

# Comparing digital cognitive assessment and blood biomarkers of dementia in older adults

<b>Submission date</b> 11/08/2020	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 17/08/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 21/12/2021	<b>Condition category</b> Nervous System Diseases	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Dementia is the loss of cognitive functioning (thinking, remembering, and reasoning) and behavioural abilities. Integrated Cognitive Assessment (ICA) is a computerised cognitive assessment tool based on image recognition and operating on the Apple iPad. The ICA uses artificial intelligence (AI)-based algorithms to distinguish between cognitively healthy and cognitively impaired participants. ICA is distinctive as it does not rely on language or education, does not require specialist clinicians to administer the test, and its duration is short (5-6 minutes). ICA is demonstrated to be free from learning bias (i.e. patients cannot memorise it after repeated use), so it can be used several times in shorter intervals to measure changes in cognition. The overall aim of this study is to assess the correlation of ICA with some of the key blood biomarkers of dementia in older adults.

### Who can participate?

Adults aged 50-90 with mild Alzheimer's dementia, mild cognitive impairment, or healthy volunteers

### What does the study involve?

Participants undergo a cognitive assessment using both the ICA and the Montreal cognitive assessment (MoCA). A blood sample will also be taken to measure the level of blood biomarkers (amyloid-beta, p-Tau, and NFL), and APOE genotyping.

### What are the possible benefits and risks of participating?

This study has a great potential to present a new approach to improve diagnostic accuracy by combining a digital biomarker with blood-based ones. Through participation in this study, participants will learn more about their cognitive status. The risks of participating in the study are generally low. Side effects from having blood drawn typically are quite minor, and may include bruising or minor swelling at the site of the injection, which can be soothed with an ice pack, and light-headedness or dizziness.

### Where is the study run from?

Royan Institute (Tehran, Iran)

When is the study starting and how long is it expected to run for?  
July 2020 to February 2021

Who is funding the study?  
Cognetivity Ltd (UK)

Who is the main contact?  
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## Additional identifiers

**EudraCT/CTIS number**

Nil known

**IRAS number****ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

CGN-2003

## **Study information**

**Scientific Title**

Association between the Integrated Cognitive Assessment (ICA) and fluid biomarkers of neurodegeneration

**Study objectives**

This study aims to explore the relationship between the ICA and blood biomarkers of neurodegeneration in healthy controls, patients with mild Alzheimer's disease and mild cognitive impairment.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Approved 03/08/2020, Tehran University of Medical Sciences research ethics committee (Central Building of Tehran University of Medical Sciences, Qods St., Keshavarz Blvd, Tehran, Iran, +98 (0) 21 64053419; ethics@behdasht.gov.ir), ref: IR.TUMS.MEDICINE.REC.1390.290

**Study design**

Observational case-control study

**Primary study design**

Observational

**Secondary study design**

Case-control study

**Study setting(s)**

Other

**Study type(s)**

Diagnostic

**Participant information sheet**

Not available in web format, please use the contact details to request a participant information sheet

**Health condition(s) or problem(s) studied**

Mild Alzheimer's disease (mild AD), mild cognitive impairment (MCI)

### **Interventions**

Participants undergo a cognitive assessment using both the ICA and the Montreal cognitive assessment (MoCA) at baseline. A blood sample will also be taken to measure the level of amyloid-beta, p-Tau, and NFL, and APOE genotyping.

### **Intervention Type**

Mixed

### **Primary outcome measure**

1. Serum amyloid-beta 40 and amyloid-beta 42 levels measured using ELISA test at baseline
2. Serum Phosphorylated Tau level measured using ELISA test at baseline
3. Serum Neurofilament light-chain (NFL) levels measured using ELISA test at baseline
4. Level of cognitive performance measured by ICA test at baseline

### **Secondary outcome measures**

1. APOE genotype determined by DNA sequencing at baseline
2. Level of cognitive performance measured by MoCA test at baseline

### **Overall study start date**

01/07/2020

### **Completion date**

01/02/2021

## **Eligibility**

### **Key inclusion criteria**

1. Capacity to understand the information about the study and to give consent to participate
2. Males and females aged between 50-90 years
3. Not currently on medication that may interfere with the study results
4. Healthy individuals; or individuals with specialist diagnosis of mild cognitive impairment or mild AD according to NINCDS-ADRDA criteria

### **Participant type(s)**

Mixed

### **Age group**

Senior

### **Sex**

Both

### **Target number of participants**

60

### **Key exclusion criteria**

1. Presence of significant cerebrovascular disease
2. Major medical co-morbidities e.g. Congestive Cardiac Failure, Diabetes Mellitus with renal

impairment

3. Major psychiatric disorder eg. Chronic psychosis, recurrent depressive disorder, generalized anxiety disorder
4. The use of cognitive-enhancing drugs e.g. cholinesterase inhibitors, unless on stable doses
5. A concurrent diagnosis of epilepsy
6. A history of alcohol misuse
7. A history of illicit drug use
8. A history of severe visual impairment, e.g. macular degeneration, diabetic retinopathy, as determined by the clinical team
9. A history of TBI
10. Presence of sleep apnoea

**Date of first enrolment**

20/08/2020

**Date of final enrolment**

30/01/2021

## **Locations**

**Countries of recruitment**

Iran

**Study participating centre**

**Royan Institute**

Banihashem Square

Banihashem Street

Ressalat Highway

Tehran

Iran

19395-4644

## **Sponsor information**

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Industry

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## Funder(s)

**Funder type**

Industry

**Funder Name**

Cognetivity Ltd

## Results and Publications

**Publication and dissemination plan**

Planned publication in a peer-reviewed journal. The protocol is not available online and there are no plans to publish the protocol or the statistical analysis plan.

**Intention to publish date**

01/12/2021

**Individual participant data (IPD) sharing plan**

The current data-sharing plans for the current study are unknown and will be made available at a later date

**IPD sharing plan summary**

Data sharing statement to be made available at a later date

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Basic results</a>			21/12/2021	No	No