ISRCTN17924218 https://doi.org/10.1186/ISRCTN17924218

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
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Additional identifiers

Protocol serial number
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

Study type(s)
Screening

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(s)
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

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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

Organisation
Royan Institute

Funder(s)

Funder type
Industry

Funder Name
Cognetivity Ltd

Results and Publications

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes