Informed Consent Form for Participation in a Research Study

The feasibility of an exercise and nutrition supportive care (palliative) intervention for advanced non-small-cell lung cancer.

Advanced Lung Cancer, Exercise and Nutrition

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NCT ID: Not yet assigned

Dr. Nicole Culos-Reed, Faculty of Kinesiology, 2500 University Drive NW, Calgary, AB,
www.thriveforcancersurvivors.com

Study Investigator: Dr. S. Nicole Culos-Reed, (Principle Investigator)
Kinesiology
University of Calgary
403-220-7540

Sponsor/Funder(s): Oncology Research Office, Tom Baker Cancer Centre

Non-Emergency contact numbers are noted at the end of this document under the section heading “WHO DO I CONTACT FOR QUESTIONS?”.

For assistance with terminology within this consent form, please refer to the Canadian Cancer Society Glossary of Terms at http://info.cancer.ca/e/glossary/glossary.html.

You are being invited to participate in a research study because you have advanced lung cancer. This consent form provides detailed information about the study to assist you with making an informed decision. Please read this document carefully and ask any questions you may have. All questions should be answered to your satisfaction before you decide whether to participate.

The study staff will tell you about timelines for making your decision. You may find it helpful to discuss the study with family and friends so that you can make the best possible decision within the given timelines.

Taking part in this study is voluntary. You may choose not to take part or, if you choose to participate, you may leave the study at any time without giving a reason. Deciding not to take part or deciding to leave the study will not result in any penalty or any loss of medical or health-related benefits to which you are entitled.

Your health care provider or the study research coordinator, all of whom are part of the research team, will discuss this study with you and will answer any questions you may have. If you do consent to participate in this study, you will need to sign and date this consent form. You will receive a copy of the signed form.

WHAT IS THE BACKGROUND INFORMATION FOR THIS STUDY?

Cancer treatments can prolong life for those with advanced lung cancer; however, these treatments are often accompanied by a number of negative symptoms and side-effects resulting in diminished quality of life. Given the complex care needs of the advanced lung cancer population, a complex multimodal intervention must be considered as part of supportive cancer care. Evidence supports that regular exercise and improved nutritional habits are beneficial for enhancing quality of life in earlier stages of lung cancer; however, there is minimal research of either intervention (and none with combined interventions) in advanced lung cancer patients. In addition to a complex multimodal intervention approach that includes nutrition and exercise, consideration of advanced cancer care symptom management is crucial for optimizing the potential benefits of either intervention component.

The Health Research Ethics Board of Alberta – Cancer Committee (HREBA-CC), which oversees the ethical acceptability of research involving humans, has reviewed and granted ethics approval for this study.

WHY IS THIS STUDY BEING DONE?

The purpose of this feasibility study is to help understand if it is possible to do the study with a small number of participants before a larger study is started. Because there will only be a small number of participants, it is not expected to give complete answers to the research questions and will not prove safety or effectiveness. The results may be used as a guide for larger studies, although there is no guarantee that those will be conducted.

WHAT WILL HAPPEN DURING THIS STUDY?

ASSIGNMENT TO A GROUP

All participants will receive the physical activity and nutrition intervention along with complex care symptom management. There will be up to 15 participants enrolled in the study. During the study, you may be given the option of deciding to participate in semi-structured interviews.

STUDY INTERVENTION

The goal of this study is to examine the feasibility of introducing an intervention that includes exercise and nutrition in conjuction with palliative symptom management, and examine the potential relationship with quality of life in advanced non-small-cell lung cancer (NSCLC) patients. We will also examine the impact of the intervention on I) fatigue, II) functional fitness and III) symptom burden. This intervention will not interfere with your ongoing care or any treatments recommended by your care team.

If you agree to take part in this study, you will:

1. Complete questionnaires at the beginning of the study and immediately after completing the 12-week physical activity program.
2. Complete fitness testing before and after the program at the University of Calgary. This procedure will take about 1 hour.
3. Attend a 90 minute long exercise session 1 time per week for 12 weeks at either the REACH Centre at the Holy Cross Hospital or at the THRIVE exercise facility at the University of Calgary.
4. The 90 minute session will include a light warm up (5-10 minutes), and 6 exercise stations with a range of functional exercises designed to target both aerobic and strength components of fitness (60 minutes), with modifications made according to your physical function at the start of the program. The main focus of the circuit will be on muscle strength, balance, flexibility and aerobic capacity as associated with beneficial daily physical function (i.e., for activities of daily living). Most group sessions will involve a series of circuit-style classes, that allow for adequate group supervision as well as the ability for individuals to work at their own pace. The exercise circuit will be followed by a 30-minute therapeutic yoga class, based on the Yoga Thrive program.
5. Complete additional home exercises throughout the week at home. For this, you will be given a home-based exercie prescription for an additional 1-2 sessions per week facilitated by provision of basic home-based fitness equipment. You will also be provided with a Fitbit device to use for the duration of the study, and returned upon completion of the exercise

program. The data obtained will be downloaded and stored with no identification other than your participant identification number.

6. Attend a clinical visit with a Complex Cancer Care Management team clinician (physician or nurse practitioner) within the first two weeks of the intervention to assess and treat symptoms that may interfere with physical activity (i.e., pain or nausea).
7. Complete an online self-administered 24-hr dietary food recall at 2 time points; prior to the start and at the end of the study intervention. Participants will also attend a nutrition evaluation and consultation with a Registered Dietitian (RD). Consultations will be scheduled according to participant need.
8. Optional – attend semi-structured interviews.
   - Your involvement may also include participation in a semi-structured interview (approximately 30 minutes long) conducted either in person at the location of your choice or over the phone. Interviews may occur within 2 weeks of program start, halfway through (at 6 weeks), or at the end of the intervention (12 weeks). The interview will include discussing your involvement with the program including barriers, preferences, feasibility and your personal well-being, including quality of life and symptom burden. You may participate in as many of the interviews as you wish.

Here is a summary of your study involvement:

TIMELINE	EVENT
Baseline assessment (Beginnng of study)	- Complete baseline questionnaires - Complete baseline fitness assessment - Complete online self-administered 24-hr dietary food recall
Intervention (During the study)	- Attend 90 minute long exercise session 1 time per week - Attend a clinical visit with a Complex Cancer Care Management team clinician (~1-2 weeks into intervention) - Schedule a nutrition evaluation/consultation with RD (according to participant need) - Optional: Attend a semi-structured interview within 2 weeks and/or at 6 weeks into the intervention
Post-intervention assessment (End of study)	- Complete post- program questionnaires - Complete post-program fitness assessment - Complete online self-administered 24-hr dietary food recall - Optional: Attend a semi-structured interview at the end of the program

STUDY PROCEDURES

Demographic and disease status data will be extracted from medical files/records, such as your Electronic Medical Records (EMR), Netcare, and/orcharts. As part of the screening procedure, you will complete the Physical Activity Readiness Questionnaire + (PAR-Q+). This will ensure that the exercise program will be safe, and that it can be tailored to your needs.

If you are ineligible to participate due to nerve, muscular, or skeletal issues after PAR-Q+ screening, you may be referred to a Cancer Physiatrist (i.e., Dr. George Francis) for evaluation and treatment.

Questionnaires:

You will be provided with a questionnaire package at the beginning of the study and immediately after the 12-week program. The purpose of the three surveys within the questionnaire is to collect information on demographics as well as information on your personal well-being, including quality of life, fatigue, and symptom burden. The questionnaire package will take about 10-15 minutes to complete, with an estimated total time of 30-45 minutes total.

The information you provide is for research purposes only and will remain strictly confidential. Some of the questions are personal; you may choose not to answer them. Even though you may have provided information on a questionnaire, these responses will not be reviewed by individuals not involved in this study, e.g., your health care practitioner.

Complex Cancer Management Team:

You will be offered a palliative symptom management consultation with a member of the Complex Cancer Care Management team at the TBCC. This is a team of physicians, a nurse practitioner, advanced practice pharmacists and a nurse coordinator. Palliative symptom management will focus on symptoms that contribute to reduced QOL (e.g. pain, fatigue, nausea), limit one's ability to engage in exercise, or present barriers to oral intake (e.g., pain management, nausea, mucositis, thrush). Clinicians will deliver pharmacologic and nonpharmacologic therapies based on their clinical judgement. Your assessments will occur in conjunction with scheduled lung cancer clinic visits, cancer therapy treatment visits, or as separate dedicated research visits when necessary. The initial assessment will occur within two weeks of the exercise program initiation. After the initial assessment, follow-up consultations can occur at the discretion of the palliative care clinicians and participants, and may occur either in person or by phone.

Online Nutrition Dietary Food Recall

At the start of the study, and again after completing the intervention, you will be instructed by the study coordinator to complete a self-administered online 24-hr dietary food recall. For this you will record for one weekday and one weekend day. The Automated Self-Administered 24-hour (ASA24®) dietary assessment tool was created by the National Cancer Institute (NCI), and is a free web-based tool that enables multiple, automatically coded, self-administered 24-hour recalls (http://asa24.ca/). You will be provided with instructions on how to use this technology: the tool is easy to use and can be completed at home. As part of the nutrition component of this study, you will also meet with a Registered Dietitian (RD) for a nutrition evaluation and consultation. The number of follow-up dietitian visits will be determined based on individual need for each participant, and post-study food recall evaluation data will be collected and analyzed to assess changes in food intake behaviours, and possible correlations to levels of exercise participation and patient-reported outcomes.

Fitness assessment:

Approximately 45 minutes long, the fitness assessment includes:

- Chair stand (# of sit to stand repetitions that can be performed in 30 sec)
- Grip Strength (musculoskeletal test)
- 6 min walk test (a submaximal walking test)
- Sit and reach (flexibility test)
- Shoulder flexion (flexibility test)

- Balance test
- Resting blood pressure and heart rate
- Body Composition: waist and hip circumference, height and weight

WHAT ARE THE POTENTIAL SIDE EFFECTS FROM PARTICIPATING IN THIS STUDY?

There are risks associated with involvement in any exercise program. The research team will watch you closely to see if you have side effects. However, screening will determine your ability to be active and involved in the program, thereby reducing the potential risks. There are no other known physical or psychological risks associated with involvement in the program. However, if at any time during the study you are identified as distressed or upset, referrals to psychosocial resources at the Tom Baker Cancer Centre will be made available.

WHAT ARE THE BENEFITS OF PARTICIPATING IN THIS STUDY?

If you agree to participate in this study, there may or may not be a direct benefit to you. An increase in physical activity may lead to an increased sense of well-being and quality of life, reduced feelings of depression, anxiety, and stress, and may improve physical fitness. These may be improved during the study, but there is no guarantee this research will help you. The information from this study may help us to provide better resources to help people cope with advanced lung cancer in the future.

WHAT ARE MY RESPONSIBILITIES AS A STUDY PARTICIPANT?

If you choose to participate in this study, you will be expected to:

- Attend all scheduled study visits and undergo all of the procedures described above. Your participation in this study does not involve anything else beyond what is specified on this informed consent.

HOW LONG WILL I BE PARTICIPATING IN THIS STUDY?

The study intervention will last for 12 weeks.

CAN I CHOOSE TO LEAVE THIS STUDY EARLY?

You can choose to end your participation in this research (called early withdrawal) at any time without having to provide a reason. If you choose to withdraw early from the study without finishing the intervention, procedure or follow-up, you are encouraged to contact the study staff.

You may be asked questions about your experience with the study intervention. You may withdraw your permission to use information that was collected about you for this study at any time by letting the study team know. However, this would also mean that you withdraw from the study.

Information that was recorded before you withdrew will be used by the researchers for the purposes of the study, but no additional information will be collected after you withdraw your permission. If you decide to leave the study, you can ask that the information that was collected about you not be used for the study. Let the study team know if you choose this.

HOW WILL MY PERSONAL INFORMATION BE KEPT CONFIDENTIAL?

If you decide to participate in this study, the study doctor and study staff will only collect the information they need for this study.

Records identifying you, including information collected from your medical files/records, such as your Electronic Medical Records (EMR), Netcare, charts, etc., will be kept confidential to the extent permitted by the applicable laws, will not be disclosed or made publicly available, except as described in this consent document.

Authorized representatives of the following organizations may look at your identifiable medical/clinical study records at the site where these records are held for quality assurance purposes and/or to verify that the information collected for the study is correct and follows proper laws and guidelines:

- Members of the Regulatory/Audit team at the Universty of Calgary*,* for quality assurance purposes;
- The Health Research Ethics Board of Alberta – Cancer Committee, which oversees the ethical conduct of this study

To protect your identity, all personal information will be kept in a file that is only identifiable by an ID number. It will be locked in a filing cabinet in a secure lab office in the Faculty of Kinesiology at the University of Calgary. All uploaded data (e.g., online diet records, Fitbit data), will be kept on a password protected secure server, on a password-protected computer in the secure lab office mentioned above. Only pre-approved staff members will have access to this data. Hard copy data (e.g., questionnaires on personal well-being, including quality of life, fatigue, and symptom burden), will be kept for 5 years, and will then be shredded. The ID number identification table will only be available to the study team, including the Principal Investigator, co-investigators and the research assistants.

The personal information including name, email and contact phone number will be removed from your questionnaire and kept in a file that is locked in a filing cabinet in a secure lab office in the Faculty of Kinesiology at the University of Calgary. This information will not be uploaded with the study data and will be kept separate from the study data. Only pre-approved staff members will have access to this data. This personal contact information may be used to contact you to determine your interest in an interview following the program.

Any disclosure of your identifiable health information will be done in accordance with federal and provincial laws including the Alberta Health Information Act (HIA). The organizations listed above are required to have organizational policies and procedures to protect the information they see or receive about you, except where disclosure may be required by law. The study team will ensure that any personal health information collected for this study is kept in a secure and confidential location in the Faculty of Kinesiology at the University of Calgary, as also required by law.

If the results of this study are published, your identity will remain confidential. It is expected that the information collected during the study will be published/presented to the scientific community at meetings and in journals.

Even though the likelihood that someone may identify you from the study data is very small, it

can never be completely eliminated. Every effort will be made to keep your identifiable information confidential, and to follow the ethical and legal rules about collecting, using and disclosing this information.

Should you wish to withdraw from the study prior to data analysis, the information that you provided will be destroyed and not included in the final report of the research project. If you withdraw after data analysis, the information you provided will be included in the final report of the research. Participation is completely voluntary and confidential. You are free to discontinue participation at any time during the study. Names will not be included in the group data. The group data will be summarized for any presentation or publication of results.

Studies involving humans sometimes collect information on race and ethnicity as well as other characteristics of individuals because these characteristics may influence how people respond to different interventions. Providing information on your race or ethnic origin is voluntary.

WILL MY HEALTHCARE PROVIDER(S) BE INFORMED OF MY PARTICIPATION IN THIS STUDY?

Your family doctor/health care provider outside of the Tom Backer Cancer Centre will not be informed by the study team that you are taking part in the study. You can choose to let your family doctor/health care provider know, if you like. If you are undecided, the study doctor can discuss this with you.

WILL THERE BE ANY COSTS INVOLVED WITH PARTICIPATING IN THIS STUDY?

There are no costs associated with participating in this research study. You will be provided with a parking pass (value $8.00) to attend your baseline and follow up testing sessions at the University of Calgary. The physical activity intervention will be available to you free of charge while you take part in this study. Participation in this study will not involve any additional costs to you or your private health care insurance.

WILL I BE COMPENSATED FOR PARTICIPATING IN THIS STUDY?

You will not be paid for taking part in this study. However, you will be provided with an exercise ball, yoga mat and resistance band to help you exercise at home. You will also be provided with a Fitbit, which will be yours to use during the duration of the intervention, and returned to the program coordination upon program completion.

Although no funds have been set aside to compensate you in the event of injury or illness related to the study treatment or procedures, you do not give up any of your legal rights for compensation by signing this form.

WHAT ARE MY RIGHTS AS A PARTICIPANT IN THIS STUDY?

You have the right to be informed of the results of this study once the entire study is complete. If you would like to be informed of these results, please contact the study doctor.

Your rights to privacy are legally protected by federal and provincial laws that require safeguards to ensure that your privacy is respected. No funds have been set aside to compensate you by the Health and Wellness Lab, the University of Calgary, Alberta Health Services or the Researchers, in the event that you suffer injury as a result of participating in this

research.

By signing this form you do not give up any of your legal rights against the hospital, investigators, sponsor, involved institutions for compensation or their agents, nor does this form relieve these parties from their legal and professional responsibilities.

WHO DO I CONTACT FOR QUESTIONS?

If you have questions about taking part in this study, or if you suffer a research-related injury, you should talk to the study doctor, co-investigator or study nurse. These person(s) are:

Dr. Nicole Culos-Reed, (Principal Investigator), Faculty of Kinesiology	(403) 220-7540
Name	Telephone
Dr. Amane Abdul-Razzak (Co-Investigator), Tom Baker Cancer Centre	(403) 944-8903
Name	Telephone
Health and Wellness Lab Study Coordinator	(403) 210-8482
Name	Telephone

If you have questions about your rights as a participant or about ethical issues related to this study and you would like to talk to someone who is not involved in the conduct of the study, please contact the Office of the Health Research Ethics Board of Alberta – Cancer Committee at:

Telephone: 780-423-5727 Toll Free: 1-877-423-5727

SIGNATURES

Part 1 - to be completed by the potential participant.

	Yes	No
Do you understand that you have been asked to take part in a research study?	☐	☐
Do you understand why this study is being done?	☐	☐
Do you understand the potential benefits of taking part in this study?	☐	☐
Do you understand what you will be asked to do should you decide to take part in this study?	☐	☐
Do you understand the alternatives to participating in this study?	☐	☐
Do you understand that you are free to leave the study at any time, without out having to give reason and without affecting your future health care?	☐	☐
Do you understand who will see your records, including health information that identifies you?	☐	☐
Do you understand that by signing this consent form you are giving us permission to access your health information and specimens if applicable?	☐	☐
Do you understand that by signing this consent form that you do not give up any of your legal rights?	☐	☐
Have you had enough opportunity to ask questions and discuss this study?	☐	☐

By signing this form I agree to participate in this study.

Signature of Participant	PRINTED NAME	Date

I consent to be contacted for potential participation in the interview portion of the study:

Signature of Participant	PRINTED NAME	Email/ Phone number

Part 2 - to be completed by the study doctor or designee who conducted the informed consent discussion. Only compete this section if the potential participant has **agreed** to participate.

I believe that the person signing this form understands what is involved in the study and has freely decided to participate.

Signature of Person Conducting the Consent Discussion	PRINTED NAME	Date

Part 3 - to be completed only if the participant is unable to read or requires assistance of an oral translator/interpreter.

- The informed consent form was accurately explained to, and apparently understood by the participant.
- Informed consent was freely given by the participant.

Signature of Impartial Witness/Interpreter	PRINTED NAME	Date

You will be given a copy of this signed and dated consent form prior to participating in this study.