TITLE: Transcranial magnetic stimulation and inhibitory control training to reduce binge eating: brain and behavioural changes (BE-NEMOIC)

Code: ProyExcel_00776

Date: April 16, 2024

INFORMATION SHEET

NAME OF THE STUDY: **TRANSCRANIAL MAGNETIC STIMULATION AND INHIBITORY CONTROL TRAINING TO REDUCE BINGE EATING: BRAIN AND BEHAVIOURAL CHANGES (BE-NEMOIC)**

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Please read this information carefully: We are asking for your **voluntary participation** in a research project. Before participating in the study, please read the information provided below and ask as many questions as you need to ensure that you understand what your participation involves.

Information about the study and your participation in the study

What is the aim of the study?

The aim of this study is to determine the efficacy of a binge eating reduction programme. The present study uses Transcranial Magnetic Stimulation (TMS) to investigate whether it improves the results of cognitive training aimed at reducing binge eating in frequency and intensity of symptoms.

In addition, we aim to better understand the relationship between human biology and binge eating. To do so, we will measure various biomarkers, i.e. biological measures related to binge eating behaviors and determine their association with other cognitive (food appraisal, craving, decision-making, inhibition, working memory, flexibility) and neuroimaging measures (activation, grey and white matter volume, connectivity) that have been previously explained in more detail in the briefing.

Where does the study take place?

This study is led by Raquel Vilar López and Alfonso Caracuel Romero, and their collaborating team. The study will take place at the Mind, Brain and Behaviour Research Centre (CIMCYC), which belongs to the University of Granada and is located on the Cartuja Campus (between the faculties of Psychology and Pharmacy).

What procedures will I carry out?

This study has an evaluation and an intervention part.

In the assessment you will carry out different tasks (pencil and paper and/or via computer and mobile phone) to find out about different aspects related to your eating habits and psychological aspects (such as impulsivity and personality), as well as your weight and height, in a session lasting about 120 minutes.

We will also collect blood, saliva, urine and faeces samples. You will be provided with two plastic bottles to collect your urine and stool samples. The saliva sample will be collected by a health professional by rubbing some swabs inside your mouth. The same healthcare

professional will also take a blood sample by vein puncture of the forearm. In addition, a functional magnetic resonance imaging (fMRI) will be performed for about 60 minutes during which you will be asked to rest and also to respond to some simple tasks.

These assessments and samples will be taken at three points in time: before starting the intervention sessions, one week after the end of the intervention sessions, and at the follow-up 3 months after the end of the intervention.

As for the intervention sessions, during the first 3 minutes we will apply a non-invasive stimulation technique (known as transcranial magnetic stimulation, or TMS). This technique consists of the application of very brief magnetic pulses, focused on the part of the brain whose function is to be enhanced. The application is carried out by means of a device in contact with the left side of your head, near the forehead, which in most cases does not cause any discomfort, is painless and has no side effects. You will then do inhibitory control training with the mobile phone for 10 minutes.

Are there any disadvantages to participating in the study?
The different evaluation sessions and cognitive tasks do not present any inconvenience for the participants, beyond the mental fatigue that some people may feel when carrying out this type of activity.

As for sample collection, it will be carried out by nursing staff and in the same way as is usually done in health check-ups. There are no risks, except for possible inconveniences that may arise in any blood collection, such as slight pain in the area of the puncture, difficulty in finding the appropriate vein that may result in having to be punctured again, or the subsequent appearance of a small haematoma (bruise or bruise) in the extraction area.

For its part, the MRI applied in the assessment has been shown to be a very safe technique even if applied on a prolonged basis. The possible adverse effects are not significant and among those reported by some people are pain if poor posture has been maintained, drowsiness, ringing or congestion in the ears due to repetitive noise (although protective earplugs will be worn), dizziness, headaches and increased body temperature. Qualified technical staff will be present at all times to deal with any problems that may arise. To ensure safety, a full interview is carried out beforehand to rule out any risk factors.

As for the stimulation technique used in this study, it has been shown to be completely safe and with the parameters we will use its effects of stimulating brain activity are completely transient, you will not notice anything and the duration is short. However, some people have experienced scalp discomfort or headaches that usually disappear over time or with a regular over-the-counter pain reliever. To mitigate possible hearing discomfort from the noise emitted by the machine, earplugs will be provided during stimulation. Although very unlikely to occur, the most serious risk with this type of technique is that seizures may occur during stimulation. Worldwide, there have been several cases of people who have experienced seizures, but without any health effects. To ensure your safety, a full interview is carried out beforehand to rule out any risk factors such as brain damage, personal or family history of epilepsy or seizures, or taking certain medications. In addition, we have medical staff and

equipment on hand at all times to deal with any problems that may arise.

Is there any benefit to participating in the study?
Participation in the study may have benefits related to improving certain aspects of impulsivity, and therefore may help you to reduce excess weight.

There is no financial consideration. You have the right to receive a report with the results of your blood test if you so wish. You will not be able to know other specific results on a personal level, but in the event that information concerning your health, or that of your family is obtained from the genetic analyses, you have the possibility to be contacted by us in order to provide you with this information.

In addition, their participation will provide scientific knowledge that will contribute to improving the design of treatments for people with binge eating.

Aspects to consider regarding biological samples
The blood analysis requires fasting for at least 6 hours beforehand, as food intake alters the blood concentrations of various parameters. The blood collected, as well as the saliva, urine and faeces samples will be prepared at CIMCYC for freezing and at the end of the project they will be transferred to external laboratories for microbiota, proteomic and genetic analyses related to the project objectives. The genetic analyses have no medical value (e.g., diagnosis or prognosis of disease) or individual benefit to you, but can help us to investigate the multiple determinants of binge eating.

If you give your consent, part of each of the samples will be kept in the CIMCYC freezer to be used, together with the information associated with them in an anonymous way, in future studies by the researchers of this project and their collaborators, when technology and scientific advances allow new analyses to be proposed. In that case, you will have at your disposal all the information about the different research projects in which your samples are used.

Confidentiality
The biological samples and personal data required (name, age, sex, health data and habits collected in the evaluation) are those necessary to meet the objectives of the study. All data obtained will be used solely and exclusively for the purposes of the study and will be treated by the research team in complete confidentiality. The results derived from this study may be published in a scientific journal or congress, always maintaining anonymity and confidentiality. Any personally identifiable information will be kept and processed under secure conditions. To protect your privacy, all information about you and the samples collected will be assigned letter and number codes in a computerised randomisation programme. The information and samples will be stored with restricted access only by project staff and in UGR facilities. Your results will be stored identified by these codes and never by name, and will be used only within the context of the project. Data may only be shared in repositories for scientific purposes in a format that ensures anonymity. The stored biological samples (15 ml of blood, 15 ml of urine, 1.5 grams of faeces, 3 saliva swabs) will be used to analyse variables related to oral and intestinal flora, proteins and genetics and will be

stored in an anonymised format.

During the study, you may at any time exercise your right of access, rectification, cancellation and opposition to your data before the responsible researcher, as established in Royal Decree 1720/2007, Organic Law 3/2018 on the Protection of Personal Data and guarantee of digital rights, and European Directive 2002/58/EC.

You can obtain further information on your rights regarding the processing of your data at http://secretariageneral.ugr.es/pages/proteccion_datos/derechos, and by contacting the following e-mail address: protecciondedatos@ugr.es.

Study participation agreement

This sheet contains information to help you decide if you want to participate in this study. **If you have any questions that remain unanswered, please ask the study leader before signing this form**. You can contact the principal investigators of the project, Raquel Vilar López and Alfonso Caracuel Romero, by email rvilar@ugr.es and acaracuel@ugr.es or by telephone 958241982 and 958242948.

Participation in this study is voluntary, and you will be able to withdraw your consent at any time without explanation. You do not have to participate in the study if you do not want to. If you finally decide to participate, you will receive a copy to keep this information and another copy to sign giving your consent.

INFORMED CONSENT FORM

Project title: Transcranial Magnetic Stimulation and Inhibitory Control Training to Reduce Binge Eating: Brain and Behavioural Changes (*BE-NEMOIC*)

PROFESSIONALS INVOLVED IN THE INFORMATION AND/OR CONSENT PROCESS:

The following professionals declare that the information regarding participation in the project and/or donation of biological samples has been explained:

Raquel Vilar López and Alfonso Caracuel Romero
Centre for Mind, Brain and Behaviour Research of the University of Granada
DNI: 46898000B y 52363377J

1. CONSENT TO PARTICIPATE IN THE STUDY:

I, Mr./Mrs. (name and surname) _____ with **DNI** nº _____ declare under my own responsibility that I have read and understood the information sheet, a copy of which has been given to me.

I have received sufficient information about my participation in the project, about the use of my personal data and/or about the donation of biological samples of blood, saliva, urine and faeces and associated information, and about the performance of genetic analyses on them.

I was able to ask questions about the information I received and talk to the right professional, who answered all my questions. I understand that my participation is voluntary.

I understand that all my data will be treated confidentially, according to the General Data Protection Regulation (EU) 2016/679 and the Organic Law 3/2018 on the Protection of Personal Data and Guarantee of Digital Rights.

I understand that I can withdraw from the study:

- Whenever I want.
- Without having to explain.
- Without this impacting on me in any way.

My biological samples will be used for the development of the research project **Transcranial Magnetic Stimulation and Inhibitory Control Training to Reduce Binge Eating: Brain and Behavioural Changes** directed by Raquel Vilar López and Alfonso Caracuel Romero. **I have also been informed of the option for a portion of the biological samples and associated information obtained in this project to be held and used in future projects and, in this regard, I take the decision that the portion of the samples not used in the original project will be:**

☐ Destroyed
☐ Irreversibly anonymised

Assigned to the CIMCYC-PROYEXCEL_00776 Private Collection for use, while maintaining my anonymity, in future studies by the researchers of this project (if this option is ticked, once the project is completed, the researcher responsible for the collection will contact me to formalise the assignment).

As my biological samples are for the Private Collection CIMCYC- PROYEXCEL_00776 (Raquel Vilar López and Alfonso Caracuel Romero) the surplus biological sample and associated data will be returned to this Private Collection.

I consent to the processing of my clinical data and/or samples:

Encrypted (they will be identified with a code that protects my identity, and it will be possible to link them back to me).

I authorise that I may be contacted at a later date:

☐ YES
☐ NO

If yes, please indicate the means of doing so:

☐ Telephone: (insert number)_____
☐ E-mail: (insert address)_____
☐ Others: _____

I wish to place restrictions on the use of the sample, so that it will not be used at: _____

I consent to receive information about genetic data and data relevant to my health and that of my family members.

Please tick as appropriate:

☐ YES
☐ NO

I know that I may revoke, at any time, the consent given in this document.

In _____, at ____de_____ of 20_____

THE DONOR