

30 July 2024

BlinkLab partners with Mental Care Group in Europe to improve and accelerate the diagnostic evaluation of ADHD

Positive results from the initial, prospective ADHD clinical trial run by BlinkLab and MCG provides a strong foundation for clinical adoption.

Highlights

- **Strategic partnership with the fifth largest outpatient mental health care provider in Europe.**
- **Partnership formalised following successful outcomes of a pilot study led by Mental Care Group that validated Blinklab's technology in a clinical setting.**
- **Initial prospective study in 184 participants showed that children with ADHD have significantly heightened sensory sensitivity, which can be objectively quantified by measuring the rate and amplitude of sound-evoked eyelid responses using the BlinkLab app.**
- **Partnership will accelerate BlinkLab's path to European and US regulatory approval for ADHD and clinical adoption. Data collected from the current clinical trial will be used as part of a large global ADHD study conducted by BlinkLab.**
- **Blinklab and MCG will scale up the rollout and validation of the solution in the coming years to a broader patient group and additional diagnosis.**

BlinkLab Limited (ASX:BB1) ("BlinkLab", "the Company"), an innovative digital healthcare company developing smartphone-based AI powered neurometric tests to aid in the diagnosis of neurodevelopmental conditions, is pleased to announce a major research and clinical partnership with Mental Care Group (MCG) in The Netherlands.

Smartphone-based digital sensory phenotyping is emerging as a promising aid in the diagnosis of ADHD. BlinkLab has developed an innovative app that administers these tests, using the smartphone's sensors to capture precise neurometric data. As part of the agreement MCG is anticipating to integrate the BlinkLab app into their processes for ADHD diagnosis. By analysing the nuanced behavioural and physiological responses collected via the app, BlinkLab will aim to identify ADHD characteristics, potentially offering patients a more rapid, accessible and objective assessment method. Through this partnership, MCG will use BlinkLab's technology to enhance their diagnostic accuracy and efficiency. This collaboration between BlinkLab and MCG exemplifies the potential of our mobile health platform to advance mental health diagnostics worldwide.

About Mental Care Group

Mental Care Group is the largest outpatient mental health care provider in the Netherlands and fifth largest in Europe. With 150 locations it includes a national network of psychologists, psychotherapists and psychiatrists serving over 80,000 patients annually. Leveraging its extensive knowledge and experience in Dutch mental healthcare, MCG focuses on all aged groups. The care offered includes treatments for anxiety disorders, depressive complaints, post-traumatic stress disorders (PTSD), ADHD and autism.

As a pioneer in e-health, MCG provides patients with multiple digital applications, including online enrolment, intake, and an extensive e-health library. Additionally, a segment of their patient base benefits from online or blended treatments. In partnership with BlinkLab, MCG envisions a transformative future where medical technology, AI, and digital applications revolutionize the prediction, diagnosis, and early intervention of healthcare needs. An example of the innovation is the patient portal that MCG developed in-house and went online this week. This collaboration aims to offer innovative treatment and support methods, enhancing patient outcomes and setting new standards in mental healthcare.

European Regulatory Approval and Clinical Adoption

BlinkLab and MCG will work together to obtain regulatory approval for the diagnostic application, and to accelerate the path to clinical adoption and reimbursement. The current study conducted in the Netherlands potentially could be used as part of the global ADHD study with BlinkLab opening additional recruitment and testing.

Shared Interests

ADHD affects 2.1-3.6% of Dutch children, with rising prevalence¹. Diagnosis typically takes

¹ Ten Have, M., Tuithof, M., van Dorsselaer, S., Schouten, F., Luik, A. I., & de Graaf, R. (2023). Prevalence and trends of common mental disorders from 2007-2009 to 2019-2022: Results from the Netherlands Mental Health Survey and Incidence Studies (NEMESIS), including comparison of prevalence rates before vs. during the

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more than 18 months, delaying necessary assistance² ³. Accelerating this timeline could greatly benefit affected children and their families. By identifying sensory processing patterns unique to ADHD, the BlinkLab test outcomes will provide valuable insights into ADHD's sensorimotor gating characteristics. Integrating technology-driven assessments will enhance diagnostic accuracy, leading to earlier and more personalised treatment. The MCG - BlinkLab collaboration is a significant step forward in merging technology with clinical assessment, offering a more efficient, objective, and measurable framework for ADHD evaluations.

Both BlinkLab and MCG are committed to reducing costs and improving outcomes for patients. This partnership will focus on accelerating the path to accurate diagnosis, ensuring rapid and effective treatment. At the end of 2023, there were almost 100,000 people on waiting lists in mental healthcare, according to the Dutch Healthcare Authority (NZa). Over half of this group has had to wait longer than the applicable standards. The consequences of the waiting lists are enormous for the patients and society. According to a recent study by the VU University Amsterdam, every month on a waiting list for mental health care reduces the chance of the patient eventually returning to work by 2 percent. Reducing waiting lists by one month would yield over 300 million euros per year⁴.

Positive Preliminary Results from the Study Conducted by MCG and BlinkLab

In a preliminary study conducted by MCG and BlinkLab, we explored the diagnostic utility of our smartphone-based neurometric evaluation for ADHD. Testing 184 children aged 6-18 we found that children with ADHD exhibit significantly heightened sensitivity to specific sounds without impaired filtering ability. This distinction may explain their increased distractibility compared to peers, demonstrating sensory sensitivity differences between people with ADHD symptoms and neurotypical controls. The BlinkLab tests offer an opportunity to integrate objective measures into the ADHD diagnostic process, moving beyond subjective questionnaires and observations. Specifically, the study utilized smartphone-based neurobehavioral testing to investigate differences in sensorimotor gating, specifically the acoustic startle response (ASR) and prepulse inhibition (PPI), between children with ADHD

COVID-19 pandemic. *World Psychiatry: Official Journal of the World Psychiatric Association (WPA)*, 22(2), 275-285. <https://doi.org/10.1002/wps.21087>

² Rocco, I., Bonati, M., Corso, B., & Minicuci, N. (2021). Quality of life improvement in children with attention-deficit hyperactivity disorder reduces family's strain: A structural equation model approach. *Child: Care, Health and Development*, 47(5), 667-674. <https://doi.org/10.1111/cch.12874>

³ van der Kolk, A., Bouwmans, C. A. M., Schawo, S. J., Buitelaar, J. K., van Agthoven, M., & Hakkaart-van Roijen, L. (2014). Association between quality of life and treatment response in children with Attention Deficit Hyperactivity Disorder and their parents. *The Journal of Mental Health Policy and Economics*, 17(3), 119-129.

⁴ Is Delayed Mental Health Treatment Detrimental To Employment? Job Market Paper, R&R at Review of Economics and Statistics, Dutch policy article: Kans op werk daalt door lange GGZ-wachlijsten, *ESB*, August 2023

and neurotypical controls. Conducted at MCG in Rotterdam, the study involved a total of 184 ($\pm 50\%$ female) participants aged 6-18 undergoing a 12-minute experiment that measured ASR and PPI at various sound intensities using facial landmark detection to track eyelid positions. Results indicated that children with ADHD showed significantly higher ASR at 10% ($p = 0.006$) and 25% ($p = 0.0003$) of maximum sound intensity, suggesting heightened sound sensitivity, while no significant differences in PPI were found. These findings highlight the potential of smartphone-based neurobehavioral testing to identify distinctive ADHD traits, potentially improving diagnostic accuracy and efficiency.

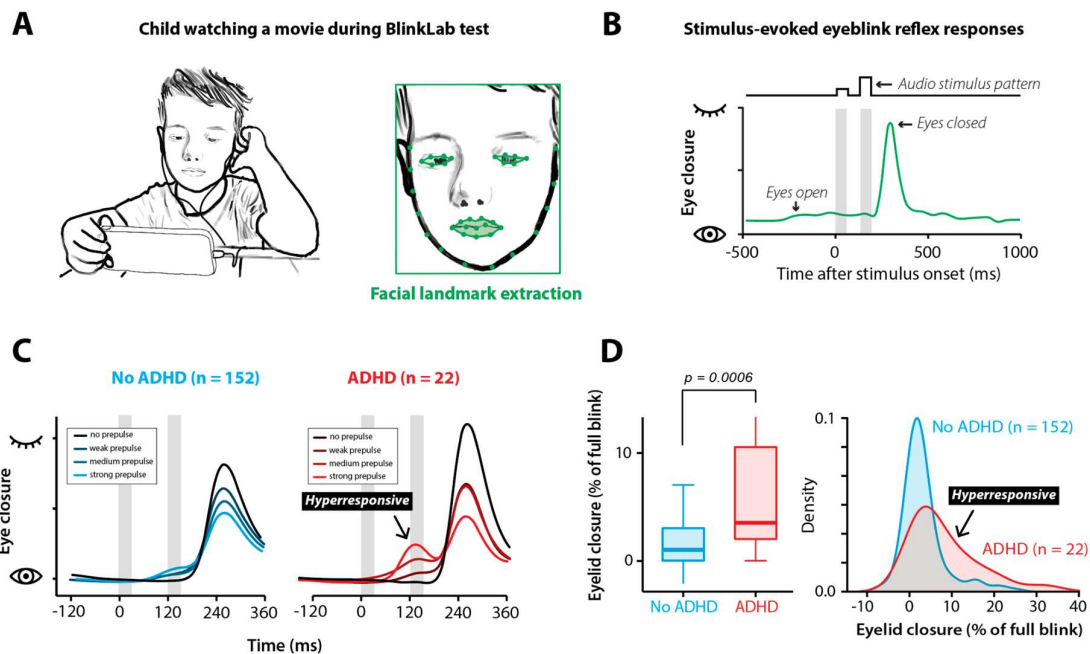


Figure | Preliminary data demonstrating the hyperresponsiveness to auditory cues in ADHD
(A) Children watch a movie on the smartphone during the BlinkLab test. **(B)** Facial landmarks and eyelid movements are extracted using AI. **(C,D)** Children with ADHD show hyperresponsiveness to weak and moderate intensity auditory stimulations indicated by the partial sound-evoked eyelid closures. In contrast to autism, children with ADHD show normal prepulse inhibition, indicated by the eyelid responses to the second sound (pulse) that become smaller when this sound is preceded by a weak auditory stimulus (prepulse).

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Jan Willem van der Windt, CEO Mental Care Group, commented:

“The Mental Care Group is dedicated to help children with ADHD in an efficient and effective manner. We are striving towards short wait times of less than six weeks, quick and objective diagnosis, measurable patient outcomes, and strong positioning by distinctive and innovative-thinking in the healthcare landscape. Unfortunately, we often see that the wait time at the Mental Care Group exceeds six weeks. This is partly due to time-consuming diagnostic processes and the lack of objective measurements, leading to uncertainty among professionals, parents, and children. Additionally, finding the right medication and dosage often takes a considerable amount of time. Clients sometimes find it difficult to indicate whether a medication is effective. Objective measurements could significantly speed up this process and really make a difference for clients, their parents and our providers. We believe that BlinkLab offers a promising solution, since their innovative AI platform can provide us with objective biomarkers related to psychological disorders such as ADHD”

Dr. Henk-Jan Boele, CEO BlinkLab, commented:

“This partnership with the Mental Care Group is a huge milestone for BlinkLab, since it will accelerate our path towards obtaining CE approval. Together with one of the largest and best players in the field of mental health care in Europe, we will work towards clinical adoption and reimbursement of BlinkLab evaluations. Data from our first study with MCG demonstrate that BlinkLab indeed can provide the clinical value that is beneficial for both healthcare professionals and families. We are grateful for the opportunity to work with MCG. Their aligned interests and commitment to patient benefit have made this collaboration incredibly rewarding.”

Terms of the “Master Agreement”:

- *Financial arrangements:* Should the parties agree to use the BlinkLab application to support MCG with the diagnostic process with respect to its patients on the basis of a separate (licence) agreement, BlinkLab will consult the MCG with respect to its pricing model for the licence fee and the MCG will receive a significant discount to such fee for the first contracting period under such (licence) agreement.
- *Intellectual property rights (IPR):* MCG and BlinkLab both keep the IPR they bring to the collaboration. If BlinkLab creates a new IP related to the application while working under the agreement, those rights belong to BlinkLab, and the MCG agrees to transfer those rights to BlinkLab. If new research or IPR is developed jointly, the parties will make separate agreements about any commercial benefits for MCG.

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- **Exclusivity:** MCG and BlinkLab agree that their cooperation shall be exclusive:
 - For the duration of the first project agreement as concluded on 29 July 2024 and, after that, for a period of two (2) years (with an extension of 1 year if certain commercial targets – to be determined between MCG and BlinkLab – are met) starting from the date on which the approved and validated BlinkLab application is used in a clinical setting as integral part of the diagnosis process;
 - With respect to ADHD, depression and anxiety disorders and all fields where the MCG has contributed substantially to the investigation(s) regarding the BlinkLab application;
 - Only for the Netherlands;
 - Within the mental health sector.
- **Term:** The Master Agreement is concluded for an indefinite term from the date of signing (29 July 2024).
- **Termination:** Either party may terminate the Master Agreement with 6 months written notice to the other party.
- **Confidentiality:** MCG and BlinkLab will treat as confidential, and preserve the confidentiality of, the other party's confidential Information.

Terms of the ADHD "Project Agreement":

- **Responsibilities:** BlinkLab will provide access to its technology, data and shall facilitate the use of its platform during the term of the Agreement.
- **Term:** Three years from the date of signing (29 July 2024), unless terminated earlier in accordance with the provisions of the Project Agreement.
- **Termination:** Either party may terminate the Project Agreement on "reasonable grounds" with a notice period of 6 months.

The Board of Directors has approved this announcement.

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About BlinkLab Limited

BlinkLab, a company founded by neuroscientists at Princeton University, over the past several years has fully developed a smartphone based diagnostic platform for autism, ADHD, schizophrenia, and other neuropsychiatric conditions. BlinkLab's most advanced product is an autism diagnostic test that leverages the power of smartphones, AI and machine learning to deliver screening tests specifically designed for children as young as 18 months old. This marks a significant advancement, considering traditional diagnoses typically occur around five years of age, often missing the crucial early window for effective intervention. BlinkLab is led by an experienced management team and directors with a proven track record in building companies and vast knowledge in digital healthcare, computer vision, AI and machine learning. Our Scientific Advisory Board consists of leading experts in the field of autism and brain development allowing us to bridge the most advanced technological innovations with groundbreaking scientific research.

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