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CONSENT TO TAKE PART IN A RESEARCH STUDY

Title of Study: Breast Cancer and Resistance Exercise Program (B-REP)
Principal Investigator: Angela Fong, PhD

STUDY SUMMARY: This consent form is part of an informed consent process for a research study and it will provide information that will help you decide whether you want to take part in this study. It is your choice to take part or not.

The **purpose of the research** is to test the feasibility and acceptability of a supervised, online-delivered, individualized, physical activity program in a sample of post-active treatment breast cancer survivors. The proposed intervention will compare a 12-week resistance-based physical activity program to a printed individualized physical activity program group on feasibility, acceptability and changes in strength as measured by 10 repetition maximum (10RM) and functional strength tests.

If you take part in the research, you will be asked to *take part in a* 12-week supervised, online, resistance-based physical activity or a control condition (printed, individualized resistance-based physical activity program that is unsupervised).

Possible harms or burdens of taking part in the study are minimal. Increased physical activity may result in muscle soreness or injury; however, each participation will be required to pass a screening test or receive medical approval prior to enrollment to ensure physical activity is appropriate.

An alternative to taking part in the research study: Your alternative to taking part in the research study is not to take part in it.

The information in this consent form will provide more details about the research study and what will be asked of you if you choose to take part in it. If you have any questions now or during the study, if you choose to take part, you should feel free to ask them and should expect to be given answers you completely understand. After your questions have been answered and you wish to take part in the research study, you will be asked to sign this consent form. You are not giving up any of your legal rights by agreeing to take part in this research or by signing this consent form.

Who is conducting this study?
Angela Fong, PhD is the Principal Investigator of this research study. A Principal Investigator has the overall responsibility for the conduct of the research. However, there are often other individuals who are part of the research team.

Angela Fong, PhD may be reached at
Rutgers Cancer Institute of New Jersey, 195 Little Albany Street, New Brunswick, NJ 08903
Telephone: 732-235-8076 (office)
Email: angela.fong@rutgers.edu

The Principal investigator or another member of the study team will also be asked to sign this informed consent. You will be given a copy of the signed consent form to keep.

Sponsor of the Study: The study is supported by the 2019 Cancer Survivorship Research Center Pilot Award Program.

Why is this study being done?

The goal of the study is to test the feasibility and acceptability of a supervised, online-delivered, individualized, physical activity program in a sample of post-active treatment breast cancer survivors. The proposed intervention will compare a 12-week resistance-based physical activity program to a printed individualized physical activity program group on feasibility, acceptability and changes in strength as measured by 10 repetition maximum (10RM) and functional strength tests.

Who may take part in this study and who may not?

Women will be eligible if they meet the following criteria: a) aged 18 years and older; b) a confirmed diagnosed of breast cancer ≤ 5 years prior to study start; c) does not have another cancer diagnosis at the same time; d) have completed active treatment ≥ 6 months prior to study commencement (hormonal therapy is acceptable); e) who are inactive, defined as engaging in ≤ 30 minutes of moderate-to-vigorous physical activity per day for 2 days per week; f) are able to exercise safely as per physical activity safety screening questionnaire, Get Active Questionnaire; g) read and understand English and; h) have regular access to an internet-connected device with a video camera. Participants will be screened over the phone by the research assistant.

Women will be excluded if they meet any of the following criteria: a) respiratory, joint, or cardiovascular problems precluding physical activity as per physical activity safety screening questionnaire; b) metastatic disease; c) planned elective surgery during the duration of the intervention and/or follow-up that would interfere with participation (e.g., breast reconstruction surgery); and d) do not have someone to supervise them while they exercised. The rationale for these criteria is that they are all contraindications to physical activity and thus, increasing physical activity for these individuals may be harmful.

Why have I been asked to take part in this study?
You are being asked to participate in the study because:

- You have been diagnosed and have completed treatment for breast cancer (hormonal therapy is acceptable)
- You are able to speak and understand English
- You are not currently exercising at levels that meet national guidelines

How long will the study take and how many subjects will take part?

The total number of subjects to be recruited is 50, where 25 participants will be selected at random to each study type. The total length of time for an individual participant's engagement in the study will be approximately 4 months or 16 weeks

What will I be asked to do if I take part in this study?

When you agree to participate in this study you will sign this informed consent document and receive a copy of it. You will have two assessments that will be supervised by research staff and complete a physical activity program.

Assessment 1: Baseline (60 to 90 minutes)

- Height and weight measurement using a medical grade scale
- Physical function assessments

- A 6-minute walk test. You will be asked to walk continuously for 6 minutes in a hallway near the fitness laboratory space and you will be monitored by a research team member.
- A measurement of lower body strength called chair sit-to-stand. From a seated position, you will be asked to stand without the assistance of your arms and sit back down for as many times as you can for 30 seconds.
- A measurement of upper body strength called arm curl test, where you will sit, and we count how many times you can lift a small dumbbell (5lbs) over 30 seconds.

- Two fitness assessments. 1) 10 repetition maximum. You will perform two exercises, a lying-down bench press and a deadlift (where you lift a weight from bent over position to a standing position). You will begin by lifting at 30% of the participant's body weight and increasing at 5lb increments. When a participant is no longer able to lift a weight, the previous weight will be recorded. 2) Functional strength test. You will perform an arm curl using different types of bands until a moderate difficulty rating (rate of perceived exertion) is reached. Combined, this information will determine the weights needed for your physical activity program.
- Questionnaires will be completed on an iPad or online through a questionnaire link:
  - Demographic information (age, race and ethnicity, if you were born in the US, marital status, household income, highest level of education completed, and employment status)
  - Health information including menopausal status
  - Current physical activity levels
  - Confidence and barriers related to exercise
  - Health-related quality of life
- You will also be given an activity monitor (accelerometer) to wear on your non-dominant hip for 7 days during waking hours. Once the 7-day wear period is over, you will mail the activity monitor back to us in a pre-paid envelope. Research staff will show you how to wear it and you will be given written instructions on how to use and care for it.

You will also be given resistance bands (up to 3) that are stretchy exercise bands. These bands are used to build muscle strength and endurance. You will be given upper and lower body exercises to do 1 to 3 times per week. You will be taught how to do these exercises and given handouts with pictures and brief descriptions. The resistance bands are yours to keep.

You may also be given dumbbells or hand weights that are meant to increase your strength. The dumbbells are yours to keep as well.

<u>Assessment 2: Scheduled at Week 12 (+ 1 to 2 weeks; 60 to 90 minutes)</u>
The same assessments as those scheduled at baseline will be completed at Week 12 visit. You will also be given an activity monitor to wear on your non-dominant hip for 7 days during waking hours.

The questionnaires will be mostly the same. You will not complete the demographics and breast cancer information questionnaires and the following questionnaires will be added:

- Satisfaction with the weekly exercise sessions (for intervention condition, only)
- Social support for exercise
- Feedback about the research study
- If you'd like to participate in future research

<u>Individualized, Resistance-Based Physical Activity Program</u>
You will complete 8 exercises in total for your upper and lower body. You will be instructed on how to do these exercises and be given instructions with photos and a brief description. You are expected to exercise

1 to 3 times per week following this program. The exercises will take about 30 to 45-mintues to complete including a warm-up and a cooldown.

Participants who are in the intervention condition, will receive 12, weekly online sessions with an exercise trainer using Zoom. The sessions will be 30 to 45-minutes in length. Zoom is a free application that can be downloaded onto your personal device. Research staff will assist you with downloading the application. The sessions with the exercise trainer will be recorded for compliance and safety and be remotely uploaded to OneDrive, which is a secure, wireless drive.

In the event that in-person research is paused for a long period of time, the two assessments will be changed as follows:

- All consents and questionnaires will be completed online. No changes to the questionnaires will be made.
- Height and weight will be self-reported and added to the questionnaires.
- Physical function assessments will be virtual using Zoom and supervised by research staff. The assessments will be the same, except the 6-minute walk will be replaced with a 2-minute step-in-place where you will march in place for 2 minutes.
- The 1 repetition maximum test will not be completed.
- All necessary materials will be mailed to your location. With the exception of the activity monitor (accelerometer), you will be able to keep the materials.

What are the risks of harm or discomforts I might experience if I take part in this study?

Increasing exercise, when properly prescribed has a low risk of injury. You will receive individual directions for your exercise so that you start slowly and progress only as you become more physically fit. Even with these precautions, sometimes people experience minor muscular discomfort when doing physical activity and this may happen to you. The resistance bands, if used incorrectly, can pose a low risk of snapping back and hurting you. For that reason, we teach you the proper use of the band. In addition, there is a low risk that you may experience anxiety when answering questions about your survivorship, psychological well- being and physical activity-related behaviors. The time spent answering questionnaires may be perceived as an inconvenience.

Reproductive Risks of Harm

If you become pregnant during the course of this study, you should notify the study doctor of this fact as soon as possible, since the risks to the fetus or to yourself are unknown to the research study team.

Are there any benefits to me if I choose to take part in this study?

The benefits of taking part in this study may be improved physical fitness, physical functioning, quality of life, depression, and fatigue. However, it is possible that you may not receive any direct benefit from taking part in this study.

What are my alternatives if I do not want to take part in this study?

There are no alternative treatments available. Your alternative is not to take part in this study.

How will I know if new information is learned that may affect whether I am willing to stay in the study?

During the study, you will be updated about any new information that may affect whether you are willing to continue taking part in the study. If new information is learned that may affect you after the study or your follow-up is completed, you will be contacted.

Will I receive the results of the research?

In general, we will not give you any individual results from the study. If we find something of urgent medical importance to you, we will inform you, although we expect that this will be a very rare occurrence.

Will there be any cost to me to take Part in this study?

There are no cost to take part in this research study. However, you may experience costs related to transportation (e.g., public transportation fares, parking). You will not be reimbursed for these costs.

Will I be paid to take part in this study?

You will receive a $50 Amazon e-gift card as thank you for taking the time to participate in the study. The e-gift card will be emailed to you once we have received your activity monitor (accelerometer) in the mail. Once you open the email, we will be notified that you have received the e-gift card. After the second assessment and once you have mailed back the activity monitor, you will also receive a FitBit®. Resistance bands and any additional materials are yours to keep.

In the event that in-person research is paused for a long period of time, you will receive a $30 Amazon e-gift card and you will keep all the study materials with the exception of the activity monitor (accelerometer).

How will information about me be kept private or confidential?
All efforts will be made to keep your personal information in your research record confidential, but total confidentiality cannot be guaranteed.

The screening and study questionnaire data will be entered and stored in a database on a designated HIPAA compliant, password-protected network drive. The database will reside on servers maintained and fully protected by a firewall. All data stored on the server will be backed up daily. All hard copies of files containing personally identifiable data will be stored in separate, locked cabinets in rooms where unauthorized persons do not have access. All personnel will be trained in appropriate security measures for handling personally identifiable data they will not disclose any such information to any person or agency. Data will be kept for at least 6 years following completion of the research as per Rutgers University Office of Research Regulatory Affairs (ORRA) guidelines

The research team may use or share your information collected or created for this study with the following people and institutions:

- The Rutgers University Institutional Review Board and Compliance Boards
- The Office for Human Research Protections in the U.S. Dept. of Health and Human Services
- The Rutgers Cancer Institute of New Jersey who have funded the study

What will happen to my information or biospecimens collected for this research after the study is over?

After information that could identify you has been removed, de-identified information collected for this research may be used by or distributed to investigators for other research without obtaining additional informed consent from you. No biospecimens will be collected for this study.

What will happen if I do not wish to take part in the study or if I later decide not to stay in the study?

It is your choice whether to take part in the research. You may choose to take part, not to take part or you may change your mind and withdraw from the study at any time. If you do not want to enter the study or decide to stop taking part, your relationship with the study staff will not change, and you may do so without penalty and without loss of benefits to which you are otherwise entitled.

You may also withdraw your consent for the use of data already collected about you, but you must do this in writing to Angela Fong, PhD may be reached at 195 Little Albany Street, New Brunswick, NJ 08903. If you take away permission, your information will no longer be used or shared in the study, but we will not be able to take back information that has already been used or shared with others.

Who can I contact if I have questions?

If you have questions, concerns or complaints about the research or if you feel you may have suffered a research related injury, you can contact the Principal Investigator: Angela Fong, PhD Department of Medicine, Division of Medical Oncology Section of Behavioral Sciences at 732-235-8076 or angela.fong@rutgers.edu.

If you have questions, concerns, problems, information or input about the research or would like to know your rights as a research subject, you can contact the Rutgers IRB Director, Brunswick/Piscataway Health Sciences IRB 335 George St., Liberty Plaza Ste. 3100, New Brunswick, NJ 08901 (732)235-9806] or the Rutgers Human Subjects Protection Program at (973) 972-1149, email us at human-subjects@ored.rutgers.edu., or write us at 65 Bergen St., Suite 507, Newark, NJ 07107.

PERMISSION (AUTHORIZATION) TO USE OR SHARE HEALTH INFORMATION THAT IDENTIFIES YOU FOR A RESEARCH STUDY

The next few paragraphs tell you about how investigators want to use and share identifiable health information from your medical record in this research. Your information will only be used as described here or as allowed or required by law. If you sign this consent form, you agree to let the investigators use your identifiable health information in the research and share it with others as described below. Ask questions if there is something you do not understand.

What Is The Purpose Of The Research And How Will My Information Be Used?
You are being invited to take part in this research study which is described at the beginning of this form. The purpose of collecting and using your health information for this study is to help investigators answer the questions that are being asked in the research.

What Information About Me Will Be Used?

- Hospital discharge summaries
- Medical history or treatment
- Consultations
- Laboratory/diagnostic tests or imaging
- Psychological testing, surveys or questionnaires
- Pathology reports, specimen(s) or slide(s)
- Operative reports (about a surgery)
- Emergency Medicine reports

Who May Use, Share or Receive My Information?

The research team may use or share your information collected or created for this study with the following people and institutions:

- Rutgers University Investigators Involved in the Study
- The Rutgers University Institutional Review Board and Compliance Boards
- The Office for Human Research Protections in the U.S. Dept. of Health and Human Services

Will I Be Able To Review My Research Record While The Research Is Ongoing?

No. We are not able to share information in the research records with you until the study is over. To ask for this information, please contact the Principal Investigator, the person in charge of this research study.

Do I Have To Give My Permission?

No. You do not have to permit use of your information. But, if you do not give permission, you cannot take part in this study. (Saying no does not stop you from getting medical care or other benefits you are eligible for outside of this study.)

If I Say Yes Now, Can I Change My Mind And Take Away My Permission Later?

Yes. You may change your mind and not allow the continued use of your information (and to stop taking part in the study) at any time. If you take away permission, your information will no longer be used or shared in the study, but we will not be able to take back information that has already been used or shared with others. If you say yes now but change your mind later for use of your information in the research, you must write to the researcher and tell him or her of your decision: Angela Fong, PhD may be reached at 195 Little Albany Street, New Brunswick, NJ 08903

How Long Will My Permission Last?

Your permission for the use and sharing of your health information will be retained for at least 3 years following completion of the research as per Rutgers University Office of Research Regulatory Affairs (ORRA) guidelines.

AGREEMENT TO TAKE PART IN RESEARCH

Subject Consent:

I have read this entire consent form, or it has been read to me, and I believe that I understand what has been discussed. All of my questions about this form and this study have been answered. I agree to take part in this study.

Subject Name (Print):_____

Subject Signature:_____ Date:_____

Signature of Investigator/Individual Obtaining Consent:

To the best of my ability, I have explained and discussed all the important details about the study including all of the information contained in this consent form.

Investigator/Person Obtaining Consent (Print):_____

Signature:_____ Date: _____

ADDENDUM: CONSENT TO AUDIO-/VISUALLY RECORD OR PHOTOGRAPH SUBJECTS

You have already agreed to take part in a research study entitled: Breast Cancer and Resistance Exercise Program (B-REP) conducted by Dr. Angela Fong PhD. We are asking your consent to allow us to videotape you as part of the research. The videotaping will involve recording the exercise sessions with the exercise trainer over Zoom if you are in the intervention group. You do not have to consent to be videotaped in order to take part in the main research.

The videotaping will be used for checking if the intervention (exercise sessions over Zoom with an exercise trainer) were delivered as planned. The research team will use a checklist to identify features and code if these features happened.

The videotaping may include the following information that can identify you including your face and your name being said aloud.

The videotaping will be stored on a folder on OneDrive, a secure, HIPAA-compliant cloud drive. The files will be named with your unique study identification and the date. The files will be stored for 6 years according to Rutgers ORRA guidelines.

The videotape from the exercise sessions will not be used by us or distributed to investigators for other research.

Your signature on this form permits the investigator named above to record you as described above during participation in the above-referenced study. The investigators will not use the recording(s) for any other reason than that/those stated in the consent form without your written consent.

AGREEMENT TO BE RECORDED

Subject Name (Print):_____

Subject Signature _____ Date _____

Investigator/Person Obtaining Consent Name (Printed):_____

Signature _____ Date _____