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Validation of the FLAME Cognitive Test System in people with mild to moderate dementia

Submission date
12/08/2024

Recruitment status
No longer recruiting

Registration date
10/09/2024

Overall study status
Completed

Last Edited
01/08/2025

Condition category
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol
Background and study aims
Over 850,000 people in the United Kingdom are diagnosed with dementia and this number is expected to rise to up to one million by the year 2040. Cognitive assessment is essential for the effective diagnosis and monitoring of the progression of dementia. Sensitive cognitive assessment tools are key to ensuring accurate, timely diagnosis and long-term monitoring of dementia, both in research and healthcare settings. Traditional cognitive assessment tools such as the Mini-Mental State Examination (MMSE) and Montreal Cognitive Assessment (MoCA) are well-validated for the detection of dementia but are not well-suited for self-administration or scalable assessment using digital platforms. The FLAME cognitive assessment system is a self-administered computerised cognitive testing tool that can be used remotely with no need for clinician supervision. The system is online and can be completed on an app or website. The FLAME cognitive assessment system has already been validated in a group of 25,000 people aged over 50 enrolled in the PROTECT-UK ageing cohort study, but it has not yet been tested in people with dementia. The FLAME validation study (FLAG) is a 12-month research study that aims to assess how the FLAME computerised cognitive test system compares with MoCA in people with mild to moderate dementia. MoCA is a pen-and-paper cognitive assessment delivered by a trained researcher. The FLAG study will provide valuable information on whether the FLAME system compares to the gold standard MoCA tool for use in cognitive monitoring and assessment.

Who can participate?
Participants aged 60 – 90 years old who have been diagnosed with mild to moderate dementia (MoCA score 15-26 inclusive or ACE score 70-90 inclusive).

What does the study involve?
Potential participants will be asked to nominate a study partner or carer to participate with them. Participants and their caregivers will be approached by telephone, email and/or SMS and invited to attend a research clinic at the GP surgery or memory clinic. Upon consent, participants will complete the MoCA and FLAME test system. They will be asked to provide a finger prick and venous blood sample and complete a study questionnaire. After providing consent, the study partner will be asked to complete two questionnaires. All study procedures will be completed on the same day.

What are the possible benefits and risks of participating?
Taking part in this study could help move the understanding of how to detect dementia earlier forward. FLAME could be used by people at home to monitor brain health and find people who need to be diagnosed and treated. The FLAME tests are difficult and it can take up to 40 minutes to complete. There is a risk of feeling tired or upset by the tests. The researcher will be available to explain the tests to the participants so they know what to expect. There is a risk of pain or discomfort from blood sampling. People often experience bruising and low levels of pain during and after giving a blood sample. These will be checked by a researcher and you can let us know about any other issues.

Where is the study run from?
The study is sponsored by the University of Exeter and will run from three UK sites

When is the study starting and how long is it expected to run for?
July 2024 to July 2025

Who is funding the study?
National Institute for Health and Care Research (NIHR)

Who is the main contact?
FLAG Study Office, Flag@exeter.ac.uk

Contact information

Type(s)
Public, Scientific

Contact name
Ms Christine Davis

Contact details
University of Exeter, College House 1.23, St Luke’s Campus, Heavitree Road
Exeter
United Kingdom
EX1 2LU
+44 (0)1392 727581
c.l.davis2@exeter.ac.uk

Type(s)
Principal Investigator

Contact name
Prof Anne Corbett

ORCID ID
https://orcid.org/0000-0003-2015-0316

Contact details
Professor of Dementia Research & PROTECT
University of Exeter

College House, St Luke’s Campus
Exeter
United Kingdom
EX1 2LU
+44 (0)1392 72 4464
a.m.j.corbett@exeter.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
338077

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 62561, NIHR204284, IRAS 338077

Study information

Scientific Title
FLAME Validation Study in Mild to Moderate Dementia (FLAG Study)

Acronym
FLAG Study

Study objectives
The FLAME validation study is a 12 month research study. It aims to assess how the FLAME computerised cognitive test system compares with MoCA in people with mild to moderate dementia. This will provide valuable information whether the FLAME system compares to the gold standard MoCA tool for use in cognitive monitoring and assessment. MoCA is a pen-and-paper cognitive assessment delivered by a trained researcher.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 22/07/2024, North West - Greater Manchester East Research Ethics Committee (3rd Floor, Barlow House 4 Minshull Street, Manchester, M1 3DZ, United Kingdom; +44 (0)207 104 8290; gmeast.rec@hra.nhs.uk), ref: 24/NW/0151

Study design
Interventional non-randomized study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Home, Hospital, Internet/virtual, Medical and other records, Telephone

Study type(s)
Screening

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
People with mild to moderate Dementia

Interventions
This is a 12-month study that aims to establish the concurrent validity of the FLAME computerised cognitive test system with other markers of cognitive decline. All data will be collected in a primary or secondary care setting, supported by a trained member of research or clinician staff. The study aims to recruit 60 people with mild-moderate dementia and 60 study partners. Participants will follow the journey below:

1. Screening and recruitment: Following the screening of existing medical records (ACE-III or MoCA score) potential participants and their caregivers will be approached by telephone, email and/or SMS and invited to attend a research clinic at the GP surgery or memory clinic. They will have the option of completing this visit at home if they wish, depending on the site. They will be provided with a Participant Information Sheet in advance for participants and study partners.

2. Consent: Participants and study partners will have the opportunity to discuss the study with a member of the research team at the site and to ask any questions they have. If they are happy to proceed they will be asked to read, complete and sign the Informed Consent Form for both participants and study partners, respectively.

3. FLAME Cognitive Assessment (participant): Participants will then proceed to the FLAME assessments. Participants will be supported to access the online FLAME test system by a member of the research team (the team will log into the study account). They will explain how the tests work and emphasise that the tests are designed to be challenging. This is important to set expectations for the tests. The participant will then complete a 5-minute practice session of the test system. After a short break, the participant will then complete the full FLAME test session, which takes up to 40 minutes. The staff member will remain in the room to provide support and help with any technical issues, but they will not help the participants complete the tests themselves. At the end of the test session, the participant will be offered refreshments and a break before proceeding.

4. Blood Sampling: Participants will then provide two blood samples which will be taken by a trained research team member. One tube of K2-EDTA will be taken from a venous sample, and two finger-prick cards will be completed. This usually requires pricking two fingers. This will take 15 minutes.

5. MoCA Assessment: Participants will then complete the MoCA assessment, performed by a trained research team member. This involves answering a series of questions and tasks that are recorded by the researcher. This will take up to 15 minutes.

6. Study Partner Assessments: During the participant assessments in stages 3-5 above, the study partner will complete two questionnaires which will be completed by a member of the research team. These are the IQCODE, in which the study partner will answer questions about the participants' cognition, and the ACDS-ADL in which they answer questions about the person's day-to-day abilities. These will take around 15 minutes

7. At the end of the visit both participant and study partner will be offered further refreshment if required. They will be provided with a web link to complete together in which they will provide their feedback on completing the FLAME cognitive test system. They can complete this at the visit or home, whichever they prefer.

8. At the end of the study participants will receive a summary report of the findings.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
FLAME composite Score measured using the FLAME cognitive test battery at baseline

Secondary outcome measures
1. Informant IQCode score measured using the informant-reported IQCode questionnaire at one timepoint
2. Informant activity of daily living score measure using the ADCS activities of daily living questionnaire at one timepoint

Overall study start date
22/07/2024

Completion date
22/07/2025

Eligibility

Key inclusion criteria
1. Adults aged 60-90 years old
2. Reside in the UK
3. Fulfilling criteria for mild to moderate dementia (MoCA score 15-26 inclusive or ACE score 70-90 inclusive)
4. Able to use a computer or tablet
5. Capacity to consent
6. Have a study partner

Participant type(s)
Patient

Age group
Mixed

Lower age limit
60 Years

Upper age limit
90 Years

Sex
Both

Target number of participants
Planned Sample Size: 60; UK Sample Size: 60

Total final enrolment
61

Key exclusion criteria
1. Visual impairment that prevents completion of computer-based tasks
2. Diagnosis of Parkinson’s Disease or stroke affecting the upper limbs or any physical disability impairing the use of computer keys or touchscreen
3. Moderate or severe learning disability

Date of first enrolment
02/09/2024

Date of final enrolment
31/03/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Devon Partnership NHS Trust
Wonford House Hospital
Dryden Road
Exeter
United Kingdom
EX2 5AF

Study participating centre

Musgrove Park Hospital (taunton)
Musgrove Park Hospital
Taunton
United Kingdom
TA1 5DA

Study participating centre
Cornwall Partnership NHS Foundation Trust
Carew House
Beacon Technology Park
Dunmere Road
Bodmin
United Kingdom
PL31 2QN

Sponsor information

Organisation
University of Exeter

Sponsor details
Research Ethics & Governance Office, Lafrowda House, St Germans Road
Exeter
England
United Kingdom
EX4 6TL
+44 (0)1392 726621
res-sponsor@exeter.ac.uk

Sponsor type
University/education

Website
https://www.exeter.ac.uk/

ROR
https://ror.org/03yghzc09

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
31/07/2026

Individual participant data (IPD) sharing plan
The 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