

Invitation for HELIUS study on brain health

You are participating in the HELIUS study. You have indicated that we may invite you for additional research.

Do you want to participate in the HELIUS study on brain health?



The aim of the study is to investigate brain health in people over the age of 50.

The brain is essential. It is needed in order to think, move and make memories. With this study, we want to investigate the brain health of people with different backgrounds. We also want to know what influence your lifestyle and environment have on brain health.



The study takes 60-90 minutes, during which you will complete questionnaires and perform tasks.

You do this together with a researcher who speaks your own language. The study will take place at your home or at a location near you. During the visit:

1. We will first ask for your consent. An example of the consent form is included with this letter.
2. You will do a number of tasks. These involve memory, language, and carrying out everyday activities. This helps us understand how thinking and doing work in different people. We won't do any brain scans or blood tests.
3. You complete 3 questionnaires. These are about mood, memory and daily life.



Do you participate?

Then send the completed answer form to us. You can also send an e-mail to helius-hersengezondheid@amsterdamumc.nl. Do you not want to participate? Please let us know too. You decide for yourself whether you will participate. Participation is voluntary and without cost. If you participate, you can always change your mind and stop at any time. You do not have to say why you stopped. The researchers will use the data collected up to the moment when you stopped.



Questions?

If you have any further questions, please send an e-mail to helius-hersengezondheid@amsterdamumc.nl or call the HELIUS secretariat. On our website www.heliusstudie.nl you can read more about the HELIUS study.

We hope you will participate!

Prof. Max Nieuwdorp and Prof. Eric Moll van Charante

Principal investigators HELIUS

Additional information about the HELIUS study on brain health

Participating in the study can have advantages and disadvantages. We list these below. Think about this carefully, and talk about it with others.

Pros: By participating in the study, you can learn more about brain health and the tasks of the brain in daily life. With your participation, you help the researchers learn more about brain health and improve tests for memory and attention.

Cons: Participating in the study will cost you time. Also, the tests and questionnaires can sometimes be difficult, for example when the topic is your memory or mood.

Participating in the study will not affect the usual care you receive from, for example, your general practitioner. Also if you choose not to participate, nothing will change in the regular care you are currently receiving.

Will you receive the results of the study?

We will organize an information session to share the results of the study with you.

What happens in case of incidental findings?

During the study, we may happen to find an unusual result, for example when a certain test is difficult or in the questionnaire about your health. If this is important for your own health, the researcher advises you to contact your GP or specialist. The cost of this will fall under your own health insurance policy. Visiting a general practitioner is not subject to a deductible.

The Medical Ethics Review Committee of Amsterdam UMC has approved this HELIUS study.

You are not additionally insured for this study, as participation does not involve any additional risks.

Do you have any questions?

If you want to talk about the research with someone who is not part of HELIUS, you can contact **Dr. Vincent van Vugt**. Phone: **+31(0)20 444 55 84** or email: v.vanvugt@amsterdamumc.nl. He knows a lot about the research but is not working on it.

General information about taking part in this kind of research can be found at:

www.rijksoverheid.nl/mensenonderzoek

If you have questions or complaints, you can contact the research team (phone: 020-5663792 or email: helius-hersengezondheid@amsterdamumc.nl). For questions or complaints about how your personal data is handled, please contact the research team first. You can also contact the Data Protection Officer at Amsterdam UMC by sending an e-mail to privacy@amsterdamumc.nl. Or you can make a complaint to the Dutch Data Protection Authority (Autoriteit Persoonsgegevens).

For what purpose will we use your data?

Are you participating in the study? Then you also give permission to collect, use, and store your data.

These are the data we use and store:

- Your contact details: address, e-mail address, phone number, contact details of your GP
- Identity information: name, date of birth, gender, ethnicity
- Data relating to your health
- (Medical) information we collect during the study



We store your data for a longer period of time By saving it, we can use it again at a later time to answer new research questions that contribute to the goal of HELIUS.	Your consent We only store data for which you have given your consent. Each measurement round, you fill out a consent form.
How long do we store your data? Up to 15 years after the end of the study. Afterwards we destroy your data.	Scientific research We will only use your data for scientific research and to publish the results in scientific journals.

How do we protect your privacy?

To protect your privacy, we encrypt your data with a unique code, for example 653982. Researchers only use that code. They do not see your name or address. Also, in reports and publications about the study, no one can see that it was about you.



- Some HELIUS employees can see your personal data without a code. That is only the case when necessary for their work for the HELIUS study. For example, to call you for an appointment. The employees sign a statement in which they promise to keep your data confidential.
- Sometimes people who need to check whether the research has been done properly and reliably look at your data without a code. For example, inspectors from Amsterdam UMC and the Health and Youth Care Inspectorate. They also keep your data confidential.

Who performs research with your research data?

- Researchers from the Amsterdam UMC and the GGD Amsterdam, or other researchers in the Netherlands or abroad. In those countries, the EU rules regarding the protection of your data do not apply. We ensure that your data are protected on the same level as required in the EU.
- We make a contract with researchers who use HELIUS data. In this contract we make agreements about what researchers are allowed to study with the data. And also how your privacy is protected. HELIUS checks whether everyone adheres to the agreements.



Do you want to read more?

Website of HELIUS: <https://heliusstudy.nl/en/privacy-policy/>

Website of the Dutch Data Protection Authority: <https://www.autoriteitpersoonsgegevens.nl/en/themes/basic-gdpr/privacy-and-personal-data>

Consent form for the HELIUS study on brain health

I have read and understood the information letter. I understand that the purpose of this study is to investigate brain health and lifestyle.

I was able to ask questions about the study. My questions were answered to my satisfaction. I had enough time to decide whether I wanted to participate. I know that participation is voluntary. I know that I can decide at any moment not to take part. I don't have to say why I want to stop. Then I will no longer be contacted for the HELIUS study on brain health, and no new data about me will be collected from that moment on.

I would like to take part in the HELIUS study and give permission for:

- The collection, use, and storage of my research data to answer the research questions of the HELIUS study.
- The access to my data by certain people who are responsible for ensuring that the HELIUS study is conducted properly and reliably. These people are listed in the information letter.

Signature of participant:

Name:

Signature:

Date : ___ / ___ / _____ (dd-mm-yyyy)

I declare that I have fully informed this participant about the study. If, during the study, information becomes available that may affect the participant's consent, I will inform the participant in time.

Signature of HELIUS staff member:

Name:

Signature:

Date: ___ / ___ / _____ (dd-mm-yyyy)

Please let us know if you want to participate.

Reply form HELIUS study on brain health:

 <input type="checkbox"/> YES , I want to participate in the HELIUS study on brain health and can be called to make an appointment.
Tick the appropriate box: <input type="checkbox"/> I am busy / on holiday and can be reached from: ____ - ____ - ____ (in dd-mm-yyyy)
 <input type="checkbox"/> NO , I don't want to take part in the HELIUS study on brain health.

Please fill in your details here:

Date of birth: ____ - ____ - ____ (dd-mm-yyyy, for example; 03-11-1967)

Telephone number 1 (mobile):

Telephone number 2 (home):

E-mail address:

Please send this form back to us within 14 days if possible. You can use the reply envelope without a stamp. Or you can send an e-mail to helius-hersengezondheid@amsterdamumc.nl Don't forget to include your choice (**yes/no**), **name, phone number, and your reference number**.

After you sign up, we will contact you as soon as we can. Thanks in advance!