**INFORMATION SHEET – VOLUNTEERS**

**PROJECT TITLE:** Cortical processes underlying cognitive and motor functions in different states of alertness: Combined brain stimulation and electroencephalography studies

**ETHICS:** This project has received ethical approval from the Psychology Research Ethics Committee of the University of Cambridge

You are being invited to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

**What is the purpose of this study?**

This study investigates component processes of cognition and action control in the alert, drowsy, or sleeping states of the mind using single or combined brain experimental techniques: 1) transcranial magnetic stimulation (TMS) or transcranial electrical stimulation (tES), are widely used, non-invasive techniques that involve electrical stimulation of areas of the brain; 2)Brain Measure techniques such as electroencephalography (EEG) or magnetoencephalography (MEG), which is a non-invasive technique that measures electric current produced by the brain and/or functional magnetic resonance (fMRI) that gauges the change in oxygen consumption in brain areas.

**Why have I been chosen?**

You have been chosen because you are a member of the CBSU Volunteer Panel, via the Department of Psychology or because you answered an advert asking for volunteers to participate in research studies using TMS, TES and EEG/MEG or fMRI

**Who is organizing this study?**

The study is organized by researchers working at the Department of Psychology, the Medical Research Council Cognition and Brain Sciences Unit (MRC CBSU), Cambridge, and the Department of Clinical Neurosciences, University of Cambridge. Your Principle Researcher is:

Dr. Tristan Bekinschtein

Department of Psychology, University of Cambridge

**What does the procedure involve?**

This study will involve one or several sessions of testing at the Herchel Smith Building, the Cognition and Brain Sciences Unit, or at the Behavioural and Clinical Neurosciences Institute, University of Cambridge, that will last anywhere from 2-4 hours or all night, including preparation and resting time (depending on the specific nature of the experiment). After signing a declaration of Informed Consent, you may be asked to fill in several questionnaires to assess, for example, your sleep quality, handedness and personality traits. There could be also a detailed interview about your experience during the experiment immediately after so we can learn from your impressions while drowsy. There will also be a safety screening form that asks about your health, pregnancy, use of a pacemaker, etc. Afterwards, an EEG cap with gel electrodes – or electrodes immersed in salty water – will be placed on your head. A good contact between the cap and your head will be ensured by gently rubbing your skin underneath each electrode. If you are participating from a EEG-fMRI combined experiment you will be taken to the MRI scanner after the electrode cap is in place. If you are participating from a MEG study you will also be taken to the MEG scanner after the EEG electrode cap is in place.

Afterwards, you will start carrying out experimental tasks, involving seeing visual stimuli or listening to sounds and responding to these stimuli depending on a particular experimental instruction. For example, we might ask you to press a button when you hear certain “target” stimuli, but refrain from pressing the button when other “non-target” stimuli are presented. You will have ample time before the real testing to practice the tasks to ensure you are comfortable with them. During some of the tasks, we might ask you to relax and allow yourself to drift into a sleepy state, if you wish to do so. In a subset of experiments, you may participate in a series of training sessions (5 to 10), and will be given online feedback in the form of an auditory tone, which you will attempt to “push” louder or softer, reflecting increases or decreases in arousal. Feedback will be given at the end of each session to describe level of improvement in modulating arousal based on this method. A small monetary reward will be tied to your performance. In a subset of experiments, we may ask you to come in for a whole-night experiment. During these experiments, we are particularly interested in what happens to your brain during transitions during different stages of sleep. Some of these sleep stages only become prevalent after many hours of sleep. These experiments will take place at the same location. During overnight experiments, you will come into the laboratory in the early evening. Once the apparatus are connected correctly, you would be made to feel comfortable and encouraged to fall asleep. The experiment would end when you wake up in the morning. If you are unable to fall asleep, or are unable to return to sleep, the experiment will be abandoned. If this is the case, we will organise a taxi to come and collect you from the laboratory. During these night experiments, two Cambridge University staff members will always be present.

While carrying out cognitive tasks, we may stimulate your brain with either TMS or tES. For TMS experiments, the TMS coil will be placed over the EEG cap and it will be used to stimulate your brain with a series of magnetic pulses. These pulses travel through your scalp and skull, causing small electrical currents in the cortex (the outer part of the brain). We will start by finding the best part of your brain to stimulate and then assess your response to the magnetic stimulation. The magnetic pulses may cause a slight sensation over your scalp, which may occasionally feel unpleasant. These trial stimulations will test TMS-induced cognitive or behavioural effects, such as light muscle twitches in the hand muscles after stimulation of the motor cortex, or the perception of flashes of light after stimulation of the visual cortex. If you respond well to these trials, you will be asked to proceed to the main experiment. For tES experiments, small electrode pads will be placed over relevant brain regions before placing on the EEG cap. The stimulus intensity for these experiments is low, and you will probably not feel anything. Sometimes, the stimulation feels like an itch or a scratch. If it is uncomfortable or painful, the intensity can be reduced.

For some sessions you may be asked to sleep for a specific amount of hours, this can either be a normal night of sleep or a restricted night of sleep. If that is the case, we would like to monitor your sleep duration and/or efficiency on the night previous to the testing session using an armwatch that measures your movement activity and other physiological measures. In that case we will arrange an appointment to give you the armband as well as the instructions. You will be required to wear the armband during the night, and hand it back at the start of the testing session the following day.

We aim to recruit participants, who took part in previous experiments involving magnetic resonance imaging (MRI) of the brain, as we will need MRI images for precise navigation of the TMS coil, as well as for the EEG data analysis. If you have not had an MRI scan before, we might ask you to attend a brief 30 min scan on a separate day. Before the MRI scan, a member of staff will ask you some questions to ensure that you have no metal within you before you enter the strong magnetic field. You will then be asked to lie in the scanner and the scanning will start. The scanning can be noisy and so we shall give you ear plugs and/or headphones to reduce this noise. It may not be appropriate for you to be scanned if you are very claustrophobic.

**What are the devices involved?**

There are four main techniques that we will be used to investigate brain function, all of which are completely safe and non-invasive; they involve no needles, drugs, radiation or x-rays. These are transcranial magnetic stimulation (TMS), transcranial electrical stimulation (tES), electoencephalography (EEG), magnetoencephalography (MEG) and magnetic resonance imaging (MRI), in the case you have not had an MRI scan before. TMS generates an electric current in an insulated coil, which produces a magnetic field around the coil. This rapidly changing magnetic field induces tiny electric currents in the brain when the coil is placed on the scalp. tES passes a small electric current between two electrodes that have been placed on your scalp. By alternating the strength of this current, it is also possible to entrain oscillating activity in the stimulated brain regions. It is completely safe. EEG measures the small electrical impulses that occur within the brain and spread onto the surface of the scalp. EEG does not send any electric current into your head; it only picks up signals coming from your brain. MEG measures the small magnetic impulses that occur within the brain and spread onto the surface of the scalp. MEG does not send any electric or magnetic current into your head; it only picks up signals coming from your brain. An MRI scanner uses a strong magnetic field to create detailed images of brain structure and function. By taking a series of images whilst you perform a task, we can build up a picture of the brain areas activated by this type of function. The scan does not involve any injections or X-rays.

Depending on the requirements of each experiment, physiological measurements might also include electrooculography (EOG), electromyography (EMG), galvanic skin response (GSR), respiration rate (RR) and heart rate (HR) measurements, all of which involve application of sensors on the skin. EOG sensors measure electric currents produced by eye movements, whereas EMG electrodes detect electric currents produced by muscle activity. GSR evaluates the ability of skin to conduct electricity. RR and HR measures the frequency of respiration and heart beat per minute. We might also use a video camera that tracks your eye movements. Each of these techniques is non-invasive and safe.

The armwatches we use to monitor the night before activity are called SenseWear Pro Armband™ (Body Media, Pittsburgh, PA), a portable sensing device 8.8 cm × 5.6 cm × 2.1 cm in size and 82 g in weight. The device can be worn on the upper arm and it measures skin temperature, galvanic skin response, heat flux, and body acceleration (movement). The device can be used to measure total and active energy expenditure, metabolic equivalent (METS), duration and quantification of physical activity, body position, sleep efficiency, and sleep duration.

**What are the possible risks/side effects of taking part?**

TMS is a safe, non-invasive technique, which has no known medium or long-term risks, although such risks cannot be completely ruled out. Occasionally, TMS may be associated with minor discomfort or mild headaches. These headaches are treatable with simple painkillers, such as aspirin. Because TMS uses magnetic fields, it can be harmful in people who have a pacemaker or metal implants in their bodies. Please inform the investigators if you might have any metal in your body. In rare instances, TMS has been reported to induce seizures in individuals already susceptible to seizures with a family history of epilepsy and, in extremely rare cases, in otherwise healthy individuals. Please inform the investigators if there might be cases of epilepsy in your family. Since the effects of magnetic stimulation on the fetus are unknown, you are advised not to take part if you might be pregnant. TMS has been used safely on thousands of individuals around the world for more than 20 years. However, should you wish to withdraw from the study you may do so at any time, with no obligation to explain your reasons.

Like TMS, tES has been used extensively in the research and clinical domains for many years. As it applies an electrical current between two electrodes placed on the surface of the scalp, there is the potential to cause damage to the stimulated cells. The likelihood of this is directly related to the stimulus intensity used, and the duration of stimulation. As such safe stimulation parameters have been established to prevent this from occurring, and the stimulation paradigm proposed in the present study falls well within these safety guidelines. When applying tES, we will check that the stimulus intensity we are using is not causing you any pain or discomfort. Further, during night experiments, we will wake you after the stimulation period and ask you whether you are feeling any pain or discomfort. If any pain or discomfort is reported, the experiment will be halted.

The MRI scanner can be loud when it takes images, so you will be given earplugs and ear defenders to block out some of the sound. Also, the MRI environment is quite confined, and people who are uncomfortable in small or confined spaces may not be able to participate. If this applies to you, remember that you may withdraw from the study at any time without explaining why. Otherwise MRI is generally thought to be a safe, non-invasive imaging technique. There are no known risks or side effects. Likewise, EEG measurements are safe, non-invasive, and they do not have any side effects. The Bodymedia Sensewear Pro Armbands are also safe and do not have any side effects.

**What are the possible benefits of taking part?**

We will reimburse you for your time: £10 per hour – but £20 to start with – during TMS-EEG, MEG/EEG and MRI experiments, and £6 per hour during behavioural testing alone (if TMS, tES, EEG or MRI imaging are not being conducted). We will also contribute towards the cost of your travel expenses, up to £3 per session or up to £20 contribution for taxi if needed after the night experiments.

We hope that you will have the pleasure of knowing that you have made a contribution to our understanding of the relationship between the brain and behaviour. If you wish, you can take away a picture of your brain on the day of your MRI scan, and we can show you your EEG brain waves. There will be no other direct benefits from being involved in the study.

**What if new information becomes available?**

If any new information pertains specifically to the health of the volunteer, the volunteer will be informed. Otherwise, new information will be disseminated through traditional scientific channels (journal articles, conference presentations).

**What happens at the end of the study?**

When data from several volunteers are collected, they will be analyzed and written up for publication in a scientific journal. The results may also be presented at scientific meetings, or in talks at academic institutions. The results will always be presented in such a way that data from individual volunteers cannot be identified.

**Confidentiality – who will have access to the data?**

Members of the research group will have access to the data. The MRC and the University of Cambridge comply with the requirements of the Data Protection Act 1998 with regard to the collection, storage, processing and disclosure of personal information and is committed to upholding the Act’s core Data Protection Principles. All enquiries concerning access to data held by the MRC Cognition and Brain Sciences Unit should be addressed to the Freedom of Information Liaison Officer at the Unit in the first instance.

**What happens if my scan shows something unusual? Will my GP be informed?**

Your GP will not be routinely informed if your participation in this study has been as a normal volunteer. This is not a diagnostic scan, but if something abnormal is detected you will be appropriately counselled and referred to an appropriate specialist in consultation with your General Practitioner, if that is what you would like. Such early detection of an abnormality has the benefit of starting treatment early but, in a small number of cases, may have implications for future employment and insurance.

**What will happen to the study results?**

They will be kept securely for a minimum of 10 years and possibly indefinitely in the University data archive in accordance with good research practice.

**Are there compensation arrangements if something goes wrong?**

In the very unlikely event of anything untoward happening, the University covers all volunteers against negligent harm.

**Can I withdraw from the study?**

You may withdraw from the study at any time without explaining why.

**Who has approved this study?**

This research study has been approved by the Cambridge Psychology Research Ethics Committee.

Thank you for considering taking part in this study. If you require any further information, we will be pleased to help you in any way we can.

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