Official title: Efficacy of kinect-based versus tablet-based cognitive training through simulations of instrumental activities of daily living: a pilot study with psychiatric patients

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DELIBERATION CE/CSCP No. 1/2021, of JANUARY 19th

Deliberation on the request for ethical approval of the research project entitled "Efficacy of kinect-based versus tablet based cognitive training through simulations of instrumental activities of daily living: a pilot study with chronic psychiatric patients" submitted to the Ethics Committee of Casa de Saúde Câmara Pestana (CSCP).

A – REPORT

A.1 The CSCP's Ethics Committee and the Clinical Board, responsible for coordinating clinical investigation processes in CSCP, analyzed the request for ethical approval of a study submitted by Joana Câmara. She is currently performing a professional internship in psychology and proposed a research project entitled "Efficacy of kinect-based versus tablet-based cognitive training through simulations of instrumental activities of daily living: a pilot study with chronic psychiatric patients." For this purpose, the models 187, 189, and 218 were carefully analyzed. The study's main goal is to contribute to the stimulation and maintenance of cognitive functioning through a combined intervention (cognitive training + physical activity/kinect-based intervention) or an individual intervention (cognitive training/tablet-based intervention).

A.2 To formalize our decision, we analyzed the following documents that were submitted by the researcher, Joana Câmara: a) study protocol, b) response to the request to conduct the study, c) statement of commitment, d) research project, and e) informed consent.

A.3 This study consists of a randomized controlled longitudinal trial that aims to: a) identify which type of intervention is more suited to patients with chronic psychiatric disorders, i.e., the combined intervention or the individual intervention; and b) to evaluate the impact of both interventions in the long-term (3 months follow-up) in several domains (e.g., cognitive functioning, quality of life, mood, and functional capacity).

This project aims to incorporate cognitive training and physical activity, representing two evidence-based interventions within the context of neurological and psychiatric disorders. The cognitive training interventions will be implemented through the Musiquence platform. In the present study, the researcher will use an updated version of the Musiquence platform to create different cognitive training tasks and interact with the training tasks through motion using a Kinect system. In addition, all cognitive training tasks will be inspired by activities of daily living to improve the ecological validity of the training.

B-IDENTIFICATION OF QUESTIONS WITH POSSIBLE ETHICAL IMPLICATIONS

B.1 All ethical principles related to the patients' privacy will be respected.

B.2 We acknowledge the practical interest of the expected results, and the methodology employed will be accordingly to patients' rights.

C-IDENTIFICATION OF QUESTIONS WITH POSSIBLE SCIENTIFIC IMPLICATIONS

C.1 All the basic principles of good clinical research (e.g., clarity of research goals, scientific hypothesis, interest, innovation, methodology, and study design) will be guaranteed.

C.2 We acknowledge the proposed study's scientific validity and practical interest, whose quality and rigor must be ensured during the investigation process.

D-CONCLUSION

After deliberation, all the conditions necessary to carry out the study were verified, namely the ethical principles related to the participant's privacy. The basic principles of clinical research are also respected in the clear presentation of the underlying objectives and hypothesis, interest, innovation, methodology, and design used in the study.

The CSCP's clinical board decided to approve the study in the CE/CSCP meeting that took place on January 19th of 2021 since it respects all the basic principles of good clinical practices in research.

Study approved unanimously at a meeting held on January 19th, 2021

President of the Ethics Committee/CSCP

Dr. Paulo Pita e Silva

Clinical board/CSCP

Dr. Luís Filipe Fernandes e Enf.ª Cristina Abreu

Study protocol

Background

Cognitive deficits are a nuclear feature of several psychiatric disorders, leading to decreased functional abilities and quality of life. Besides facilitating the inclusion of more ecologically valid stimuli and training tasks, technology-based cognitive training methods allow more dynamic interactions with the cognitive training content, which can enhance patients' motivation and engagement in the therapeutic process. The modality of interaction with the cognitive training content may influence patients' response to cognitive training interventions. For instance, cognitive training through the tablet essentially requires hand movements (e.g., interaction with the training tasks by touching the correct stimuli). In contrast, cognitive training through the Kinect – a more natural user interface – involves performing broad range movements (e.g., interaction with the training tasks by making specific "body" movements to select the correct stimuli). Literature shows that natural user interfaces provide a training experience closer to reality. As a result, we hypothesize that cognitive training using natural user interfaces can lead to more significant gains in cognitive and non-cognitive domains and, possibly, enhance transfer for daily life outcomes.

Objectives

This study aims to analyze which cognitive training experimental condition – Tablet versus Kinect – results in greater cognitive, mood, quality of life, and functional gains in a sample of chronic psychiatric patients.

Methods

Trial Design

Single-blind pilot randomized controlled trial.

Inclusion criteria

- Chronic Psychiatric diagnosis;
- Maximum age: 75 years old;
- Being able to read and write;
- Relatively preserved language abilities (expressive and receptive language);
- Preserved visual and auditory acuity;
- Having no motor limitations;
- Having no medical history of neurological conditions (e.g., stroke, traumatic brain injury, multiple sclerosis, etc.)

Exclusion criteria

- Experiencing an acute psychiatric episode.

Procedure

Eligible patients will be randomly allocated to both training conditions – kinect and tablet-based cognitive training. Then, a certified psychologist will collect patients' sociodemographic and clinical data and perform a baseline neuropsychological assessment. The 14-session cognitive training program inspired by instrumental activities of daily living will be applied to all patients. Sessions will be around 30 minutes and will be administered 2 times per week. The computerized cognitive training application used will be Musiquence, which was initially developed for cognitive stimulation purposes within the context of dementia syndromes. Both groups will perform the

same cognitive training program; the only thing that will differ will be the setup (kinect versus tablet).

Neuropsychological assessment

A comprehensive neuropsychological assessment will be delivered to all patients in three different moments, namely:

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

The neuropsychological assessment protocol encompasses a set o primary and secondary outcome measures that will be briefly described below:

Primary outcome measures

- Global cognitive functioning: Montreal Cognitive Assessment (MoCA) (Freitas et al., 2013);
- Processing speed: Symbol Search and Digital Symbol Coding from Weschler Adult Intelligence Scale – Third Edition (WAIS-III; Weschler, 1997; 2008);
- Attention: Toulouse-Piéron Cancellation Test (TP) (Toulouse & Piéron, 1986);
- Verbal memory: Free and Cued Selective Reminding Test (FCSRT) (Lemos et al., 2015);
- Visual memory and visuospatial abilities: Rey Complex Figure Test (RCFT) (Rey, 1998);
- Executive functions: Frontal Assessment Battery (FAB) (Lima et al., 2008), Semantic and Phonemic Verbal Fluency Tests (Cavaco et al., 2013);

Secondary outcome measures

- Depressive symptoms: Beck Depression Inventory II (BDI-II) (Beck et al., 1996);
- Quality of life: World Health Organization Quality of Life – Bref (WHOQOL-Bref) (Quality of life) (Canavarro et al., 2006);
- Functional abilities: Adults and Older Adults Functional Assessment Inventory (IAFAI) (Sousa et al., 2013).