Supportive Care Intervention (ROAR-LCT) for Patients With Stage IIIA, IIIB, and IV Lung Cancer, ROAR-LCT Trial
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The Ohio State University Combined Consent to Participate in Research and HIPAA Research Authorization

Study Title:	Resiliency among Older Adults Receiving Lung Cancer Treatment (ROAR-LCT) -Phase II
Principal Investigator:	Carolyn Presley, MD, MHS
Sponsor:	National Institute on Aging (pending K76AG074923-01 GRANT13279915)

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

Key Information About This Study

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

This research is being conducted to determine if physical therapy and relaxation techniques along with cancer treatment can improve physical and emotional wellbeing in adult patients with lung cancer.

100 patients will participate in this study for approximately 13 weeks.

You will be randomly assigned to one of the following two groups; Group 1 will receive a referral to outpatient physical therapy and receive an information packet with a CD on progressive muscle relaxation. Group 2 will participate in a weekly virtual health assisted physical therapy and relaxation intervention.

All the participants will undergo treatment as prescribed by their treating physician. Additionally, for the first 12 sessions, participants assigned to the weekly physical therapy program will receive physical therapy and psychology visits in-person and/or virtually.

You will answer questions related to your general physical and emotional health. After the 12 sessions up to 2 years, health information will be gathered from the participants medical records. Stool samples will be collected 4 times during the study. Stool samples will need to be collected at home within 24 hours of your next treatment visit. Participation in this study is your choice, however if you do take part in the study, you will be able to stop at any time. Participants may benefit from the intervention provided in the study if they take part.

1. Why is this study being done?

You are invited to participate in this research study because you have thoracic cancer (including lung and/or other cancer in the chest). They will be referred to as lung cancer for the purpose of this study.

Lung cancers are one of the most common cancers. Lung cancers occur in the chest and often cause symptoms for patients. Poor physical performance and negative mood are two risk factors for a decline in functional status. Physical therapy and relaxation interventions (i.e. progressive muscle relaxation) are two such interventions that may improve symptoms and quality of life for patients with lung cancer.

Using a team approach, starting these intervention programs early alongside cancer treatment can improve symptoms, improve functional status and quality of life, help with emotional needs of patients, and may even prolong life.

The goal of this study is to provide early physical therapy and psychosocial care alongside cancer treatment as part of routine care. We will assess symptom control for participants when they receive their physical therapy alongside their cancer treatment versus those who receive standard of care. We will also collect information related to your treatment and hospitalizations. Your participation in this study is voluntary. You may decide to not take part or to withdraw from the study at any time without losing any benefit of your current care.

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

100 patients from the OSUCCC Thoracic Oncology Clinic will be asked to join this study.

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

All the study participants will receive standard of care treatment for their lung cancer. Only those in group 1 will receive an outpatient physical therapy referral from their treating oncologist. Those assigned to group 2 will be seen by our in-clinic physical therapist within 3 weeks of starting the study. You will have a total of 12 sessions, each for physical therapy and progressive muscle relaxation training. These sessions will be conducted virtually and in-person depending on in-person clinic limitations and your personal preference. We will try to combine your in-person sessions along with your doctor visit every month. In between sessions will occur either through telehealth or virtual-health and can be scheduled at yours and the therapists convenience.

The physical therapy sessions will include warm up exercises followed by strength building and cooling-down exercises. This warmup is approximately 10 minutes of using a portable exercise peddler with either your feet or hands and is followed up by core exercises. The core exercises will include seated posterior pelvic tilts and seated without back support seated marches. The resistance training exercises will include shoulder press, triceps extension, bicep curls, upper extremity side raises, chest press, calf raises, marches, standing side leg lifts, leg extension in standing, seated knee extension and clamshells. The resistance exercises will be done in 2 sets of 10 reps using resistance bands appropriate for your level of fitness. The cool-down portion will include stretches targeting upper muscles(chest, shoulders, and triceps), lower muscles(calves, quadriceps, and hamstrings) and trunk. Each stretch will be held for 30 seconds each. Participants may keep the study resistance bands at the end of the study.

You may be asked to practice respiratory muscle training as part of your physical therapy appointments. In this case, you will be provided with a handheld training device that is designed to support strong breath and to strengthen the muscles of your lungs and diaphragm. The physical therapist will instruct you how to use this device and tailor the number of sets of exercises you are to perform based on your individual capabilities and goals. Resistance and repetitions may gradually increase as you progress throughout the study and as the muscles in your lungs and diaphrahm strengthen. You will be allowed to keep this device at the end of the study.

During the muscle relaxation you will be taught how to tense and relax different muscles in your body. You will also learn how to incorporate mindful breathing techniques during these relaxation sessions. This will take about 15 -20 minutes.

Telehealth or virtual-health is when you use your mobile phone or another devices such as an iPad or another type of tablet, with a camera, to do a live, real-time, video visit with the physical therapist or study team member. We will give you instructions and also show you how to connect to the video visits.
This study will explore the microbiome as a biomarker of treatment responses and correlating with assessment scores, with the hope that it will be a therapeutic target in future studies.

All the study participants will be asked to give stool samples as part of the study. We want to examine the bacteria and viruses in the gut that help us digest our food and regulate our immune system and its potential role in one's response to treatment among patients with a lung cancer. Your stool sample will help us to explore possible ways to target microbiome as a therapeutic approach through lifestyle changes such as exercise or diet changes. You will be provided with a stool collection kit to take home along with instructions on how we would like the samples collected, and you will bring the sample back with you on your next visit and a study team member will collect it from you upon arrival of that visit.

All study participants will be asked to wear a Fitbit activity tracker for the duration of the study. The study research coordinator will assist you in completing a data authorization to allow study personnel access to activity and exercise levels, heart rate, and information on the quality of your sleep. You may withdraw your data authorization access at any time.

Each participant will be asked to fill out the surveys at each study visit to assess your symptoms. Each study visit that we ask you to complete surveys should take roughly 30 minutes each visit. This can be done during your infusion visits or during any clinic downtime that you may have. These can also be emailed to you and completed from your home at your own convenience. You will not have to spend any extra time in clinic in order to complete these surveys.

At the end of the study, all participants will be asked to participate in an interview to get your feedback on your time in the ROAR study. This interview is meant to address concerns you may have had or any parts you enjoyed about this study. This is an optional interview that may help our team improve future research studies.

4. How long will I be in the study?

You will be in the study for 13 weeks. If you are in group 1, you will no longer see the physical therapist upon completion of your 12 sessions but will continue with your cancer treatment by your oncologist. There will be one follow up visit at month 6 where you may be asked to repeat some of the study assessments. At the 2 year point, 24 months, we will stop collecting data from your medical chart.

5. Can I stop being in the study?

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

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

Our study team anticipates that there will be minimal physical and psychological risks or discomforts for the study participants. There is a small risk that patients have some distress associated with the completion of the study questionnaires. However, if this occurs, questions are easily skipped and the study staff will speak to the participant about the distress that the surveys have caused and will offer referral to a mental health professional if necessary.

There is also a small risk of injury due to the prescribed exercise intervention. Patients will be taught by a licensed Physical Therapist how to safely perform these exercises and instructed to only perform each task to the level of his or her physical ability. A safety checklist will be performed by your physical therapist at the beginning of every physical therapy session. In the case of an injury, the on-study Physical Therapists will assess the patient and his or her exercise intervention may be modified accordingly.

There are no known risks associated with the collection of the stool sample. However, some people may be bothered by collecting their stool.

Research using your specimens may include mapping your DNA (whole genome sequencing). This information could identify you. Ask the study team if you have questions.

A federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information from this research.
- Health insurance companies and group health plans may not use your genetic information when making decisions about your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

All health insurance companies and group health plans must follow this federal law. This law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. Under Ohio law, health insurance companies cannot ask about the results of a genetic test or use any information obtained from genetic testing to make decisions about providing coverage or benefits for health care services.

There is an additional risk with the collection of data from the study surveys and your Fitbit device. The data authorization access flow is done to minimize the risk of sharing your activity information with our team. Your information will be stored in a secure database that only approved study members have access to. We will work to make sure that no one sees your survey responses without approval. But, because we are using the Internet, there is a chance that someone could access your online responses without permission. In some cases, this information could be used to identify you. Your data will be protected with a code to reduce the risk that other people can view the responses

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

Potential benefits gained include

- Your symptoms will be assessed at every clinic visit.
- You will receive either a referral to outside physical therapy or receive physical therapy from a licensed therapist in-person and through tele or virtual health.
    - Those assigned to receive physical therapy from our study team will not be charged for Virtual Health Visits
- You will receive either an information packet and a cd/link to the relaxation technique or receive progressive muscle relaxation sessions from the study graduate students (MA and PhD level) in clinical psychology
    - Those assigned to receive progressive muscle relaxation from our study team will not be charged for Virtual Health Visits
- Others may benefit from the information gained from this research study
- You may or may not have more energy, improved mood, or other positive outcomes from participating in this study

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

You may choose not to participate without penalty or loss of benefits to which you are otherwise entitled. You may request an outpatient referral to physical therapy which will be considered standard of care and may or may not be covered by your insurance.

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

There are no costs of taking part in this study. If you are randomized to group 1, you will receive a referral to physical therapy. If you choose to follow up with physical therapy, these visits will be billed to your insurance as standard of care. If you are placed in group 2, you will have two in-person physical therapy visits that will be billed to your insurance as standard of care. You may be responsible for any co-pays for these visits. Any virtual health visits that you participate in will be billed to the study and you will not be responsible for any co-pays.

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

At the end of the study, you will have to return the tablet or mobile device to clinic that we gave to you for the completion of your virtual health visits. You will be compensated with a $50 Visa gift card for completion of at least three out of the five survey time points as thanks for your participation.

By law, payments to participants are considered taxable income.

If you are randomized to the group 2 you will be provided with an exercise peddler and you may keep this device upon completion of participation.

Both groups of this study will not be required to return their Fitbit device at the end of the study. You may keep this device and withdraw access to your information at any time.

Biological materials are stored for this study in a secured lab freezer. Biospecimens are retained until all samples from all participants have been collected and are then processed in a single batch to reduce the differences in how the lab processes samples.

After all of the data have been generated and checked for quality, the remaining samples will be destroyed.

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

If you suffer an injury from participating in this study, you should notify the researcher or study doctor immediately, who will determine if you should obtain medical treatment at The Ohio State University Wexner Medical Center.

The cost for this treatment will be billed to you or your medical or hospital insurance. The Ohio State University has no funds set aside for the payment of health care expenses for this study.

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

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

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

You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled.

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

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

Yes, they may be used or shared with other researchers without your additional informed consent.

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

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

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

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

Additionally, your activity information will be shared with study personnel after you complete the Fitbit data access authorization. The study CRC will help you with this process. Information that will be shared from your study, Fitbit device include: your activity and exercise levels, information on your sleep quality, and your heart rate. You may withdraw the access to your Fitbit tracker information at any time during the study. To keep your activity tracker information confidential, only with study team members will have access. At the end of the study, any information that could be used to identify you will be destroyed.

Research results will not be provided to the participants upon completion as the main outcome of this study is feasibility of study design and is not powered to detect clinically relevant results.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At

most, the website will include a summary of the results. You can search the website at any time.

The NIH has issued a Certificate of Confidentiality for this study. This Certificate provides extra protection for you and your study information, documents, or samples (blood, tissue, etc.). The Certificates are issued so that we cannot be required to disclose any identifiable, sensitive information collected about you as a part of this study in a lawsuit or legal proceeding. We are also prevented from releasing your study information without your consent. This is a layer of protection over and above the already existing protections in place for you and your information, documents, or samples.
However, these protections do not apply in some situations. For example, we may have to release your information if a law requires us to do so, the Agency that is funding this study requests the information, or if the FDA tells us to release this information. We may also use your information to conduct other scientific research as allowed by federal regulations.

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

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

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

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

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

- Past and present medical records;
- Research records;
- Records about phone calls made as part of this research;
- Records about your study visits;
- Information that includes personal identifiers, such as your name, or a number associated with you as an individual;
- Information gathered for this research about:
  Hepatitis infection

  Other reportable infectious diseases

Physical exams
Laboratory, x-ray, and other test results
Diaries and questionnaires
The diagnosis and treatment of a mental health condition
Lab results from your clinic visits

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

Researchers and study staff.

III. Who might get this information?

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

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

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

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

VI. When will my permission end?

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

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

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

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

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

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

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

X. May I review or copy my information?

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

16. Who can answer my questions about the study?

For study questions, concerns, or complaints, to withdraw consent and HIPAA authorization, or if you feel you have been harmed as a result of study participation, you may contact Dr. Carolyn Presley at 614-293-6786.

For questions related to your privacy rights under HIPAA or related to this research authorization, please contact the privacy officer, Kathleen Ojala, at 614-293-6482 or Kathleen.Ojala@osumc.edu.

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact the Office of Responsible Research Practices at 1-800-678-6251.

If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact Dr. Carolyn Presley 614-293-6786.

Signing the consent form

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

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

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

Investigator/Research Staff

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

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

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

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