eCOA Prompted MADRS Interview: Balancing Thorough Assessment and Efficiency

SUBMISSION DETAILS

What is the Methodological Question Being Addressed? Do modes of MADRS administration significantly differ in depth of assessment and efficiency?

Introduction The Structured Interview Guide for the Montgomery Asberg Depression Rating Scale (SIGMA) and the electronic Computer Prompted Structured Interview (CPI) are widely used in Major Depressive Disorder (MDD) clinical trials to evaluate treatment efficacy and guide subject selection. CPI is an interview driven by an algorithm that selects the next question based on last response and offers on screen prompts that help the rater guide the interview. We compared the CPI and paper prompted interview (PPI) SIGMA to assess whether there is a difference in interview duration times and to understand if a particular mode of administration is better able to balance thorough clinical assessment with interviewing efficiency.

Methods Data were obtained from 6 MDD studies that used different formats of MADRS administration (SIGMA or CPI delivered on the Rater Station device) and were divided into two groups based on subject depressive severity:
More Severe Group. (MADRS total score > 30) This data set contained 2,339 visits and of those visits, 1,087 visits (46.5%) used CPI and 1,252 visits (37.6%) used SIGMA.
Less Severe Group. (MADRS total score ≤ 30) This data set contained 9,566 visits and of those visits, 9,321 used CPI (97.4%) and 245 (1.67%) used SIGMA.
Up-Sampling was completed resulting in 2,504 visits in Group 1 and 18,642 visits in Group 2 with equal percentage distribution of the two types of scale administrations.

Results For both groups, a Shapiro-Wilk test for normality on interview duration by scale format found the distribution to be significantly different from a normal distribution. A Kruskal Wallis test found the influence of scale format on interview duration to be significant ($p < 0.0001$). A subsequent post-hoc Dunn test found SIGMA vs. CPI comparison to be significant.
For More Severe Group, the CPI had a longer mean interview duration of 20.40 minutes and SIGMA had an interview duration of 17.59 minutes.
For Less Severe Group, the SIGMA had the longer mean interview duration of 17.61 minutes and CPI had an interview duration of 10.70 minutes.

Conclusion Results demonstrate a significant difference in interview duration between the MADRS scale administration formats for both groups. For More Severe Group, the CPI interview had a significantly longer duration compared to the SIGMA. For Less Severe Group, the CPI had significantly shorter duration than the SIGMA.
These findings support the value of the CPI for subjects across the severity continuum. In particular, results suggest that the CPI promotes thorough evaluation for subjects with relatively greater severity, and facilitates administration efficiency for subjects with relatively lower severity. These findings can be attributed to the CPI's computerized question mapping that encourages

investigators to ask all necessary questions to gather the information needed to rate with precision, while guiding raters to skip unnecessary probes for more efficient interviewing with subjects who have a relatively lower level of severity.

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