- University of Texas at El Paso (UTEP) Institutional Review Board

Informed Consent Form for Research Involving Human Subjects

Protocol Title: The impact of gastric sleeve bariatric surgery or semaglutide treatment on cognition, mood and neural connectivity in an obese Hispanic population

Principal Investigator: Travis Moschak PhD

UTEP Psychology Department

In this consent form, "you" always means the study subject. If you are a legally authorized representative, please remember that "you" refers to the study subject.

Introduction

You are being asked to take part voluntarily in the research project described below. You are encouraged to take your time in making your decision. It is important that you read the information that describes the study. Please ask the study researcher or the study staff to explain any words or information that you do not clearly understand.

Why is this study being done?

The objective of this study is to determine how rapid weight loss changes mood, cognition and the anatomy and connectivity of the brain.

Approximately, 32 participants *between 21 and 50 years of age* undergoing bariatric surgery or semaglutide treatment *and 32 participants not undergoing surgery or treatment* will be enrolling in this study at UTEP.

You are being asked to be in the study because you met the requirements of being an individual who is intending to undergo bariatric surgery or semaglutide treatment or because you meet the criteria for a control participant not undergoing treatment. You are not claustrophobic, do not have prosthesis or pacemakers, neurological disorders, and, in the case of women, you are not pregnant.

1. If you decide to enroll in this study, your involvement will last approximately two hours each session (two sessions are video calls and two are in-person visits, this is a total of about 8 hours during four different days.

What is involved in the study?

If you agree to take part in this study, your participation will be divided into four days. During the first day, you will be contacted by a password-protect web video call. You will be asked to sign the consent form, and to complete a Magnetic Resonance Imaging (MRI) screening questionnaire to verify that you meet the criteria for the MRI portion of the study. You will also complete several questionnaires assessing drug use, attitudes about food, and your mental state. Finally, you will complete a 3 short behavioral tasks assessing reaction time and memory. Results from the questionnaires and behavioral tests will be emailed back to research staff. In total, this should take approximately 2 hours. You will receive a $50 Amazon gift card as compensation.

The second day will occur within 1 week of the first. Here, you will meet a member of the study team at the University Medical Center lobby (4845 Alameda Avenue, 79905). You will be taken to MRI suite. If you are a woman of childbearing potential, you will have a pregnancy test before starting the MRI. Tests will be provided, self-administered and results confirmed by staff on site. If you are pregnant, you will be excluded from this portion of the study, and you will be compensated with $50 for your time. After that, you will go inside the MRI suite and will be instructed to stay still for the duration of the scan. The study visits should last approximately 2 hours. You will receive a compensation of $50 in cash.

The third day will occur approximately 6 months following the second day. You will be contacted by a password-protected web video call and will be asked to complete several questionnaires assessing drug use, attitudes about food, and your mental state. Finally, you will complete 3 short behavioral tasks assessing reaction time and memory. In total, this should take approximately 2 hours. You will receive a $50 Amazon gift card as compensation.

The fourth day and last in-person visit will occur within 1 week of the third day. Here, you will return to the University Medical Center (4845 Alameda Avenue, 79905) for a second MRI. If you are a woman of childbearing potential, you will have a pregnancy test before starting the MRI. Tests will be provided, self-administered and results confirmed by staff on site. If you are pregnant, you will be excluded from this portion of the study, and you will be compensated with $50 for your time. The study visits should last approximately 2 hours. You will receive a second compensation of $50 in cash.

Additionally, if you are in the bariatric surgery or semaglutide group, we may use the results from your laboratory blood work (Complete Blood Count, Comprehensive Metabolic Panel, Hemoglobin A1C, and Lipid Panel) as a biomarker in our study. All data we use in this manner will be anonymized and will not identify you.

What are the risks and discomforts of the study?

The risks associated with this research are no greater than those involved in daily activities.

Functional magnetic resonance imaging (fMRI) measures the small changes in blood flow that occur with brain activity. It may be used to examine the brain's functional anatomy, evaluate the effects of stroke or other disease, or to guide brain treatment. fMRI may detect how the brain connections change within the brain, changes that cannot be found with other imaging techniques. Please tell the research team about any health problems, recent surgeries, or allergies, and whether there is a possibility you are pregnant. If you have claustrophobia, you cannot participate in this study.

Additionally, if during the MRI procedure the MRI technician observes any abnormalities, a Radiologist will review the MRI and/or you will be notified of the results for further evaluation. A community resource list will be made available. MRI data is analyzed as a group, and MRI's are not read individually by the radiologist unless any abnormalities are observed by the MRI tech.

In case of research related injury or accidents we do not offer to pay for medical care.

Are there benefits to taking part in this study?

You are not likely to benefit by taking part in this study. This research may help us to understand the brain mechanisms involved following bariatric surgery and semaglutide treatment.

What are my costs?

There are no direct costs.

Will I be paid to participate in this study?

You will be compensated for your participation in the form of $100 dollars worth of Amazon gift cards and $100 in cash. If you are unable to complete all 4 visits (two web calls and two in-person visits), you will be paid for those visits you complete ($50 Amazon gift card per web call and $50 cash per in-person visit). For reporting purposes, you are required to provide a Social Security Number (SSN) or Tax Information Number (TIN) to the Primary Investigator (PI) to receive cash or gift cards from UTEP. This information is not a part of your research data and will be shared only with the applicable UTEP office for business purposes.

What other options are there?

You have the option not to take part in this study. There will be no penalties involved if you choose not to take part in this study.

What if I want to withdraw, or am asked to withdraw from this study?

Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you do not take part in the study, there will be no penalty or loss of benefit. *By agreeing to participate in the study you accept that you have read the risks associated with an MRI study and that you have no medical devices, orthopedic implants or metal implants in your body. You will be asked to wear a gown and remove all jewelry, earrings, and piercings.*
If you choose to take part, you have the right to skip any questions or stop at any time. However, we encourage you to talk to a member of the research group so that they know why you are leaving the study. If there are any new findings during the study that may affect whether you want to continue to take part, you will be told about them.

The researcher may decide to stop your participation without your permission, if he or she thinks that being in the study may cause you harm.

Who do I call if I have questions or problems?

You may ask any questions you have now. If you have questions later, you may call any of the following persons involved in the study:

Dr. Hugo Sandoval Ph.D.

(915) 861-1620
Hugo.Sandoval@ttuhsc.edu

Dr. Travis Moschak Ph.D.
(915) 747-6537
tmmoschak@utep.edu

Dr. Laura O'Dell Ph.D.
(915) 747-6557
lodell@utep.edu

If you have questions or concerns about your participation as a research subject, please contact the UTEP Institutional Review Board (IRB) at (915-747-7693) or irb.orsp@utep.edu.

What about confidentiality?

Your part in this study is confidential. The following procedures will be followed to keep their personal information confidential. Evaluations and consent will take place through a password-protected video call, and will be stored in a password-protected folder on a computer held in a locked office (Biosci Res Bldg Room # 2.170). All MRIs will be acquired at University Medical Center at El Paso (48 45 Alameda Ave, 79905) located at 6.3 miles away from UTEP.

The results of this research study may be presented at meetings or in publications; however, your name will not be disclosed in those presentations.
Organizations that may inspect and/or copy your research records for quality assurance and data analysis include, but are not necessarily limited to:

- Office of Human Research Protections
- UTEP Institutional Review Board

Because of the need to release information to these parties, absolute confidentiality cannot be guaranteed.

All records will be stored in a password-protected folder on a computer held in a locked office (Biosci Res Bldg Room2.170).

Contact for Future Research

I agree that my study doctor, or someone on the study team, may contact me to see if I wish to participate in other research in the future.

__AR__Yes _____No

Initial in the space above

Authorization Statement

I have read each page of this paper about the study (or it was read to me). I will be given a copy of the form to keep. I know I can stop being in this study without penalty. I know that being in this study is voluntary and I choose to be in this study.

Anita Ramirez
Participant's Name (printed)

2/11/25

Participant's Signature Date

2/11/2025

Signature of Person Obtaining Consent Date