Presented at the 22nd Annual ISCTM Scientific Meeting, Feb 18 - 20, 2026, Washington, D.C.

Assessing PANSS change in the screening period in acute schizophrenia clinical trials

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METHODOLOGICAL ISSUE BEING ADDRESSED

To examine how individual PANSS items, subscales, and factors change during the screening phase of acute schizophrenia clinical trials.

INTRODUCTION

- Screening phases in acute schizophrenia trials often involve a wash-out of prior antipsychotic medication before randomization.
- Observed mean changes in the PANSS during screening are typically minimal.
- This retrospective analysis aimed to clarify the magnitude and pattern of changes at the PANSS item, PANSS subscale, PANSS factor and PANSS total score levels.

METHODS

- Screening and baseline PANSS scores were pooled from 16 monotherapy trials including 6,422 participants with acute schizophrenia.
- For each subject, the change from screening to baseline was computed across 30 PANSS items, the three subscales, the five factors, and the total PANSS.
- Linear mixed-effects models were fitted for each variable, with change as the dependent variable, the screening score as a covariate, and random intercepts for protocol.

RESULTS (SEE FIGURES 1 AND 2)

- **Significant changes were identified in 18 of 30 PANSS items:**
  - 15 worsened (mean change 0.027–0.10), most notably Somatic Concern (G1)
  - 3 improved (0.04–0.07), led by Active Social Avoidance (G16).
- **Among the subscales**
  - The Negative subscale exhibited the greatest worsening
  - The Positive subscale remained stable
- **Among the factors**
  - Disorganized Thought worsened most
  - Hostility/Excitement and Anxiety/Depression remained largely unchanged
- **Mean total PANSS increased by 0.67 points between screening and baseline**

FIGURE 1: CHANGES IN SCREENING PERIOD ON THE PANSS ITEM LEVEL

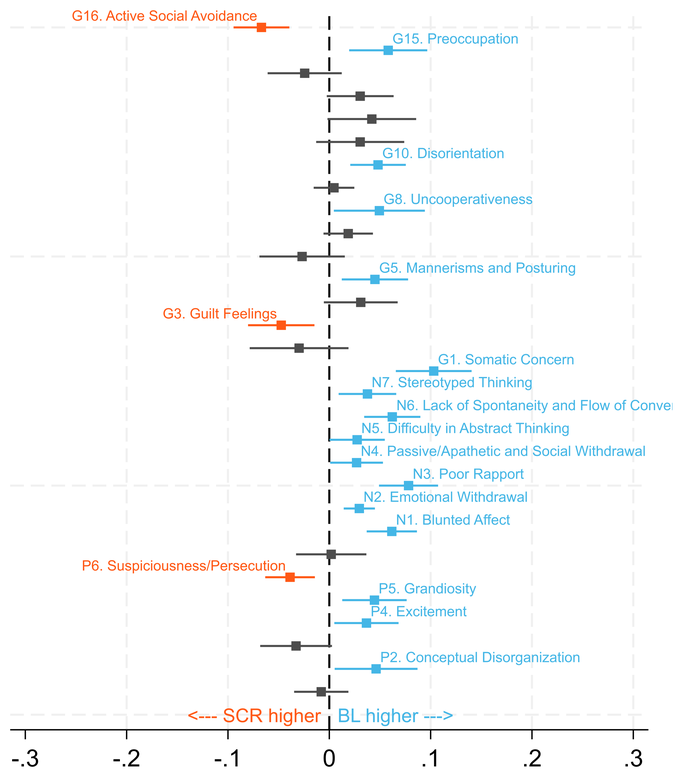
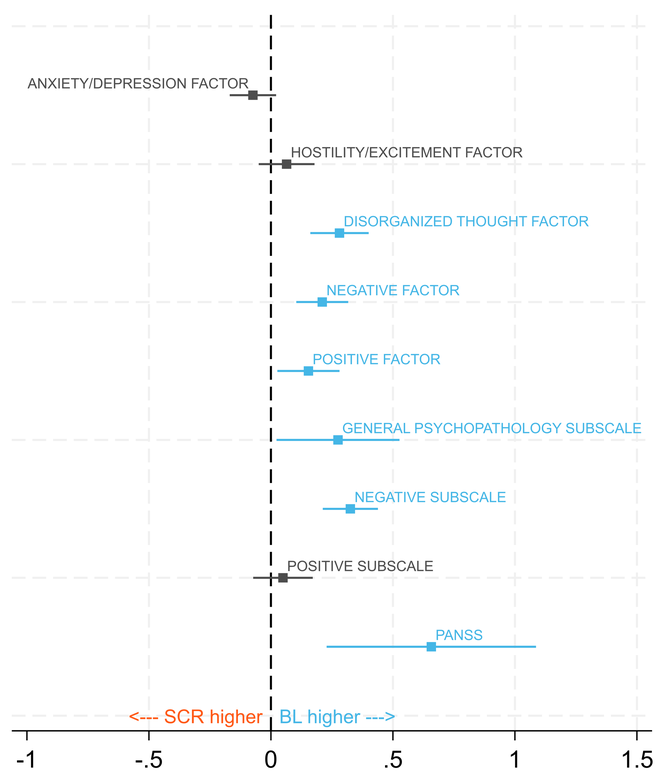


FIGURE 2: CHANGES IN SCREENING PERIOD ON THE PANSS SUBSCALE, FACTOR AND TOTAL LEVEL



CONCLUSIONS

- Despite medication wash-out, symptom changes during screening were small, with total PANSS worsening by less than one point.
- Approximately half of participants showed symptom worsening, while others remained stable or improved.
- Unexpectedly, negative symptoms exhibited the most consistent deterioration, a pattern that merits further study.
- Suspiciousness/persecution and Active social avoidance both improved consistent with the notion that the hospital environment may have had a palliative effect.
- We hypothesize that factors beyond medication discontinuation—such as setting or informant changes—may have contributed to this pattern.

Disclosure: Authors declare no conflicts of interest

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