General information about the study

Many thanks for your interest in our study, “Investigations into the effect of light on human physiology and cognition”. Please take your time to read the text carefully. If you have any questions, we will be happy to answer them. By signing below, you can then declare that you are aware of this information and that you are willing to participate in the study.

Purpose: What is the objective of the study?

The study is a research project of the Max Planck Institute for Biological Cybernetics (MPI) in collaboration with the Technical University of Munich (TUM). In the study we want to examine how our brain and body react to light in the evening.

The data collected will be scientifically evaluated exclusively for research purposes. The research data may also be analysed for related questions within MPI and TUM.

Inclusion and exclusion criteria

The planned study is open to participation by healthy people between 18 and 40 years old. People who regularly take medications, are smokers, suffer from epilepsy, have a previous history of alcohol and drug abuse, have trouble sleeping or have an extremely early or late sleep-wake cycle cannot participate. Other requirements are normal vision and normal colour perception.

Participation also requires written consent.

Study procedure

Procedure for participation in the study

Participation in the study takes place in several steps. After contact is made, you will receive a link to complete a questionnaire where will ask you about your age and health. In this screening we will also collect sensitive data in accordance with data protection law (art. 9 GDPR), especially health data. Before the online screening we will ask you to confirm your consent.

We will then determine your suitability for participation in the study in an in-person max. one-hour screening session at the Max Planck Institute for Biological Cybernetics. This screening session will begin with a conversation about the study and the opportunity to ask questions of the study team. The actual screening session will begin after consent to participation in the study. Here, you will complete questionnaires about your general health, alcohol consumption, sleep and light exposure. Furthermore, your visual function and colour perception will be tested.

If you fulfil the requirements for participation, you will begin wearing an actimetry watch, which you will wear for the entire duration of the participation. In addition, you will complete a sleep diary every day. The actual measurements will be taken over a period of four weeks. On four evenings, each one week apart, you will then participate in the actual measurements for six hours at a time. For this, you will come into the laboratory 5 hours before your usual bedtime and stay until one hour after your usual bedtime. During these six hours in the laboratory, you will remain in twilight.

There will be three participants at a time participating in the study. Your privacy will be protected by means of partition screens. During the evening you will have access to a toilet and water. It will not be possible to eat or to drink other drinks during the evening. With the exception of visits to the toilet, you will spend the evening sitting down. We will offer you the option to listen to audiobooks or musical albums pre-selected from a library through your own headphones.

While you are with us in the laboratory, we will measure your body temperature by means of a temperature capsule. In addition to these continuous measurements, we will take the following measurements every half hour:

- Reaction time measurements by means of a computer programme
- Completion of questionnaires about condition and perception
- Saliva sample

Two hours before your usual bedtime you will then be subjected to a two-hour exposure to light. The light stimulus will be presented via a virtual reality headset, which you will wear on your head. Every half hour, you can take a break and remove the headset. After the exposure to light, you will remain in the laboratory for another hour. After the end of the study you can go home.

Investigation methods

During the examinations, sensitive data and particularly health data will be collected. These are explained below.

Screening

Computer-aided questionnaires

You will complete various questionnaires during the screening session. In the questionnaires, questions will be asked about your health, alcohol consumption, sleep and light exposure.

Visual function

During the screening session we will test your visual function. We will do this with the aid of special equipment that measures your visual acuity, colour perception and spatial perception. In addition, your visual function will also be tested by our ophthalmologist, Dr med. Stephan Munkwitz, and an image of your retina will be made.

Blood sampling for genotyping

During the screening session 5 ml blood will be taken from you. We want to find out whether there is a link with sensitivity to evening light in people with variants in certain genes responsible for sensitivity of the eye to light and for the internal clock. The blood sample will be taken by our ophthalmologist, Dr. med. Stephan Munkwitz, using a routine method. Blood samples will initially be stored on our premises in a locked refrigerator and then transported to Tübingen University Hospital (UKT). There, your genetic material will be extracted from the blood and then examined for different variants by the Molecular Genetics Group (Dr. Susanne Kohl). At no time will your entire genome be sequenced, but only variants of two specific genes. After processing, the samples will be destroyed. The Molecular Genetics Group will not receive any information about you.

Measurements before your time in the laboratory

Actimetry and sleep diary

You will wear an actimetry watch from 10 days before your first time in the laboratory. This is a sort of wristwatch that measures your movement and exposure to light. You will wear this for 24 hours and remove it only when swimming, showering and bathing, and during contact sports. The actimetric measurements will enable us to determine your sleep-wake cycle. In addition to the actimetry watch you will complete a sleep diary every morning on an app on your smartphone. Through this app, you will also be asked to log eating and exercise timing.

Regular sleep-wake cycle

From one week before your first time in the laboratory until your last visit in the laboratory you will keep to a regular sleep-wake cycle, which we will establish together with you. This cycle will be based on your usual bedtimes and getting up times. During your participation in the study, we ask that you do not change diet and exercise habits. Throughout the duration of the study, you will be asked to abstain from alcohol, nicotine and caffeine intake. On the day of the study, we ask you to abstain from painkillers, refrain from intense physical exercise, and avoid the following foods: bananas, chocolate, pineapple, orange, lemon and other citreous fruits.

Measurements during your time in the laboratory

Immediately prior to each laboratory visit, we confirm that you have not consumed alcohol or cannabis. We do this using a breathalyzer and a urine sample with a THC test stick. If we find evidence that you are under the influence of alcohol or cannabis, we will exclude you.

Exposure to light

You will spend your time in the laboratory under twilight conditions. In the two hours before your usual bedtime, you will then be subjected to a light scenario by means of virtual reality glasses.

Eye movements and pupillometry

The virtual reality glasses include a near-infrared camera to measure your eye movements and pupil size, which we will record during the study. The measuring technology is based on an LED, which illuminates your eye at a wavelength of approx. 850 nm and thus makes the pupil more visible for a near-infrared camera. The illuminance of the LED is very low and photometrically harmless.

Body temperature

Your body temperature will be measured by means of a very small temperature capsule, which has a radio connection to a receiver. You will swallow the temperature capsule and you will then excrete it within 24 to 48 hours. The temperature capsule is a disposable device, which is supplied sterile. The temperature capsule is read using a receiver device, which is accessible only to the investigators. It cannot be read with another receiver, owing to the manufacturer's configuration of the device. As the measurements will be recorded continuously, there is no need to read the pill again and it is simply excreted with your stool. The connection to the receiver device functions via RFID technology, i.e. a radio technology that allows contactless transmission.

The temperature capsule bears the CE marking and is harmless for you to use. This system using a temperature capsule is used routinely in research. To our knowledge, in our experience and according to the information from the manufacturer, no complications have occurred.

The temperature capsule is not suitable for use in MRI. You will therefore wear a wristband indicating that you cannot undergo MRI during participation in the study.

Subjective assessments

During the evening we will ask you to assess your sleepiness and mood on a subjective scale. During the exposure to light, we will also ask you questions about the light.

EEG

In some studies, we may record your brain waves by means of an electroencephalograph. This functions by means of electrodes in contact with your scalp.

Saliva samples and melatonin

Throughout the evening you will give a saliva sample every half hour. This will be done using a so-called salivette. For this you will take a piece of cotton wool in your mouth, which will become soaked with saliva and then be placed in a plastic tube.

Risks, insurance & compensation for expenses

What are the benefits and risks?

The analysis will be used for research purposes with the aim of improving our understanding of the effect of light on the brain and the body and the processing of signals in the brain. Personally, you will have no immediate advantage or benefit from participation in the study.

The study will have no negative impact on you. It is associated with no risks to your physical health or mental well-being. You will go to bed up to one hour later than usual, which is associated with no long-term impact.

Long-term wearing of the actimetry watch will have no negative impact. If your skin is irritated under the wristband, this can be countered with a simple moisturising cream.

Wearing the virtual reality glasses may be uncomfortable over a prolonged period. After the first half hour wearing the glasses, you will therefore have the opportunity to remove the glasses. There are no risks from the near-infrared camera in the glasses, which measures your pupil size and eye movements.

During the study you will be subjected to flickering light, which may seem uncomfortable. However, the flicker frequency will have no long-term impact on your vision and perception.

We would like to take saliva samples from you. In this case we require at least 1 ml per saliva sample. For comparison: a teaspoon holds roughly 5 ml water. The repeated chewing on cotton wool in the salivette may be uncomfortable. There will be an opportunity for you to have for a drink of water after the saliva sample.

The saliva samples will be handled only pseudonymously, and it will not be possible to identify individuals. Your saliva samples will be processed only by authorised personnel at the Max Planck Institute for Biological Cybernetics and the Technical University of Munich. The saliva samples will be stored securely and in locked refrigerators and freezers at all times.

You may find the blood sampling uncomfortable. Our ophthalmologist is experienced at blood sampling and will make the blood sampling as comfortable as possible. If you feel unwell during or after the blood sampling, we have a couch on which you can rest. In addition, we have water and fruit juice available at all times. Your blood samples will be processed only by authorised personnel at the Max Planck Institute for Biological Cybernetics, Tübingen University Hospital and the Technical University of Munich. The blood samples and genetic material will be stored securely and in locked refrigerators and freezers at all times.

Am I insured?

The Max Planck Institute for Biological Cybernetics is covered by business and product liability insurance (Basler, policy number 3184047).

Will I receive reimbursement of expenses?

You will receive reimbursement of expenses for participation in this study. You will receive € 30 for each laboratory session (4 sessions x € 30 = € 120). On completion of all study sessions, you will be eligible to receive a bonus of up to € 140 maximum, which will be allocated as follows: € 7 for each day of consistently wearing the actiwatch and adhering to the regular sleep-wake times, starting from the second day of the study (20 days x € 7 = € 140). The maximum total reimbursement is € 260.

Data handling

How and for how long will my data be stored?

All data collected from you will be stored and scientifically evaluated in accordance with data protection law (EU General Data Protection Regulation, German Federal Data Protection Act). Your contact data (name, address, telephone number, e-mail address etc.) and research data will be stored separately and linked together only by an individual code number. The actual research data will also be stored and linked together under this code number. During analysis the scientists will see only this code number and not your name. They will therefore not know during analysis from whom the research data originate. A link between the research data and your contact data can be established

only with the code number. This attribution may be made only by authorised personnel involved in the respective study. All your data will be secured in accordance with current technical standards and subject to strict access control. All staff at the Max Planck Institute for Biological Cybernetics will handle your information confidentially and have been placed under obligation to do so.

The data for the study will be stored at the Max Planck Institute for Biological Cybernetics and the Technical University of Munich. After a period of 12 months the code number will be deleted, so that you can no longer be identified from the research data without the use of additional information.

Blood and genetic material obtained from the blood will be stored at the Max Planck Institute after analysis for specific gene variants. The laboratory at UKT, which performs the analyses, will receive only the blood sample and a further, anonymised code number, which has a unique link to the code number under which the other research data are stored. This link will be visible only to the core team at MPI and TUM. Any inference of and link to other research data by UKT is therefore not possible.

The research data will be stored for at least 10 years, for reasons of good scientific practice established by the German Research Foundation (DFG) and the rules of the Max Planck Society. The purpose of this is for other scientists to be able to verify the accuracy of the results obtained. The samples will then be destroyed.

The data collected in the online screening will be deleted after exclusion and anonymized in case of inclusion.

The biomaterials supplied by you are provided for research purposes only. They are to be used for many different research purposes in the area of chronobiology and sleep physiology, for general scientific knowledge acquisition.

Data transmission

The research data will furthermore be transferred to a repository and submitted to a scientific journal for publication, such that the research data may be stored and used beyond the period of 10 years. Concerning this, please also read the information in the following section.

After completion of the data collection, it is planned that the research data will be submitted to FigShare.org, a research database operated in Great Britain, for archiving and further scientific use. Other scientists will therefore also be able to analyse the data for other scientific questions. Only anonymised data will be used here. As there will no longer be any personal link, it will no longer be possible to delete your research data from the data sets.

Your contact data will be used only within the Max Planck Institute for Biological Cybernetics and the Technical University of Munich. We will transmit only research data and no contact data to external scientists without your consent. Individual participants will no longer be identifiable here. For the external scientists it will not be possible to identify you from your research data, which will be transmitted only in anonymised form.

Data transfer

The study is a collaborative project with the Technical University of Munich. The research data collected in the project will be exchanged and analysed only within the framework of the research project. Contact data and data collected in the telephone screening before inclusion or exclusion will not be transmitted.

How will the results be published?

The results of the study will be published only with no direct personal link and may also be used for teaching. In the case of publication of study results your identity will remain confidential. This means: it will not be possible to identify from the results which person provided the information, nor will your participation in an investigation be identifiable from the research data.

It is planned that the results will be published in scientific journals, which also require storage of the underlying research data. The purpose of this is for other scientists to be able to verify the results. Associated research data may therefore be submitted to the journals and published there without names and contact data. Please note that these scientific data will consequently be available worldwide.

Receiving your results

In the consent form, you will be offered the option to receive a summary of some of your individual results collected throughout the study. This summary will be delivered to you in person after completion of the study, and will contain no personal identifying information. The following data will be included in the summary:

- Your daily activity, rest and light exposure throughout the duration of the study.
- Your self-reported sleep, wake and food intake times.
- Your average reaction time during each of the evening laboratory visits.
- Your body temperature during each of the evening laboratory visits.
- Your self-reported sleepiness during each of the evening laboratory visits.

These results are only relevant for research purposes and do not constitute a clinical report or diagnosis. None of the data included in this summary is expected to have clinical significance.

It is possible that during the visual screening tests, there might be incidental findings that could be of high significance to your health. You will be asked in a separate consent form whether you wish to receive feedback in such a case. Please note that no individual diagnosis will be made for you and discoveries/findings may also be overlooked.

Voluntary nature

Participation in the study is voluntary and you have the option to terminate your involvement at any time without giving reasons, with no negative consequences for you. You can terminate it at any time and with no disadvantage to you, even if investigations have already begun.

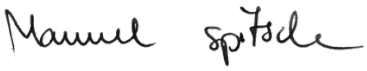
At any time, you may revoke your consent to the data processing described, with effect for the future.

Do you have any further questions?

If you have any further questions about the procedure of the study, data protection, your rights etc., please contact the study team.

We would be grateful if you would agree to participate in this study. If you have any further questions, please do not hesitate to contact us.

With our sincere thanks and best regards



Prof Dr Manuel Spitschan and the study team

Consents (1/4)

Declaration of consent to participation in the study

1. I have been informed about the study “Investigations into the effect of light on human physiology and cognition”, its course, significance, scope and risks, and I have read and understood the study information.
2. I have had the opportunity to clarify all open questions.
3. I have the right to request further information about the study at any time.
4. I voluntarily agree to participate in the study described in the study information.
5. I have been informed that I may withdraw from this study at any time without incurring any disadvantage.

Title, forename, surname (please use block letters)

Date of birth

Location	Date	Signature

Location	Date	Signature of the study assistant

Consents (2/4)

Declaration of consent under data protection law: online screening

Note: The following declaration of consent to the online screening will be obtained via a webform, before the start of screening questionnaires.

1. I have been informed about the study “Investigations into the effect of light on human physiology and cognition”, its course, significance, scope and risks, and I have read and understood the study information.

2. I voluntarily agree to participate in the online screening described in the study information.

3. I have read and understood the study information.

4. I have been informed that my consent is voluntary and that I may withdraw it at any time for the future. I have also been informed about my further rights to information, correction, erasure, the possibility of data portability, and complaint and contact options.

5. I consent to the collection, processing and analysis of my data by the Max Planck Institute for Biological Cybernetics and the Technical University of Munich.

6. The data may be collected by the Max Planck Institute for Biological Cybernetics and the Technical University of Munich within the framework of scientific research to determine suitability for further participation in the study. In accordance with this statement the data from the telephone screening will be deleted and not linked with the data collected subsequently.

7. I have been informed that I may revoke my consents at any time with effect for the future.

☐ Yes ☐ No

Location, date

Consents (3/4)

Declaration of consent under data protection law: screening and main study

1. I have read and understood the study information.
2. I have been informed that my consent is voluntary and that I may withdraw it at any time for the future. I have also been informed about my further rights to information, correction, erasure, the possibility of data portability, and complaint and contact options.
3. I consent to the collection, processing and analysis of my data by the Max Planck Institute for Biological Cybernetics and the Technical University of Munich.
4. The data may be used by the Max Planck Institute for Biological Cybernetics and the Technical University of Munich for the outlined purpose within the framework of scientific research.
5. I consent to the storage of research data without mention of my name for the publication of research results in scientific journals for review (re-analysis).
6. I consent to the analysis of my collected research data, as described in the study information, within the Max Planck Institute for Biological Cybernetics and the Technical University of Munich for scientific purposes for related questions.

   ☐ Yes ☐ No

7. I consent to the availability of my anonymised research data in FigShare.org, as described in the study information, for scientific analysis even after completion of the study.

   ☐ Yes ☐ No

8. I consent to the amalgamation and analysis of research data from this study with other research data collected at the Max Planck Institute for Biological Cybernetics and the Technical University of Munich.

   ☐ Yes ☐ No

9. I have been informed that I may revoke my consents at any time with effect for the future.

10. I wish to receive a summary of some my individual results, which will be delivered in person after completion of the study. I understand that these results are only relevant for research purposes, and do not constitute a clinical report or diagnosis.

    ☐ Yes ☐ No

_____

Forename, surname (please use block letters)

_____	_____	_____
Location	Date	Signature

Consents (4/4)

Declaration of consent for random findings

In individual cases it is possible a researcher may conclude that an analysis result during the eye screening is of significant importance for your health. This is true particularly if it gives rise to strong suspicion of a serious, possibly previously undetected illness, which could be treated or the onset of which could be prevented. In such a case you may receive feedback.

If you do not wish to receive feedback, please delete the option to be contacted again. By notifying us, you can change your decision for or against the feedback option at any time. Please note that you may have to disclose to other bodies the health information obtained through such feedback (e.g. before taking out health or life insurance) and you may incur disadvantages as a result.

Please note that no individual diagnosis will be made for you and discoveries/findings may also be overlooked.

I consent to you contacting me to inform me of any random findings.

☐ Yes ☐ No

Forename, surname (please use block letters)		
Location	Date	Signature

Information on data collection in accordance with article 13 of the General Data Protection Regulation (GDPR)

Responsibility for this

Institution responsible: Max-Planck-Institut für biologische Kybernetik, Max-Planck-Ring 8-14, 72076 Tübingen, Germany

Contact: Prof Dr Manuel Spitschan. Telephone: +49 (0)7071 601-1670. E-mail: manuel.spitschan@tuebingen.mpg.de.

Legal responsibility lies with the Max Planck Society for the Advancement of Science: Max-Planck-Gesellschaft zur Förderung der Wissenschaften e.V. (MPG), Hofgartenstraße 8, 80539 Munich, Germany. Telephone: +49 (0)89 2108-0.

Data Protection Officer contact data

Your contact at the Max Planck Institute for Biological Cybernetics: Mihai Vintiloiu, Max-Planck-Institut für biologische Kybernetik, Max-Planck-Ring 8-14, 72076 Tübingen, Germany. Telephone: +49 (0)7071 601-909. E-mail: mihai.vintiloiu@tuebingen.mpg.de.

MPG Data Protection Officer: Heidi Schuster, Hofgartenstraße 8, 80539 Munich, Germany. Telephone: +49 (0)89 2108-1554. E-mail: datenschutz@mpg.de.

Purposes of data processing

The data will be collected for implementation of the research project “Investigations into the effect of light on human physiology and cognition” and for the purposes described in the study information.

Your data required for accounting purposes owing to payment for the reimbursement of expenses will be processed separately from the data for research purposes.

Legal basis of data processing

The legal basis for the processing of your data for research purposes is your consent in accordance with art. 6 par. 1 letter a and/or art. 9 par. 2 letter a GDPR.

The mandatory requirements of the German Fiscal Code form the legal basis for the processing of your data for accounting purposes.

Recipients or categories of recipients

The data will be transmitted as described in the study description. External service providers may be commissioned to perform subtasks.

Storage duration

The data for research purposes will be stored for the duration stated in the study description. Research data must be stored for at least 10 years for reasons of good scientific practice of the German Research Foundation and in accordance with the rules of the Max Planck Society.

The data for accounting purposes will be kept for 10 years.

Your rights

You are not obliged to provide your data. At any time and without negative consequences you may revoke your consent to the storage of your contact data with effect for the future. You may also revoke your consent to the use of your research data at any time, without stating reasons and without negative consequences for you for the future and you may request the deletion of research data. We will comply with your request for deletion in accordance with the statutory requirements. In the case of revocation, if permitted by the statutory requirements, you can decide whether your data and biomaterials should be destroyed or may be used for other scientific purposes without the possibility of attribution to your name or contact data. In this case we would delete the identification code from which it is possible to determine the person from whom the data or samples originate. Please note that your research data can no longer be attributed to you personally after deletion of the code number from the contact data. If you revoke consent to the storage of your contact data, attribution of the study data will no longer be possible.

Your data cannot be removed from analyses already performed. To the extent permitted by law you still have the right to obtain information about the personal data held by us and its disclosure to third parties and you have the right to correction, erasure or restriction of the processing of personal data relating to you.

You also have the right to contact the regulatory authority for data protection: The authority responsible for the Max Planck Society is the Bavarian State Office for Data Protection Supervision: Bayerisches Landesamt für Datenschutzaufsicht, Postfach 606, 91511 Ansbach, Germany.

Study contact number

You can give notice of changes to your contact data here. You can also clarify questions about the participation or object to your participation in “Investigations into the effect of light on human physiology and cognition” for the future and assert rights to erasure, revocation and information with: Prof Dr Manuel Spitschan, Max-Planck-Institut für biologische Kybernetik, Max-Planck-Ring 8-14, 72076 Tübingen, Germany. Telephone: +49 (0)7071 601-1670. E-mail: manuel.spitschan@tuebingen.mpg.de.