INFORMED CONSENT OF THE PARTICIPANT

Latvijas
Biozinātņu un tehnoloģiju
universitāte

We invite you to participate in a study on the analysis of the polar lipid composition of buttermilk and their effect on the blood lipid profile

Objectives of the study:

1. to analyse the factors influencing the composition and content of polar lipids in milk;
2. to determine polar lipids in milk and its processed products;
3. to assess the effect of buttermilk polar lipids on plasma lipids.

Background to the study:

Hormonal changes in a woman's life cycle affect her lipid profile. The transition from childbearing age to menopause occurs most frequently between 45-55 years when low-density lipoprotein cholesterol (LDL-C) levels increase by an average of 2 mg/dL (0.11 mmol/L) per year. At the same time, ageing is associated with an increase in total cholesterol (TC) and triglycerides (TG) and a decrease in high-density lipoprotein cholesterol (HDL-C). These changes in the lipid profile increase the risk of cardiovascular disease (CVDs), which is the leading cause of death in Europe and Latvia. Buttermilk is a by-product of milk processing, produced by butter-making, and rich in polar lipids. Animal studies have shown that sphingolipids lower cholesterol, but in vivo studies are lacking. Consumption of buttermilk may reduce plasma cholesterol concentrations by inhibiting its bioavailability in the intestine.

Benefits of the study:

You will have the opportunity to gain insight into your diet's nutrient supply and get a blood lipid profile. At a societal level, the potential benefit of your participation in the study will be identifying the role of buttermilk intake in CVDs prevention.

Study risks:

The study involves collecting venous blood samples for the following parameters: TC, LDL-C, HDL-C, TG, alanine aminotransferase (ALT) and glucose. Venous puncture is one of the most common invasive medical procedures medical staff perform in the laboratory or its branches. The most common risks associated with venipuncture during blood sampling are haematoma and pain at the puncture site. Much less common risks are infection, bleeding from the puncture site, hypotension, loss of consciousness and fainting, phlebitis, nerve damage, haemoconcentration, arterial puncture, petechiae, allergic reaction to disinfectant solution, latex, fear and phobia of needle stick, blood, swelling at the puncture site, thrombosis.

Your participation:

Your participation in the study involves completing a questionnaire, food diaries, and blood tests and possibly consuming buttermilk regularly during the study.

Contact details in case of questions or queries:
Svetlana Aleksejeva,s.aleksejeva@gmail.com , tel. 29422183

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Right to refuse or terminate participation in the study:
Participation in the study is voluntary. You may withdraw from the study at any time.

Inclusion criteria:

- reside in Latvia;
- women;
- perimenopause symptoms (with vasomotor symptoms (hot flushes, night sweats) and infrequent periods);
- 45-55 years;
- moderately elevated LDL-C (3.01-4.12 mmol L^{-1}) within the last 6 months;
- stable body weight (+/- 2 kg) in the previous 6 months.

Study exclusion criteria:

- noncompliance with the inclusion criteria;
- history of primary hyperlipidemia;
- CVDs (ischemic heart disease, myocardial infarction, stroke, history of chronic heart failure, angina pectoris, arrhythmia);
- endocrine diseases (type 1 or type 2 diabetes mellitus, thyroid pathology (hypothyroidism, hyperthyroidism), adrenal disease (Cushing's syndrome, secondary renal failure));
- liver diseases (non-alcoholic fatty liver disease (NATAS), alcoholic fatty liver disease (ATAS), hepatitis, cirrhosis, chronic liver failure); chronic kidney disease; history of gastrointestinal surgery;
- hormonal therapy;
- immunosuppressive therapy;
- pharmacological treatment of hyperlipidemia or hypertension therapy (drugs, food supplements).

Study design:
Before starting the study, a researcher will contact you, who will explain the research and ask you to sign an informed consent form. You can only participate in the study after signing the informed consent form.
Before starting the study, you will be asked to fill in a questionnaire with the researcher with general questions on demographics, dietary habits, smoking, drinking and physical activity habits, and health status. In addition, you will be asked to complete a 24-hour diet diary with the researcher, in which you will need to record everything you have eaten for the previous day.
At the start of the study, you will be asked to complete a food diary, which asks you to record everything you eat over 72 hours, and a food frequency questionnaire.
Data from the 24-hour diet diary, 72-hour diet diary and food frequency questionnaire will be used to analyse your dietary data. The questionnaires will be anonymised, and you will be given a unique code, which will be indicated on the informed consent form, the study questionnaire, and the diet diary.
At the start of the study, you must have blood tests to determine your TC, LDL-C, HDL-C, TG, ALT and glucose. Blood sample collection will be possible at an accredited laboratory, which

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will be contracted, and locations and possible collection times will be communicated to you by the researcher.
After the blood test, your participation in the study can begin, which will last for 28 days. If you are in the control group, you will not need additional dietary changes during this period. However, participants in the intervention group will be required to consume the recommended amount of buttermilk the researchers provided daily for 28 days. You will be told more about the product at your first appointment.
You will automatically receive reminders to take your buttermilk if you are in the intervention group.
Throughout the study, you can contact the researcher with any questions.
At the end of the study, you will need a repeat blood test to determine the following parameters: TC, LDL-C, HDL-C, TG, ALT, and glucose. The blood sample will be collected from an accredited laboratory, which will be contracted. The researcher will communicate locations and possible times to you.

Ethical considerations and data protection:
The permission of the Ethics Committee of Riga Stradiņš University will be obtained before the start of the study.
The research will follow the guidelines of the Declaration of Helsinki and the Convention for the Protection of Human Rights and Dignity of Human Beings in Biology and Medicine, as well as other laws and regulations, taking precautions to avoid harm to human subjects. Your privacy rights during the study will be safeguarded following the General Data Protection Regulation (Regulation No 2016/679 of the European Parliament and the Council) and the Law on the Processing of Personal Data of the Republic of Latvia.
The study's data will be kept entirely confidential and accessible only to the closed research team associated with it. Data processing and storage will be carried out according to the requirements of the legislation on the protection of natural persons in the processing of personal data. Throughout the study, data from identifiable individuals will be processed as necessary to unambiguously identify dietary questionnaire data and laboratory analysis results.

Study researchers:
The research will be carried out by Mg. sc. sal. Svetlana Aleksejeva Dr. sc. ing, prof. Inga Ciproviča and Dr. med., asoc. prof. Laila Meija.

I have read the information above. I have been briefed on the purpose and process of the study. I have had the opportunity to ask questions and have received answers. I have been informed that I can withdraw from the study at any time and that this will not affect my future medical care. I agree to participate in the study voluntarily.
By signing below, you confirm that you have read and understood the above information and agree to participate in the study to assess the functional properties of buttermilk.

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INFORMED CONSENT OF THE PARTICIPANT

Name, surname, and signature of the participant:

_____

Name, surname

____.____._____

Date (dd.mm.yyyy)

Researcher's name, signature:____*Svetlana Aleksejeva*_____

Name, surname

____.____._____

Date (dd.mm.yyyy)

This part of the consent form (page 5) should be handed over to the researcher.

The remainder of the consent form (pages 1-4) remains with the participant.

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By signing below, you confirm that you have read and understood the above information and agree to participate in the study to assess the functional properties of buttermilk.

Name, surname, signature of the participant:

_____
Name, surname

____.____._____
Date (dd.mm.yyyy)

Receipt of results
If you would like to receive the results of your dietary analysis, please provide your email address:

_____
e-mail (in block capitals)

Receiving reminders
If you will be part of a study group, please provide your telephone number to receive reminders about the product:

_____
phone number

To receive reminders, please tick your preferred app (you can tick more than one app):

☐ WhatsApp ☐ Telegram ☐ Text message

Researcher's name, signature: *Svetlana Aleksejeva* _____
Name, surname

____.____._____
Date (dd.mm.yyyy)

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