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RESPONSIBLE FOR THE STUDY

Research principal and data controller: Region SkånePrincipal investigator: Bengt Zöller, Specialist in General Medicine and Clinical Chemistry, Associate Professor in Internal Medicine. If you have any questions regarding the study, please contactAssociate Professor Bengt Zöller, Centre for Primary Care ResearchTel: 040 39 19 54E-mail: Bengt.Zoller@med.lu.seDoctoral student Peter NymbergTel: 070 57 59 810E-mail: peter.nymberg@med.lu.seOther participating researchersProfessor Kristina SundquistProfessor Jan SundquistAssociate Professor Eva Ekvall-HanssonPhD Emelie StenmanPhD Susanna Calling

Increased physical activity through Mindfulness for Prevention of cardiovascular disease

Hereby, you are asked to participate in a research study. The study is carried out by the Centre for Primary Health Care Research, and is approved by the Regional Ethical Review Board in Lund (2016/404) and by the head of operations at the health centre.

We target you between 40 and 65 years old and experience you as having a low level of physical activity

HOW DOES THE STUDY WORK?

For a week, you need to wear an accelerometer, which is a small apparatus that registers movement This must be discontinued at shower and bath. We also ask you to fill out various questionnaires concerning your health and heredityfor cardiovascular disease. Since then, You are welcome to come back one morning for sampling and measurements of height, weight, blood pressure and blood samples, 36 ml, from arm folds, regarding biomarkers. Before the sampling you must be fasting for at least 8 hours. The study contains three different intervention groups, You will be randomly allocated to one of the the three different groups. It is important that you come ***fasting until sampling. You will then receive a survey of lifestyle habits and heredity for cardiovascular disease during a visit to the district nurse. Any treatment and follow-up will be offered in consultation with your doctorGroups 1 and 2 will participate in group meetings 1 time per week*** for 8 weeks, as well as 20 minutes of daily mindfulness practice. Group 3 will receive a prescription for physical activity and train accordingly. Everyone participating in the study will be called back after 3 months for renewal measurements, questionnaires, as well as blood tests, about 36 ml, for follow-up of health parameters. For the evaluation, new measurement of activity with an accelerometer will also be needed. This procedure will be repeated after 6 and 12 months. POSSIBLE BENEFITSThe advantages of the research study are that we get to investigate whether there are better ways to counteract physical inactivity. You will receive an examination of your health. If it turns out that you need to see a doctor, this will be communicated. Regardless of which group you are drawn to, you will get help to increase your physical activity to improve your health. If the research study works well, the method can be introduced into everyday clinical practice at health centers.

POSSIBLE RISKS AND SIDE EFFECTSThe blood sampling in the study is carried out in the usual way and, as with all sampling, may cause some discomfort. Physical activity always involves a certain risk of pain and injuries such as muscle soreness or strains. Otherwise, research studies carry side effects or risks.

DATA MANAGEMENT & CONFIDENTIALAll survey results, apart from the frozen samples and questionnaires, will be obtained from the health centres' electronic health records and/or specific forms in which your personal data has been replaced with serial numbers. We only take part of information related to the risk assessment for cardiovascular disease, all data is handled confidentially. All information about you and your health is handled computerized under customary confidentiality in accordance with the Patient Data Act (2008:355) and the Personal Data Act (1998:204). Region Skåne is responsible for your personal data. Questionnaires and frozen samples will be marked with the same serial number as above. The serial number will be kept in the patient record. An identification list of personal data (including personal identity numbers) and serial numbers is stored at the Centre for Primary Health Care Research in a secure manner so that no unauthorised person can access it. Your answers and results will be processed so that no unauthorised persons can access them. The results of the study may be published in one or more reports and/or scientific journals. In such publications, your identity will NOT be revealed and the results will be presented at group level. HOW DO I GET INFORMATION ABOUT THE RESULTS OF THE STUDY? You can obtain your own individual data from your health centre. The overall results of the study will be published via scientific journals. INSURANCEIn case as a patient in Region Skåne, you are covered by patient injury insurance.

BIOBANK PROVERBThe swarm samples taken in connection with the visit will be frozen and stored in biobank department BD47, Wallenberg Laboratory floor 3, SUS, Malmö, a region linked by Skåne for analyses of molecules, including genes that may be associated with the prediction of cardiovascular disease. According to the Biobank Act (2002:297), biobank means "biological material from one or more people that is collected and preserved for an indefinite period of time and whose origin can be traced to the person or people from whom the material originates". You can read more about how biobanks work at

www.rbcsyd.se

The blood tests are coded, i.e. they are NOT marked with a given name or social security number. They can only be attributed directly to you with the help of an identification list. The retention of the identifier list is described under the heading Data and privacy management below. Proceeds will be stored in locked freezers at the Centre for Primary Health Care Research premises, where only authorised staff have access. The samples may only be used in the way you have consented to. The samples may be used for future, unplanned research. In that case, this will take place after new approval by the Ethical Review Board and new consent from you. It is completely voluntary to submit blood samples to a biobank and you have the right to have your sample removed at any time without this affecting your treatment and care. If you wish to do this or have questions about the biobank, please contact AnnaHedelius, biomedical analyst at the Centre for Primary Care Research, tel; 040 3314 73; e-post;anna.hedelius@med.lu.se

You are hereby asked to participate in a research study. The study, which is being carried out by the Centre for Primary Health Care Research, has been approved by the Regional Ethical Review Board in Lund and by the head of operations at the health centre. Please read this information carefully before you decide to participate. Feel free to ask us questions about ambiguities. Cardiovascular disease is the leading cause of illness and premature death. The risk factors are the same all over the world: too little exercise, poor diet, smoking, large waist circumference, high blood lipids, high alcohol intake and psychosocial health. Between 2016 and 2018, this project aims to investigate whether mindfulness can further enhance the motivation to be physically active compared to physical activity on prescription. It is about an addition to regular conversation therapy increased motivation. The project is aimed at those who need to move more. The project will involve different health centres in Skåne and is aimed at people aged between 40 and 65. At the same time, we want to investigate the relationship between physical activity, self-rated health and biomarkers in the blood. Biomarkers are substances (genes, proteins, enzymes) that can be objectively measured, and when detected or exceed a certain metric, can constitute an indicator of normal biological or pathological processes.

VOLUNTARINESSThe participation in the study is completely voluntary and even if you refrain from taking your care, your care will not be affected. In the event of participation, you have the right to cancel participation at any time, without special explanation. Stopping the study will not in any way affect your usual care. You also have the right to request that the blood samples in the biobank and/or the answers to the questionnaires be destroyed/deleted or labelled so that they cannot be traced to you in any way.

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Increased physical activity through mindfulness for the prevention of cardiovascular disease

Patient ID number:

Consent

I have been verbally informed about the study. I have also taken part of written information and had the opportunity to ask questions and received answers to these. I agree to participate in the physical activity study and know that my participation is completely voluntary and that I can at any time and without further explanation cancel my participation and request that the blood samples in the biobank and/or the answers in the questionnaires be destroyed/deleted or marked so that they cannot be traced to me in any way (this will not in any way affect my usual care). I allow information regarding my risk of suffering from cardiovascular disease to be obtained from the health center's patient record system. I allow the collected and coded data to be stored and processed by the researchers and healthcare providers participating in the study in accordance with applicable laws and permits. I am informed that an identification list with personal data (including social security number) and serial number is stored at the Centre for Primary Health Care Research in a secure manner so that no unauthorized person can access it. I consent to blood samples being saved in a biobank and handled for current and possible future analyses. If the samples will be used for future, unplanned research, this will be done after new approval by the Ethical Review Board and my written approval. I have also been informed about and agree that Swedish authorities and the person who performs quality control of the study may compare the information reported in the study with those in my patient record. This may be done on the condition that the information that becomes available is not passed on without maintaining customary confidentiality.

Signature of the participant | Datum (åå-mm-dd) | Name clarification

I have given you information about the study

Signature of the person who Informed

Datum (åå-mm-dd)

Name clarification

To be archived!! A copy for the research subject.