

# Flame system: Computerised cognitive assessment for remote brain health monitoring

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## **Monitoring brain health, particularly cognition, in older adults is increasingly recognised as a significant priority for research, healthcare and broader public health. Find out here about the development and validation of the FLAME System, a computerised cognitive assessment for remote brain health monitoring**

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The opportunity to delay or reduce the risk of dementia in people with early cognitive decline or Alzheimer's Disease is considerable. After a period of limited progress, new treatments for Alzheimer's Disease, such as donanemab, are now emerging.

There is also good evidence for health and lifestyle factors that influence prognosis and risk and for lifestyle interventions that maintain cognition. <sup>(1)</sup> Yet people with early pre-clinical impairments are currently not being identified efficiently. 99% of people with Mild Cognitive Impairment never even receive a diagnosis and do not reach health services until their cognition declines. <sup>(2)</sup>

In addition to this clear clinical need for effective cognitive monitoring, there is also a growing demand for a large-scale, community-based solution that would support people in ageing healthily and tracking their brain health from home. Meanwhile, in research settings, the newly invigorated pipeline of new treatments requires accurate identification of pre-clinical stage participants for clinical trials and the ability to sensitively monitor cognitive change and track response to treatment.



## FLAME Cognitive Test System



PROTECT



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### Cognitive monitoring

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Diagnosis of MCI and dementia in healthcare and research traditionally involves a staged assessment pathway of neuropsychological assessment, supplemented by an evolving field of neuroimaging and biomarker technologies. This process is costly and cannot be used to monitor cognitive progression or response to disease-modifying treatments on a large scale. It also does not address the 99% of people who do not access healthcare services with early impairment or the broader group of people who are concerned about their brain health.

There is an urgent need for more sensitive, scalable and accessible cognitive monitoring, which would ensure people with early cognitive impairment would access treatment and support at the right time. They would provide older adults in the community with a means to proactively manage their brain health. Such a tool would also be of enormous value to academic and commercial research to identify participants and monitor progression through clinical trials of new treatments.

Early cognitive decline is subtle and subjective, making it challenging to assess accurately and objectively using traditional methods. <sup>(3)</sup> Computerised cognitive testing enables consistent, non-biased recording of responses and reaction time sensitivity, with domain-specific endpoints, better patient acceptability and the potential for remote testing without the need for clinical supervision. <sup>(4)</sup> This offers the potential for widespread cognitive assessment and the opportunity to detect, support and treat early cognitive impairment whilst driving efficiency and filling gaps in clinical pathways.

### Cognitive monitoring technology

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Over 30 digital cognitive assessment systems exist, but the field is hampered by a lack of longitudinal data validation, proven long-term engagement of users and remote use capability. (5) There is a clear need for a more innovative approach to cognitive monitoring technology to address these issues. We have addressed this issue through our research portfolio, PROTECT, which combines computerised cognitive testing with an innovative online platform that enables large-scale research into brain health.

PROTECT is an online ageing cohort with extensive longitudinal cognitive and health data from over 50,000 participants in the UK, Norway, Canada and the US. PROTECT has established the effectiveness of remote, online research methodology and has facilitated the validation of a highly sensitive, accurate cognitive test system, FLAME (Factors for Longitudinal Assessment of Attention, Memory and Executive Function).

### **FLAME: Cognitive monitoring research**

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The cognitive tests in FLAME are built on over 40 years of research and use. The foundation of the cognitive test algorithm and paradigms stems from leading cognitive assessment platforms such as the CDR system, CANTAB and Cogstate. Considering this, some of these tests have been used in over 1,400 clinical trials. They are included in several hundred peer-reviewed research papers, covering an impressive collection of nootropic, cognitive impairment, and disease state data, including Parkinson's Disease, Huntington's Disease, Multiple Sclerosis, REM sleep disturbance behaviour and COVID-19. (6)

FLAME was developed through a principal components analysis in which only components providing eigenvalues greater than unity and cognitive factor loadings of 0.4 or above were derived into the final composite assessment measure and is derived from test paradigms with extensive concurrent validation data. (7)

FLAME builds on both these systems and has undergone extensive internal validation using longitudinal data collected through the PROTECT-UK ageing cohort of 25,000 people over 50[AC8]. (8) The system can detect statistically meaningful age-related cognitive decline, with concurrent validity with established, FDA-approved criteria for early cognitive impairment ( $P < 0.0001$ ) and sensitivity to the trajectory of cognitive decline in healthy and impaired individuals. This outperforms other available test systems and confirms that FLAME is suitable for use in both healthcare and research settings.

### **More on FLAME, including cognitive performance**

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Furthermore, FLAME has good construct validity, showing a correlation with functional, subjective and informant-reported cognitive decline, as is recommended in clinical guidance. FLAME component tests have also shown sensitivity to detect statistically significant associations and unique patterns of cognitive performance with known medical and lifestyle risk factors through multiple regression analyses.

FLAME is, therefore, positioned to support meaningful assessment and monitoring of brain health across clinical, community, and research contexts. It is already in use in several pharmacological and non-drug intervention clinical trials, available in multiple languages, and can be used as a standalone or integrated software solution. Our research is now entering a programme of translational work to validate FLAME for clinical and community-based applications.

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