
- **Body composition testing**
- **Questionnaires**
- **Cardiopulmonary fitness and strength testing**

If these tests show that you are eligible to participate in the research study, you may begin the study treatment. If you do not meet the eligibility criteria, you will not be able to participate in this research study.

Research Study Plan:

For this study, 10 eligible participants will participate. The study will begin with a visit to the MGH Lifestyle Medicine Clinic where you will have a physical examination and a medical history will be obtained. At this appointment you will have screening test which include an electrocardiogram of your heart, blood tests, and a special x-ray to assess your body composition (DXA scan). You will be asked to fill out questionnaires about your quality of life, level of physical activity, energy, level, purpose in life, mood, and sleep quality. We will also do a baseline assessment of the distance that you can walk in 6 minutes and a strength assessment at this appointment. Once you have completed these assessments, you will undergo a fitness test (cardiopulmonary exercise test, CPET) at the training facility where you will be doing the Haymakers for Hope exercise program. Once these screening assessments are complete, you may begin the exercise program.

The exercise program consists of 4, one-hour exercise sessions per week for 16 weeks.

Once you have completed the exercise program, you will return to the MGH Lifestyle Medicine Clinic to repeat the same assessments that were done at the start of the study. You will also have repeat exercise testing at the end of the 16 weeks at the training facility.

	Screening	16-week Program	Post-study follow-up[11]
H4H 16-week program		X	
Procedures			
Informed consent	X		
Eligibility criteria	X		
Demographics/Medical History	X		
ECOG performance status	X		X
12-lead ECG	X		

Physical examination	X		X
Neurological examination	X		X
Height	X		X
Weight	X		X
Vital signs[1]	X		X
Pregnancy Test[2]	X		
CPET[3]	X		X
6-minute walk test	X		X
Muscle strength[4]	X		X
Blood biomarkers[5]	X		X
Imaging			
DXA[6]	X		X
PRO[6] Assessments			
FACT-G[8]	X		X
FACIT-Fatigue[9]	X		X
HADS[10]	X		X
Rand Medical Outcomes Survey	X		X
Ryff Purpose in Life	X		X
Godin Leisure-Time Exercise Questionnaire	X		X
Other Assessments			
Adverse Event Evaluation			X

1 - Temperature, pulse/heart rate, respiratory rate, and blood pressure. Measured in sitting position.

2 - Pregnancy Test: Women of child-bearing potential within 7 days of enrollment

3 - Cardiopulmonary Exercise Testing

4 - Grip strength, 30-second chair stand test

5 - Blood biomarkers - expanded lipid profile, hemoglobin A1c, c-reactive protein, interleukin-6, tumor necrosis factor alpha, insulin, leptin, adiponectin, insulin-like growth factor, and homeostatic model assessment of insulin resistance

6 - Dual-energy x-ray absorptiometry

7 - Patient-reported outcome

8 - Functional Assessment of Cancer Therapy – General

9 - Functional Assessment of Chronic Illness Therapy – Fatigue

10 - Hospital Anxiety and Depression Scale

11 - Post-study follow-up to be completed at 4 months ± 30 days

Planned Follow-up:
We will conduct follow-up assessments after the completion of the 16-week program.

In addition, you can stop participating in the research study at any time, however, any information collected up to the point of your withdrawal cannot be removed from the study.

C. WHAT ARE THE RISKS OR DISCOMFORTS OF THE RESEARCH STUDY?

There are risks to taking part in any research study. We want to make sure you know about a few key risks right now.

Exercise Program
The major risks of participating in this supervised exercise program offered by trained Haymakers for Hope include fatigue, muscle soreness, and possible joint or skeletal injury. These risks will be reduced by proper warm-up/cool down periods, conservative and individual exercise prescriptions and progression, and careful monitoring by the exercise trainer. Any exercise program is associated with a somewhat increased risk of having a sudden heart attack. However, this risk is greatly reduced by having a trainer work with the participant.

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Non-Physical Risks:
Because of side effects or the time required for tests and clinic visits while you are on this research study, you may be unable to keep up with your normal daily activities.

The questionnaires used in this study may be upsetting. If you find the questionnaires upsetting, you may speak with the research doctor or ask to be referred for additional emotional support.

During the research study, you will be provided with any new information that may affect your health or willingness to participate. You may be asked to sign a new consent form that shows that you have been informed of new information relating to this research study.

D. WHAT WILL HAPPEN IF I AM REMOVED FROM THE STUDY OR DECIDE TO END MY PARTICIPATION IN THE RESEARCH?

You may be taken off the research study for any reason including:

- It is considered to be in your best interest
- The study treatment or procedures are found to be unsafe or ineffective
- There is any problem with following study treatments and procedures
- You are a female and become pregnant or plan to become pregnant
- Your condition worsens
- A decision is made to end the study
- Or for other unforeseen reasons that make it necessary to stop your participation in the research study

You can also choose to stop participating in the research study at any time. Tell the research doctor if you are thinking about stopping or decide to stop. He or she will tell you how to stop. Leaving the research study will not affect your medical care outside of the research study.

It is important to note that although you may withdraw from study participation, any information collected up to the point of your withdrawal cannot be removed from study records.

E. WILL I BE PAID TO TAKE PART IN THIS RESEARCH STUDY?

You will not be paid for participating in this study.

F. WHAT ARE YOUR COSTS?

Taking part in this research study may lead to added costs to you or your insurance company. This may mean that you need to make more visits to the clinic or hospital than if you were getting the usual approach to treat your disease. You may:

- Have more travel costs
- Need to take more time off work
- Have other additional personal costs

You or your insurance company will be charged for portions of your care during this research study that are considered standard care, including the office visits. Standard of care is the care that you would receive regardless of whether you were enrolled in the study or not. You may be responsible for co-payments, co-insurance, premiums and deductibles that are typical for your insurance coverage. You will not be billed for research tests done as part of the study which include the blood tests, DXA scans, CPET testing, or questionnaires.

If you have questions about your insurance coverage, or the items you might be required to pay for, please call financial services for information. The contact information for financial services are:

- Massachusetts General Hospital: (617) 726-2191

The National Cancer Institute provides an online resource to help people participating in cancer clinical trials understand which services their insurance company is required by law to pay. This can be found at the website below or can be provided by the study team:

www.cancer.gov
or 1-800-4-CANCER (1-800-422-6237)

G. WHAT HAPPENS IF I AM INJURED OR BECOME SICK BECAUSE I TOOK PART IN THIS RESEARCH STUDY?

If you think you have been injured as a result of taking part in this research study, tell the person in charge of this research study as soon as possible. The research doctor's name and phone number are listed in this consent form.

The treating hospital will offer you the care needed to treat injuries directly resulting from taking part in this research. These treatments may be billed to you or your insurance company and you may have to pay for these treatments. You will be responsible for and have to pay deductibles, co-payments and co-insurance. There are no plans to pay you or give you other compensation for the injury.

You do not give up your legal rights by signing this form.

We will need to collect certain personal information about you for insurance or payment reporting purposes, such as your name, date of birth, gender, social security number or Medicare identification number and information related to this research study. We may be required to report this information to the Centers for Medicare & Medicaid Services. We will not use this information for any other purpose.

If you go to the Emergency Room or to another hospital or doctor it is important that you tell them that you are in this research. If possible, you should give them a copy of this consent form.

H. WHOM DO I CONTACT IF I HAVE QUESTIONS ABOUT THE RESEARCH STUDY?

If you have questions about the study, please contact the research doctor or study staff as listed below:

Massachusetts General Hospital
- Elizabeth O'Donnell, MD: (617) 724-4000

For questions about your rights as a research participant, please contact a representative of the Office for Human Research Studies at Dana-Farber Cancer Institute (617) 632-3029. This can include questions about your participation in the study, concerns about the study, a research related injury, or if you feel/felt under pressure to enroll in this research study or to continue to participate in this research study.

I. RETURN OF RESEARCH RESULTS

Most tests done on samples in research studies are only for research and have no clear meaning for health care. If the research with your identifiable

information or samples gives results that do have meaning for your health, the researchers may contact you to let you know what they have found.

J. CLINICALTRIALS.GOV (CT.GOV)

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.

K. FUTURE USE OF DATA AND SPECIMENS

Your personal information and/or biospecimens collected during this study will not be used or distributed for future research studies even if the information is de-identified and cannot be linked back to you.

L. CONFIDENTIALITY

We will take measures to protect the privacy and security of all your personal information, but we cannot guarantee complete confidentiality of study data.

Medical information created by this research study may become part of your hospital medical record and may be forwarded to your primary doctor. Information that does not become part of your medical record will be stored in your study file. It may also become part of a DF/HCC research database called CORIS.

The study team plans to publish the results of this research study and when we do, we may be asked to make the data we collect available to other researchers. We will not include information that identifies you in any publications or to the researchers who request the data to do additional research.

There is a risk that deidentified research data that is shared with outside collaborators may be reidentified. When deidentified data and specimens are shared with outside collaborators agreements limit what the outside collaborators can do with the information to help prevent reidentification.

M. PRIVACY OF PROTECTED HEALTH INFORMATION (HIPAA AUTHORIZATION)

The Health Insurance Portability and Accountability Act (HIPAA) is a federal law that requires Dana-Farber/Harvard Cancer Center (DF/HCC) and its affiliated research doctors, health care providers, and physician network to protect the privacy of information that identifies you and relates to your past, present, and future physical and mental health conditions ("protected health information"). If you enroll in this research study, your "protected health information" will be used and shared with others as explained below.

1. What protected health information about me will be used or shared with others during this research?

- Existing medical records, including mental health records.
- New health information created from study-related tests, procedures, visits, and/or questionnaires

2. Why will protected information about me be used or shared with others?

The main reasons include the following:

- To conduct and oversee the research described earlier in this form;
- To ensure the research meets legal, institutional, and accreditation requirements;
- To conduct public health activities (including reporting of adverse events or situations where you or others may be at risk of harm); and
- To provide the study sponsor with information arising from an adverse event or other event that relates to the safety or toxicity of the study intervention
- To better understand the diseases being studied and to improve the design of future studies; and,
- Other reasons may include for treatment, payment, or health care operations. For example, some medical information produced by this research study may become part of your hospital medical record because the information may be necessary for your medical care. (You will also be given a notice for use and sharing of protected health information.)

3. Who will use or share protected health information about me?

- DF/HCC and its affiliated research doctors and entities participating in the research will use and share your protected health information. In addition, other DF/HCC offices that deal with research oversight, billing or quality assurance will be able to use and share your protected health information.

4. With whom outside of DF/HCC may my protected health information be shared?

While all reasonable efforts will be made to protect the confidentiality of your protected health information, it may also be shared with the following entities:

- Outside individuals or entities that have a need to access this information to perform functions relating to the conduct of this research such as analysis by outside laboratories on behalf of DF/HCC and its affiliates (for example, data storage companies, insurers, or legal advisors).
- The sponsor(s) of the study, its subcontractors, representatives, business partners, and its agent(s)
- Other research doctors and medical centers participating in this research, if applicable
- Federal and state agencies (for example, the Department of Health and Human Services, the Food and Drug Administration, the National Institutes of Health, and/or the Office for Human Research Protections), or other domestic or foreign government bodies if required by law and/or necessary for oversight purposes. A qualified representative of the FDA and the National Cancer Institute may review your medical records.
- Hospital accrediting agencies
- A data safety monitoring board organized to oversee this research, if applicable
- Other, N/A

Some who may receive your protected health information may not have to satisfy the privacy rules and requirements. They, in fact, may share your information with others without your permission.

5. For how long will protected health information about me be used or shared with others?

- There is no scheduled date at which your protected health information that is being used or shared for this research will be destroyed, because research is an ongoing process.

6. Statement of privacy rights:

- You have the right to withdraw your permission for the research doctors and participating DF/HCC entities to use or share your protected health information. We will not be able to withdraw all the information that already has been used or shared with others to carry out related activities such as oversight, or that is needed to ensure quality of the study. To withdraw your permission, you must do so in writing by contacting the researcher listed above in the section: “Whom do I contact if I have questions about the research study?”
- You have the right to request access to your protected health information that is used or shared during this research and that is related to your treatment or payment for your treatment, but you may access this information only after the study is completed. To request this information, please contact the researcher listed above in the section: “Whom do I contact if I have questions about the research study?”

N. DOCUMENTATION OF CONSENT

My signature below indicates:

- I have had enough time to read the consent and think about participating in this study;
- I have had all of my questions answered to my satisfaction;
- I am willing to participate in this study;
- I have been told that my participation is voluntary and I can withdraw at any time

Signature of Participant or Legally Authorized Representative

Date

Relationship of Legally Authorized Representative to Participant

DFCI Protocol Number: 19-426	Approved Date (DFCI IRB Approval): 12/12/2019
Date Posted for Use: 01/06/2020	

To be completed by person obtaining consent:

Adult Participant

The consent discussion was initiated on _____ (date).

Signature of individual obtaining consent: _____

Printed name of above: _____

Date: _____

☐ A copy of this signed consent form will be given to the participant or legally authorized representative.

☐ 1) The participant is an adult and provided consent to participate.

☐ 1a) Participant (or legally authorized representative) is a non-English speaker and signed the translated Short Form in lieu of English consent document:

☐ *As someone who understands both English and the language used by the participant, I interpreted and/or witnessed, in the participant's language, the researcher's presentation of the English consent form. The participant was given the opportunity to ask questions.*

Signature of Interpreter/Witness: _____

Printed Name of Interpreter/Witness: _____

Date: _____

☐ 1b) Participant is physically unable to sign the consent form because:

☐ The participant is illiterate.

☐ The participant has a physical disability.

☐ Other (please describe): _____

The consent form was presented to the participant who was given the opportunity to ask questions and who communicated agreement to participate in the research.

Signature of Witness: _____

Printed Name of Witness: _____

Date: _____

☐ 2) The participant is an adult who lacks capacity to provide consent and his/her legally authorized representative:

- ☐ 2a) gave permission for the adult participant to participate
- ☐ 2b) did not give permission for the adult participant to participate

To be completed by person obtaining consent: