



refuel



REFUEL: STUDY SUMMARY

TITLE: “REFUEL” Active Women’s Study II: The Impact of Increased Caloric Intake on Bone Health and Menstrual Cyclicity in Energy Deficient Exercising Women.

Principal Investigator: Mary Jane De Souza, Ph.D., FACSM

Purpose: This study is designed to examine the effects of increased food intake on the menstrual cycle and bone health in physically active women who have irregular or absent (amenorrhea) menstrual cycles. Irregular or absent (amenorrhea) menstrual cycles cause bone loss, and infertility. The research study will examine whether a 12 month period of increased food intake will cause menstrual cycles to resume, and bones to get stronger.

Study Design: Potential volunteers will include women that have irregular or absent (amenorrhea) menstrual cycles and who exercise regularly, but will also include women with regular menstrual cycles who also exercise regularly. The women who are experiencing abnormal menstrual cycles will be randomized into two groups. One group will be asked to increase their daily caloric intake by about 20-30% for one year, with the goal of resuming normal menstrual cycles, and increasing the strength of one’s bones. This will be done with the help of a nutritionist who will examine the foods you eat, and recommend three different types of sports bars and drinks from which you can choose. The other group will be asked to maintain their normal diet and exercise routines and participate in the same testing as the first group. This group may undergo some changes in their diet, but only if these changes are necessary to keep a volunteer at the original weight they were at the beginning of the study. The group of regularly menstruating women, who exercise regularly, will also be asked to maintain their normal exercise and diet regimen. The testing involved in the study includes many procedures that require travel to a laboratory at the University of Toronto Athletic Centre. These procedures include collecting daily samples of urine, providing blood samples from a vein in one’s arm, keeping diet and physical activity logs, meeting with a dietician, meeting with a psychologist, getting weighed, and participating in tests to measure bone strength and fitness, and filling out questionnaires.

Eligibility Criteria: 1) be between the ages of 18 and 35 yrs, 2) be in good health, 3) be free of any chronic illness, including history of hyperprolactinemia, thyroid, or metabolic disease, 4) not experience regular menstrual bleeding within the past 3 months or six or less menstrual cycles per year, OR have regular menstrual cycles of 26-32 days for the past 6 months, 5) participate in aerobic or resistance training for at least 2h/week if menstruating regularly, or 3 hr/week if irregular or absent menstrual cycles, 6) not be taking any form of hormonal therapy for at least 6 months, 7) be at least 5 years since first menstrual cycle, 8) weight stable and not have gained 2 kg in the last 6 months, 9) BMI between 16-25 (kg/m²). You will be excluded from this study if 1) you have a chronic disease, such as thyroid disease, diabetes, or hyperprolactinemia, 2) are sedentary with less than 2 hr/week of aerobic or resistance training, 3) smoke, 4) are pregnant or planning a pregnancy during the course of the study, 5) consume medications or dietary supplements that are incompatible with measuring hormones or metabolism, 6) are currently diagnosed with a clinical eating disorder or other clinical psychiatric disorder, and 7) other contraindications that would preclude participation.

Benefits and Risks: The benefits will include a complete report of the tests, and an explanation of the results of this study. With increased knowledge of menstrual status, heart health, body composition, bone density, nutritional and activity patterns you will be more informed about your overall health. There are some risks involved, such as a decrease in body satisfaction, possible weight gain, and musculoskeletal injuries. Volunteers will get compensated monetarily for their time.



REFUEL: IMPORTANCE AND BENEFITS OF THE STUDY

Benefits to Me, the Participant:

- You will have bone density, hormone levels, body fat, and fitness levels measured.
- You will receive information about the importance of adequate food intake for reproductive health.
- You will receive nutrition and diet analysis, and measures of daily energy intake and expenditure.
- In return for your participation, you will receive a complete report of your scores on the tests and procedures, and an explanation of the meaningfulness of the results of this study from the study doctor.
- Volunteers will get compensated monetarily for their time.

Benefits to Society:

- By participating in this research, you will help increase our knowledge of how energy levels and diet affect the menstrual cycle and bones.
- These results may help doctors and scientists understand how they prevent and reverse menstrual problems and the bone loss that occurs in some women who exercise.
- The results from this study will indicate whether the bone loss that occurs when the menstrual cycle stops, can be reversed with increased food intake to match exercise needs.

Risks:

- There are risks associated with study participation, which include but are not limited to:
 - The risks associated with single blood samples obtained with a needle and syringe may for example: local discomfort, occasional dizziness and nausea, and black and blue marks.
 - The discomfort associated with increasing the amount of food you eat - for those volunteers with irregular or absent menstrual cycles who are in the intervention group required to eat more calories, or for EAMD Controls who elect to increase their calories.
 - Frequent lab visits, repeated testing, collecting one's urine for the duration of the study may represent inconveniences for participants
- A full explanation of all the risks associated with the study is available in the informed consent



REFUEL: ELIGIBILITY

Inclusion Criteria

For inclusion into this study you must:

- Be between the ages of 18 and 35 years
- Be in good health
- Be free of any chronic illness, including history of hyperprolactinemia, thyroid, or metabolic disease
- Not experience regular menstrual bleeding within the past 3 months or six or less menstrual cycles per year, OR have regular menstrual cycles of 26-32 days for the past 6 months
- Participate in aerobic or resistance training for at least 2h/week if menstruating regularly, or 3 hr/week if irregular or absent menstrual cycles
- Not be taking any form of hormonal therapy for at least 6 months
- Be at least 5 years since first menstrual cycle
- Be weight stable and not have gained 2 kg in the last 6 months
- Have a BMI between 16-25 (kg/m²).

Exclusion Criteria

You will be excluded from this study if you:

- Have a chronic disease, such as thyroid disease, diabetes, or hyperprolactinemia,
- are sedentary with less than 2 hr/week of aerobic or resistance training
- Smoke
- Are pregnant or planning a pregnancy during the course of the study
- Consume medications or dietary supplements that are incompatible with measuring hormones or metabolism
- Are currently diagnosed with a clinical eating disorder or other clinical psychiatric disorder
- Have other contraindications that would preclude participation



REFUEL: FLOWCHART

