Invitation to participate in the research project:

"CLINICAL DECISION SUPPORT SYSTEM FOR PERSONALIZED TREATMENT IN PATIENTS WITH MUSCULOSKELETAL DISORDERS"

PURPOSE OF THE PROJECT AND WHY YOU ARE ASKED

This is an invitation to participate in a research project to investigate the treatment effect of a decision support system for physiotherapists and their patients in primary health care. You are asked to participate because you consult a physiotherapist in primary health care, and where your physiotherapist has asked you if NTNU can send you information about the study.

WHAT DOES THE PROJECT IMPLY FOR YOU?

This study examines whether using a decision support system in physiotherapy provides a better treatment effect compared to regular physiotherapy treatment. The decision support system will display anonymized information about previous successful patients with similar findings and symptoms as you, what treatment they received and their treatment outcome. By this you and your physiotherapist can together decide the best treatment for you based on knowledge of good treatment results in previous similar patients. This information will be used to refine or add components to usual care to improve the likelihood for successful treatment effect, and where suggested treatment methods and management procedures are part of current physiotherapy practice. Physiotherapists are randomly selected to be part of the group where the physiotherapist and you as patient have access to the decision support system (in addition to regular treatment) or to a control group where you as a patient receive usual care from your physiotherapist.

You will be asked to fill out a questionnaire about your background and state of health before you see the physiotherapist the first time. You will also receive a questionnaire electronically after 3, 6 and 12 months. Completing the questionnaire takes approx. 15 minutes each time. In the questionnaires, we ask about health conditions that may be important for your musculoskeletal disorders, such as your ability to function, pain symptoms, activity level, sleep, anxiety, depression, and ability to work. After 2, 4 and 8 weeks, you will also receive a link via text message with two to six short questions to investigate how you are doing. In addition, you and your physiotherapist will answer a few questions together at start-up and after 3 months. Results from the examination and the treatment given are registered by the physiotherapist. If you receive treatment by a physiotherapist in the control group, you must complete the same registrations as above, but you and your physiotherapist will not have access to the decision support system. Information about you will be included in the decision support system for new patients. The information will be anonymized so that you cannot be recognized. Some will be asked to participate in an interview to examine the usability of the decision support system.

For personal information, we will register your e-mail address and telephone number to send you the electronic questionnaires.

POSSIBLE BENEFITS AND DISADVANTAGES

Several of the questions you answer through the project is information your physiotherapist will usually obtain during your consultations. For the group where the physiotherapist and you as a patient have access to the decision support system, the physiotherapist will use information from the questionnaires to adjust your treatment. Filling out the questionnaires is not particularly difficult, and you will use approx. 15 minutes to fill in the questions at start-up before coming to your first consultation, and at 3, 6 and 12 months. The questions via SMS link will only take 1-2

minutes. Your participation in the project does not entail any disadvantages in relation to the treatment you otherwise would receive from your physiotherapist.

VOLUNTARY PARTICIPATION AND OPPORTUNITY TO WITH YOUR CONSENT

It is voluntary to participate in the project. If you want to participate, you tick the "agree" box at the end of this information sheet. You can withdraw your consent at any time and without giving any reason. It will not have any negative consequences for you or your treatment if you do not want to participate or later choose to withdraw. If you withdraw your consent, your health information will not be further researched. The right to demand destruction, deletion or extradition does not apply if the information is anonymized. This right can also be restricted if the information has already been included in completed analyses.

If you later want to withdraw or have questions about the project, you can contact the project manager (see contact information below).

WHAT HAPPENS TO THE INFORMATION ABOUT YOU?

The information registered about you should only be used as described under the purpose of the project. Any extensions in use and storage time can only take place after approval from the Regional Ethics Committee (REK) and other relevant authorities. You have the right to access the information that is registered about you and the right to have any erroneous information corrected. You also have the right to access security measures applied in handling and processing of your information. You can complain about the processing of your information to the Data Inspectorate and the institution's privacy representative or Ombud.

All information will be processed without name and birth number or other directly recognizable personal information (which is coded). A code connects you to your information through your mobile number. Only project manager Ottar Vasseljen or others approved by the project manager have access to this list.

We also want to be able to link your questionnaire data to public registers. Research on this data will be anonymized. Relevant registers are the Health Finance Administration (HELFO), registers in NAV, the Norwegian Neck and Back Register and the Norwegian Patient Register (NPR).

The information about you will be kept for five years after the end of the project for control reasons.

INSURANCE

You are insured through the Patient Injuries Act since you are a patient to a certified physiotherapist.

APPROVALS

The Regional Committee for Medical and Health Research Ethics has made a research ethics assessment and approved the project (case number 49308, approved 08.09.2020). NTNU and project manager Ottar Vasseljen are responsible for the privacy of the project. We process the information based on your consent.

CONTACT INFORMATION

If you have questions about the project or wish to withdraw from participation, you can contact project manager Ottar Vasseljen, tel. No. 73597521, email ottar.vasseljen@ntnu.no, or Ingebrigt Meisingset, tel. No. 73598901, email ingebrigt.meisingset@ntnu.no

If you have questions about privacy in the project, you can contact the privacy representative (Ombud) at the institution: thomas.helgesen@ntnu.no

I agree to participate in the project and that my personal information is used as described

□ I agree

□ I do not agree