

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

21<sup>st</sup> November 2022

## OBJECTIVES

### GENERAL OBJECTIVE

TO DEVELOP AN ASSESSMENT PROTOCOL BASED ON ANALYSIS OF VARIABLES THAT MAY PREDICT SAFE "FITNESS TO DRIVE" ("Fitness to drive") IN PATIENTS WITH STROKE

### SPECIFIC OBJECTIVES

1. SELECTION AND CREATION OF A BATTERY OF NON-DRIVING TESTS: COGNITIVE TESTS, PERSONALITY TESTS, RISK ESTIMATION AND ASSESSMENT OF DRIVING STYLES THAT MAY PREDICT SAFE "FITNESS TO DRIVE" ("Fitness to drive") IN PATIENTS WITH STROKE:
  - Creation of the driving planning test: Evaluation of driving planning on Map (COMAP)
  - Cross-cultural adaptation and validation in Spanish population of Stroke Driver's Screening Assessment (SDSA).
  - Cognitive tests to predict driving performance and identify cognitive deficits, including general cognitive tests, attentional tests, speed of processing, visual memory and executive functions.
  - Personality and Risk Estimation Tests: Risk Estimation Test: DOSPERT-i.e. Recreational Risk Perception and Sensitivity to Reward and Punishment Test - SPSRQ-20 SR\* - Sensitivity to Reward.
  - Assessment of driving styles: Multidimensional Driving Styles (MDSI), self-reported driving styles questionnaire: Maladaptive vs. Adaptive (Cautious) Padilla, Castro, Doncel, Taubman-Ben-Ari, 2019).
  - PERFORMANCE-BASED TESTS ON HAZARD PERCEPTION AND RISK ESTIMATION, using recordings of naturalistic driving situations (Castro et al., 2014; Ventsislavova et al., 2016).
2. CREATION OF A DRIVING SIMULATOR DRIVING PERFORMANCE ASSESSMENT TEST. The test called EDEC (Performance Evaluation of Driving) will be designed through a panel of experts (content validity) and the psychometric properties will be analysed.

## HYPOTHESIS

Based on the literature on the subject of driving after stroke, our hypothesis is that this selection of non-driving, performance-based tests in conjunction with the two newly created tests: COMAP and EDEC will be crucial in establishing a decision as to whether a patient with stroke, who previously had a driving licence, is able to drive safely.

In relation to the SDSA battery, our hypothesis is that the translated and cross-culturally adapted version will be a tool with good reliability and validity.

## METHODOLOGY

### STUDY DESIGN

Validation of an assessment protocol for safe driving ability in stroke patients, analysing the ability of selected tests designed to predict safe driving in on-road tests.

### PARTICIPANTS AND INCLUSION CRITERIA

For the study, there will be 2 groups: (participants will sign the informed consent to participate in the study).

Patient group: 50 adults (between 18 years and 70 years) in chronic phase of stroke (>6 months since stroke) who have a driving licence and have been driving in the three months prior to stroke.

Exclusion criteria:

- Patients must have medical clearance to participate in the study (indicating that they are medically stable to participate in the study, regardless of whether they can drive or not).
- Patients will be excluded if they have a stroke score below 24 on the Mini Mental State Examination, epileptic seizures, visual impairments (uncorrected visual acuity with glasses, diplopia, severe campimetric or visual field deficits, etc.), attentional hemineglect syndrome, severe motor/balance disturbances and people who don't know/can read.
- They will be required to be able to move independently in a standing position, even if they need the help of assistive devices to do so.

Control group: 50 adults, matched in age, healthy, matched in driving experience (number of years of driving licence, kilometres driven in the last year, frequency of driving -daily, weekly, monthly, monthly, yearly, etc... ), age, sex and educational level with the following characteristics age, sex and educational level with the group of people with stroke with a valid driving licence.

### RECRUITMENT

Patients will be recruited from the Regional University Hospital of Malaga and the Hospital of Torremolinos (Malaga), both hospitals provide care for most of the stroke patients in the province of Malaga from the public system. In addition, SINERGIA AISSE neurorehabilitation center and acquired brain injured association ADACEMA (Málaga) and ACTIVANEURO (Málaga).

## VARIABLES

Variable	Type	Value
Age	Continuous quantitative	Years
Sex	Qualitative dichotomous	Male / Female
Marital status	Qualitative categorical	Single/ Married/Widowed/ Single/ Married/Widowed/ Single/ Married/Widowed/ Single/ Married/Widowed Divorced
Educational level	Qualitative categorical	Primary Education Secondary Education Vocational training University students
Radiological report of brain damage	Qualitative	
Localisation of brain damage	Qualitative categorical	Right/Left Frontal/parietal/temporal/occipital
Date brain damage	Continuous quantitative	Years and months
Rehabilitation time	Continuous quantitative	Years and months
Years with driving licence	Continuous quantitative	Years and months
Kilometres travelled in the last year	Continuous quantitative	Approximate number of kilometres
Driving frequency	Qualitative categorical	daily, weekly, monthly, monthly, yearly
Mini Mental State Examination	Continuous quantitative	Total score: 0-30
VOSP	Continuous quantitative	Sub-test scores: - Shape detection: 0-20 - Test 3: Object decision: 0-20 - Test 4: Progressive silhouettes: 1- - Test 5: Position discrimination:0-20 - Test 7: Locating numbers:0-10
The Used Field of View Test (UFOV)	Continuous quantitative	Time (milliseconds) Stimulus identification:16ms-500ms Divided attention:16ms-500ms Selective Attention: 43ms-500 ms Total subtests 1-3: 86ms-1500ms
Trail Making Test Part A and B	Continuous quantitative	Total score. Errors and time taken (seconds)
"Continuous Performance Test (CPT).	Continuous quantitative	False positives Omissions Reaction time
PASAT	Continuous quantitative	Errors: 0-60 Realisation time
Five-Digit Test.	Continuous quantitative	6 variables (both scalar and percentile scores) - Reading - Counting - Election - Alternation - Inhibition - Flexibility
Ineco Frontal Screening	Continuous quantitative	Total score 0-30
Iowa Gambling Test	Continuous quantitative	Total score for each block of 20 cards (5 blocks). The task score is obtained by subtracting the total number of choices of the disadvantageous decks from the number of choices of the advantageous decks.
Weekly. Weekly Calendar Planning Activity (WCPA).	Continuous quantitative	- Planning time - Execution time - Correct quotations - Errors

		<ul style="list-style-type: none"> <li>- Strategies used</li> </ul>
COMAP. Test of Planning Strategies for Mapped Driving.	Continuous quantitative	<ul style="list-style-type: none"> <li>- Planning and implementation time (seconds)</li> <li>- Signal knowledge: 0-4</li> <li>- Rule tracking: 0-9</li> <li>- Calculation of time in appointments:0-24</li> <li>- Planning: 0-63</li> <li>- Strategies used: 0-</li> </ul>
"Stroke Drivers Screening Assessment (SDSA)	Continuous quantitative	Reaction time and errors for these subtests: <ul style="list-style-type: none"> <li>- Dot Cancellation: Time, errors, false positives</li> <li>- Direction Test. Score</li> <li>- Compass Test. Score</li> <li>- Road Sign Recognition Test Score</li> </ul>
DOSPRT	Continuous quantitative	Score dimensions: Ethical= 6-42 Financial/Investment=3-21 Financial/Game=3-21 Social=6-42 Health/Security=6-42 Recreational=6-42
SPSRQ-20 (Sensitivity to Punishment and Sensitivity to Reward Questionnaire)	Continuous quantitative	Total score: 20-80
Multi-driving Styles Inventory. DRIVING STYLES SCALE	Continuous quantitative	Scoring for each driving style: Reckless:7-42 Aggressive:4-24 Anxious:4-24 Distracted:8-48 Cautious:7-42 Stress Reduction:4-24
Danger Prediction Test	Continuous quantitative	0-10
Risk Estimation Test	Continuous quantitative	10-60
Performance Evaluation of Driving (EDEC)		The variables are not yet determined, because it is also the aim of the project to design this test.
On Road Assessment	Qualitative categorical	Insurance/Borderline/Insurance
Psycho-technical driving test	Continuous quantitative	Concentrated attention, Multiple reactions, Anticipatory speed, Bimanual coordination, Decision making and Personality * Average response time, in hundredths of a second. For its calculation, omissions and null responses are not taken into account. Omissions and null responses are not taken into account in the calculation. * No unanswered stimuli, i.e. errors of omission: the subject does not respond to a stimulus. No unanswered stimuli, i.e. errors of omission: the subject does not respond to a stimulus. * No confusions in front of stimuli, i.e. errors due to confusion: the subject presses the wrong button/pedal. presses the wrong button/pedal. * No non-stimulus responses, or null responses: the subject anticipates and

		<p>presses a button or pedal without the stimulus.</p> <p>No stimulus responses, or null responses: the subject anticipates and presses a button or pedal without any stimulus appearing.</p> <p>* Percentages of confusions, omissions and null responses.</p>
--	--	---

### **Tests for inclusion/exclusion of patients**

- Boston test (reading comprehension): The person has to read 4 sentences and determine the correct option to finish the sentence (4 options).
- Test Snellen: is a visual test carried out on the patient to evaluate their eye capacity and to see if there is any alteration that may be hindering their vision, thus measuring their visual acuity.
- Time up and go: is a test used to assess a person's mobility and requires both static and dynamic balance. It uses the time that a person takes to rise from a chair, walk three meters, turn around 180 degrees, walk back to the chair, and sit down while turning 180 degrees.
- 5 Sit to Stand Test: measures one aspect of transfer skill. The test provides a method to quantify functional lower extremity strength and/or identify movement strategies a patient uses to complete transitional movements.
  
- Evaluation of simulator performance possibility and pain.

### **PROCEDURE**

The occupational therapists will contact those responsible for the recruitment centres to indicate the inclusion/exclusion criteria for participation in the present study. Participants who meet the criteria will be informed about the study and if they voluntarily agree to participate, they will be asked to sign a consent form authorising them to give their telephone number to the researchers. The researchers will provide more detailed information about the study by telephone, and if the person agrees, an appointment will be made to carry out the assessment.

The total duration of the evaluation protocol will be approximately 7 hours, although it depends on the participant's performance. It will be divided between the sessions required by the person, depending on their abilities, but will be at least 3 sessions.

In the first session, the participant is again informed about the project and encouraged to ask any questions he/she may have. The person will be offered an information sheet and the participant will have to sign the informed consent form. The assessment will then begin, asking questions about socio-demographic data, collecting information about the injury and data in relation to driving. Subsequently, the list of off-road tests indicated in the protocol will be administered. In all sessions, approximately 30 minutes of driving time will be spent on the driving simulator in order to mitigate possible non-serious adverse effects such as dizziness. Once the off-road tests have been completed, the in-car simulator test will be carried out, followed by the on-road test. For the on-road test, in all patients, a 30-minute session will be devoted to adapt to that driving

mode. The on-road test will be carried out in the presence of 3 people: a driving school teacher and 2 researchers.

At the end of the on-road test, general feedback will be given by the driving instructor.