Information Sheet on Transcranial Direct Current Stimulation (TDCS)

TDCS is a safe technique. But there are some small risks, which are described below. These risks are based on a review of 567 TDCS sessions and from questionnaire responses from 102 participants.

1. Tingling: The most common report – by 70% of participants – is that if a tingling sensation under the electrodes. This is present during and shortly after the period of stimulation, and has no adverse effects or risks. A small proportion of participants report this sensation as burning (22%) or painful (18%), although they scored the burning or painful sensation as quite mild (under 2 on a 5-point scale from none to intense).

2. Fatigue: The next common report – by 35% of participants – was of tiredness during the stimulation, and 25% reported this continued afterwards. The authors of the study suggest this may be due to the prolonged and uninteresting tasks the participants were doing.

3. Headache: Less than 10% of participants reported a headache after the stimulation. Such headaches are usually mild and can be treated with normal over-the-counter painkillers, if required. There is no evidence that TDCS leads to any change in frequency or severity of headaches.

Overall, less than 20% of the participants rated the stimulation procedure as mildly unpleasant and 80% reported that it was not unpleasant.

4. Seizures: TDCS has the potential to excite the brain and induce brief seizures, although this has never yet occurred, to our knowledge. These seizures are related to epileptic seizures but are short-lasting localised fits rather than grand mal epileptic seizures. They can be confused with syncope – a temporary faint or swoon – induced by anxiety. The risk of a seizure is very low – there have been no reported incidences that we know of (0%). We use published safety guidelines and expect the risk to be very low.

Importantly, the protocols used in this experiment are designed to depress the brain’s excitability, and this should reduce rather than increased risk of seizure induction.

Outcome: TDCS-induced seizures would be expected to last between tens of seconds to several minutes. There is no evidence to suggest that a TDCS-induced fit would be followed by any spontaneous fits – hence there is no evidence of any long term effect. Moreover, a seizure would occur at the time of experimental stimulation, if at all. So there is no risk of a delayed seizure outside of the care of the experimenter.

Some people, especially those with a history of epilepsy, may be prone to have a seizure related to an epileptic fit. Participants will complete a screening questionnaire before signing the consent form.

As TDCS uses an electric current we would exclude participants that have any metal devices such as cochlea implants or cardiac pacemakers. Metal implants in the head (excluding standard orthodontic braces, fillings etc) would also exclude participants from the study. These exclusions would be identified by the screening questionnaire.

If you want to learn more about TDCS you may want to visit the following web-site: http://www.magstim.com/downloads/guidesandreview.html

Reference

UoB ethical review ref. ERN_09-417
Copy to be retained by Participant

Participant Consent

Participant Number: ___

Please give full name in capitals ____________________________

Information on TDCS

I confirm that I have read the consent form and have completed the above questionnaire. The nature, purpose and possible consequences of the procedures have been explained. I understand that I may withdraw from the study at any time. I confirm that I have been through the TDCS screening procedures, and that I am happy to participate in this study.

Name (in CAPITALS)__________________________________________________

Signature _______________________________________  Date _________________

Have you read the invitation letter/information sheet? YES NO

Have you had an opportunity to ask questions and discuss this study? YES NO

Have you received satisfactory answers to your questions? YES NO

Have you received enough information about the study? YES NO

Have you completed the screening questionnaire? YES NO

Who have you spoken to?  
Professor Chris Miall
Another person?

Name: . . . . . . . . . . . . . . . . . .

Do you understand that your are free to leave the study:  
• at any time ?  
• without having to give a reason for leaving ?  
• and without affecting your medical care? YES NO

Please note: All data arising from this study will be held and used in accordance with the Data Protection Act (1984). The results if the study will not be made available in a way which could reveal the identity of individuals.

UoB ethical review ref. ERN_09-417

TDCS of the cerebellum    version 1.1  2-July-2009
Copy to be retained by Experimenter

Participant Consent

Participant Number: ___

Please give full name in capitals ____________________________

Information on TDCS

I confirm that I have read the consent form and have completed the above questionnaire. The nature, purpose and possible consequences of the procedures have been explained. I understand that I may withdraw from the study at any time. I confirm that I have been through the TDCS screening procedures, and that I am happy to participate in this study.

Name (in CAPITALS)__________________________________________________

Signature _______________________________________ Date _________________

Participant Questionnaire

Ppt.No _______

Gender: O male O female
Dominant Hand: O left O right
Native English Speaker: O yes O no
Age (please specify) ___yrs.

Have you read the invitation letter/information sheet? YES NO

Do you understand that your are free to leave the study:
• at any time?
• without having to give a reason for leaving?
• and without affecting your medical care?

Professor Chris Miall
Another person?

Name: . . . . . . . . . . . . . . . . . . .

UoB ethical review ref. ERN_09-417

Please note: All data arising from this study will be held and used in accordance with the Data Protection Act (1984). The results if the study will not be made available in a way which could reveal the identity of individuals.
If you agree to take part in this study, please answer the following questions. The information you provide is for screening purposes only and will be kept completely confidential.

<table>
<thead>
<tr>
<th>Question</th>
<th>YES / NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Have you ever suffered from any neurological or psychiatric conditions?</td>
<td></td>
</tr>
<tr>
<td>If YES please give details (nature of condition, duration, current medication, etc)</td>
<td></td>
</tr>
<tr>
<td>Have you ever suffered from epilepsy, febrile convulsions in infancy or had recurrent fainting spells?</td>
<td>YES / NO</td>
</tr>
<tr>
<td>Does anyone in your immediate or distant family suffer from epilepsy?</td>
<td>YES / NO</td>
</tr>
<tr>
<td>If YES please state your relationship to the affected family member.</td>
<td></td>
</tr>
<tr>
<td>Do you suffer from migraine?</td>
<td>YES / NO</td>
</tr>
<tr>
<td>Have you ever undergone a neurosurgical procedure (including eye surgery)?</td>
<td>YES / NO</td>
</tr>
<tr>
<td>If YES please give details.</td>
<td></td>
</tr>
<tr>
<td>Do you currently have any of the following fitted to your body?</td>
<td>YES / NO</td>
</tr>
<tr>
<td>Heart pacemaker</td>
<td></td>
</tr>
<tr>
<td>Cochlear implant</td>
<td></td>
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<tr>
<td>Medication pump</td>
<td></td>
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<tr>
<td>Surgical clips</td>
<td></td>
</tr>
<tr>
<td>Are you currently taking any unprescribed or prescribed medication?</td>
<td>YES / NO</td>
</tr>
<tr>
<td>If YES please give details.</td>
<td></td>
</tr>
<tr>
<td>Are you currently undergoing anti - malarial treatment?</td>
<td>YES / NO</td>
</tr>
<tr>
<td>Have you drunk more than 3 units of alcohol in the last 24 hours?</td>
<td>YES / NO</td>
</tr>
<tr>
<td>Have you drunk alcohol already today?</td>
<td>YES / NO</td>
</tr>
<tr>
<td>Have you had more than one cup of coffee, or other sources of caffeine, in the last hour?</td>
<td>YES / NO</td>
</tr>
<tr>
<td>Have you used recreational drugs in the last 24 hours?</td>
<td>YES / NO</td>
</tr>
<tr>
<td>Did you have very little sleep last night?</td>
<td>YES / NO</td>
</tr>
<tr>
<td>Have you already participated in a TMS or TDCS experiment today?</td>
<td>YES / NO</td>
</tr>
<tr>
<td>Have you participated in more than 1 TMS or TDCS experiment in the last 6 months?</td>
<td>YES / NO</td>
</tr>
<tr>
<td>Are you taking any prescribed drugs (prescribed by your GP or a hospital)?</td>
<td>YES / NO</td>
</tr>
<tr>
<td>Is there any chance that you could be pregnant?</td>
<td>YES / NO</td>
</tr>
<tr>
<td>Are you left or right handed?</td>
<td>Left / Right</td>
</tr>
</tbody>
</table>

Date of Birth _____/_____/_____

Signed: ..........................................................Date: ........................................

Name (in block letters): ..................................................................………....... ..............

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