Study protocol

Official title: A comparison between personalized and adaptive tablet-based cognitive training and paper-and-pencil cognitive training: a randomized controlled trial with community-dwelling stroke patients

Unique protocol: 43/2019

Document data: 28th of October 2019

Study protocol

"A comparison between personalized and adaptive tablet-based cognitive training and paper-and-pencil cognitive training: a randomized controlled trial with community-dwelling stroke patients"

Protocol for a randomized controlled trial:

Stroke is the second leading cause of death and disability worldwide. Post-stroke cognitive impairment is highly prevalent and disabling, affecting individuals' emotional state, quality of life, and functional abilities. This study aims to assess the efficacy of two cognitive training programs - one tablet-based (NeuroAIreh@b) and one in paper-and-pencil format (Task Generator) - in improving cognitive and noncognitive outcomes among community-dwelling stroke survivors.

Stroke survivors will be recruited at Funchal Central Hospital (Hospital Central do Funchal – Dr. Nélio Mendonça). All participants who agree to participate in the study must give verbal and written informed consent according to the model available in annex 1. Importantly, participants can cease their collaboration at any time.

The investigators expect to recruit 45 participants for this study:

- 15 participants for the tablet-based cognitive training group (NeuroAIreh@b) (experimental group 1);
- 15 participants for the paper-and-pencil cognitive training group (Task Generator) (experimental group 2);
- 15 participants for the waiting-list control group (passive control group).

Design

Inclusion criteria:

- Stroke diagnosis;
- Maximum age: 75 years old;
- Education: at least three years of formal education;
- Relatively preserved language abilities (expressive and receptive language);
- Residing in the community;
- Availability to go to the hospital 2x/week;
- Preserved visual and auditory acuity;
- Physically able to operate the tablet and perform the paper-and-pencil training;
- Motivation to participate.

Exclusion criteria:

- Diagnosis of concomitant neurological and/or psychiatric disorders;
- Hemianopsia;
- Unilateral neglect;
- Aphasia syndromes.

Procedure:

Study protocol

Eligible participants will be randomly allocated to one of the three groups.

Participants in the experimental groups, i.e., NeuroAIreh@b and Task Generator groups, will perform 12 bi-weekly sessions, lasting 30 minutes each, for a total of six weeks.

Finally, participants in the waiting-list control group will not be enrolled in any intervention during the course of the study. At the end of the study, these participants will be granted the possibility of enrolling in an intervention of their choice.

Neuropsychological assessment:

The neuropsychological assessment will be performed at three different timings:

- Baseline: at least one one week prior to study commencement;
- Post-intervention: at least one week after the end of the interventions;
- Follow-up: after three months since the post-intervention.

The clinical assessment will consist of the administration of several performance-based instruments and self-report scales that are validated for the Portuguese population, namely:

- **Cognitive screening:** Montreal Cognitive Assessment;
- **Processing speed**: Symbol Search and Digit Symbol Subtests;
- **Attention:** Toulouse-Piéron;
- **Subjective memory complaints:** Subjective Memory Complaints Questionnaire (SMCQ);
- **Verbal memory:** Auditory Verbal Learning Test (AVLT);
- **Visual memory:** Rey-Complex Figure Test (RCFT) (3-minutes immediate recall trial);
- **Executive Functions:** Verbal fluency tests (semantic and phonemic fluency), and RCFT (copy trial);
- **Anxiety and Depression:** Hospital Anxiety and Depression Scale (HADS)
- **Quality of Life:** Quality of Life after Brain Injury (QOLIBRI);
- **Functional abilities:** Adults and Older Adults Functional Assessment Inventory (IAFAI);
- **Motivation for the intervention:** Motivation for Traumatic Brain Injury Rehabilitation Questionnaire (MOT-Q).

Informed consent

I understand that all information derived from the study "A comparison between personalized and adaptive tablet-based cognitive training and paper-and-pencil cognitive training: a randomized controlled trial with community-dwelling stroke patients" is property of the responsible research team. I consent that the anonymous data about me (results, images, and videos properly anonymized) can be saved and processed for scientific evaluation. I understand the meaning of the information about the study, and my questions have been satisfactorily answered. I had enough time to decide on participation in this study.

I hereby consent to my participation and the collection and use of information.

I will receive a signed and dated copy of this informed consent.

Participants' signature

…….

Investigator

…….

Date: ___/___/___

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(CES & CCI of SESARAM, EPE)
APPROVAL number 43/2019

About the Order/Study:
"BRaNT (Belief Revision applied to Neurorehabilitation Therapy: funded by FCT: 02/SAICT/2017)."

A - REPORT

A.1 The Ethics Committee for Health (CES) and the Scientific Committee for Research (CCI) of the Health Service of the Autonomous Region of Madeira, EPE (SESARAM, EPE), analysed the document number 65 of 2019, request submitted by the **Professor Sergi Bermúdez**, associate professor at the University of Madeira, for the completion of the research project **"BRaNT (Belief Revision applied to Neurorehabilitation Therapy: funded by FCT: 02/SAICT/2017)"**. This is a study that aims to create a computerized profile of stroke victims in recovery.

A.2 The document under analysis consists of: an official letter sent to SESARAM's Administration Board, EPE, (EE971662) dated October 22nd of 2019, which includes a submission questionnaire, information of the service's directions, supervisor's information, study project, individuals' information sheet and informed consent.

A.3 This is a randomized and controlled clinical study, which aims to investigate the impact of BRaNT technology on the recovery of stroke victims, where usability tests are being performed. Initially, pilot studies will be carried out to establish the most suitable configuration. In a second phase, it is intended to conduct a randomized and controlled clinical trial to assess the impact of the proposed system in comparison to the conventional rehabilitation in about 20 users. Users to be included in the study should be subacute stroke victims for up to 6 months, with a cognitive deficit assessed by the Montreal Cognitive Assessment (MoCA) according to normative data for age and education, with education greater than or equal to the 4th grade, age greater than or equal to 55 years old, with cooperation and motivation to voluntarily participate in the study, ability to be seated, and integrated into the rehabilitation program of the Physical Medicine and Rehabilitation Department in a cognitive rehabilitation unit.

On the upper right corner of this document, is written by hand in blue ink:
Authorized
Investigated Information
Miguel Freitas
13.02.2020

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B - IDENTIFICATION OF ISSUES WITH POTENTIAL ETHICAL IMPLICATIONS

B.1 Ethical principles related to the study, namely with regard to the anonymity of its users, will be safeguarded during the course of it.

B.2 The practical interest of the results is recognized so the methodology protects the users' rights.

C - IDENTIFICATION OF ISSUES WITH POSSIBLE SCIENTIFIC IMPLICATIONS.

C.1 The basic principles of the clinical research, which respects to the clarity's exposition of the objectives and underlying hypothesis, interest and innovation, methodology and the study's design will be safeguarded.

C.2 The scientific validity and practical interest of the proposed study, whose quality and rigor must be ensured during the investigation are recognised.

D - CONCLUSION

The CES/SESARAM, EPE issued a **Favourable Opinion** as no ethical issues are being placed.

The CCI/SESARAM, EPE issued a **Favourable Opinion** as the basic principles of the Good Clinical Practice in Research are being met.

Approved at the meeting on October 28th of 2019 by CES with unanimity.
Approved after CCI's evaluation.
The President of the CES/SÉSARAM, EPE
Unreadable signature
(Ricardo Santos)
The Responsible for the CCI/SESARAM, EPE
Unreadable signature
(Paula Pinto)

There is a round stamp in blue ink on the left down corner of this document that says the following:
AUTONOMOUS REGION OF MADEIRA
ETHIC COMMISSION
REGIONAL HEALTH SERVICE, E.P E

This is a faithful and accurate translation which I sign and certify ----------
Mirla Maria Batista Fernandes----------
Interpreter Translator----------
Nº 3888/05----------
Funchal, November 08 of 2021----------