

**The effect of functional dairy products enriched with dietary fibers on human health  
and gut microbiota**

**Subject information and consent form**

**Number of the clinical trial application/approval: 2099/228**

**Project number: 2014-2020.4.02.19-0198**

**Approved by Human Research Ethical Committee of National Institute for Health  
Development**

**11.03.2020**

## Information

### **The effect of functional dairy products enriched with dietary fibers on human health and gut microbiota**

Name.....

ID code.....

CONTACT DATA e-mail: \_\_\_\_\_  
phone: \_\_\_\_\_

E-mail is used only to transmit survey-related information.

- ☐ I would like to get feedback about the test results
- ☐ Please send the results of the tests in encrypted e-mail to the address stated above.
- ☐ I do not want feedback on my test results.

This study is carried out by the Center of Food and Fermentation Technologies (TFTAK), Akadeemia 15A, Tallinn. Principal investigator is Madis Jaagura.

## **Background to the study**

The model milk product developed within the project is a unique fiber-rich product both on the Estonian market and in the Baltic Sea region. At present, there are a few dairy products on the market with a fiber content ranging from 2.6 to 3.5 g / 100 g containing mainly inulin isolated from chicory, i.e., only one specific fiber. This project aims to add 6 g / 100 g or 3 g per 100 kcal of fiber to various dairy products. Enriching products with both soluble and insoluble fibers, ensuring fiber diversity. This is very important to ensure the maximum beneficial effect to the diversity and general well-being of the gut microbiome.

## **Purpose of the study**

The first objective of this research project is to assess the suitability of various fibers and other health-promoting components for the production of innovative functional dairy products. The second objective is to develop fiber-enriched dairy products and assess the impact of these products on human health.

## **How you can contribute to the study**

### **The decision about the participation**

Your participation in this study is voluntary and you may terminate your participation in the study at any time. In the case of participation, a written consent has to be provided.

### **Protection of trial subject's rights**

This trial has been approved by the Human Research Ethical Committee of National Institute for Health Development. Anonymized data and samples will be stored indefinitely, but the status will be reviewed every five years to assess whether subsequent storage is reasonable and required. Conservation and maintenance of anonymized data and original samples is justified if sample quality for subsequent analysis or importance and potential usage for scientific research are preserved.

### **Results**

Results of this study will be used for scientific research, all the results will be made accessible to the public in generalized, aggregated form.

### **Benefits of the study and feedback to participants**

Participants are eligible for two free microbiome analyzes and blood tests, worth almost € 350. If agreed, participants will be provided with the results of both microbiome and blood tests in encrypted form. If the participant has any questions about the results of the microbiome analysis, physical advice will be provided either on-site at TFTAK or by e-mail. Please consult your family doctor or general practitioner regarding the blood test results. In our opinion, there are no risks associated with participating in the study.

### **Participant consent form**

All medical information concerning me will be treated as confidential. After signing the consent form the further use of personal data will take place on the basis of the participant code.

I have been informed that my participation in this study is voluntary. I may terminate my participation in the study at any time without giving reasons for my decision. Refusal to participate or subsequent withdrawal will not have any negative consequences for me. Upon termination, personalized data will be deleted. I have read the aims of the study and the content of the study has been explained to me. I consent to the processing of my personal data as described in this document. Data collected about me may only be published in a non-personalized form. If you have any additional questions, I know who I can contact from the Center of Food and Fermentation Technologies (TFTAK).

I agree to participate in the study "**The effect of functional dairy products enriched with dietary fibers on human health and gut microbiota**" and the processing of the study data in accordance with the General Data Protection Regulation and confirm this with my signature.

Date, month, year \_\_\_\_\_

Signature: \_\_\_\_\_

Name and signature of the person who provided the information and delivered the informed consent form to the participant:

\_\_\_\_\_

**In the case of additional questions, please contact with:**

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