Date: 25.01-2023

WOULD YOU LIKE TO PARTICIPATE IN THE RESEARCH PROJECT

The Benefit of Nurses in Follow-up of Headache Patients The Purpose of the Project and Why You Are Being Asked Long waiting lists at neurological outpatient clinics often limit the possibilities for follow-up of headache patients, and typically, this would occur in collaboration with a general practitioner. By utilizing headache nurses, the capacity for follow-up in specialized healthcare can be improved. In this study, we aim to assess the benefit of headache nurses in the follow-up of headache patients. You are eligible for the study if you have been assessed at a neurological outpatient clinic and have been prescribed at least one preventive medicine for trial. You will be approached for participation in the study by qualified study personnel not involved in your treatment.

What Does the PROJECT Entail for You?

If you participate, you will be randomly assigned to one of two groups (A or B), where you are guaranteed at least one follow-up visit at the neurological outpatient clinic after approximately 3 months. You will be asked to keep a headache diary continuously throughout the period and answer some questions. If you end up in Group A after the randomization, you will be followed up by a headache nurse at the neurological outpatient clinic, where you will be contacted twice via phone or video consultation, and the concluding visit will take place after approximately 3 months in person. If you end up in Group B after the randomization, as is the current practice, you will not have fixed follow-up appointments, but you can contact the neurological outpatient clinic via contact-headache@ntnu.no or contact your general practitioner if you have questions. The concluding visit will take place at the neurological outpatient clinic after approximately 3 months.

Possible Advantages and Disadvantages

By participating in this study, you are guaranteed at least one follow-up visit. Through the registration in the headache diary, the effect of preventive treatment and any side effects will be assessed, and advice on potential treatment changes will be provided. One possible disadvantage is that you will be asked to keep a digital headache diary continuously for about 3 months.

Voluntary Participation and the Possibility to Withdraw Your Consent

Participation in the project is voluntary. If you wish to participate, you sign the consent form on the last page. You can withdraw your consent at any time without providing any reason by contacting contact-headache@ntnu.no via email or by calling your local neurological outpatient clinic. It will have no negative consequences

for you or your treatment if you choose not to participate or later decide to withdraw. If you withdraw your consent, your registered information will not be further researched. You can request access to the information stored about you by contacting contact-headache@ntnu.no via email. This information will be provided within 30 days. You can also request that your information in the project be deleted. The right to request destruction, deletion, or disclosure does not apply if the material or information is anonymized or published. If you later want to withdraw or have questions about the project, you can contact the project leader (see contact information on the last page).

What Happens to the INFORMATION About You?

The information recorded about you will only be used as described under the purpose of the project and is planned to be used by January 31, 2028. Any extensions in use and storage time can only occur after approval from the Regional Ethics Committee (REK) and other relevant authorities. You have the right to access which information is recorded about you and the right to have any errors in the recorded information corrected. You also have the right to access the security measures in the processing of the information. You can complain about the processing of your information to the Data Inspectorate and the institution's data protection officer. All information will be processed without names and social security numbers or other directly identifying information (=coded information). A code links you to your information through a name list. Only study personnel have access to this list. After the research project is completed, your information will be stored for five years for control purposes.

Insurance Participants in this study are insured under the Patient Injury Act.

Approvals

The Regional Committee for Medical and Health Research Ethics has conducted a research ethics assessment and approved the project (REK no. 554940). St. Olav's Hospital is responsible for privacy in the project. We process the information based on the EU General Data Protection Regulation Article 6 no. 1a and Article 9 no. 2a, your consent. You have the right to complain about the processing of your information to St. Olav's Hospital's data protection officer and the Data Inspectorate.

CONTACT INFORMATION

If you have questions about the study or want to withdraw from participation, you can contact via email at contact-headache@ntnu.no or contact your local neurological outpatient clinic. If you have questions about privacy in the project, you can contact the data protection officer at St. Olav's Hospital: personvernombudet@stolav.no

I CONSENT TO PARTICIPATE IN THE PROJECT AND TO HAVE MY PERSONAL INFORMATION USED AS DESCRIBED

Place and date: [Participant's Signature]

[Participant's Name in printed letters]

I confirm having provided information about the project.

Place and date: [Project Worker's Signature]