

Official Title of the Study: **Clinical Validation of a Cognitive Stimulation Platform for Individuals With Dementia – Musiquence**

Unique Protocol ID: **9/CEUMA/2021**

Document Date: **27/05/2021**



DELIBERATION No. 9/CEUMa/2021, of 18 MARCH

Deliberation on the request for ethical approval of the research project: "*Validação clínica de uma plataforma de estimulação cognitiva para pessoas com demência – o Musiquence*" submitted to the Ethics Committee of the University of Madeira (*Comissão de Ética da Universidade da Madeira* (CEUMa)).

A – REPORT

The request for ethical approval of document no. 9 of 2021 refers to the study "*Validação clínica de uma plataforma de estimulação cognitiva para pessoas com demência – o Musiquence*", to be developed within a partnership between UMa and M-ITI (Madeira Interactive Technologies Institute). This project was submitted by **Sergi Bermúdez i Badia**, Principal Investigator, Associate Professor of the Faculty of Exact Sciences and Engineering of the University of Madeira and Integrated Researcher at NOVA LINCS, in collaboration with **Luís Duarte Andrade Ferreira**, PhD student of the Faculty of Sciences and Technology of the Universidade Nova de Lisboa and NOVA LINCS. The research team also comprises **Sofia Cavaco**, from the Faculty of Sciences and Technologies of the Universidade Nova de Lisboa, and **Mónica Paula Gouveia Spínola**, from M-ITI and NOVA LINCS.

The request under review consists of the documents sent to the President of the Ethics Committee by email on 15 February 2021, which are part of the debriefing form, namely a) Submission form for ethical approval; b) Information to participants and informed consent; c) Neuropsychological evaluation protocol; d) Approval issued by the Data Protection Committee of the University of Madeira; e) Authorisation from the three external institutions involved (*Casa de Saúde Câmara Pestana, Centro de Dia Lugar de Memórias and Centro Social e Paroquial de São Bento*) and f) Curriculum Vitae of the four participants named above.

The document a) Submission form for ethical approval explicitly contains information related to identification of the project or study (title, scope, expected start and end dates, study and information collection locations; research team, type of study, a summary description of the protocol (research theoretical basis and scientific justification, objectives and purposes of the study, methodology and data collection tools); participants (inclusion and exclusion criteria and sample size); recruitment and screening criteria; risks and benefits; report of results to participants; dissemination; informed consent and statement of responsibility.

This study aims at the clinical validation of *Musiquence* - a platform that makes use of music and reminiscence for the cognitive stimulation of people with dementia. Sociodemographic data will be collected from all participants (age, education, diagnosis and profession) to characterise the sample. Cognitive, emotional, functional and quality of life data will also be collected through neuropsychological assessments, as well as, performance data from participants (response time, number of errors, distance from the target stimulus), from the cognitive stimulation platform, to assess the impact of the applied cognitive stimulation programme.

B – CONCLUSION

The CEUMa deliberated to approve the study, taking into account the assumptions indicated by the Principal Investigator.

This approval is subject to rectification in b) Information to participants and informed consent, which shall include, when applicable, the signature of the legal representative of the participant.



Accordingly, in paragraph b) of item 6 of the Submission form for ethical approval the field "Participants unable to give informed consent" should be ticked.

Approved unanimously at a meeting held on March 18th, 2021.

João da Piedade Alvares Ferreira
The President of CEUMa

Study Protocol

Dementia is a clinical syndrome characterized by a progressive and irreversible deterioration of cognitive functioning that impairs behavioral and functional domains. Within non-pharmacological approaches, Cognitive Stimulation Therapy (CST) is the most studied and well-established intervention for individuals with mild to moderate dementia. The underlying assumptions behind cognitive-based interventions of CST are:

1. IwD can benefit from cognitive stimulation if mobilized relatively preserved cognitive functions (e.g., crystallized abilities such as semantic memory and verbal skills);
2. Even in advanced age, exposure to enriched environments (i.e., socially, and cognitively challenging) can enhance cognitive reserve and neuroplasticity.

Concerning the first assumption of cognitive-based interventions (a1), it is known that even in moderate to advanced stages of dementia, musical memory is one of the abilities that remain intact. It is hypothesized that music processing abilities precede the development of lexical language functions. This hypothesis is corroborated by findings that demonstrate that IwD are still responsive to music even when unable to communicate verbally or recognize words. Additionally, music is frequently associated with life experiences. Also, literature has reported that memories associated with specific music would be recollected longer than memories with no association to music; this suggests that using music as a reminiscence element on cognitive stimulation programs can have a promising effect on cognition. According to the second assumption of CST (a2), facilitating an enriching environment for IwD using, for, music and reminiscence elements could impact cognitive reserve and neuroplasticity.

In this context, Ferreira et al. developed a platform – Musiquence - that incorporates music and reminiscence in cognitive stimulation activities for IwD. Musiquence allows the gamification and personalization of 6 types of activities:

- Reality Orientation – a quiz-like activity that includes date and time information.
- Creative Drawings – a puzzle-like game in which the participant draws the missing pieces.
- Activities of Daily Living (ADL) – a puzzle-like game in which the participants have to perform a set of chores (i.e., brush the teeth), and the missing pieces are completed with real physical objects (i.e., toothpaste).
- Search Objects activity – exploration game in which the participants must find hidden images (e.g., cats) that are only visible through a virtual magnifying glass.
- Knowledge Quiz – participants must select the correct answer to a question among incorrect ones.
- Association activity – participants must categorize the items according to the instructions. For example, separate cars from motorcycles and locate them in the correct container.

The platform is compatible with different technologies that allow adaptation to the patients' needs (motor difficulties, vision problems, tremble). Cognitive stimulation content can be personalized to the user since the caregivers can add text, images, and music when creating the tasks.

The present study aims to clinically validate the Musiquence platform – a platform that allows the incorporation of music and reminiscence in cognitive stimulation activities for individuals with dementia.

Inclusion Criteria:

- Mild to moderate stage of dementia (with formal diagnosis);
- Ability to move upper limbs;
- Maintained auditory acuity;
- Relatively preserved language skills.

Exclusion Criteria:

- Moderate to severe depressive symptomatology;
- Moderate to severe anxious symptomatology;
- Bedridden.

Procedure

Individuals with dementia who meet the previous criteria will perform a 14-session cognitive stimulation program, using Musiquence. The program will be implemented in an augmented reality format.

To this end, sociodemographic data will be collected from all participants (age, education, diagnosis, profession) for sample characterization purposes. Data on the cognitive, emotional, functional, and quality of life of the participants will also be collected, through neuropsychological assessments, the participants performance in the cognitive stimulation platform used (response time, number of errors, distance from the target stimulus).

Neuropsychological Assessment

The neuropsychological assessment protocol will be performed in three different timings:

- Pre-intervention: baseline assessment, immediately before the intervention.
- Post-intervention: immediately after the intervention.
- Follow-up: 3 months after the intervention.

The neuropsychological assessment protocol consists of a set of scales commonly used with the Portuguese population and aims to assess different domains:

1. Cognition

- Mini-mental state examination (MMSE; Folstein et al., 1975)
- Alzheimer's Disease Assessment Scale – Cognitive Scale (Adas-Cog; Rosen et al., 1984)

- Kettler Laurent Thierrau (KLT) (Kettler et al., 1964)
- Symbol Search and Digital Symbol Coding from Weschler Adult Intelligence Scale – Third Edition (WAIS-III; Weschler, 1997; 2008)
- Semantic and Phonemic Verbal Fluencia (SVF and PVF; Cavaco et al., 2013)

2. Humor/Emotion

- Cornell Scale for Depression in Dementia (Alexpulos et al., 1988)
- Rating Anxiety in Dementia (RAID; Shankar et al., 1999)

3. Functionality

- Adults and Older Adults Functional Assessment Inventory (IAFAI; Sousa et al., 2013)

4. Quality of Life

- Quality of Life – Alzheimer’s Disease (QoL-AD, Logsdon et al., 1999)