

OPUS YOUNG: BLINDED SUMMARY; KEY FINDINGS FINAL, August 5, 2026

Importance: Impairments in personal and social functioning are common among adolescents with psychosis and represent an important target for intervention. Robust evidence from pragmatic randomized clinical trials evaluating long-term improvements in functioning remains limited.

Objective: To determine whether Group A improves personal and social functioning compared with Group B over 24 months in adolescents receiving mental health care.

Design, Setting, and Participants: Pragmatic, parallel group, randomized clinical trial conducted in Denmark. Participants with psychosis aged 12-17 years were randomized 1:1 to Group A or Group B using stratified randomization based on age (<15 vs ≥15 years) and baseline Personal and Social Performance (PSP) total score (<45 vs ≥45) and followed for 24 months. Analyses were performed according to the intention-to-treat principle using a prespecified mixed model for repeated measures.

Interventions: Participants were randomized to Group A or Group B.

Main Outcomes and Measures: The primary outcome was change in personal and social functioning measured using the PSP scale total score (range, 1-100; higher scores indicate better functioning). The primary efficacy analysis adhered to the intention-to-treat principle by comparing participants according to their randomized treatment assignment regardless of treatment adherence or protocol deviations: The primary analysis used a mixed model for repeated measures including repeated PSP measurements at baseline (t=0), 12 months, and 24 months, adjusted for baseline PSP, treatment group, visit, treatment-by-visit interaction, and the randomization stratification factors.

Results: A total of 290 youths (mean [SD] age, 15.6 [1.6] years; 210 [72%] girls) were randomized to A (n = 146) or B (n = 144), with primary outcome data available in 131 (90%) and 116 (81%), respectively, at 24 months. The mean (SD) baseline PSP total score was 49.9 (13.8), consistent with a population on average experiencing marked functional impairment, with substantial limitations in personal and social functioning. At the prespecified primary endpoint of 24 months, adjusted mean change in PSP scores were 3.87 in Group A (SE: 0.91) and 1.13 in Group B (SE: 0.95), corresponding to an adjusted mean difference of 2.74 points (95% CI, 0.21 to 5.27; P= 0.034).

At the 24-month follow-up, both groups showed improvement in positive symptoms (measured by the Scale for the Assessment of Positive Symptoms), with no evidence of a between-group difference (mean change, -1.20 vs -0.96; mean difference, -0.24 [95% CI, -0.52 to 0.04]; P = .10). Similarly, there was no evidence of a between-group difference in negative symptoms (measured by the Scale for the Assessment of Negative Symptoms; mean change, -0.18 vs 0.02; mean difference, -0.19 [95% CI, -0.42 to 0.03]; P = .09).

Conclusions and Relevance

Among youth with psychosis, both interventions were associated with improved outcomes over 24 months. Although the between-group difference favored group A over group B for the primary endpoint, the observed treatment effect did not reach the prespecified minimally important difference and should therefore be interpreted in the context of its clinical importance. These findings suggest that group A may offer an advantage over group B as a first-line psychosocial intervention for youth with psychosis.

Trial Registration: *ClinicalTrials.gov* identifier: NCT04916626