INFORMATION AND CONSENT FORM
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NCT06117319

Project title

RD-19-0277 - Development and validation of sports facilities in a supportive environment to improve the well-being of the elderly

Phase 2: Determination and validation of solutions for offering physical activities in an enabling environment through social analysis of acceptance and integration among seniors wishing to maintain and improve their motor and abilities

Project team

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Why are we giving you this form?

We invite you to take part in a study designed to find out more about the interests, abilities and motivation in terms of physical activities of people in retirement homes, in order to optimize current practices and develop new activities within the residences. It also aims to determine the appreciation and need for new activities within Groupe Maurice.

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 you feel the need.

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.

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

The aim of this phase of the project is to identify and validate solutions for offering physical activities in an enabling environment, through social analysis of acceptance and integration among seniors wishing to maintain and improve their motor and cognitive abilities. More specifically, a number of equipment, activities and technologies best suited to the clientele predetermined on the basis of the literature and previous data collection will be proposed to the regular clientele of Groupe Maurice's residences. Acceptance and integration of these activities will be observed and measured.

The results obtained will be used to determine the feasibility of the new activities in the user's environment, and to elaborate the user's needs. They will also be used to assess the suitability of the

proposals in order to establish a list of relevant activities, equipment and technologies to be used in the development and validation of exercise programs. Ultimately, this will help Groupe Maurice not only increase the utilization rate of its various leisure facilities, but also introduce new activities to enhance the physical and psychological well-being of its residents.

In order to identify and validate solutions for offering activities in an enabling environment, an activity will be proposed in the form of training sessions in the use of virtual reality in Groupe Maurice residences.

What will you have to do?

The virtual reality (VR) activity will take the form of five (5) training sessions focusing on the Discovery/Exploration theme
By registering for the activity, you are expected to participate in all sessions.
The sessions are detailed as follows:

- Session 1: VR basics
    - This session includes familiarization with the equipment, securing the person, choosing a game, getting comfortable in the virtual world, as well as the procedure for cleaning the elements.
- Session 2: game mode
    - This session includes a review period, individual practice mode and mode.
- Session 3: Library game
    - navigation
- Session 4: mode of play
    - This session includes a review period, the common structure of the games, navigating the menu and settings, and choosing .
- Session 5: Playing games
    - Summary of sessions

For each session, in small groups of 3 people, you will be invited to try out games related to the Discovery/Travel theme. Particular care is taken in the choice of games to avoid any situation involving violent or shocking scenes, both emotionally and physically. The games tested refer to the discovery of places requiring only low- to moderate-intensity movements of the upper limbs. You will learn to use the virtual reality equipment (headset and virtual reality controllers) with the assistance of members of the research team. Sitting will be mandatory during the tests to avoid falls. If you lose your bearings, you'll be able to tap the headset twice to return to a normal view of the physical environment
A questionnaire will be distributed for each session. The questions will focus on your perception of the following points:

- Your state of mind at the start of the session
- Your level of apprehension at the start of the session
- Your comfort level at the end of the session
- Your sense of control at the end of the session
- Your satisfaction with the management
- Comments if you have any
- Your desire to play virtual reality games

Sessions will be captured on audio/video recordings to optimize data capture
As a security measure, you will test the games from your TOPMED user account, and you will not enter any personal data about yourself. Screens will be set up between each participant to maximize the

confidentiality of data used by headset manufacturers and third parties (META, game producers and others)

Probable duration of project stages

The project includes several (5) virtual reality training sessions.
When you sign up for the activity, you are expected to attend all sessions.
Each virtual reality session takes 45 minutes, as detailed below.
Participation in 5 sessions (Total: 225 minutes)

One session (Total 45 minutes)

- The session will take place in a room determined by Groupe Maurice or any other room deemed suitable by the project partners.
- At the first session, a 10-minute period is set aside to explain the project and clarify the content of the consent form, if necessary, then have it signed.
- Each session begins with a questionnaire (2 minutes) and a review of the previous session (10 minutes)
- The session alternates explanations and game/application trials, on the theme of Discovery/Travel, in a seated position. During each session, you'll explore the games with a guide who will take you through the experience.
- At the end of the session, a member of the research team will be present to complete the questionnaire (5 minutes).
- Experiences with the helmet will be visible through a process called mirroring. The latter will be recorded in order to collect data relating to the session.
- The entire session will be audio/video recorded so that all observations and data can be collected.

Possible disadvantages / advantages

Risks:

- With regard to 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 cybermalaise 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 your well-being. To this end, the instructor will regularly ask you questions about the sensations you experienced while trying out the activities. At the end of the trial, you will be given a snack and a suitable place to rest 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** may experience more serious events and must therefore be **withdrawn from the sessions**. If these risks apply to you, please notify us now.

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. Cyberkinetosis 2. Consequences for the sensorimotor system 3. Disruption of circadian rhythms 4. Epilepsy		Prevention: -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 - Provision of a space for participants to rest after the trial If appearance: -Pause or stop test Applicable to all symptoms: -Members of the research team are certified in first aid. -In Groupe Maurice residences, the care team will be present on site. -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, headache, 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 static postural 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.	
Salivary 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. expertise report

Disadvantages:

- The research project has no drawbacks

Advantages:

- There are no direct and immediate benefits to participants from taking part in the activity. This data collection will provide measures on participants' interests, abilities and motivations in terms of physical activities, which is an advantage for SEC Fonds Immobiliers Groupe Maurice to optimize its offer of activity services within their residences and develop new activity programs adapted to the clientele.

Information

We will be collecting experience data in connection with training on the testing of virtual reality games. Specifically, we are interested in following themes: state of mind, level of apprehension, level of comfort, feeling of control, satisfaction with the training, intention to play virtual reality games. We will collect information from the mirroring recordings. During these sessions, each task will be observed to measure participants' ability to complete it alone or with assistance. Audio-visual recordings will be made to facilitate data collection. We will not ask you for any identifying information unless you choose to be recontacted for another project.

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.

Sponsors

Natural Sciences and Engineering Research Council of Canada (NSERC)
SEC Fonds Immobiliers Groupe Maurice.

Team remuneration

Project team members are remunerated by an NSERC grant and by SEC Fonds Immobiliers Groupe Maurice.

Marketing

It is possible that a new service offering will be developed by Groupe Maurice as a result of this research. If this is the case, you will not receive any direct or indirect benefit.

Voluntary participation and right to withdraw

Your participation in this research project is voluntary. You are therefore free to refuse to take part. You may also withdraw from this project at any time, without having to give any reasons, by making your decision known to the researcher in charge of the project or to one of the staff members assigned to the project. You may also request the withdrawal of your data collected as part of the project. Your decision not to participate in this research project or to withdraw will have no impact on the quality of the care and services to which you are entitled, or on your relationship with the researcher in charge of the project and other stakeholders.
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 during the sessions is confidential, anonymized and will only be used for the purposes of this research project, unless otherwise agreed by the participant. 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. Only members of the research team (all subject to confidentiality) will have access to participant identification information and encrypted research data.

Unless required by law, no information that could directly or indirectly reveal your identity will be broadcast or published 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 movements
- Data on participants' physical environment

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

- Explanation and signing of FICs in a separate room without
- Topmed user accounts on behalf of participants
- 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 for a period of five (5) years. 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 statistical data only, and under no circumstances will the names of participants be published or divulged to anyone

Data access

All research data will be accessible to the project team. Project sponsors will not have access to research data. Participants will not have access to research data. The Research Ethics Committee, Veritas IRB, will have access to research data for verification in the event of a complaint. Where appropriate, data will be made available to them for viewing only via videoconferencing.

Legal rights

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

Compensation

Your legal rights will be maintained. A compensation of $25 per session will be provided for each participant

You have the right to change your mind

Your participation should be entirely voluntary. You may refuse to take part in this project. You can stop taking part at any time without prejudice, simply by notifying the person in charge of the research project.

New information

In the event of any inconvenience arising from the completion of the questionnaire, you will be notified promptly.

For more information?

Contact
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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

Declaration of

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

☐ I agree to be filmed during

Signature: _____ Date : _____

☐ I agree to be contacted to participate in future research projects

E-mail: _____ Telephone : _____

Member of the research team who interacted with the

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.

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 : _____