Philipps Universität Marburg

Klinik für Psychiatrie und Psychotherapie
Philipps-Universität Marburg

Direktor: Prof. Dr. T. Kircher

Project Manager:

Prof. Dr. B. Straube / Prof. Dr. T. Kircher
Clinic for Psychiatry and Psychotherapy at the Philipps University of Marburg
Rudolf-Bultmann-Strasse 8, 35039 Marburg
Tel: 06421-58-66429 (Secretary Kircher: 58-66219)
Fax:06421-58-68939

Information for subjects for research projects with EEG examinations in preparation for the oral explanation by the investigator for the experiment "Delay Detection" within the study
"EEG correlates of dysfunctional prediction mechanisms in schizophrenia."

Dear participant,

We would like to ask you to participate voluntarily in the above-mentioned study. In this information sheet, we will provide you with background information on the study, describe the planned examinations, explain possible risks and finally state exclusion criteria for participation in the study.

(1) Information about the planned study:

The study is part of a research study to investigate the EEG correlates of dysfunctional prediction mechanisms in schizophrenia. The particular aim is to research the temporal and spatial correlates of the perception of action consequences. Electroencephalography (EEG) is used to measure these processes in the millisecond and second range.

The EEG examinations themselves are divided into a preparation phase (filling out questionnaires; putting on the EEG cap; instructions on the experiment; approx. 30 minutes), the EEG examination (approx. 60 minutes) and the follow-up phase (removing the EEG cap; washing hair; follow-up questions; approx. 30 minutes). The tasks you carry out on the computer during the EEG examination are very simple. You will be asked whether there was a time delay between a flashing circle on the computer screen and the pressing of a button.

Participation in this study is voluntary. You can withdraw your consent at any time and without giving reasons, without this causing you any disadvantages. We will pay you an expense allowance of €20 for participation (for a time commitment of approximately 2 hours). You will not derive any direct or indirect benefit from participating in this study beyond the expense allowance.

(2) We hereby request your consent to the following examinations:

Before taking part in the study, you should have already completed a telephone screening interview. At the beginning of the study, you will be asked to complete a questionnaire to determine your handedness (Edinburgh Handedness Inventory, EHI). During the EEG study, the experiment asks you to either press a button or the button (and your finger) will move by itself. You will then see a flashing circle on the computer screen. You will then be asked to decide whether or not there was a delay between pressing the button and the circle appearing.

(3) Procedure of the EEG examination and possible dangers

Electroencephalography (EEG, from Greek *encephalon* brain, *gráphein* write) is a method of medical diagnostics and neurological research for measuring the summed electrical activity of the brain by recording voltage fluctuations on the surface of the head.

The use of an EEG system has been extensively tested and does not lead to any other known risks. For the successful use of the EEG, it is necessary to establish contact between the electrodes and the scalp. To do this, an electrode gel is used which is massaged through the hair. The electrode gel is skin-friendly and washable. However, the hair must be washed after the measurement.

(4) Exclusion criteria

Psychiatric or neurological illness, first-degree relatives with schizophrenia, left-handedness, drug and alcohol addiction, acute illnesses or severe chronic internal diseases and limited or revoked legal capacity or capacity to give consent.

(5) Data protection

Storage and evaluation of data

The data important for this study, including your personal data, will be stored and evaluated. The storage, evaluation and, if necessary, forwarding of this study-related data will be carried out pseudonymously. Pseudonymized means that no details of names, initials and dates of

birth are used, only a number and/or letter code, so that the personal data can no longer be assigned to a specific data subject without the use of additional information ("key"). This is only possible for the study director using a key list that is stored separately and securely. This key list will be destroyed after the study has ended.

Sharing of research data

The data collected in this study, especially the EEG data, can be uploaded in non-personal form to freely accessible databases (e.g. https://openfmri.org) and made available to the general public. On the one hand, this should increase the quality of research and the transparency of data analysis, as other researchers will have the opportunity to check published results using the raw data. On the other hand, data already collected should also be able to be used for future research projects. These projects could pursue different objectives than the current study.

If data from this study is passed on to such a database, it will always be passed on *anonymously* . Anonymized means that, based on current knowledge and current technical methods, researchers who access these databases have no way of assigning this data to a specific person. There is no "key list" that brings together research data and personal data.

European General Data Protection Regulation (GDPR)

The European General Data Protection Regulation (GDPR) came into force on May 25, 2018. This changed data protection regulations in Europe and resulted in new requirements for the processing of personal data.

In the following, we would like to inform you about the rights set out in the GDPR (Article 12 ff. GDPR):

Legal basis

The legal basis for processing personal data concerning you in clinical studies is your voluntary written consent in accordance with the GDPR as well as the Declaration of Helsinki (World Medical Association declaration on the ethical principles for medical research involving human subjects) and the Guidelines for Good Clinical Practice.

You have the following rights regarding your data (Article 13 ff. GDPR):

Right to information

You have the right to information about the personal data concerning you that is collected, processed or possibly transmitted to third parties within the framework of the clinical study (handing over a *free* copy) (Article 15 GDPR).

Right to rectification
You have the right to have inaccurate personal data concerning you rectified (Articles 16 and 19 GDPR).

Right to erasure
You have the right to have personal data concerning you erased, for example if this data is no longer necessary for the purpose for which it was collected (Articles 17 and 19 GDPR).

Right to restriction of processing
Under certain circumstances, you have the right to request restriction of processing, i.e. the data may only be stored, not processed. You must request this. Please contact your examiner or the data protection officer of the test center (Articles 18 and 19 GDPR).

In case of rectification, erasure or restriction of processing, all those who have your data will also be notified (Article 17 (2) and Article 19 GDPR).

Right to data portability
You have the right to receive the personal data concerning you that you have made available to the person responsible for the clinical study. This allows you to request that this data be transmitted either to you or, where technically possible, to another body designated by you (Article 20 GDPR).

Right to object
You have the right, to object at any time to specific decisions or measures regarding the processing of personal data concerning you (Article 21 GDPR). Such processing will then generally no longer take place.

Consent to the processing of personal data and right to withdraw this consent
The processing of your personal data is only lawful with your consent (Article 6 GDPR).

You have the right to withdraw your consent to the processing of personal data at any time. However, the data collected up to this point may be processed by the bodies named in the subject information and consent form for the respective clinical study (Article 7, paragraph 3 GDPR).

Notification of personal data breaches ("data breaches")
If a personal data breach is likely to result in a high risk to your personal rights and freedoms, you will be notified immediately (Article 34 GDPR).

If you wish to exercise any of these rights, please contact your examiner or the data protection officer at your test center. You also have the **right to lodge a complaint with the supervisory authority(ies)** if you believe that the processing of personal data concerning you violates the GDPR (**see contact details**).

contact details

Data protection: Contact details of the test centre

Data Protection Officer		**Data protection supervisory authority**	
Data protection officer of the Philipps University of Marburg, Dr. Rainer Viergutz		The Hessian Data Protection Commissioner	
Address:	Biegenstraße 10 35032 Marburg (Parcel post: 35037 Marburg)	Address:	Gustav-Stresemann-Ring 1 65189 Wiesbaden
Phone:	06421-2826155	Phone:	Telephone: 0611-140 80
e-mail	datenschutz@uni-marburg.de	e-mail	poststelle@datenschutz.hessen.de

Person responsible for data processing	
	Prof. Dr. Benjamin Straube Clinic for Psychiatry and Psychotherapy, Philipps University Marburg
Address:	Rudolf-Bultmann-Str. 8 35039 Marburg
Phone:	06421- 58-66429
e-mail	straubeb@staff.uni-marburg.de

If you have any further questions, the investigator in charge will be happy to answer them.

Declaration of consent to participate in the research project

If you are willing to participate, we ask you to completely fill out and sign the consent form before the examination.

I hereby confirm that the examiner, Mr./Ms. ....., has informed me about the nature, significance, risks and implications of the intended examination and that I have had sufficient time to consider my decision. I have read the subject information. I feel sufficiently informed and have understood what it is about. The examiner has given me sufficient opportunity to ask questions, all of which were answered adequately for me. I have had enough time to make a decision.

I understand that personal data and medical findings are collected in scientific studies. The transfer, storage and evaluation of this study-related data is carried out in accordance with legal provisions and requires my voluntary consent before participation in the study. I agree that data collected as part of this study may be recorded on questionnaires and electronic data storage devices and analyzed without naming names for the purpose of scientific evaluation. I also agree that the data collected may be published in an anonymized form.

I have received a copy of the subject information and this signed consent form. My consent to participate in this research project as a subject is voluntary. I have been informed that I can revoke my consent at any time without giving reasons and without disadvantages.

I hereby agree to participate as a test subject in the research project: Experiment "Delay Detection" within the study "EEG correlates of dysfunctional prediction mechanisms in schizophrenia."

TO BE COMPLETED BY THE SUBJECT:

Surname: ……..

Birth date: ……

Date / time: ……

Place: ……. Signature: …….

TO BE COMPLETED BY THE EXAMINATOR:

I have verbally informed the test subject about the nature, significance, scope and risks of the research project.

Date / time: …….

Location: ……..

Investigator: …….