Appendix 1. Information sheet and informed consent form (for relatives and patients) for the purposes of the presented study.

Specific information document to grant Informed Consent

Research Study: Brain and cognitive mechanisms of anosognosia in patients with acquired brain damage: New assessment and intervention strategies based on everyday tasks

Project financed by MINECO, ref. PSI2016-80331-P

Principal Researcher: María Jesús Funes Molina

There is a close relationship between awareness of capabilities and limitations and the possibility that people achieve recovery and rehabilitation after brain damage.

The objective of this research project is to study in a thorough way the awareness of deficits and their repercussions for the full performance of activities of daily living. With this information, we intend to create a better evaluation process of people with disabilities in awareness both cognitively and occupationally, with the aim of improving intervention techniques.

PROCESS

- Evaluation of the family member/caregiver. The participants’ relatives/caregivers will be asked to fill in the Cog-Awareness ADL Scale. This scale aims to capture the various errors of a cognitive nature that the patient presents when carrying out their daily activities. To complete it, they will only be required to answer certain questions regarding their relatives’ performance of activities of daily living. Similarly, they will be required to fill in the Patient Competency Rating Scale, a validated scale to measure the patient’s metacognitive knowledge. The approximate duration to complete both scales is 30 minutes.

- Evaluation of the patient. Patients will be undergo a series of functional and neuropsychological tests to complete the study. The tests will address both functional abilities and the assessment of cognitive processes such as attention, memory, and control and planning functions. These tests will be carried out with paper and pencil, on a computer and with real objects, the latter will be recorded on video. Likewise, they will be asked to fill in the Cog-Awareness ADL Scale according to their own perception. The time needed to complete the entire evaluation is approximately six hours, but it will be carried out in the necessary roughly three to four sessions, according to the patient’s own preference.

In order to know what type of brain damage produces alterations in awareness of deficits (anosognosia), we need to know the aetiology and extent of the injury in each case and thus relate it to the measures of awareness of those deficits. For this reason, it is necessary for patients to give permission to transfer their clinical and neuroimaging data to researchers from the healthcentres where they are treated which are cooperating with the project.

VOLUNTARY PARTICIPATION AND CONFIDENTIALITY

These procedures do not pose any risk to participants as they only require verbal or manual responses.

Participation in the research is completely voluntary and the data obtained will always be confidential according to European Union (EU) Regulation 2016/679 of the European Parliament and of the Council of April 27, 2016 on Data Protection. You have the right to withdraw your consent at the time you consider it appropriate, without obligation to justify your decision and without any adverse consequences, being your data from this study withdrawn at any moment. In addition, the personal data involved (such as age, sex,
academic training and health data) only includes items that are necessary to meet 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 the purposes of the investigation.

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

Access to such 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 community through conferences and/or publications.

In accordance with current law, each participant has the right to access their personal data. Likewise, and if justified, you have the right to rectification and deletion. Therefore, if the participant wants to abandon the research, they can withdraw their consent at any time, without having to justify why and without this resulting in any adverse consequence for them. From that moment on, your data will be withdrawn from the study.

If this fact sheet does not answer any questions you might have, you can ask for additional information about the investigation and the procedure at any time.

**ADDITIONAL INFORMATION ANNEX**

Since last 25 May 2018, the new legislation in the Europe Union (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. Therefore, it is important that you know the following information: In addition to the rights that you already know about (access, modification, disagreement and deletion of data), you can now also limit the processing of data that are incorrect, request a copy or transfer to a third person (portability) the data that you have provided for the study. To exercise your rights, contact the principal researcher of the study, María Jesús Funes Molina (mjfunes@ugr.es) or to the Delegate of Data Protection of the University of Granada, Ms. 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, e-mail: protecciondedatos@ugr.es) is responsible for the processing of your data and they undertake to comply with the data protection regulations in force.

You have the right to:

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

The data collected for the study will be identified by a code, so that information that could identify you is not included, and only the study investigators will be able to connect such data to you and your medical history. Therefore, your identity will not be revealed to any other person except to the health authorities, if they require it or in cases of medical emergency. The Research Ethics Committees, the representatives of the Health Authority in inspection matters, may only access it to verify personal data, clinical study procedures and compliance with the rules of good clinical practice (always maintaining the confidentiality of the information).
If we transfer your encrypted data outside the EU to the entities of our group, service providers or scientific researchers that collaborate with us, the participant's data will be protected with safeguards such as contracts or other mechanisms by the protection authorities of data. If the participant wants to know more about it, he or she can contact the Data Protection Officer of the University of Granada, Ms. Rosa Ma García Pérez, delegadapd@ugr.es

* Expected data retention period:

The data retention periods are those provided for in the legislation on archives for Public Administrations (among other regulations, Law 7/2011, on Documents, Archives and Documentary Heritage of Andalusia, Law 16/1985, of 25 June, on Heritage History and Regulation of the University Archive of the UGR, approved by the Governing Council of the University of Granada on 27 November 2008. The personal data strictly necessary to confirm the actions that were carried out will be kept indefinitely.

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


(Project funded by MINECO, Principal Investigator: María Jesús Funes Molina, ref. PSI2016-80331-P).

Researcher____________________________________________________________________________

Participant____________________________________________________________________________

This document is intended to record that you, or whoever represents you, has given your consent to participate in this research and, therefore, authorizes 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 and tasks necessary for it.

CONSENT

I declare that I am satisfied with the research and the protocol that has been proposed to me, and that I have received and satisfactorily understood all the information that I consider necessary to make my decision. I give my consent that the collaborating health centres of the project that have collected my clinical and neuroimaging data related to my acquired brain damage may transfer them to the project researchers for its treatment. Likewise, I have been informed about my right to withdraw my consent when I consider it appropriate, without any obligation to justify my decision and without any adverse consequences, being the data from this study withdrawn at any moment. I also state that I have been informed of my right to request further additional information should I need it.

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<th>Participant’s signature</th>
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Representation by:
- [ ] The person concerned
- [ ] Disability person concerned

Signature revoke the consent

Name: ID: Date: