

ADAS-Cog in focus: Understanding administration and scoring errors in Alzheimer's disease clinical research

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BACKGROUND

The Alzheimer's Disease Assessment Scale - Cognitive Subscale (ADAS-Cog) is the most commonly used cognitive efficacy measure in Alzheimer's disease clinical trials.

Performance of external expert review of the cognitive scales such as the ADAS-Cog allows a detection of scale administration and/or scoring errors and their subsequent remediation.

Our research aimed to identify the most frequent administration and scoring errors on the ADAS-Cog and to determine if an association exists between scoring and administration errors both within and across study visits.

RESULTS

- A total of 47,238 ADAS-Cog assessments were reviewed.
- ADAS-Cog administration and/or scoring errors occurred in 9,288 (19.6%) visits.
- Administration errors were found in 4467 instances (9.46%) and scoring errors were found in 6494 instances (13.75%).
- The items with the largest number of errors (Figure 1) were the following: Number Cancellation (23.38%), Constructional Praxis (20.48%), Orientation (12.25%), Word Recognition (11.9%) Naming Objects and Fingers (10.84%).
- The presence of administration and scoring errors (Figure 2) were not statistically significantly associated within visits ($\chi^2(1)=733.5, p>0.5$).
- There was a mean change in the number of flags per visit of -0.0287, representing a reduction of 8.38% relative to the baseline number of flags per visit (Figure 3).

Figure 1. Percentage of errors in ADAS-Cog per item

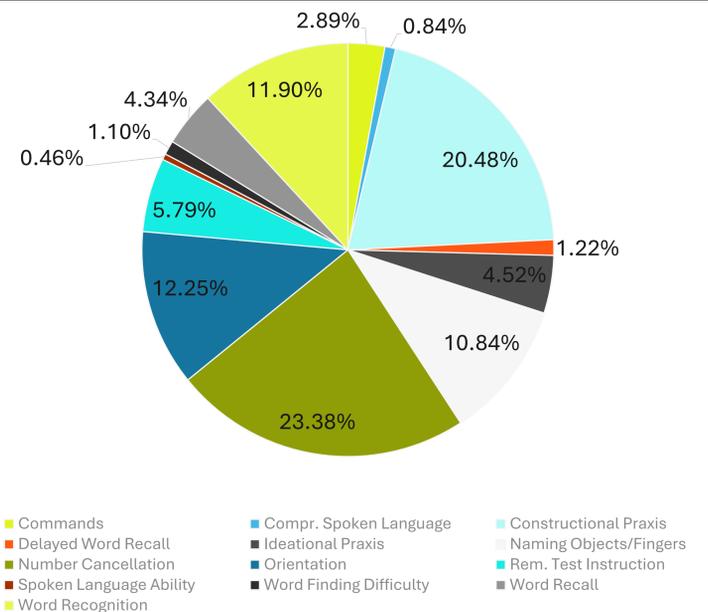


Figure 2. Administration and scoring errors in ADAS-Cog per item

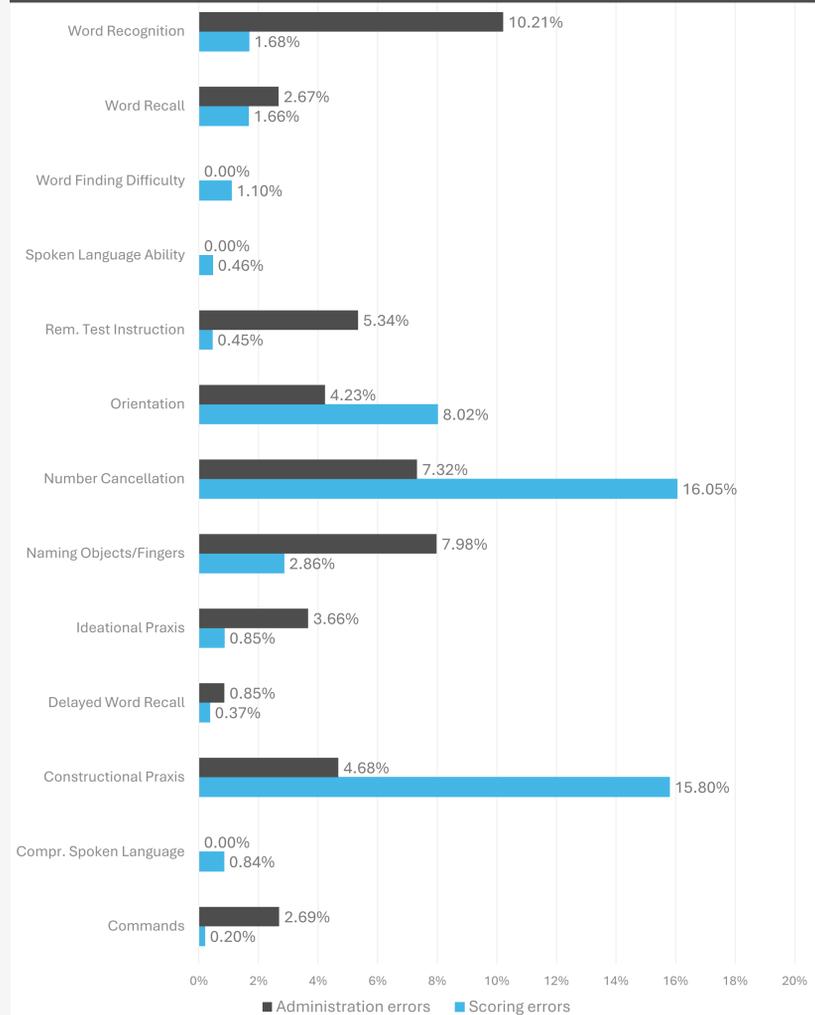
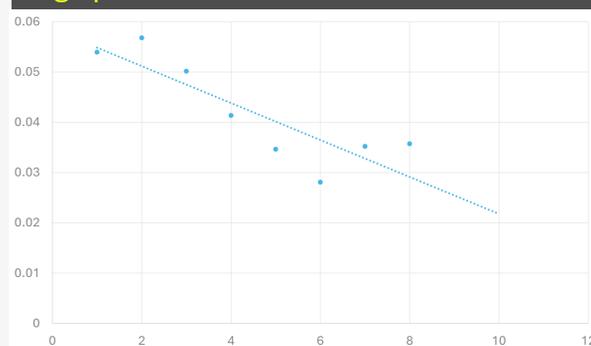


Figure 3. Mean change in number of flags per visit



METHODS

- Data were pooled from 14 global dementia clinical trials where the ADAS-Cog was used as an efficacy outcome.
- ADAS-Cog recordings and data were reviewed by expert clinical reviewers who were trained and calibrated for the identification and remediation of administration and/or scoring errors.
- The most frequently occurring administration and scoring errors for each item on the ADAS-Cog scale were evaluated.
- The association between administration and scoring errors within visits and across visits over time were analyzed using Chi-square test and regression analysis.

CONCLUSIONS

- Our study identified a substantial prevalence of scoring and administration errors on the ADAS-Cog, which tend to occur independently of one another. The number of flags decreased across flag reviews over the course of the clinical trials, which can be partially explained by ongoing remediation and rater re-training.
- The lack of association between administration and scoring errors may be explained by unique scale specificities such as differences in manual versions and unfamiliarity with administration and scoring conventions.