Improving insulin resistance in gynecological cancer patients post-treatment using integrative and functional medicine (IFM) food plans

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Purpose

This is a research study to see if following a provided food plan would improve insulin resistance in gynecological cancer patients. Insulin resistance is when the body has difficulty lowering the amount of sugar in the blood. One study suggests that patients with gynecological cancers are more likely to be insulin resistant and/or have higher levels of fasting insulin. You are being asked to be in this study because of your cancer diagnosis and the fact that you are in the 3 to 24 months post treatment window.

Description of Study Procedures

About 128 women will take part in this study at Woman's Hospital.

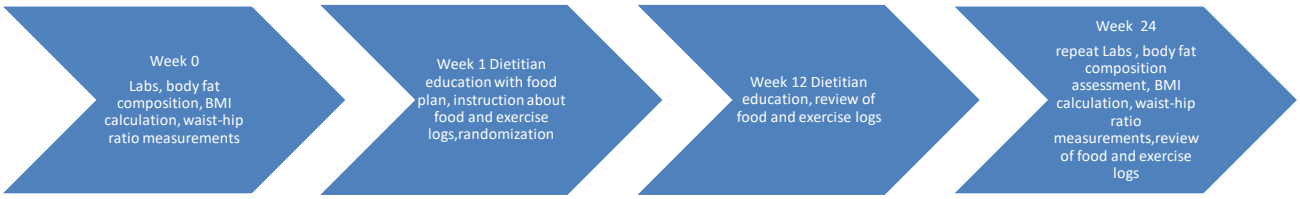
Your participation in this study will take about 8 hours over the course of 24 weeks.

At the beginning of the study you will have a fasting oral glucose tolerance test where a healthcare provider will take a fasting lab draw of blood to test your fasting glucose level first. They'll then ask you to drink 8 ounces of a syrupy glucose solution that contains 75 grams of sugar. You'll then wait in the office for two hours. The healthcare provider will draw blood at the half hour, one hour, and two-hour marks. You will repeat this test at the end of the study. Your blood samples will be tested to identify the glucose (sugar) and insulin levels and to use these levels to calculate insulin action. This testing will be repeated at the end of the study in week 24.

You will follow a 24-week food plan provided by a registered dietitian at week 1. You will meet with a registered dietitian at week 1 and week 12 in a group setting. You will keep a daily food log and exercise log that will be explained at week 1 and reviewed at week 12 and week 24. You will either follow a Mediterranean diet or a ketogenic diet. You will be put into a diet group by a randomization procedure which is like flipping a coin.

In addition, you will have the following measurements taken at baseline and at 24 weeks:

Body fat determination using the Fit3D body scanner which is a noninvasive body scanner used to take measurements and a 3-dimensional view of the body, BMI calculation, and waist-hip ratio.



Risks

The risks of having your blood drawn include local pain, bruising, swelling, bleeding and infection at the site of the vein puncture. Some people may experience lightheadedness, dizziness and rarely fainting.

Benefits

We hope that those who follow the food plan will lose an average of 5% of their body weight, and will improve their insulin sensitivity. We do not know if this will happen. We hope this food plan will decrease the risk of cancer recurrence. There may be no benefit to you. We hope this study will help cancer patients in the future.

Alternatives to Taking Part

The alternative is not to take part in the study.

Can you Stop being in the Study?

Taking part in this study is voluntary. You can withdraw at any time. Not being in the study will not involve any penalty or loss of benefits to which you are otherwise entitled. Should you wish to withdraw, please contact Brooke Schoonenberg at 225-924-8936. The investigator may remove you from the study if you are not following study procedures.

You will be notified of any new information which may affect your willingness to take part in the study.

Confidentiality

If the results of this study are published, you will not be identified in any way. Your personal information may be disclosed if required by law. We will keep your study records for as long as you are being tracked by the gynecological oncology team at Woman's Hospital. **Every effort will be made to keep your study information confidential. Absolute confidentiality cannot be guaranteed. Your study records will be part of your medical chart.** Your records will be stored in a locked cabinet or password-protected file.

Some entities may view or copy your study-related information. These entities include: Woman's Hospital Foundation Institutional Review Board, Woman's Hospital Research Department, Woman's Hospital Research and Development Committee, and federal agencies as required by law.

Collection of Identifiable Private Information

Your data collected as part of the research, from which identifiers are removed, will not be used or distributed for future research studies.

Financial Information

You will not be paid for taking part in the study. The study pays for the lab and group visit with a registered dietitian.

Who Do You Contact for Questions About the Study?

If you have any questions about the study procedures, please contact the study investigator, Brooke Schoonenberg, at 225-924-8936. For questions about your rights as a research subject, contact Ericka Seidemann, Human Protections Administrator, at (225) 231-5296. A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U. S. law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Signatures

This study has been explained to me and my questions have been answered. I can call the study investigator(s), listed on page 1, with any further questions I may have. I have been given a copy of this consent form. I agree to take part in this study. I have not waived any of my legal rights by signing this form.

_____ _____

Signature of Subject Date

_____ _____

Signature of Investigator Date

_____ _____

Signature of Person Obtaining Consent Date

The study subject has indicated to me that the subject is unable to read. I certify that I have read this consent form to the subject and explained that by completing the signature line above the subject has agreed to take part.

_____

Signature of Reader

_____

Signature of Witness