

Improving Administration and Scoring in CAPS-5

Submitter Elisa Conrad

Affiliation WCG Clinical Endpoint Solutions

SUBMISSION DETAILS

I agree to provide poster pdf for attendee download. Yes

Poster PDF for download <blank>

Methodological Issue Being Addressed The Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) is recognized as the gold standard for clinical trial outcomes and is typically implemented using a structured pencil and paper clinical interview. However, the scale's intricate administration and scoring processes have been noted to introduce the potential for increased error and variability among raters that may adversely impact data quality and signal detection.

Introduction In an effort to reduce administration and scoring errors, an electronic (eCOA) version of the CAPS-5 was built by expert clinicians to provide administration and scoring guidance throughout the form. Most importantly, this electronic version of the form automates the severity score at the item, symptom cluster, and total symptom severity levels, components often miscalculated and misinterpreted in the paper form.

Methods Among clinical trial participants, CAPS-5 paper-based assessments (n=195) were compared to those administered on eCOA (n=356) by a team of calibrated reviewers using audio recordings and source data. The proportion of assessments with quality issues, such as scoring and administration errors, was calculated in both groups. To control for potential differences in disease severity between assessments with quality issues and those without, the predictive impact of severity on review outcome was also investigated.

Training for both groups of raters (paper and electronic) administering the CAPS-5 was identical and encompassed a didactic tutorial on the CAPS-5, covering development, principles of use, interview techniques, and scoring approaches. A post-test, mandating a minimum score of 80%, ensured comprehension. Trainees below this threshold underwent remediation and a subsequent retest. Following this, inter-rater reliability was evaluated through a videotaped CAPS-5 interview, compared against gold-standard scores. Attaining 80% agreement in this reliability exercise was required; those who did not meet these criteria, underwent remediation and retesting. A final applied training session, led by scale experts, evaluated assessment techniques, adherence to scoring guidelines, administration protocols, and general knowledge about the indication and scale.

Results Paper administrations of the CAPS-5 evidenced over twice the rate of quality issues (29%) versus eCOA (13%) This difference was statistically significant ($\chi^2 = 22.049$, $df = 1$, $p = 0.000002657$). A binary logistic regression predicting review outcome from CAPS-5 severity score was not statistically significant ($p = 0.971$), providing no evidence that the patient's disease severity had an impact on whether or not an assessment had quality issues.

Conclusion In PTSD clinical trials, rater error in CAPS-5 assessments is a source of variability, reducing power and increasing the risk of trial failure. The present study was intended to help evaluate the impact of utilizing an electronic adaptation of the scale in reducing rater error compared to traditional paper and pencil administrations. The use of an electronic platform, with real-time clinical guidance, automated scoring, and other features, can help standardize scale administration and scoring, substantially reducing error variance and improving signal detection.

Co-Authors

* Presenting Author

First Name	Last Name	Affiliation
Elisa *	Conrad *	WCG Clinical Endpoint Solutions
Neelee	Chini	WCG Clinical Endpoint Solutions
Raymond	Blattner	WCG Clinical Endpoint Solutions
Selam	Negash	WCG Clinical Endpoint Solutions
Christopher	Poppe	WCG Clinical Endpoint Solutions
Mark	Opler	WCG Clinical Endpoint Solutions

Keywords

Keywords
CAPS-5
PTSD
eCOA
data quality
signal detection

Guidelines I have read and understand the Poster Guidelines

Disclosures All authors are employees of WCG, Clinical Endpoint Solutions

Related Tables and Supporting Materials <blank>