Evaluation of Cognitive Improvement After Bariatric Surgery Using a Virtual Reality Program and the Neuropsi Neuropsychological Battery

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“EFFECT OF BARIATRIC SURGERY ON COGNITIVE PERFORMANCE EVALUATED THROUGH A VIRTUAL REALITY PROGRAM AND THE NEUROPSI BATTERY”

INFORMED CONSENT LETTER TO PARTICIPATE IN A RESEARCH PROJECT

- **Principal Investigator Data:**
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- **Consent Version:** 3
- **Place and Date of Presentation:** Hospital General de México 06/13/2024.

1. INTRODUCTION

Please take as much time as you need to read this document and ask the investigator any questions you may have.

This informed consent complies with the guidelines established in the Regulation of the General Health Law on Health Research (RLGSMI), the Declaration of Helsinki, and the Good Clinical Practices issued by the National Bioethics Commission (CONBIOETICA).

To decide whether or not to participate in this study, you must have sufficient knowledge of the risks and benefits in order to make an informed decision.

Your participation is **VOLUNTARY**, and you can choose not to participate or withdraw from the study without affecting your medical treatment or care at the Hospital General de México Dr. Eduardo Liceaga. Furthermore, if you decide to participate, you also have the freedom to withdraw your consent and interrupt your participation in the investigation at any time without harming your care at the Hospital. After reading this letter, you may accept your participation by signing at the end of the document.

2. INVITATION TO PARTICIPATE AND PROJECT DESCRIPTION

Dear Mr./Ms. _____ you are invited to participate in this research study, which aims to: Know the state of health of your brain through a computer game (called NeuroTracker) and by answering questions related to remembering

words, numbers, and figures, as well as writing, drawing, and repeating words, on paper (written test known as Neuropsi Attention and Memory) before and after bariatric surgery.
We also want to know if, after bariatric surgery, some of your daily life activities have improved, such as mood, enjoyment of physical, social, work, and sexual activities (questionnaire called BAROS). The reason this study is being carried out is to determine whether bariatric surgery helps improve brain health and quality of life.
The study will last: **12 months**, and the number of participants to be recruited is: **21**. You were invited to the study because you meet the following characteristics: **bariatric surgery candidate.**

3. STUDY PROCEDURES

In your participation in the study, the following will be carried out:

1. **Neuropsychological Tests (Neuropsy Attention and Memory):** This will be conducted during a routine appointment at the Comprehensive Diabetes and Obesity Care Clinic (CAIDO) by answering some pencil-and-paper questions that the doctor will ask me; this appointment will take place during my usual consultation. These tests are used to determine if the brain is functioning normally.
2. **Quality of Life Questionnaire (BAROS):** This will be done during routine consultation by answering a series of questions about weight loss, health, and quality of life before and after surgery. The answers are used to determine whether the surgery was successful and how it affects your daily life.
3. **Game/Condition (a) (Neurotracker):** The game takes place on a computer and involves following the movement of several "little balls" displayed on the screen. These balls will light up, and my task is to identify where each one ends up when the game concludes. Initially, the balls are at rest, and only a few will light up during the game. Each session lasts 10 minutes, and I will participate in the game four times during my visit. This visit will be at the Research and Technological Development Unit (UIDT), located in Unit 110. A doctor associated with the project will schedule my appointment and guide me to the computer area within the hospital.
4. **Laboratory Studies:** Laboratory studies will be taken from your clinical record to have the data before and after your surgery, at 3 and 6 months. These studies will be routinely ordered by your treating physician.

- **Visit 1:** Signing of informed consent, data registration, and application of Neuropsi battery.

- **Visit 2:** Application of BAROS Battery and Neurotracker 4 sessions.
- **Visit 3:** Application of Neurotracker 4 sessions.
- **Visit 4:** Application of Neurotracker 4 sessions.
- **Visit 5:** Bariatric Surgery is performed.
- **Visit 6:** Application of Neurotracker 4 sessions.
- **Visit 7:** Application of Neurotracker 4 sessions.
- **Visit 8:** Application of Neurotracker 4 sessions.
- **Visit 9:** Application of Neuropsi Battery.
- **Visit 10:** Application of Neurotracker 4 sessions and BAROS Battery.
- **Visit 11:** Application of Neurotracker 4 sessions.
- **Visit 12:** Application of Neurotracker 4 sessions.

Location: Comprehensive Diabetes and Obesity Care Clinic (CAIDO) located in Pavilion 401-PB, of the Outpatient Clinic and in the laboratory of the Research and Technological Development Unit (UDIT) located in Unit 110 between Internal Medicine and Geriatrics of the Hospital General de México.

Duration per visit: 1:30 hrs approx.

4. DISCONFORT, ADVERSE EVENTS, AND RISKS

- The Regulation of the General Health Law on Health Research indicates that the procedures: Application of Neuropsychological Batteries, B.A.R.O.S, and Neurotracker are considered to have a **minimum research risk level** according to the Regulation of the General Health Law on Health Research.

5. POTENTIAL BENEFITS

Thanks to your valuable participation in the study group, we will have the opportunity to evaluate if bariatric surgery helped you improve your mental skills, after 3 and 6 months, using a computer game and a questionnaire. These findings will be published for your knowledge and the general public. **In case any neuropsychological difficulty is found, you will be referred to the Neurology Service for review. The patient will be summoned for the delivery of the neuropsychological test results**.

6. ECONOMIC CONSIDERATIONS AND COMPENSATION

Your participation in this study will not generate any extra cost for you; all expenses generated by this research will be covered by the research budget.

7. ACTIONS TO FOLLOW AFTER THE STUDY ENDS:

What the treating physician indicates.

8. AVAILABILITY OF OTHER MEDICAL TREATMENT

Does not apply

9. CONFIDENTIALITY AND HANDLING OF YOUR INFORMATION

Your name will not be used in any of the studies. Study monitors or auditors may have access to participant information. We request your authorization to contact you, if necessary, to ask for information that could be relevant to the development of this project. Your name and other personal information will be deleted before using the data, and all your personal information will be codified. If you request it, your primary care physician will be informed about your participation in the study.

10. IDENTIFICATION OF INVESTIGATORS

In case you suffer harm related to the study or have questions regarding your participation, procedures, risks, benefits, and other matters related to your participation in the research or treatment, you can call**: Argelia Pérez Pacheco** at the telephone number: **55 27892000 ext 1242** 24 hours a day. If you have questions about your rights as a study participant, you can contact the President of the Research Ethics Committee of this hospital, Dra.. Nallely Bueno Hernández at the telephone number 27892000 Ext. 1147.

DECLARATION OF INFORMED CONSENT

I, _____, declare that it is my decision to participate in the study: _____. And that my participation is voluntary.

I have been informed that I can refuse to participate or end my participation at any time in the study without suffering any penalty or loss of benefits.

If I suspend my participation, I will receive the usual medical treatment I am entitled to at the Hospital General de México Dr. Eduardo Liceaga and will not suffer prejudice in my medical care or in future research studies.

I can request additional information about the potential risks or benefits derived from my participation in the study. I can obtain the results of my clinical exams if I request them. If I have questions about the study, I can contact the Principal Investigator.

I understand that if I have questions about my rights as a study participant, I can speak with the president of the Hospital's Research Ethics Committee, Dr. **Nallely Bueno Hernández**, at the telephone number **27 89 2000 Ext. 1147**. And if I have doubts related to my participation in the study or the treatment, I can contact: _____ at the telephone number: _____.

I must inform the investigators of any change in my health status (for example, use of new medications, changes in tobacco consumption) or in the city where I reside, as soon as possible.

I have read and understood all the information given to me about my participation in the study. I have had the opportunity to discuss it and ask questions. All questions have been answered to my satisfaction.

I have understood that I will receive a signed copy of this informed consent.

PARTICIPANT NAME:

_____

_____ **Signature:** _____ **Date of CCI application:** _____

WITNESS 1

Name:_____**Telephone:**_____

_____ **Address:** _____

Relationship:_____**Date:**_____

_____ **Signature:** _____

WITNESS 2

Name:_____Telephone:_____

_____Address:_____Relationship:_____

_____Date:_____

Signature: _____

I have explained to Mr./Ms._____ the nature and purposes of the research; I have explained the risks and benefits involved in their participation, I have answered the questions as much as possible, and asked about the existence of any doubts. I accept that I have read and know the corresponding regulations for conducting research in human beings and I adhere to them.

NAME OF THE INVESTIGATOR WHO APPLIES THE LETTER: _____.

Signature: _____ Date of application: _____