INFORMATION AND CONSENT FORM

Comparison of the Effects of Virtual Reality, Hypnosis, and Their Combination (VRH) on Experimental Pain Modulation: A Within-Subjects Psychophysiological Study

Short title: RVH EXPE

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Research Project Title:

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INTRODUCTION

You are invited to take part in a research project on non-pharmacological pain management. Before agreeing to participate, please take the time to carefully read this form so that you fully understand what your participation involves. This form explains the study's objectives, procedures, benefits, risks and inconveniences, and your rights as a participant. Please feel free to ask the researcher or a member of their team any questions you find useful.

NATURE AND OBJECTIVES OF THE RESEARCH PROJECT

Pain related to medical procedures remains a significant challenge in clinical settings, despite available pharmacological treatments. Non-pharmacological approaches, such as virtual reality and hypnosis, have demonstrated their ability to reduce pain in various contexts.

This study aims to compare the effects of three approaches on the perception of experimental pain:

- virtual reality (VR) alone;
- hypnosis (H) alone;
- the combination of both (VRH).

Approximately 40 adult participants will be recruited from the general population to take part in this study, which will take place in the laboratory located in the Rachel-Tourigny pavilion at Hôpital Maisonneuve-Rosemont.

STUDY PROCEDURES

Your participation will take place in a single meeting (called a session) lasting approximately 2 hours and 20 minutes.

a. Pre-screening and form delivery (before the session)

Before the session, a team member will have contacted you by phone or online form (REDCap) to verify your eligibility (general health status, current medication, exclusion criteria). If you receive this form, it is because you

are eligible. If you wish to participate, you may read and provide your consent through this information and consent form. You will have at least 48 hours to read it, reflect on it, and ask questions before the session.

b. Experimental session (140 minutes)

The session will take place in the laboratory and will include the following steps:

- Welcome, signing of the information and consent form, and completion of questionnaires (sociodemographic information, prior experience with hypnosis and virtual reality, anxiety and mood levels, hypnotic susceptibility). This should take approximately 50 minutes.
- Installation of recording equipment: dry-electrode EEG cap (no gel, 24 sensors) for measuring brain electrical activity; cardiac, respiratory, and skin conductance sensors; electrical stimulation electrodes at the ankle; EMG electrodes at the thigh to measure the physical reaction to pain.
- Individual calibration of the electrical stimulation: intensity will be gradually increased to determine your moderate and tolerable pain level (around 4 to 6 on a 0-10 scale).
- Three experimental conditions, each lasting 12 to 15 minutes, presented in random order: (1) Virtual reality alone (VR) — you will wear a VR headset and audio headphones, immersed in a calming visual and auditory natural environment designed to capture your attention and promote relaxation during painful stimulation. (2) Hypnosis alone (H) — during painful stimulation, you will listen to an audio recording guided by a trained therapist's voice, inviting you to relax and direct your attention toward pleasant or neutral sensations. (3) Combination of virtual reality and hypnosis (VRH) — during painful stimulation, you will simultaneously wear the VR headset and listen to the hypnosis recording, combining both approaches to amplify relaxation and distraction effects.
- Painful stimulation: repeated electrical stimulations (approximately 30 per condition, 90 in total) will be delivered during each condition.
- Rest periods of 5 to 10 minutes are provided between conditions.
- Final evaluations (questionnaires about your experience) and discussion, taking approximately 10 minutes, allowing you to share your impressions and rest before leaving the laboratory.

BENEFITS ASSOCIATED WITH THE RESEARCH PROJECT

You will not receive any direct personal benefit from your participation. However, the knowledge gained may help improve non-pharmacological pain management approaches for patients who will benefit in the future.

RISKS AND INCONVENIENCES ASSOCIATED WITH THE RESEARCH PROJECT

The risks associated with this study are considered low to moderate.

a. Electrical stimulation

Electrical stimulation at the ankle will induce a moderate, brief painful sensation. Intensity will be individually adjusted and will not exceed a pre-established safety threshold (40 mA maximum). This widely used research method causes no tissue damage. You may request immediate discontinuation at any time.

b. Virtual reality

Use of the VR headset may, in some individuals, cause transient effects such as mild dizziness, nausea, or visual discomfort (cybersickness). The selected environments minimize these effects. You may stop the immersion at any time.

c. Hypnosis

Hypnotic procedures are non-invasive and safe. You may experience deep relaxation or unusual sensations (altered time perception, bodily lightness or heaviness). No suggestions with negative emotional content are used.

d. EEG and physiological recordings

These recordings are entirely non-invasive. Dry electrodes avoid the inconvenience of conductive gel (no irritation, no residue in hair). Wearing the EEG cap may cause mild discomfort. Positioning of EMG electrodes at the thigh requires removal of pants or wearing provided shorts; your privacy will be strictly respected during setup.

e. General inconvenience

The main inconvenience is the time required for your participation (approximately 2 hours in total).

VOLUNTARY PARTICIPATION AND RIGHT TO WITHDRAW

Your participation in this research project is voluntary. You are free to refuse to participate. You may also withdraw from this project at any time, without giving reasons, by informing the research team.

Your decision not to participate or to withdraw from this project will have no impact on the quality of care and services to which you are entitled, or on your relationship with the teams providing them.

The principal investigator or the Research Ethics Board of the CIUSSS de l'Est-de-l'Île-de-Montréal may end your participation without your consent. This may occur if new findings or information indicate that your continued participation is no longer in your interest, if you do not follow study instructions, or for administrative reasons.

Unless you indicate otherwise, if you withdraw or are withdrawn from the project, information already collected will nonetheless be retained, analyzed, or used to ensure the integrity of the project.

Any new knowledge acquired during the project that could affect your decision to continue participating will be communicated to you promptly.

CONFIDENTIALITY

During your participation, the principal investigator and research staff will collect, in a research file, information about you necessary to meet the scientific objectives of this project.

All information collected will remain confidential within the limits provided by law. You will be identified only by a code number. The key linking your name to your research file will be kept by the principal investigator.

Research data will be retained for at least 7 years by the principal investigator.

Research data may be published or discussed scientifically, but it will not be possible to identify you.

For monitoring, control, protection, and safety purposes, your file may be reviewed by a person mandated by regulatory bodies, in Canada or abroad, such as Health Canada, as well as by representatives of the funding organization, the institution, or the Research Ethics Board of the CIUSSS de l'Est-de-l'Île-de-Montréal. These individuals and organizations adhere to a confidentiality policy.

You have the right to consult your research file to verify the information collected and to have it corrected if needed. However, access to certain information before the end of the study could result in your withdrawal from the project to preserve its integrity.

COMPENSATION

As compensation for expenses incurred due to your participation in this research project, you will receive an amount of $60 (via prepaid Visa card). If you withdraw from the project (or your participation is ended) before its completion, compensation will be proportional to the duration of your participation.

IN CASE OF INJURY

Should you suffer any injury as a result of any procedure related to this research project, you will receive all care and services required by your health condition.

By agreeing to participate in this research project, you do not waive any of your rights and you do not release the principal investigator, the funding organization, or the institution from their civil and professional liability.

CONTACT PERSONS

If you have questions or experience problems related to the research project, or if you wish to withdraw, you may contact the principal investigator or a member of the research team at: 514-252-3400, extension 4443.

For any questions regarding your rights as a research participant, or if you have complaints or comments, you may contact the Commissioner for Complaints and Quality of Services of the CIUSSS de l'Est-de-l'Île-de-Montréal at 514-252-3400, extension 3510.

ETHICAL OVERSIGHT OF THE RESEARCH PROJECT

The Research Ethics Board of the CIUSSS de l'Est-de-l'Île-de-Montréal and the Research Ethics Committee of Université de Montréal have approved this project and will oversee its conduct. For any information, you may contact the secretariat of the Research Ethics Board of the CIUSSS de l'Est-de-l'Île-de-Montréal at 514-252-3400, extension 5708.

SIGNATURES

Participant's Signature

I have read the information and consent form. The research project and this information and consent form have been explained to me. My questions have been answered, and I have been given the time needed to make a decision. After reflection, I consent to participate in this research project under the conditions stated herein.

Participant's Name: _____ Signature: _____ Date: _____

Signature of the Person Obtaining Consent

I have explained the research project and this information and consent form to the participant and have answered the questions asked.

Name: _____ Signature: _____ Date: _____