Efficacy of a Computerized Program of Cognitive Rehabilitation of Attention in People with Acquired Brain Injury (ABI): Pilot Study

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Efficacy of a Computerized Program of Cognitive Rehabilitation of Attention in People with Acquired Brain Injury (ABI): Pilot Study

INFORMATION DOCUMENT

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Collaborating institutions: Biocruces Bizkaia Health Research Institute and Aita Menni Hospital.

INTRODUCTION

Our therapeutic team, aware that you have suffered Acquired Brain Injury, wishes to invite you to participate in a research study that can provide us with knowledge that will help you and / or other people in the future.

Participation in the research is completely voluntary and may decide not to participate or may withdraw from the study at any time.

This document tries to give you as complete and understandable information as possible about what you intend to do. If after reading it you are struck by doubts, do not hesitate to ask them to those responsible for the study.

PURPOSE OF THE STUDY

To determine the effectiveness of the NeuronUp APT attentional rehabilitation program in people with ACD. For this, we need to recruit 46 people with ACD, which will subsequently be divided into 2 groups, an experimental group that will receive the intervention and a control group that will be evaluated but will not receive the attention intervention. This division will be carried out by randomization by blocks.

The study will be carried out by completing different scales, questionnaires and cognitive tests, in order to assess in this way the cognitive and attentional alterations or deficits manifested by

people with ABI in the different stages of the study (pre-intervention, post-intervention and at 6 months, after the end of the intervention of the attention program).

In the first phase (pre-intervention), the patient's sociodemographic information will be collected, and different cognitive tests will be administered. In the post-intervention phase the person will be reassessed and in the third phase (6 months) another cognitive assessment will be performed.

PROCEDURE OF THE STUDY AND DATA MANAGEMENT

The data obtained will be statistically processed and may be used in subsequent studies on alterations after ABI, unless you indicate otherwise. The data will be treated under strict compliance with Law 14/2007 of Biomedical Research and Organic Law 3/2018 of December 5, Protection of Personal Data and Guarantee of Digital Rights.

BENEFITS

Acquire a more thorough knowledge of some of the neuropsychological alterations secondary to ABI, mainly on the attentional alterations, which usually affect the independence of the person in their day to day.

RISKS AND DISCOMFORTS

The interview with the team members will not entail any physical or psychological risk. The only possible inconvenience may be the appearance of fatigue or tiredness on the part of the person evaluated, so that the appropriate breaks will be taken, in order to avoid it.

ECONOMIC ISSUES

Neither the interview, nor evaluation or intervention sessions that you need during the rehabilitation intervention of the care will be an economic cost for you. Participants will not receive financial or other remuneration.

CONFIDENTIALITY

All information that can identify the participant will be handled confidentially. The data obtained, both from the interview and from the evaluations carried out and from the rehabilitation program itself will be encrypted using an identification number and therefore, will be anonymous.

When the results of the research study are disclosed in journals or scientific meetings, the identity of the participants will be omitted.

CONTACT PERSON

If any problem arises or you have any questions regarding the study, or your rights as a participant in the research study or any other issue related to the present study, do not hesitate to express it. The contact person will be: Naiara Mimentza Larrinaga on the phone: 943 79 44 11 (Aita Menni Hospital).

We suggest that you keep a copy of this document for later reference.

INFORMED CONSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY

I, Mr. /Ms. ....., I have read the information sheet given to me, I have received enough information about the study and I have been able to ask questions about it.

I have spoken with....., I understand that my participation is voluntary and that I can withdraw from the study at any time, without having to give explanations and without affecting my care doctors.

However, the data collected about me will be treated under strict compliance with Law 14/2007 of Biomedical Research and Organic Law 3/2018 of December 5, Protection of Personal Data and Guarantee of Digital Rights.

Therefore, I freely give my consent to participate in this study.

Patient's signature

Signature of the researcher

In .... to ..... of .... of 20.....