DONDERS INSTITUTE

GENERAL PARTICIPANT INFORMATION

Version 3.3

With this letter, we would like to invite you to take part in a neuroscientific study at the Donders Centre for Cognitive Neuroimaging. Participation is voluntary.
In this information sheet, you can read about the study, what it means for you and what the pros and cons are. It is a lot of information. Can you please read the information and decide if you want to take part?

Ask your questions
You can make your decision based on the content in this information sheet. We also suggest the following:
- ask questions to the researcher who gave you this information
- talk to your partner, family or friends about this study
- ask questions to the independent expert: Roel Willems; please find contact information of the independent expert in Appendix A.
- Read the information on https://www.government.nl/topics/medical-research/participating-in-medical-research

1. General information

The Donders Centre for Cognitive Neuroimaging (DCCN) has set up this study. Below, we call the DCCN the sponsor. Researchers can be trainees and/or research assistants conducting the study. The Medical Ethics Review Committee, CMO Arnhem-Nijmegen has approved this study.

2. What is the purpose of the study?

The Donders Institute is an academic research centre investigating the function of the brain. The DCCN is sponsor of this study and part of the Donders Institute. It has at its disposal several scanners using different techniques in order to measure brain activity, e.g. MRI scanners, several EEG devices, a NIRS, a tCS and a MEG device. For our research, we need healthy volunteers (16 years and older) to participate in various experiments, for example language, visual or auditory tests. In some experiments, additional stimuli will be applied in order to activate certain relevant brain areas or to register brain activity during sleep. In all cases, you will be informed about these procedures in timely fashion prior to participation. All our research and all of the scanning methods are of negligible risk and minimal burden. No invasive procedures are involved.

3. What is the background of the study?

Research at the DCCN focuses mainly on the cognitive functions of the brain, such as learning, attention, memory, language, reasoning, decision-making etc. The aim is to better understand these complex functions. The centre has access to devices which measure brain activity. Depending on the research question, a certain device and technique can be used. In the technique-specific brochures, additional information will be given.

4. What happens during the study?

No extra preparation is required before participation. It is important that you are fit, alert and that you have not consumed alcohol the night before. The researcher will send you all relevant information. Besides this general information brochure you will receive :

1. Technique specific information: please read which technique will be applied in the concerned study: EEG, MEG, (f)NIRS, tCS en/or (f)MRI. For MRI and MEG research, it is important that you do not have any metal in/on your body during the experiment. You can read more about this in the information folders on MRI and MEG.
2. Study specific information: the researcher will provide you with additional study related information and -conditions: e.g. you will be asked to watch a movie or pictures on a monitor, to listen to sounds (via earphones), to perform a task, to undergo a specific stimulation of the skin; frequently you are asked to simply do nothing and lie down on the bench while scanning takes place.

The researcher will make sure you will receive all information in timely fashion before participation. Please read the information carefully. The time investment per study will deviate from 30 minutes up to a couple of hours: this includes preparation time and pauses between the measurements. The time in the MRI scanner is limited to maximal 1 hours per experiment.

When you arrive, please take a seat in the waiting room, which is on the left side of the entrance hall. The researcher will come to pick you up and take you to the experiment room. He/she will explain to you the aims of the research and the applied measurement techniques. You will receive instructions about what you are asked to do during the experimentIn all cases, the researcher will answer all your remaining questions concerning the experiment before participation. Once everything has been fully explained, he/she will ask you to sign the consent form.

5. What agreements do we make with you?

We want the study to go well. That is why we want to make the following agreements with you:

- ✓ without your cancellation, we expect you on time for the appointment
- ✓ for reimbursement after participation, you must be registered in the SONA system: https://radboud.sona-systems.com
- ✓ you should contact the researcher in these situations:
  - you are encountering problems with your health
  - you do not want to participate any further in the study
  - your mobile number, address or email address has been changed

If you are pregnant or expect to be pregnant, you cannot participate in either of the studies. What should you do in case you get pregnant during the study? Notify the researcher as soon as possible. In consultation with the researcher, you need to stop with participation as soon as possible.

6. What side effects, adverse effects or discomforts could you experience?

In general, there are only negligible adverse or side effects known as result of taking part in one of the used techniques. There might be a possible discomfort encountered while laying flat in the MRI scanner or the application of the electrodes or devices. Before the electrodes are attached the skin will be first slightly decreased with scrub crème, next the electrode will be applied with an adhesive plaster. This procedure might cause a slight, but transient irritation of the skin. Taking part in an MRI study can induce temporary but transient side effects. This will be explained in the technique-specific information brochure.

7. What are the pros and cons if you take part in the study?

Taking part in the study can have pros and cons. We will list them below. Think about this carefully and talk to other people about it.
You yourself do not benefit from taking part in this study. But if you take part, you will help the researchers gain more insight into the function of the brain.

Potential disadvantages:
You may encounter discomfort from (extra) measurements during the study:

- For example, the application of electrodes to measure eye movements of muscle activity.
- You need to follow appointments and instructions as part of the study

It is possible that an incidental discovery is made during an MRI scan that is not directly related to the research but does concern your health. If the radiologist indicates additional examination is required, you will be informed. The radiologist will indicate whether you need to consult your GP or specialist and discuss with you what needs to happen next. The cost of this will fall under your own health insurance policy. Prior to participation, you are required to provide name and address of your home physician. In case you do not have a home physician (in the Netherlands), you are requested to register as a patient at the Academic General Practitioner Centre Heijendaal. You cannot participate in any research at the DCCN if you do not want be informed about an incidental finding.
We want to emphasise that the researchers at the DCCN do not examine the data acquired from a medical perspective. Participation in any of the experiments cannot be considered as a medical or screening test.

8. When does the study end?

The researcher will let you know if there is any new information about the study that is important to you. The researcher will then ask you if you want to continue to take part.

In these situations, the study will stop for you:

- all measurements according to the schedule are finished and /or the end of the whole study has been reached
- you have become pregnant
- you want to stop participating in the study yourself. You can stop at any time. Report this to the researcher immediately. You do not have to explain why you want to stop.
- the researcher thinks it is better for you to stop
- one of the following national authorities decides that the study should stop:
  - the Medical Ethics Review Committee assessing the study
  - the sponsor/DCCN
  - the Heatlth Care Inspectorate

What happens if you stop participating in the study?
The researchers use the data and body material (for example: a saliva sample) that have been collected up to the moment that you decide to stop participating in the study. If you wish, we will destroy the collected body material. Please let the researcher know.

9. What happens after the study has ended?

You can ask the researcher to keep you informed about the research results. Since data analyses and publication are time consuming, it is not feasible for the researcher to agree on a notification term. In general, the researcher will ask you to get in touch over time.

10. How will we process your data and body material?

Are you participating in the research?
In that case you give permission to the researchers to collect, use and store your data and/or biomaterial (for example saliva).

Which personal data will be stored?
- contact information: your name, email address and phone number. After the study is completed for all participants, your personal and contact information will be discarded unless you give us permission to approach you for future research.

Which other data will be stored?
- information from questionnaires concerning your personal health and personal features, such as gender, year of birth, handedness, color blindness, etc.
- other (medical) data that we collected and that are important for the study.

Why are we collecting, using and storing your data and biomaterial?
We use the data and biomaterial to answer the research questions from the study. We will share our answers with other researchers in the form of publications.

How do we protect your privacy during participation?
To protect your privacy we assign a code to all your data and biomaterial. The key that links you to this code is stored in a secure place in our research centre. When processing your data and biomaterial we only use this code. In reports and publications about the research no one will be able to reveal your identity.

Who is able to see my information?
Some people can see not only the code, but are also able to see your identifiable information. These persons check whether the researchers conduct the research in a proper way. The following persons can have access to your identifiable information:
- Members of the committee for safe conduct of research.
- A monitor that works for the researcher or sponsor.
- National regulatory affairs authorities, for instance the Health Care Inspectorate.

These people will keep your information confidential. We ask your consent for them to access your information.

How long will we preserve your research data and biomaterial?
We will keep your research data and biomaterial for at least 10 years after study completion in the research centre. The biomaterial will be preserved to allow additional analyses related to the original research question. As soon this is no longer necessary the biomaterial will be destroyed.

Are we allowed to use your research data for other research purposes?
Your research data are of potential interest for other scientific research. Research data are increasingly shared with other researchers or research groups. This is important to confirm the reliability of the results. It can also increase the efficiency of research. Before we share research data with others we will remove identifiable features from the data and mask your identity as much as possible. In this way it will be very difficult for other persons to trace the data to your identity. Given the nature of certain research data, or the specific combinations of research data,

we cannot guarantee full anonymity. For this reason, researchers that receive your data are required to agree to make no attempt to unmask your identity.
If you do not agree with the data collection and sharing of your coded and masked research data, you cannot participate in this research.

Audio, video and photography.
Some types of research data, like video or audio recordings, are by nature (direct or indirect) identifiable. Personal or facial features will be removed as good as possible before the data will be processed for further use. It is, however, not always possible to completely de-identify video/ audio recordings which make them traceable to your person. For the further use of these recordings you can indicate separately on the informed consent whether or not you agree processing these data beyond the scope of the study you have been participating in.

How about sharing my research data and my privacy?
Your data will be shared and processed under strict conditions and in compliance with the European General Data Protection Regulation (GDPR). Your name and contact information will never be shared with others. Directly identifiable research data (for example video or audio recordings) will only be shared with others with your explicit consent that you can indicate on the form.
Future research?
You are requested to indicate whether we can approach you for future research. If you consent, we will store the contact information to make this possible.

Is it possible to withdraw your consent to use your research data?
Yes, you can withdraw your consent for us to use your data at any time. This concerns the present study and the use of your data in other research.
Please note: Are you withdrawing your consent after the researchers have completed the collection of the data for a study? In that case the researchers have the right to continue to use the already collected research data. The researchers will destroy your biomaterial when you withdraw your consent. The results of biomaterials that have been processed and analyzed up to that point may still be used.

Would you like to know more about your privacy rights?
For more information with respect to compliance of your rights regarding processing your personal data, you may check the website www.autoriteitpersoonsgegevens.nl. In case of a complaint, we recommend to first discuss this with the researcher. The DCCN is responsible for correct processing of your personal data. If you prefer to discuss this with the Privacy Protection Officer of Radboud University, you can send an email to privacy@ru.nl. You can also submit a complaint to the Authority Personal Data.

11. Will you receive compensation if you participate in a study?

The payment for each experiment:

From 18 years of age		Between 16-18 years of age	
Behavioural:	€ 10 per hour	Behavioural:	€ 5 per hour
EEG:	€ 10 per hour	EEG:	€ 5 per hour
MEG:	€ 10 per hour	MEG:	€ 5per hour
fNIRS	€ 10 per hour	fNIRS:	€ 5per hour
tCS	€ 10 per hour	tCS:	€ 5per hour
fMRI:	€ 10per hour	fMRI	€ 5 per hour
Online testing	€ 6 start fee +		

The Radboud University is obliged to notify the tax authorities about the reimbursement you will receive for participation in the experiment(s) at the DCCN. You need to inform the tax authorities about the reimbursement(s) as part of your income tax declaration.
We need to provide the tax authorities with: your social security number (BSN), your name, address and date of birth. We will not indicate the background for the reimbursement, thus the tax authorities will not be informed about your participation in research at the DCCN.
https://www.belastingdienst.nl/wps/wcm/connect/nl/home/home

The DCCN will transfer the payment directly to your bank account within six weeks of your participation. For our administration, we need your bank IBAN-account number, address and BSN (SOFI number).

12. Are you insured during the study?

Insurance has been taken out for everyone who takes part in a study at the DCCN, i.e. a medical liability insurance and in some cases an additional subject insurance. The insurance pays for damage caused by the study, but not for all damage. You can find more information about this insurance and any exceptions in Appendix B. It also says to whom you can report damage.

13. When will we contact your general practitioner?

We will only inform your general practitioner is case an incidental finding is found which concerns your health.

14. Do you have any questions?

You can ask questions about the study to the researcher or research team of your study. Would you like to get advice from someone who is independent from the study? Then contact Roel Willems, r.willems@donders.ru.nl He knows a lot about the study, but is not a part of this study.
Do you have a complaint? Share your experiences via our feedback webform. This form is available: https://www.ru.nl/donders/forms/feedback-webform-dccn-en/
We appreciate your feedback, and if desired, we will contact you.

15. How do you give consent for the study?

You will receive a study-specific information brochure from the researcher sufficiently in advance (i.e. 24 hours) of the initiation of study-related procedures. This will allow you time to reflect on the potential benefits and risks and possible discomforts. Prior to participation, you and the researcher will fill out a screening form in order to check if you are fit to participate in the study. Additionally, you are obligated to sign a study-specific informed consent form in which you confirm that you have been informed to your satisfaction and are willing and able to voluntarily participate. The researcher will also sign the form, confirming that you have been informed about the experiment.
For some of the studies, you will receive additional technique or study specific information prior to participation. You are encouraged to answer any related questions. Would you like to participate? If you feel your questions are answered and would like to take part, the researcher will ask you to sign the informed consent. See Appendix C.

16. Finally

If you, for some reason, are not able to come in time, please inform the researcher or research centre in a timely fashion. DCCN number: 024-3610750.

A special brochure has been developed by the Ministry of Health: “Medisch-Wetenschappelijk onderzoek / general information for the subject” The brochure can downloaded from www.ccmo-online.nl. Hard copies of the information brochure are available at the reception area of the Donders Centre for Cognitive Neuroimaging.

17. Appendix

A. Contact information
B. Information Insurance
C. Informed Consent Example
D. Technique-specific information brochure(s); version 3.0

Appendix A

Contact information:

Donders Centre for Cognitive Neuroimaging

Visiting address: Kapittelweg 29
6525 EN Nijmegen

P.O. Box 9101
6500 HB Nijmegen
Tel: 024-3610750

Independent expert

Dr. Roel Willems: r.willems@donders.ru.nl

Complaints

Sabine Kooijman: sabine.kooijman@donders.ru.nl

Feedbackformulier: http://www.ru.nl/donders/proefpersonen/proefpersonen-info/

Data protection helpdesk Radboud University:

privacy@ru.nl

Additional information about your rights:

Privacy: www.autoriteitpersoonsgegevens.nl ; mijnprivacy@ru.nl

Brochure “Deelname wetenschappelijk onderzoek” (in Dutch):

https://www.rijksoverheid.nl/onderwerpen/medisch-wetenschappelijk-onderzoek/meedoen-aan-medisch-wetenschappelijk-onderzoek

Appendix B

Insurance text

For participants of all research at the Donders Centre for Cognitive Neuroimaging, a standard medical liability insurance is established.

For some studies, an additional law-imposed subject insurance is established. This insurance covers losses caused by death or injury resulting from participation in this scientific research, which reveals itself during the participation of the subject in the scientific research or within four years thereafter. The personal injury is deemed to have revealed itself at the time it is reported to the insurer.
In the event of a claim, you may contact the insurer directly.

The insurer is:
Onderlinge Waarborgmaatschappij Centramed B.A.
P.O. Box 7374
2701 AJ Zoetermeer, The Netherlands
Tel.: +31 70 3017070
Email: Schade@centramed.nl

The insurance provides a maximum coverage of € 650,000 per subject and € 5,000,000 for the entire research, and € 7,500,000 per annum for all examinations of the same client.
The above amounts are included in the "Besluit verplichte verzekering bij medisch-wetenschappelijk onderzoek met mensen". Information on this "besluit" can be found at the website of the Central Committee Clinical Research Involving Human Subjects: www.ccmo.nl.

The insurance covers losses resulting from experiments. The insurance does **not** cover:
- claims for injury that is inevitable or practically inevitable, given the nature of the experiment
- injury to the health which also would have occurred if you had not participated in the experiment
- injury caused by the subject's non- or partial adherence to directions or instructions
- injury to the descendent(s), as a result of an adverse effect of the experiment on the subject or on the subject's descendent(s)
- injury caused by an existing treatment method in an experiment into existing treatment methods
- injury resulting from the occurrence of a risk of which the subject was warned in the written information, unless the risk occurs in a more serious degree than was expected or said risk was highly unlikely to occur

Appendix C: EXAMPLE Participant-Informed Consent

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☐ ***MEG*** ☐ ***EEG*** ☐ ***MRI*** ☐ ***NIRS*** ☐ ***tCS*** ☐ ***BEHAV.***

****Tick the applicable boxes***

:

<u>To be filled in by the participant:</u>

- I have been both verbally and written informed satisfactorily about the study, based on the general information brochure version 3.3, and the technique specific information brochure(s), version 3.0.
- I have read the information sheet. I was able to ask questions. My questions have been answered well enough. I had enough time to decide if I wanted to take part.
- I know that taking part is voluntary. I also know that I can decide not to take part in the study at any time, or to stop taking part. I do not have to explain why.
- I give consent to give my home physician and/or medical specialist information about accidental discoveries made during the study that are important for my health.
- I give consent to collect and use and store my data and body material for a minimal period of 10 years
- I know that some people will be able to see all of my data to review the study. These people are mentioned in this information sheet. I give consent to let them see my data for this review.
- I know that my experimental data will be stored in such a way that they are not directly identifiable, and that these data will be shared for other research purposes, as mentioned in the information letter.
- I know that I cannot be pregnant during the study.

Please tick yes or no in the table below.

I give consent to approach me after this study to participate in in a follow up study.	Yes ☐	No ☐
< if applicable> I agree to further use (direct or indirect identifiable) video and/or audio data beyond the scope of this study, as stated in the information sheet.	Yes ☐	No ☐

➢ I want to take part in this study.

My name is (subject): ……

Signature: …….. Date : __/__/__

EXAMPLE : PART OF INFORMED CONSENT

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To be filled in by the researcher:

I declare that I have fully informed this subject about the study mentioned.

If any information becomes known during the study that could influence the subject's consent, I will let this subject know in good time.

Researcher name : .....

Project number:……..

Signature:…… Date: __/__/__

<if applicable>
Additional information was given by:

Name:……..

Job title:……

Signature:…… Date: __/__/__

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Appendix D

Study-specific Information brochures version(s) 3.0 as applicable for this study:

- MRI ☐
- MEG ☐
- EEG ☐
- NIRS ☐
- tACS ☐