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

Submission date
11/08/2020

Recruitment status
No longer recruiting

Registration date
17/08/2020

Overall study status
Completed

Last Edited
21/12/2021

Condition category
Nervous System Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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?
1. Dr Seyed-Mahdi Khaligh-Razavi (scientific)
Seyed@Cognetivity.com
2. Dr Zahra Vahabi (neurologist)
zvahabi@sina.tums.ac.ir
3. Chris Kalafatis (old age psychiatrist)
chris@cognetivity.com

Contact information

Type(s)
Scientific

Contact name
Dr Seyed-Mahdi Khaligh-Razavi

ORCID ID
https://orcid.org/0000-0002-5700-1704

Contact details
Cognetivity Ltd
3 Waterhouse Sq
138 Holborn
London
United Kingdom
EC1N 2SW
+44 (0)2030023628
Seyed@Cognetivity.com

Type(s)
Scientific

Contact name
Dr Zahra Vahabi

Contact details
Tehran University of Medical Sciences
Tehran
Iran
1417653911
+98 (0)21 8889 6692
zvahabi@sina.tums.ac.ir

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

Organisation
Cognetivity Ltd

Sponsor details
3 Waterhouse Square
138 Holborn
London
United Kingdom
EC1N 2SW
+44 (0)7890696924
Seyed@Cognetivity.com

Sponsor type
Industry

Website
https://www.cognetivity.com/

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?
Basic results			21/12/2021	No	No