DMP TITLE: COGNITIVE CONTROL IN AN AGING SOCIETY

ADMINISTRATIVE DETAILS

Project Name: Cognitive Control in an aging society

Principal Investigator / Researcher: PIs: Eva Van den Bussche and Céline Gillebert

Researchers (PhD): Elise Palmans and Febe Demeyer

Institution: KU Leuven

Description: We live in an aging society, which is accompanied by increasing challenges at the individual, interpersonal, clinical, and societal level. The aging challenge also consists of a rise in the number of older adults suffering from neurological disorders such as stroke. At the same time, our world is also becoming increasingly more complex: it requires efficient and flexible cognitive skills, such as cognitive control. We are continuously bombarded with sensory input. Our cognitive system needs to selectively process relevant input, maintain this input and inhibit irrelevant input, to achieve our goals. However, precisely these cognitive control skills gradually deteriorate with age and can suddenly be affected after stroke. As pharmacological treatments for cognitive decline have limited efficacy, there is an urgent need for non-pharmacological methods to address cognitive impairment. This project specifically aims to unravel the behavioral and neural mechanisms underlying impairment in cognitive control in healthy older adults and stroke survivors. To achieve this, four objectives are formulated. First, we will pinpoint which, when and how cognitive control functions decline in healthy aging. Second, we will expose neural markers and networks of cognitive control decline in healthy aging. Third, we will unravel patterns of stroke-induced cognitive control deficits in stroke survivors. Fourth, we will map the lesion neuroanatomy of post-stroke cognitive control deficits at the network level. To reach these objectives, we propose a multi-method approach, combining cross-sectional, longitudinal and patient studies, behavioral and neuroimaging (EEG and fMRI) techniques and advanced statistical tools (structural equation modeling, network and connectivity analyses). Ultimately, this project will provide the basis for developing new, non-pharmacological intervention programs to delay, decelerate or decrease cognitive control impairment.

1. GENERAL INFORMATION

Name of the project lead (PI): Cognitive control in an aging society
Internal Funds Project number & title: Cognitive control in an aging society (**PXF-E0434-C14/21/046**)

2. DATA DESCRIPTION

2.1. Will you generate/collect new data and/or make use of existing data?

We will collect and generate new data, and use collected data for clinical purposes (e.g., medical reports).

2.2. What data will you collect, generate or reuse? Describe the origin, type and format of the data (per dataset) and its (estimated) volume. This may be easiest in a numbered list or table and per objective of the project.

Type of data	Format	Volume	How created?
Research data			
Experimental data: behavioral performance,	Excel (.xlsx, .csv)	± 12,5 GB	Automatically by Python script, run in

namely accuracy and reaction time (Obj 1 + 2 + 3 + 4)		Obj 1 + 2: about 1731 participants: 201 younger adults + 405 older adults + 225 older adults who will be followed for 5 additional time moments) Obj 3 + 4: about 112 participants: 64 stroke patients + 48 controls	PsychoPy Experiment Runner
Merged experimental behavioral data (Obj 1 + 2 + 3 + 4)	Excel (.xlsx, .csv)	± 0,5 GB	Experimental data will be merged over participants, using R
SPSS datasets of raw & aggregated behavioral data (Obj 1 + 2)	SPSS (.sav, .spss)	± 0,25 GB	SPSS
R datasets of raw & aggregated behavioral data (Obj 1 + 2 + 3 + 4)	R data file (.RDS)	± 0,25 GB	R
Experimental data: EEG data (Obj 2)	.bdf (specific BioSemi EEG format)	About 75 GB	Saved in ActiView (BioSemi software for EEG data collection)
Experimental data: EEG data - preprocessed (Obj 2)	.set and .ftd	About 80 GB	Processed in EEGlab (Matlab package)
Experimental data: structural (MRI and CT) and functional (MRI) brain imaging data, and reports of radiologists (Obj 4)	DICOM, NIfTI and text (.txt)	About 192 GB (FLAIR and rs-fMRI data of 64 stroke patients & task-related fMRI data of 48 matched older adults)	Processed in SPM (Matlab package)
Demographics and health questionnaire (e.g., age, biological sex, education level, handedness, color blindness, sleep, coffee and alcohol use, medical history,…) (Obj 1 + 2 + 3 + 4)	On paper, data transferred to Excel (.csv)	Obj 1 + 2: 201+ 405 + 5 follow-ups for 225 older adults = about 1731 paper versions Obj 3 + 4: 64 stroke patients + 48 matched healthy controls = about 112 paper versions	Completed by the participant during the experiment Assessment by the experimenter in stroke patients
NASA Task Load Index (Obj 1 + 2)	On paper, pdf (.pdf)	about 1731 paper versions	Completed by the participant during the experiment

Montreal Cognitive Assessment (Obj 1 + 2)	On paper	About 405 paper versions + (225x5) = 1530 paper versions	Assessment by the experimenter during the experiment
Geriatric Depression Scale (Obj 1 + 2)	On paper	About 405 + (225x5) = 1530 paper versions	Completed by the participant during the experiment
Subjective Cognitive Decline Questionnaire (Obj 1 + 2)	On paper	About 405 + (225x5) = 1530 paper versions	Completed by the participant during the experiment
Oxford Cognitive Screen (Obj 3 + 4)	On paper, scanned paper file saved as pdf, Excel (.csv)	112 paper versions + about 900 MB pdf and Excel: 64 stroke patients + 48 matched healthy controls	Assessment by the experimenter during the experiment
Cognitive Failures Questionnaire (Obj 3 + 4)	On paper, scanned paper file saved as pdf, Excel (.csv)	112 paper versions (1 page each) + 90 MB (scanned paper file per participant) + 10 MB (Excel): 64 stroke patients + 48 matched healthy controls	Questions asked by the experimenter to the participant
Documentation			
Informed consents (Obj 1 + 2 + 3 + 4)	Word (.docx), pdf (.pdf) generated, printed for participant	Obj 1 + 2: about 1731 paper versions Obj 3 + 4: 112 paper versions	Self-generated, signed by participant before start experiment
Information letters (Obj 1 + 2 + 3 + 4)	Word (.docx), pdf (.pdf) generated, printed for participant	Obj 1 + 2: about 1731 paper versions Obj 3 + 4: 112 paper versions	Self-generated, signed by participant before start experiment
Annex COVID-measures (Obj 1 + 2 + 3 + 4) → As long as annex is needed	Word (.docx), pdf (.pdf) generated, printed for participant	Obj 1 + 2: about 1731 paper versions Obj 3 + 4: 112 paper versions	Created in Word, printed
Debriefing participants (Obj 1 + 2 + 3 + 4)	Word (.docx), pdf (.pdf) generated, printed for participant	Obj 1 + 2: about 1731 paper versions Obj 3 + 4: 112 paper versions	Created in Word, printed
Patient reports (Obj 3 + 4)	Word (.docx), pdf (.pdf) generated	64 stroke patients	Generated by Rmarkdown
Code for patient reports (Obj 3 + 4)	Rmarkdown (.Rmd)	64 stroke patients	Created in Rmarkdown in Rstudio

Reminder e-mails to young adult participants in EMS (Obj 1)	EMS-messages	201 e-mails	Written in Word, sent with EMS
Overview of registration participants (Obj 1 + 2 + 3 + 4)	Excel worksheet (.xlsx)	100 KB	Completed by experimenter(s) in Excel
Manual study protocol + data collection (Obj 1 + 2)	Word (.docx)	46 KB	Written in Word
Manual study protocol + data collection (Obj 3 + 4)	Word (.docx)	5 MB	Written in Word
EEG preprocessing manual (Obj 2)	Word (.docx)	6.7 MB	Word + screenshots from EEGlab (Matlab package)
Manual for lesion delineation (Obj 4)	PDF (.pdf), R-code (.R)	40 MB	Written in Word, code for analysis in RStudio
Manual for MRI data processing and analysis (Obj 4)	Word (.docx)	3.8 MB	Word
Code for computer tasks + adapted version for stroke population (Obj 1 + 2 + 3 + 4)	Python (.py)	± 320 KB	Created in Python / PsychoPy
Code for data cleaning (Obj 1 + 2 + 3 + 4)	SPSS-syntax (.spss)	± 32 KB	SPSS
Code for analysis (Obj 1 + 2 + 3 + 4)	R-code (.R),	< 1 MB	RStudio
Scoring grids for paper questionnaires (Obj 1 + 2 + 3 + 4)	Images (.jpeg)	± 13 MB	Images that are created by scanning the relevant information from a book
R code to merge individual datasets into merged datasets (Obj 1 + 2 + 3 + 4)	R-code (.R)	15 KB	RStudio

3. ETHICAL AND LEGAL ISSUES

3.1. Will you use personal data? If so, shortly describe the kind of personal data you will use. Add the reference to the file in KU Leuven's Record of Processing Activities. Be aware that registering the fact that you process personal data is a legal obligation.

- Yes

We will use **demographic information** such as age and biological sex. Additionally, we will register **participants' signatures** on the informed consent, together with the name and contact information (e-mail address, telephone number) of the participant. Contact details are only provided if the participant want to be informed about the (group-level) outcome of the study. Also, **personal data concerning health** will be processed in this project. More specifically, we will check the presence of neurocognitive, neurological, psychiatric disorders,

and cancer treatment in the last two years. The presence of bad or impaired vision, hearing and colorblindness will also be checked. In addition, medication intake, depressive symptoms, drug or alcohol abuse and current sleep/alcohol/coffee pattern will be processed. All data will be **pseudonymized**.
We will submit a **PRET application** for each Work Package (WP) for ethical review to ensure we fulfill the legal obligations and our handling of personal data. These applications and their approvals will be added to this DMP. All studies will be approved by an ethics committee before initiation of our studies.

3.2. Are there any ethical issues concerning the creation and/or use of the data (e.g. experiments on humans or animals, dual use)? If so, add the reference to the formal approval by the relevant ethical review committee(s).

- Yes

We will submit PRET applications for all our upcoming WPs. All studies will be approved by the ethics committee before initiation to ensure that we fulfill legal obligations of personal data. Part of the first work package of Objective 1 has already received ethical approval (G-2020-1679-R3(AMD)).

3.3. Does your research possibly result in research data with potential for tech transfer and valorisation? Will IP restrictions be claimed for the data you created? If so, for what data and which restrictions will be asserted?

- No

3.4. Do existing 3rd party agreements restrict dissemination or exploitation of the data you (re)use? If so, to what data do they relate and what restrictions regarding reuse and sharing are in place?

- No

4. DOCUMENTATION AND METADATA

4.1. What documentation will be provided to enable understanding and reuse of the data collected/generated in this project?

First, each programming task is accompanied by a **ReadMe text file** (.txt) with details about the number of trials, different conditions, a task description, etc. Second, **explanatory comments** will be added to all coding scripts for clarification so that third parties and we ourselves are able to understand the code and reproduce it in the future. Third, details on the several steps of all analyses and data cleaning (behavioral, EEG and MRI) will be noted in different **Word files**. Finally, we will also make a **codebook** in an Excel-document to provide specific information about the experimental data and questionnaires, such as the variable labels, their description and ranges.

4.2. Will a metadata standard be used? If so, describe in detail which standard will be used. If not, state in detail which metadata will be created to make the data easy/easier to find and reuse.

- No

The meta-data will consist of a Read me.txt, codebook.xlsx, cleaning and analysis Word files to process the raw data into merged files that are ready for analysis. Descriptive meta-data

will also be provided. Here, we will describe pseudonymized information about all participants that were enrolled in the study (e.g., age, biological sex, native language, handedness, which phases of the study they completed and when, whether they completed the entire study or dropped out, whether they meet the inclusion criteria, other remarks, etc). In addition, unique identifiers (DOI) will be added to the pseudonymized data on the Open Science Framework to make the data easy to find. We will seek the advice of colleagues in our discipline and research support staff at KU Leuven to decide which metadata standard (if any) is appropriate for this project. See also previous question for more detailed information about the specific meta-data.

5. DATA STORAGE AND BACKUP DURING THE PROJECT

5.1. Where will the data be stored?

Data will be stored on the secured KU Leuven network drives of the researchers (Elise Palmans and Febe Demeyer) and of the supervisors (Eva Van den Bussche and Céline Gillebert) and on a **password-protected and encrypted external hard drive**. The KU Leuven network drive is the university's secure environment for private data, the KU Leuven **OneDrive for Business**. Paper material (e.g., questionnaires) will be stored in a **locked closet** at the supervisors' offices. Only the main researchers will have access to personal data (i.e., informed consents, screening data). We will also use the **J-drive**, which is a shared network drive that is primarily intended for sharing files with colleagues. Here, we will store data that is relevant for all researchers of this project.

5.2. How will the data be backed up?

Automatic backup is provided for the KU Leuven OneDrive for Business.

5.3. Is there currently sufficient storage & backup capacity during the project? If yes, specify concisely. If no or insufficient storage or backup capacities are available, then explain how this will be taken care of.

- Yes
  The KU Leuven OneDrive for Business has a storage capacity of 2 terabytes (TB) (https://admin.kuleuven.be/icts/services/onedrive). This capacity can be extended to 5 TB without costs. Therefore, we do not anticipate insufficient storage or backup limitations.

5.4. What are the expected costs for data storage and backup during the project? How will these costs be covered?

Usage of the KU Leuven OneDrive for Business is free. Therefore, there are no expected costs.

5.5. Data security: how will you ensure that the data are securely stored and not accessed or modified by unauthorized persons?

Since we will be working with sensitive personal data, the data will be stored on KU Leuven OneDrive for Business, based on the recommendations made by KU Leuven. The laptops of the researchers are fully encrypted and password-protected, and a two-step verification is provided for the KU Leuven account. In addition, the J-drive is also fully encrypted and password-protected and is only accessible to the involved researchers using their employee ID. If files need to be transferred after data collection, the Belnet filesender will be used as an alternative to OneDrive for Business.

6. DATA PRESERVATION AFTER THE END OF THE PROJECT

6.1. Which data will be retained for the expected 10 year period after the end of the project? If only a selection of the data can/will be preserved, clearly state why this is the case (legal or contractual restrictions, physical preservation issues, ...).

All relevant data (i.e., data at the basis for publications), will be preserved after the end of the project alongside a codebook (Excel-file), explaining the data. We will ensure that personal information, which also contains identifiable information, is properly protected by clearly indicating which files contain personal information and we will pseudonymize all relevant files. The pseudonymized data will also be made publicly available through the Open Science Framework (https://osf.io/) for an indefinite period. Data will be retained for at least 10 years, conform the KU Leuven Research Data Management policy.

6.2. Where will these data be archived (= stored for the long term)?

To archive data securely at the end of the project, we will store all digital data on the KU Leuven OneDrive for Business of the supervisors (with automatic back-up procedures) for at least 10 years after the end of the project, conform the KU Leuven RDM policy. Paper data will be stored in a closed locket of the supervisors (Eva Van den Bussche and Céline Gillebert), organized in a folder per study. Pseudonymized data will be made publicly available through the Open Science Framework.

6.3. What are the expected costs for data preservation during these 10 years? How will the costs be covered?

Data preservation on the KU Leuven OneDrive for Business and Open Science Framework is free of charge. Storage capacity on the OneDrive for Business can be extended to 5 TB without costs. We do not expect to exceed 5 TB. In case we do exceed this limit, possible expenses will be covered by the research groups.

7. DATA SHARING AND RE-USE

7.1. Are there any factors restricting or preventing the sharing of (some of) the data (e.g. as defined in an agreement with a 3rd party, legal restrictions or because of IP potential)?

- Yes

Since we will be working with personal data, legal restrictions (e.g., GDPR) are in place. Only pseudonymized data will be shared.

7.2. Which data will be made available after the end of the project?

All coded, pseudonymized data will be openly available with a DOI at the Open Science Framework, which is an open access repository. All pseudonymized datasets only contain variables that are required to reproduce the results of our studies.

We will also share our data according to the FAIR principles to increase the impact of our research and increase the possibilities to replicate our research:

- **Findability**: We will ensure that the data are findable by assigning meta-data to our data folders and by using a DOI that will be given to the data.
- **Accessibility**: We will ensure that the data are accessible by indicating how others can get access to the data. A http protocol will be included to make the data available through the Internet.

- **Interoperable**: We will ensure the data are interoperable by using open file formats and standards whenever needed and possible.
- **Reusable**: We will ensure the data are reusable by connecting them with highly qualitative documentation and metadata.

7.3. Where/how will the data be made available for reuse?

- In an Open Access repository

The coded, pseudonymized data will be made openly available in a .csv format at an open access repository, the Open Science Framework. Participants' personal information (e.g., contact information, names, bank account, medical background, etc) will never be shared.

7.4. When will the data be made available?

- Immediately after the end of the project

The coded and pseudonymized data will be made openly available in a .csv format after the end of the project at the Open Science Framework, which is an open access repository.

7.5. Who will be able to access the data and under what conditions?

The coded, pseudonymized data will be made openly available.

7.6. What are the expected costs for data sharing? How will these costs be covered?

There are no expected costs for sharing the data at the Open Science Framework as this is free of charge.

8. RESPONSIBILITIES

8.1. Who will be responsible for the data documentation & metadata?

The researchers: Elise Palmans and Febe Demeyer.

8.2. Who will be responsible for data storage & back up during the project?

The researchers: Elise Palmans and Febe Demeyer. The supervisors (Eva Van den Bussche and Céline Gillebert) are responsible for ensuring that the researchers implement research data management.

8.3. Who will be responsible for ensuring data preservation and sharing?

The researchers: Elise Palmans and Febe Demeyer are responsible for data preservation and sharing during the project. After the research project ends, preservation and reuse of the data is the responsibility of the supervisors, Eva Van den Bussche and Céline Gillebert.

8.4. Who bears the end responsibility for updating & implementing this DMP?

The supervisors, Eva Van den Bussche and Céline Gillebert, are responsible for ensuring that the researchers (Elise Palmans and Febe Demeyer) update and implement this Data Management Plan. The supervisors bear the end responsibility.