Study data	
☐ **MR scanner Psychiatry (S00000)** *Department of Psychiatry, Psychotherapy, and Psychosomatics* Univ.-Prof. Dr. med. Dr. rer. nat. Klaus Mathiak	☐ **MR scanner Basement (B00000)** *Department of Neurology* Univ.-Prof. Dr. med. Ferdinand Binkofski *Brain Imaging Facility, IZKF* PD Dr. phil. Rea Rodriguez-Raecke
Reg. number.: S	Reg. number: B
Date:	☐ Patient ☐ Volunteer ☐ Phantom
Radiographer/standin:	MR assistant:
Study name (abbreviation from MRI registration form):	

To be completed by patient/volunteer:			
Last name:		**First Name:**	
Date of birth (DD/MM/YYYY):	**Weight:**	**kg // Height:**	**cm**
Gender: ☐ Female ☐ Male ☐ Diverse			
Handedness: ☐ Right ☐ Left ☐ Ambidextrous			

Measurement protocol

☐ See MR logbook for full information

No.	Sequence	No.	Sequence
1		17	
2		18	
3		19	
4		20	
5		21	
6		22	
7		23	
8		24	
9		25	
10		26	
11		27	
12		28	
13		29	
14		30	
15		31	
16		32	

Dear participant,

The purpose of the following text is to prepare you for the informed consent interview. Please read it carefully before the interview and complete the questionnaire thoroughly.

What examination is planned?

You are scheduled to undergo magnetic resonance imaging (MRI). This imaging procedure uses radio waves and magnetic fields to create images of the brain. The examination is performed only within the CE-marked operating mode of the MR device and with CE-certified coils.

What is the procedure of the magnetic resonance examination?

For the examination, you are positioned on an examination table (see Figure 1 on page 4) and your whole body is slowly moved in the magnetic field of the tube-shaped scanner. There, short radio wave pulses stimulate the hydrogen atoms in the tissue, causing them to emit electromagnetic signals. A computer records these signals and uses them to generate two- or three-dimensional images. The result of the examination provides insights into the shape, anatomy, and/or function of the brain.
During the examination, study staff will have direct visual contact with you, or you will be monitored by a video camera from the control room. Please remain calm and relaxed during the examination. The operation of the magnetic coils causes a loud metallic clicking or knocking noise. You will be given earplugs in addition to headphones to dampen the noise. The examination is painless and usually takes between 30 and 60 minutes but can take longer depending on the study. The magnetic field and radio waves do not put any strain on the body.
To avoid potential injury, please maintain the instructed posture also after the examination is completed until the study staff has moved you completely out of the scanner and removed any equipment.

Risks and possible complications

Despite all due care, complications may occur that require additional treatment. Pre-existing and comorbid conditions as well as individual characteristics can significantly influence the frequency of complications. We would like to inform you that approximately 3% of all healthy people have normal anatomical variations or structural deviations, which are generally of no pathological value. This percentage is higher in older people (approximately 10%). In rare cases, however, incidental findings may occur, revealing medically relevant deviations. However, the type of scan and specific settings used to obtain the images for this study are not suitable for reliable detection of structural deviations, and comprehensive conclusions about the nature of any potential deviation cannot be drawn from the acquired images. This is because the settings for the current measurements are optimized for specific research purposes, e.g. the functional behavior of individual brain sections; the current measurements are not optimized for diagnostic purposes. In principle, you have a “right not to know” in the event of an incidental finding. However, participation in the study at the Aachen study site is excluded if you do not wish to be informed

about an incidental finding, because withholding potentially treatable, clinically relevant incidental findings creates a significant ethical conflict for the study staff, as potential treatment options remain unused and a deterioration in health may occur. By signing this consent form, you therefore agree that any incidental finding will be communicated to you. If you do not wish this, please inform the study staff. This procedure may not apply to other study sites that implement the right not to know about incidental findings of a subject. You can therefore obtain separate information about the handling of incidental findings at other sites. In the event of an incidental finding, we will suggest further examinations (e.g. by a specialist in neuroradiology). You can decide yourself whether to undergo the suggested further examinations or to decline them. Such an incidental finding may have social and psychological consequences for you – as a patient in that case.

General risks

In exceptional cases, temporary or very rarely permanent hearing problems or disturbances (e.g. tinnitus) and occasional headaches may occur.
Very rarely, a previously unknown fear of confined spaces (claustrophobia) and/or panic attacks may occur for the first time in a closed MRI scanner and potentially reoccur.
Dyes containing metal in tattoos and make-up/eye make-up products can cause skin irritation and may affect the quality of the images obtained.
Crossing your hands over your chest while lying in the MRI scanner may cause local heating or, in rare cases, skin burns may occur at the contact points where the skin of your hands, arms, or legs touches. To prevent this, you will be positioned correctly, possibly with padding under the limbs. Therefore, please do not change your posture in the MRI scanner during the examination unless instructed to.

Behavioral instructions: What do I have to do and what should I not do?

Before the examination, present any existing medical ID cards/passports (e.g. marcumar. allergy, pacemaker/implant, diabetic passports, X-ray passports etc.). Be sure to inform the study staff if you have permanent make-up or tattoos as well as a transdermal patch on your body.
Metallic or magnetic implants containing iron, cobalt, or nickel (e.g. pacemakers, automatic insulin pumps, implanted hearing aids [e.g. cochlear implants], metal endoprostheses, metal parts or metal splinters in the body, magnetically attached dentures) may be damaged by the examination and/or cause serious injury.

It is very important that you indicate all implants or other metal parts before the examination!

For modern MRI devices with higher field strengths, some implants such as IUDs (contraceptive coil, copper T, etc) are not generally approved by the manufacturer. We cannot rule out the possibility of dislocation (slippage) of the IUD and therefore impairment of the contraceptive effect as a result of the MRI procedure. A subsequent check by your gynecologist to ensure the correct position of the IUD is recommended. Metal parts worn on the body can also cause injuries and complications in the magnetic field. Therefore, please remove all metal objects before entering the examination room. Pay particular attention to the following common items:

- Jewelry (e.g. earrings, necklaces, rings) and piercings, watches, glasses, removable dentures, braces, arm or leg prostheses, hearing aids, sensors for blood sugar monitoring, metal parts on clothing (e.g. belt buckles, large zippers) or sports/functional underwear made of special material.

- Keys, coins, hair clips, writing instruments or other objects containing metal. Also check for cards with magnetic strips (e.g. credit-, telephone-, and insurance cards). In addition to disrupting the examination, the information on these cards may be deleted by the magnetic field.

If you feel unwell (e.g. nausea, breathing difficulties, pain) at any point during the examination, please inform the study staff immediately!
Please clarify any questions with the staff before entering the MR examination room.

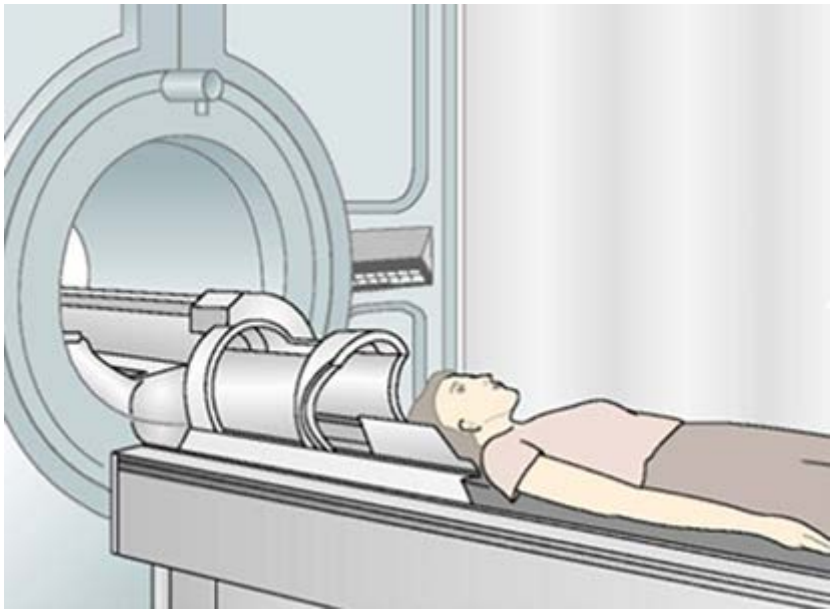

Figure 1: Positioning on the examination table

Questionnaire for MRI safety and medical history

Please answer the following questions carefully so that we can prevent any potential risks. Please check the appropriate box and underline or complete where needed. We will be happy to help you fill in the form should you have any questions.

Are there any implants in your body?
☐ No ☐ Yes, please check which:
- ☐ Pacemaker
- ☐ Defibrillator
- ☐ (Artificial) heart valve
- ☐ Stent
- ☐ Artificial joint

☐ Silicone implants
☐ Hydrogel
☐ Teeth (e.g. screwed-in dental implant)
☐ Metal (e.g. surgical screws, plates, nails)
☐ Shunt
☐ Catheter
☐ (Inguinal) hernia mesh
☐ and/or: _____

Are there any metal parts or magnetic implants in or on your body?
☐ No ☐ Yes, please check which:

☐ Braces
☐ Removable dentures
☐ Orthodontic therapeutic aids (e.g. telescopic prosthesis, retainer wire)
☐ Medication pump
☐ Cochlear implant
☐ Hearing aid
☐ Neurostimulator
☐ Metal pins/splinters
☐ Piercing
☐ Vascular clip
☐ (Hormone) contraceptive coil/copper T
☐ Permanent make-up
☐ and/or: _____

☐ Yes ☐ No Have you ever had a surgery? Old and/or minor operations should also be indicated.
If yes, please describe the operation and confirm with your signature that no metal parts remain in your body.

Type of surgery: _____

If applicable: In my case, no metal parts from the surgery remain in my body.
Signature:

_____

☐ Yes ☐ No Did any complications ever occur during a surgery?

☐ Yes ☐ No Have you had metal splinters in your body, e.g. through (metal) grinding work, accidents, or gunshot wounds?

☐ Yes ☐ No Do you have a tattoo?
If yes, where? _____

☐ Yes ☐ No Do you wear any piercings?
If yes, where? _____

☐ Yes ☐ No Do you wear a patch on your skin that releases any kind of medication (transdermal patch)?
If yes, which patch? _____

☐ Yes ☐ No Are you claustrophobic (fear of enclosed spaces)?
☐ Yes ☐ No Are you sensitive to noise or do you experience continuous (ringing) sounds, e.g. tinnitus?
☐ Yes ☐ No Do you suffer from hearing loss or a hearing impairment?
☐ Yes ☐ No Have you ever had a seizure (e.g. epilepsy, febrile seizure)?
☐ Yes ☐ No Do you have circulatory or breathing difficulties, e.g. when lying flat?
☐ Yes ☐ No Do you suffer from back or neck pain?

Do you have any known allergies?

☐ No Yes, please check which:

- ☐ Latex
- ☐ Disinfectants
- ☐ Patch (e.g. band-aid, Durapore)
- ☐ Plastics
- ☐ and/or: _____

Additional questions for women:

Are you currently pregnant? ☐ Certainly not ☐ Yes ☐ Not sure

Do you wear a gynecological implant, for example for contraception?
(e.g. hormonal rods, such as Implanon, or hormonal IUDs, such as Skyla, Liletta, Kyleena, Jaydess, Nuva ring, Mirena ring, Gynefix copper chain, copper IUD, contraceptive coil, or diaphragm)?

☐ Yes ☐ No If yes, please state the exact product name.

_____

_____

Additional notes of the study staff:

I have informed the patient/volunteer about the examination using the present information sheet and have discussed the following aspects and individual particularities (e.g. individual risk profile, coexisting medical conditions, medication, additional safety measures, behavioral instructions, special burdens, duration of the interview, ability of minors to consent, representation of caregivers, explanations to questions of the subject, etc.):

_____

_____

_____

_____

_____

_____

Declaration of consent

I have read and understood the information sheet. I was informed in detail about the planned examination, its nature and significance, risks, and possible complications in an informed consent discussion with the study representative _____.
My questions were answered completely and comprehensibly.

I was informed that I can additionally request to be briefed on MRI risks by a physician, even if the MRI risk briefing is provided by MRI-trained staff certified according to DIN 6876:2019-05.

□ I would like the MRI risk briefing to be provided by a physician.

□ I voluntarily waive the right to have the MRI risk briefing provided by a physician and agree to receive the MRI risk briefing from MRI-trained staff certified according to DIN 6876:2019-05.

I was informed that a physician is on call and will be consulted if necessary. I have no further questions, feel sufficiently informed, do not require any additional time for consideration, and consent to the planned examination.

I will follow the behavioral instructions. I confirm that the information provided above is correct and to the best of my knowledge. I will remove all removable metal items (cell phone, piercings, coins, keys, watch, EC/credit cards, knives, belt with metal buckle, wired bra, etc.) before entering the examination room. I have been informed that the University Hospital RWTH Aachen assumes no liability for any damage caused by my failure to comply with the behavioral instructions or due to my withholding of important information from the study staff. I have received a copy of this form.

Study participant/volunteer:

Last name: _____ First name: _____

Place, Date: _____ Signature: _____

Study representative:

Study name: _____

Place, Date: _____ Signature: _____

The following examination is planned:
Magnetic resonance imaging (MRI) of the head