Information and consent form for the research project: "EEG gamma activity entrainment by periodic visual stimulation in sleep"

Participant information

Dear prospective participant,

We would like to ask you if you would like to take part in a scientific study. In this information sheet you will find everything you need to know about it.

We plan to enrol up to 30 participants in the study.

The study was planned by the Clinic and Polyclinic for Psychiatry and Psychotherapy, Klinikum rechts der Isar of the Technical University of Munich, and will be conducted in cooperation with the Faculty of Psychology (Ludwig Maximilian University of Munich) and the Faculty of Sport and Health Sciences (Technical University of Munich).

Our institution is financing the study itself.

It was reviewed by an independent ethics committee. No objections to the conduct of this study were raised during the consultation.

Your participation in this study is voluntary. You can also terminate your participation at any time during the course of the study without indicating any reason. There will be no disadvantages for you as a result.

Please read this information carefully. The investigator will talk to you about the study and answer your questions.

Why is this study being conducted?

Effective non-drug approaches are still lacking for the prevention of Alzheimer's dementia. We want to investigate whether a specific form of flickering light used during sleep could be useful. This needs to be tested in healthy volunteers first.

The study will compare one night without and one night with light administered through a special sleep mask per subject. If, as expected, the light stimulation leads to a slight increase in a certain form of brain activity, this offers the basis for an application in older subjects at risk of dementia.

What is the study procedure?

The study is expected to take 21 hours for each participant, including a short session on an afternoon of your choice and 2 nights at the weekend (due to lab availability). The procedure is as follows:

1. In an initial one-hour session in the psychiatry laboratory (Klinikum rechts der Isar), we will explain the study procedure in detail, go through the exclusion criteria, perform a brief colour vision test, and obtain your consent. If you enrol in the study, we will then

carry out an EEG (electroencephalogram) measurement, i.e., your electrical brain activity will be recorded. During this recording, you will wear the sleep mask with built-in LEDs developed for the experiment with your eyes closed while the light stimulation is administered.

The main part of the experiment is divided into two nights, taking place in a row on a weekend after the first session. Please allocate 10 hours of your time per night.

2. On the first night, you will be asked to come to the lab 1.5 hours before your usual bedtime on free days. First, a urine test for drug screening will be performed. If no test is positive, you will be allowed to go about your usual nightly routine, then the brain activity and sleep measurement systems will be prepared. The sleep mask will be put on but will remain off that night. After 8 hours at the latest, if you do not wake up before that, you will be woken up and un-wired. We will then ask you to complete a short sleep quality questionnaire before you leave the laboratory.
3. Second night: At the end of the day, you will return to the lab at the same time as on the night before. The procedure is identical to the first night, except that no urine test will be performed, and the sleep mask will be activated at a given time during the night. To determine the optimal timing, the experimenter will observe the sleep data output by the measurement systems in an adjacent room. The light stimulation is gently faded in after you have fallen asleep until it reaches the desired level. The stimulation remains on overnight. If you wake up unexpectedly during the night, the experimenter will pause the stimulation until you are asleep again. The next morning, you will fill out the questionnaire again, after which the experiment is terminated for you.

Is there a personal benefit from participating in the study?

No personal benefit is expected from participating in the study. However, the results of the study are likely to be helpful for others in the future.

What are the risks of participating in the study?

Visual stimulation: Many experiments use visual stimuli that flicker at certain frequencies to achieve a clear brain signal. This can be done, for example, using a computer monitor or masks with built-in LED lights. You may not notice that the LEDs change rapidly between light and dark and in most cases this is not experienced as uncomfortable. Some people report mild headaches. As long as you have no diagnosis of epilepsy, no other risks are expected.

Sleep: The experiment may possibly affect your sleep quality, on the two nights in the sleep lab. No health risks are expected as a result.

Is there any expense allowance?

You will receive 100 € as an expense allowance for full participation in the study. We also offer you a personalized sleep report.

What is expected of participants?

In the 7 days before your first night at the sleep lab, please keep your sleep-wake rhythm as constant as possible. For example, if you usually go to bed between 22:00 and 23:00 and get up between 07:00 and 08:00, please stick to these times.

In the 3 days before the first night, as well as on the two days of the measurements, please do not consume any alcohol or any other drugs (incl. cannabis and nicotine) and at most only the amount of caffeine that is usual for you. If you drink e.g., 1-2 cups of coffee a day, please stick to these amounts. If you usually take a nap, please do not sleep longer than usual during the day, otherwise do not nap at all.

This will give us the most accurate account of your sleep in the laboratory. Thank you in advance for your consideration.

Is it possible to withdraw from the study during the course?

Participation in the study is voluntary and consent can be withdrawn at any time during the study.

If subjects reveal sleep disorders (e.g., sleep apnoea, sleepwalking...) during the first night in the sleep laboratory, their participation in the study can be terminated prematurely. Exclusion from the study is also possible for organisational reasons.

Information on data protection

In this study, the Klinikum rechts der Isar of TUM is responsible for data processing.

The legal basis for processing your data is your personal consent (Art. 6 para. 1 lit. a, Art. 9 para. 2 lit. a DSGVO). Your data will be treated confidentially at all times.

The data will be collected for the purpose of this study described above and used within this framework.

We also plan to make additional use of the data outside of this study. The fully anonymised data will potentially be uploaded to an online platform ("Open Science Framework") after the completion of the study, so that other researchers can replicate and recalculate the results of the present study or analyse them in other ways. This maximises the public benefit from the data and ensures transparency. It is not possible to draw conclusions about individual persons.

We guarantee that the data collected here will only be used for further research purposes if an ethics committee has also advised on the new project and raised no objections. Explicit consent (tick yes/no in the consent form) is required for this further use.

The data also includes personal identifying data such as name, age and gender.

All data by which you could be directly identified, e.g. your name or date of birth, are replaced by an identification code (pseudonymised). This makes it almost impossible for unauthorised persons to identify you.

The data will be stored at the Faculty of Sport and Health Sciences at TUM and, in the case of personal data, deleted 2 years after the end of the study.

We do not transfer the collected data to other institutions in Germany, the EU, or to a third country outside the EU or to an international organisation.

Consent to the processing of your data is voluntary. You can revoke your consent at any time without giving reasons and without disadvantages for you. After that, no more data will be collected. The lawfulness of the processing carried out on the basis of the consent until the revocation is not affected by this.

In the event of revocation, you may request the deletion of the collected data. If you agree to this at the time of your revocation, the data can be further used anonymously (without attribution to your person).

You have the right to obtain information about the data concerning you, also in the form of a free copy. Furthermore, you can request the correction, blocking, restriction of processing or deletion as well as, if applicable, a transfer of the data.

In these cases, please contact:

Prof. Dr. Manuel Spitschan
Mail: manuel.spitschan@tum.de
Tel: 08928924544
Technical University of Munich
Faculty of Sport and Health Sciences
Georg-Brauchle-Ring 60
80992 Munich

If you have any questions about data protection, please contact the data protection officer:

Data Protection Officer of the Klinikum rechts der Isar
Postal address: Ismaninger Straße 22, 81675 Munich, Germany
E-mail: datenschutz@mri.tum.de

Data Protection Officer of the Technical University of Munich

Postal address: Arcisstr. 21, 80333 Munich
Telephone: 089/289-17052
E-mail: beauftragter@datenschutz.tum.de

You have the right to complain to any data protection supervisory authority. You can find a list of the supervisory authorities in Germany at:
https://www.bfdi.bund.de/DE/Infothek/Anschriften_Links/anschriften_links-node.html

You can reach the supervisory authority responsible for you at:

Bavarian State Commissioner for Data Protection
Postal address: P.O. Box 22 12 19, 80502 Munich, Germany
Home address: Wagmüllerstraße 18, 80538 Munich, Germany
E-mail: poststelle@datenschutz-bayern.de

Information and consent form for the research project: "EEG gamma activity entrainment by periodic visual stimulation in sleep"

Consent form

I have obtained and read the written information and consent form for the above-mentioned study. I have been informed in detail in writing and verbally about the purpose and the course of the study, the benefits and risks of participation, the rights and obligations. I had the opportunity to ask questions. These were answered satisfactorily and completely. In addition to the written information, the following points were discussed:

_____

_____

I have been informed that my participation is voluntary and that I have the right to withdraw my consent at any time without giving reasons and without incurring any disadvantages.

Consent to data processing

The processing and use of personal data for the above-mentioned study will be carried out exclusively as described in the section "Information on data protection".

I also expressly consent to the use of the personal data for further research purposes outside this study, as described in the section on data protection.

☐ Yes, I agree to the extended use.

☐ No, I do not consent to the extended use. Participation in the study is nevertheless possible.

I hereby voluntarily consent to participate in the above study and to the processing of my personal data as described.

_____

Name of the participating person in capital letters

_____

Place, date Signature of the **participant**

_____

Name of the investigator in capital letters

_____

Place, date Signature of the **investigator**