Technoleg Iechyd Cymru
Health Technology Wales

# Topic Exploration Report [1]

## Digital tools incorporating cognitive eye vergence markers to diagnose attention deficit hyperactivity disorder (ADHD) in adults and children

### What is a Topic Exploration Report?

Topic Exploration Reports are not health technology assessments. These reports provide a high-level briefing on new topics submitted to Health Technology Wales and are not based on exhaustive or systematic literature searches. Instead, they rely on a focussed scan of key resources.

### What evidence is used in a Topic Exploration Report?

Priority is given to summarising the most relevant or useful evidence, rather than covering all possible evidence. Information reported is typically based on abstracts and study authors' own conclusions, rather than detailed scrutiny of full texts.

### What are the aims of a Topic Exploration Report?

Topic Exploration Reports offer an overview of the available evidence on a topic and aim to highlight any uncertainties or gaps in the evidence. These reports outline the quantity and type of evidence found, but no critical appraisal or formal evidence synthesis is conducted.

### How should a Topic Exploration Report be used?

Topic Exploration Reports can be used to indicate what evidence may be available for a topic, and do not provide definitive guidance on how a technology should be used. The evidence presented within the reports should be interpreted with caution.

[1] Cyfieithu dogfennau HTW wedi'u cyhoeddi o'r Saesneg i'r Gymraeg
Translation of published technical HTW documents from English into Welsh

| | |
|---|---|
| **Topic exploration report number** | TER586 |
| **Topic** | Digital tools incorporating cognitive eye vergence markers to diagnose attention deficit hyperactivity disorder (ADHD) in adults and children |
| **Summary of findings** | BGaze Clinic by BrainGaze is a computerised ADHD assessment. It takes 12 minutes to complete and involves using an eye tracker that captures cognitive eye vergence, and computerised semi-structured interview and ADHD rating scales. BGaze Clinic is intended to be used as an adjunct to current practice to support the diagnosis of ADHD in the care pathway, with reference and adherence to NICE guidelines.<br><br>HTW researchers searched for BGaze Clinic and cognitive vergence for the diagnosis of ADHD and found one NICE guideline on digital technologies for assessing ADHD, one NICE guidance on diagnosing and managing ADHD, four cohort studies about cognitive vergence and/or BGaze Clinic for the diagnosis of ADHD, and one conference abstract.<br><br>Diagnostic accuracy outcomes, and associations between ADHD and atypical eye vergence were reported, although other outcomes such as improvement in patient management, reduction in waiting times, and cost savings when compared to the current standard care pathway were not reported. Overall, a study of adults with ADHD found BGaze Clinic to have a diagnostic accuracy value of 79% and a study of children with ADHD found BGaze Clinic to have a diagnostic accuracy of 96.3%.<br><br>Information from the topic proposer at BrainGaze Ltd confirms there is an ongoing non-randomised cross-sectional study due to complete within the next two years that will explore eye vergence markers in ADHD and autism spectrum disorder (ASD). |

## Introduction and aims

***Context***

ADHD is a neurodevelopmental condition. Symptoms include hyperactivity, impulsivity and inattention, that interferes with daily and occupational functioning (NICE 2024b). It is estimated that 5% of children and 3-4% of adults have been diagnosed with ADHD in the UK, which is 2.6 million people (708,000 children, 1.9 million adults) (NICE 2024a). ADHD is more commonly diagnosed in boys than girls (NICE 2024a). Waiting times for an initial assessment can take several years which has created a backlog of people awaiting an ADHD diagnosis. Delays in getting a diagnosis, can also delay treatment, which can lead to issues such as academic struggles, employment difficulties, and mental health challenges. Currently, there is no simple test to diagnose ADHD, and the process relies on clinical, observational and neuropsychological assessments, such as self-reports and questionnaires.

***Health Technology***

BGaze Clinic is an online clinical, diagnostic support system that includes computerised ADHD assessment which takes 12 minutes to complete with an administrator. It tracks involuntary eye movements and uses AI to produce a 3-page analysis report on cognitive eye vergence. The product provides semi-structured interviews for clinicians with automated DSM-5 (Diagnostic and Statistical Manual of Mental Disorders) and ICD-10 (International Statistical Classification of Diseases and Related Health Problems) scoring sheets. Vergence refers to the coordinated movement of both eyes in opposite directions to maintain clear, single vision. The BGaze Clinic platform is based on the concept that atypical eye vergence is observed in people with ADHD. The new technology could potentially standardise ADHD assessments, reduce the need for clinician's time, and could potentially speed up time to diagnosis.

HTW researchers searched for evidence on BGaze Clinic and atypical cognitive vergence for the diagnosis of ADHD. Information from the topic proposer confirms that BGaze Clinic by BrainGaze is CE marked as a class IIa medical device. It is also compliant with NHS DSP Toolkit, GDPR and HIPAA. No other technologies incorporating cognitive eye vergence with automated analysis and clinical assessment to diagnose ADHD were identified.

## Evidence overview

**Overview**

HTW researchers identified one NICE guideline on the diagnosis and management of ADHD, one guideline on digital technologies for assessing ADHD, four cohort studies and one conference abstract. HTW researchers identified two cohort studies reporting on the diagnostic accuracy of the BGaze product to identify participants with ADHD and two other studies were identified where atypical eye vergence was assessed in children with ADHD or ASD when compared with people considered to be neurotypical. Overall, a study of adults with ADHD found BGaze Clinic to have a diagnostic accuracy value of 79% (Jiménez et al. 2021) and a study of children with ADHD found BGaze Clinic to have a diagnostic accuracy of 96.3% (Varela Casal et al. 2019). HTW researchers did not identify any other studies where additional outcomes were reported such as waiting times within the ADHD care pathway.

**Guidance and guidelines**

NICE guideline [NG87] makes recommendations on how to diagnose ADHD (NICE 2018). Recommendation 1.3.1 states that a diagnosis of ADHD should be made by a specialist psychiatrist, paediatrician or other appropriately qualified healthcare professional with training and expertise ADHD. The recommendation states that a diagnosis should be based on a full clinical and psychosocial assessment of the person, a full developmental and psychiatric history, and observer reports and assessment of the person's mental state. Recommendation

## Evidence overview

1.3.2 states that a diagnosis of ADHD should not be made solely based on a rating scale, however, rating scales such as the Conners' rating scales and the Strengths and Difficulties Questionnaire can be valuable to a clinician, and observations (for example, at school) are useful when there is doubt about symptoms when making a diagnosis. Currently, two main diagnostic systems are used: the International Classification of Mental and Behavioural Disorders 10th revision (ICD-10) and the Diagnostic and Statistical Manual of Mental Disorders 5th edition (DSM-5).

NICE diagnostic guidance [DG60] on digital technologies for assessing ADHD recommended the use of QbTest (with standard clinical assessment by a healthcare profession) to help diagnose ADHD in children aged 6-17 years old, although further research is needed on the test in people over 18 years and to evaluate response to treatment (NICE 2024b). The QbTest is a continuous performance test with a motion tracking system suitable for people aged 6 to 60 years. The guidance states that digital technologies that combine measures of cognition and motor (physical) activity may help professionals when diagnosing ADHD. This could reduce the number or length of clinical appointments needed to reach a diagnosis, reducing patient waiting lists and freeing up NHS resources. It may also provide people with quicker access to appropriate further care or assessment (NICE 2024b). None of the digital technologies assessed by NICE included an eye tracking function measuring cognitive vergence.

### Cohort studies

HTW researchers identified two published cohort studies reporting the diagnostic accuracy of BGaze Clinic in adults with ADHD (Jiménez et al. 2021) and children (Varela Casal et al. 2019). Two other cohort studies about cognitive eye vergence were also identified.

Jiménez et al. (2021) assessed whether atypical eye vergence could be a diagnostic biomarker for ADHD in adults using the BGaze system with binocular eye tracker (Tobii) (N=144). Of these adults, 108 were previously diagnosed with ADHD and 36 were clinical controls. Most participants who were previously diagnosed with ADHD were taking medication. Cohorts were recruited from hospitals in Spain and in the UK. The study assessed eye vergence whilst performing an attention task. The diagnosis of ADHD was made using the American Psychiatric Association's DSM and psychologists evaluated ADHD severity using the Wender Utah Rating Scale, Conners' Adult ADHD Rating Scale, and a neuropsychological assessment. The diagnostic accuracy was 79%, the false positive rate was 25% and the false negative rate was 20.55%.

Varela Casal et al. (2019) validated vergence using BGaze Clinic with a binocular eye tracker (Tobii) as a marker to classify ADHD in children aged 7-17 years who were previously diagnosed with ADHD (n=43) when compared with age-matched clinical controls (n=19) and other peers (n=30) in Spain. The diagnostic accuracy was reported as 96.3% (false positive, 5.12%; false negative, 0%; area under the curve [AUC]: 0.99).

Two papers investigated whether the eye vergence (not assessed using the BGaze system), is altered in children with ADHD and/or ASD when compared to controls (Solé Puig et al. 2015, Bustos-Valenzuela et al. 2022) although neither report diagnostic accuracy values or other outcomes. Bustos-Valenzuela et al. (2022) found that children with ADHD and ASD showed shorter gaze fixation duration and weaker cognitive vergence responses to the eye regions of the face stimuli compared to children considered neurotypical. Solé Puig et al. (2015) observed deficient binocular vision in children with ADHD.

### Conference abstracts

Esposito et al. (2016) conducted a validation study of BGaze Clinic which was published as an abstract. The study included 270 children (41 were diagnosed with ADHD and 229 were considered neurotypical). The study recorded eye vergence in children whilst they performed a

## Evidence overview

visual detection task. Four types of machine learning algorithm was evaluated, and 138 trained models were tested with a validation set consisting of 232 children, including 22 children with ADHD. Across the 138 models, the average diagnostic accuracy was reported as 90.84% and an average AUC of 0.95.

**Cost-effectiveness outcomes**

BrainGaze Ltd sent HTW a health economics study on the BGaze system for mental health care from a Catalan health system perspective in Spain. Authors concluded that the Catalan health system could save more than one million euros using the BGaze system to diagnose ADHD in children and adolescents.

HTW researchers did not identify any published cost-effectiveness outcomes from a UK NHS perspective. Information from the topic proposer suggests the cost of rolling out BGaze Clinic would be £400 per patient which includes the cost of the tool, and the cost of the healthcare professionals involved.

**Ongoing studies**

Information from the topic proposer at BrainGaze Ltd confirms there is an ongoing cross-sectional study due to complete within the next two years. The study will explore eye vergence markers in adults and children with ADHD and ASD using BGaze Clinic and a Tobii 5L eye movement tracker, which is also CE marked. The primary outcome is to evaluate the sensitivity and specificity of cognitive eye vergence data. The study will aim to recruit 150 participants for the intervention group and 50 participants for the control group, and those with significant uncorrected ophthalmologic/visual problems will be excluded from the study.

## Areas of uncertainty

- The studies identified in this TER evaluated the accuracy of the cognitive vergence element of the BGaze system, and there is a lack of evidence evaluating the system as a whole and its use in a clinical setting.
- There is lack of evidence reporting outcomes such as improvements in patient management, time to diagnosis and treatment, reduction in referrals, cost savings and increased efficiency when compared to the current standard pathway in the diagnosis of ADHD.
- Further details on the artificial intelligence component of the technology would be useful, such as what type of machine learning is used.
- Further evidence on how the technology could potentially reduce carbon emissions would be welcomed.
- It is uncertain whether the technology could be used among people with oculomotor conditions such as deprivation amblyopia.

## Literature search results

| Health technology assessments and guidance |
|---|
| NICE. (2018). Attention deficit hyperactivity disorder: diagnosis and management. NICE guideline [NG87]. National Institute for Health and Care Excellence. Available at: https://www.nice.org.uk/guidance/ng87 [Accessed 16 January 2025].<br><br>NICE. (2024a). Attention deficit hyperactivity disorder: How common is it? : National Institute for Health and Care Excellence. Available at: https://cks.nice.org.uk/topics/attention-deficit-hyperactivity-disorder/background-information/prevalence/ [Accessed 16 January 2025].<br><br>NICE. (2024b). Digital technologies for assessing attention deficit hyperactivity disorder (ADHD). Diagnostics guidance DG60. National Institute for Health and Care Excellence. Available at: https://www.nice.org.uk/guidance/dg60 [Accessed 16 January 2025]. |
| **Evidence reviews and economic evaluations** |
| No evidence identified |
| **Individual studies** |
| Bustos-Valenzuela P, Romeo A, Boxhoorn S, et al. (2022). Atypical cognitive vergence responses in children with attention deficit hyperactivity disorder but not with autism spectrum disorder in a facial emotion recognition task. Psychiatry Research Communications. 2(2): 100045. doi: https://doi.org/10.1016/j.psycom.2022.100045<br><br>Esposito FL, Varela P, Alkan EO, et al. (2016). Validation of BGaze method supporting ADHD diagnosis. European Psychiatry. 33(S1): S135-S. doi: 10.1016/j.eurpsy.2016.01.211. Available at: https://www.cambridge.org/core/journals/european-psychiatry/article/validation-of-bgaze-method-supporting-adhd-diagnosis/D6E4F8068FA5109C9D464B401A690FD0<br><br>Jiménez EC, Avella-Garcia C, Kustow J, et al. (2021). Eye Vergence Responses During an Attention Task in Adults With ADHD and Clinical Controls. Journal of Attention Disorders. 25(9): 1302-10. doi: 10.1177/1087054719897806. Available at: https://pubmed.ncbi.nlm.nih.gov/31959011/<br><br>Solé Puig M, Pérez Zapata L, Puigcerver L, et al. (2015). Attention-Related Eye Vergence Measured in Children with Attention Deficit Hyperactivity Disorder. PLOS ONE. 10(12): e0145281. doi: 10.1371/journal.pone.0145281. Available: https://pmc.ncbi.nlm.nih.gov/articles/PMC4690612/<br><br>Varela Casal P, Lorena Esposito F, Morata Martínez I, et al. (2019). Clinical Validation of Eye Vergence as an Objective Marker for Diagnosis of ADHD in Children. Journal of Attention Disorders. 23(6): 599-614. doi: 10.1177/1087054717749931. Available at: https://pubmed.ncbi.nlm.nih.gov/29357741/ |

| | |
|---|---|
| **Date of search** | 13 January 2025 |
| **Concepts used** | BrainGaze, BGaze Clinic, cognitive vergence, attention deficit hyperactivity disorder, ADHD. |

## Proposed research question and evidence selection criteria (if selected)

| | |
|---|---|
| **Proposed Research question** | **What is the clinical and cost-effectiveness of BGaze Clinic for the diagnosis of ADHD?** |

| | Inclusion criteria | Exclusion criteria |
|---|---|---|
| **Population** | Adults or children awaiting ADHD diagnosis | People awaiting diagnosis for Alzheimer's disease or other cognitive disorders |
| **Intervention** | BGaze/other similar technology using eye vergence testing | |
| **Comparison/ Comparators** | Standard diagnosis from healthcare professional<br>Potentially the QbTest, recommended by NICE | |
| **Outcome measures** | Diagnostic accuracy outcomes (e.g., sensitivity, specificity, positive predictive values, negative predictive values)<br>Time to diagnosis and time to treatment<br>Reductions in referrals and/or waiting times<br>Health related QoL<br>Resource use<br>Economic outcomes | |

| | |
|---|---|
| **Proposed speciality** | **Mental and behavioural disorders** |