

# Manual of Procedures FLADEX Project

MOP Chapter 5.1: Cognitive assessment



Promoting Fitness & Health  
through Physical Activity



UNIVERSIDAD  
DE GRANADA

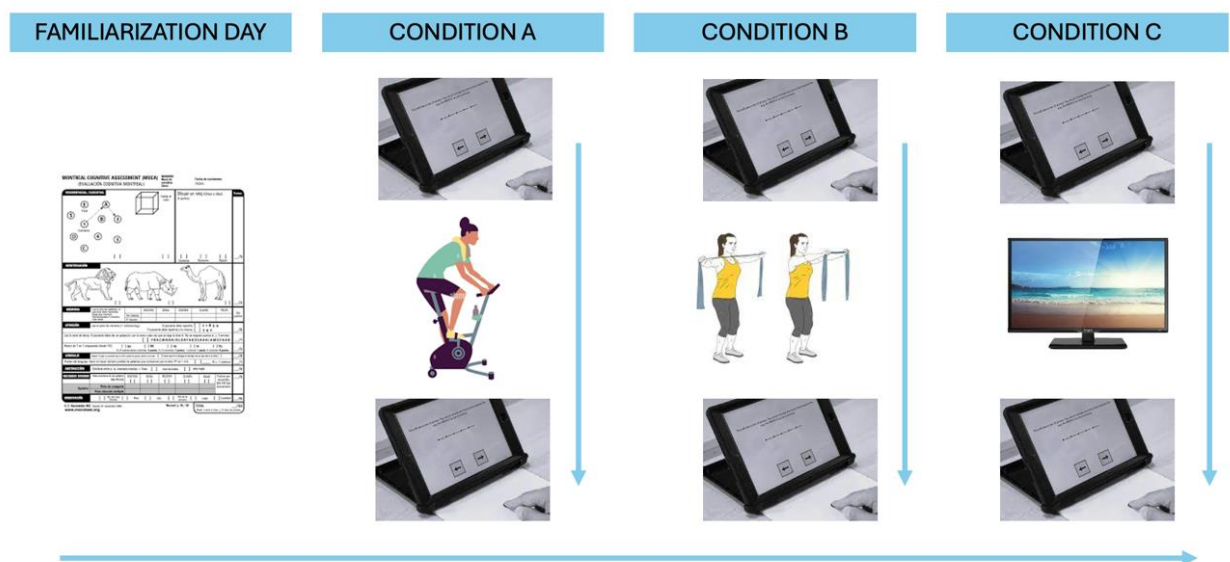
## Chapter 5.1: Cognitive Assessment

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## 1. Introduction

A secondary aim of the project entitled "Understanding cerebral blood flow dynamics for Alzheimer's Disease prevention through EXercise: the flADeX study" is to investigate the acute effect of a single session of resistance exercise versus moderate aerobic exercise versus a resting condition on cognition function in older adults. Therefore, it is essential to collect standard, reliable, and high-quality cognitive data during the project. During the familiarization session, a paper cognitive test will be conducted using the Montreal Cognitive Assessment (MoCA) for descriptive purposes. During each condition (out of three), two computerized tests (flanker and picture sequence memory test-PSMT) will be conducted pre- and post-condition using the NIH Toolbox <sup>2,3</sup>. The domains measured through these tasks performed on iPad include general and higher-order mental abilities such as inhibition/attention and episodic memory. Since the administration method of a cognitive test can affect the validity of the responses, all personnel administering the tests must comply with the procedural standards described in this chapter.



**Figure 1.** Distribution of cognitive tests during the sessions.

## 2. Familiarization session: MoCA test

### 2.1 Equipment required

- Pen
- Annex.5.1. MoCA\_Record
- Annex.5.2. MoCA\_Identification

- Annex.5.3. MoCA\_Manual

- Stopwatch

- Table partition

- Acrylic

## 2.2. Material's place and assessments' location

MoCA test will be performed at Instituto Mixto Universitario Deporte y Salud (IMUDS) during the familiarization session.

## 2.3 Test Day Procedure

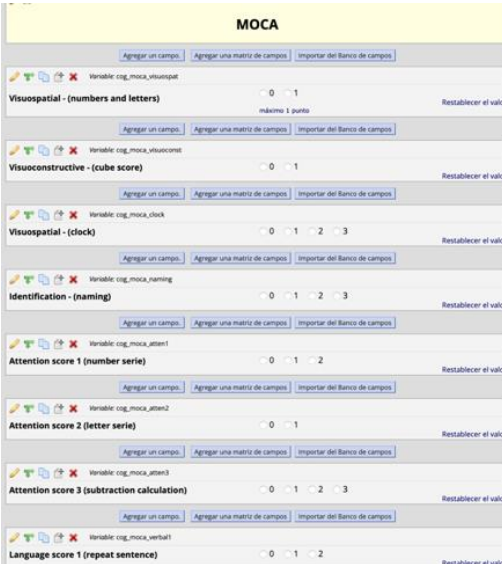
The instructions in Annex.5.3. MoCA\_Manual should be repeated only once, unless otherwise specified (e.g. the participant is absent-minded or the assessor himself/herself has not given the information adequately) and should be read verbatim.

## 2.4. Post-test procedure

The data obtained from the cognitive tests will be corrected by the same evaluator trained in neuropsychological testing.

### 2.4.1. Entering data into REDCap

Once the session has ended, the corresponding data will be entered into the REDCAP platform immediately.



**MOCA**

Agregar un campo | Agregar una matriz de campos | Importar del Banco de campos

Variable: cng\_moca\_visuospat | 0 | 1 | Restablecer el valor  
Visuospatial - (numbers and letters) | máximo: 1 punto

Agregar un campo | Agregar una matriz de campos | Importar del Banco de campos

Variable: cng\_moca\_visuconstr | 0 | 1 | Restablecer el valor  
Visuoconstructive - (cube score)

Agregar un campo | Agregar una matriz de campos | Importar del Banco de campos

Variable: cng\_moca\_clock | 0 | 1 | 2 | 3 | Restablecer el valor  
Visuospatial - (clock)

Agregar un campo | Agregar una matriz de campos | Importar del Banco de campos

Variable: cng\_moca\_naming | 0 | 1 | 2 | 3 | Restablecer el valor  
Identification - (naming)

Agregar un campo | Agregar una matriz de campos | Importar del Banco de campos

Variable: cng\_moca\_aten1 | 0 | 1 | 2 | Restablecer el valor  
Attention score 1 (number serie)

Agregar un campo | Agregar una matriz de campos | Importar del Banco de campos

Variable: cng\_moca\_aten2 | 0 | 1 | Restablecer el valor  
Attention score 2 (letter serie)

Agregar un campo | Agregar una matriz de campos | Importar del Banco de campos

Variable: cng\_moca\_aten3 | 0 | 1 | 2 | 3 | Restablecer el valor  
Attention score 3 (subtraction calculation)

Agregar un campo | Agregar una matriz de campos | Importar del Banco de campos

Variable: cng\_moca\_verbal1 | 0 | 1 | 2 | Restablecer el valor  
Language score 1 (repeat sentence)

Figure 2. Redcap MoCA instrument.

### 2.4.2. Scanning of answer sheets

After entering the corresponding data in the REDCAP platform, all the registrations and the tests carried out must be scanned to ensure that the information is duplicated. The file should be scanned in a single PDF and named as “Participant ID\_MOCA” (i.e., 101\_MOCA).

## 3. Condition sessions: NIH Toolbox tests

### 3.1 Equipment required

- 2 iPad charged: iPad AGUEDA 1 and iPad AGUEDA 2
- Chargers for iPads
- Passwords to access iPads: Password iPad AGUEDA 1 y 2: xxxx
- Door sign (Annex.5.4. Process\_test)
- Annex.5.5. Home\_base

### 3.2. Material's place and assessments' location

The iPADS belonging to the flADeX project will be stored in cupboard 1 in the Physio room. Computerized tests will be performed in Lab11 at Centro de Investigación Mente, Cerebro y Comportamiento (CIMCYC).

### 3.3 Test Day procedure

The first step before starting any cognitive test is to go to the assigned room (Lab11) to perform these cognitive tests and place the sign "PRUEBA EN PROCESO, NO MOLESTAR" on the door (see **Annex.5.4. Process\_test**). The NIH Toolbox tests are presented in Table 1.

**Table 1.** Information about cognitive tests.

Nomenclature	Test	Time	Material	Cognitive domain	Place
F	NIH Flanker Inhibitory Control and Attention	4 min	IPAD Annex.5.5. Home_base	Inhibitory control Attention	Lab 11
PSMT1, PSMT2 & PSMT3	NIH Picture Sequence Memory Test	5 min	IPAD	Episodic memory	Lab 11

### 3.3.1. Randomization of testing order

Randomization of testing order for cognitive tests (PSMT and Flanker), and within PSMT forms (Flanker tests only has one form) will be performed for the flADeX study.

#### ○ *Randomization for the PSMT forms*

The PSMT has 3 different forms (PSMT1, PSMT2 and PSMT3). To reduce possible fatigue and learning effects, a different form of the PSMT will be used for each intervention condition/visit (A: aerobic, B: resistance, and C: control resting). Then, each participant will be randomly assigned to one of six orders of PSMT forms (Table 2).

**Table 2.** Models of the PSMT for the randomization.

Models (Order)	Visit1	Visit2	Visit3
<b>Model1</b>	PSMT1	PSMT2	PSMT3
<b>Model2</b>	PSMT1	PSMT3	PSMT2
<b>Model3</b>	PSMT2	PSMT1	PSMT3
<b>Model4</b>	PSMT2	PSMT3	PSMT1
<b>Model5</b>	PSMT3	PSMT1	PSMT2
<b>Model6</b>	PSMT3	PSMT2	PSMT1

#### ○ *Randomization for the cognitive tests*

The order to perform the Flanker and PSMT tests will be also randomized for each participant, **and this order will be the same for the 3 conditions**. The results of the randomization of the cognitive tests for each participant are presented in Annex.5.0.Randomization.csv, where 1 represents Flanker and 2 represents PSMT. Thus, 10 participants will always perform the Flanker test first and then the PSMT, while another 10 participants will always perform the PSMT first and then the Flanker test.

The above randomization will be performed at <https://www.sealedenvelope.com>. How to cite this tool: Sealed Envelope Ltd. 2022. Create a blocked randomization list. [Online] Available from: <https://www.sealedenvelope.com/simple-randomiser/v1/lists> [Accessed 10 Jul 2024].

### 3.3.2 Creation of test battery

The test battery for the flADeX study will be created using the NIH Toolbox app as follows:

1. Once the application is open, select "Batteries".
2. On the next screen, select "Add New Battery/Agregar Nueva Bateria" (on the top right).
3. We will indicate one of the six names depending on the order of the tests (FLADEX\_Model1, FLADEX\_Model2, FLADEX\_Model3, FLADEX\_Model4, FLADEX\_Model5 or FLADEX\_Model6) in the "Battery Name/Nombre de la Bateria" section.
4. Now, select "Add Instruments/Agregar Instruments". Once you click there, you will get a new screen where you should select "All instruments/Todos los instrumentos", which appears as a tab on the top right-hand side.
5. In the search engine that is located just below with a magnifying glass, write the names of the tests to be added: Flanker Inhibitory Control for Age 12+ v2.1 (Spanish for 18+), and Attention and Picture Sequence Memory Test for Age 8+ v2.1. (Spanish for 18+) Form A-ir al parque/Form B-trabajar en la granja/Form C-Ir a la feria.
6. Once the tests are selected, click on the right boxes with a "tick", and click on "Done".
7. The six batteries have been created, and the corresponding model according to the order in Annex.5.0Randomizer.csv should be selected for assessments.

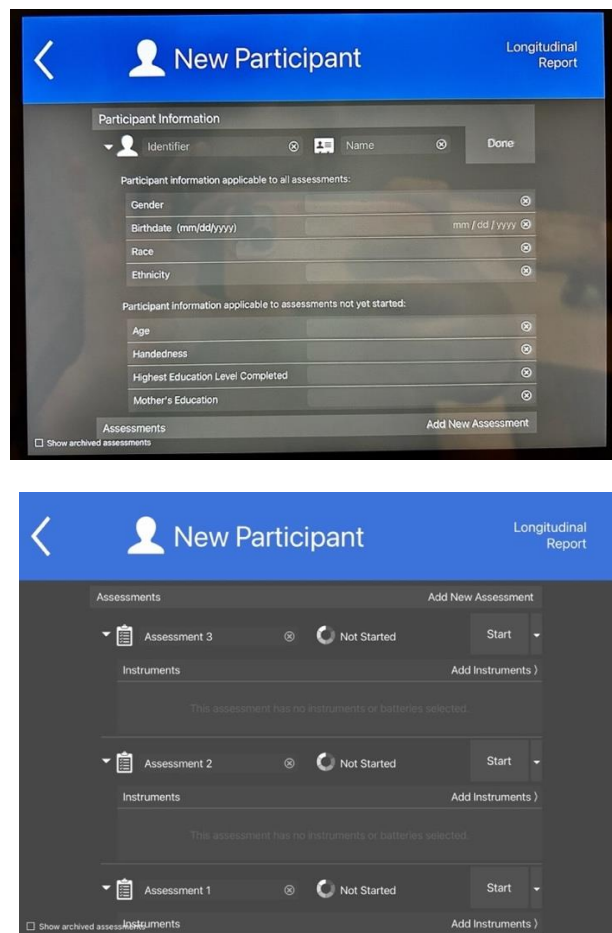
### 3.3.3. Admission of participants

Participants should be logged in beforehand to the NIH Toolbox as follow:

1. Unlock the iPad by entering the password "xxxx".
2. Open the NIH Toolbox application for iPad, select "Participants/Participants", and enter the unlock code of the app, which is "xxxx".
3. To create a new participant, click on "Add new Participant/Agregar a un nuevo participante" (on the top right-hand side of the screen), and include participant's details from the flADex database correctly (**Figure 3**):
  - In both Identifier and Name, the ID number of the participant should be included, e.g. 101.
  - Gender
  - Date of birth (mm/dd/yyyy)
  - Age is automatically calculated
  - Dominant hand: it is supposed to be always the right hand.
  - Maximum level of education completed. The NIH Toolbox software has an educational categorization based on the American educational system. Enter the maximum level of education completed.

- To add assessments, go to the “Add New Assessment/Agregar una nueva evaluación” tab. Each assessment should be entered based on the following conditions: A (Aerobic exercise), B (Resistance exercise), or C (Resting), as well as the ID number and time of the assessment. The time is marked as "1" for pre-condition assessments and "2" for post-condition assessments. To enter the information, follow this order: first, input the participant’s ID number, followed by the condition, and then the time, as shown in the example:

**E.g. 101\_A\_1 (Participant ID 101, Aerobic exercise, Pre-condition)**



**Figure 3.** “New participant” adding tab

### 3.3.4. Instrument entry

1. Prepare the iPad with the case on the table and Annex.5.5. Home\_base.
2. Underneath the iPad, with the front corners on top (This will be kept here for the rest of the iPad tests).



3. After this, include the test battery created in the app by clicking "Add new Assessment/Agregar nueva Medida" and then "Add instruments/Agregar instrumentos". Click on the section to the right of "All batteries/Todas las baterías". Scroll down and select the Fladex model.
4. Place the iPad directly in front of the participant, with the "iPad Home Base" card laminated underneath the iPad. Hold the iPad in place if the participant tends to touch too hard.
5. Make sure the participant knows how to touch the screen correctly and with the right pressure before continuing with the first iPad test.
6. Remind participants to use the right hand as they are right-handed if needed.

### 3.3.5 Application of the tests

- **NIH Toolbox: Flanker**

- **Duration:** 4 minutes

- **Description:** It is a measure of inhibitory control and attention. The task requires the participant to concentrate on a particular stimulus while inhibiting lateral stimuli.

- **Instructions:** The iPad executes the task and displays instructions on the screen while the Administrator must read them with the participant and point out the relevant aspects of the stimuli on the screen. The screen will display an arrow flanked by two other arrows on either side. The participant is instructed to choose one of the two buttons on the screen that corresponds to the direction in which the arrow is placed in the middle points. In congruent trials, all arrows point in the same direction. In incongruent trials, the flanking arrows point in the opposite direction to the central arrow. Congruent and incongruent trials are mixed.

- **NIH Toolbox: Picture Sequence**

- **Duration:** 5 minutes

- **Description:** In this episodic memory measure, sequences of pictures, objects, and activities are presented in a particular order. Participants are asked to reproduce the sequence of images shown on the screen.

- **Instructions:** First a demonstration sequence is shown to the participants to teach them how to move the images on the screen, as well as a practice sequence. Participants respond by dragging images from the yellow square on the screen to the grey squares on the screen. Participants can verbalize the labels of the images as they move the images, but they may not touch the screen while the images are presented. If participants attempt to touch the screen while the images are being presented or while the examiner is giving instructions, say: "Do not touch the screen until I tell you it is your turn."

### 3.4. Post-test procedure

After performing the NIH Toolbox tests, a series of steps must be strictly followed to ensure that all data are recorded correctly and to avoid loss of data due to misplacement.

#### 3.4.1 NIH Toolbox Results Submission

Each week, we will do a backup copy and download all data from previous weeks. We will have to enter the program app. Click on "Export data/Exportación de datos". In the search engine select:

1. "*Never exported/Nunca exportados*" Here we select the participants from the flADeX project. We can also do a selective search by date, which will help us to locate the participants according to the evaluations.
2. Click on the boxes to the right of the participants to select them. Click on "Continue/Continuar", which appears at the bottom right.
3. In the next step, select "Send via email.../Enviar vía email". Then, click on "Continue".
4. Select all the files that appear and click on "Create files/Crear archivos".
5. Now you will see an Email options message. Click on "Do not Encrypt".
6. Finally, write the iPad used and the dates you are exporting in the message subject (i.e. Agueda 2 – Abril 29 – Mayo 3 2024) and send the email to [fladex@ugr.es](mailto:fladex@ugr.es).

#### 3.4.2 Upload files on the sever

Six CSV files are created from the NIH toolbox:

- Registration data
- Assessment scores
- Assessment data
- Narrow structure registration data
- Narrow structure assessment scores
- Narrow structure assessment data

Upload these files on the NIH folder of the AGUEDA server ([//profith2.ugr.es/fladex/Participants/NIH](http://profith2.ugr.es/fladex/Participants/NIH)) in the same day.

In addition, once data collection phase is completed, all the data will be exported again in a single Excel sheet to facilitate the processing and subsequent analysis of the data.

#### 3.4.3 REDCap data entry and validation

The "Nih Toolbox" form should be completed in the REDCap platform. In addition, data revision must be performed at the end of the assessment day by the cognitive evaluator. This person (i.e., Andrea Coca-Pulido) will oversee checking the data answered in the REDCap platform and checking the Excel data uploaded to the server.

#### 4. Standardised Administration Guidelines

Variability in administration introduces bias in data collection. These test administration guidelines are designed for each evaluator to administer the tests in the same way. In summary, different evaluators should obtain the same responses from the same participants. The following guidelines are required to promote standardization:

- o It is important to develop a **trusting relationship** with the participant so that he/she feels comfortable with the evaluator. Although cognitive tests are not physically invasive, participants often feel exposed when performing these tasks. Evaluators need to be mindful of creating a safe and trusting environment so that the participants can be honest and give their best.
- o Inform participants that many of the tests are designed to be difficult and that no one does them perfectly. **We simply want them to do their best and answer as accurately and honestly as possible.**
- o During the test, **the evaluator does not provide verbal or non-verbal responses that may influence the answers.** Examples of this could be e.g. showing surprise, liking or disapproval of an answer. The assessor must be honest and not be influenced by the answers.
- o **The evaluator should be thoroughly familiar with all tests and questionnaires before administering them.** This will allow the participant's questions and concerns to be more easily addressed. It is recommended that each evaluator practice several tests with other staff members on a routine basis to ensure that no unintentional changes are made in the test administration.
- o The evaluator must **treat all subjects with respect and patience**, regardless of how they dress, speak, and act.
- o Must **read all test instructions "verbatim"** on both practice and actual tests.
- o You must **administer the tests in the order according to the protocols.** The sequence is essential for the maintenance of standardization.
- o Try to provide as **little explanation as possible.**
- o **You should avoid interpreting or paraphrasing test instructions** or questions as this may alter the meaning.
- o You may not help in completing a task unless it is specifically allowed in the instructions.
- o **You may not post any score sheets in a place where the participant can see them.**
- o You must **elicit and record the answers**, not suggest any answers.

If participants ask for **assistance during the test**, respond with: “I **cannot provide reminders** or instructions during the test. Please **answer to the best of your ability.**”

If necessary, give phrases of encouragement between tasks, but do not give information regarding the correction of answers, nor hints for the execution of the answers. If the participant persists in asking how their score was, simply state that you are not allowed to give feedback. Examples include:

*"Hazlo lo mejor que puedas"*

*"Estás haciendo lo que se te pide que hagas"*

*"Estas pruebas fueron diseñadas para que nadie pudiera hacerlas de forma perfecta"*

## 5. Index of Annexes Cognitive Tests

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- Annex.5.2. MoCA\_Identification
- Annex.5.3. MoCA\_Manual
- Annex.5.4. Process\_test
- Annex.5.5. Home\_base

## 6. References

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