Research Project Protocol

TITLE	Development and evaluation of virtual reality experiences for cognitive stimulation at the El Carme Socio-Health Center in Badalona Healthcare Services (BSA)
PROTOCOL CODE	PI-23-195
PROMOTER	Badalona Assistance Services

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SUBSTANTIAL MODIFICATIONS TO THE PROTOCOL

Modification date	Modified section	Justification for the change
31/07/2023	CI - BSA Data Protection Officer contact added	Assessed and approved by the BSA research committee, with the indication of this modification.
23/09/2023	Changes in the CI and in the patient information sheet: -New versions of the patient information sheet and the IC according to CEIC models. (annexes 1 and 2.1) -Added the intervention information. -Added the CI version for a family member or legal representative (Annex 2.2)	Clarifications requested by the CEIC
23/09/2023	Added to section 5.2 Design the detailed explanation of the intervention.	Clarifications requested by the CEIC
23/09/2023	Eliminated references to data will be coded so that the participants are not identified.	Clarifications requested by the CEIC

1. PROTOCOL SUMMARY

Title and subtitles, version and date of the protocol	Development and evaluation of virtual reality experiences for cognitive stimulation at the El Carme Socio-Health Center in Badalona Healthcare Services (BSA). Version 1. 07/18/2023
Name, surname of the main author and organization for which he or she works	José Ferrer Costa (ORCID: 0000-0002-3789-6272) - MFiC, Innovation and projects. Badalona Assistance Services. Contact: jfcosta@bsa.cat

1. BACKGROUND AND JUSTIFICATION

The increasing prevalence of cognitive impairment and dementias, such as Alzheimer's disease, presents a significant challenge to global public health, with rapid intensification concomitant with population aging (United Nations, 2015). The impairment of memory, attention and executive functions that characterize these conditions substantially impacts the quality of life of patients, also exerting a considerable burden on caregivers and health systems.

The term "dementia" encompasses various diseases and conditions that lead to a deterioration in memory, language, problem-solving abilities and other cognitive skills, consequently altering a person's ability to carry out activities of daily living. . This global problem affects more than 55 million people, and adds around 10 million new cases annually (World Health Organization, 2023). This constant increase calls for the design, implementation and evaluation of innovative therapeutic strategies to support the care and management of people with dementia and related conditions.

The treatment of dementia is approached from several perspectives, including pharmacological and non-pharmacological interventions. While the former are aimed at managing the cognitive and non-cognitive symptoms of the disease, they do not provide a cure and can cause side effects. On the other hand, non-pharmacological interventions, such as cognitive rehabilitation programs, focus on training and improving cognitive abilities and teaching new strategies and skills to compensate for affected abilities. However, its effectiveness may be limited due to the difficulty of transferring learned skills to everyday contexts, given the artificiality of training environments.

Healthy aging is a key goal for the world's rapidly aging population. As we look for ways to promote cognition and well-being in old age, technology-based interventions have become a popular approach. However, access to and effectiveness of these interventions can be affected by various barriers, such as unfamiliarity with or lack of access to the technology. According to a recent study by Zuschnegg et al. (2023), the results demonstrated that CCIs have a significant effect on memory, working memory, attention/concentration/processing speed and executive function in individuals with mild cognitive impairment, but no significant improvements were observed in global cognition and language. This study also highlighted the need for more research examining the effectiveness of these interventions in more realistic settings, such as participants' homes. This study aims to explore and evaluate the effectiveness of computer-based cognitive interventions (CCIs) in improving memory and cognition in community-dwelling older people, and analyze the barriers and facilitators to the use of CCIs, expanding thus the existing research.

In this scenario, virtual reality (VR) has stood out as a powerful tool for cognitive stimulation in people with cognitive impairment. Its immersive and engaging nature allows it to provide an ecological, safe and controlled environment, in which users can practice cognitive and physical skills in digitally recreated everyday situations. Recent studies support the potential of VR to improve cognitive skills and reduce interference in individuals with mild cognitive impairment (MCI) (Goméz et al., 2022; Papaioannou et al., 2022; Chen et al., 2021; Bauer et al., 2022 al., 2020). A recent meta-analysis and systematic review provides additional evidence by showing a positive impact of VR-based cognitive rehabilitation programs on cognitive and functional outcomes, including improvements in cognitive functions, daily functioning, depressive symptoms, and quality of life (Bitch A . et al., 2023).

For the design of our project, the work of Muñoz et al. (2022) offers a solid foundation on which the “SWOT” matrix and general design guidelines for Human-Computer Interaction (HCI) are provided. These resources are useful to identify strengths, opportunities, weaknesses and

threats of the use of virtual reality technology in cognitive rehabilitation and to optimize the usability of HCI in interventions that use this technology. Furthermore, a recent study conducted by Qiu et al. (2022) supports the acceptability and tolerance of a virtual reality-based cognitive training program in older adults, reflecting that the majority of participants found VR attractive and easy to use, without serious or severe adverse events.

The main objective of this project is to carry out a pilot study to clinically evaluate the effectiveness of virtual reality (VR) sessions in a selected group of 20 patients from the El Carme Socio-Health Center in Badalona. These VR sessions will consist of 360-degree immersive experiences, designed and provided by Reality Telling, that will focus on recreating familiar environments and implementing memory and attention training exercises.

The purpose of these sessions is twofold. On the one hand, we seek to validate the acceptability of these immersive experiences among patients and healthcare professionals, evaluating their willingness to adopt and interact with this innovative form of therapeutic intervention. On the other hand, we propose to examine the impact of immersive experiences in terms of improving cognitive performance, as well as on the commitment and motivation of patients towards their own cognitive rehabilitation process.

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3. HYPOTHESIS OR STUDY QUESTION

Main Hypothesis:
The application of a cognitive stimulation program with virtual reality will be well accepted by patients with mild cognitive impairment.

Secondary Hypotheses:

- Virtual reality interventions will be perceived as useful and motivating by patients, promoting positive adherence to the cognitive stimulation program.
- Patients will improve their cognitive performance (attention and memory) on cognitive scales after the sessions.
- Virtual reality interventions will be perceived as useful and applicable as a tool in the clinical practice of cognitive stimulation by healthcare professionals.

4. GOALS

4.1. Main objective

To evaluate the acceptability of the cognitive stimulation program based on virtual reality among patients with mild or moderate cognitive impairment at the El Carme Socio-Health Center in Badalona.

4.2. Goals specific

To investigate whether VR interventions are perceived as useful and motivating by patients, which would translate into positive adherence to the cognitive stimulation program.

Measure changes in cognitive performance (particularly in attention and memory) of patients before and after the VR intervention to evaluate the effectiveness of the cognitive stimulation program.

Understand how healthcare professionals perceive VR interventions in terms of their applicability in the clinical practice of cognitive stimulation.

Identify possible improvements in the implementation of the VR program based on the comments and suggestions of patients and healthcare personnel.

Collect data and information that could be useful in developing future VR experiences for patients with cognitive impairment.

5. RESEARCH METHODS

5.1 Study type

Type of study: Non-randomized prospective pilot study interventionist

Study Description: This is an interventional study where an intervention not used in conventional practice will be evaluated, which consists of the use of virtual reality experiences for cognitive stimulation in patients with mild or moderate cognitive impairment. The VR experiences will be developed in collaboration with a technological partner, with the aim of potentially being incorporated into the cognitive rehabilitation program at the El Carme Socio-Health Center (CSSC) Day Hospital.

5.2 Design

This study will be prospective and non-randomized in design. Patients will be selected from among those who already attend cognitive rehabilitation sessions at the CSSC Day Hospital. There will be no control group in this pilot study, as the primary objective is to evaluate the usability and acceptability of the intervention.

Experimental group: This group will be made up of 20 patients who attend cognitive rehabilitation sessions at the CSSC Day Hospital. These patients will participate in 8 cognitive rehabilitation sessions that will incorporate the VR experiences developed for this study.

Intervention

Sessions:
The 8 sessions will be held two days a week, at the time when the included participants have an appointment for the conventional cognitive rehabilitation program at the CSSC Day Hospital.

Equipment and Technology:
We use Oculus Quest 2 glasses and their hand tracking technology, which allows for a more immersive and less complicated experience for participants, especially those with MCI.

Developed Virtual Reality Experiences:

A) Interactive Cognitive Stimulation Exercises (Declarative Memory, Executive Functions):

Developed jointly by the BSA VR and Reality Telling teams, following the researchers' guidelines, three types of sequential interactive exercises have been created:

Step 1- Make a Purchase at the Supermarket:

- Scenario: Virtual supermarket.
- Avatar: An animated avatar greets the participant and provides instructions.
- Objective: Select ingredients to make a potato omelet or gazpacho.
- Interaction: Participants use hand tracking technology to grab products and place them in a virtual cart.
- Feedback: A success or error audio is emitted based on the product selection.

Step 2- Pay for the Purchase:

- Scenario: Checkout area of the virtual supermarket.
- Avatar: An animated avatar greets the participant and provides instructions.
- Objective: Pay the exact amount for the selected products.
- Interaction: Select 3D models of bills and coins to reach the correct sum.
- Feedback: An avatar and audio provide confirmation or correction.

Step 3- Sort the Recipe Steps:

- Scenario: Virtual kitchen.
- Avatar: An animated avatar greets the participant and provides instructions.
- Objective: Sort photos of the recipe steps.
- Interaction: Drag and drop photos into a numbered panel.
- Feedback: Confirmation of the avatar.

Scenario details:

- Step 1: Make a purchase at the supermarket. Upon entering the supermarket, an animated avatar greets the participant and explains that they must select the correct products to make a potato omelet or gazpacho. The products are arranged on a shelf, there are correct products and others incorrect. Participants must select by grabbing the products with their hand and taking them to the shopping cart. When you drop the products into the cart, the program recognizes them as correct or incorrect. If it is a correct product, an event audio plays and the product stays in the cart, if it is an incorrect one, an audio plays explaining that this product is incorrect, and the object automatically returns to the shelf.
- Step 2: Pay for the purchase. In this exercise, the avatar explains that the ATM is not working and requests that they pay for the purchase with the exact value. We have created some 3D models of money and coins that are arranged next to the ATM. The value of money is added up on a screen as you select each of these models. If we go beyond the desired total, an audio plays explaining that we must try again, and the sum returns to zero. When the desired value is reached, it adds a congratulating audio.
- Step 3: Order the steps of the recipe. In a kitchen, an animated avatar explains the exercise. We have before us some photos with the steps of the recipes for a tortilla or a gazpacho, and a box with 6 numbered spaces. The goal is to sort the photos of the steps, placing each of them in the numbered box in the correct order.

B) Cognitive Stimulation with Videos (Attention and Episodic Memory):

- Description of the Videos: 360-degree videos have been recorded in known environments in Badalona to maximize the familiarity and comfort of the participants, who are mostly residents of the area. The videos are of two types: static, where the perspective does not change; and in movement, which simulates a slow walk.

- Real-time tracking technology: An application will be used that will allow the therapist to follow the video in real time on a tablet. This will facilitate the interaction between the therapist and the participant, improving the effectiveness of cognitive stimulation. - Video

Listing:

- Video 1 (6:24) “Plaça de la Vila Badalona”. Static video in front of the Badalona town hall.
- Video 2 (5:00) “Carrer de Mar Badalona”. Motion video walking slowly along the main pedestrian street of Badalona
- Video 3 (3:06) “Pas soterrani cap a la platja”. In motion walking slowly from the end of Calle de Mar to the beach.
- Video 4 (2:00) “Walking along the Passeig Maritim Badalona - Part 1”. In motion walking at the beginning of the Passeig Marítim de Badalona.
- Video 5 (2:00) “Walking along the Passeig Maritim Badalona - Part 2”. In motion walking along the Passeig Marítim.
- Video 6 (3:30) “Walking along the Passeig Maritim Badalona - Part 3”. In motion walking along the Passeig Marítim from Anis del Mono to Pont del Petroli.
- Video 7 (5:00) “You saw the Pont del Petroli Badalona”. Static on a balcony with views of the sea and the Pont del Petroli.
- Video 8 (5:00) "Badalona Coconut Beach". Static on the Passeig Marítim.

- Cognitive Stimulation Procedure with the videos:

- Method: Visual-verbal stimulation in real time carried out by a researcher who accompanies the session.
- Activity: While watching the videos, the researcher accompanying the session asks the participants to pay attention to specific elements, such as if they recognize the place, how many bicycles they have passed, if they have seen a dog, etc.
- Interrogation:

  At the beginning of the session, the type of visualization to be carried out will be entered (*“Next you will watch a video of a square in which you will see different scenes. Stay tuned.”)*.

  While viewing the scenes, you will be asked questions regarding the environment and the elements that appear to encourage attention. *(“Do you recognize the square? Have you ever been? What is it called? What are you seeing? Pay close attention to all the details.”).*

  At the end of each video, open and multiple choice questions will be asked. *(“Have you seen any animals? How many dogs have you seen passing by, 2 or 5?…”)* to evaluate attention and memory regarding the elements shown.
- Objectives: The objective of this intervention is to stimulate and evaluate aspects of cognitive function such as attention (focused, sustained and alternating), memory and visuospatial function (immediate, working, episodic, semantic, spatial orientation, visual memory).
- Participant Feedback: At the end of the session, feedback will be collected from participants to improve future interactions of the exercise.

5.3 Participating population

Source population: The source population of the study will be the patients who attend the cognitive rehabilitation program at the Centro Sociosanitario El Carme (CSSC) in Badalona Serviceis Asistencianals.

Location: El Carme Socio-Health Center (CSSC), Badalona, Spain.

Selection period: Participants will be selected from September to October 2023.

Inclusion criteria:
- Participants must be at least 60 years old, with no maximum age limit.
- Participants must be classified as having mild cognitive impairment with an MMSE score > 23.
- Participants must be currently attending cognitive rehabilitation sessions at the CSSC Day Hospital.
- Participants must be able to give informed consent or, in the event of incapacity, consent must be obtained from their legal representative.

- **Exclusion criteria**

- Patients with a serious or unstable illness that may interfere with their participation in the study.
- Patients with severe psychiatric disorders, such as psychotic disorders, delusions or hallucinations that may be exacerbated by the use of virtual reality.
- Patients with severe visual limitations that would prevent the use of virtual reality.
- The presence of eye diseases that cause blurred vision that cannot be corrected with contact lenses or glasses.
- Presence of hearing pathologies that cause a significant decrease in hearing without hearing aids.
- High sensitivity to motion sickness.
- Epileptic subject.
- Patients who are unable or unwilling to give informed consent.

Withdrawal criteria

Withdrawal criteria will include the appearance of health problems that may interfere with continued participation in the study, or withdrawal of consent by the participant.

Sampling type

The type of sampling will be non-probabilistic sequential. All patients who meet the inclusion criteria and do not meet any of the exclusion criteria will be invited to participate until the desired number of participants is reached.

5.4 Study variables

5.4.1 Variables result, exposure or effect

Main Outcome Variable:

Acceptability and usability of VR exercises: This will be measured using a user satisfaction questionnaire and the System Usability Scale (SUS). HE will managen after the last session (the eighth).

Secondary Outcome Variables:

Cognitive function (memory and attention), measured through standardized tests: - Specific to attention and memory (Digits, TMT [Annex 3], SDMT [Annex 4]).

General cognitive function tests:

- Montreal Cognitive Assessment (MoCA) [anexo 5]
- Mini-Mental State Examination (MMSE) [anexo 6]

The evaluations will be carried out before starting the training program and at the end of it (after the eighth session).

Usability of the system by professionals:

This will be evaluated using the System Usability Scale (SUS) for patients and professionals [Annex 7 and 8]. It will be administered to professionals after completing the training program.

5.4.2 Other variables

- Age
- Sex
- Etiology of cognitive impairment
- Schooling
- Exposure to other treatments: Any additional medication or cognitive therapy that the patient is simultaneously participating in will be recorded.

5.5 Study Evaluations:

Visit	Procedures
Selection visit (Pre-study)	Informed consent, collection of demographic data and results of cognitive function variables
Visit 1 (Session 1)	Starting VR training sessions
Visit 2 (Session 8 - Final)	Completion of the VR training sessions, questionnaires on cognitive function and satisfaction and usability variables.

5.6 Sample size

The sample size for this pilot study has been established at 20 patients. This decision is based on several factors:

Preliminary nature of the study: As this is a pilot study, the primary objective is to evaluate the usability and acceptability of the virtual reality intervention, rather than to demonstrate effectiveness. Pilot studies typically have smaller sample sizes than full studies.

Resources and capacity: The capacity of the El Carme Socio-Health Center in Badalona and the available resources (both in terms of staff and virtual reality equipment) also influence the sample size. Ensuring that each participant can receive appropriate care and support is

critical to accurate data collection and a positive patient experience.

Patient variability: Although the sample size is small, it is expected to reflect the diversity of the patient population in terms of severity of cognitive impairment, gender, age, etc. This diversity may provide a deeper understanding of how different types of patients may interact with virtual reality technology.

5.7 Statistical analysis

The data collected during the study will be analyzed using statistical methods appropriate for each type of variable. All analyses will be performed using statistical software SPSS 27.0.

Acceptability and Usability: Scores obtained on the System Usability Scale (SUS) will be analyzed descriptively to provide an overall measure of the acceptability and usability of the VR intervention.

Cognitive function: Depending on the normality of the variables, statistical tests will be applied to compare scores (parametric Student's T or non-parametric Wilcoxon (in the case of failure to comply with the assumption of normality).

Demographic and clinical variables: Correlation and multiple regression analyzes will be used to examine relationships between demographic and clinical variables (e.g., age, gender, etiology, education) and changes in acceptability, usability, cognitive function, and quality of life. .

The hypotheses will be evaluated at the significance level of $p < 0.05$ (95% confidence level). As this is a pilot study, the results will be used primarily to generate hypotheses for future research and to provide effect size estimates that may be useful for sample size calculation in future studies.

5.8 Limitations

1. Study design and sample size

Limitation: The study is characterized by being a non-randomized pilot, without a control group, and of short duration. Likewise, it is carried out with a sample of 20 participants, which may limit its representativeness.

Mitigation strategy: The preliminary nature of the study and the resources available at the El Carme Socio-Health Center in Badalona influence the decision to have a small sample size. The main objective is to evaluate the usability and acceptability of the VR intervention, rather than to demonstrate its effectiveness. Although the sample size is small, it is expected to reflect the diversity of the patient population, providing a deep understanding of how different types of patients may interact with VR. Furthermore, the results of the pilot study will provide crucial preliminary information for future larger and well-controlled investigations.

2. Outcome measures

Limitation: Measures of acceptability, usability, and cognitive function are largely self-reported, which may introduce bias.

Mitigation strategy: Despite this limitation, the best available tests have been selected, recognizing that no test is perfect and that all have some limitations. In future research, we will seek to incorporate additional objective measures, if possible.

3. Variability in VR exposure and effect of healthcare personnel

Limitation: Individual experience with VR may vary due to factors such as degree of cognitive impairment, familiarity with the technology, and ability to follow instructions. Furthermore, the improvement in cognitive function could be influenced by the interaction with healthcare personnel during VR sessions.

Mitigation strategy: An attempt will be made to standardize the administration of VR as much as possible and variables such as the duration and content of the interaction with healthcare personnel will be controlled.

4. Training of health personnel

Limitation: Healthcare personnel must be familiar with this technology for its effective implementation.

Mitigation strategy: Extensive training and ongoing support will be offered to healthcare personnel. Additionally, it will be built on an existing VR application, designed specifically for the hospital environment.

These limitations have been taken into account during the planning of the study and will be discussed in detail in the presentations and publications resulting from the study. Findings from the pilot study will be used to inform and improve the design of future research in this field.

6. SOURCES OF OBTAINING AND MANAGING DATA

6.1 Data source

Data collection in this pilot study will be carried out through primary sources. Data will be obtained directly from participants:

The acceptability and usability of the VR exercises will be measured through questionnaires that participants will complete after each VR session.

Cognitive function and quality of life will be measured through standardized tests that participants will complete before, during and after the VR training program.

Variables such as age, gender and degree of cognitive impairment will be collected through interviews and medical records.

Exposure to other treatments will be recorded through interviews with participants and review of their medical records.

6.2 Data management and quality control

Data recording will be carried out using standardized spreadsheet templates to ensure

consistency in data collection. The data of each participant will be registered using a unique identification code for each participant to maintain confidentiality.

To ensure data security, data will be stored in a secure folder within the BSA intranet. This folder will have restricted access to the main investigators of the study to maintain the privacy of the data and avoid unauthorized manipulations.

Finally, before analyzing the data, it will be cleaned and reviewed to detect and correct any inconsistencies or errors. This stage will ensure that the results of the statistical analysis are based on accurate and valid data.

7. PROTECTION OF PERSONS UNDER INVESTIGATION

7.1 Benefit-risk evaluation for research subjects

This interventional study uses virtual reality (VR) for cognitive stimulation of patients with cognitive impairment. The following potential risks and benefits to participants have been identified, along with specific mitigation strategies for the identified risks.

Risks and Mitigation Strategies:

1- Side effects of VR: Some patients may experience dizziness or disorientation with VR. To mitigate this risk, static or smooth motion VR experiences will be designed, and the technology will be introduced gradually. Side effects will be carefully monitored, especially in patients with conditions that may increase risk.

2- Patient acceptance: Since VR is a relatively new technology, it can be intimidating for some patients. To overcome this barrier, the potential benefits of VR will be effectively communicated and patient concerns will be proactively managed. Engagement with healthcare personnel during the process can improve patient acceptance and adherence.

3- Technical problems: Like any technology, VR can face technical problems such as hardware or software failures, or Internet connectivity problems. To mitigate this risk, backup equipment will be available and appropriate training will be provided to healthcare personnel to handle VR equipment. Fast and efficient technical support will also be guaranteed to resolve any issues that may arise.

4- Technical problems: Like any technology, VR can face technical problems such as hardware or software failures, or Internet connectivity problems. To mitigate this risk, backup equipment will be available and appropriate training will be provided to healthcare personnel to handle VR equipment. Fast and efficient technical support will also be guaranteed to resolve any issues that may arise.

5- Exclusion of certain patients: Some patients may not be able to participate due to severe cognitive impairment, dizziness, certain visual impairments or other health conditions, which could potentially lead to feelings of exclusion or frustration. To mitigate this risk, communication with patients about the limitations of who can participate in the study will be clear, explaining health and safety reasons. For those patients who are unable to participate, other alternative activities or interventions will be explored.

6- Physical safety: There is a risk of patients tripping or falling while using VR due to spatial disorientation. To mitigate this risk, patients will be seated during VR sessions and will be

closely supervised by healthcare personnel to ensure their safety. Additionally, the area around the patient will be free of obstacles.

7- Withdrawal effect: If the VR tool is withdrawn after the conclusion of the study, the patients who participated may show less interest in continuing with the conventional cognitive stimulation program. To mitigate this risk, if the results of the study are positive and show significant benefits for patients, a commitment will be made to keep this tool in use within the cognitive stimulation program.

Benefits

1- Cognitive stimulation: VR offers an interactive and attractive medium for cognitive stimulation, which can be more motivating and attractive for patients than traditional therapies.

2- Improved emotional well-being: Patients may experience an improvement in their emotional well-being when participating in immersive VR experiences, especially if the sessions are designed to be enjoyable and fun.

3- Contribution to research: Patients will participate in a study that may contribute to improving the understanding and treatment of cognitive impairment.

To ensure the safety and comfort of participants, healthcare personnel will receive extensive training in the use of VR. All necessary precautions will be taken to minimize risks and participants will be closely monitored for any side effects. It is hoped that participation in the study can have a positive impact on the cognition and emotional well-being of the participants, and that it contributes to research in this field.

7.2 Information to subjects and informed consent

The research team is committed to ensuring that all potential participants receive clear, complete and understandable information about the study. This information will include details about the purpose of the research, the procedures that will be carried out, the possible benefits and risks, and the management of the confidentiality of personal information and the results of the study.

To achieve this goal, the following methods will be used:

Informed Consent Document: An Informed Consent document has been developed and will be provided to each potential participant. This document will include detailed information about the study, including the purpose, procedures, possible risks and benefits. The document will also emphasize that participation in the study is completely voluntary, and that the individual has the right to withdraw from the study at any time without repercussions on his or her medical care.

Information Sheet for Participants: Potential participants will be provided with an Information Sheet, which will complement the Informed Consent document, offering a summary of key study information in an easy-to-understand format.

Information Sessions: During meetings with potential participants, they will be given the opportunity to ask questions and discuss any concerns they may have. Before obtaining consent, it will be verified that the participant has fully understood the information provided. To facilitate understanding, all aspects of the study will be explained using simple

and accessible language.

Consent of Legal Representatives: In cases of patients with moderate cognitive impairment who may have difficulties understanding the information provided or giving their consent, informed consent will be requested from their legal representative. The legal representative will be present during the explanation of the information and obtaining consent.

The principle of autonomy of the participants will be respected at all times. No individual will be included in the study without having provided valid informed consent, either directly or through their legal representative. A record of the consent process will be maintained for each participant to ensure transparency and accountability.

7.3 Confidentiality and data protection

This study fully complies with Spanish and European data protection regulations, including Organic Law 3/2018, of December 5, on the Protection of Personal Data and guarantee of digital rights, as well as Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and the free circulation of such data.

Origin of data: Data will be obtained both directly from patients through questionnaires and evaluations, and from their medical records to collect demographic and clinical data.

Consent for data processing: Informed consent will be obtained from all patients for the processing of their data. Additionally, we will keep this data pseudonymized to protect the identity of patients.

External promoter with access to data: There is no external promoter with access to data. Only the principal investigators of the study will have access to the full data.

Collaboration with companies: We work in collaboration with the company Reality Telling, however, the results of the study will only be shared with them after being analyzed and without personal data that allows the participants to be identified. In no case will raw data be shared directly from participants or any personal data that may identify them.

Data storage location and IT tools: Data will be stored securely within the BSA intranet. The computer tools we use to manage and analyze data are secure and have been approved by the Information Systems Department.

Security measures: We have implemented rigorous security measures, including access codes and passwords, to ensure that only members of the research team have access to the data.

International Data Transfers: No international data transfers are planned.

High-risk treatments: High-risk treatments are not foreseen, such as data profiling techniques, automated decision making, artificial intelligence, data exploitation with Big Data technologies, biometrics or geolocation systems. All data will be used exclusively for the purposes of this study and will be handled in accordance with applicable data protection regulations..

8. MANAGEMENT AND COMMUNICATION OF ADVERSE REACTIONS

As this study uses virtual reality in cognitive stimulation for patients with cognitive impairment and does not involve the use of medications, the management and communication of adverse drug reactions is not applicable in this context.

However, any adverse side effects associated with the use of virtual reality technology, such as dizziness, nausea or disorientation, will be carefully recorded and monitored by the research team. Healthcare professionals are trained to handle these incidents and will provide necessary care to study participants should these adverse effects occur.

The research team agrees to inform the collaborating company, Reality Telling, about any incident that occurs during the study, respecting the confidentiality of the participants. In the event of a serious adverse reaction, the research team will take necessary steps to ensure the safety of the participant and determine whether their participation in the study needs to be adjusted or discontinued.

9. DISSEMINATION AND COMMUNICATION PLANS OF RESULTS

Our goal is to share the findings of this study on the use of virtual reality in cognitive decline with the scientific and medical community. Consequently, we intend to try to publish the results of this study in a peer-reviewed scientific journal and, to the extent possible, present them at a relevant conference or conference in the field. While we cannot guarantee acceptance on such platforms, we are committed to transparency and ethics, and we we will strive for making our findings widely accessible.

10. SOURCE OF FINANCING

This study benefits from a grant from the AMB, which is intended for the creation of digital content from Reality Telling, the company in charge of developing the virtual reality program. As recipients of this scholarship, Reality Telling assumes the responsibility of coordinating the procurement of all hardware equipment necessary for the sessions. This includes organizing and securing resources to obtain virtual reality glasses, tablets, bags, modems and SIM cards for Internet connection, if necessary.

In addition, Reality Telling guarantees the necessary training for the efficient use of these technological tools in the context of research. This support eliminates any significant additional costs associated with the development and implementation of the virtual reality program.

BSA professionals, within the framework of their regular responsibilities, will conduct the investigation. While this involves time commitment to study design, data collection and analysis, and preparation of results for publication, these costs are part of BSA's regular operations and do not require additional funding.

Additional costs may be associated with publishing study results. Should these arise, we will seek additional funding through other available scholarships or grants. If such financing is not obtained, these costs will be assumed by BSA. In this way, we ensure that both the financing and the resources necessary to carry out and disseminate the study are duly guaranteed.

11. WORK PLAN FOR CONDUCTING THE STUDY

Phase 1 (July-September 2023): Definition and validation of the beneficiaries, formulation of the study protocol and initial development of the VR exercises.
Milestone 1: Formulation of the study protocol, assessment and approval by the BSA research committees and the GTP CEIC (July-September 2023)
Milestone 2: Start of development of VR exercises (July-August 2023)

Phase 2 (September-November 2023): Completion of the development of the VR exercises, recruitment of patients who will participate in the study and training of the CSSC Day Hospital staff for the implementation of the immersive VR experiences. Preparation for the start of data collection.
Milestone 3: Completion of the development of VR exercises (September-October 2023) Milestone 4: Patient recruitment (September-October 2023)
Milestone 5: Training of Day Hospital staff for the implementation of immersive VR experiences (September-October 2023)
Milestone 6: Preparation for the start of data collection (November 2023)
Milestone 7: Start of data collection: November 2023

Phase 3 (November-December 2023): Implementation of the pilot study with selected patients and data collection. Completion of data collection at the end of this period.
Milestone 8: Start of the pilot study (November 2023)
Milestone 9: Completion of the pilot study and data collection (December 2023)

End of data collection: December 2023 - January 2024
Interim reports of results (if applicable): Not applicable in this study due to its short duration.

Final report: January 2024
Milestone 10: Preparation of the final report (January 2024)
Milestone 11: Presentation of the final report that includes the results of the pilot study, analysis of the data collected, conclusions and recommendations for future research or implementations based on VR experiences (January 2024)

Phase	Milestone	Chronology
Phase 1	Milestone 1: Formulation of the study protocol, assessment and approval by the BSA research committees and the GTP CEIC	July-September 2023
August-September 2023	Milestone 2: Start of development of VR exercises	July-August 2023
Phase 2:	Milestone 3: Completion of VR exercises development	September October 2023

September-November 2023	Milestone 4: Patient recruitment	September October 2023
	Milestone 5: Training of Day Hospital staff for the implementation of immersive VR experiences	September October 2023
	Milestone 6: Preparation for the start of data collection	November 2023
	Milestone 7: Start of data collection	November 2023
Phase 3:	Milestone 8: Start of the pilot study	November 2023
November-December 2023	Milestone 9: Completion of the pilot study and data collection	December 2023- January 2024
Final Report:	Milestone 10: Preparation of the final report	January 2024
January 2024	Milestone 11: Presentation of the final report	January 2024

ANNEX 1. Patient information sheet

PATIENT INFORMATION SHEET AND INFORMED CONSENT TO PARTICIPATE IN A RESEARCH PROJECT

Project Title: Development and evaluation of virtual reality experiences for cognitive stimulation at the El Carme Socio-Health Center in Badalona Servicios Asistenciales (BSA)

PROMOTER	**Badalona Assistance Services (BSA)**
Protocol Code	PI-23-195

PRINCIPAL INVESTIGATOR	Jose Ferrer Costa	
CONTACT PHONE	+34 937407482	

CENTER	Badalona Assistance Services				
SERVICE	Innovation and Projects				
CENTER ADDRESS	C/ Via Augusta, 9-13				
POPULATION	Badalona	**CP**	08911	**PROVINCE**	Barcelona

We are writing to you to inform you about a research study that is being carried out at Badalona Serveis Assistencials (BSA) in which we invite you to participate. This project focuses on evaluating the potential of virtual reality (VR) experiences as a cognitive stimulation tool for people with mild or moderate cognitive impairment. This study is approved by the Research Ethics Committee. Our intention is that you receive correct and sufficient information to accept or not participate in this study. Therefore, read this document carefully and we will clarify any doubts that may arise.

Voluntary participation

You should know that your participation in this study is voluntary and that you may decide NOT to participate. If you decide to participate, you can change your decision and withdraw consent at any time, without altering your relationship with your doctor or causing any harm to your medical care.

Objective of the Study

Main Objective:

We want to know if the cognitive stimulation program with Virtual Reality is well accepted by patients with mild or moderate cognitive impairment.

Specific Objectives:

Is it Useful and Motivating?

We are interested in knowing if the VR activities are useful to you and if they motivate you to continue participating in the program.
Does it improve your Cognition?
We will measure how certain mental skills, such as attention and memory, change before and after using the VR program.

Professional Opinion:
We want to understand what healthcare professionals think about using VR in their daily work with patients like you.

How can we improve?

Your opinion and that of the medical staff will help us improve the program for future patients.

Basis for Future Studies:
The data we collect could help develop better VR programs in the future.

Study Description
Various research has shown that VR can be effective in improving cognitive abilities. This study seeks to investigate how personalization of VR experiences can increase the effectiveness of these interventions.
This intervention program offers 8 cognitive rehabilitation sessions through Virtual Reality, which will take place twice a week in accordance with your regular appointments at the CSSC Day Hospital. For the intervention, the Oculus Quest 2 glasses will be used, providing a more immersive experience.

Study activities. What does your participation entail?:
The study activities are divided into interactive exercises and immersive videos using virtual reality glasses.
Below we describe the exercises that will be carried out:

Interactive exercises in virtual reality:
Step 1: Make a Supermarket Purchase: You will select ingredients to make a recipe in a virtual supermarket. An animated avatar will guide you.
Step 2: Pay for the Purchase: You will have to pay the exact amount for the products selected in the virtual checkout.
Step 3: Sort the Recipe Steps: You will need to sort photos of the recipe steps in a virtual kitchen.
Note: During these exercises, you will always be accompanied by a therapist to ensure your safety and guide you through the activities.

Cognitive Stimulation with Immersive Videos:
360-degree videos have been recorded in familiar environments in Badalona to maximize the familiarity and comfort of the participants. The videos are of two types: static, where the perspective does not change; and in movement, which simulates a slow walk.

A therapist will interact with you in real time through an application to guide attention and memory exercise.

Participation in this study will not entail any change in your treatment or the rest of your medical treatment.
Your participation will involve recording it in your medical history and recording scales and questionnaires that you must complete with one of the study professionals to assess the results.

Risks and Preventive Measures
Although the risks associated with VR use are generally low, some patients may experience dizziness or disorientation. However, we have implemented measures to minimize these risks, including designing VR experiences with smooth movements and gradually introducing the technology.

Possible Benefits
It is essential that you understand that your participation in this study does not guarantee direct benefits to your health. Our primary purpose is to investigate and gain a greater understanding of the potential of virtual reality experiences in cognitive stimulation for people with mild to moderate cognitive impairment.

However, participating in this study has some additional advantages that could be considered indirect benefits:

- Learning New Technologies: You will have the opportunity to become familiar with the innovative technology of Virtual Reality, a tool that is increasingly being used in the field of healthcare.
- Cognitive Stimulation: Although we cannot guarantee specific results, it is expected that the use of VR can enhance the effects of cognitive rehabilitation, improving areas such as memory and attention.
- Rewarding Experience: VR sessions are gamified, that is, they have a game format, which could result in a personally rewarding experience and a time of distraction and entertainment.

Finally, it is important to note that although we are evaluating new interventions, we cannot anticipate the specific medical benefits of these. However, the data we collect could be very useful to improve the care of future patients with similar conditions.

Expenses and Economic Compensation
Your participation in this study will not involve any additional costs for you. You will not receive any financial compensation for participating in the study.

Who finances the study?
This study has external funding received by a scholarship. However, we want to assure you that this does not affect the integrity or objectives of the study.

Confidentiality and Data Protection
In accordance with articles 6.1.a and 9.2.a of Regulation (EU) 2016/679 of the European Parliament and of the Council, of April 27, 2016, regarding the protection of

natural persons with regard to the processing of personal data and the free circulation of this data (GDPR), we need your consent to use your health data within the framework of this research project. The data will be kept in accordance with applicable legislation and as long as it is necessary for the development of this project.

The processing of your data will be carried out in compliance with the RGPD and Organic Law 3/2018, on Data Protection and Guarantee of Digital Rights (LOPD-GDD). Therefore, you have the right to exercise your rights of access, rectification, deletion, opposition, limitation of processing and data portability, in front of the Catalan Institute of Health, with NIF Q-5855029-Y and address in Gran Via de les Corts Catalanes 587, Barcelona, through the main researcher of the project. You can contact the BSA Data Protection Officer via dpd@bsa.cat.

We inform you that you have the right to withdraw your consent for the processing of this data at any time, by communicating this to the principal investigator. You also have the right to file a claim with the Catalan Data Protection Authority if you consider that your rights have been violated.

No communications of data to third parties are foreseen, beyond those legally established, nor are international data transfers foreseen.

We will collect data before and after the sessions to evaluate the effectiveness of the VR experiences. This data will include measures of your cognitive performance, as well as your impressions and experiences with VR. All data collected will be treated with the utmost confidentiality and will only be used for scientific purposes, to validate our hypotheses and improve this potential therapeutic tool.

Informed Consent
Before participating, you will need to sign an Informed Consent document that explains the study in detail.

Contact in case of doubts
If you have any questions or require more information, please do not hesitate to contact our research team.
Research Team: jfcosta@bsa.cat, +34 937407482
BSA Data Protection Officer: dpd@bsa.cat, Tel. 93 253 18 20

We appreciate your consideration and look forward to your participation in this important study.

Sincerely,
The BSA research team.

Additional documentation: A copy of this document and the signed Informed Consent will be provided for your reference.

ANNEX 2.1. Informed consent form for the patient

Informed Consent (IC) Sheet

Project Title: Development and evaluation of virtual reality experiences for cognitive stimulation at the El Carme Socio-Health Center in Badalona Servicios Asistenciales (BSA)

PROMOTER	**Badalona Assistance Services (BSA)**
Protocol Code	PI-23-195

PRINCIPAL INVESTIGATOR	Jose Ferrer Costa	
CONTACT PHONE	+34 937407482	

CENTER	Badalona Assistance Services				
SERVICE	Innovation and Projects				
CENTER ADDRESS	C/ Via Augusta, 9-13				
POPULATION	Badalona	**CP**	08911	**PROVINCE**	Barcelona

(Name and surname)

I have read the information sheet that has been given to me.

I have been able to ask about the study.

I have received sufficient information about the study.

I have spoken with: ,.

I understand that my participation is voluntary.

I understand that I can withdraw from the study:

1st whenever

2nd without having to give explanations

3rd without this affecting my medical care.

I freely give my consent to participate in the study.

Patient signature Investigator's signature

Date: Date:

ANNEX 2.2. Informed consent sheet for the family member or legal representative

Informed Consent (IC) Sheet

Project Title: Development and evaluation of virtual reality experiences for cognitive stimulation at the El Carme Socio-Health Center in Badalona Servicios Asistenciales BSA)

PROMOTER	**Badalona Assistance Services (BSA)**
Protocol Code	PI-23-195

PRINCIPAL INVESTIGATOR	Jose Ferrer Costa	
CONTACT PHONE	+34 937407482	

CENTER	Badalona Assistance Services				
SERVICE	Innovation and Projects				
CENTER ADDRESS	C/ Via Augusta, 9-13				
POPULATION	Badalona	**CP**	08911	**PROVINCE**	Barcelona

(Name and surname of the representative)

I declare under my responsibility that:

(Name and surname of the patient)

I have read the information sheet that has been given to me.

I have been able to ask about the study.

I have received sufficient information about the study.

I have spoken with: ,.

I understand that your participation is voluntary.

I understand that you can withdraw from the study:

1st whenever

2nd without having to give explanations

3º without this affecting your medical care.

I freely give my consent to participate in the study.

Signature of representative Investigator's signature

Date:	Date:

Trail Making Test (TMT) Parts A & B

Instructions:

Both parts of the Trail Making Test consist of 25 circles distributed over a sheet of paper. In Part A, the circles are numbered 1 – 25, and the patient should draw lines to connect the numbers in ascending order. In Part B, the circles include both numbers (1 – 13) and letters (A – L); as in Part A, the patient draws lines to connect the circles in an ascending pattern, but with the added task of alternating between the numbers and letters (i.e., 1-A-2-B-3-C, etc.). The patient should be instructed to connect the circles as quickly as possible, without lifting the pen or pencil from the paper. Time the patient as he or she connects the "trail." If the patient makes an error, point it out immediately and allow the patient to correct it. Errors affect the patient's score only in that the correction of errors is included in the completion time for the task. It is unnecessary to continue the test if the patient has not completed both parts after five minutes have elapsed.

Step 1: Give the patient a copy of the Trail Making Test Part A worksheet and a pen or pencil.

Step 2: Demonstrate the test to the patient using the sample sheet (Trail Making Part A – *SAMPLE*).

Step 3: Time the patient as he or she follows the “trail” made by the numbers on the test. Step 4: Record the time.

Step 5: Repeat the procedure for Trail Making Test Part B.

Scoring:

Results for both TMT A and B are reported as the number of seconds required to complete the task; therefore, higher scores reveal greater impairment.

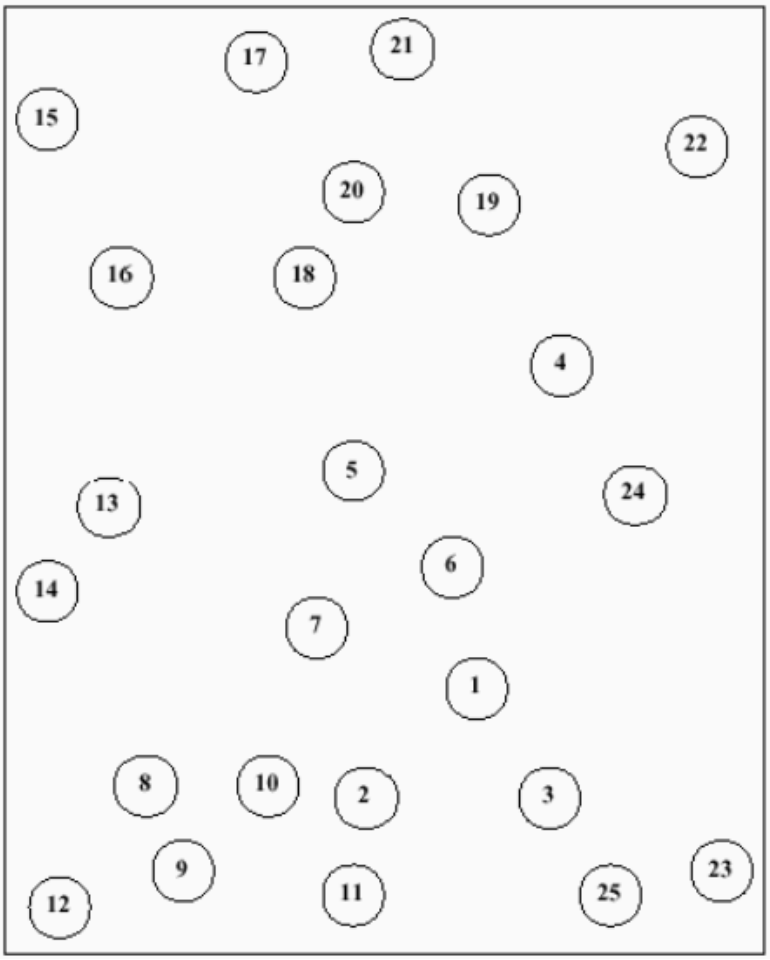
Average Deficient Rule of Thumb Trail A 29 seconds > 78 seconds Most in 90 seconds **Trail B**

75 seconds > 273 seconds Most in 3 minutes

Sources:

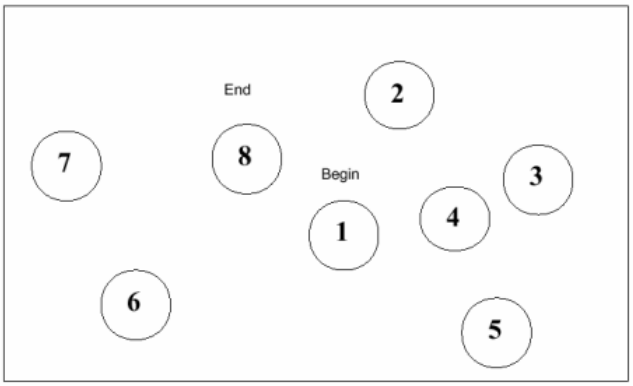
- Corrigan JD, Hinkeldey MS. Relationships between parts A and B of the Trail Making Test. *J Clin Psychol*. 1987;43(4):402–409.
- Gaudino EA, Geisler MW, Squires NK. Construct validity in the Trail Making Test: what makes Part B harder? *J Clin Exp Neuropsychol*. 1995;17(4):529-535.
- Lezak MD, Howieson DB, Loring DW. *Neuropsychological Assessment*. 4th ed. New York: Oxford University Press; 2004.
- Reitan RM. Validity of the Trail Making test as an indicator of organic brain damage. *Percept Mot Skills*. 1958;8:271-276.

Trail Making Test Part A



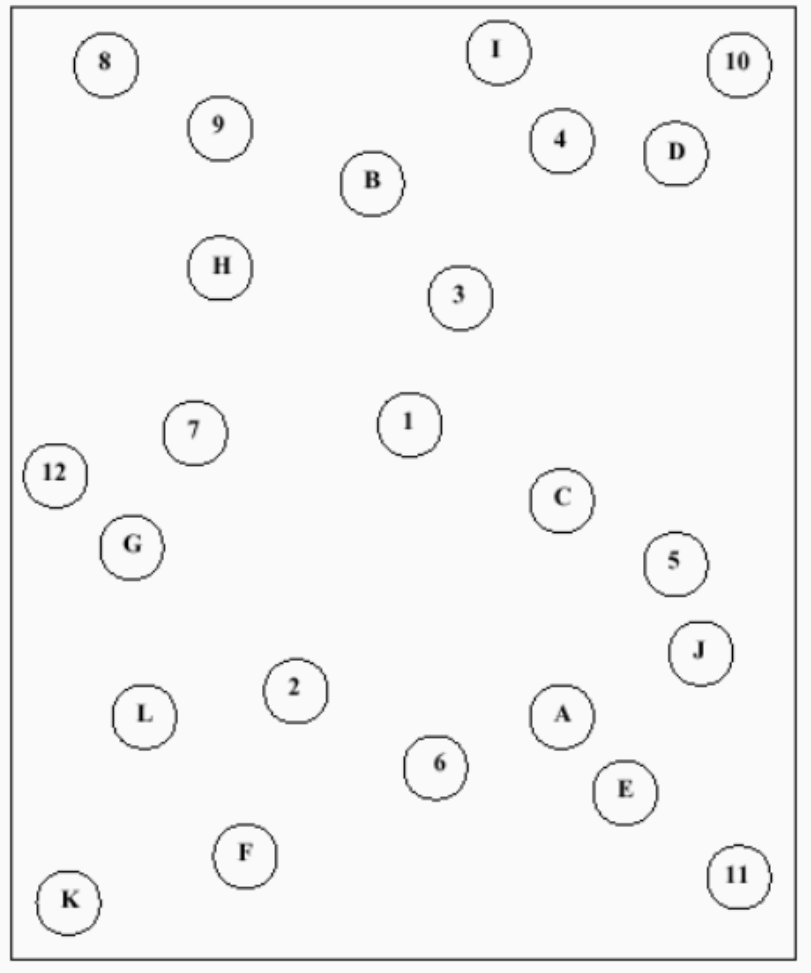
Patient's Name: Date:

Trail Making Test Part A – *SAMPLE*

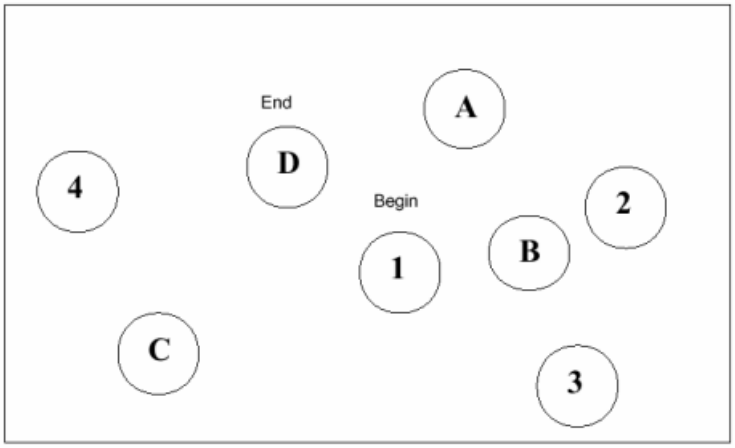


Trail Making Test Part B

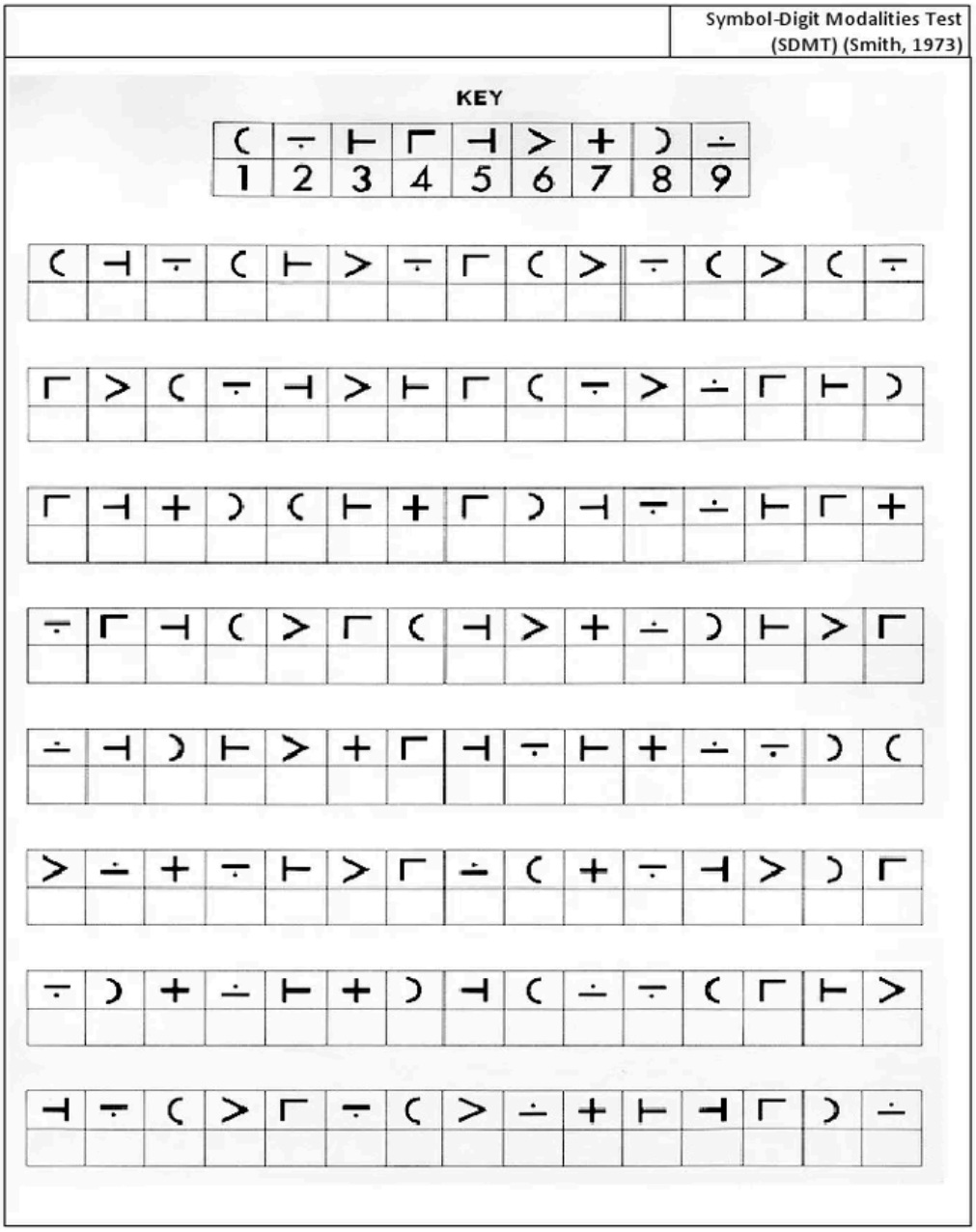
Patient's Name: Date:



Trail Making Test Part B – *SAMPLE*



ANNEX 4. Attention and memory test: SDMT

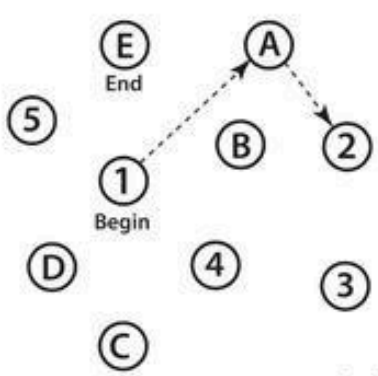


ANEXO 5. Montreal Cognitive Assessment (MoCA)

MONTREAL COGNITIVE ASSESSMENT (MOCA®)
Version 8.1 English

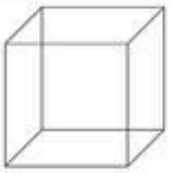
Name:
Education: Date of birth:
Sex: DATE:

VISUOSPATIAL/EXECUTIVE — POINTS



[ ]

Copy cube



[ ]

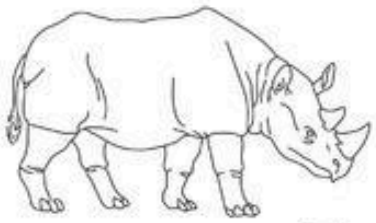
Draw CLOCK (Ten past eleven)
(3 points)

[ ] Contour [ ] Numbers [ ] Hands

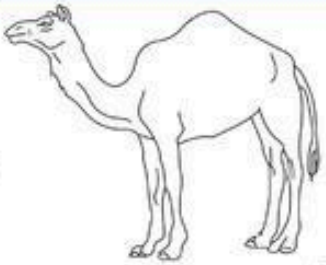
__/5

NAMING

[ ]



[ ]



[ ]

__/3

MEMORY Read list of words, subject must repeat them. Do 2 trials, even if 1st trial is successful. Do a recall after 5 minutes.

	FACE	VELVET	CHURCH	DAISY	RED
1ST TRIAL					
2ND TRIAL					

NO POINTS

ATTENTION Read list of digits (1 digit/ sec.). Subject has to repeat them in the forward order. [ ] 2 1 8 5 4
Subject has to repeat them in the backward order. [ ] 7 4 2 __/2

Read list of letters. The subject must tap with his hand at each letter A. No points if ≥ 2 errors
[ ] F B A C M N A A J K L B A F A K D E A A A J A M O F A A B __/1

Serial 7 subtraction starting at 100. [ ] 93 [ ] 86 [ ] 79 [ ] 72 [ ] 65
4 or 5 correct subtractions: **3 pts**, 2 or 3 correct: **2 pts**, 1 correct: **1 pt**, 0 correct: **0 pt** __/3

LANGUAGE Repeat: I only know that John is the one to help today. [ ]
The cat always hid under the couch when dogs were in the room. [ ] __/2

Fluency / Name maximum number of words in one minute that begin with the letter F. [ ] _____ (N ≥ 11 words) __/1

ABSTRACTION Similarity between e.g. banana - orange = fruit [ ] train - bicycle [ ] watch - ruler __/2

DELAYED RECALL

	(MIS)	Has to recall words WITH NO CUE	FACE	VELVET	CHURCH	DAISY	RED	Points for UNCUED recall only
Memory Index Score (MIS)	X3		[ ]	[ ]	[ ]	[ ]	[ ]	
	X2	Category cue						MIS = ____ /15
	X1	Multiple choice cue						

__/5

ORIENTATION [ ] Date [ ] Month [ ] Year [ ] Day [ ] Place [ ] City __/6

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Administered by: _____

Training and Certification are required to ensure accuracy

MIS: /15
(Normal ≥ 26/30)
Add 1 point if ≤ 12 yr edu

TOTAL __/30

ANEXO 6. Mini-Mental State Examination (MMSE)

Mini-Mental State Examination (MMSE)

Patient's code: Date:

***Instructions:* Ask the questions in the order listed. Score one point for each correct response within each question or activity.**

Maximum Score	Patient's Score	Questions
5		"What is the year? Season? Date? Day of the week? Month?"
5		"Where are we now: State? County? Town/city? Hospital? Floor?"
3		The examiner names three unrelated objects clearly and slowly, then asks the patient to name all three of them. The patient's response is used for scoring. The examiner repeats them until patient learns all of them, if possible. Number of trials: _____
5		"I would like you to count backward from 100 by sevens." (93, 86, 79, 72, 65, …) Stop after five answers. Alternative: "Spell WORLD backwards." (D-L-R-O-W)
3		"Earlier I told you the names of three things. Can you tell me what those were?"
2		Show the patient two simple objects, such as a wristwatch and a pencil, and ask the patient to name them.
1		"Repeat the phrase: 'No ifs, ands, or buts.'"
3		"Take the paper in your right hand, fold it in half, and put it on the floor." (The examiner gives the patient a piece of blank paper.)
1		"Please read this and do what it says." (Written instruction is "Close your eyes.")
1		"Make up and write a sentence about anything." (This sentence must contain a noun and a verb.)
1		"Please copy this picture." (The examiner gives the patient a blank piece of paper and asks him/her to draw the symbol below. All 10 angles must be present and two must intersect.)
30		TOTAL

(Adapted from Rovner & Folstein, 1987)

Source: www.medicine.uiowa.edu/igec/tools/cognitive/MMSE.pdf Provided by NHCQF, 0106-410

Instructions for administration and scoring of the MMSE

Orientation (10 points):

- Ask for the date. Then specifically ask for parts omitted (e.g., "Can you also tell me what season it is?"). One point for each correct answer.
- Ask in turn, "Can you tell me the name of this hospital (town, county, etc.)?" One point for each correct answer.

Registration (3 points):

- Say the names of three unrelated objects clearly and slowly, allowing approximately one second for each. After you have said all three, ask the patient to repeat them. The number of objects the patient names correctly upon the first repetition determines the score (0-3). If the patient does not repeat all three objects the first time, continue saying the names until the patient is able to repeat all three items, up to six trials. Record the number of trials it takes for the patient to learn the words. If the patient does not eventually learn all three, recall cannot be meaningfully tested.
- After completing this task, tell the patient, "Try to remember the words, as I will ask for them in a little while."

Attention and Calculation (5 points):

- Ask the patient to begin with 100 and count backward by sevens. Stop after five subtractions (93, 86, 79, 72, 65). Score the total number of correct answers.
- If the patient cannot or will not perform the subtraction task, ask the patient to spell the word "world" backwards. The score is the number of letters in correct order (e.g., dlrow=5, dlorw=3).

Recall (3 points):

- Ask the patient if he or she can recall the three words you previously asked him or her to remember. Score the total number of correct answers (0-3).

Language and Praxis (9 points):

- Naming: Show the patient a wrist watch and ask the patient what it is. Repeat with a pencil. Score one point for each correct naming (0-2).
- Repetition: Ask the patient to repeat the sentence after you ("No ifs, ands, or buts."). Allow only one trial. Score 0 or 1.
- 3-Stage Command: Give the patient a piece of blank paper and say, "Take this paper in your right hand, fold it in half, and put it on the floor." Score one point for each part of the command correctly executed.
- Reading: On a blank piece of paper print the sentence, "Close your eyes," in letters large enough for the patient to see clearly. Ask the patient to read the sentence and do what it says. Score one point only if the patient actually closes his or her eyes. This is not a test of memory, so you may prompt the patient to "do what it says" after the patient reads the sentence.

- Writing: Give the patient a blank piece of paper and ask him or her to write a sentence for you. Do not dictate a sentence; it should be written spontaneously. The sentence must contain a subject and a verb and make sense. Correct grammar and punctuation are not necessary.
- Copying: Show the patient the picture of two intersecting pentagons and ask the patient to copy the figure exactly as it is. All ten angles must be present and two must intersect to score one point. Ignore tremor and rotation.

(Folstein, Folstein & McHugh, 1975)

Interpretation of the MMSE

Method	Score	Interpretation
Single Cutoff	<24	Abnormal
Range	<21 >25	Increased odds of dementia Decreased odds of dementia
Education	21 <23 <24	Abnormal for 8th grade education Abnormal for high school education Abnormal for college education
Severity	24-30 18-23 0-17	No cognitive impairment Mild cognitive impairment Severe cognitive impairment

Sources:

- Crum RM, Anthony JC, Bassett SS, Folstein MF. Population-based norms for the mini-mental state examination by age and educational level. *JAMA*. 1993;269(18):2386-2391.
- Folstein MF, Folstein SE, McHugh PR. "Mini-mental state": a practical method for grading the cognitive state of patients for the clinician. *J Psychiatr Res*. 1975;12:189-198.
- Rovner BW, Folstein MF. Mini-mental state exam in clinical practice. *Hosp Pract*. 1987;22(1A):99, 103, 106, 110.
- Tombaugh TN, McIntyre NJ. The mini-mental state examination: a comprehensive review. *J Am Geriatr Soc*. 1992;40(9):922-935.

Source: www.medicine.uiowa.edu/igec/tools/cognitive/MMSE.pdf Provided by NHCQF, 0106-410

ANNEX 7. System Usability Scale (SUS) for patients

System Usability Scale (SUS) for patients					
Simulation assessment - System usability scale	**Strongly disagree**	**little disagree**	**Neutral**	**little agree**	**I quite agree**
1 I think I would like to use this program frequently					
2 I think the program is too complex					
3 I think that exercises with glasses are more entertaining than in a conventional way					
4 I think the simulation options are clear and well integrated 5 I think some options are difficult to follow 6 I think people will be able to learn how to use this system easily 7 I felt comfortable using this system					
8 I had to learn many things before I could use the system					
VR headset rating - Quest 2	**Strongly disagree**	**little disagree**	**Neutral**	**little agree**	**I quite agree**
1 The glasses were very heavy and uncomfortable					
2 The use of glasses and controls has been very complicated					
3 I have felt tiredness in my arms and fingers					
4 I have felt visual discomfort					
5 I have felt dizzy					
6 I have felt a headache					
7 I had to stop the simulation due to the aforementioned discomfort					
8 I think it would be comfortable to wear these glasses for a long time					

COMMENTS:

ANNEX 8. System Usability Scale (SUS) for professionals

System Usability Scale (SUS) for professionals					
Simulation assessment - System usability scale	**Strongly disagree**	**little disagree**	**Neutral**	**little agree**	**I quite agree**
1 I believe this program will help improve the quality of patient care.					
2 I think the program interface is intuitive for the user.					
3 I believe that the program can be easily integrated into daily care practice.					
4 I believe that the functions and features of simulation are clear and relevant to patient care. 5 Some of the functionality of this system may be difficult for patients to understand or use. 6 I believe that patients will be able to learn to use this system easily. 7 I have felt comfortable using this system for patient care. 8 I have needed additional time to learn how to use this system correctly. **VR headset rating - Quest 2**	**Strongly disagree**	**little disagree**	**Neutral**	**little agree**	**I quite agree**
1 I think the weight and design of the glasses couldbe uncomfortable for patients.					
2 I think that the use of glasses and controls could be complicated for some patients.					
3 I think patients would be able to wear these glasses for an extended period of time without discomfort.					

COMMENTS: