Ageing well by being connected - Phase 2

Presented to the Veritas Research Ethics Committee

TOPMED

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PROJECT TITLE

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 activities in an enabling environment through social analysis of acceptance and integration among seniors wishing to maintain and improve their motor and cognitive skills.

START AND END DATES

January to August 2023

PROJECT DESCRIPTION

Issue

In Canada, 88% of adults aged 65 and over are sedentary or very inactive. Yet World Health Organization (WHO) health guidelines suggest at least 150 minutes of activity per week, with a minimum 10-minute session of moderate-to-high intensity aerobic training. According to Health Canada, improving or maintaining physical capacity has been shown to improve seniors' quality of life in terms of mobility, mental health, psychological well-being and long-term functional autonomy. What's more, maintaining muscular strength slows down the progression of osteoporosis, reduces the risk of falls and prevents the onset of various heart and artery diseases. Regular physical activity in the elderly therefore helps prevent premature deterioration in health in a number of ways

Groupe Maurice has been a leader in the design, development and management of state-of-the-art retirement residences in Quebec since 1998. With 36 private residences for seniors in Quebec, Groupe Maurice has created environments that enable its customers to blossom, socialize and enjoy the lifestyle they're looking for. The company's aim is to improve quality of life and maintain autonomy by providing resources for physical exercise. However, indoor and outdoor exercise facilities are under-utilized in relation to Groupe Maurice's projections. In order to increase utilization and, above all, optimize training rooms, Groupe Maurice has chosen to develop an empowering environment concept with semi-customized, evolving exercise programs. This concept is based on the provision of resources that encourage autonomy in the practice of activities according to the user's condition. However, in order to improve equipment use and compliance with exercise programs, it is necessary to know more about the interests, habits, abilities and motivation of current residents

Groupe Maurice's clientele is made up of retired people: the average minimum age in our residences is around 65. The quality of life of this population and the preservation of their autonomy are directly linked to their physical capacity. The company therefore aims to create an enabling environment based on the development of an adapted gym and environment, as well as an exercise and activity program specific to the needs of its clientele.

State of knowledge and relevance

Aging is a biosocial process that results in a non-linear and non-constant deterioration in the function of physiological systems associated with anatomical and structural changes. In concrete terms, age-

related physiological and cognitive changes can be observed in the following aspects: body composition, cardiorespiratory capacity, musculoskeletal system, central nervous system (CNS) and brain, sensory and perceptual system.

All these changes have a major impact on people's motor and cognitive skills. Overall, from a motor point of view, aging leads to an increase in movement time. As a result, walking speed slows progressively; indeed, walking speed is a tool for identifying frailty in the elderly. In addition, a reduction in postural maintenance, with more pronounced oscillation and difficulties in controlling static balance, as well as in adjusting to disruptive elements, are also observed and result in an increased risk of falls. More than a quarter of people over 65 living at home fall at least once a year. These falls have serious consequences for the health and quality of life of the elderly, sometimes leading to serious injury, loss of autonomy or even death. On the cognitive level, processes linked to memory, attention and processing speed are often affected, but not all forms of expression of these functions are equally affected. In the field of attention, for example, selective attention, assessed by the ability to inhibit an automatic response (e.g., reading a word in the Stroop task), and divided attention, required to accomplish concurrent tasks (e.g., driving while adjusting one's radio), are forms of attention that are particularly sensitive to advancing age, while visual search (e.g., identifying a target among distractors) is rather spared. In the field of memory, immediate or very short-term recall of information declines with age, while in long-term memory, voluntary and explicit recall of new information is more affected than implicit recall, triggered by recognition of familiar information, for example. Empirical evidence also supports the view that higher cognitive functions are affected, such as arithmetic and problem-solving skills. This deterioration, whether progressive or sudden, leads to functional limitation, disability and, ultimately, death. This decline is gradual and varies from one individual to another, depending on genetics, morphology and functional characteristics.

In 2015, the World Health Organization issued recommendations on the importance of healthy aging. This expression does not mean an absence of disease, but the development and maintenance of functional abilities that enable older people to enjoy a state of well-being. In its action plan, the WHO presents physical activity as one of the two key behaviors for healthy aging (along with nutrition). The physiological benefits of physical exercise have been repeatedly demonstrated for all populations for decades. It has been associated with improved cardiorespiratory fitness, balance control and muscular strength, as well as a reduction in coronary heart disease and type II diabetes, and improved ability to carry out daily activities in the elderly. What's more, physical exercise is also linked to the likelihood of living longer with independence and a good quality of life

Physical exercises can be distinguished according to their level of demand in three major functional areas: force, energy and information. In fact, these three domains cover all the major mechanisms underlying the realization of a "physical exercise": force produces movement, energy enables the continuity of this movement to be maintained, information enables movement to be associated with a goal, its execution to be controlled (speed, precision, direction, etc.) and the level of effort (force, energy) associated with its realization to be regulated. These three areas are always involved simultaneously in the production of a movement (and therefore of physical exercise), but to different degrees. From a functional point of view, the "force" domain refers to muscular and neuromuscular aspects, the "energy" domain encompasses cardiovascular, cardiorespiratory and metabolic (muscular, cerebral) aspects, while the "information" domain encompasses all mechanisms of information processing, executive control or memorization, i.e. it refers to both cognitive and sensorimotor processes. According to this model, any motor skill, and consequently any physical exercise, always mobilizes both sensory-motor and cognitive mechanisms

Physical exercise has beneficial effects that go far beyond physiology. Exercise also has positive effects on brain plasticity and cognition, slowing down brain ageing and reducing the risk of dementia and Alzheimer's disease, as well as improving psychological well-being by improving sleep quality and reducing symptoms of anxiety and depression through the production of beta-endorphin and serotonin. In particular, physical exercise improves self-esteem and self-confidence, enabling the elderly to feel energetic and useful. Last but not least, physical activity enriches the social life of the elderly, as it is a means of socializing (creating links, breaking solitude)

With its 36 private residences for seniors in Quebec, Groupe Maurice has created environments that allow its customers to develop, socialize and enjoy the lifestyle they're looking for, with indoor training rooms and outdoor exercise facilities. For the time being, the professionally supervised classes offered in their residences are often fully booked. This reflects an interest on the part of residents in physical activity, which does not materialize once they are on their own. Against this backdrop, Groupe Maurice is keen to increase the utilization rate of the various facilities dedicated to physical exercise (gym, yoga room, swimming pool, outdoor gardens, etc.), as well as introduce new leisure activities.

The development of semi-customized activities that can be adapted to the specific pathologies and limitations of users would enable more appropriate conditions of use, greater benefits in terms of physical performance and quality of life, and ultimately, the anticipation of more consistent practice

The aim is to identify activities that not only meet their needs, but also their desires, so as to encourage the regular practice of empowering leisure activities.

Research objectives

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 preceding literature and 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 new activities in the user's environment. 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.

Financing
The project is funded by NSERC under the *Applied Research and Development* program in partnership with SEC Fonds Immobilier Groupe Maurice

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METHODOLOGY

Specific population

Regular clientele of Groupe Maurice residences: Groupe Maurice's regular clientele refers to retired people living in a dwelling outside the care unit of one of the group's residences.

Research location

Residents of seniors' residences will not have to come to TOPMED's premises to test the equipment and activities on offer. TOPMED's research team will travel to the residences to carry out the activities. The location of the activities will be determined jointly with Groupe Maurice. In the event of health measures, activities will be adapted accordingly. Ideally, activities will be carried out remotely, if possible.

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

Measurement, assessment and collection tools

assess the feasibility and take-up of new activities such as virtual reality, a training activity will be offered in the form of virtual reality workshops at Groupe Maurice residences

This training will take place over 5 weeks, with one session per week. All groups will have a group trainer. Two types of mutual aid will be tested: Individual help (one trainer per participant) and group help (help with other participants).
A questionnaire will be distributed to participants. This questionnaire will contain the following information:

- State of mind
- Level of apprehension

These two variables will be completed at the beginning of the session

- Comfort level
- Level of sense of control
- Satisfaction with supervision
    - Comments can be added to these three variables
- Intended future use

These four variables and comments will be requested at the end of each session.

- Training benefits
- Training adaptation
- Difficulty of training

These three variables will be requested in the final session.

During these sessions, tasks will be observed to measure participants' ability to complete them alone or with assistance. Attendance will be taken at the start of each session.

The sessions, as well as the mirror images of the navigations, will be filmed and audio-recorded.

For security reasons, participants will test the games from TOPMED user accounts and will not enter any personal data about themselves. Screens will be set up between each participant to maximize the confidentiality of data used by helmet manufacturers and third parties (META, game producers and others)

Estimated duration of activities

The project includes several (5) training sessions on virtual reality (VR). The participant agrees to attend all workshops. Failure to attend a workshop may result in the participant's exclusion from the project.
Participation in 5 workshops (Total: 225 minutes)
Each virtual reality workshop takes 45 minutes, as detailed below
A Workshop (Total 45 minutes)

- The training session alone will last 40 minutes.
- The session will take place in a room determined by Groupe Maurice (e.g. a church hall or cinema).
- During the first session, time is set aside to explain the project and clarify the content of the consent form, if necessary, then have it signed (10 minutes).
- Each workshop begins with a questionnaire (2 minutes) and a review of the previous session (10 minutes).
- The session alternates between explanations and game trials in a seated position. During each session, the participant will explore games and applications with an attendant who will guide them through the experience. Content is chosen and adapted to take into account the sensitivities of the target audience (no violent content or content giving extreme and negative sensations).
- Following the trial, a member of the research team will accompany the participant with a questionnaire (5 minutes).
- The participants' visual experiences 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.

The sessions will be organized 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: Multiplayer game mode
    - This session includes a review period, individual practice mode and multiplayer mode.
- Session 3: Library game
    - Library navigation
- Session 4: Individual play
    - This session includes a review period, the common structure of the games, navigating the menu and settings, and choosing options.
- Session 5: Game practice
    - Summary of previous sessions

PARTICIPATION OF HUMAN, ANIMAL OR MATERIAL SUBJECTS

For activities with regular customers, we will be recruiting 48 senior volunteers to evaluate the virtual reality activity in seniors' residences. To do this, we are targeting four (4) residences co-identified with the partner. Four (4) groups will be formed per residence. Each group will be made up of 3 people (i.e. 12 people per residence). Each group will complete five (5) virtual reality training sessions.

Inclusion criteria for workshop participants :

- Voluntary residents who are part of the regular independent clientele in a Groupe Maurice residence.

Exclusion criteria for workshop participants

Exclusion criteria will be established according to the activity tested.

- For the virtual reality activity, exclusion criteria include wearing a pacemaker.
- People with a pre-existing epilepsy condition or at risk of epilepsy will not be able to take part in this training.
- Exclusion criteria will be verified by Groupe Maurice residences staff when registering for workshops. The criteria will be reiterated by research staff on the day of the activity before consent forms are signed
- Failure to attend a session may result in exclusion.

SCIENTIFIC JUSTIFICATION FOR USING LIVING SUBJECTS

The participation of human subjects is essential in this phase in order to better define and respond to the real needs of people in retirement homes, and thus promote acceptance of the new activities and facilities proposed later on.

RECRUITMENT

Virtual reality activities will be publicized in Maurice Group's internal communications media, which will be co-determined with them. In addition, posters will be distributed to residents' mailboxes. These activities will be integrated into the residences' calendar in agreement with Groupe Maurice. On a voluntary basis, participants will be able to register for virtual reality training. Consent forms will be distributed only to these people in the residences following registration. A period of two (2) weeks will be allowed for reading and reflection. At the first meeting, the consent form will be distributed again and explained, before the participants decide whether to sign it. Sessions then take place with participants who have agreed

Participants may accept to be recontacted to be invited to a transfer activity with validation of prior learning.

MEASURES AND STRATEGIES PLANNED FOR THE PROTECTION OF VULNERABLE PERSONS OR PERSONS WITH A DEPENDENT RELATIONSHIP (if the subjects are minors or adults under guardianship or curatorship, or if they have a client-professional, student-teacher or employee-employer relationship with a member of the research team

In this project, all participants are recruited on a voluntary basis. The data acquired will be anonymized for participants

RISKS, DRAWBACKS, AND MITIGATION MEASURES

With regard to virtual reality activity, discomfort linked to the graphics and the conflicting, multi-sensory aspect of immersion sessions could arise during the use of immersive technologies. This discomfort could take the form of simulation sickness 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. The table on the following pages details the possible risks and their degree of severity. These discomforts naturally need to be spotted, and short sessions will be held to prevent them. 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 offered a snack and will be able to rest in a suitable space until their symptoms disappear, if necessary. 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		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 - 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, 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.	
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	
Theme 2. Sensory-motor consequences (impairment of manual dexterity, ability to orientate the body)	The risks presented under this heading 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 for 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

- Monitoring symptoms of cyberkinetosis
- If they wish, they can terminate the activity at any time
- Snacks distributed to all participants

ADVANTAGES

No immediate benefit for volunteers for taking part in the project.
The advantage for Groupe Maurice and TOPMED of involving people in the project is that it will provide data on the validation of activity programs, particularly in terms of their feasibility and conditions for implementation.

FREE AND INFORMED CONSENT

An information sheet and consent form for participants will be made available at Groupe Maurice residences. A period of two (2) weeks, or more if necessary, will be allowed for reading and reflection. Should participants have any questions, they can contact TOPMED staff by e-mail or directly by telephone for further explanations. The resident agrees to attend all training sessions.

Participants may terminate their participation at any time without negative consequences or prejudice and without having to justify their decision. In this case, participants must inform the responsible researcher or a member of the research team. Thereafter, all material allowing the identification of the participant and the data provided will be destroyed unless the participant authorizes the researcher to use them for the research despite the withdrawal. In this case, the data will be retained in accordance with the measures described below, which will be applied to all participants

CONFIDENTIALITY AND PROTECTION OF INFORMATION

The information collected in the questionnaires is confidential and will only be used for the purposes of this research project. 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, no information that could directly or indirectly reveal your identity will be distributed or published without your prior explicit consent
When the completed consent form and questionnaire are delivered to a residence's reception desk in a sealed envelope, the envelope is placed in a locked filing cabinet in the residence until it is retrieved by a member of the research team
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 the 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 information and consent forms in a separate room without VR headsets
- Topmed user accounts on behalf of participants

- No use of participants' names or any personal identifying information aloud in the presence of VR 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.

Results will be anonymous. 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 participants' names be published or divulged to anyone.

DATA ACCESS

All research data will be accessible to the project team, subject to a confidentiality clause. 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. If needed, data will be made available to them for viewing only via videoconferencing.

CONTINOUS EXAMINATION

Should any inconvenience arise during project validation, subjects will be promptly notified.

DISSEMINATION ACTIVITIES

No disclosure to participants will be made following the completion of questionnaires and the running of workshops.
Results will not be published.

COMPENSATION

Compensation of $25 per session will be provided for each participant.

RESPONSIBILITIES

The legal rights of each participant will be maintained.

CONFLICT OF INTEREST AND PROPOSED MITIGATION MEASURES (existence or appearance of conflict of interest: financial interest, link with funding source, link with volunteers)

No conflict of interest.

PROJECT SEQUENCE

Recruitment

- Posting in residences via Groupe Maurice's internal communication channels and distribution to residents' mailboxes

Related documents

-
- Affiche-VRRésidence_GIBRALTAR_2023
- Affiche-VRRésidence_MARGO_2023
- Affiche-VRRésidence_QUARTIERSUD_2023

Admission

- Voluntary registration of participants in residence at points identified with the partner two weeks before the workshops. Participants must register for all workshops.
- Groupe Maurice staff will check exclusion criteria when registering for workshops.

The course

- Five sessions on offer
- At the start of session 1: distribution and explanation of paper Information and Consent Forms at registration. Reminder of exclusion criteria
- At the start of sessions: validation of attendance at the beginning of workshops by a member of the research team
- Completion of Satisfaction Questionnaire-Part 1 (Beginning of session)
- Video/audio recording of session and mirroring begins
- Test of associated games in a seated position
- End of audiovisual recording
- Satisfaction questionnaire - Part 2 (End of session)
- Total session time: 40 minutes

Related documents

- 277_FIC-VR-ClientReg
- 277_Symptom
- 277_ActéVR_QSatisf
- 277_ActVR_MeasuresER

Data processing

Compilation of audiovisual recordings.