

# Flaw in Alzheimer's drug trial test

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New research led by Plymouth University Peninsula Schools of Medicine and Dentistry suggests that the cognitive test used in Alzheimer's drug trials is flawed.

The current standard [cognitive test](#) for the disease is the ADAS Cog. The new research, published as two studies in *Alzheimer's & Dementia: The Journal of the Alzheimer's Association*, investigates the role of the [test](#) and questions its effectiveness.

The studies show that the ADAS Cog is not subtle enough to properly track changes in the early stages of Alzheimer's. This is important because data from this key stage is required to show whether or not a new drug is working. The study also showed that the modern method of "Rasch analysis" confirmed the flaw.

In their first study, the researchers examined 675 measurements from people, aged 53 to 90, with mild Alzheimer's disease across five time points – 0, six, 12, 18 and 24 months. In terms of final patient score the ADAS-cog seemed sound. But by breaking down all the data to component level, a different story emerged. A "ceiling effect" was exposed for eight out of the 11 parts of the ADAS-cog with many patients – ranging from 32 to 83 per cent - "passing" the section when in reality much greater variance between the patients almost certainly existed and needed scoring.

In the second study, the research team moved on to use the modern method of "Rasch analysis" to further test the data. This confirmed the

flaw. The more sophisticated method of analysis also suggested a number of possible pathways to improvement including making parts of the ADAS-cog test more difficult as well as re-thinking the scoring structure.

As a consequence, the Plymouth-based research team is suggesting urgent changes to the ADAS Cog – and is not ruling out the need for a new test.

The study was led by Professor Jeremy Hobart. He said: "It is impossible to say precisely the extent to which the ADAS Cog's flaws have undermined the numerous clinical trials in which it has been used. It has been used, unchanged, for many years and its apparent contribution to suboptimal trials has led a number of drug companies to rethink their strategies. However, it is very clear that in its current form the ADAS Cog underestimates cognitive differences between people and changes over time. To determine if treatments, developed from painstaking years of research, work in expensive studies we need to invest in developing measurement instruments that are fit for purpose. This requires the routine use of different methods. In its current form, the ADAS Cog is not working in people with mild [Alzheimer's](#) disease."

Provided by University of Plymouth

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