Cover Page for ClinicalTrials.gov

Document:
Informed Consent Form

Official Study Title:
Physical Activity as Adjunct Treatment for Opioid Substitution Therapy

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INFORMED CONSENT FORM FOR RESEARCH PROJECT

PHYSICAL ACTIVITY AS ADJUNCT TREATMENT FOR OPIOID SUBSTITUTION THERAPY

BACKGROUND AND PURPOSE

You are being invited to participate in a research project to investigate the effect of exercise on physical and mental health. The purpose of this project is to investigate the physical form of patients in opioid substitution treatment, whether exercise will improve their physical health, and the effect on the patient's mental health and cognitive functioning. The goal is better form, health and quality of life, as well as affecting the treatment options given to patients.

You are invited to participate in this study because you are in opioid substitution treatment administered by Haukeland University Hospital and because you have experience, knowledge and views that can shed light on this topic.

WHAT DOES PARTICIPATION ENTAIL?

If you are willing to participate in the study, you will undergo various PC-based tests that deal with psychological, physical and mental conditions. We will ask quite detailed about symptoms of various mental and social issues. The tests will take approx. 2-3 hours to carry out, with breaks along the way. In addition, we will measure your endurance, strength and balance. These tests will be conducted at Solli DPS and last approx. 30 min. All tests will be carried out at baseline and after three and six months.

The participants will be randomly divided into two groups. Randomization means that you are put into a group by chance. There is no way to predict which group you will be assigned to. One group starts with exercise immediately, while the other starts after a three-months waiting period.

If you decide to participate, you will be assigned a training contact. Together you will create a training plan that goes over 12 weeks, with two or three sessions per week. You agree to meet at scheduled times for the exercise sessions, to notify your training contact well in advance if you are unable to meet at the agreed time, and to not meet intoxicated or with withdrawal symptoms.
We will also call you/send you a message every two weeks to get a picture of substance abuse and exercise activity.

POSSIBLE BENEFITS AND DISADVANTAGES

There is no particular risk for you to participate. Questions about mental and social conditions can be perceived as incommodious, but our experience is that most people consider it positive to tell us about their situation and to try different tests to help develop new knowledge.

The physiological examination is not associated with discomfort beyond some physical exhaustion. The exercise also does not pose any particular risk to you. It will be tailored to your physical condition and training desire.

VOLUNTARY PARTICIPATION AND WITHDRAWAL OF CONSENT

Taking part in this study is voluntary. You may choose not to take part or may leave the study at any time without giving a reason. Deciding not to take part or deciding to leave the study later will not result in any penalty or any loss of benefits to which you are entitled. We will nevertheless ask for permission to use the data that was recorded before you withdrew. If you wish to participate, you sign the declaration of consent on the last page.

WHAT HAPPENS WITH YOUR INFORMATION?

Test results will be safely stored on a secure server and unauthorized persons will not have access. The results and all information about you will only be used as described in the intent of the study.

All information and test results will be anonymized. Only a code connects you to your data. This code is kept separate from the data itself. All information will be treated confidentially and will not be passed on. It will not be possible to identify individuals in the results of the study when published.

The project manager/main researcher is responsible for the daily operation of the research project and that information about you is handled in a secure manner. Your personal information will be deleted five years after the end of the project.

APPROVAL AND QUESTIONS

The project is approved by the Regional Committee for Medical and Health Research Ethics, REK Vest (2013/00731).

Questions can be addressed to:

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STATEMENT OF CONSENT

I WANT TO PARTICIPATE IN THE PROJECT

Based on the information I have received in writing and verbally, I volunteer to participate in the project. I am aware that the study lasts for 3 years and that the results will be published in scientific papers and form the basis for a doctoral degree at the University in Bergen.

I am informed that participation is voluntary and that I can withdraw from the study at any time – but that the information that was recorded before my withdrawal still can be included in the data material. I am award that the information I give is anonymized both in terms of storage and during production in scientific articles.

I also agree that the research team can try to establish contact with me via the information I have given below, including contacting relatives/friends if it is not possible to get hold of me via my ordinary mobile number.

Place and date

Participant's signature

Participant's name in printed letters

Mobile number: _____

Alternative mobile: _____

E-mail: _____

E-mail 2: _____

Address: _____

Next of kin/friend: _____