Study information for participants

BraNeReg
Brain Network Regulation: Learn to self-regulate your own brain activity by means of neurofeedback

Introduction
Dear reader,

We kindly ask you to participate in this scientific study. Participation is on a voluntary basis, and in order to participate, we need your written approval (which we will complete during your first visit). Before you decide whether or not to participate, we ask you to read through this document which contains information on the study. Please read this information carefully and contact one of the researchers in case of any unclarities or further questions. We will contact you again in 48 hours so that you have enough time to read the documents and so that you can make an informed choice about participating in the study. If you are done reading the documents earlier, you can of course let us know if you want to participate by replying to the email you received. We would kindly ask you to participate only if you are able to finish the whole study. Your first appointment will be planned after you have confirmed your participation. For this study, it is important that you have a Windows or Mac laptop.

1. Description of the study

The current study has been set-up and will take place at the Donders Center for Cognitive Neuroscience (DCCN). It concerns a real-time functional MRI neurofeedback (NF) study, where you will be trained to regulate your own brain activity. A more elaborate explanation of neurofeedback can be found on page 7 of this document. The experiment will consist of at least 8 visits to the DCCN in total (with an additional 9th visit, if needed). During 6 (or 7) of these visits, you will be in the MRI scanner (for 2 of those visits only shortly). Inside the scanner, you will undergo neurofeedback training and perform several experimental tasks. Besides these 6 visits where you will be in the MRI scanner, 2 additional visits to the DCCN will be planned which will consist of performing several computer-based experimental tasks outside the scanner.

2. Overview of study

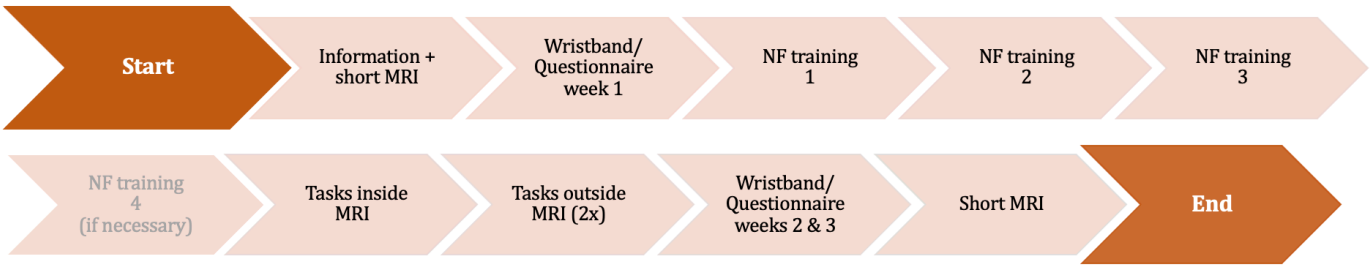
At the end of this section, you can find a table with a short overview of the study and a timeline.
After you agree to participate in this study we will make an appointment for your first visit to the Donders Institute. During the first visit you will be informed about the study, before the acquisition of a short (15-minutes) anatomical and functional MRI scan. We will also provide information and instructions on the wristband you will be wearing and questionnaires you will have to answer through your phone (see section 4). For this, you are asked to bring your own laptop to the first meeting, so we will be able to explain to you how to sync the data from your wristband (which has to be done each day). We would ask

you to install a synchronization software on your laptop (which is currently only available for Windows and MacOS). You will also complete several questionnaires which will take around 30-40 minutes. These questionnaires can also be completed at home on your phone or laptop. Lastly, we will take some time to schedule all the following visits to the DCCN together.
After your first week of wearing the wristband and answering the daily questionnaires through your phone, you will return to the DCCN. During visits 2-4, you will be trained on a NF task (see section 4) in which you will learn to self-regulate your own brain activity. You will be inside the scanner for 75 minutes, 60 minutes and 60 minutes, respectively. Around 15 minutes will be added to each session for pre-scan preparations and post-scan questions. After these visits on which you will be trained with NF, a last 135-minute scanning session will take place (visit 5). This includes a 15-minute break in between, where you will be taken out of the scanner. Whilst inside the scanner, you will perform several experimental tasks, and you will be asked to apply the strategies you have learned during the preceding NF training sessions. The maximum amount of time between two consecutive visits is 1 week, but preferably less (around 4 days).

On the 6th and the 7th visit, you will perform several experimental tasks outside of the scanner (6 tasks in total, divided over the 2 visits). Both of these visits will take 120 minutes. After the 7th session, the last two weeks of wearing the wristband and answering daily questionnaires will start. At the end of those 2 weeks, you will return to the DCCN for your last visit (visit 8), which will be the shortest. During this visit, you will be inside scanner for half an hour only. Thereafter, the study is finished. During the last two MRI session, as well as the two behavioural sessions, physiological measures will be obtained, namely: respiration, heart rate, skin conductance and pupil size.

In case we observe that 3 neurofeedback training sessions are not sufficient, we will include a 4th training session after the 3rd one. This session will again take 60 minutes and will be exactly the same as the preceding training sessions. You will be reimbursed for this extra training session.

<u>Timeline</u>



Overview

What	Visit DCCN? (visit nr.)	Explanation	Total duration
Introduction, Short MRI and Questionnaires	Yes (1)	- General introduction to the study - Short MRI scan (15-30 min.) - Wristband & questionnaire explanation and set-up - answer several questionnaires either at Donders or at home on your laptop/mobile phone.	60 min. 30-40 min.
Questionnaires + wristband week 1	No	- You will wear a wristband and you will answer 8 questionnaires each day - Each day you have to charge your wristband and sync the data to your laptop	1 week (questionnaires: 6 x 2 min. + 2 x 3 min. each day)
NF training 1	Yes (2)	1st Neurofeedback training session (MRI)	75 min. (± 15)
NF training 2	Yes (3)	2nd Neurofeedback training session (MRI)	60 min. (± 15)
NF training 3	Yes (4)	3rd Neurofeedback training session (MRI)	60 min. (± 15)
NF training 4	Yes (4.5)	In case it is needed, a 4th training session is added (MRI)	60 min. (± 15)
Tasks (MRI)	Yes (5)	Perform tasks inside MRI scanner + apply learned strategies	135 min. (including a 15 min. break in between)
Computer tasks (no MRI)	Yes (6)	Perform computer tasks outside of scanner + apply learned strategies	120 min.
Computer tasks (no MRI)	Yes (7)	Perform computer tasks outside of scanner + apply learned strategies	120 min.
Questionnaires + wristband weeks 2 & 3	No	Over the duration of 2 weeks, you will again wear the wristband and answer questionnaires.	2 weeks (6 x 2 min. + 2 x 3 min. each day)

		- week 2: similar to wristband/questionnaire week 1. Wear wristband and complete 8 questionnaires a day. - week 3: Besides wearing a wristband and completing the questionnaires, you will be asked to apply strategies you have learned through NF training (at least 3 times a day) - Each day you have to charge your wristband and sync the data to your laptop - These 2 weeks will start right after visit 7	
Short MRI scan	Yes (8)	Short scanning session	30 min.

3. Training and tasks

Regulation task (neurofeedback training)

While in the MRI scanner, your task will be to regulate your brain activity, by, for instance, thinking of something specific, performing some mental task internally, or getting into a certain emotion, feeling, mood or state of mind. Once the task is over, you will receive feedback, reflecting your performance. No concrete strategies will be given prior to the experiment on how to achieve successful brain regulation. The objective of the study is that you will learn the brain regulation based on the feedback provided after the task is performed. You can use this information to evaluate your performance and potentially adapt and improve your regulation strategies.

In addition to receiving feedback on the performance directly after each trial, performance points will be awarded and announced in the end of each run. Once the study is concluded, the total amount of points of each participant will be calculated and the three participants with the highest scores will receive an extra monetary price equal to €25 (in addition to the standard reimbursement).

Regulation without feedback and behavioral tasks

During the 5th and the 8th visit of the study, the task will be slightly different. You will still regulate your brain activity, as explained above, but you will not receive any feedback of your effort. During the 5th visit, you will perform several behavioral tasks in addition to the regulation task. You have to try to regulate your brain activity by applying the strategies you have learned throughout the training sessions whilst you are performing the behavioral tasks. As mentioned, no feedback on how you are doing will be provided. During the 8th visit, you will not have to perform any additional behavioral task, only the regulation task.

This will all be clearly explained to you during the meetings.

Lastly, you will also complete several behavioral computer tasks outside of the scanner. Again, you are asked to regulate your brain activation during the performance of tasks by applying the strategies you have developed. Outside of the scanner, just like inside the scanner, several physiological measures will be obtained, namely: pulse, respiration, skin conductance. Besides that, your eye movements will be tracked.

During all of these sessions, performance points will still be accumulated.

4. Wristband & questionnaires

As mentioned, you will be asked to wear a wristband that measures several physiological aspects throughout the day, namely: pulse, skin conductance, movement and body temperature. In total, the wristband will be worn for 3 weeks and during these 3 weeks, you will also have to complete several questionnaires that will be presented to you throughout the day. There will be 6 short questionnaires (~2 min) and 2 longer questionnaires (~3 min) per day. You will receive an SMS with a link to a webpage every time a questionnaire has to be completed. During the last week, you will be asked to perform the regulation strategies you have learned during the NF training in the scanner for at least 3 times a day.
You have to charge your wristband and transfer data from your wristband to your laptop each day. Therefore, we would like you to bring your laptop to the first visit. Further details regarding the questionnaires and wristband measures will be explained to you during this first visit, where you will also be familiarized with the wristband itself. Besides that, you will be given some take-home explanations on the wristband and questionnaires to ensure you will know exactly what to do when you are at home.

5. Reimbursement

The total amount of hours that are required for this study are 20 - 21, divided over 29 - 30 days (3 weeks of daily questionnaires + 8 - 9 visits to the DCCN). We would kindly ask you to participate only if you are able to finish the whole study. Participation will be reimbursed at €190 - €200 (8-9 visits). If you decide to quit before the end of the study, you will receive a lower compensation.

As mentioned earlier, some participants will receive an extra monetary price. Therefore, participation to this study will be reimbursed after the conclusion of the whole study (approximately end of September). The total amount will then be calculated, and it will be transferred to the bank account specified in your SONA account.

6. Pros and cons

This study requires effort from your side, with many visits to the DCCN. However, you will undergo NF training which is a relatively new, exciting and progressive type of MRI research. A possible con might be that, especially in the beginning, developing strategies to regulate your brain activity might be quite effortful. It could take some time to develop the correct strategies. Besides that, being in an MRI scanner might be experienced as a bit uncomfortable, since you are in a small space. We will make sure though to make the process as comfortable as possible. Lastly, we ask you to transfer the data from your wristband and to charge your wristband every day. This requires a bit of effort from your side, but it is not that time consuming and we will clearly explain to you what steps have to be taken. The positive side about this is that you will not have to visit the DCCN during these weeks.

7. In case you decide to participate

We would like to inform you that participation in this study is on a voluntary basis and that participants have the right to withdraw at any time without giving a reason.

8. Further information

This information will be available during all of the visits to the DCCN. Additionally, oral instructions about the task will also be given in the beginning of each visit. Nonetheless, if something is not clear, or if you have further questions you can contact us using the contact information below.

Responsible researcher:	Florian Krause (f.krause@donders.ru.nl)
Contact:	Maud Schepers (Maud.Schepers@radboudumc.nl) +316 57 63 89 41
DCCN address:	Kapittelweg 29, 6525 EN Nijmegen

General information about biofeedback and neurofeedback

This study entails so-called biofeedback or neurofeedback: That is, (part of) the data that is recorded from you can be presented directly back to you during your participation in this research, while it is being recorded.

There is also the possibility that you were assigned to a control group. In that case the feedback you will receive does not originate from you (i.e. it is a recording of another person, or randomly generated feedback), or you will not receive any feedback at all.

Biofeedback

During biofeedback, data about a particular body function is recorded from you (e.g. with measurements of muscle activity, a heart rate monitor, or a respiration belt). This data is then directly presented back to you while it is being recorded. The feedback will be either visually displayed on a computer screen, auditory through headphones, or via some other way.
Repeatedly receiving this feedback allows you to learn to actively alter the body function that is recorded (for example the frequency of your heart rate).

The details of the feedback (whether you receive it, where the signal originates from and/or what it represents) are study-specific depending on the study, the researcher will inform you about these details.

Neurofeedback

Neurofeedback is a form of biofeedback (see above) in which the recorded body function is activity from your brain (measured with e.g. functional Magnetic Resonance Imaging, Electroencephalography, Magnetoencephalography, or functional Near-Infrared Spectroscopy).

Safety

Biofeedback and neurofeedback are generally safe methods. There are no known negative side effects that are specific to the method with only occasional reports of fatigue, headache, anxiety and difficulty falling asleep. Depending on the type of feedback used in the current study you will receive additional safety information from the researcher about the particular technique used.

DONDERS INSTITUTE

GENERAL INFORMATION
Version 2.2

This folder contains important information if you consider participating in one of the studies at the Donders Institute. Please read the following information carefully.
The Donders Institute is a university research centre investigating the brain. **The Donders Centre for Cognitive Neuroimaging** (DCCN) is part of the Donders Institute and has at its disposal several scanners using different techniques in order to measure brain activity, among which MRI scanners, several EEG devices, a NIRS-, a tCS- and a MEG device. For our research we need healthy adult volunteers (18 years and older) to participate in various experiments by means of investigating language, visual or auditory pathways. In some experiments additional stimuli will be applied in order to activate certain relevant brain areas, or 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.

Medical ethics Check

Before conducting research in healthy subjects, a study has to be reviewed and approved by an independent medical ethics committee (view: www.cmoregio-a-n.nl)
Above mentioned research conducted at the DCCN is covered by an overall protocol, approved by the 'Commissie Mensgebonden Onderzoek Regio Arnhem-Nijmegen' and registered under CMO number 2014/288.

Medical data

We want to emphasize 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 nor screening test. In exceptional circumstances the new data collected may give indications concerning your health conditions. Prior to participation you are required to provide name and address of your home physician. In case of a suspected abnormality (incidental finding) which is of clinical relevance you will be informed by 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 Center Heijendaal. In the exceptional circumstance of a clinically relevant finding you will be either informed by your own home physician or the general practitioner of the Academic Center. Your insurance policy will cover these costs; In case you are uninsured the Academic GP Center is required to charge you a minimal amount for consultation.
You cannot participate in any research at the DCCN if you **do not** want be informed about an incidental finding.

Pregnancy

If you are pregnant or expect to be pregnant you can**not** participate in either of the studies.

Information about the experiment and giving consent

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 the researcher will with you fill out a screening form in order to check if you are fit to participate in the study. Additionally, you are tied to sign a study specific informed consent form in which you confirm that you have been informed satisfactory and are willing and able to voluntarily participate. The researcher will also sign the form confirming that you have been informed about the experiment. The researcher will also ensure your privacy and the necessary privacy conditions will be met. You have the right to withdraw from the experiment at any time without having to give a reason. You can request disposal of your experimental data up to 1 month after participation in the study. After that your data will be anonymized and stored in a repository. An example of a study specific "informed consent" is attached to the applicable study specific information brochure.

Insurance

On legal grounds a liability insurance and in some cases an additional subject insurance has been concluded for all subjects participating in studies at the DCCN as part of the Donders Institute. The subject insurance covers damage due to participation in the study, becoming apparent during participation in the study or within four years after termination of participation in the study. (additional information in the supplement)

Use and preservation of your personal data and body.

Before and during study conduct it is necessary to collect, use and preserve personal information. This concerns personal data like name, address, date of birth etc. and some additional medical background information. Sometimes also body material (e.g. saliva) is collected. Use and preservation of these data are necessary to answer the scientific research question(s) and to publish results. We will ask your permission/ consent forthis.
If you do not agree you cannot participate in this research.

Confidentiality of your data and body material.

All data will be coded in order to protect your privacy. Your name and other information, which might lead to your identity, will be kept separate from the experimental data. Only with a so called key file your experimental data can be linked to your identity. This key file is kept by the researcher. Other researchers involved will only have access to your coded experimental data.

Experimental data collected during the study are treated confidentially. The researcher stores all data under a subject code. In the records of the research only this code will be used. Only the researcher knows the combination between you and the code. In some studies, additional audio and/or video recording will be applied during the experiment. This material will be only used for scientific purposes. Sometimes the measurements will take place during sleep in the evening or night. The experimenter will always inform you about this prior to participation additionally asking for your approval. In all cases your privacy will be protected according to the European General Data Protection Regulation. Results and publication of experimental data will always be coded.

Right to inspection

Few other people have the right to inspect your data. This concerns the coded as well as the uncoded data from which they may infer your identity. This is necessary in order to check if the research was properly and reliably performed. Persons or agencies who have access to check your data are: a controller working for the sponsor, national or international regulatory bodies, e.g. Inspectorate of the Ministry of Health. They will protect and keep your personal information secret. You are requested to approve/ consent for this right to inspection. In case you do not agree, you cannot participate in this study.

Preservation time on data and body material.

On location of the sponsor the data will be preserved for an established period of time, i.e. 10 years. The collected body material (saliva) will be destroyed immediately after data-analyses.

Sharing of your experimental data and approach future studies.

Experimental data are more and more shared for strict scientific purposes with other researchers or research consortia. This is important to check and/ or replicate the research results. Prior to sharing your experimental data, the data will be completely anonymized (i.e. not traceable to your identity). If you do not agree with this sharing policy, you cannot participate.
With respect to the informed consent procedure:

- ✓ Some experimental data cannot be anonymized due to their nature, e.g. video- or audio recordings). You have the right to disapprove sharing these data with other researchers beyond the scope of the study.

You are always asked whether you are willing to be approached for participation in future studies.

Preparation for the experiment

No extra preparation is required before participation. It is important that you are fit, alert and that you have not drank alcohol the night before. 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.

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 the aims of the research and the applied measurement techniques to you. You will receive instructions about what you are asked to do during the experiment. such as watching a monitor, listen to sounds (possibly over a headset), perform a reaction task, make different movements or just lie still and relax. For some experiments you will be additionally informed about the study specific procedures prior to participation. In all cases the experimenter 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. Subsequent procedures depend on which technique is being used. You can read more about this in the information sheets on EEG, MEG, NIRS, tCS and MRI.

Payment

The payment for each experiment is:

From 18 years of age		Between 16-18 years of age	
Behavioural:	€ 8 per hour	Behavioral:	€ 4 per hour
EEG:	€ 8 per hour	EEG:	€ 4 per hour
MEG:	€ 8 per hour	MEG:	€ 4 per hour
fNIRS	€ 8 per hour	fNIRS:	€ 4 per hour
tCS	€ 8 per hour	tCS:	€ 4 per hour
fMRI:	€ 10 per hour	fMRI	€ 5 per hour

The DCCN will transfer the payment directly to your bank account within 6 weeks of your participation. For our administration we need your bank IBAN -account number, address and BSN (SOFI number).

Independent expert

When you have additional questions prior or during a study you may address these to an assigned independent expert. The independent expert is not involved in the study however capable of answering your questions.
Contact information of the assigned expert can be found in the study specific information brochure.

Additional information and contact

If you are unable to make it to the appointment (on time), please let us know as soon as possible. Telephone number: 024 – 36 10750. You may also call the number mentioned above for additional information or if you would like to withdraw from participation.
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. Hardcopies of the informationbrochure are available at the reception of the Donders Centre for Cognitive Neuroimaging.

After participation

It's possible to share your experience regarding your participation. Are you satisfied or perhaps not at all? Please let us know by means of a feedback-web form. You can find this form on the internet Participant Information site. http://www.ru.nl/donders/proefpersonen/proefpersonen-info/engelse-versie/participants/
We really appreciate your feedback!

More information concerning your rights for processing data.
For more information with respect to compliance of your rights processing your personal data, you may contact the responsible entity for processing your data: the Radboud University.

You may contact the data Protection Officer of the Radboud University : Ronald Sarelse. Tel. 024-3612340; mail r.sarelse@ru.nl. More information about your rights regarding processing of your personal data you can find on: https://autoriteitpersoonsgegevens.nl/en

Registration of the Research
This research is also registrered in the medical scientific research overview: the register of the CCMO in the Hague. This website does not consist of any information which might lead to your identity.

Annex to the Participants' information (March 2017)

The Donders Centre for Cognitive Neuroimaging has taken out insurance for the subjects in this scientific research. 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 cover 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 Humans: 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 the 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.

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Donders Centre for Cognitive Neuroimaging

INFORMATION ABOUT MRI

version 2.2

General

MRI stands for 'Magnetic Resonance Imaging'. This method allows us to take images of the inside of the human body. By using a strong magnetic field and radio waves radio signals are generated in the body. These signals are picked up by an antenna and with the help of a computer pictures of cross-sections of the human body can be produced. At the Donders Institute mainly a variation of this technique called fMRI (f = functional) is used. With fMRI it is possible to see both the structure and the activity of the brain. An fMRI experiment usually lasts one to two hours.

Preparation

Metal objects are attracted to the magnet and/or disturb the measurement. Also there is a slight chance metal can warm-up. Therefore, please take into account the following:

- The clothing on your upper body may not contain any metal (e.g. zips, buttons, hooks, braces). This also applies to bras containing a metal brace wire.
- Jewellery, piercings, hairpins, glasses, etc with metal parts must be removed. Please do not use mascara as this sometimes contains metal fragments.
- Coins, keys, cigarette lighters, cell phones, penknives, cufflinks etc must be removed and can be stored in a locker. The same goes for bank cards, credit cards and chipcards. Otherwise the strong magnetic field will erase the information stored on the magnetic strip.

The experiment

After the researcher has informed you about the experiment you will enter the shielded magnet room and lie down on the movable table. Please relax and lie as comfortably as possible. During the experiment the scanner will make a lot of knocking sounds and noises of varying volumes. Ear protection is a must. Hence you will be given headphones or earplugs to reduce the noise. A frame (= the antenna) is placed over your head. It is important to lie as still as possible during the scanning. Hence your head is fixated with small cushions. Before the researcher moves you inside the scanner you will be given a rubber ball to hold in your hand. If you squeeze the ball during the experiment this will sound an alarm which tells the researcher to stop the experiment. During the scan the door to the MRI room is shut, but not locked.
An experiment consists of several scans. The shortest lasts for 10 seconds and the longest about forty minutes. In total a scan session lasts one to two hours. Via the intercom the researcher keep you informed about the progress of the experiment. not be locked. The researcher can see you via a video camera and you can communicate via an intercom. Sometimes the experiment will be video and/or -audio recorded for strict scientific purposes. The experimenter will inform you about this in timely fashion prior to the experiment.

Additional information

The risk associated with participation can be considered as negligible. No invasive procedures are involved.
You can **NOT** participate in a MRI-experiment if one of the following applies:

- Metal parts, that cannot be removed, are present in or on your upper body, e.g. plates, screws, aneurysm clips, metal splinters, piercings or medical plasters.
- Dental fillings, crowns, a metal wire behind the teeth, tattoos and contraceptive coils are allowed. The researcher will additionally inform you.
- Clothing on the upper body containing any metal e.g. zips, buttons, hooks, braces, metal yarn (LUREX). This also applies to bras containing a metal brace wire.
- You have an active implant, a pacemaker, insulin pump, neurostimulator and/or ossicle prosthesis.

If one of the below issues is applicable, please contact the researcher prior to the experiment

- You have a history of brain surgery.
- You suffer from epilepsy.
- You suffer from claustrophobia.
- You are pregnant or you think you are.
- You are younger than 16 years of age.

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Donders Centre for Cognitive Neuroimaging

SCREENING FORM MRI
Version 2.2

To be filled out prior to the start of the experiment

	Please answer the following questions first	Yes	No
-	Do you have any metal objects in your upper body? *Exception: dental fillings or crowns.*		
-	Do you have metal fragments in your body, in particular in the eye, e.g., caused by injuries when working with metal?		
-	Do you wear jewelry / piercings that you cannot take off?		
-	Have you had brain surgery?		
-	Do you have an active implant? *(e.g. pacemaker, neurostimulator, insulin pump, ossicle prosthesis)*		
-	Are you using a medical plaster that cannot or may not be taken off? (e.g. nicotineplaster)		
-	Do you suffer from epilepsy?		
-	Do you suffer from claustrophobia?		
-	Are you pregnant or think you are?		
-	Are you younger than 16 years?		

If answered YES to one of the above questions you CANNOT participate in the experiment.

Do you have a metal wire behind your teeth and /or a tattoo?		

If answered YES: The researcher needs to inform you about the risks.

Name: Weight: ..... kg.

Date of birth: (dd/mm/yyyy) Length: ..... cm.

Name home physician:

Address :

Note: Only in case of no (Dutch) home physician please check the information of the Academic General Practitioner Heydendaal : www.ugc-heyendael.nl' (see also available information brochure) :

I agree to be informed by the Academic GP in case of a clinically relevant finding YES*

***encircle**

** This form is applicable for research in healthy, competent adolescents/adults (≥16 year). The subject involved needs to provide his or her written consent personally. The questions above only apply for performing an (f)MRI in the head/neck area.* ***P.T.O***

SCREENING FORM MRI
Version 2.2

To be filled out completely by the RESEARCHER after the experiment

Name: Project number:

Function: Sona systems study name:

Signature: Date:

☐ Payment .....euro

☐ No payment

Reporting of events or findings:

Adverse Event **YES/ NO***

If YES: dd/mm/yyyy time

- Date and time of occurrence …….. …….
- Description:
- Severity mild/ moderate/ serious*
- Relation to procedure: none/ unlikely /possible / likely / definite*
- Action taken:
- Abated/ follow up:

○ **Follow Standard Operating procedure Adverse Event!**

Incidental Finding **YES/ NO***

If YES: dd/mm/yyyy

Date: …….

- **Follow Standard Operating Procedure Incidental Finding!**

**make a choice*

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Donders Centre for Cognitive Neuroimaging

STUDYSPECIFIC INFORMED CONSENT FORM

For participation in: *

☐ **MEG** ☐ **EEG** ☐ **MRI** ☐ **NIRS** ☐ **tCS** ☐ **Behavioural**

***tick the appropriate box(es)**

I confirm that:

- I was satisfactorily informed about the study concerned both verbally and in writing by means of the general information brochure and additional study specific information brochure(s) (*CMO2014/288; May 2018, version(s) 2.2*).
- I have had the opportunity to put forward questions regarding the study and that these questions have been answered satisfactorily
- I have carefully considered my participation in the experiment.
- I participate of my own free will.

I agree that:

- My data/ body material will be collected and used for the purpose mentioned in the information brochure.
- I will be informed by my home physician or the academic GP of General Practitioner Center Heijendaal about any new information which is of medical relevance to me.
- For study purposes audio and/or video recordings may be made
- Beyond the scope of this study: my anonymized experimental data will be shared with other researchers or research groups

I understand that:

- I have the right to withdraw from the experiment at any time without having to give a reason.
- I have the right to request disposal of my experimental data up to 1 month after participation
- My data will be protected according to applicable European privacy law.
- My consent will be sought every time I participate in a new experiment.
- For compliance check of the research few persons may have access to my (personal) data. These persons are mentioned in the information brochure. I consent for this.

I give my consent to take part in this experiment:

Name:…… Date of birth: ..... (dd-mm-yyyy)

Signature:..... Date and place:……..

I agree that for scientific purposes collected potential identifiable photo/video/audio recordings beyond the scope of this study will be shared with other researchers or research groups.

YES? NO/ not applicable*

I may be approached for a future neuroscientific study. **YES/ NO***

(*encircle choice)

To be filled by the RESEARCHER prior to the start of the experiment:

The undersigned declares that the person named above has been informed both in writing and in person about the experiment. He /she guarantees subjects' privacy protection.

Name:…… Project code:……

SONA title of the study:……

Signature:..... Date (dd-mm-yyyy):……