VIRTA / Intervention study

Cover letter – Informed consent

Date of the document 15.3 2020

Effects of 10 weeks of lifestyle coaching on cardiometabolic risk factors, workability and subjective wellbeing – a randomized controlled study

NCT ID not yet assigned

Study

Effects of 10 weeks of lifestyle coaching on cardiometabolic risk factors, workability and subjective wellbeing – a randomized controlled study

CONSENT TO PARTICIPATE

I have been asked to participate in a study evaluating the effect of lifestyle coaching on metabolic risk markers for chronic diseases, workability and subjective wellbeing. The study is conducted by Lääkärikeskus Aava Oy ("Aava") who partners with National Institute for Health and Welfare, Synlab Oy Finland (Synlab) and Nightingale Health Ltd ("Nightingale") for making blood analysis and Firstbeat Technologies Ltd ("Firstbeat") for heart rate variability analysis in the study. Research groups in universities and Finnish Institute of Occupational Health are also in the study analysing results.

In the study, data is gathered primarily from me in questionnaires and measurements (blood tests, heart rate test, physiological assessment). Data is also gathered from coaching sessions by the coach and from patient records within limits. I have understood that participating in the study allocates me to either 1) group making only the screening assessment in the beginning; 2) group receiving personal coaching; 3) group receiving group coaching; or 4) a control group for coaching receiving same measurements as in the coaching groups but no coaching. Allocation to the groups cannot be decided by myself.

Conducting the study and processing personal information in connection to the study complies with the Medical Research Act (1999/488) and the EU General Data Protection Regulation (2016/679). Aava receives all personal data in the study and pseudonymises it to the research database, which can be analysed by Aava's research partners without possibility for identifying a person. Firstbeat receives identifiable personal data necessary to carry out the heart rate analysis.

I have received, read and understood the following documents about the study: Recruitment advertisement, Information sheet, Research privacy policy. Based on these documents I have received an adequate clarification regarding the study and the collection, processing and disclosure of data in conjunction with the study. The content of the information sheet has been explained to me also orally and I have received a sufficient answer to all my questions relating to the study. I have been informed about my rights regarding the processing of my personal data and the means to use these rights. The information was given by _____ on __/__/ 20__. I have had sufficient time to consider my participation in the study.

For the study, it is necessary to collect and process information concerning my health, which is defined as sensitive data in accordance with the data protection legislation. I have been told where the information concerning me will be acquired from and purposes to use the data are described in more detail in the information sheet.

All the information collected about me during the study will be confidential.

I understand that my participation in this study is completely voluntary. I am also aware, that participating in the study does not bind me in any way and I have the right at any time to withdraw from the study without having to give any reason. My refusal to participate or withdrawal ***of consent*** from the study does not affect my subsequent medical treatment or care. If I withdraw my consent from the study, the information gathered until then will not be used as part of the study and will be destroyed.

With my signature I confirm my participation in this study and hereby consent to being a voluntary study subject and to processing of personal data described in the information sheet and research privacy policy.

_____ _____

Signature Date

_____ _____

Name in block letters Date of Birth

_____

Address

Consent received

_____ _____

Signature of the study personnel Date

_____

Name in block letters

The original signed consent and a copy of the information sheet will remain in the files of the study principal investigator. The information sheet, research privacy policy and a copy of the consent will be given to the study subject.