ExeHeart Patient Consent Form

Diakonhjemmet Sykehus

INFORMED CONSENT FORM FOR THE RESEARCH PROJECT

ExeHeart- IMPROVED CARDIOVACULAR HEALTH FOR PATIENTS WITH INFLAMMATORY JOINT DISEASE

This is an invitation to participate in a research study where the purpose is to investigate measures that can improve cardiovascular health management for patients presenting with inflammatory joint disease.

Patients with inflammatory joint disease have an increased risk of cardiovascular disease. Despite this knowledge, cardiovascular disease is underdiagnosed and undertreated in this patient group. Reduced physical fitness (VO2peak) is a strong and modifiable (something that can be changed) risk factor for future cardiovascular disease. High-intensity exercise can increase physical fitness and potentially prevent cardiovascular disease, as well as promote quality of life and coping without harmful side effects.

The purpose of this study is to investigate the association and effect of high-intensity interval exercise on physical fitness (VO2peak), cardiovascular health and disease activity in patients with inflammatory joint disease. The exercise will be supervised by physiotherapists in primary care and we aim to assess if patients and physiotherapists are able to complete the exercise program in accordance with the protocol. Furthermore, we will investigate whether a simple fitness calculator is suitable to detect change in physical fitness. Additionally, some participants will be invited to participate in interviews focusing on individual experience in participating in the study and exercise program.

Results from the study can provide valuable information regarding the effect of exercise on cardiovascular disease risk factors risk factors in patients with inflammatory joint disease and whether this mode of exercise is feasible in a primary health care setting. Furthermore, exploring the validity of the fitness calculator may impact how fitness calculators can be used in clinical practice.

We invite you to participate in the project should you meet the following criteria: You have an inflammatory joint disease (rheumatic disease) that has been diagnosed by a physician. Additionally, you are 18-70 years old and speak Norwegian or English. Furthermore, you must be able to walk continuously for 15 minutes or more. You cannot have sustained surgery or injuries to your legs / feet during the last 12 months. You can't participate if you have a neurological disease or a cardiovascular disease where exercise at maximum effort is discouraged. Should you already exercise regularly high intensity regularly (once a week or more) and have been doing so for the past three months, you will not be able to participate in the study.

Diakonhjemmet hospital is the responsible institution for the study.

WHAT DOES PARTICIPATION ENTAIL?

If you consent to participate in the study, you will be invited to three individual consultations at Diakonhjemmet hospital over the course of 6 months. After the first consultation, you will be randomly allocated to the exercise group or the control group. If you are allocated to the exercise group, you will have the opportunity to exercise two times per week for 12 weeks with supervision from a physiotherapist at a primary care clinic in the municipality of Oslo. Furthermore, after the first four weeks, we recommend you to include an additional non-supervised weekly exercise session. The exercise program will be individually tailored and will include endurance exercise at an intensity where you will be out of breath and perspiring. Duration of workout sessions is roughly 45 minutes including warm-up and cool-down. The exercise sessions are designed as interval training - that is, you alternate between bouts of high intensity for 3-4 minutes interspaced with bouts if low intensity for 2-3 minutes. The exercise may be done on a bicycle, elliptical machine, walking uphill or jogging / running.

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If you are allocated to the control group, you will receive standard treatment and follow-up at Diakonhjemmet hospital. Additionally, you will be offered a guided exercise session with a physiotherapist after your 6-month follow-up session. Regardless of group allocation, you will continue with regular follow-up at the Rheumatology outpatient clinic and the Preventive Cardio-Rheuma clinic.

Study procedures at the start of the study:

As part of the first study consultation at Diakonhjemmet hospital, information will be obtained from your recent examination at the Preventive Cardio-Rheuma clinic. This includes information from your medical record regarding a questionnaire on cardiovascular disease risk factors, blood samples and clinical examinations (ECG, blood pressure, measurement of arterial stiffness and ultrasound of the carotid arteries).

Furthermore, you will be asked to complete:

Questionnaire regarding personal information (age, gender, education, work, marital status), exercise habits as well as barriers and facilitators to physical activity. You will be asked questions regarding use of healthcare services, medication, pain, fatigue, disease activity, disease duration, physical function, psychological function and coping. We estimate that you will spend approx. 10-15 minutes to answer the questionnaires.

Measure of disease activity where we register tender and swollen joints.

Measurement of weight, height, waist circumference and body composition.

Resting heart rate that you measure in the morning prior to your consultation. Resting heart rate will also be measured during the consultation at Diakonhjemmet hospital.

Lung function and physical fitness (VO2peak) - CPET
First, you will be asked to perform tests of pulmonary function/breathing tests (spirometry) to measure the amount of air you can breathe in and out of your lungs, as well as how fast you can the blow the air out of your lungs. Next, you are asked to talk on the treadmill with gradual increase of speed and inclination until you reach exhaustion. This test usually takes 8-12 minutes. You breathe through a mask attached to a device that allows us to collect information on your level of exertion. Electrodes attached to the skin on your chest allows us to measure the electrical activity of your heart during the treadmill test. A blood pressure monitor connected is connected to one arm and blood pressure is measured at regular intervals during the treadmill test. After completing the treadmill test, a small blood sample will be taken from the pulpa of one finger to assess the level of lactate (lactic acid) in your blood.

You are asked to refrain from all demanding physical activity (exercise) and alcohol the last 48 hours before the treadmill test. Caffeinated beverages and nicotine can be consumed up to four hours before the test. You are asked to refrain from eating the last two hours leading up to the treadmill test, but you may drink water.

Study procedures at 12 weeks and 6 months:

At 12-week and 6-month follow-up, you will be asked to take blood samples at Diakonhjemmet hospital prior to the clinical consultation.

Furthermore, you are invited to complete the same examinations (disease activity, measurements of weight, height and waist circumference, body composition, resting heart rate, blood pressure, arterial stiffness and test of physical fitness / CPET) and answer the same questionnaire as at the start of the study .

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After completing the exercise training, participants in the exercise group will be forwarded a questionnaire with questions on how the exercise was carried out and how the individual participant experienced the exercise program.

We will conduct interviews with some of the participants in the exercise group. The purpose of the interviews is to examine possible barriers and facilitators to implementation of the exercise program. The duration of interviews is estimated to 45-60 minutes and the interviews will be done face-to-face or as a video consultation.

All information will be de-identified and treated confidentially. Only those involved in the project will have access to the information. Master students affiliated to the project will be able to access data through the Data Processor Agreement at Diakonhjemmet Hospital.

BENEFITS AND RISKS

Many individuals want to assess their physical fitness with tests that we use in this research project. Should you consent to participate, you will receive information regarding your physical fitness and how your individual fitness compares to reference values from a healthy population. This may help you in your future motivation for exercise. Participating in the study will entail time and attention on your part. Physical fitness tests involve walking/running to a level of exhaustion and will and will be perceived as physically strenuous. The blood sample taken from a finger after completing the fitness test will be experienced as a small sting. If you are allocated to the exercise group, you will receive supervised training from a physiotherapist for 12 weeks. If you are allocated to the control group, you will be offered an individual consultation with a physiotherapist after completing all study visits.

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VOLUNTARY PARTICIPATION

Participation in the study is voluntary. Should you choose to participate, please sign the declaration of consent on the last page. You can withdraw your consent at any time without giving any reason. This will not have any consequences for your further treatment. If you withdraw from the project, you can request that all your collected data and information be deleted, unless the information has already been included in data analysis or used in scientific publications. Project managers are Professor Hanne Dagfinrud and senior researcher Anne Therese Tveter. Contact information for withdrawal of consent or any other questions regarding the project:

Principal investigator and PhD fellow Kristine Røren Nordén, email: kristineroren.norden@diakonsyk.no, tel: 92043801.

Senior researcher Anne Therese Tveter, email: annetherese.tveter@diakonsyk.no, tel: 91115550

CONFIDENTIALITY

All collected data and information may only be used as described in the purpose of the study. You have the right to access the information that is registered about you and to have any errors in the information corrected.

All information will be processed without name and birth number or other identifiable information. A code list links you to your information by a name list. Everyone that has access to study files have a duty of confidentiality. Study results will be published in international, peer-reviewed journals. All data will be anonymized and no study participants will be identifiable in the published results. You will be forwarded the articles at your request.

The project manager is responsible for the day-to-day running of the study and oversees that all information and data are processed in a secure manner. The information registered about you should only be used as described in purpose of the project, and may be used until 2029. Any time extensions for use and storage can only take place after approval from the regional ethics committee and other relevant authorities.

INSURANCE

Participants in the study are insured through the Patient Injuries Act.

APPROVAL

The project has been approved by the Regional Committee for Medical and Health Research Ethics, REK ref. No. 201227.

CONSENT TO PARTICIPATION IN THE PROJECT

If you consent to participate in the project, we ask you to sign and enter the telephone number on the enclosed consent form.

I CONSENT TO PARTICIPATE IN THE PROJECT

I have read the information letter and consent to participate in the research project.

Signature: **Place and date:**

First name (block letters): **Surname (block letters):**

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Mobile phone number:

E-mail address:

☐ I consent to be contacted for participation in the interview after completing the training intervention. (You can participate in ExeHeart even if you do not participate in the interviews)

I confirm that I have provided information about the project

Place and date

Signature

Project affiliation