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Accelerating dementia pathway technologies

Submission date
03/02/2020

Recruitment status
No longer recruiting

Registration date
09/03/2020

Overall study status
Completed

Last Edited
02/10/2023

Condition category
Nervous System Diseases

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Current plain English summary as of 28/09/2022:
Background and study aims
At present, GPs clinical judgement is the key driver for instigating full evaluations at memory clinics for conditions such as dementia. Existing tests used by GPs are crude or time-consuming and tend to only detect cognitive impairment when the disease has progressed significantly. The Integrated Cognitive Assessment CognICA is a quick and easy-to-use test of cognitive performance, using an iPad. Users are shown a series of images in quick succession and for each, they are asked to respond 'yes' or 'no' to whether they contained an image of an animal or not. The accuracy and speed of responses are then assessed using Artificial Intelligence that compares CognICA tests previously taken by healthy and cognitively impaired individuals. The patients who participated were referred to a memory clinic within the NHS. They were 55-90 years old and did not already have a diagnosis of dementia.
In this study, patients who have been referred to NHS memory clinics will be asked to take CognICA, as well as all of the other standard assessments taken as part of their appointment. The CognICA result did not inform the diagnosis of the patient or any other aspect of their care. Once the diagnosis of the patient was known, the CognICA result was compared against the GP referral and the final diagnosis to determine whether CognICA predicted correctly the patient's status. From this, it was determined whether the use of CognICA could have prevented the referral of patients who were found to be healthy. Reducing the number of false referrals is a benefit to the welfare of the patient, for the reduction of waiting times and also saves money for the NHS. The aim of this study was to build practical and economic evidence to support the use of the CognICA as an inexpensive dementia screening tool in the NHS.

Who can participate?
Patients between the ages of 55-90 who have been referred to a memory clinic within Sussex Partnership NHS Foundation Trust and do not already have a diagnosis of dementia can participate in this study. Please refer to the Inclusion/Exclusion Criteria for further information.

What does the study involve?
Participants will be asked to attend an appointment at a designated memory clinic where they will fill in a number of questionnaires and take a survey delivered using an iPad.

What are the possible benefits and risks of participating?
There are no anticipated direct benefits to participants, however, it is hoped that if the ICA is adopted it may provide significant benefit to others in the future.

Where is the study run from?
Sussex Partnership NHS Foundation Trust (UK)

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

Who is funding the study?
Innovate UK

Who is the main contact?
Dr Chris Kalafatis (scientific), chris@cognetivity.com

Previous plain English summary:
Background and study aims
Dementia is a brain condition, which causes a gradual loss of mental ability, including problems with memory, understanding, judgement, thinking and language. Early identification and diagnosis of Dementia are essential for improved health outcomes and service provision. Primary care is invariably the main point of identification.
At present, GPs clinical judgement is the key driver for instigating full evaluations at memory clinics for conditions such as dementia. Clinical practice is known to be inefficient and variable across GP clinics. Existing cognitive tests used in primary care are crude or time-consuming, and tend to only detect cognitive impairment when the disease has progressed significantly. The more detailed tests used in memory clinics or neuropsychological assessments are expensive and often intrusive for the patient and are therefore not suitable for use as a screening tool.
The Integrated Cognitive Assessment (ICA) is a quick and easy to use test of cognitive performance, using an iPad. Users are shown a series of images in quick succession and for each they are asked to respond ‘yes’ or ‘no’ to whether they contained an image of an animal or not. The accuracy and speed of responses are then assessed using Artificial Intelligence that compares ICA tests previously taken by healthy and cognitively impaired individuals. This enables the ICA to provide an objective indication of cognitive performance and the likelihood of impairment. The ICA is registered with UK regulators as a medical device.
In this study, patients who have been referred to NHS memory clinics will be asked to take the ICA, as well as all of the other standard assessments taken as part of their appointment. The ICA result will not inform the diagnosis of the patient or any other aspect of their care. Once the diagnosis of the patient is known, the ICA result will then be compared against the GP referral and the final diagnosis to determine whether the ICA predicted correctly. From this it will be determined whether the use of the ICA could have prevented the referral of patients who were found to be healthy.
The aim of this study is therefore to build clinical and economic evidence to support the use of the ICA as an inexpensive dementia screening tool in the NHS. The study aims to demonstrate whether the use of ICA can improve the dementia care pathway by streamlining the diagnosis of dementia and improving the efficiency of GP referrals and therefore minimising the need for repeated, costly and time-consuming assessments.

Who can participate?
Patients between the ages of 55-90 who have been referred to a memory clinic within Sussex

Partnership NHS Foundation Trust and do not already have a diagnosis of dementia can participate in this study. Please refer to the Inclusion/Exclusion Criteria for further information.

What does the study involve?
Participants will be asked to attend an appointment at a designated memory clinic where they will fill in a number of questionnaires and take a survey delivered using an iPad.

What are the possible benefits and risks of participating?
There are no anticipated direct benefits to participants, however, it is hoped that if the ICA is adopted it may provide significant benefit to others in the future.

Where is the study run from?
Sussex Partnership NHS Foundation Trust (UK)

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

Who is funding the study?
Innovate UK

Who is the main contact?
1. Benjamin Austin (public), qms@cognetivity.com
2. Panagiotis Apostolou (public), panos@cognetivity.com
3. Dr Chris Kalafatis (scientific), chris@cognetivity.com

Contact information

Type(s)
Scientific

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Additional identifiers

Integrated Research Application System (IRAS)
277157

Protocol serial number
CGN-2001

Study information

Scientific Title
Real-world evidence study of primary care referrals to NHS memory clinics and the clinical and economic case for the adoption of the Integrated Cognitive Assessment to improve the dementia diagnosis pathway

Acronym
ADePT

Study objectives
This study will develop a real-world evidence basis to support the adoption of ICA as an inexpensive screening tool for the detection of cognitive impairment and improving the efficiency of the dementia care pathway.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 27/02/2020, North of Scotland Research Ethics Committee (Summerfield House, 2 Eday Road, Aberdeen, AB15 6RE, UK; +44 (0)1224 558458; nosres@nhs.net), ref: 20/NS/0029

Primary study design
Observational

Study design
Observational cross sectional study

Study type(s)
Screening

Health condition(s) or problem(s) studied
Alzheimer's Disease, Dementia, Mild Cognitive Impairment

Interventions
Participants enrolled in the study will be required to attend one visit at a designated memory clinic (AV1). Information sheets and consent forms shall typically be sent to participants by post with their appointment letter. They may also be provided to potential participants during ‘Appointment 1’. Diagnostic assessments (i.e. ‘Appointment 2’) typically occur within a period of 8 weeks from the appointment letter being sent. AV1 shall occur on the same day as Appointment 2, or up to 28 days after appointment 2.

The schedule of events for AV1 is as follows:
1. Informed Consent
2. Inclusion/Exclusion
3. Demographics*
4. Medical History*

5. History of previous cognitive and functional assessments:
a. History of ACE-III or MoCA*
b. Previous Cognitive Test Scores from GP (if available)*
c. Functional assessment scale (if used)*
6. ICA
7. Adverse Events
8. Enquiry on stimulants, fatigue, sleep
9. ICA Usability Questionnaire*
10. CGN Cognitive Health Questionnaire**
11. Memory Clinic Diagnosis*
*From medical notes obtained from GP and/or Memory Clinic Assessment
** The CGN Cognitive Health Questionnaire can be completed in person with the informant (study partner) or the participant (if the informant is not available or not willing to participate) or via telephone call with the informant only.

The Integrated Cognitive Assessment (ICA) is a 5-minute computerised cognitive assessment tool based on a rapid categorisation task. The test is software-based, self-administered and independent of language and education. It is designed for use on an Apple iPad. The accuracy and speed of responses are assessed during the test. The test data is then assessed using Artificial Intelligence (AI) to compare ICA tests previously taken by healthy and cognitively impaired individuals. This enables the ICA to provide an objective indication of cognitive performance and potential impairment.

The product has the following Intended Use:
The Integrated Cognitive Assessment (ICA) is an adjunctive tool providing objective measures of cognitive function for the clinical evaluation of cognitive performance in individuals aged 55 to 90 years old.

The ICA is defined as a Software as Medical Device (SaMD) and is registered as a Class I Medical Device under the Medical Device Directive (MDD 93/42/EEC) with the UK Medicines and Healthcare products Regulatory Agency (MHRA).

Intervention Type
Other

Primary outcome(s)
GP referrals with specialist diagnosis of MCI/Dementia:
1. Unnecessary GP referrals according to clinic diagnosis (GP referred but confirmed healthy /other at clinic)
2. Necessary GP referrals according to clinic diagnosis (GP referred and confirmed Dementia/MCI at clinic)

Comparison of ICA outcome with specialist diagnosis of MCI/Dementia:
3. Unnecessary ICA referrals according to clinic diagnosis (ICA outcome Dementia/MCI but confirmed healthy/other at clinic)
4. Necessary ICA referrals according to clinic diagnosis (ICA outcome Dementia/MCI and confirmed Dementia/MCI at clinic)
5. Number of ICA incorrectly not referred according to clinic diagnosis (ICA outcome healthy but confirmed Dementia/MCI at clinic)

Key secondary outcome(s)

Comparison of GP referrals with specialist diagnosis of all types of cognitive impairment:
1. Unnecessary GP referrals according to clinic diagnosis (GP referred but confirmed healthy at clinic)
2. Necessary GP referrals according to clinic diagnosis (GP referred and confirmed Dementia/MCI /Other cognitive impairment at clinic)

Comparison of ICA outcome with specialist diagnosis of all types of cognitive impairment:
3. Unnecessary ICA referrals according to clinic diagnosis (ICA outcome Dementia/MCI/Other but confirmed healthy at clinic)
4. Necessary ICA referrals according to clinic diagnosis (ICA outcome Dementia/MCI and Dementia/MCI/Other confirmed at clinic)
5. Number of ICA incorrectly not referred according to clinic diagnosis (ICA outcome healthy but Dementia/MCI/Other confirmed at clinic)

6. Qualitative measures of suitability and usability of the ICA in real world clinical environments (ICA Usability Questionnaire)

Completion date
30/09/2021

Eligibility

Key inclusion criteria
Patients aged between 55-90 years old at the time of AV1 who are referred to the memory clinic who have the capacity to consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
55 Years

Upper age limit
90 Years

Sex
All

Total final enrolment
99

Key exclusion criteria
1. Upper limb arthropathy or motor dysfunction that limits the use of a tablet computer
2. Visual impairment severe enough to limit the use of a tablet computer. As guidance

participants who cannot read the small print in a newspaper (even with corrected vision) should be excluded
3. Patients with a known diagnosis of Dementia
4. Patients already receiving Cholinesterase Inhibitors and/or Memantine

Date of first enrolment
01/11/2020

Date of final enrolment
30/09/2021

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Sussex Partnership NHS Foundation Trust
Swandean
Arundel Road
Worthing
United Kingdom
BN13 3EP

Sponsor information

Organisation
Cognetivity Ltd.

Funder(s)

Funder type
Government

Funder Name
Innovate UK

Alternative Name(s)
Technology Strategy Board

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be 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		13/09/2023	02/10/2023	Yes	No
Protocol article		30/11/2021	22/12/2021	Yes	No
HRA research summary			28/06/2023	No	No
Other publications	Health economic analysis	29/09/2023	02/10/2023	Yes	No