Prognostic Factors for Primary Headaches in Primary Care: A Prospective Cohort Study

Dear participant,

With this information letter, we would like to ask you to participate in our study. The Vrije Universiteit Amsterdam (VU) has set up this study. It is being conducted in collaboration with the University of Amsterdam (UvA).
In this letter you will receive an explanation of what the investigation entails. Here you can read what the purpose of the study is, what data we want to collect, how much time or effort the study requires of you and what the advantages and disadvantages are of participating in the study. Read this information carefully and ask the researcher for an explanation if you have any questions.

Once you have read the information carefully and asked any questions you may have, you can decide whether you want to participate in the study. Participation is voluntary. If you would like to participate, please complete the consent form attached.

1. What is the purpose of the research?

This study aims to identify the factors that influence the course of headaches in individuals with tension-type headaches and/or migraines.

2. Why are we conducting this research?

Tension-type headaches and migraines are the most common types of headaches. Despite the prevalence of these complaints, much remains unclear about the course of these types of headaches. One of the topics to know and understand more about are the factors that influence the course of headache. Therefore, this study aims to provide greater clarity on this subject, thereby better assisting individuals with tension-type headaches and migraines.

3. How does the research work?

Step 1: Are you eligible to participate ?

First, we would like to determine whether you are eligible to participate in the study.
That is why we are asking you a number of questions:

- Are you aged 18 and over,
- Do you have a presentation of primary headache (tension-type headache, migraine) for more than 4 weeks
- Are you able to read Dutch or English.

And further:

- Have you undergone neck or brain surgery?
- Do you have a systemic/autoimmune disorder?
- Do you have a central neurological disorder (e.g., stroke/brain hemorrhage, dementia, Parkinson's disease, and/or multiple sclerosis)?

If you answer “no” to the above three questions, you are eligible for this study. After reviewing the headache diary and meeting the inclusion criteria, you will be eligible to participate in the study.

Step 2: The nature and design of the study
The study consists of four measurements taken over a 12-month period. The first measurement consists of general questions about you, your headaches, and your health. In addition, questions will be asked about the following topics: psychosocial factors such as stress, anxiety, sleep, and work.
The next measurements will be taken after 3, 6, and 12 months. These follow-up measurements will include questions regarding your headaches, treatment, and your recovery. In the week before a follow-up measurement, you will receive an email reminder for this measurement. All measurements will be online. It allows you to choose a convenient time to complete the questionnaires.

4. What is expected of you?
You are expected to spend a total of approximately 2 hours of your own time completing all questionnaires (baseline and all follow-up measurements). The first baseline measurement will take 30-40 minutes of your time, and the follow-up measurements will take approximately 20 minutes each.

5. What are the possible advantages and disadvantages?
You will probably not benefit directly from participating in this study. However, your participation may contribute to increasing knowledge about the course of tension-type headaches and migraines. This information will help improve healthcare for people with tension-type headaches and/or migraines.

Disadvantages of participating in the study may include:

- Extra time required. This study requires a total time investment of approximately 2 hours.

6. What if you no longer want to participate or want to stop the study?

You decide whether to participate in the study. Participation is voluntary. If you decide not to participate, you do not need to do anything else. You do not have to sign anything, and you don't need to explain why you don't want to participate. If you do participate, you can always change your mind and withdraw , even during the study. The data collected up to that point will still be used for the study.

7. When is the study end for you?

Your participation in the study will end when all measurements are taken or when you have completed all questionnaires, if you choose to stop, or if the researchers think it is better for you to stop. The entire study is over when all participants have finished.

8. How is your data used, stored and processed?

What data is collected?

- Demographic data: information such as your email address, sex and age will be asked in this survey.
- Health information: your headache symptoms, general health, medication use, and sleeping habits will be assessed. In addition, psychological factors such as stress will be asked in this survey.

How do we protect your privacy?

We handle your personal data with care and secure it properly. In reports and publications about the research, no data that can be traced back to you will be included. Additionally, all employees involved in this study are required to maintain strict confidentiality.
To further protect your privacy, we replace your directly identifiable personal data with a code. The key linking your name to the code is stored separately in a secure location. When analysing the collected data, we only use that code. All your data remains confidential. Only the research team knows what code you have.

Who can see your data?

Researchers involved in the study can view and use your personal data to conduct the research. If these are researchers from different research institutions, clear agreements are made to ensure that your data is processed securely. Sometimes students or additional researchers also participate in the research. Agreements will also be made with them regarding the safe use of your data. Those who can view your data are required to keep it confidential.

Additionally, it is possible that the research or the scientific publications resulting from it may be subject to review. If access to the data is necessary for this purpose, agreements will be made to ensure that your data is processed securely. Those who can view your data are required to keep it confidential.

How long do we keep your data?

The researchers will retain your data for up to 10 years after the last publication related to the study.

In the attached privacy statement, you will find more information about how we process your personal data in this study.

Can we use your data for other research?

Your data may still be relevant for other scientific research in the field of headaches and its course. In the consent form, you can indicate whether you agree to the reuse of your data for other research. If you do not consent, you can still participate in this study.

9. Is there a fee for participating?

Participation in the study is free of charge. You will not be paid for participating in this study.

10. Ethics Review and Complaints

The research design has been assessed by the Scientific and Ethical Review Board of the Faculty of Behavioral and Movement Sciences, VU University Amsterdam, and complies with the Faculty's ethical guidelines. If you have any complaints, you can initially contact the researcher. If your complaint is not resolved, you can file a complaint via vcwe.fgb@vu.nl. If you have any questions about the privacy of your data, please contact *functionarisgegevensbescherming@vu.nl.*

11. Do you have any questions?

If you have any questions, please contact:

Principal investigator

Name: René Castien

Email: r.f.castien@vu.nl

Phone number: 0650231808

Executive investigator

Name: Tim Jongejans

Email: t.jongejans@student.vu.nl

Phone number: 0653119779

12. How do you give consent for this research?

You can take your time to think about participating in this study. Afterwards, you can tell the researcher whether you understand the information and whether you would like to participate. If you agree to participate, please fill out the consent form. You will receive the consent form by email after registering using the registration form on the website.