LIVERPOOL JOHN MOORES UNIVERSITY Participant Information Sheet for Healthy Adult Individuals

LJMU's Research Ethics Committee Approval Reference: 18/NSP/069

YOU WILL BE GIVEN A COPY OF THIS INFORMATION SHEET

Title of Project*:* Is Brain Activity during Action Observation Modulated by people' body weight?: a transcranial Direct Current Stimulation study

Name of Researcher: Dr Valentina Cazzato, Liverpool John Moores University, School of Natural Science and Psychology

You are being invited to take part in a research study in which transcranial Direct Current Stimulation (tDCS) will be used. 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. Don't hesitate to ask if there is anything that is not clear or if you would like more information. You are free to take as much time as you like to decide whether you wish to participate.

1. What is the purpose of the study?

The brain is divided up into many different parts. Each part carries out a specific job, such as perception of colours, performing an action or understanding speech. The different parts of the brain communicate with each other while you are performing a particular behaviour (e.g. watching objects on the screen or pressing a button on a keyboard). By studying your brain using transcranial Direct Current Stimulation (tDCS) we are able to measure how different brain regions are involved and how they communicate with one another to enable you to carry out these different behaviours.

With this study, we aim at understanding if the activity of the left primary cortex in the brain is necessary to the automatic tendency to mimic other people during social interactions. In particular, we want to know whether people' understanding of familiar actions changes when these actions are performed by physically similar or dissimilar others, when physical similarity is conveyed by body weight and body mass index (BMI). Furthermore, we are interested in understanding whether there is a link between this region in the brain and prejudice towards obese people. Your task will involve simple judgements about stimuli (i.e., cubes) that are presented on a PC, that is to indicate the correct cube size (light or heavy). The study will involve one or two appointments (depending on what condition/order of the study you will be assigned to) overall lasting approximately 1 hour and 30 minutes.

2. What is transcranial direct current stimulation (tDCS)?

tDCS is a method by which a weak direct current (delivered by a battery) is delivered to the brain to stimulate a designated brain area, through a pair of two large sponge electrodes. tDCS works by exciting or inhibiting neuronal activity. In this study tDCS will be used to inhibit the neurons in the left motor cortex. This means that the neurons in the left motor cortex are likely to fire less often during and immediately after tDCS.

tDCS was reintroduced as a neuro-modulation technique around the turn of this century. It is currently used in a large number of universities and hospitals worldwide to study and improve brain

functioning in normal volunteers and patients. The technique is considered to be generally safe for use in neurologically healthy individuals

3. Who can take part?

Not everyone can take part in this study. Misleading and spurious results might be obtained if:

- ***you are under 18yrs old;***
- ***you are underweight (i.e., your Body Mass index is below 18.5 - you can work out your BMI by using the NHS online calculator at: http://www.nhs.uk/tools/pages/healthyweightcalculator.aspx);***
- ***you have acute eczema on the scalp;***
- ***you are Left-Handed;***
- ***you are pregnant or likely to be pregnant;***
- ***you experience frequent or severe headaches;***
- ***you have a cardiac pacemaker;***
- ***you wear a cochlear implant (in your ears);***
- ***you have a brain or high spinal cord stimulator in place;***
- ***you or your family have epileptic seizures ever;***
- ***you have a history of drug or alcohol abuse;***
- ***you have severe heart disease;***
- ***you have metallic implants in the head;***
- ***you have a medication infusion device;***
- ***you drank more than 3 units of alcohol in the last 24 hours;***
- ***you have used recreational drugs in the last 24 hours;***
- ***taking any prescribed or unprescribed medications (or herbal remedies);***
- ***you suffer from a psychiatric disorder (e.g., Eating Disorders, Autism Spectrum Disorder);***
- ***you have any uncorrectable vision problems (people who wear glasses and contact lenses can participate);***

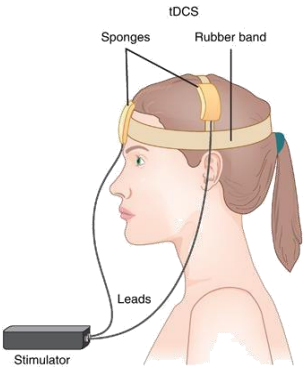
People who have a medical condition or who are taking prescription medication should discuss this with the researcher before agreeing to take part.
We will aim to recruit a total of 32 participants, 16 women and 16 men.

4. Do I have to take part?

No, you do not have to participate. *It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep, you will be asked to fill out a* ***safety screening questionnaire****, and you will then be asked to sign a form agreeing to take part. If you decide to take part you can still change your mind and withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect you in any way. There will be no adverse consequences in terms of your education, that is, there will be no impact on your assessment or class of degree (if student), or employment status (if staff member).*

5. What will happen to me if I take part?

Before taking part in any tests, you will be asked to fill out a ***safety screening questionnaire****. This questionnaire will ask you about your medical history, whether you have any metal in the brain, any medication you are currently on, and about recent alcohol and recreational drug use. You will be required to fill out this questionnaire and to sign a consent form before any testing takes place. If you do not wish to answer these questions, you may withdraw from the experiment without giving a reason. The information you provide will be treated as strictly confidential and will be held in secure conditions.*



On the day of the experiment, two large sponge electrodes soaked in saline water will then be placed to your head just above the brain sites in which we are interested in this study, as shown in the figure. There is no need for hair removal. The electrodes will be fixed by adjustable rubber bands. During stimulation a very weak direct current ***(1mA)*** *will be delivered by a battery driven stimulator to decrease the activity of the left motor cortex. Stimulation will last up to 10 min. This will result in a decrease of brain activity up to about one hour. We are interested in the effect of such decrease of brain activity at the left motor cortex on a certain behavioural task. Therefore, stimulation will immediately be followed by a test on the computer which will consist of pressing a button on a PC and responding as quickly and accurately as possible whether a cube being lifted by a person is heavy or light. Then, you will be asked to complete a series of questionnaires investigating eating attitude and cultural standards of attractiveness.* ***Please, bear in mind that these questionnaires are not designed to make a diagnosis of an Eating Disorders or to take the place of a professional diagnosis or consultation and no information about your results/scores will be disclosed to you as it will all be kept completely anonymous.*** *Finally, your weight and height will be taken by using a scale.*

You will receive a £10 shopping voucher and/or SONA points if you are a LJMU BSc student for participating.

6. Are there any risks / benefits involved?

Risks associated with tDCS. *tDCS is generally considered to be safe. tDCS neither causes epileptic seizures nor reduces the seizure threshold. Thus, seizures do not appear to be a risk for healthy subjects. However, this may not be true for patients with epilepsy.* ***Therefore, it is important that you tell us now if you have ever experienced a seizure yourself, or if there is any history of seizures in your family.***

Other potential adverse effects of tDCS

The most common transient adverse effects are mild tingling sensations, light itching sensations, or more rarely, a light burning sensation. These effects typically occur at the beginning of the tDCS and disappear quickly.

Participants sometimes reported transient headaches, mild discomfort, or skin irritation. These are generally mild discomforts that respond promptly to aspirin, panadol or other common analgesics. Note that mild redness under the electrodes is usually not a hint of skin damage, but most probably caused by neurally driven dilation of blood vessels, which is not harmful. In rare cases (2-3%), tDCS might lead to nausea or dizziness. ***If you feel any pain, nausea, or other discomfort during the procedure please alert the experimenter immediately so that testing can be discontinued****.*

Certain factors can influence how you will respond to tDCS. These include fatigue, or recent consumption of alcohol or drugs. Therefore, prior to each session involving tDCS, we will ask if you have consumed more than three units of alcohol (i.e. more than 1 pint of lager beer, more than 1 large glass (250ml) of wine, more than 70 ml of spirits such as vodka, gin, whisky) or any recreational drugs 24 hours before the session, if you have had a good night's sleep, and if you have consumed more than two cups of coffee in the two hours before the session. If your answer predisposes you to an increased risk of adverse effects, then we will arrange an alternative time for your testing session.

Finally, it is important to realise that tDCS has only been studied systematically for the last 10-15 years and there is still more to be learned about it. Neither animal nor human studies have shown any risks of long-term effects to the brain or its functions after tDCS, but there are few relevant data in humans to date. Therefore, adverse effects that cannot be foreseen today are theoretically possible.

Risks associated with the task at the computer. *You may feel pressured during the cognitive task at the PC to perform better or if you find the process difficult. To reduce this, breaks will be given after each test in order for you to feel relaxed again. At each break you will be asked how you feel and if you still feel comfortable to carry on. Furthermore, answering some of the experiment's questions may raise the possibility that you think you have a problem with eating or body image perception.* ***In the unlikely case of this happening, please feel free to contact the researcher or your medical GP or if you are a student contact the free counselling services available at the LJMU****. You have the right not to answer questions you do not wish to and/or to withdraw at any stage of data collection. There are no implications of this choice. There are no perceived possible long-term adverse risk effects.*

Benefits. *Taking part is of no direct benefit to you. We hope that the information we get from this study may help us to understand more about how the brain works and treat future patients with psychiatric problems (e.g., Eating Disorders, Autism Spectrum Disorder) better.*

7. What do I have to do before the tDCS sessions?

Certain factors can predispose an individual to an adverse effect during tDCS. These include fatigue, recent consumption of alcohol or recreational drugs, or a large amount of caffeine.

Prior to each session, please ensure that:

- ***You have had a good night's sleep the night before;***
- ***You have not consumed recreational drugs or more than 3 units of alcohol (i.e. more than 1 pint of lager beer, more than 1 large glass (250ml) of wine, more than 70 ml of spirits such as vodka, gin, whisky) the night before;***
- ***You have not consumed more than 2 cups of coffee in the two hours before your Session.***

8. What happens when the research study stops?

We hope to publish the results of this study in a scientific journal. We may also present the results at a scientific conference or a seminar in a university. We may also publish results on our website. We would be happy to discuss the results of the study with you and to send you a copy of the published results. It will not be possible to identify you in any report or publication since all acquired data will be anonymised.

9. What will happen to the data provided and how will my taking part in this project be kept confidential?

The information you provide as part of the study is the research study data. Any research study data from which you can be identified (e.g. from identifiers such as your name, date of birth, etc.), is known as personal data. This includes more sensitive categories of personal data (sensitive data) such as your race; ethnic origin; gender, weight, height. Personal data does not include data that cannot be identified to an individual (e.g. data collected anonymously or where identifiers have been removed).

If necessary, personal data will be stored confidentially for 5 years after the study has finished [OR] as long as it is necessary to verify and defend, when required, the process and outcomes of research. The time period may be a number of years. Your data will only be viewed by the researcher/research team. Personal data collected from you will be recorded using a linked code – the link from the code to your identity will be stored securely and separately from the coded data. All electronic data will be stored on a password-protected computer file in room 3.06 (Tom Reilly Building, LJMU). All paper records will be stored in a locked filing cabinet in room 3.06 (Tom Reilly Building, LJMU). Your consent information will be kept separately from your responses in order to minimise risk in the event of a data breach. We will not name you in any of our reports or publications. You will not be identifiable in any ensuing reports or publications.

Anonymised data might be used for additional or subsequent research studies and we might share anonymised data with other investigators (e.g. in online databases). All personal information that could identify you will be removed or changed before information is shared with other researchers or results are made public.

10. Limits to confidentiality

Please note that confidentiality may not be guaranteed; for example, due to the limited size of the participant sample, the position of the participant or information included in reports, participants might be indirectly identifiable in transcripts and reports. The investigator will work with the participant in an attempt to minimise and manage the potential for indirect identification of participants.

The Investigator will keep confidential anything they learn or observe related to illegal activity unless related to the abuse of children or vulnerable adults, money laundering or acts of terrorism.

In certain exceptional circumstances where you or others may be at significant risk of harm, the investigator may need to report this to an appropriate authority. This would usually be discussed with you first. Examples of those exceptional circumstances when confidential information may have to be disclosed are:

- *The investigator believes you are at serious risk of harm, either from yourself or others*
- *The investigator suspects a child may be at risk of harm*
- *You pose a serious risk of harm to, or threaten or abuse others*
- *As a statutory requirement e.g. reporting certain infectious diseases*
- *Under a court order requiring the University to divulge information*
- *We are passed information relating to an act of terrorism*

11. Who is organising the study?

This study is organised by Liverpool John Moores University.

12. Who has reviewed this study?

This study has been reviewed by, and received ethics clearance through, the Liverpool John Moores University Research Ethics Committee (Reference number: 18/NSP/069).

13. What if something goes wrong?

If you have a concern about any aspect of this study, please contact the relevant investigator who will do their best to answer your query. The researcher should acknowledge your concern within 10 working days and give you an indication of how they intend to deal with it. If you wish to make a complaint, please contact the chair of the Liverpool John Moores University Research Ethics Committee (researchethics@ljmu.ac.uk) and your communication will be re-directed to an independent person as appropriate.

14. Data Protection Notice

The data controller for this study will be Liverpool John Moores University (LJMU). The LJMU Data Protection Office provides oversight of LJMU activities involving the processing of personal data, and can be contacted at secretariat@ljmu.ac.uk. This means that we are responsible for looking after your information and using it properly. LJMU's Data Protection Officer can also be contacted at

secretariat@ljmu.ac.uk. The University will process your personal data for the purpose of research. Research is a task that we perform in the public interest.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained.
You can find out more about how we use your information by contacting secretariat@ljmu.ac.uk.

If you are concerned about how your personal data is being processed, please contact LJMU in the first instance at secretariat@ljmu.ac.uk. If you remain unsatisfied, you may wish to contact the Information Commissioner's Office (ICO). Contact details, and details of data subject rights, are available on the ICO website at: https://ico.org.uk/for-organisations/data-protection-reform/overview-of-the-gdpr/individuals-rights/

15. Contact for further information:

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Thank you for reading this information sheet and for considering to take part in this study.

Note: A copy of the participant information sheet should be retained by the participant with a copy of the signed consent form.