INFORMATION SHEET AND INFORMED CONSENT FORM
Code: SICEIA-2024-000656
Date: October 28, 2024

STUDY NAME: **Transcranial magnetic stimulation and inhibitory control training for the treatment of excess weight: Behavioral and brain changes (InhibE)**

Responsible researchers: Raquel Vilar López and Alfonso Caracuel Romero
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Please read this information carefully : Your voluntary participation in a research project is requested . Before participating in the study, please read the information we provide below and ask as many questions as you need to ensure that you understand what your participation entails.

Information about the study and your participation in it

What are the objectives of the study?

The objective of this study is to determine the effectiveness of a program for the treatment of excess weight. The present study uses Transcranial Magnetic Stimulation (TMS) to investigate whether it improves the results of cognitive training aimed at the adherence of healthy habits and weight loss.

Additionally, we aim to better understand the relationship between human biology and excess weight. To do this, various biomarkers will be measured, that is, biological measures related to weight, and their association with other cognitive measures will be determined (food evaluation, frequency of physical exercise, decision making, inhibition, working memory, flexibility). and brain neuroimaging (activation, gray and white matter volume, connectivity) that have already been previously explained in more detail in the information session.

Where is the study carried out?

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

What procedures will I carry out?

This study has an evaluation part and an intervention part.

In the evaluation you will carry out different tasks (pencil and paper and/or through the computer and mobile phone) with which we can learn different aspects related to your way of eating and psychological aspects (such as impulsivity and personality), as well as your weight and height, in a session of about 120 minutes.

We will also collect samples of blood, saliva, urine and feces. To do this, you will be provided with two plastic containers to collect your urine and stool samples. The saliva sample will be collected by a healthcare professional by rubbing swabs inside your mouth. The same health professional will extract the blood sample through a venipuncture of the forearm. Additionally, a functional magnetic resonance imaging

(fMRI) will be performed for about 60 minutes in which we will ask you to rest and also respond to some simple tasks.
These evaluations and sampling will be carried out at three time points: before starting the intervention sessions, the week after finishing said sessions, and in the follow-up that we will carry out 3 months after finishing the intervention.

Regarding the intervention sessions, during the first 3 minutes we will apply a non-invasive stimulation technique (known as transcranial magnetic stimulation, TMS, or TMS in English). This technique consists of the application of very brief magnetic pulses, focused on the part of the brain whose function you want to enhance. The application is carried out using a device in contact with the left side of your head, near the forehead, and in most cases it does not cause any discomfort, is not painful and has no side effects. Next, you will carry out inhibitory control training with your mobile phone for 10 minutes.

Are there any drawbacks 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 from carrying out these types of activities.

Regarding the taking of samples, it will be carried out by nursing staff and in the same way as it is usually carried out in health checks. It does not carry risks, except for possible inconveniences that could appear in any blood draw, such as slight pain in the area of the puncture, difficulty in finding the appropriate vein that may lead to having to be punctured again, or the subsequent appearance of a small hematoma. (bruise or bruise) in the extraction area.

For its part, magnetic resonance applied in the evaluation has proven to be a very safe technique even if applied for a prolonged period. The possible adverse effects are not significant and among those that some people have reported are pain if poor posture has been maintained, drowsiness, ringing or congestion in the ears due to repetitive noise (although you will need protective earplugs), dizziness, headaches. and increased body temperature. Qualified technical personnel will be present at all times to address any inconvenience that may arise. To ensure safety, a full interview is conducted first to rule out any risk factors.

As for the stimulation technique used in this study, it has been proven completely safe and with the parameters that we will use, its brain activity stimulation effects are completely transient, you will not notice anything and the duration is short. However, some people have experienced scalp discomfort or headaches that usually go away with time or by taking a regular over-the-counter pain reliever. To mitigate possible hearing discomfort due to the noise emitted by the machine, we will provide you with earplugs during stimulation. Although it is very unlikely to occur, the most serious risk of this type of technique is that seizures may occur during stimulation. Worldwide , there have been several cases of people who have experienced seizures, although without any effect on their health. To ensure your safety, a complete interview is carried out first to rule out

any risk factors such as brain damage, a personal or family history of epilepsy or seizures, or taking certain medications. In addition, at all times we have the presence of health personnel and equipment to deal with any inconvenience that may arise.

Is there any benefit from participating in the study?

Participation in the study could provide you with benefits related to the improvement of certain aspects of impulsivity, and therefore could help you reduce excess weight. There is no financial compensation. You have the right to receive a report of your blood test results if you wish. You will not be able to know other specific results on a personal level, but in the event that information related to your health, or that of your family, is obtained through genetic analysis, you have the possibility of us contacting you in order to provide you with said information. .

In addition, your participation will provide scientific knowledge that will contribute to improving the design of treatments for excess weight.

Aspects to consider about biological samples

To perform the blood test, you must be fasting for at least 6 hours beforehand, since eating food alters the blood concentrations of various parameters. The blood collected, as well as saliva, urine and feces samples, will be prepared at the CIMCYC for freezing and at the end of the project they will be transferred to external laboratories to carry out microbiota, proteomic and genetic analyzes related to the objectives of the project. Genetic testing has no medical value (eg, diagnosis or prognosis of diseases) or individual benefit to you, but it can help us investigate the multiple determinants of excess weight. If you give your consent, a part of each of the samples will be kept in the CIMCYC freezer to be used, along with the information associated with them in an anonymous way, in future studies by the researchers of this project and its collaborators, when technology and scientific advances allow new analyzes 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 cover the objectives of the study. All data obtained will be used solely and exclusively for the objectives of the study and will be treated by the research team in a completely confidential manner. The results derived from this study can be published in a scientific journal or conference, always maintaining anonymity and confidentiality. Any personally identifiable information will be kept and processed securely. To protect your privacy, all information about you and samples collected will be assigned letter and number codes in a computerized randomization program. The information and samples will be guarded with restricted access and exclusively by personnel belonging to the project 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 guarantees the maintenance of anonymity. The stored biological samples (15 ml of blood, 15 ml of urine, 1.5 grams of feces, 3 saliva swabs) will be used to analyze variables related to oral and intestinal flora, proteins and genetics and will remain guarded. with guarantees of anonymity.

During the completion of 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 by royal decree 1720/2007, Organic Law 3/2018 on the Protection of Personal Data and guarantee of digital rights, and the European directive 2002/58/EC.
You can obtain additional information on your rights regarding the processing of your data at http://secretariageneral.ugr.es/pages/proteccion_datos/derechos , and by contacting the email address: protecciondedatos@ugr.es

Study Participation Agreement
This sheet contains information so you can decide if you want to participate in this study. **If you have any questions that remain unanswered, please ask the study manager before signing this form** . You can contact the main researchers of the project, Raquel Vilar López and Alfonso Caracuel Romero, through email rvilar@ugr.es and acaracuel@ugr.es or by calling 958241982 and 958242948 .
Participation in this study is voluntary, and you will have the possibility to revoke your consent at any time and without having to give explanations. You do not have to participate in the study if you do not want to. If you ultimately decide to participate, you will receive a copy to keep this information and another to sign giving your consent.

INFORMED CONSENT SHEET

Project title: Transcranial magnetic stimulation and inhibitory control training for the treatment of excess weight: Behavioral and brain changes (InhibE)

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

Mind, Brain and Behavior Research Center of the University of Granada

ID: 46898000B and 52363377J

1. CONSENT TO PARTICIPATE IN THE STUDY:

I, Mr./Ms. (name and surname) _____
with **ID number** _____

I declare under my 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 feces and associated information, and about the performance of genetic analyzes on them.

I have been able to ask questions about the information received and speak with the indicated professional, who has resolved all the doubts I have raised.

I understand that my participation is voluntary.

I understand that all my data will be treated confidentially, according to Regulation (EU) 2016/679 General Data Protection and 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 you want.
- Without having to give explanations.
- Without this affecting me in any way.

My biological samples will be used for the development of the research project **Transcranial magnetic stimulation and training in inhibitory control for the treatment of excess weight: Behavioral and brain changes (InhibE)** directed by Raquel Vilar López and Alfonso Caracuel Romero.

I have also been informed of the option that a portion of the biological samples and associated information obtained in this project be safeguarded and used in future projects and, in this regard, I make the decision that the portion of the samples not used in the original project are:

☐ Destroyed

☐ Irreversibly anonymized

☐ On loan to the Private Collection C0008387 for use, maintaining my anonymity, in future studies by the researchers of this project (if this option is checked, once the project is finished the Researcher responsible for said collection will contact me to formalize said transfer).

Because my biological samples are for the Private Collection CIMCYC-PDI2022-137524OB-100 (Raquel Vilar López and Alfonso Caracuel Romero), the surplus biological sample and associated data will return to said Private Collection.

I give my consent for the clinical data and/or samples to be treated in the following manner:

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

I authorize you to contact me later:

☐ YES

☐ NO

If yes, please indicate the means to do so:

☐ Telephone: (insert number)_____

☐ Email: (insert address)_____

☐ Others: (identify)_____

I wish to establish restrictions regarding the use of the sample, so that it is not used in: _____

I authorize receiving information about genetic data and data relevant to my health and that of my family members.

Check what applies:

☐ YES

☐ NO

I know that I can revoke, at any time, the consent granted in this document.

On _____, on ____of_____, 20_____

THE DONOR