

Frequently Asked Questions

How long will the visit take?

The total time for the baseline visit is approximately two and a half hours.

How long will I be in the study?

Your participation in the study will last 6-7 weeks.

How many people will participate?

116 patients will be enrolled.

Is there any cost to participating?

There will be no cost to you.

What risks are involved?

There are little to no risks being involved in this study. Specifics will be discussed if you enroll.

Are there any benefits to participating?

You may or may not benefit from this study.

Will I get any payments for participating?

You will not be paid for this study; however, each patient will receive an EXCAP exercise program.

Can I leave the study?

You may discontinue participation at any time without risking loss of present or future care.



If you have noticed any changes in your cognitive functioning and would like more information, please contact:

Alex Skwirz, MS

Health Project Coordinator

Surgery-Cancer Control

265 Crittenden Blvd

Rochester, NY 14642

Phone: (585) 276-7142

Email: alex_skwirz@urmc.rochester.edu

Dr. Michelle Janelsins

Research Assistant Professor

Surgery-Cancer Control

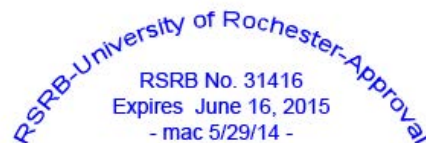
265 Crittenden Blvd

Rochester, NY 14642

Phone: (585) 276-4656

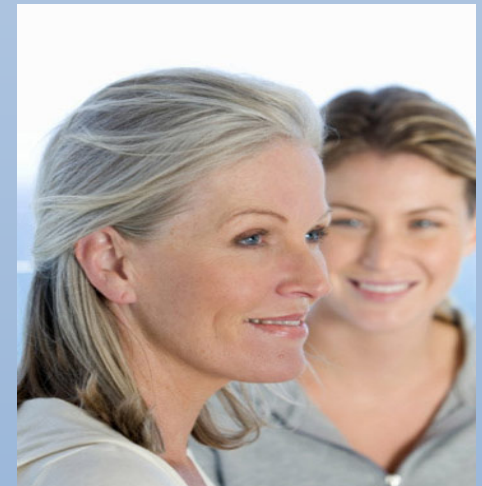
Email: michelle_janelsins@urmc.rochester.edu

The Department of Surgery-Cancer Control would like to thank you for considering participating in this project.



Patient Information:

A Phase II Study of the Effects of Physical Activity and Low Dose Ibuprofen on Cognitive Function in Cancer Patients Undergoing Chemotherapy



University of Rochester Medical Center
Department of Surgery-Cancer Control



Cognitive Impairment in Cancer Patients

Many cancer patients report mild to moderate cancer-related cognitive difficulties (such as problems remembering things, multi-tasking, or concentrating) during and following treatment of their cancer and currently, we do not have a treatment for these problems.

We believe that cognitive difficulties related to cancer and chemotherapy treatments may be related to increased inflammation in the body. This has been associated with cognitive difficulties in other diseases and the same may be true for cancer and cognition. Both exercise and ibuprofen have also been associated with reducing levels of inflammation. In this study, researchers will also investigate how exercise and ibuprofen influence levels of cytokines during your chemotherapy.

The researchers leading this study are also interested in how cognitive difficulties may relate to other symptoms you may or may not develop such as fatigue, sleep problems, anxiety, and how exercise and ibuprofen may affect these symptoms.

What To Expect

If you agree to participate, your standard of care will not change.

You will be asked to complete the following at the beginning and end of the study:

1. Filling out questionnaires
2. Completing computerized and paper based cognitive tests
3. Fitness evaluations
 - a. Bioelectrical impedance analysis (BIA) to measure lean body mass
 - b. Cardiovascular treadmill test
 - c. Resting metabolic testing
 - d. 2 tests for muscular strength
4. Wearing a pedometer (3 days)
5. A fasting blood draw (less than 2 tablespoons)
6. Daily diary about your symptoms (3 days)
7. Exercise program
8. A study coordinator will contact you once a week for updates

Study Groups

After completing baseline measures you will be assigned at random to one of four groups:

Group 1: Placebo 200 mg twice daily

Group 2: Placebo 200 mg twice daily + Exercise (EXCAP)

Group 3: Ibuprofen 200mg twice daily

Group 4: Ibuprofen 200mg twice daily + Exercise (EXCAP)

Exercise for Cancer Patients (EXCAP)



The exercise program being studied in this research consists of both aerobic and resistance training components using a pedometer to measure the distance walked each day as well as using resistance bands.

Ibuprofen



The anti-inflammatory being studied in this research is a low dose over the counter ibuprofen.