a place of mind
THE UNIVERSITY OF BRITISH COLUMBIA

Centre for Chronic Disease Prevention and Management
Faculty of Medicine
Okanagan Campus
1088 Discovery Avenue
Kelowna, BC Canada V1V 1V7

Participant information and consent form

1. **Title**: **A**ppetite and Energy **B**alance Parameters across the Menstrual **C**ycle (the ABC study)

2. **Study personnel:**

Principal Investigator: Sarah Purcell, PhD
School of Medicine
The University of British Columbia, Centre for Chronic Disease Prevention and Management
Phone: 604-341-6809

Co-investigators: Jonathan Little, PhD
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The University of British Columbia
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Sponsor/Funder: Start-up funds awarded to Dr. Sarah Purcell

24-hour emergency telephone number: Dr. Sarah Purcell: 604-341-6809

3. Invitation

You are being invited to participate in this research because you are a sedentary female between the ages of 18 - 35 years, with a body mass index between 18.5 – 24.9 kg/m^2 (body weight in kilograms, per height in meter squared), with a regular menstrual cycle and no major health conditions.

4. Your participation is voluntary

Your participation is voluntary. You have the right to refuse to participate in this study. If you decide to participate, you may still choose to withdraw from the study at any time without any negative consequences to the medical care, education, or other services to which you are entitled or are presently receiving.

This consent form describes why the research is being done, procedures that are being carried out, and potential risks and benefits. Please review the consent document carefully when deciding whether or not you wish to be part of the research and sign this consent only if you accept being a research participant. Please take time to read the following information carefully and to discuss it with your family, friends, and doctor before you decide.

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5. Who is conducting the study?

The study is being conducted by Dr. Sarah Purcell, an Assistant Professor in the School of Medicine and Department of Biology at The University of British Columbia (UBC). This study is receiving internal funding, but not receiving funds from an external agency or sponsor.

6. Background

Females who have not undergone menopause ("pre-menopausal") often have fluctuations in the food they eat ("dietary intake") across the menstrual cycle. Understanding the determinants of dietary intake in different states of hormone balance may be important for preventing obesity and designing better nutrition recommendations. To date, little research has assessed the relationships between dietary intake and appetite, energy metabolism, body composition (i.e., the proportion of muscle and fat), and physical activity in different phases of the menstrual cycle. This study will compare appetite and dietary intake (and their relationship) in laboratory and free-living settings in healthy pre-menopausal women at two points during the menstrual cycle. Data on sex hormones, energy metabolism, body composition, physical activity and premenstrual symptoms will also be collected to assess their potential relationship with dietary intake.

7. What is the purpose of the study?

The main purpose of this study is to describe dietary intake across the menstrual cycle in healthy pre-menopausal women and in relation to appetite, sex hormones, energy metabolism, body composition, physical activity, and premenstrual symptoms. This may be used to develop better ways to change dietary intake across the menstrual cycle or understand the effect of sex hormones on dietary intake in different populations. We are hoping to enroll up to 23 participants in this study.

8. Who can participate in this study?

In addition to the eligibility criteria you have already told us about, you may be eligible to participate in this study if you: are of female sex, aged 18 – 35 years, have not given birth, have a regular menstrual cycle, not currently pregnant or lactating and not planning on becoming pregnant in the next 12 weeks, and are able and willing to fast for 12 hours before each study day visit.,

9. Who should not participate in this study?

In addition to the eligibility criteria you have already told us about, you should not participate in this study if you: have any major health conditions (i.e., cardiovascular disease, diabetes, cancer, thyroid disease, human immunodeficiency virus, hepatitis B or C, renal disease, hepatic disease, or polycystic ovary syndrome), are currently pregnant or lactating or are likely to become pregnant in the next 12 weeks, and are willing to abstain from cannabis-containing products (including cannabidiol-based products) for two weeks prior to the first study day visit and until the second study day visit and free-living assessments are completed (if applicable). You may also be

ineligible if you currently or in the past six months: have used contraceptive pills, have a hormonal intrauterine device ("IUD"), or have regularly used tobacco or nicotine products.

10. What does this study involve?

This study involves a total time commitment of equal to approximately (~) 13 hours. After review of this consent, we will conduct an in-person screening and baseline visit to confirm your eligibility and collect measures of your body composition and food preferences (~1.5 hours). We will ask you to collect urine samples and ovulation test strips at home for up to 7 days to help us identify your ovulation and inform the date of your study day visits. You will be asked to contact the study team when you start a new cycle (i.e., the onset of menstruation) or when a positive result is detected with the ovulation test strips. We will also ask you to record premenstrual symptoms and measure your waking body temperature for up to 70 days. You will complete two study day visits: one in the luteal phase and one in the follicular phase of the menstrual cycle. The follicular phase the time between the first day of your period and release of egg from your ovary (ovulation) and lasts between 11-17 days. The luteal phase is the time between ovulation and the beginning of the next period and lasts between 11-27 days. Prior to each study day, you will need to pick up and consume two days of food. During each ~4.5 hour study day visit, we will measure your energy metabolism, take two saliva samples, and measure your appetite in response to a standard breakfast. We will then give you a buffet-type meal and send you home with 3 days of food in which you can eat as little or as much as you would like. You will track your diet and appetite for three days and wear and activity monitor for seven days.

If You Decide to Join This Study: Specific Procedures

If you agree to take part in this study, the procedures and visits you can expect will include the following:

- **Eligibility and consent:** You will first complete a pre-screening questionnaire. If it seems like you may be eligible based on this questionnaire, you will undergo a phone/email meeting with a member of the research team in order to go over the specific procedures of the study. Virtual meetings will be held in a secure University of British Columbia Zoom meeting. We will review the eligibility criteria and informed consent with you over video or in person. REDCap e-consent auto-archiver will also be used; it adds an extra certification page before the end of the survey, which participants much confirm, and stores a static copy of the consent form and response in the file repository. The study team will send a pdf copy of their signed consent, and participants will also have the option to download the pdf of the consent once signed.
- **Screening/baseline visit:** After providing written consent, will schedule a ~1.5 hour visit that takes place at the Upper Campus Health building and the Arts building. We will measure your height, weight, and blood pressure and ask you to complete questionnaires regarding your demographics and medical history, previous menstrual cycle dates, food preferences, and screening for disordered eating, alcohol or drug abuse, and untreated depression. You will be escorted to the Arts

building to have your body composition (amount of muscle and fat) measured using a DEXA scan (dual energy X-ray absorptiometry). For this procedure, you will need to remove any metal objects (if applicable and possible) and lie on your back upon a hospital-type bed for about 10 minutes while the machine is positioned over areas of your body. You will have the option to wear a hospital gown or your regular clothes during this procedure. You will also be provided with 30 ovulation test strips and disposable urine collection cups to track what menstrual phase you are in.

- **Ovulation and symptom tracking:** Scheduling of the study day visits will be based on your menstrual cycle. You will be given a digital thermometer to place under your tongue to measure your body temperature each morning. You will send these results in using a link to a survey to help us identify your ovulation. You will be asked to contact a member of the study team to schedule your study day visits at the onset of menstruation or when you detect two days of higher-than-average body temperature. Luteal-phase study day visits will be scheduled 6–10 d after ovulation test and follicular-phase study day visits will be scheduled 2–5 days before the next estimated ovulation date to coincide with peak hormone concentrations. You may schedule either the luteal- or follicular-phase study day visits first, according to preference and availability. You will also be asked to track psychological and physical symptoms of pre-menstrual syndrome each day for up to 35 days at the onset of your menstrual period (until the beginning of your next cycle).
- **Run-in diet**: You will be asked to pick up and consume all the food provided two days before each study day visit. You may pick this food up from the UCH building at the UBC Okanagan Campus or one of 16 other locations in the greater Kelowna area (the study team will just need to know this information ahead of time). You will be asked to consume only the provided food but may consume caffeine during this time.
- **Study day visits**: Before each visit, you will be asked to refrain from food and calorie- or caffeine-containing beverages for at least 12 hours, alcohol for at least 24 hours, and vigorous-intensity exercise for at least 48 hours before each study visit. Each study day visit will take place at the UCH building and be scheduled to start sometime between 7 – 9:30am. We will conduct the study procedures in the following order:
    1. *Body weight* on a digital scale
    2. *Collection of saliva samples* for analysis of active estrogen and progesterone before and after your resting metabolic rate test. Note that there is no saliva banking or genetics research done using these samples. The samples will be identified by your study ID with no personal identifiers. Before analysis, they will be stored in a freezer in a locked laboratory on the 3rd floor of the Reichwald Health Sciences building in Dr. Jonathan Little's laboratory (co-investigator). Any leftover samples will be destroyed after analysis.
    3. *Resting metabolic rate (RMR):* RMR will be measured for 15-20 minutes after a period of 25-30 minutes of quiet rest using an indirect calorimeter with face mask (Korr Medical Technologies ReeVue). This test measures

oxygen consumed and to estimate RMR (in kilocalories/day). During the test, you will breathe normally through a facemask, while relaxed but not falling asleep.

4. *Appetite ratings:* You will be asked 3 questions regarding appetite before your breakfast meal and every 30 minutes after for three hours.
5. *Standard breakfast meal:* You will be given a breakfast meal to eat within 20 minutes.
6. *Image ratings:* You will be asked to rate images of foods using a computer program. The images will be presented on a laptop computer or iPad. Each photo will be shown, and you will be asked to rate: 1) how pleasant the image is, 2) how appealing the food appears in the image, and 3) your desire to eat the food item.
7. *Questionnaires:* You will be asked to fill out questionnaires that gives us information on your eating habits, hunger, and food cravings.
8. *Eat lunch* in a private room. For this meal you will be allowed to eat as much or as little as you like.

- **Post study-day visits**: After each study day visit, we will ask you to:
    1. Consume as much or as little of three consecutive days of food we will provide you with. You will be asked to return uneaten food to a member of the study team after the three-day assessment.
    2. Use the camera function on your own smart phone to take pictures of all food and drink intake for the same three days you eat the food provided. You will upload these pictures to a survey that will be sent to you in your email (described below). You will receive several emails with unique survey links each day around your usual eating times. If you do not have an email that you can use, you will be permitted to record your food with pen and paper.
    3. You will be asked a brief set of questions about your appetite periodically during the three days you are eating the provided food after each study day visit. These questions will be sent to you via email around the times we expect you to be eating (according to your usual schedule). Additional email prompts will be sent to you if you fail to answer the questions.
    4. You will be asked to wear an activity monitor for the remainder of the study day visit and the following a 7-day period. The activity monitor is a small device that is attached to your thigh using a non-allergenic adhesive tape. This device is very small and will not restrict your movement. You will wear this device during all your waking hours, except bathing and swimming, for seven days in a row. We will also ask you to record your sleep, exercise, and wake times on a paper sheet to help us interpret your activity.

11. What are the possible harms and discomforts?

The DEXA scan gives you a small amount of radiation. ~~By comparison, the average person in North America receives approximately the same amount of radiation every day from their natural environment (e.g., the sun, other radioactive materials that are~~

~~found naturally in the earth's air and soil).~~ By comparison, the approximate effective dose for a DEXA scan is 0.001 mSv, comparable to 3 hours of natural background radiation (vs. chest x-ray at 0.1 mSv). In this scan the only part of the body exposed is the skin, which is less vulnerable to radiation than most other parts of the body. There is also a small risk of food borne illness from the provided food, although this risk is about the same or less than contracting food borne illness from other sources. We will provide you with storing and reheating instructions to help minimize your risk. There is also a risk that some of the questionnaires may make you feel uncomfortable or embarrassed; in this case, you do not have to answer any questions you are uncomfortable answering.

12. What are the potential benefits of participating?

You may not receive any direct benefits from taking part in this study. We hope that the results will help us better understand the determinants of altered dietary intake and may help us design better nutrition interventions for other people in the future.

13. After the study is finished

Once you have completed the study, you can request your body composition and resting metabolic rate (RMR) tests, free of charge.

14. What happens if I decide to withdraw my consent to participate?

You may withdraw from this study at any time without giving reasons. If you choose to enter the study and then decide to withdraw at a later time, you have the right to request the withdrawal of your information and your saliva sample collected during the study. This request will be respected to the extent possible. Please note, however, that there may be exceptions where the data will not be able to be withdrawn - for example, where the data is no longer identifiable (meaning it cannot be linked in any way back to your identity) or where the data has been merged with other data. If you would like to request the withdrawal of your data or saliva samples, please let the principal investigator of the study know.

15. How will my taking part in this study be kept confidential?

Your confidentiality will be respected. However, research records and health or other source records identifying you may be inspected in the presence of the Investigator or designate and by representatives of UBC's Clinical Research Ethics Board for the purpose of monitoring the research. No information or records that disclose your identity will be published without your consent, nor will any information or records that disclose your identity be removed or released without your consent unless required by law. No data will be sent outside of Canadian borders. During the screening process, you will be asked questions about your mental health, as undiagnosed or untreated mental health problems may impact appetite and food intake. A member of the research team may need to tell someone if you indicate harming yourself or others verbally or on one of the screening forms. A researcher may give you names and contact information for places you can call or go to for help, or may help you call a doctor, relative, or help line.

You will be assigned a unique study number as a participant in this study. This number will not include any personal information that could identify you (e.g., it will not include your Personal Health Number, SIN, or your initials, etc.). Only this number will be used on any research-related information collected about you during the course of this study, so that your identity will be kept confidential. Information that contains your identity will remain only with the Principal Investigator and/or designate. The list that matches your name to the unique study number that is used on your research-related information will not be removed or released without your consent unless required by law.

Your rights to privacy are legally protected by federal and provincial laws that require safeguards to ensure that your privacy is respected. You also have the legal right of access to the information about you and, if need be, an opportunity to correct any errors in this information. Further details about these laws are available on request to the study team.

Studies involving humans now routinely collect information on race and ethnic origin as well as other characteristics of individuals because these characteristics may influence study outcomes. You should be aware that providing this information is not mandatory.

You will receive emails with links to surveys where you can upload your food photographs and complete questions about your appetite. This information is collected directly in the University of British Columbia's REDCap, which securely stores your data. Only members of the research team that are directly involved in this study will have access to the REDCap project with your information.

16. What happens if something goes wrong?

By signing this form, you do not give up any of your legal rights and you do not release the principal investigator, participating institutions, or anyone else from their legal and professional duties. If you become ill or physically injured as a result of participation in this study, medical treatment will be provided at no additional cost to you. The costs of your medical treatment will be paid by your provincial medical plan.

17. What will the study cost me?

All research-related procedures that you will receive during your participation in this study will be provided at no cost to you.

- **Reimbursement:**
  If applicable, a member of the research team will pay for parking on study days at the UCH building. Alternatively, we will provide public transit tickets for you if you are not planning on driving to your appointment or do not have a transit pass. We can also provide a transit ticket(s) for you to pick up your study food, if needed.
- **Renumeration:**
  You will receive a $50 Amazon gift card after each study day visit, which will add up to a total of $100 if you complete all visits.

18. If I have questions about the study procedures during my participation, who should I speak to?

If you have any questions or desire further information about this study before or during participation, or if you experience any adverse effects, you can contact Dr. Sarah Purcell at 604-341-6809.

19. Who do I contact if I have any questions or concerns about my rights as a participant?

If you have any concerns or complaints about your rights as a research participant and/or your experiences while participating in this study, contact the Research Participant Complaint Line in the University of British Columbia Office of Research Ethics by e-mail at RSIL@ors.ubc.ca or by phone at 604-822-8598 (Toll Free: 1-877-822-8598.)

20. Signatures

Appetite and Energy **B**alance Parameters across the Menstrual **C**ycle (the ABC study)

Participant Consent

My signature on this consent form means:

- I have read and understood the information in this consent form.
- I have been able to ask questions and have had satisfactory responses to my questions.
- I understand that my participation in this study is voluntary.
- I understand that I am completely free at any time to refuse to participate or to withdraw from this study at any time.
- I understand that I am not waiving any of my legal rights as a result of signing this consent form.
- I understand that there is no guarantee that this study will provide any benefits to me.

I will receive a signed and dated copy of this consent form for my own records.
I consent to participate in this study.

_____	_____	_____
Participant's Signature	Printed name	Date

_____	_____	_____	_____
Signature of Person Obtaining Consent	Printed name	Study Role	Date

Future Contact

Are you interested in learning about other studies conducted by Dr. Purcell in the future?☐ Yes ☐ No Initials_____

Note that for any future studies, a separate consent form will be provided to you for review.