RESEARCH PROJECT: Development of an assessment protocol sensitive to the cognitive processes necessary for driving after stroke

21st November 2022

SPECIFIC INFORMATION SHEET TO GRANT INFORMED CONSENT

Research study: Elaboration of an evaluation protocol sensitive to the cognitive processes necessary for driving after stroke

(Project financed by PAIDI 2020, Principal Investigator: Cándida Castro Ramírez, ref. P20_00338).

The alterations that occur after a can affect the ability to safely maneuver a motor vehicle. However, the assessment of the driving ability of stroke patients remains unclear. It discusses which cognitive functions are determinant for the task of driving and, even more, it discusses which aspects are relevant to carry out safe driving. Currently, in the Spanish context, there is no valid evaluation protocol that includes the main tests that could be decisive for driving again after a stroke.

The aim of this collaboration is to study and test a new assessment protocol that is sensitive to the cognitive processes required for driving. This will allow us to identify what people will be able to drive at the time of evaluation and which need intervention of the altered processes before they can drive.

PROCESS

Participants will be administered a series of functional and neuropsychological tests to complete the study. The tests will address both the evaluation of cognitive processes such as attention, memory and control and planning functions, such as performance tests and other specific driving:

1. **Cognitive tests**, in which they will take written or computer tests (2:30 hours).
2. **Functional performance tests**, in which you will carry out tests to assess your motor performance to drive a driving simulator (40 minutes).

3. Tests on the perception of dangers**, risk estimation, personality tests and driving styles**, in which you will be asked to answer some questions after watching some videos (1 hour).

4. **Test on a simulator driving**. The person will take a "virtual" tour in a simulator with equipment similar to that of a real car (1:30 hour). Using a simulator can cause dizziness similar to what some people experience when traveling in a car, which can cause headache, dizziness or nausea, among other symptoms. This is common, and the research team is prepared with protocols to prevent or mitigate it if it occurs.

5. **Driving assessment in a driving school car, in real traffic.** This test will be performed with a driving school instructor and a specialist occupational therapist (1:30 hours). This real practice will be carried out in a car equipped with a driving school prepared for the acquisition of driving skills with all the necessary security measures. Firstly, it will be on a closed circuit and if the test is successful, a test will be carried out on a circuit open to traffic. In the event that it is required, the controls of the car will be adapted to allow driving.

The duration to complete the entire evaluation is 7 hours approximately, but they will be carried out in the necessary sessions according to the preference and needs of the individual competitor.

To determine the possibility of participation of the person in this study based on medical and clinical criteria, we need to know in each case the etiology and extent of the lesion, as well as the present symptoms. That is why it is necessary that the participants give permission for the health centers to which they belong and that are collaborators in the project, to transfer said clinical and neuroimaging data to the researchers.

WILL AND CONFIDENTIALITY

These procedures do not pose any risk to the person since they only require verbal or manual responses.

Participation in the research is completely voluntary and the data obtained will always be confidential according to Regulation EU 2016/679 of the European Parliament and of the Council of April 27, 2016 on Data Protection (RGPD). You have the right to withdraw your consent at any time you deem appropriate, without the obligation to justify your will and without any adverse consequences for you, and your data will be withdrawn from the study at that time. In addition, the personal data that is required (such as age, sex, academic background, health data, contact details and driving experience) are those necessary to cover the objectives of the study. Your name will not appear in any of the study reports, and your identity will not be disclosed to anyone except for research purposes.

Any personal information that may be identifiable will be stored and processed by computer means under secure conditions and with restricted access. The adequate storage of the videos derived from the participation in the research will be guaranteed to allow total confidentiality.

Access to said information is restricted to authorized personnel who are obliged to maintain the confidentiality of the information. The results of the research will be

disseminated among the corresponding health services and the scientific community through congresses and/or publications.

In accordance with current law, each participant has the right to access their personal data; likewise, and if justified, he has the right to rectify and cancel it. Therefore, if the participant wants to abandon the research, they can withdraw their consent whenever they want, without having to justify why and without this resulting in any adverse consequences for them. From that moment on, your data will be withdrawn from the study.

If this fact sheet is not enough for the participant, you can always ask for additional information about the investigation and the procedure.

ADDITIONAL INFORMATION ANNEX:

Since last May 25, 2018, the new legislation in the EU on personal data has been fully applied, specifically Regulation (EU) 2016/679 of the European Parliament and of the Council of April 27, 2016 on Data Protection (RGPD). Therefore, it is important that you know the following information: In addition to the rights you already know (access, modification, opposition and cancellation of data) you can now also limit the processing of data that is incorrect, request a copy or that it be transferred to a third (portability) the data that you have provided for the study. To exercise your rights, contact the main researcher of the study, Ms. Candida Castro Ramírez (candida@ugr.es) or to the Data Protection Delegate of the University of Granada, Mrs. Rosa Ma García Pérez (delegadapd@ugr.es)

You have the right to contact the Data Protection Agency if you are not satisfied. The General Secretariat of the University of Granada (Hospital Real Avenida del Hospicio s/n 18071 Granada, Telephone: + 34 958 243021, Email: protecciondedatos@ugr.es) is responsible for the processing of your data and undertakes to comply with current data protection regulations.

You have the right to:

- Request access to the personal data we process about you.
- Request its rectification or deletion.
- Request the limitation of data processing.
- Oppose data processing.

The data collected for the study will be identified by means of a code, so that information that could identify you is not included, and only the study researchers will be able to associate said data with you and your medical history. Therefore, your identity will not be revealed to any other person except the health authorities, when required or in cases of medical urgency. The Research Ethics Committees, the representatives of the Health Authority in inspection matters, may only access to verify personal data, clinical study procedures and compliance with the rules of good clinical practice (always maintaining the confidentiality of the information). information).

If we transfer your encrypted data outside the EU to our group entities, service providers or scientific researchers who collaborate with us, the participant's data will be protected with safeguards such as contracts or other mechanisms by data protection authorities. data. If the participant wants to know more about it, they can contact the Data Protection Delegate of the University of Granada, Mrs. Rosa Ma García Pérez, delegatedapd@ugr.es

* Expected period of data conservation: The data conservation periods are those established in the archive legislation for Public Administrations (among other regulations, Law 7/2011, on Documents, Archives and Documentary Heritage of Andalusia, Law 16/1985 , of June 25,

Historical Heritage and Regulations of the University Archive of the UGR, approved by the Governing Council of the University of Granada on 11.27.2008 Personal data strictly necessary to prove the actions carried out will be kept indefinitely.

*Automated decisions, profiles and applied logic: Your data will not be used for automated decisions or profiling.

PATIENT/PARTICIPANT INFORMED CONSENT

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(Project financed by PAIDI 2020, Principal Investigator: Cándida Castro Ramírez, ref. P20_00338).

Name and surname of the person reporting:

Name and surname of the Participant:

ID:

The purpose of this document is to record that you, or your representative, have given your consent to participate in this research and, therefore, authorize us to collect and use your data as described in the information sheet.

Before signing this document, you must have been informed verbally and in writing about the investigation and the administration of the tests, tests and tasks necessary for it.

CONSENT

I declare that I agree with the investigation and the protocol that have been proposed to me, and that I have received and satisfactorily understood all the information that I consider necessary to make my decision. In the case of patients, I give my consent that the collaborating health centers of the project that have collected my clinical and neuroimaging data related to my acquired brain damage, can transfer them to the project researchers so that they can be treated by them. Likewise, I have been informed of my right to withdraw my consent at any time I deem appropriate, without the obligation to justify my will and without any adverse consequences for me resulting from it, my study data being withdrawn at that time.

<table>
<tr><td>Signature of the participant

Date:
PHONE</td><td>signature person represents

ID:
Date:
PHONE:</td><td>Signature of informant:

Date:</td></tr>
<tr><td>Representation by:

o Will of the person concerned
o Minority of age
o Incapacity person concerned</td><td colspan="2">SIGNATURE FOR REVOCATION

Name:
ID:
Date:</td></tr>
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