Information sheet for participants to an experiment

**Title of the study:** **Neural mechanisms of serial order processing in working memory**

Official title: Neurale mechanismen van het verwerken van seriële orde in het werkgeheugen

Dear,

You are invited to participate in a scientific study. Before you decide to participate in this study, take sufficient time to read this information sheet carefully and discuss this with the investigator or other people of your choice. Please take time to ask questions if there are any uncertainties or if you require additional information. This process is called "informed consent" for participation in an experiment. Once you have decided to participate in the study, you will be asked to sign the consent form at the end of this information sheet.

# What is the purpose of this study?

We invite you to participate in a study in which we investigate how our working memory (also known as short-term memory) functions using brain scans. We are asking ourselves which parts of the brain are responsible for storing information in memory and which parts are involved in retrieving that information from memory. In a well-functioning working memory, it is not only important what information is stored, but also in what order (serial order) this happens. Think of a phone number: it is not enough to remember the numbers. If you do not remember them in the correct order, you will not reach the desired person. This study examines which specific brain regions are involved in maintaining the correct order of information in short-term memory. The sponsor of this study is Ghent University.

# what does participation in the study include for you?

Participation in this study consists of performing simple working memory tasks while a number of brain scans will be recorded. You will see a series of items (words, letters, numbers or simple visual objects) that you will have to keep in memory in correct order. Afterwards two items are shown and you have to indicate whether they are in the same order as you have memorized them.

For the brain scans, we use magnetic resonance imaging or MRI. This technique allows us to visualize what your brain looks like (which brain regions can be distinguished; these are called anatomical scans) and can also indicate which parts of the brain are active during the performance of certain tasks (such as working memory tasks in this case; these are called functional scans).

The total duration of the study participation will be 1 hour. A complete overview of the procedures and study progress is given below in the "procedures" and "study progress" section.

# How many patients will participate in this study?

A total of 100 persons will participate in this study.

# WHAT IS THE DURATION OF THIS STUDY?

The expected total duration of the study is 1 hour and includes only one visit to UZ Ghent, consisting of 10 minutes briefing and debriefing, completing a few questionnaires included, 5 minutes of anatomical scanning and 45 minutes of functional scanning while the working memory tasks are executed.

# What is expected from you?

If you decide to participate in this study, we ask you to cooperate with the investigator and that you follow his/her instructions carefully.

It is important that you respect the items mentioned below:

To take part in the study, you must be between the ages of 18 and 40. You must be right handed. You must not be pregnant, you may not be wearing protheses or artificial implants (including fixed dental brace), you may not suffer from claustrophobia, you may not have an elevated risk of epilepsy (epilepsy in the family, 24 sleep deprivation prior to testing, excessive use of or deprivation of alcohol, use of anti-depressants, neuroleptica, cocaine, or neurostimulantia) and you may not have a medical history of cardiovascular, neurological or psychiatric disease. In addition, you must respect the following points described in the procedure (6) and risks (9) below.

# WHICH procedures WILL be performed in the context of the study?

## Procedures:

1. Briefing

During briefing, it is clearly discussed what the study entails and what is expected from you. You will be explained clearly what MRI recordings implies, in order to make you feel comfortable. A standard questionnaire will be administered to rule out possible risks during the scan. There will be time and space for questions.

2. Brain scan

You will lie on your back in a supine position in the tube of the scanner. You do not have to undress, but all metal or magnetic objects (watches, jewelry, bank cards, etc.) must be discarded. The tube is fairly narrow, but you can look out through a mirror. The device also makes a lot of noise during the recordings so you wear earplugs and protective headphones. You always stay in touch with the researchers via a microphone, so that you can always ask additional questions. For people with claustrophobia, it can be uncomfortable to lie in the scanner tube and participation is not recommended. If you feel unwell, you can let us know with a simple push of a button. The experiment is then immediately stopped.

During the scan, an anatomical brain scan will first be recorded. The duration of the anatomical scans is approximately 5 minutes. Afterwards, you perform tasks by pressing buttons in response to the stimulus material presented, in casu the items to be memorized. The total time in the scanner is approximately 1 hour.

3. Briefing

At the end of the brain scans, when you left the scanner, you will be asked to complete a short post-checklist that asks for your experiences in the scanner. Finally, we will go over your impressions of the research together (debriefing).

## Study progress:

If you decide to participate in the study and if all the conditions for participation are met, you will need to undergo the following tests and investigations:

* Briefing
  + Explanation of the study and room for questions
  + Consent form
  + MRI pre-checklist
  + Hand preference Questionnaire
* Preparation for the scanner
  + Take off or remove any metal/magnetic objects (jewelry, bank cards, underwired bras etc.)
  + Lie on your back in a supine position in the scanner
  + Putting on headphones and microphones
  + Explanation of emergency buttons
  + Explanation for avoiding head movements
* In the scanner
  + Brain anatomy scan (5 minuten)
  + working memory tasks (45 min)
* Debriefing
  + MRI post-checklist
  + Impressions regarding research

# WHAT ARE YOUR RIGHTS WHEN PARTICIPATING IN THIS STUDY?

## Your rights when participating in the study

Participation in this study is entirely free and voluntary. You can refuse to participate in the study and you are free to withdraw from this study at any time, without having to justify your decision. This will not affect your medical follow-up, the quality of your subsequent care or the relationship with the investigator or the treating doctor.

Your participation in this study will be terminated if the doctor believes that this is in your interest. You may also be withdrawn prematurely from the study by the investigator if you don’t follow the procedures described in this information sheet properly or if you don’t respect the items described.

If you are withdrawn from the study, the pseudonymised data already collected will remain in the database for analysis, but no new data will be added.

This study was evaluated by the Ethics Committee of University Hospital Ghent and University Ghent. Under no circumstances should you take the favorable opinion of the Ethics Committee as an incentive to participate in this study.

## Rights in relation to the processing of your personal data

In accordance with the General Data Protection Regulation (or GDPR) (EU) 2016/679 of April 27, 2016 and the Belgian law of July 30 2018, on the protection of individuals related to the processing of personal data and on the free movement of such data your privacy will be respected and you will be able to access the data collected about you. Each error can be corrected at your request.

Your other rights (i.e. including the right to restrict the processing of your (personal) data, the right to have your (already collected) data erased in certain circumstances, and the right to lodge a complaint) are also safeguarded.

For more information on the rights you have and how to exercise them, please visit the UGhent website (<https://www.ugent.be/nl/univgent/privacy/privacyverklaring.htm>).

Your participation in the study means that your data will be processed for the purpose of the scientific study. This processing of data is necessary for the performance of a task carried out in the public interest, as mentioned in article 6, paragraph 1 (e) and is necessary for the purpose of scientific research in accordance with Article 9, paragraph 2 (j) of the General Data Protection Regulation.

All information collected during this study will be pseudonymised (here your data can still be linked to your personal file by means of a code.). The key to the codes assigned to you will only be accessible to the investigator or to his/her appointed replacement.

The pseudonymised data collected can be shared with other (future) researchers. This may lead to re-use of your pseudonymised data for future academic research projects and studies, exclusively in the context of the same or a similar disease/pathology or treatment. Such new studies and re-use of data always need to be submitted to and approved by the ethics committee. If you wish your data not to be used for future research, you can contact the DPO for this purpose (see contact below).

Only pseudonymised data will be used for analysis and in any type of documentation, reports or publications (in the medical scientific literature and/or at medical conferences) concerning this study. Therefore, confidentiality of the data will always be guaranteed.

Both personal data and data concerning your health will be processed and kept for at least 10 years after the end of the study and for safety reasons regarding the study conducted and its follow-up (if any).

In the context of data protection, the data will only be processed by personnel belonging to the research team and designated by and under the responsibility of the principal investigator, including internal employees with a non-healthcare profession.

In case your data has to be transferred to a country outside the European Economic Area (EEA), UGhent will ascertain whether the country of destination offers an adequate level of protection. If the country to which UGhent wishes to transfer data does not offer adequate guarantees, UGhent itself will enforce adequate guarantees by means of model agreements, made available by the European Commission, or other accepted measures. The processing of your data is based on consent, as mentioned in GDPR article 6, paragraph 1(a). Your explicit consent for this data transfer is asked in the consent form below.

Representatives of the promoter, auditors, the Medical Ethics Committee and the competent authorities, all bound by professional secrecy, can have direct access to your records under the responsibility of the investigator (or one of his/her collaborators) in order to check the study procedures and/or the data, without violating its confidentiality. This is only possible within the limits of the relevant laws. By signing this consent form and having received the preliminary explanations, you consent to this access.

To obtain more substantive information about the study and to exercise your rights, please contact the study team.

The Data Protection Officer can also provide you with further information on the protection of your personal data if required. Contact details: Hanne Elsen, privacy@ugent.be.

The Belgian supervisory Data Protection Authority responsible for enforcing data protection legislation can be reached via the following contact details:

Data Protection Authority (DPA)

Rue de la Presse 35 – 1000 Brussels

Tel: +32 2 274 48 00

E-mail: contact@apd-gba.be

Website: www.dataprotectionauthority.be

# WHAT ARE THE RISKS AND EXPECTED BENEFITS OF PARTICIPATING IN THIS STUDY?

Participation in this study will not bring you any immediate therapeutic benefit.

The MRI technique does not require injections or medication and is completely harmless. There are no other techniques that have such a spatial resolution of cognitive processes:

**Not allowed** to participate (the existence of possible risk factors will be verified before the study):

1) If you wear **protheses** or **artificial implants**, you are not allowed to take part in the study. Also who wear **dental braces** or other important **dental prostheses** are not accepted for participation due to an excess of artifacts in the images. If you (think) are pregnant, or cannot guarantee adequate contraceptive measures for the duration of the study, you will not be able to participate.

2) The scanner tube is relatively narrow. Therefore, individuals with **claustrophobia** should not participate in the study.

3) There is a very small risk of triggering an epileptic seizure during the visual stimulation because many changes are displayed in visual information. This risk is higher if you or a family member has **epilepsy**, if you are taking medication that increases the risk of epilepsy (such as anti-depressants, neuroleptics, cocaine and stimulants), if you have sleep deprivation in the 24 hours before the test, or if you are use of alcohol or alcohol withdrawal.

The likelihood of you being harmed by participating in this study is extremely low. All the tests carried out are completely painless and harmless. No injections or medications are given by mouth. The only downside to this research is the possible burden it can cause.

As part of this exam, an anatomical brain scan is also done. We are not actively looking for abnormalities or conditions, but if an unexpected brain condition requiring medical attention is incidentally detected on these scans, the radiologist will inform you about it and may refer you to your treating physician for further investigation.If you don't want to, you can't participate in the study. We emphasize that this anatomical scan is not a full-fledged diagnostic tool and cannot by itself provide a definitive answer on the presence or absence of a disorder.

You have the right to ask questions about the possible and/or known risks of this study at any time. You will be notified if information becomes available in the course of the study that could affect your willingness to continue participating in this study. If you nevertheless experience any disadvantage as a result of your participation in the study, you will receive appropriate treatment.

# ARE THERE ANY COSTS ASSOCIATED WITH THE PARTICIPATION IN THIS STUDY?

There are no additional costs if you participate in this study.

# IS there A REIMBURSEMENT FOR PARTICIPATION IN THIS STUDY?

You will be financially compensated for your participation in this study. A compensation of 25 euros is provided. You also receive a digital image of your brain.

# TO WHOM YOU CAN TURN IN CASE OF PROBLEMS OR IF YOU HAVE QUESTIONS?

If an injury occurs as a consequence of the study or if you would like to receive more information about this study or about your rights, you can contact the investigator or an employee of his/her team at any time during the course of the study:

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MR-afdeling (-1K12)

Universitair ziekenhuis Gent C. Heymanslaan 10

9000 Gent

09/332.40.72 (secretariaat)

**INFORMED CONSENT FORM FOR PARTICIPANTS TO AN EXPERIMENT**

|  |  |
| --- | --- |
| Reference number of the participant for this study |  |

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| --- |
| I have read and understood the document “Information sheet for participants to an experiment” page 1 to 7 and I have received a copy of this document. I have been informed about the nature of the study, its purpose, its duration, the foreseeable effects of the study and what is expected of me. I have been informed about the possible risks and benefits of the study. I have had the opportunity and sufficient time to think about it and to discuss it with a person of my choice. I have had the opportunity to ask any question that came to my mind and have obtained a satisfactory response to my questions, also on medical questions. |
| I understand that participation in the study is voluntary and that I can withdraw from the study at any time without giving a reason for this decision and without this having any influence on my further treatment. |
| I understand that auditors, representatives of the sponsor, the Medical Ethics Committee and the competent authorities may want to inspect my data in order to check the collected information. My privacy will be respected at all times. |
| I am aware that this study has been approved by an independent Medical Ethics Committee at UZ Ghent and Ghent University. This approval should under no circumstances be taken as an incentive to participate in this study. |
| I have been informed that both personal data and data concerning my health are processed and stored for at least 10 years after the end of the study. I am aware that I am entitled to access and correct this information. If I want access to my data, I will address the doctor-investigator who is responsible for the processing of the data. |
| I am aware that my pseudonymised data will be used for **current** scientific research. |
| I am aware that my pseudonymised data may be used for **future academic scientific research** within the framework of the same / a similar research field. Such new study should always be submitted and approved by the ethics committee. If I wish my data not to be used for future research, I will contact the DPO (see contact details under section 7). |
| I understand that in case an unexpected brain disease is identified that requires medical attention, the radiologist will inform me and will refer me to my GP for further investigation. |
|  |

Tick by the participant if agreed

|  |  |
| --- | --- |
| I agree to participate in this study consisting of the following **mandatory interventions** as explained under section 6 of the information letter:   * Participation to the anatomcial and functional brain scans and the execution of cognitive tasks during the scans * Completing the checklists |  |
| I declare not to be pregnant |  | |

I agree to participate in the following **optional aspects** of the study :

|  |  |
| --- | --- |
| * My data can be shared for further scientific research, with researchers within and outside the European Economic Area (EEA) or with an international organization. All necessary measures will be taken to protection of my personal data. By ticking this box I give my explicit consent to transfer data outside the EEA. |  |

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| --- | --- | --- |
| Name and first name of the participant | Signature | Date |
| Name and first name investigator\* | Signature | Date |

2 copies must be completed. The original is kept by the investigator in the hospital for a period of at least 10 years, the copy is given to the participant.

\*Tick by the investigator if agreed

|  |  |
| --- | --- |
| I declare that I have provided the necessary information regarding this study (the nature, the purpose, and the foreseeable effects) orally and a copy of the information document to the participant. |  |
| I confirm that no pressure has been exerted on the participant to allow him/her to participate in the study and I am prepared to answer any additional questions. |  |