

URCC 08106

Northwest Community Clinical Oncology Program (NWCCOP)

315 Martin Luther King Jr. Way

Tacoma, WA 98405

Phone: (253) 403-1461

Fax: (253) 403-1615

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CONSENT FORM

URCC 08106: A Study of the Effects of Exercise on Cancer-Related Fatigue

INVESTIGATORS:

Lauren K. Colman, MD, Chris Chen, MD, W. Welby Cox, MD, FACP,
Xinda Wang, MD, Daniel Moore, MD, Troy Wadsworth, MD,
1003 South 5th Street-3rd Floor, Tacoma, WA 98405 (253) 403-1677.

Robert McCroskey, MD, Sibel Blau, MD, Andrea Rose, MD,
400-15th Avenue SE, Puyallup, WA 98372 (253) 841-4296.

Frank Senecal, MD, Thomas Baker, MD, Lorrin Yee, MD, Moacyr Oliveira, MD
1624 South I Street, Tacoma, WA 98405 (253) 383-3366.

Paul Robertson, MD, Steven Gorton, MD, James Lechner, MD, Harry Griffith, MD,
Xingwei Sui, MD, 4525 Third Ave. SE, Suite 200, Lacey, WA 98503 (360) 754-3934.

Dustan Osborn, MD, Ronald Goldberg, MD, Nicole Grous, MD, Min Kang, MD,
3920 Capital Mall Drive SW, Suite 100, Olympia, WA 98502
360-753-4700 and 222-2nd Street NE, Suite B, Auburn, WA 98002 (253) 887-9333.

John Rieke, MD, Suraj Singh, MD, Carolyn Rutter, MD, 1003 South 5th Street, 1st Floor,
Tacoma, WA 98405 (253) 403-4994.

Michael Liao, MD, 400 -15th Ave SE, Puyallup, WA 98372 (253) 697-4829

URCC 08106: A Study of the Effects of Exercise on Cancer-Related Fatigue

This is a clinical trial (a type of research study). Clinical trials include only people who choose to take part. Please take your time to make your decision about taking part. You may discuss your decision with your friends and family. You can also discuss it with your health care team. If you have any questions, you can ask your study doctor for more explanation.

You are being asked to participate in this research study because you are scheduled to receive chemotherapy treatments for your cancer.

The study is being conducted by the University of Rochester Cancer Center and its affiliates in the Community Clinical Oncology Program.

Why is this study being done?

The purpose of this study is to determine if the *Exercise for Cancer Patients* (EXCAP) program, a home-based walking and muscle strengthening exercise program will be helpful in reducing cancer-related fatigue during chemotherapy. The EXCAP program is a moderately-intense, home-based, daily exercise program. The EXCAP program is made up of two parts: 1) aerobic exercise (walking that will increase your heart rate and your breath rate). You will wear a pedometer which is a small device worn on your waistband that counts the number of steps you take each day, and 2) strength exercise—You will use color coded bands that stretch and make your muscles work as you do the exercises.

How many people will take part in the study?

Approximately 492 participants will take part in this study nationally.

What will happen if I take part in this research study?

If you agree to be in the study, you will be randomized into one of the two groups described below. Randomization means that you are put into a group by chance. It is like flipping a coin. A computer program will place you in one of the two study groups. Neither you nor the researcher will choose what group you will be in. You will have an equal chance of being placed in either group.

The two groups differ by when the participants do the 6-week EXCAP program. Participants in the first group can choose to do the exact same 6-week EXCAP program as the second group immediately after completing the second set of study assessments, and participants in the second group will receive the exact same 6-week EXCAP program after completing baseline assessments and getting their first chemotherapy treatment. This type of study design is called a “wait-list control” design. It allows the researcher to compare the group who is not participating in EXCAP with the group who is participating in the EXCAP on fatigue, aerobic capacity, strength, and quality of life, and also allows every participant in the study to receive the EXCAP program.

- Group 1 Participants will complete baseline assessments prior to starting chemotherapy. For the next six weeks, this group will not participate in the EXCAP program, but will continue with the study requirements outlined below. During the seventh week on study, they will complete the same assessments as they did during the first week on study. Study participation ends here, but participants in this group can choose to participate in the exact same 6-week EXCAP program immediately after completing all study assessments. There is no charge for this program.
- Group 2 Participants in this group will complete baseline assessments prior to starting chemotherapy. During the next six weeks, they will receive a 6-week EXCAP program. They will then complete a second assessment identical to the one completed prior to the start of the EXCAP program.

Details of study activities are outlined below. A study calendar will be provided.

Before you begin the study:

- You will provide information about yourself in a brief interview with research staff
- Your medical records will be used by researchers to provide relevant clinical information (e.g., cancer diagnosis, treatment, other chronic illness, laboratory tests).

During the study:

Week 1 (4 days before you start your chemotherapy) Baseline Assessment (identical for both Group 1 and Group 2):

- You will complete a diary every day for 4 days that will provide information about your fatigue, quality of life, medications you take, physical activity, sleep and hot flashes. You will be given a pedometer to wear and will record the total number of steps you walk each day in your daily diary for 4 days. The diary will take less than one minute to complete once each day.
- The day before your first chemotherapy treatment, you will complete a packet of paper and pencil questionnaires that ask about your experiences of fatigue, quality of life, physical activity, depression, anxiety, sleep, medications and other aids to help with fatigue, and other symptoms. This packet usually takes about 20-25 minutes to complete and can be done at home.
- On the day of your first chemotherapy treatment, you complete a 6-minute walk test to measure your aerobic capacity and a handgrip test to measure your strength prior to receiving your chemotherapy.

Weeks 2-7 (EXCAP program for Group 2 or waiting period for Group 1):

- Participants in both Groups 1 and 2 will continue to complete the daily diaries.
- If you are assigned to Group 2, you will participate in the 6-week EXCAP program
- If you are assigned to Group 1, you will only complete the daily diaries during this time.

Week 7 (Final Assessment—exactly the same as Week 1):

- You will continue to complete a diary every day. You will wear a pedometer for 4 days and record the total number of steps you walk each day in your daily diary.
- The day before your next chemotherapy treatment, you will complete a packet of paper and pencil questionnaires that ask about your experiences of fatigue, quality of life, physical activity, depression, anxiety, sleep, medications and other aids to help with fatigue, and other symptoms. This packet usually takes about 20-25 minutes to complete and can be done at home.
- On the day of your chemotherapy treatment, you complete a 6-minute walk test to measure your aerobic capacity and a handgrip test to measure your strength prior to receiving your chemotherapy.

After Week 7:

- Study requirements for all participants are complete. Those participants who were randomized to Group 1 can choose to participate in the 6-week EXCAP program at this time.
- This is the final assessment for both groups.

We will call you to tell you about any meetings the researcher schedules for participants regarding the study. We will also call during Week 1 and Week 7 to remind you to complete your questionnaires, and during Weeks 2, 4 and 6 to remind you to continue completing your daily diaries, and for those assigned to Group 2, to continue with the EXCAP program. We will also remind you to return the materials.

How long will I be in the study?

The study will last approximately seven weeks. This includes one week for completing the baseline assessments and six weeks of EXCAP participation or waiting. The completion of the second set of assessments occurs during the last week of EXCAP participation or waiting. Those who are in Group 1, the wait-list control group, can participate in the 6-week EXCAP program immediately following completion of the assessments at the end of the study.

Can I stop being in the study?

You can stop participating at any time. Tell the research staff if you are thinking about stopping or decide to stop.

The researcher may decide to take you off this study if continuing on the study would not be in your best medical interest, funding for this research is stopped, your condition worsens, or new information becomes available.

What side effects or risks can I expect from being in the study?

Potential risks in taking part in the exercise intervention are minimal. Starting a low to moderate walking and strengthening exercise program is not associated with any severe side effects, and risks are minimal for individuals with no heart, lung, bone, muscular, or age-identified high risk factors as determined by the patient's treating physician (or designee). The chance of a heart-related event is rare once heart disease

has been excluded with reasonable certainty. Approximately 1 death per 15,000-20,000 healthy men per year occurs during jogging; this risk is much lower in women. An increase in blood pressure may occur with all types of exercise but it subsides when the exercise session ends. Although unlikely, the risks involved in a low to moderate intensity walking and strengthening exercise program involve muscles and bones and include possibly mild muscle soreness, a muscle strain, or related injuries such as tripping. There are additional risks from moderate and vigorous exercise if you are pregnant which may include a low level of oxygen is available to the fetus or mother, fetal distress from lack of normal body temperature that can result in possible birth defects and an increased number of contractions. However, current studies indicate that most healthy women with an uncomplicated pregnancy do not need to limit their exercise for fear of adverse effects. Generally, participation in a wide range of recreational activities appears safe during and after pregnancy. Overall, the risk level for participation in a low to moderate intensity home-based walking and strengthening program is minimal. Every effort will be made to minimize the risks through: 1) the approval of the patient's physician (or designee) to enter the study and complete all study tests and the exercise intervention; 2) the use of standardized guidelines for exercise testing and prescription provided by the American College of Sports Medicine; and 3) the use of trained technicians. If you experience chest pains, unusual pain, or any other side effects that concern you while participating in this study you should contact your doctor at the number listed on the cover page. No adverse reactions have been reported by any of the participants who have completed the current pilot intervention.

Are there benefits to taking part in the study?

If you agree to take part in this study, there may or many not be direct medical benefit to you. We hope the information learned from this study will benefit other people undergoing chemotherapy treatments with fatigue, decreased aerobic capacity, decreased strength and, and impaired quality of life in the future.

What other choices do I have if I do not take part in this study?

Instead of being in this study, you can choose not to participate, participate in a different study that is available or participate in a different exercise program that is approved by your physician.

Will my medical information be kept private?

Efforts will be made to keep your personal information confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law, or other people need to see the information. While they normally protect the privacy of the information, they may not be required to do so by law.

The Federal Health Insurance Portability and Accountability Act (HIPAA) requires us to get your permission to use health information about you that we either create or use as part of the research. This permission is called an Authorization. We will use your research record/completed study questionnaires, related information from your medical record, study evaluations, and actigraph information.

We will use your health information to: conduct the study, monitor aspects of your health status (such as your level of fatigue, sleepiness, physical complaints and overall adjustment to cancer), obtain information regarding your treatment type, schedule, side effects and demographic information, measure the effects of the intervention on your fatigue, aerobic capacity, strength, and quality of life, to determine research results, and possibly to develop new tests and procedures. Health information is used to report results of research to sponsors and federal regulators. It may be audited to make sure we are following regulations, policies and study plans. If you have never received a copy of the HIPAA Notice, please ask the researcher for one.

If you decide to take part, your Authorization for this study will not expire unless you cancel (revoke) it. The information collected during your participation will be kept indefinitely. You can always cancel this Authorization by writing to the study investigator. If you cancel your Authorization, you will also be removed from the study. However, standard medical care and any other benefits to which you are otherwise entitled will not be affected. Canceling your Authorization only affects uses and sharing of information after the study investigator gets your written request. Information gathered before then may need to be used and given to others. For example, by Federal law, we must send study information to the FDA for drug and device studies it regulates. Information that may need to be reported to FDA cannot be removed from your research records.

As stated in the section on Voluntary Participation, you can also refuse to sign this consent/Authorization and not be part of the study. You can also tell us you want to leave the study at any time without canceling the Authorization. By signing this consent form, you give us permission to use and/or share your health information as stated above.

To meet regulations or for reasons related to this research, the study investigator may be required to share a copy of this consent form and records that identify you. Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as: US Food and Drug Administration (FDA), the National Cancer Institute (NCI) and/or the University of Rochester.

The results of this research study may be presented at meetings or in publications; however, your name will be kept private.

What about future research participation?

Would you like to be contacted and informed of future research studies for which you may be eligible based on your participation in this study? Choosing to be informed about these future studies, does not obligate you to participate in them, and will not affect your ability to participate in the current study. Participation in these future studies may or may not provide a direct medical benefit to you, however we hope the information learned from these future studies will benefit other cancer survivors.

Circle YES if you would be willing to have someone contact you at some time in the future to learn more about research opportunities like this one, or NO if you do not want to be contacted.

YES

NO

What are the costs of taking part in this study?

There is no cost to you to take part in this research study. The EXCAP program is provided free of charge.

You will receive no payment for taking part in this study.

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

In the case of injury or illness resulting from this study, emergency medical treatment is available but will be provided at the usual charge. No funds have been set aside to compensate you in the event of injury.

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

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and or loss of benefits to which you are entitled.

We will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

Who can answer my questions about the study?

You can talk to your study doctor about any questions or concerns you have about this study. Contact your study doctor at the number listed on the cover page.

For questions about your rights as a research participant, contact the: MultiCare Health System Institutional Review Board (a group of people who review the research to protect your rights) at 253-403-3877.

Where can I get more information?

You may call the National Cancer Institute's Cancer Information Service at 1-800-4-CANCER (1-800-422-6237) or TTY: 1-800-332-8615

You may also visit the NCI web site at <http://cancer.gov/>

- For NCI's clinical trials information, go to <http://cancer.gov/clinicaltrials/>
- For NCI's general information about cancer, go to <http://cancer.gov/cancerinfo/>

You will get a copy of this form. If you want more information about this study, ask your study doctor. You may also request a copy of the protocol (full study plan).

Signature

I have been given a copy of all pages of this form. I have read it or it has been read to me. I understand the information and have had my questions answered. I agree to take part in this study.

Signature of Patient or Patient's Legal Representative: _____ Date: _____

Printed Name of Legal Representative (if any): _____

Representative's Authority to Act for Patient: _____

Signature of Person Obtaining Authorization: _____

Authorization (Permission) to Use or Disclose (Release) Identifiable Health Information for Research

Participant's Name: _____

Birth Date: _____

1. What is the purpose of this form?

The University of Rochester (URCC) is an organization that does research to learn about the causes of cancer, and how to prevent and treat cancer. Researchers would like to use your health information for research. This information may include data that identifies you. Please carefully review the information below. If you agree that researchers can use your personal health information, you must sign and date this form to give them your permission.

2. What personal health information do the researchers want to use?

The researchers want to copy and use the portions of your medical record that they will need for their research. If you enter a URCC research study, information that will be used and/or released may include the following:

- the history and diagnosis of your disease;
- specific information about the treatments you received, including previous treatment(s) you may have had;
- information about other medical conditions that may affect your treatment;
- medical data, including laboratory test results, tumor measurements, CT scans, MRIs, x-rays, and pathology results;
- information on side effects (adverse events) you may experience, and how these were treated;
- long-term information about your general health status and the status of your disease;
- data that may be related to tissue and/or blood samples that may be collected from you; and
- numbers or codes that will identify you, such as your social security number and medical record number.

You may request a blank copy of the URCC data forms from the study doctor or his/her research staff to learn what information will be shared.

3. Why do the researchers want my personal health information?

The Northwest Community Clinical Oncology Program (Northwest CCOP) will collect your health information and share it with the URCC Biostatistical Center and the URCC Operations Center if you enter a cooperative group research study. The URCC centers will use your information in their cancer research study. You are being asked to take part in a study known as URCC 08106: A Study of the Effects of Exercise on Cancer-Related Fatigue.

4. *Who will be able to use my personal health information?*

The Northwest CCOP will use your health information for research. As part of this research, they may give your information to the following groups taking part in the research. The Northwest CCOP may also permit these groups to come in to review your original records that are kept by the Northwest CCOP so that they can monitor their research study.

- the URCC Operations Center;
- the URCC Biostatistical Center;
- National Cancer Institute (NCI)
- Public Health agencies and other government agencies (including non-U.S.) as authorized or required by law;
- other people or organizations assisting with URCC research efforts, the company(ies) sponsoring the research; and
- central laboratories, central review centers, and central reviewers. The central laboratories and review agencies may also give your health information to those groups listed in the five bullets above.

5. *How will information about me be kept private?*

The URCC will keep all patient information private to the extent possible, even though the URCC is not required to follow the federal privacy laws. Only researchers working with the URCC will have access to your information. The URCC will not release personal health information about you to others except as authorized or required by law. However, once your information is given to other organizations that are not required to follow federal privacy laws, we cannot assure that the information will remain protected.

6. *What happens if I do not sign this permission form?*

If you do not sign this permission form, you will not be able to take part in the research study for which you are being considered.

7. *If I sign this form, will I automatically be entered into the research study?*

No, you cannot be entered into any research study without further discussion and separate consent. After discussion, you may decide to take part in the research study. At that time, you will be asked to sign a specific research consent form.

8. *What happens if I want to withdraw my permission?*

You can change your mind at any time and withdraw your permission to allow your personal health information to be used in the research. If this happens, you must withdraw your permission in writing. Beginning on the date you withdraw your permission, no new personal health information will be used for research. However, researchers may continue to use the health information that was provided before you withdrew your permission.

If you sign this form and enter the research study, but later change your mind and withdraw your permission, you will be removed from the research study at that time.

To withdraw your permission, please contact the person below. She will make sure your written request to withdraw your permission is processed correctly.

Karyn Hart, RHIT, CCRP
Program Coordinator
Northwest CCOP
315 Martin Luther King, Jr. Way
Tacoma, WA 98405
(253) 403-1461

9. How long will this permission last?

If you agree by signing this form that researchers can use your personal health information, this permission has no expiration date. However, as stated above, you can change your mind and withdraw your permission at any time.

10. What are my rights regarding access to my personal health information?

You have the right to refuse to sign this permission form. You have the right to review and/or copy records of your personal health information kept by Northwest CCOP. You do not have the right to review and/or copy records kept by the URCC or other researchers associated with the research study.

Signatures

I agree that my personal health information may be used for the research purposes described in this form.

Signature of Patient
or Patient's Legal Representative: _____ Date: _____

Printed Name of Legal Representative (if any): _____

Representative's Authority to Act for Patient: _____

Signature of Person Obtaining Permission: _____ Date: _____

Printed Name of Person Obtaining Permission: _____