INVITATION TO PARTICIPATE IN THE LAST-LONG PROJECT

This is an invitation to participate in a project on long term follow-up after stroke, the LAST-long project. The aim of LAST-long is to evaluate a new model for community-based long-term follow-up after stroke, and to investigate if this model improves health and function in the long term. You are being invited because you are living in one of the participating municipalities (Trondheim, Asker, Bærum, Lillestrøm, Lørenskog or Ålesund) and were admitted to one of the corresponding hospitals (Trondheim University Hospital, Akershus University Hospital, Bærum Hospital or Ålesund hospital) with the diagnosis of stroke about 3 months ago.

NTNU – The Norwegian University of Science and Technology, Department of Neuromedicine and Movement Science, is responsible for the project.

WHAT DOES PARTICIPATION IN THE PROJECT MEAN?

All participants in the project will receive standard care in line with local procedures and the Norwegian guidelines for treatment and rehabilitation after stroke. Half of the participants will be randomly selected for regular follow-up by a stroke-coordinator in their municipality. The selection is performed by a computer program.

If you are selected for closer follow-up, you will have regular meetings with the stroke-coordinator over a period of 18 months. The frequency of the meetings will vary somewhat depending on your needs, approximately once per month, and will take place either at your home or at the municipality’s locations. Some meetings can also take place by telephone. The coordinators have a background in the health professional sector survivors and have good knowledge of the various health services in the municipality, in addition to specific
knowledge of common challenges that can be experienced after a stroke. To be able to optimize the follow-up, the stroke-coordinator will receive relevant information about your health from your hospital record and from the tests that are carried out upon inclusion to the project. Furthermore, together with the coordinator, you will set up an action plan with treatment goals and relevant measures that are regularly assessed and adjusted.

Regardless of which group you are allocated to, we will collect and register information about your state of health, use of health services and how you experience your health and life situation. After 6, 12 and 18 months, you will be called in for a project control with examinations and questions about physical function, cognitive function, mental health, and medication use. A study assistant will help you fill in all the forms. Blood tests will be taken, and blood pressure, height and weight will be measured. Finally, you will have a small sensor attached to your thigh that measures physical activity over 7 days. The whole assessment takes approximately 2 hours. All assessments are voluntary, and you are free to refrain from specific unwanted procedures. If we discover any unusual results from the examinations, we will, in agreement with yourself, contact your general practitioner and arrange for you to receive further follow-up there. Your next-of-kin will also be asked how your stroke affects their everyday life. To ensure the quality of the study, it will be necessary to supplement our data with information from your patient record. Your consent to the study also gives consent to collect relevant information from your medical record. We also collect additional information from various health registers. The relevant registers are the Norwegian Stroke Register, the Norwegian Patient Register (NPR), the Municipal Patient and User Register (KPR) and the municipal record system, the Prescription Drug Register, the Cause of Death Register, Helfo (the Health Administration system) and NAV for information on work participation.

**POSSIBLE ADVANTAGES AND DISADVANTAGES**

All participants, regardless of the group they are allocated to, receive standard follow-up in their municipality. The intervention represents something new in the way the long-term follow-up after stroke is organized, primarily with a closer follow-up by the stroke-
Long term follow-up after stroke. The LAST-long project, 18th May 2021, version 6

coordinator in the primary health care setting. There is no additional risk and no financial burden associated with participating in the study and there is also no discomfort associated with carrying out the physical tests. By participating, you will spend time and attention on health and illness. This may give unnecessary focus and concern related to risk factors, but also an opportunity for early treatment and prevention.

**VOLUNTARY PARTICIPATION AND POSSIBILITY TO WITHDRAW**

Participation in the project is voluntary. If you wish to participate, you sign the declaration of consent on the last page. You can withdraw your consent at any time and without giving any reason. This will have no consequences for your further treatment. If you withdraw from the project, you can demand to have data that is already collected deleted, unless the data has already been included in analyzes or used in scientific publications. If you wish to withdraw or have questions about the project later on, you can contact NN.

**HOW IS YOUR DATA TREATED?**

The information recorded about you can 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 the right to have any errors in the registered information corrected.

All information will be processed without names and national identification numbers or other directly identifying information. A code links you to your information through a list of names.

The project manager is responsible for the running of the research project day-to-day and that information about you is processed securely. Information about you will be anonymized or deleted no later than five years after the end of the project.
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INSURANCE

All participants are insured through Norsk Pasientskadeerstatning.

DATA SHARING

Sharing data from research projects across different countries has proven to be useful for improving the treatment of stroke survivors. Such sharing of data may also be relevant for this project. By participating in the project, you therefore agree that de-identified information about your health and function can be shared with researchers in other EU/EEA countries, Australia, or the USA. These may be countries with laws that do not satisfy European privacy legislation. However, the code that links you to your personally identifiable information will not be disclosed.

FOLLOW-UP PROJECT

We may want to extend the follow-up period for the project to more than 18 months. You will be contacted and asked for another consent if that will be the case.

ETHICAL APPROVAL

The Regional Committee for Medical and Healthcare Research Ethics has approved the project [REC no 2018/1809].

According to the new personal data act, the Norwegian University of Science and Technology and project leader NN have an independent responsibility to ensure that the processing of your information has a legal basis. This project has a legal basis in the EU's general data protection regulation article 6a and article 9 no. 2 and your consent. You have the right to complain about the processing of your information to the Norwegian Data Protection Authority.
CONTACT INFORMATION

Please contact project leader NN if you have any further questions regarding the project.

You can contact the data protection officer at NTNU, NN if you have any questions regarding the administration of your personal data in the project.
I HEREBY CONSENT TO PARTICIPATE IN THE PROJECT AND THAT PERSONAL INFORMATION ABOUT MYSELF IS USED IN LINE WITH THE GIVEN INFORMATION

Place and date: ____________________________
Participant’s signature: _______________________

Participant’s name in capital letters

Please tick if you do not want to have blood tests: [ ]

I confirm that I have given oral and written information about the project:

(Signature, role in the project, date)