INFORMATION AND CONSENT FORM

APPROVED IN FRENCH ON SEPTEMBER 8TH 2023

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NCT06076148

Title of research project :

Aging well by being connected - Phase 1

Project team (manager and other people working with volunteers)

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Funding agency :

Natural Sciences and Engineering Research Council of Canada (NSERC).

Why do we give you this form?

We invite you to take part in a study to find out more about interest in physical, cognitive and social activities and immersive technologies, such as virtual reality, in order to optimize intervention solutions and improve the supply of tools for healthy aging.

The information provided is intended to help you understand exactly what is required so that you can decide whether or not to participate in this study. Please read the form carefully and ask any questions you may have before making your decision. Take all the time you need, and consult the people of your choice if necessary.

Your participation should be entirely voluntary. You may refuse to take part in this project without giving any reason and without any penalty. There will be no infringement of your rights, interests or well-being.

This form enables you to find out more about the project. It is a copy of the form embedded in the questionnaire link. Your consent to participate will be validated if you accept the conditions inside the questionnaire contained by clicking on the web link and complete the questionnaire.

Why are we doing this study (overall project objective)?

The majority of the population aged 50 and over is made up of the baby-boomer generation. Their lifestyle habits differ from those of the previous generation, whether in terms of diet, exercise, leisure activities, travel or technology use

Immersive technologies involve immersing users in an environment with which they can interact using their sensory and sensorimotor capacities. Among these technologies, virtual reality (VR) enables the user to be totally immersed in a virtual, interactive universe, simulated and calculated in real time. VR is achieved using computer-generated images of a virtual 3D environment, broadcast via glasses, VR headsets, virtual cellars or large screens.
For our interventions to be used and adapted, it is important to understand the needs and expectations of the 50+ population, and to take into account the different age groups. Questionnaires and focus groups with the population concerned are essential elements in identifying their needs and expectations. Participants will be able to try out virtual reality games using Meta Quest 2 headsets. The games tested will be both individual and collaborative.

Inclusion and exclusion criteria

- Be aged 50 or over
- To be autonomous
- The experimental nature of the research requires participants to be fully physically fit. Consequently, people with functional limitations cannot participate in the study.
- Group interviews require the sharing of experience, which presupposes the participation of people capable of communicating their opinions and reflecting collectively on their experiences. Thus, people with cognitive impairments are excluded from the research.
- In view of the technology used for the research, people at risk of epilepsy cannot take part in this project.
- Also, people with pacemakers are not eligible to participate in this research.

What do you need to do (list the procedural steps in detail)?

Your participation will take place in 3 stages, as follows:

1) Completion of a pre-interview questionnaire (20 minutes)

You will be invited to complete an online questionnaire. This questionnaire, which is a prelude to the group interviews, asks about your lifestyle habits and your comfort level with virtual technologies. More specifically, the questions cover the following themes:

- Consent and future plans
- Personal information
- State of health
- Health monitoring question
- Activity habits and preferences
- Technologies and exergames
- Virtual leisure activities
- Virtual physical activities
- Virtual games

Once the questionnaire has been completed, you will be contacted by the research team to schedule two meetings.

2) Group discussion-formula for individual games (2h25min)

The meeting will take place at TOPMED's premises on the grounds of Collège Mérici, 755 Grande-Allée Ouest, Quebec City.

During the session, a balance test will be carried out to determine your position during the game trials (sitting-standing). Then, in groups of 6 to 8 people, you will be asked to try out three virtual reality games corresponding to the following themes: a cognitive game, a physical activity game and a relaxation game. During the tests, you'll be asked to wear a virtual reality headset, manipulate controllers and mobilize your upper and lower limbs.

Following the tests, a discussion (1h10min) will be held on the following topics:

- Your satisfaction with the experience ;
- Integrating virtual reality ;
- The acceptability of this technology.

At the end of the session, you'll be asked to fill in a questionnaire about your experience. This questionnaire will be based on the one you filled in before coming to the session. (10 minutes)

- A section is added on your wish to participate in the continuation of the research project.

The course of the individual virtual reality game session will be recorded on audio and video for data collection purposes.

3) Discussion group-Collaborative games (2h25min)

The meeting will take place at TOPMED's premises on the grounds of Collège Mérici, 755 Grande-Allée Ouest, Quebec City.

During the session, in groups of 4, you will test two virtual reality games corresponding to the following themes: a socialization game and a physical activity game. The games will be tested in a sitting and standing position, depending on the balance test performed during the first session. During the tests, you will be required to wear a virtual reality headset, manipulate controllers and mobilize your upper and lower limbs.

Following the tests, a discussion will be held on the following topics:

- Your satisfaction with the experience ;
- Integrating virtual reality ;
- The acceptability of this technology.

At the end of the session, you'll be asked to fill in a questionnaire about your experience. This questionnaire will be based on the one you filled in before coming to the session. (10 minutes)

- A section is added on your wish to participate in the continuation of the research project.

The course of the collaborative virtual reality game session will be recorded on audio and video for data collection purposes.

Probable duration of project stages (questionnaire, data collection, etc.)

Completion of initial questionnaire: 20 min

Duration for **each** discussion group: 2h20min

- Reading and explanation of the FIC: 10 min
- Balance test: 10 minutes
- Virtual reality games test: 40 min
- Sharing experience: 70 min
- Post focus group questionnaire: 10 min

Possible disadvantages / advantages

Risks

Preliminary questionnaire

There is no risk associated with completing the questionnaire prior to the group interview.

Group interviews

Despite the means put in place to ensure the confidentiality of group discussions, certain risks inherent in this type of consultation cannot be avoided. In other words, the research team cannot guarantee that every participant in the group will keep the information exchanged confidential.

Virtual reality activity

- Discomfort linked to the graphics and the conflicting, multi-sensory aspect of immersion sessions could arise when using immersive technologies. This discomfort could take the form of cybermalaises akin to motion sickness, affecting participants to varying degrees: visual fatigue and headaches, temporary loss of visuo-spatial cues and dizziness, or nausea and even vagal discomfort. These discomforts naturally need to be spotted, and short sessions will be carried out to prevent them. The table on the following pages details the possible risks and their degree of seriousness. The experimenter will be on hand at all times to ensure the participant's well-being. To this end, the group interviewer will regularly ask questions about the sensations felt by the participant while trying out the activities. At the end of the trial, participants will be provided with a snack, and will be able to rest in a suitable space until any symptoms disappear. A member of the research team will remain with the participant for as long as necessary.

- Participants with pacemakers or at risk of epilepsy could experience more serious events and should therefore be withdrawn from the workshops.

Known or foreseeable risk(s)	Frequency and severity	Proposed mitigation measures	Warnings
All the risks below are related to the use of immersive technologies. They are presented under four themes: 1. Cybercynetosis 2. Consequences for the sensorimotor system 3. Disruption of circadian rhythms 4. Epilepsy		<u>Prevention:</u> -Dress lightly to limit the rise in body temperature -Knowledge and control of symptoms by the research team -Continuous questioning about the presence of symptoms - Controlling and limiting exposure time - Space for participants to rest after the trial <u>If appearance:</u> -Pause or stop test <u>Applicable to all symptoms:</u> -Members of the research team are certified in first aid. -A snack will be distributed after participation to prevent discomfort.	Three warnings for all symptoms: -Light clothing must be provided -Be aware that using headphones can mess up your hair -Symptoms may persist after exposure. -Allow an hour to two hours' rest after play trials. -No strenuous or prolonged physical exercise after the trial session -No driving for the duration of symptoms
Topic 1. Cyberkinetosis (Symptoms similar to motion sickness) (includes pallor, malaise, visual disturbances, disorientation, headaches, fatigue, dizziness, nausea, vomiting, tachycardia, hypersalivation)	Cyberkinetosis is thought to affect 30-50% of users. Symptoms generally appear within the first 5 minutes and disappear rapidly.		-People considered sensitive: pregnant women; people with vestibular disorders; people suffering from motion sickness; people with postural static anomalies and dynamic balance with proprioception disorders; Migraine sufferers; people with oculomotor disorders; people with anxiety or anxiety attacks. -Appearance in relation to content and visual field requested

Impaired vision	Proven risk	See measurements at the beginning of the table	
Fatigue and eye strain	Proven risk	See measurements at the beginning of the table	
Head/eye pain discomfort	Proven risk	See measurements at the beginning of the table	
Pallor	Proven risk	See measurements at the beginning of the table	
Dizziness and vertigo	Proven risk	-Ask participants to eat lightly before the physical test session to prevent the onset of symptoms.	
Excessive sweating	Proven risk	See measurements at the beginning of the table	
Feeling of discomfort	Proven risk	See measurements at the beginning of the table	
Nausea	Proven risk	-Ask participants to eat lightly before the test session to prevent the onset of symptoms.	
Saliva increase	Proven risk	See measurements at the beginning of the table	
Disorientation	Proven risk	See measurements at the beginning of the table	
Tachycardia	Proven risk	See measurements at the beginning of the table	Wearing a pacemaker or cardiac pacemaker is an exclusion criterion.
Loss of consciousness	Proven risk	See measurements at the beginning of the table	
Topic 2. Sensorimotor consequences (impaired manual dexterity, ability to orientate the body)	The risks presented under this theme are present and recognized in the literature.		
Contraction of eyes or muscles	Proven risk	See measurements at the beginning of the table	

Hand-eye coordination disorder	Proven risk	See measurements at the beginning of the table	
Involuntary movements	Proven risk	Prevention: Warm-up and stretching time before and after the trial	
Balance disorders	Proven risk	Suggested sitting, hydration	
Theme 3. Disruption of circadian rhythms (sleep onset, sleep time)	The risks presented under this theme are present and recognized in the literature.		-People considered sensitive: aphakics (lack of crystalline lens) and pseudo-phakics (artificial lens); people suffering from eye pathologies or abnormalities; people suffering from sleep disorders; people suffering from photosensitive epilepsy.
Sleepiness	Proven risk	See measurements at the beginning of the table	
Sleep time	Proven risk	See measurements at the beginning of the table	-For people sensitive to blue light, avoid screens two hours before going to bed.
Topic 4. Epilepsy			
Epileptic seizures	Proven risk	-Pre-diagnosed epileptic risk is an exclusion criterion.	-Taking neuroleptics favors the onset of epileptic episodes. This constitutes a contraindication to participation in the study.

Adapted from ANSES. (2021). Potential health effects related to exposure to virtual and/or augmented reality technologies. Collective expertise report

Mitigation measures :

- Monitoring symptoms of cyberkinetosis.
- If you wish, you can end your participation at any time.
- A snack is served at the end of the session.

Advantages:

- You may derive some personal benefit from your participation in this research project, but we cannot assure you of this. On the other hand, your participation will enable us to gather empirical data on the interests of people aged 50 and over in physical activities and immersive technologies. This is an advantage for TOPMED and its partners.

Information requested

We will collect data related to your experience with immersive technologies and virtual reality games. Specifically for the preliminary questionnaire, we are interested in the following themes: personal information (socio-demographic data), health status, health monitoring, activity habits and preferences, technology and exergames, virtual leisure activities and virtual games. During the group interview on the individual games, we'll gather your opinions on satisfaction with the experience, the integration of virtual reality and the acceptability of this technology. At the end of the interview, we'll collect data on the same themes as the first questionnaire, to see whether the experience has had an impact on your perception of the technology. During these discussions, we may ask you for identifying information. In addition, in each questionnaire we will ask you if you are interested in participating in future TOPMED research projects.

Privacy

As this is a research and development project for a new service, you are required to maintain confidentiality so as not to harm the company's potential new service offering.

Project sponsors

Natural Sciences and Engineering Research Council of Canada (NSERC)

Voluntary participation and withdrawal

You are free to choose whether or not to participate in this study and/or to participate in future research projects with TOPMED. You may also terminate your participation at any time, without prejudice and without having to justify your decision. If you decide to end your participation, it is important to notify the investigator whose contact details are included in this document. All material enabling you to be identified, and the data you have provided, will then be destroyed, unless you authorize the researcher to use them for research purposes, despite your withdrawal. In this case, they will be kept in accordance with the measures described below, which will be applied to all participants.

We would like to thank you for your invaluable collaboration in carrying out this research. We appreciate your time and attention.

Privacy and confidentiality

The information collected in the questionnaires and during the sessions is confidential, coded and will only be used for the purposes of this research project, unless otherwise agreed by the participant.

For the questionnaire: The tool presented in digital form is created with the Lime Survey platform. The processed information is hosted in Canada on the platform's encrypted servers (Secure Socket Layer procedure), which comply with the RGPD standard.

During interviews, the participant's name and those mentioned during the interview will be replaced by a code in the form of a number

Only members of the research team (all of whom are bound by confidentiality agreements) will have access to participants' identifying information and encrypted research data.

All data collected is encrypted on servers or stored in a locked file cabinet at TOPMED, Mérici Collégial Privé, 755 Grande Allée Ouest, Québec, Qc, G1S 1C1.

Unless required by law, we will not disclose or publish any information that may directly or indirectly reveal your identity without your prior explicit consent

Audiovisual recordings will only be viewed by members of the research team and will not be distributed.

The data acquired by the producers of headsets and games may contain :

- Video data
- Audio data
- Data associated with user movements
- Data on users' physical environment

This technology cannot be used without data exchange with these companies. To maximize participant confidentiality, we will implement the following solutions:

Explanation of FIC in a separate room without helmets

User accounts on behalf of TOPMED

No use of participants' names or any personal identifying information aloud in the presence of headsets (microphones and cameras)

Separating screens to protect participants' identities

Data will be stored in encrypted form for a period of five (5) years, then anonymized in a database for retention for a period of ten (10) years for statistical reference purposes. If data is stored on a USB key or other external medium, it will be encrypted.

Participants will not be identified by name in the results, but will be identified by a number. Any scientific publication resulting from this research project will present both statistical and qualitative data. Should the research team use verbatim extracts, the names of the participants will be replaced by a number.

Under no circumstances will the names of participants be published or divulged to anyone.

Personal injury compensation, legal rights

By signing the consent form, you do not waive any of your legal rights.

Compensation

There is no compensation for your participation in the preliminary questionnaire.

A compensation of $25 per meeting is provided for your participation ($50 in all). If necessary, a parking sticker can be provided for the duration of your attendance at the meeting.

You have the right to change your mind

Your participation should be entirely voluntary. You may refuse to take part in this project

New information

Should any inconvenience arise following the test, subjects will be promptly notified.

Project questions and contacts :

If you have any questions about the research project or if an unusual change in your condition (injury, side effects, etc.) occurs during the project, you can contact :

Edith Martin, Director of Research and Innovation, TOPMED
Tel.: (418) 780-1301
E-mail: emartin@topmed.ca

Estelle Houguet, Project Manager, TOPMED
E-mail: ehouguet@topmed.ca

Ethics review

This study has been reviewed by the Veritas Independent Review Board (IRB). If you have any questions about your rights as a research participant or about the researcher's responsibilities, you can contact the director of Veritas IRB 24 hours a day, 7 days a week at 514-337-0442 or toll-free at 1-866-384 -4221. An IRB is a group of scientific and non-scientific individuals who perform the initial and ongoing ethical review of research projects with the rights and welfare of the subject in mind. If you have any comments, complaints or concerns related to the study, you should first contact the study investigator. Please call the IRB if you need to speak to someone independent of the principal investigator and research staff, and/or if the investigator and research staff could not be reached.

If you have any complaints, please contact the Collège Mérici resource person:
Luce Poulin, Acting Director of Studies
Tel: (418) 683-1591 p. 2255
E-mail : lpoulin@merici.ca

Declaration of consent

I, (print name) _____, acknowledge that I have read the form and understand the information provided to me in order to give informed consent. All my questions have been answered to my complete satisfaction. I have had sufficient time to consider my decision whether or not to participate in this study. I understand that my participation in this study is entirely voluntary and that I may decide to withdraw at any time, without penalty.

I voluntarily consent to participate in this study.

I authorize the TOPMED research team to record my voice, portrait and person on videotape, audiotape or other audiovisual or electronic medium for data collection purposes.

Signature: _____ Date:_____

I agree to be contacted for future Topmed research projects.

Email : _____Telephone :_____

Member of the research team who interacted with the subject

To the best of my knowledge, the information on this consent form and the information I have provided in response to any questions fairly describes the project. I agree to conduct this study in accordance with all ethical standards applicable to projects involving the participation of human subjects. I undertake to ensure that the subject receives a copy of this consent form.

Name (print name)_____

Signature : _____ Date:_____

Project Manager

I undertake to conduct this study in accordance with all ethical standards applicable to projects involving the participation of human subjects.

Signature :_____ Date:_____