Version 4.0, 02. januar 2024

Acute Effects of Endurance Exercise with Moderate and High Intensity on Breast Milk Composition Among Women with Overweight/Obesity

Acronym: YT

NCT number: NCT05745922

Document date: 02. January 2024

Document type: Informed consent participant (Translated from Norwegian)

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REQUEST FOR PARTICIPATION IN THE RESEARCH PROJECT

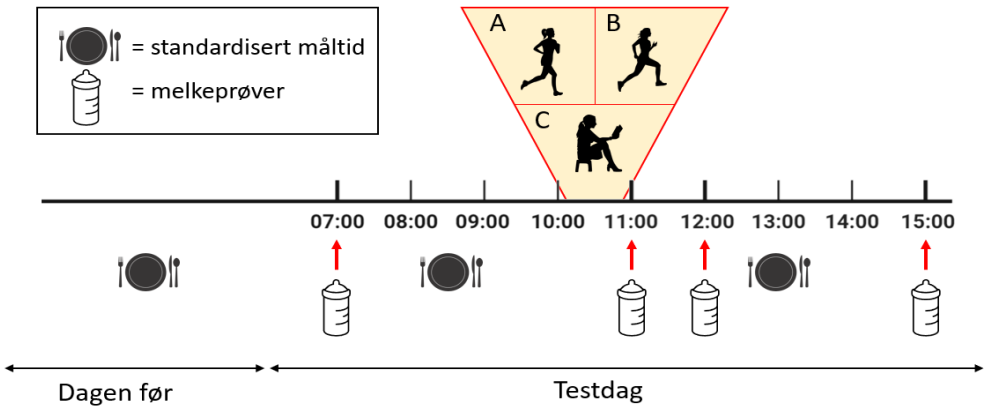
Acute effects of moderate and high-intensity endurance training on breast milk composition

THE PURPOSE OF THE PROJECT AND WHY WE ASK FOR YOUR PARTICIPATION

We wish to invite you to participate in a research project that will investigate whether exercise affects the composition of breast milk. To participate, you must have a body mass index (BMI) of 25 kg/m^2 or more before pregnancy (otherwise 28 kg/m^2 or more after birth), be exclusively breastfeeding an infant who was born between 5 weeks and 6 days and 8 weeks and 6 days ago at the start of the study. This period applies to when the first of the three test days (A, B or C in the figure below) is carried out. Exclusive breastfeeding means that the child only receives breast milk (water and any medications/supplements are OK). You must be able to walk or run on a treadmill for at least 50 minutes. You must also understand spoken and written Norwegian to participate. The study is conducted at the Faculty of Medicine and Health Sciences, NTNU.

WHAT THE PROJECT INVOLVES FROM YOU

In this project, we will collect and record information about you. We will record your age and when the child was born, and the child's gender, weight, length and head circumference at birth, whether you had any illnesses during pregnancy, your physical activity level, and whether you smoke and whether you take any medications. We will measure your height, weight, body composition and physical fitness at the start of the study. We will also measure the baby's weight, length and body composition. You will also be asked to fill out a questionnaire (about background, physical activity and breastfeeding). You will have to come in for testing on a total of four separate days. On the first day, measurements of weight, height and body composition will be taken, as well as a physical test where you walk or run on a treadmill to exhaustion. The testing on this day will take about 50 minutes. Two of the next three times you come in, you will complete a training session: one session with moderate-intensity and one session with high-intensity (interval training). The third time you will just sit in a chair and rest in the laboratory. The order of these three will be random, and they will be carried out approximately one week apart. The training sessions are adapted to your physical condition. We ask that you provide breast milk samples (approximately 25 mL each time) at four times during the three test days. You can see an overview of these times in the figure below.



The figure shows the study design and breast milk sample collection. On the test days, you will meet at our training lab at St. Olavs Hospital just prior to 10:00. On all three days, you must be here until approximately 12:15. We will look after your baby while you train and pump milk (and possibly shower). You will collect the other milk samples yourself, at specific times.

Since diet has an impact on the composition of breast milk, we will ask you to eat the same food the night before the test days and for breakfast and lunch on all three test days. This is done by recording everything you eat and drink during the first testing in a food diary. It will also be an advantage if you take pictures of your meals and save them, so that it will be easier to repeat during the next test round.

POSSIBLE ADVANTAGES AND DISADVANTAGES

The benefits you will gain by joining this project are that you will have your physical fitness (endurance) and body composition measured. We cannot see that the project entails any disadvantages for you, beyond the time spent participating and any discomfort when pumping milk.

VOLUNTARY PARTICIPATION AND POSSIBILITY TO WITHDRAW YOUR CONSENT

Participation in the project is voluntary. If you wish to participate, please sign the consent form on the last page. You may withdraw your consent at any time without giving any reason. There will be no negative consequences for you if you do not wish to participate or later choose to withdraw. If you withdraw your consent, your information and biological material will not be used for research. You may request access to the information stored about you, which will then be provided within 30 days. You may also request that your information in the project be deleted and that the biological material (milk samples) be destroyed.

The right to request destruction, deletion or disclosure does not apply if the material or information has been anonymized or published. This right may also be limited if the information has been included in analyses performed.

If you later wish to withdraw or have questions about the project, you can contact the project manager (see contact information on the last page).

WHAT HAPPENS TO YOUR INFORMATION?

The information registered about you will only be used as described above in the purpose of the project section and is planned to be used until 2029. Any extensions for use and retention of information can only take place after approval from REK and other relevant authorities. You have the right to access the information that is registered about you and the right to have any errors in the information that is registered corrected. You also have the right to access security measures when processing the information. You can complain about the processing of your information to the Norwegian Data Protection Authority and the institution's privacy officer.

All information will be processed without name and personal identification number or other directly identifiable information (= coded information). A code links you to your information through a list of names. Only project manager Trine Moholdt, doctoral fellows Mäeliss Lemoine and Emily Rose Ashby, medical student Rebecca Holm, and project staff member Guro Rosvold have access to this list.

After the research project is completed, your information will be kept for five years for control purposes.

INFORMATION SHARING AND TRANSFER ABROAD

By participating in the project, you also agree that coded milk samples may be transferred abroad as part of research collaboration and publication in line with the purpose stated at the beginning. We plan to send milk samples to the USA for analysis, which means that they will be sent to countries with laws that do not satisfy European data protection legislation. NTNU is responsible for ensuring that the transfer of information is in accordance with Norwegian law and the EU's data protection legislation (GDPR). The code that links you to your

personal identifiable information will not be disclosed. As part of making research more open, we also want to share the analysis results openly with other researchers. This sharing will be de-identified. You can choose whether you want to consent to your data being included in such open sharing on the consent form on the last page.

WHAT HAPPENS TO SAMPLES TAKEN FROM YOU?

The samples taken from you will be stored in a research biobank associated with the project. The milk samples will be stored in a biobank. They will be physically stored in a freezer located in the Emergency Department, Heart and Lung Center at St. Olavs Hospital. The person responsible for this biobank is Trine Moholdt.

The biobank will cease at the end of the project.

Since there are some analysis methods that we do not have sufficient access to in Norway, we will send samples taken in the project to other countries for analysis. In this project, it is most relevant to send the samples to the USA. The material sent will be deidentified and the material will be destroyed after the analyses have been completed.

INSURANCE

The participants in the project are covered by the Patient Injuries Act.

ECONOMY

The project is funded by the European Research Council. Participants in the project will not receive any remuneration but will receive an electric breast pump worth approximately 1200, - which they can keep after the project ends. There are no conflicts of interest for the project leader or project staff.

APPROVALS

The Regional Committee for Medical and Health Research Ethics has conducted a research ethics assessment and approved the project. The case number at REK is 562012.

NTNU and project manager, Trine Moholdt, are responsible for the privacy of the project.

We process the information based on informed consent.

CONTACT INFORMATION

If you have any questions about the project, experience any adverse events or side effects, or wish to withdraw from participation, please contact Trine Moholdt, by phone 97098594 or via email trine.moholdt@ntnu.no.

If you have any questions about privacy in the project, please contact the data protection officer at the institution: thomas.helgesen@ntnu.no.

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I AGREE TO PARTICIPATE IN THE PROJECT AND TO THE USE OF MY AND MY CHILD'S PERSONAL INFORMATION AND BIOLOGICAL MATERIAL AS DESCRIBED

Please check one of the two boxes below:

I agree to my data being included in the open sharing of analysis results ☐

I do NOT agree to my data being included in the open sharing of analysis results ☐

Place and date

Participant's signature

Participant's printed name in capital letters