



Positive results from the first of four clinical studies to evaluate Brain+’ Starry Night cognitive test for early detection of Alzheimer’s Disease

BRAIN+ A/S (BRAINP)

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The information communicated in this announcement is “inside information” for the purposes of article 7 of the Market Abuse Regulation 596/2014

- *Important first step in the clinical validation of Brain+’s gamified version of a proven lab-test to detect early cognitive deficits*
- *Early detection of Alzheimer’s disease opens up potential for more effective therapeutic interventions*
- *Three other studies on Starry Night will read out later in 2022*

A study led by Professor Masud Husain, at the University of Oxford, has evaluated the feasibility and performance of the Starry Night cognitive test intended for early detection of Alzheimer’s disease. The Starry Night test is developed by Brain+ as a gamified version of a lab-test, developed by Professor Husain’s team and proven to be sufficiently sensitive to detect pre-symptomatic Alzheimer’s disease.

Alzheimer’s disease can begin to create changes in the brain up to 20 years before symptoms are detected, at which point the disease has already caused significant cognitive impairment. If Alzheimer’s can be detected at an earlier stage, it would allow more effective action to be taken, with either lifestyle interventions, traditional pharmaceuticals or digital therapeutics such as cognitive training – or a combination of all of these.

The Oxford study of the Starry Night test had a total of 131 healthy participants of all adult ages, including people over the age of 50. The objective of the study was to evaluate the Brain+ Starry Night test against the original lab-test by comparing test outcomes. The results showed that the critical test outcomes were comparable between the two tests, thus validating the feasibility of the Starry Night test. As a secondary result, the study showed that the Starry Night test can be successfully used by individuals without regular access to neurology clinics. This is important, since it demonstrates that the test is suitable for scalable remote testing in people's homes.

Masud Husain, Professor of Neurology & Cognitive Neuroscience, University of Oxford *"I am delighted with the validation of a gamified version of our lab-test as it opens up the possibility for remote testing and data collection at a much larger scale without people needing to come to the clinic. As we build a large dataset on the Starry Night test, we hope to eventually enable remote cognitive precision testing and early pre-symptomatic detection of Alzheimer's disease."*

The study is the first of four clinical studies, all evaluating the Starry Night test and expected to read out in 2022. The studies are conducted and fully funded as part of the EU Horizon 2020 *Alzheimer's Detect and Prevent Project*, in which Brain+ is partnering with leading European academic brain clinics, Alzheimer's Europe and the European Brain Council.

Simon Nielsen, PhD, Director of Research & Innovation, Brain+ *"The demonstration of Starry Night's feasibility to read out as the original test is an important first step towards validation of our gamified and scalable approach to early dementia detection. Early detection and disease monitoring is highly relevant for Brain+'s ambitions to not only treat dementia, but to also address earlier stages of the disease. Following the positive readout of this first study, we are looking forward to seeing the results later this year from the studies of our test in people with dementia symptoms, conducted at University of Oxford, Nottingham University, and Århus University to clinically validate the test within early AD detection."*

Considering the findings from this study, Brain+ will now begin the planning of a large-scale trial to gather normative data on Starry Night. This will provide a population performance baseline, against which to compare individuals at risk of developing Alzheimer's disease for more effective future disease detection and treatment.

About the Starry Night cognitive test – How does it work?

The Starry Night test works on the well-described clinical findings that individuals at high risk of developing Alzheimer's dementia, but showing no apparent symptoms, exhibit a particular pattern of cognitive deficits related to memory and attention. The Starry Night test is designed as a game which builds on the thoroughly researched lab-test developed in Masud Husain's lab at Oxford University. The Starry Night test is designed to run on smartphones and tablets, so people can perform it from home, allowing scalable and remote testing.

About the Alzheimer's Detect and Prevent project.

The Starry Night test has been developed as part of an EU-Horizon2020 funded innovation project led by Brain+ and with partners University of Oxford, Nottingham University, Aarhus University, Aarhus University Hospital, Alzheimer Europe and the European Brain Council. The total project budget is €3.5 million, and the project runs from November 2018 to April 2022. The main objective is to engage people early before Alzheimer's disease manifests to detect the disease to enable prevention efforts. The project focuses on enabling early presymptomatic detection of Alzheimer's

Disease with a special memory test developed by the University of Oxford, which during the project has been further co-developed and gamified with Brain+. The test, called Starry Night, is being validated in four studies, two at University of Oxford, one at Nottingham University, and one at Aarhus University. A second work stream aims to reduce risk of Alzheimer's disease in healthy elderlies, who are at risk of Alzheimer's disease, via general cognitive training. This is being validated in studies with the University of Nottingham. Read more here about the project: <https://www.addp.eu>

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About BRAIN+ [BRAINP]

The mission of Brain+ is to restore patients' independence and quality of life by treating and detecting cognitive decline in Alzheimer's disease and dementia through software-as-medicine applications. Brain+ has developed a set of software-as-medicine technologies, which enable the Company to create a unique and differentiated product offering. These technologies, combined with a strong clinical pipeline, puts Brain+ in a strong position to grow towards a market leader position in the Digital Therapeutics (DTx) space.