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Introduction: Lack of insight in schizophrenia is frequently associated with deficits in self-assessment of cognitive and functional abilities, as well as quality of life outcomes.

Objective: The aim of this analysis was to evaluate the impact of treatment-related improvement in illness awareness on changes in cognition and functional outcomes in a double-blind, controlled study.

Methods: Clinically unstable patients with schizophrenia (N=488) were randomized to once-daily, fixed dose treatment with lurasidone 80 mg (LUR 80), lurasidone 160 mg (LUR 160), quetiapine XR 600 mg (QXR) or placebo (PBO), followed by a 12-month, double-blind extension. Impairment of insight (G12 'lack of judgment and insight'), cognitive performance, quality of well-being (QWB scale), and UPSA-B were assessed at baseline, week-6 and month-6 of extension (32 weeks). Mixed effects model was applied.

Results: PANSS insight scores were significantly improved for all treatment groups compared to placebo after 6 weeks. Improvement in insight at week-32 was significantly greater in subjects treated with lurasidone compared with quetiapine XR. Improved insight at week-6 was a significant mediator for the effect of LUR160 (vs. placebo) on neurocognitive composite score ($p<0.05$), UPSA-B total score ($p<0.05$), and QWB ($p<0.05$) at week-6. Improved insight was significantly associated with increase in UPSA-B score and health-related quality of life at weeks 19 and 32.

Conclusion: Improvement in insight at week-32 was significantly greater in subjects treated with lurasidone compared with quetiapine XR. Our findings suggest treatment-related improvement in illness awareness had significant impact on cognition and functional outcomes in a double-blind, controlled study.