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# Validating a self-administered, language-independent iPad-based test for assessment and monitoring of cognitive impairment in patients with multiple sclerosis (MS)

**Submission date**
12/02/2018

**Recruitment status**
No longer recruiting

**Registration date**
16/02/2018

**Overall study status**
Completed

**Last Edited**
22/06/2020

**Condition category**
Nervous System Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

## Plain English summary of protocol

Background and study aims
Multiple sclerosis (MS) is a condition that affects the brain and spinal cord. Cognitive impairment is common in patients with MS however it is not routinely assessed in the clinic setting. Cognitive impairment causes a decline in memory and thinking skills. The currently available reference tests for assessing cognitive impairment in MS are typically long and need an expert to administer the test. Researches have developed a 5-minute iPad based test that is self-administered and language independent to measure cognitive dysfunction in patients with MS. This test is called an Integrated Cognitive Assessment tool (or ICA). The aim of this study is to validate an iPad-based test in assessing cognitive dysfunction in patients with MS to show that the test outcome has construct validity with BICAMS (Brief International Cognitive Assessment for MS).

Who can participate?
MS patients and healthy controls that are within the same age-range.

What does the study involve?
All participants are randomly allocated to the order in which they undergo two difference types of cognitive assessment. Participants take the recently developed integrated cognitive assessment (ICA) test on an iPad that takes about five minutes. Each participant also takes the BICAMS test that lasts about 20 minutes. BICAMS is a battery of three pen and paper test. This includes the Symbol Digit Modalities Test (SDMT) which measures cognitive processing speed, the California Verbal Learning Test and the Brief Visuospatial Memory Test. In the follow-up session, each participant takes the SDMT test, and the ICA iPad test.

What are the possible benefits and risks of participating?
Participants will benefit from a comprehensive cognitive assessment, and a follow-up after

about four month. There are no risks associated with participating in the study, particularly because the study only contains behavioral cognitive assessments (i.e. pen and paper tests, and a computerized test).

Where is the study run from?
MS specialist clinic, Aria Medical Complex (Iran)

When is the study starting and how long is it expected to run for?
December 2017 to July 2018

Who is funding the study?
Cognetivity Ltd (UK)

Who is the main contact?
Dr Seyed-Mahdi Khaligh-Razavi (Scientific)

# Contact information

### Type(s)
Scientific

### Contact name
Dr Seyed-Mahdi Khaligh-Razavi

### Contact details
Royan Institute
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# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
CGN-1702

# Study information

### Scientific Title
A brief language-independent and self-administered computerized tool for cognitive assessment in multiple sclerosis (MS)

### Study objectives

The aim of this study is to validate an iPad-based test in assessing cognitive dysfunction in patients with MS. We will show that the test outcome has construct validity with BICAMS (Brief International Cognitive Assessment for MS).

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Research Ethics Commitee of Royan Institute, 08/08/2017, ref: IR.ACECR.ROYAN.REC.IR.ACECR.ROYAN.REC.1396.98

## Study design
Single-center observational case-control study

## Primary study design
Observational

## Secondary study design
Case-control study

## Study setting(s)
Other

## Study type(s)
Screening

## Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

## Health condition(s) or problem(s) studied
Multiple sclerosis

## Interventions
After enrollment in the study, both MS and healthy participants go through two types of cognitive assessment in a randomized order. Participants take the recently developed integrated cognitive assessment (ICA) test on an iPad that takes about five minutes. Each participant also take the BICAMS test that lasts about 20 minutes. BICAMS is a battery of three pen and paper tests:
1. Symbol Digit Modalities Test (SDMT) which is a measure of cognitive processing speed and takes about 5 minute
2. The initial learning trials of the California Verbal Learning Test 2nd Edition (CVLT-II), which takes 10 minutes to complete
3. The Brief Visuospatial Memory Test-Revised (BVMT-R), which takes 5 minutes

In the follow-up session, each participant takes the SDMT test (~5 min duration), and the ICA iPad test (~5min) in a randomized order.

## Intervention Type
Behavioural

### Primary outcome measure
1. Cognitive dysfunction is measured using the BICAMS score at baseline, and four months
2. Cognitive dysfunction is measured using the Integrated Congitive Assessmnet (ICA) score at baseline and four months

### Secondary outcome measures
1. Reliability for SDMT is measured by correlating SDMT categorizations (i.e. cognitively intact, mildly impaired, severely impaired) made on the first visit and the second visit
2. Reliability for ICA is measured by correlating ICA categorizations (i.e. cognitively intact, mildly impaired, severely impaired) made on the first visit and the second visit

### Overall study start date
01/12/2017

### Completion date
30/07/2018

## Eligibility

### Key inclusion criteria
1. Definite diagnosis of MS in all the following categories, regardless of age, sex and education level:
1.1. RR: relapsing remitting
1.2. PP: primary progressive
1.3. SP: secondary progressive
2. Healthy controls within an age-range similar to the MS patients

### Participant type(s)
Mixed

### Age group
Adult

### Sex
Both

### Target number of participants
160 participants in total. (80 MS; 80 healthy controls )

### Total final enrolment
174

### Key exclusion criteria
1. Moderate to Severe Depression as measured by Beck’s Score
2. Interfering motor problems (e.g. upper limb motor dysfunction)
3. Vision problems that cannot be corrected with eye-glasses such that it prevents participant from reading
4. Presence of other neurological disorders medical illnesses that affect brain function and cognition

5. History of seizures
6. History of drug or alcohol abuse

### Date of first enrolment
05/01/2018

### Date of final enrolment
30/04/2018

## Locations

### Countries of recruitment
Iran

### Study participating centre
**MS Specialist Clinic Aria Medical Complex**
No. 218, Mollasadra St
Tehran
Iran
143591537

## Sponsor information

### Organisation
Cognetivity Ltd

### Sponsor details
3 Waterhouse Square
138 Holborn
London
United Kingdom
EC1N 2SW

### Sponsor type
Industry

### Website
http://cognetivity.com/

### Organisation
Royan Institute

### Sponsor details

Banihashem Square
Tehran
Iran
148- 6635

### Sponsor type
Research organisation

### Website
http://www.royaninstitute.org/cmsen/

## Funder(s)

### Funder type
Industry

### Funder Name
Cognetivity Ltd

## Results and Publications

### Publication and dissemination plan
Planned publication in Multiple Sclerosis Journal ( MSJ) or other similarly prestigious peer-reviewed journals. No such additional documents are currently available for publication/pre-print.

### Intention to publish date
30/09/2018

### 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? |
|---|---|---|---|---|---|
| Results article | results | 01/12/2020 | 22/06/2020 | Yes | No |