Consent form **Date April 17th 2024**

A 3-month lifestyle change program's impact on body composition, resting metabolic rate, health-related quality of life and diet

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Ethical approval: The Regional Committee for Medical and Health Research Ethics: 761798

WOULD YOU LIKE TO PARTICIPATE IN THE RESEARCH PROJECT

Weight reduction and lifestyle change on body composition, resting metabolic rate, health-related quality of life and diet in adults with overweight and obesity?

THE PURPOSE OF THE PROJECT AND WHY YOU ARE ASKED

This is a question for you to participate in a research project to map how weight reduction affects body composition (the composition of fat and muscle mass), metabolism, food intake and health-related quality of life. The purpose of the study is to map weight reduction for people with BMI ≥25 kg/m^2 for a period of three months (12 weeks) and after one year. We want to look at changes in body composition (muscle mass and fat mass), metabolism, diet and health-related quality of life from the time you start Kickstart, after three months and one year.

All participants at Kickstart who have a BMI of 25kg/m^2 or more will be asked to participate in the project. If you are one of the first 25 participants in the research project, you will be offered to participate in a substudy where you can measure your body composition with a device called Dual-Energy X-Ray Absorptiometry (DEXA), and measure your energy expenditure at rest (resting metabolism) with an indirect calorimetry. The measurement methods are safe and do not pose any risk to you. The measurements are carried out at the University of Oslo, and require two additional appointments that take about an hour each time. All participants in the study will also be invited to fill out questionnaires about diet and quality of life one year after the start.

WHAT DOES THE PROJECT MEAN FOR YOU?

If you choose to participate in the project, it means that health information about you will be collected from your Kickstart medical record. This includes information about your age, gender, weight, height, waist circumference, fat and muscle mass, and possibly some blood test results such as iron and vitamin D status. DEXA measurements will be taken at the start of Kickstart and at the end of the project, after three months. In addition, we would like to ask you if you would like to complete a questionnaire on health-related quality of life (RAND-36), which consists of questions about how you experience your health. The questionnaire consists of questions about physical function, pain, vitality, social function, whether you have experienced changes in your role due to physical or emotional challenges, and about your general physical

and mental health. You will also be asked to complete a questionnaire about your intake of different food groups (Digikost). Both questionnaires are validated and can be completed digitally on Kickstart. The questionnaires should be completed at Kickstart initiation, and after three months. In addition, you will be invited to complete the questionnaires after one year.

POTENTIAL ADVANTAGES AND DISADVANTAGES

The advantages of participating in the study are that you will contribute to increased knowledge about the effects of weight loss and lifestyle changes on muscle mass, metabolism and quality of life. This is important knowledge in public health work, i.e. the work to prevent lifestyle diseases in the population. Some of the participants will be offered free measurements of muscle mass and resting metabolism. This measurement usually costs 4,000 NOK. Measurement of muscle mass is done by a DXA examination, which involves you lying quietly on an open bench with normal clothing (without metal parts) for about seven minutes. The DXA machine produces a weak radiation, but the level is very low compared to a regular X-ray and more similar to what we are exposed to on a daily basis. You will also have to answer two digital questionnaires at the start of Kickstart, and at three months after start. One year after start, you will be invited to fill out the questionnaires again. This is done from home. Estimated time spent is approximately 20 minutes per questionnaire.

VOLUNTARY PARTICIPATION AND POSSIBILITY TO WITHDRAW YOUR CONSENT
Participation in the project is voluntary. If you wish to participate, sign the consent form on the last page. You can withdraw your consent at any time and without giving any reason. There will be no negative consequences for you or your follow-up at Kickstart if you do not wish to participate or later choose to withdraw. If you withdraw your consent, no further research will be conducted on your information and blood samples. You can request access to the information stored about you, which will then be provided within 30 days. You can also request that your information in the project be deleted and that the biological material be destroyed. The right to request destruction, deletion or provision 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 under the purpose of the project, and is planned to be used until 2028. Any extensions in use and storage period 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 the 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 Nima Wesseltoft-Rao has access to this list. After the research project is completed, the information about you will be stored for five years for control purposes. VID University of Applied Sciences 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 personally identifiable information will not be disclosed.

FOLLOW-UP PROJECT

If a follow-up project is relevant, participants will be contacted again. You can then say yes or no to participating in the follow-up project.

APPROVALS

The Regional Committee for Medical and Health Research Ethics has conducted a research ethics assessment and approved the project. Case number 761798. VID University College and project manager Nima Wesseltoft-Rao are responsible for the privacy of the project. We process the information based on your consent. On behalf of VID and the University of Oslo, Sikt – the Knowledge Sector's service provider has assessed that the processing of personal data in this project is in accordance with the privacy regulations.

CONTACT INFORMATION

If you have questions about the project, experience adverse events or side effects, or wish to withdraw from participation, you can contact Nima Wesseltoft-Rao. Telephone: 92851839. E-mail: nima.wesseltoft-rao@vid.no . If you have any questions about privacy in the project, you can contact the data protection officer at the institution: Email: personverntjenester@sikt.no or phone: 73 98 40 40.

I AGREE TO PARTICIPATE IN THE PROJECT AND TO HAVE MY PERSONAL INFORMATION AND BIOLOGICAL MATERIAL USED AS DESCRIBED

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