

# Accelerating dementia pathway technologies

<b>Submission date</b> 03/02/2020	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 09/03/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 02/10/2023	<b>Condition category</b> Nervous System Diseases	<input type="checkbox"/> 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](mailto:chris@cognetivity.com)

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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](mailto:qms@cognetivity.com)
2. Panagiotis Apostolou (public), [panos@cognetivity.com](mailto:panos@cognetivity.com)
3. Dr Chris Kalafatis (scientific), [chris@cognetivity.com](mailto:chris@cognetivity.com)

## Contact information

**Type(s)**

Scientific

**Contact name**

Dr Chris Kalafatis

**ORCID ID**

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**Contact details**

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## Additional identifiers

**Clinical Trials Information System (CTIS)**

Nil known

## **Integrated Research Application System (IRAS)**

277157

## **ClinicalTrials.gov (NCT)**

Nil known

## **Protocol serial number**

CGN-2001, IRAS 277157

# **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

## **Study design**

Observational cross sectional study

## **Primary study design**

Observational

## **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**

**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)

UK Research and Innovation Innovate UK, innovateuk

### 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?
<a href="#">Results article</a>		13/09/2023	02/10/2023	Yes	No
<a href="#">Protocol article</a>		30/11/2021	22/12/2021	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Other publications</a>	Health economic analysis	29/09/2023	02/10/2023	Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes