Added value of functional neuroimaging to assess decision-making capacity of older adults with neurocognitive disorders: protocol for a prospective, monocentric, single-arm study (IMAGISION)

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Added value of functional neuroimaging to assess decision-making capacity of older adults with neurocognitive disorders: protocol for a prospective, monocentric, single-arm study (IMAGISION)

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ABSTRACT

Introduction Assessment of decision-making capacity (DMC) is essential in daily life as well as for defining a person-centred care plan. Nevertheless, in ageing, especially if signs of dementia appear, it becomes difficult to assess decision-making ability and raises ethical questions. Currently, the assessment of DMC is based on the clinician's evaluation, completed by neuropsychological tests. Functional MRI (fMRI) could bring added value to the diagnosis of DMC in difficult situations.

Methods and analysis IMAGISION is a prospective, monocentric, single-arm study evaluating fMRI compared with clinical assessment of DMC. The study will begin during Fall 2021 and should be completed by Spring 2023. Participants will be recruited from a memory clinic where they will come for an assessment of their cognitive abilities due to decision-making needs to support ageing in place. They will be older people over 70 years of age, living at home, presenting with a diagnosis of mild dementia, and no exclusion criteria of MRI. They will be clinically assessed by a geriatrician on their DMC, based on the neuropsychological tests usually performed. Participants will then perform a behavioural task in fMRI (Balloon Analogue Risk Task) to analyse the activation areas. Additional semistructured interviews will be conducted to explore real life implications. The main analysis will study concordance/discordance between the clinical classification and the activation of fMRI regions of interest. Reclassification as 'capable', based on fMRI, of patients for whom clinical diagnosis is 'questionable' will be considered as a diagnostic gain.

Ethics and dissemination IMAGISION has been authorised by a research ethics board (Comité de Protection des Personnes, Bordeaux, II) in France, in accordance with French legislation on interventional biomedical research, under the reference IDRCB number 2019-A00863-54, since 30 September 2020. Participants will sign an informed consent form. The results of the study will be presented in international peer-reviewed scientific journals, international scientific conferences and public lectures.

Strengths and limitations of this study

- This study deals with a common problem in daily practice, with a mixed approach between clinical, functional MRI (fMRI) and comprehensive analysis by interviews.
- The methodology used, based on the successive recruitment of participants, allows an exhaustive approach, avoiding selection bias.
- However, the heterogeneity of the cognitive profiles, as well as the small size of our sample and the monocentric design of the study may lead to some limitations in the extrapolation of the results.
- Because of its cost and limited availability, fMRI cannot be a tool that can be used in routine practice for all patients—it will therefore be necessary, in the long term, to determine the particularly complex clinical situations that justify the use of such tools.
- A larger and longer, multicentre study will be necessary in the future to validate the clinical use and to conduct subgroup analyses according to cognitive profiles and complexity situations.

Trial registration number NCT03931148

INTRODUCTION

It is during the ageing of patients, particularly those with multiple pathologies, and in whom cognitive disorders appear, that the most complex and ethical questions arise[1 2] both in the medical field (advance directives, decisions to continue, implement, limit or stop treatments, investigations or not) and in the medicosocial and social fields (organisation of home support, institutionalisation, etc). In this context, these patients are frequently referred to geriatric consultations or memory

centres for an overall assessment of their cognitive functions and their daily life skills in order to optimise their care plan and anticipate their medical and medicosocial outcome.[3 4] This person-centred care plan is therefore based on an assessment of the older person's life project and decisions concerning his or her future, in particular through the question of home care or institutionalisation.[5]

Assessment of decision-making capacity (DMC) is essential in this respect. However, the tendency is to consider decision-making autonomy in a binary mode, where autonomy is preserved versus affected, while in reality it is more like a continuum.[6] Indeed, the decision-making autonomy of older people with cognitive impairment is relative and dependent on their neuropsychological disorders and previous experiences they remember, as well as on the ability of their relatives to support them. Considering that the older person, particularly with neurocognitive impairment, is no longer competent to decide the living place for himself or herself, has a major impact. The result is often a procedure for placing them under legal protection or, at the very least, a daily questioning of their opinions and life choices.[1 7]

Decision-making refers to a process that includes several steps from analysing a problem to taking action to solve it.[8 9] In addition to mobilising the sensory functions necessary for communication and language skills involved in integration of information, decision-making involves complex neuropsychological processes. Indeed, decision-making is largely part of executive functioning and involves other processes such as flexibility, inhibition, working memory and emotion recognition.

Nowadays, evaluating decision-making skills of older adults with dementia or mild cognitive impairment is done through a global gerontological assessment[10] and, in various situations, multidisciplinary evaluations involving neuropsychologists and/or occupational therapists. In that way, cognitive assessment items such as the Mini-Mental Status Examination (MMSE)[11] or the Montreal Cognitive Assessment (MoCA)[12 13] can be combined with an assessment of life and instrumental life abilities.[14–16] Sometimes, when decision-making ability is clear, these tests and clinical interviews can be sufficient for clinicians in their assessment. But, more often, such simple assessments of cognitive functions are not sufficient to assess a phenomenon as complex as decision-making and need to be completed by complementary neuropsychological assessment exploring the different skills involved in decision-making ability. In order to analyse these different cognitive components necessary for decision-making, different evaluation scales exist, potentially used separately or combined: evaluation of apathy,[17] evaluation of social cognition,[18–20] evaluation of more specific executive functions such as inhibition, using the Stroop-Victoria Test,[21] and mental flexibility using the Trail Making Test,[22] evaluation of depressive risk using the 15-item Geriatric Depression Scale (GDS-15),[23] and, finally, evaluation of one's capacity for discernment using the Judgement Assessment Tool.[24]

However, to date, these tests are time-consuming and require training in their administration. Moreover, none of them is specific to DMC, and, as they cannot be done during the medical consultation, they must be performed during an additional neuropsychological assessment. Finally, because of their low specificity to decision-making, it is the global synthesis by the clinician which, in the end, determines the decisional aptitude. In certain situations, such as when patients maintain significant cognitive reserve capacities, or in the case of Diogenes syndromes, the complexity of the evaluation and the implications for the future of the older person in terms of choice of living environment, for example, lead to a need for a more specific 'objectification' of decision-making skills.

Several specific behavioural tasks have been developed to study DMC associated with risk-taking behaviour. These tasks model decision-making according to so-called 'under-risk' models (known probability of occurrence of an event) or 'under-ambiguity' models (unknown probability of occurrence of an event). Even if these tasks are not yet used in routine clinical practice, some of them have been tested even in subjects with neurocognitive disorders, as described in a recent systematic review.[25] Among these models, the Iowa Gambling Task (IGT) is a behavioural task for evaluating decision-making under conditions of uncertainty that has been studied extensively.[26 27] Other tests can be used, such as the Balloon Analogue Risk Task (BART), which is a decision-making assessment task associated with risk taking and allows the study of emotional and impulsivity components.[28] Their behavioural use may expose clinicians to the same limitations as the more traditional tests. Nevertheless, the development of functional imaging has made it possible to explore this under the neurological functional aspect in addition to behavioural approaches.[29] In this case, it is not so much the behavioural score that counts, but rather the analysis of brain function during the performance of a given task. This is particularly the case in functional MRI (fMRI) which is a neurological imaging technique whose main strength lies in its spatial resolution. Thus, this technique allows a fine analysis of the recruitment of the different areas, already known to be involved in decision-making tasks, such as the prefrontal dorsolateral and orbitofrontal cortex and the deep nuclei.[25 30 31]

To date, it is the clinician's assessment, based on a global analysis of their clinical evaluation and the neuropsychological assessment, which enables the decision-making ability to be assessed.[10] Given the difficulty it represents, and the ethical and societal issues raised, the research question concerns the contribution of neuroimaging technologies as an aid to the evaluation of DMC. The question which arises is therefore that of the development of diagnostic aid tools for complex situations in which the clinician is in difficulty. Thus, it appeared necessary to conduct a mixed clinical study, particularly to explore complex choice situations such as the decision to live at home versus moving to a nursing home in anticipation of the evolution of dementia. This study will

integrate different approaches: usual clinical assessment of decision-making abilities, advanced neuropsychological explorations and an evaluation of decision-making ability using functional neuroimaging. The study will be completed by analysing the arguments of patients, caregivers and geriatricians through qualitative interviews. The objective will be to evaluate the added value of functional neuroimaging (fMRI) to assess DMC of older adults with neurocognitive disorders. More specifically, the objective will be to determine if patients with 'questionable' decision-making abilities can by reclassified as 'able to make decisions for themselves' using activation of areas involved in risky decision-making during fMRI.

METHODS AND ANALYSIS

Study design

IMAGISION is a prospective monocentric single-arm study evaluating an innovative diagnosis procedure. As such, the usual recommendations for reporting are based on the STARD (Standards for Reporting of Diagnostic Accuracy Studies) methodology.[32] The study will begin in Fall 2021 at the University Hospital of Besançon (France) and should be completed in Spring 2023.

Participants

The study population will include older adults over 70 years of age, living at home, presenting neurocognitive disorders with impaired functional independence. These participants will need to be referred to the university hospital where the research takes place by their general practitioner for a geriatric cognitive assessment due to the need for complex decision-making especially associated with ageing in place (stopping driving, setting up home support) or moving to a nursing home. The assessment will be done through memory clinics, day care units or possibly week care to explore their neurocognitive disorders.

The inclusion criteria will be: subjects aged 70 years or older, including adults under legal protection; right-handed; with a suspected diagnosis of mild-to-moderate dementia based on clinical assessment (neurocognitive impairment with impact on activities of daily living); living at home and having at least one informal caregiver. The participants (or their legal representatives) will be asked to sign the informed consent form. Given the topic of the research, in order to avoid any doubt about the capacity to consent, it will be verified by the University of California, San Diego, Brief Assessment of Capacity to Consent (UBACC)[33]—French version[34] and the caregiver will be involved in signing the consent.

The criteria for non-inclusion will be the following: having a major neurocognitive disorder of moderate-to-severe intensity (based on clinical assessment and/or MMSE <15); subjects referred for consultation, but not presenting with dementia after clinical investigation (based on clinical assessment and/or MMSE >27 or MoCA>26); subjects presenting with a delirium syndrome (positive CAM (Confusion Assessment Method)) at the time of inclusion or presenting with a severe psychiatric pathology (in particular severe depression, score >20 on GDS-30); subjects presenting with phasic disorders not allowing neuropsychological explorations or a semi-directed interview; and contraindications to MRI scanning.

All patients corresponding to these eligibility criteria will be offered participation in the study, even if their DMC status seems obvious at the outset. Indeed, in order to identify the added value of neurofunctional imaging, it is necessary to include all eligible participants, and then to dissociate them, based on the analysis of individual characteristics, on the one hand, and the associated qualitative study, on the other hand. This will allow to analyse individual characteristics (patient's typology) and arguments explaining the results. Thus, patients will be included consecutively, subject to their consent, until the required number of subjects is reached (see below).

Test methods

Reference standard: clinician assessment of decision-making ability

The standard of reference for our study will be the clinician's assessment of the patient's decision-making ability on decision associated with ageing in place (stopping driving, setting up home support) or moving to a nursing home, within the context of a geriatric consultation or day/week hospital stay (figure 1).

This geriatric consultation or day/week hospitalisation includes, in a standardised way, the collection of data from a standardised gerontological evaluation (ADL (Activities of Daily Living), iADL (instrumental ADL), GDS-30), the evaluation of comorbidities (Charlson Index), a somatic examination including neurological and gait testing (gait speed), and the performance of cognitive tests such as MoCA or MMSE associated with Frontal Assessment Battery[35] to identify neurocognitive disorders.

If additional neuropsychological explorations are deemed necessary by the geriatrician to conclude on decision-making abilities, specific neuropsychological tests evaluating the different skills necessary for decision-making will be carried out. These tests are standardised and stratified according to age and level of education. These additional neuropsychological tests within the context of this research project may assess:

- Executive functions using the Stroop-Victoria Test[21] and the Trail Making Test.[22]
- Judgement abilities with the Judgement Assessment Tool.[24]
- Anosognosia using AQ-D (Anosognosia Questionnaire for Dementia.).[36]
- Apathy using the Apathy Inventory.[17]
- Social cognition using the mini-SEA face task.[18–20]

The limits used to identify normal or pathological values of these neuropsychological tests are determined based on cut-off scores and Z-scores calculated from available age and education-derived norms. These data, standardised, are described in main publications or on French

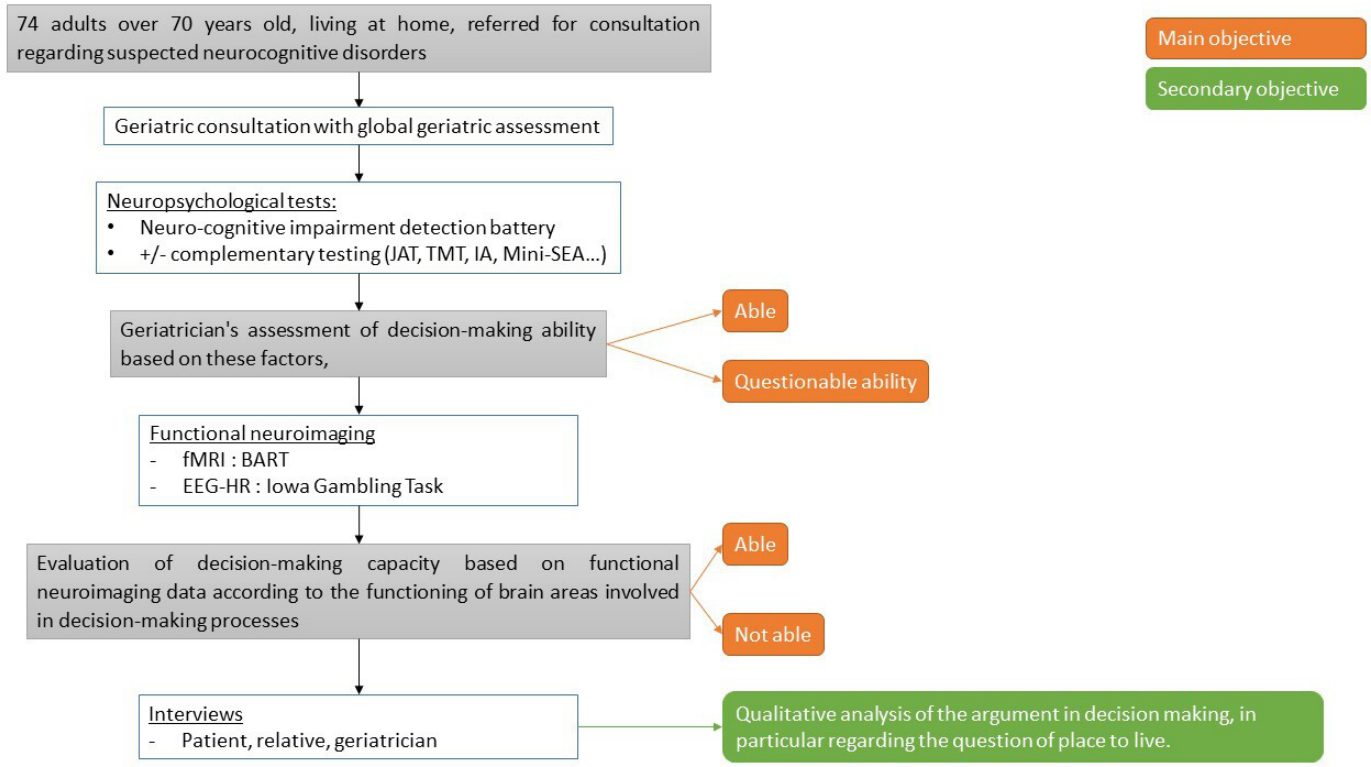

Figure 1 Flow chart. BART, Balloon Analogue Risk Task; EEG-HR, high-resolution electroencephalography; fMRI, functional MRI; IA, Inventaire Apathie; JAT, Jugement Assessment Tool; SEA, Social cognition and EmotionaL Assesment; TM, Trail Making Test.

validation of the test. Some authors have developed tools to help clinicians calculate scores:

- For the Stroop-Victoria Test, see https://psitec.univ-lille3.fr/wp-content/uploads/2017/08/1-Stroop_Victoria-feuille_cotation.xls.
- For the Judgement Assessment Tool, see https://aqnp.ca/research/jat/.

At the end of the initial consultation, the geriatrician will classify each patient either as 'preserved decision-making ability' or 'questionable decision-making ability'.

Depending on the additional tests that have been spontaneously performed during the consultation, the patient will be rescheduled to perform the other tests in order to complete the data collection. The patient will also be scheduled for a second appointment to perform the functional neuroimaging evaluation (index test). Finally, a semidirected interview will be conducted with the patient and his caregiver, to specifically explore the question of the ageing in place and its consequences.

In order to harmonise the clinician's evaluation and to avoid personal bias, the clinical records of each participant will be presented and validated by a medical team including the geriatricians and neurologists involved in this study. This is where the final consensus on the clinical decisional aptitude of each patient will be decided. This harmonisation of classifications will be done on the basis of the data collected during the consultation, and blind to the complementary neuropsychological, semidirected interview and functional neuroimaging data.

Index test: functional neuroimaging

The assessment of the clinician's decision-making ability will be compared with the activation of the brain areas of interest involved in decision-making, during the performance of a decision-making task under risk, the BART. Behavioural data from this decision-making task will not be interpreted in the primary analysis.

The paradigm used will be derived from the Lejuez paradigm,[28] and will consist of three sessions of 20 blocks, comparing control balloons (no active decision) and balloons with a random probability of explosion, representing decision-making under uncertainty. The period of interest will represent the decision phase to continue the inflation of the balloon or to put virtual money into a virtual kitty.

fMRI predetermined regions of interest (ROIs) involved in decision-making ability[31] will include, namely

- The dorsolateral prefrontal cortex.
- The orbitofrontal cortex.
- The insula.

Patients who present with at least homolateral activation of one of the above-mentioned ROIs during the time of decision to inflate the test balloons or to put money into the kitty will be considered as 'compatible with the ability to make decisions' on neurofunctional imaging, while patients who do not activate the ROIs in the same situation will be considered as 'compatible with questionable decision-making ability'.

Neurofunctional analyses will be blinded to the clinical and neuropsychological data used as the basis for the standard reference.

Whenever possible, patients will also have a high-resolution electroencephalography (EEG-HR) examination. Indeed, while fMRI is distinguished by its high spatial resolution, EEG-HR studies more specifically the temporality in cognitive functioning. Many studies point to the impact of the slowing down of the processing speed in cognitive ageing, which makes the realisation of a task in EEG-HR a relevant complementary data. Nevertheless, in case of fatigue or difficulty, fMRI will be preferred, and EEG-HR will only be used as complementary data. In EEG-HR, patients will perform a validated decision task (IGT) adapted to EEG-HR, and simplified to a binary decision.[30] The interest will be on amplitude of the P300 (positive wave at 300 millisecondes) and FRN (Feedback-Related Negativity) waves.

Complementary information: qualitative interviews

Analysing how the patient develops an argument concerning the choice of the place of living will be carried out by semidirected interviews. They will be conducted with the patient, their caregiver, and a home professional. As much as possible, the interview will be conducted at home. In that case, an observation grid of the living environment will be associated. The objective of the interview (see Interview guide in table 1) with the patient is to identify the way in which the awareness of the cognitive pathology impacts, or not, the DMC, mainly to decide place to live, and to identify how the argument is constructed. But the interview will also look at whether decision-making ability affects other areas of life (eg, driving), and how these are managed by the participant and/or their relatives. Anosognosia, impulsive decision-making and endangerment will be explored by triangulation with the relative and the referring healthcare professional.

To validate the clinical relevance of the research, at the end of the analysis, a synthetic presentation of the results will be presented to the clinician in charge of the patient, and he/she will be asked to indicate whether these elements modify his/her clinical judgement, and if so, on which arguments, and on which specific decision-making impact.

Table 1 Interview guide

Main intervention	Elements to explore
You were contacted for this study because you are being cared for by Dr X. Can you tell me what made you consult him?	► How was the decision to consult made? – By whom? – After how long of evolution?
Following this consultation, a diagnosis of cognitive impairment was made. I would like to discuss this diagnosis with you. What do you think your illness is?	► Perception of cognitive illness – Diagnosis ? – Impact on daily life? – Impact on caregivers?
Has this diagnosis changed your way of life? *If needed:* ► *For example, tell me about your day yesterday.* ► *Now, and following the announcement of this disease, what helps you in your life?*	► Perception of residual independence ► Support organisation ► Role of the activities: – Therapeutic (day care, etc) – Leisure time ► Role of family caregivers
Dr. X had told you about this study. How did the decision to participate come about? In your daily life, are you confronted with situations that require you to make decisions?	► Perception of what a decision is ► Perceived residual decision-making capacity ► Perceived impact of memory impairment on decision-making
How do you think your memory loss and/or cognitive impairment will affect your future life?	► Perception of vulnerability ► Perceived loss of functional independence ► Perceived loss of decision-making autonomy
I would like to talk a little about your home. Could you describe it to me?	► Perception of the strengths and weaknesses of the habitat ► Perceived emotional attachment to the home ► Assessment of the ability to describe the physical location
Talking about your home, how would you like to live in the future?	► Exploring attachment in the home ► How the issue of habitat was previously addressed (was it addressed?)
Do you think that the evolution of your disease could lead you to change your residence?	► Exploring vulnerability in the home
Thank you for that. Before we finish, is there anything else you would like to add? Something we haven't talked about that you think is important to add?	

This will identify situations in which this reclassification would make clinical sense by leading to a change in the assessment made by the clinician.

Analysis

Statistical methods description

Quantitative data will be described in the following way: number, mean, SD, quartiles and extreme values. Qualitative and semiquantitative data will be described with the frequency and proportion of each modality.

The main statistical analysis will consist of a descriptive analysis of the concordance/discordance data between the standardised global gerontological assessment (clinical consultation supplemented by neuropsychological tests to establish the clinical diagnosis of decision-making ability) and the objectification of the activation areas by functional imaging.

- Concordance: corresponds to situations where the clinical assessment is consistent with the fMRI activation pattern. A distinction is made between:
  - Positive concordance corresponds to a positive neuropsychological evaluation (able patients=no cognitive impairment impacting decision-making) and activation of ROI on fMRI.
  - Negative concordance corresponds to a negative neuropsychological evaluation (patients with doubt about ability, that is, presence of cognitive disorders impacting decision-making) and the absence of activation of ROI of fMRI;
  - Absolute concordance or global concordance is the sum of the positive concordance and the negative concordance;
- Discordance: corresponds to situations where the clinical assessment is discordant with the fMRI activation pattern.

Each proportion will be presented with its 95% bilateral CI.

Statistical strategy

McNemar's χ^2 test and Cohen's κ will be used to study the correlation between fMRI, EEG and standardised neuropsychological and gerontological consultations (2*two crosses: decision-able/doubtful decision-able).

Activation data from functional imaging (fMRI, EEG) will be coded as two-modality categorical variables (ability/doubt about ability) and will be linked to neuropsychological tests of executive skills, social cognition, apathy assessment, decision-making and depression tests using regression models according to their distribution. Normality of the data will be tested using the Shapiro-Wilk test. If this is not verified, non-parametrical tests will be used.

Student's t-test or the non-parametrical Wilcoxon test will allow to compare respectively the means or the ranks of each test (mentioned above) according to the aptitude result from the functional imaging. A multivariate analysis of variance will be used to study the relationship between decision-making ability based on functional imagery and the joint neuropsychological test battery (possibly adjusted for age, gender, comorbidities, etc).

Diagnostic strategy validation

A pathway tree will be created for each subject and then for each group of subjects, which will make it possible to visualise the contribution of each tool to the 'diagnostic' classification strategy (able/doubtful on ability).

This arborescence will allow the identification of situations that lead to divergent evaluations between imaging, neuropsychological tests and global gerontological evaluation. The individual characteristics of discordant subjects whose evaluation could be qualified as complex will be studied in order to confirm or invalidate the imaging diagnosis (according to clinical plausibility in particular).

After having confronted the various explorations, a *diagnostic gain is expected* in complex situations due to functional neuroimaging (discordance in non-able people with objectification of the activation of the ventromedial and dorsolateral prefrontal cortex areas).

Number of subjects needed

Based on the following hypothesis:

- A 90% positive concordance and a 90% negative concordance; that is, a *10% gain*.
- A 2:1 split between patients with doubt about ability and able patients (estimate based on clinical practice).
- A 95% bilateral CI

It is necessary to include 74 subjects in our cohort to obtain the expected result. Expectation of the overall precision is around 15% (based on hypothesis 1, 2 and 3 and overall agreement of 90% (0.81; 0.96)), using an exact estimation method (Clopper-Pearson).

Intermediate analyses

It is anticipated to conduct a preliminary analysis halfway through the recruitment (36 subjects) to estimate participant ability profile, to adapt, if necessary, the number of participants required.

Analysis of missing and/or incomplete data

The analysable population of the study will consist of all included patients who meet the eligibility criteria (inclusion and non-inclusion) and who have not refused the use of their data. Patients who have been withdrawn from the study will not be analysed.

No additional enrolment is planned; patients for whom imaging results are not usable will be substituted after agreement with the principal investigator. For the primary outcome, the statistical analysis will be based on complete data (no statistical procedure for replacing missing data). All the data filled in at the different times of the study relating to the analysable population will be used.

Results organisation

The quantitative analysis results will be organised according to the following elements:

- The cohort data will be compared between patients identified as 'questionable ability' according to the

clinical evaluation (reference) and the neuroimaging evaluation, in order to see if the imaging allows to reclassify patients as 'able'. To do this, the neuroimaging examinations will be performed blinded to the clinician's assessment.

- In addition, the results of the functional neuroimaging tests will be analysed in comparison with the neuropsychological tests performed, to verify the correlation between the results of the neuropsychological tests of decision-making ability and the results of the neuroimaging tests, and thus to identify, among the battery of tests used, those that are the most discriminating in the evaluation of decision-making ability. In addition, the correlation between patients classified as 'able' by the clinical evaluation and the neuroimaging will be verified since it establishes the validity of the process. Finally, the neuropsychological tests that will be carried out will allow us to identify the stage of neurocognitive disorders in patients. These elements can be correlated with the analysis of decision-making abilities in order to demonstrate a correlation between neurocognitive disorders, their stage and decision-making ability.

Methodology for qualitative analysis of interviews

All interviews will be transcribed anonymously and confidentially. Thus, the names of the places and persons mentioned in the interview will be pseudonymised. Rigorous analysis of the interviews is only possible if the content of the recording is transcribed in writing.

A thematic analysis will be conducted to build a thematic tree. The analysis of the qualitative data from the semistructured interviews follows the logic of grounded theory, which is based on the data collected, from which an explanatory theory answering the initial question is constructed.[37 38]

Pilot study

To implement our study, it was necessary to carry out a primary inclusion of archetypal patients in a pilot study. This pilot study was conducted at the Research Centre of the Institut Universitaire de Gériatrie de Montréal, Montreal, Quebec from January 2020. In accordance with the legislation in application in Quebec, the protocol for the pilot study has been validated by the ethical committee (Comité d'Ethique de la Recherche Vieillissement – Neuroimagerie) in Montreal, Quebec, under the identification CER VN 18–19 – 42, since 3 April 2019. The data collected are not part of the main study presented in this article.

The challenge of a pilot study was to proof our concept by ROI activation in fMRI during our task and the concordance with neuropsychological assessment. Other objectives were to verify the clinical feasibility of our protocol with older adults with cognitive impairment; and to verify that all relevant tasks and information can be recorded, both clinically and in fMRI.

Nevertheless, due to the consequences of the COVID-19 epidemic, the data collected before the successive lockdowns, of the frail older adults, were only complete for 4 older healthy subjects and 2 patients corresponding to the inclusion criteria for an objective of 12 older adults in each group. Although these data do not cover all the objectives of the pilot study, they are sufficient to prove our concept.

Patient and public involvement

Patients and the public were not formally involved in the IMAGISION study except through the participation of their representative in the ethical committees. Although the research question stems from clinical interactions with patients, they were not directly involved in the design of the protocol. The pilot study allowed, based on the feedback from the participants, an adaptation of the procedures, resulting in particular in a better organisation of fMRI time. Nevertheless a general public conference will take place at the end of the research, for which all participants will be invited. The data collected will be individually accessible on request, and may be transmitted by the referring geriatrician.

ETHICS AND DISSEMINATION

Ethical issues

The protocol presented has been validated by an ethics committee (Comité de Protection des Personnes - Bordeaux II), in accordance with French legislation on interventional biomedical research, under the reference IDRCB: 2019-A00863-54, since 30 September 2020. The participants or their legal representative has to sign consent to participate in the research. Given the topic, the capacity to understand and approve the consent must be verified using the UBACC checklist. All of these procedures have been updated to comply with COVID-19 pandemic health requirements.

Dissemination

The dissemination plan will contain the following elements: data from the pilot study (proof of concept and feasibility); preliminary data from the first 36 patients to support the distribution between 'able' and 'questionable ability' patients; final data.

All the results will be presented in international peer-reviewed scientific journals in the neurosciences and clinical fields and at international scientific conferences, and will be disseminated to stakeholders and participants through public conferences in Besançon and Montreal.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

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