Impact of within PANSS Logical Errors on PANSS Marder Negative Factor Internal Consistency – an Exploratory Post-hoc Analysis

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The Methodological Question Being Addressed

Does the presence of within PANSS logical errors affect the internal consistency of PANSS Negative Factor subscale?

Introduction

We have recently developed a battery of within PANSS logical errors extending the originally published battery (Rabinowitz, 2017) focusing predominantly on positive symptoms with logical inconsistencies between PANSS negative symptoms (Kott, 2017). The presence of these "negative symptom" errors in a database of over 73,000 visits varied between 14.8 affected visits in acute schizophrenia trials to 22.1% in studies in negative symptoms.
In the current post-hoc analysis of 4 multicentric schizophrenia clinical trials we assessed the impact of the presence of these PANSS "negative symptom" errors on the internal consistency of the PANSS Negative Factor (Marder, 1997)

Methods

Baseline visit data from 4 negative symptom schizophrenia clinical trials with available PANSS item scores were included in the analysis. We dichotomized the data into two groups by the presence of at least one within PANSS error. We calculated unstandardized Cronbach's alpha coefficients to estimate the internal consistency of the PANSS Negative factor per each group and protocol and statistically compared the obtained estimates within each protocol between the two groups.

Results

The dataset consisted of 2,123 baseline visits. At least 1 within PANSS error was recorded in 717 (33.8%) visits. Of the visits affected by within PANSS errors, the majority, 499 (69.6%) were affected by a single error, and 152 (21.2%) by 2 within PANSS errors. The largest number of errors recorded per visit was 6 identified in a single subject. The unstandardized Cronbach's alpha of the PANSS Negative Factor ranged from 0.69 to 0.78 in the groups with no within PANSS errors and 0.52 to 0.78 in the groups with at least 1 within PANSS error present. 3 out 4 of the estimated coefficients were statistically significantly higher in the group with no within PANSS errors compared to the groups with at least 1 within PANSS error present. In one protocol there were no differences between the estimates.

Discussion

Our data indicate that the presence of within PANSS errors can in most instances significantly decrease the internal consistency of the PANSS negative factor. The presence of within PANSS errors may reflect simple clerical errors, lack of understanding of the PANSS scale or in the worst case scenario possible data manipulation to assure subject's eligibility into the trial. Real time data quality

monitoring solutions consisting of intelligent eCOA providing immediate alerts and notifications, audio and video recordings of interviews and predictive analytics should be implemented in clinical trials to identify and minimize the presence of these errors in the dataset. We plan to further assess whether the presence of within PANSS errors influences the placebo response or drug/placebo separation in trials focusing on negative symptoms.

References

Rabinowitz, Jonathan; Schooler, Nina R.; Anderson, Ariana; Ayearst, Lindsay; Daniel, David; Davidson, Michael et al. (2017): Consistency checks to improve measurement with the Positive and Negative Syndrome Scale (PANSS). In *Schizophr. Res. DOI:* 10.1016/j.schres.2017.03.017.

Kott, Alan; Daniel, David G. (2017): Data quality concerns associated with PANSS negative items – an exploratory analysis. Poster presentation. CNS Summit Annual Meeting. Boca Raton, FL, USA, 11/16/2017.

Disclosure:

All authors are full time employees of Bracket.