INTERNATIONAL INFORMATION TO PARTICIPATE IN THE AI-MIND PROJECT

Intelligent digital tools for screening of brain connectivity and dementia risk estimation in people affected by mild cognitive impairment

In this research project we will test and validate two medical tools based on advanced algorithm models (artificial intelligence; AI) where the purpose is to develop clinical decision-making tools to support future diagnostics and treatment for dementia and cognitive impairment. The tools that are planned to be developed can both be used to map the causes of illness and contribute to a more precise assessment of the risk for developing dementia in people who are affected by mild cognitive impairment. From research we know today that the first changes in the brain network start as early as 20 years before the dementia disease can be detected with today's diagnostic tools. Furthermore, we know from large international studies that simple lifestyle changes and medical intervention can stop or slow down the development of dementia, if the risk is identified early enough.

You may be asked to participate in this project if you are experiencing cognitive challenges, and your doctor has the opinion that you may be interested in participating.

Read the information about this study carefully: What does it involve, how is your data handled and what are your rights as a participant?

WHAT IS THE PROJECT ABOUT?

As a participant, you will follow the study protocol that forms the basis of the research project (AI-Mind study protocol) over a period of two years. This will take place in parallel with the ordinary medical follow-up you receive from the responsible health personnel and treatment institution. Specific to the study will be that you complete four sessions of electroencephalographic recording (EEG recording) and four sessions of digital cognitive testing on tablets. These are procedures that are currently part of standard medical assessment. In addition, we will perform blood sampling for genetic testing (APOE allele) and protein analyzes (p-Tau 181/250) at your first visit. The APOE gene analysis will provide information about your gene variant, which is relevant for mapping your genetic predisposition. The protein assay levels will provide information on plasma protein levels of the p-Tau 181/250 protein, which may indicate a risk of developing future cognitive challenges.

Upon arrival, you will be met by one of our responsible researchers who will inform you about the various procedures in detail, as well as conduct a short interview about your background. The approximate time frame for the whole day is two hours at your first visit, which includes 15 minutes of interview, 10 minutes of EEG, 30 minutes of cognitive testing, 10 minutes of blood sampling. In addition, approximately 60 minutes of preparation and waiting time between procedures must be expected. The remaining three follow-up sessions over the next two years will be the same, with the exception of blood sampling, which will only be conducted at the first meeting.

Additional information that is collected in the research project is routine information from follow-up with your local doctor. This includes:

- A previous MRI scan of your head that was performed as part of the routine examination during an ordinary hospital visit. This image will also be used in the analysis of EEG.

• Test results from neuropsychological examination performed during your routine follow-up are obtained for comparison with the result of your digital cognitive test.

Information collected about you in the research project will be stored on a secure IT server approved by Oslo University Hospital as the responsible institution for the project.

FORESEEABLE BENEFITS AND PREDICTABLE RISKS AND BURDENS OF TAKING PART

As this is not an intervention study, no new medications or invasive procedures will be performed. The protocol follows standardised medical procedures, and we expect no significant burden with the exception of an additional 1-2 hours of time. In principle, you will be informed about all results of the project's data analyses. Your data is analysed exclusively at the group level. We will always deliver individual test results to you and your doctor. If you do not wish to receive your personal results after the project end, you need to actively inform us.

The benefits for the individual patient will, depending on the outcome of the study, potentially take effect after the end of the project period, in the form of inclusion in a new, improved clinical routine for individual patients.

VOLUNTARY PARTICIPATION AND THE POSSIBLITY TO WITHDRAW CONSENT

Your participation is always voluntary. If you want to participate, you must sign the national consent form. You can withdraw your consent at any time and for no reason. If you decide to withdraw your consent to the project, you can demand that the results of your tests and personal information be deleted, unless your data has already been analysed and used in scientific publications (this is completely anonymised). If you have questions regarding the project, you can contact either the national project manager (Ira Haraldsen, contact@aimind.eu, +47 920 11 533, Oslo University Hospital) or the responsible data protection officer (DPO) in Norway (Tor Åsmund Marthinsen, toamar@ous-hf.no, +47 23015022, Oslo University Hospital).

In case you and / or your doctor have serious concerns about your medical condition and participation in the research project, you or your doctor can inform us so that you can be removed from the study. You will then continue the regular doctor visits with your doctor and will not be invited to further research visits with us.

WHAT WILL HAPPEN TO YOUR PERSONAL DATA CONCERNING HEALTH?

The information collected about you in this research project will only be used as described in the purpose of this project. You have the right to access information registered about you, as well as to stipulate that any errors in your registered information to be corrected. You also have the right to know what security measures apply when your personal data is processed.

All information will be treated pseudonymously, and we will not use your name or personal identification number, or any other information that can directly identifying for you. A code sheet links you and your personal data. Only the national project manager and the national DPO have access to the key code.

All information about you will be completely anonymised five years after the project is completed.

SHARING AND DATA AND TRANSFER OF PERSONAL DATA

By participating in this study, you also agree that the information collected about you in this research project can be shared with collaborators abroad. The sharing and transferal of data will only take place with pseudonymised/deidentified data and the recipient will not have access to the code key described above. Sharing research data across national borders is important, and it is crucial to have access to large enough data sets for the development of such decision-making tools and algorithms described in the project.

All data will be shared through a high-security data server in Norway, which is subject to and follows the European Open Science Cloud initiatives. This is a solution that satisfies the requirements for data security in

accordance with the EU Privacy Regulation. At the same time, all data sharing and transmission will be subject to separate EU-approved agreements. The project management will also, in consultation with the hospital's Privacy Officer, ensure that your personal information is handled in accordance with European and national regulations.

WHAT WILL HAPPEN TO THE TESTS YOU HAVE TAKEN?

The samples will be stored in a research biobank ("AI-MIND Norway") at Oslo University Hospital. If you agree to participate in the study, you also agree that your sample is included in the biobank. Oslo University Hospital by Ira Haraldsen is responsible for the research biobank. The biobank will be closed five years after the end of the project in 2031, and the material will then be destroyed according to internal guidelines.

GENETIC TESTING

If you agree to participate in the research project, you also agree that genetic testing of the biological material collected from you can be done. The genetic testing performed in this study involves allele analysis of the APOE gene. These analyses include the classification of allele types, as different allele types and combinations are associated with different risk factors for dementia. The results of APOE allele analysis alone cannot determine a person's disease risk.

In the event that accidental findings of pathological significance are observed, we will contact your responsible physician and you will receive treatment in accordance with national guidelines in consultation with your regular therapist. The project management has considered it unlikely that any random findings will be uncovered that will provide a basis for contacting the responsible doctor.

INSURANCE

For this study, the national insurances are covered by the each national Patient Injuries Act and the Product Liability Act.

FOLLOW-UP PROJECT

If a follow-up project becomes relevant, you will be contacted again.

ADDITONAL MEASURES DURING THE COVID-19 PANDEMIC

Due to the Covid-19 pandemic, our clinical study will take the necessary actions to secure the safety of you as participant and our clinical staff. This study will follow the European guidelines for trial management during the Covid-19 *GUIDANCE ON THE MANAGEMENT OF CLINICAL TRIALS DURING THE COVID-19 (CORONAVIRUS) PANDEMIC*, *EU Commission, Apr. 2020* and *Points to consider on implications of Coronavirus disease (COVID-19) on methodological aspects of ongoing clinical trials*, *EMA/158330/2020 Rev. 1 3 Committee for Human Medicinal Products (CHMP).* In addition, we will follow all up-to-date national and institutional guidelines and regulations. For more information, please see the information letter provided by your national AI-Mind unit.

APPROVAL

The national Committees for Medical and Health Research Ethics have reviewed the Research project under the project identification number 204084 and approved 03.02.2021.

In accordance with the general data protection regulation (GDPR), Data Protection Officer Åsmund Marthinsen, Oslo University Hospital, Norway and the international project coordinator Dr. Ira Haraldsen are responsible for ensuring that all processing of your personal data is in accordance with current national and European regulations as mentioned above. You have the right to submit a complaint about the processing of your personal health information to Datatilsynet (Datatilsynet, postkasse@datatilsynet.no, 22 39 69 00, Postboks 458 Sentrum 0105 Oslo).

CONTACT INFORMATION

If you have questions regarding the AI-Mind research project, you can contact the local project coordinator, and or the international project coordinator, Ira Haraldsen, email contact@ai-mind.eu, Oslo University Hospital, 0402 Post box Nydalen Oslo, Norway].

You can also get in touch with the privacy officer at Oslo University Hospital if you have questions related to the use of your personal health information in the research project [toamar@ous-hf.no].