

## Plain language results summary

In this cluster randomised controlled trial, 24 primary health care centres (PHC) were randomly allocated to either the STOPS+ intervention or usual care. In total, 701 patients were screened and 526 took part in the study (260 in STOPS+ and 266 in Enhanced Treatment as Usual (ETAU) arms). The study aimed to examine whether the STOPS+ intervention improved adherence with treatment, level of functioning, symptoms, and quality of life. Participants were followed up over 6 and 12 months, and a total of 455 (86.5%) patients completed the 12 months follow-up in both groups.

The baseline demographic and clinical features were broadly similar in the two groups. The mean age in both groups was about 34 years, and about two thirds of patients were male (73.1% STOPS+ vs 75.6% ETAU). At baseline, Global Assessment of Functioning (GAF) was also similar (15.2% STOPS+ vs 15.6% ETAU) across arms, indicating that both groups had severe symptoms with serious impairments in functioning. This was also reflected in other clinical measures such as Brief Psychiatric Rating Scale (BPRS) (13.8% STOPS+ vs 13.4% ETAU), and Clinical Global Impression (CGI) scales.

At 6-month and 12-month follow-up, the STOPS+ group generally had slightly better outcomes, including higher functioning (1.43 (-1.10, 3.96) {P=0.27}), better medication adherence (the odds ratio for 'always' taking medication over 'not always' taking medication was 2.17 (95%CI 0.85, 5.56 {P=0.10}) for STOPS+ vs ETAU), and improved quality of life (3.03 (0.25, 5.81) {P=0.033}). Functioning improved slightly more in the STOPS+ group compared to ETAU, though this was not statistically significant. Similarly, treatment adherence improved in both groups but there was no statistically significant difference. No significant differences in side effects or adverse problems were seen between the groups.

We conclude that an intervention comprising treatment supervision by family members and involving primary care in the treatment of schizophrenia did not result in significantly better outcomes in terms of treatment adherence, schizophrenia symptoms and/or level of functioning when compared to ETAU in a low- and middle-income country (LMIC) setting like Pakistan. It is noteworthy that both groups showed significant improvements compared to the baseline in most outcome measures. It is possible that the ETAU group received enhanced care in the form of free access to drug treatment (unlike usual treatment in Pakistan, where patients almost always buy pharmacological treatment as an out-of-pocket expense). This may partially explain the lack of statistically significant differences between groups. This implies that providing essential medication free of cost to all patients experiencing schizophrenia may significantly improve treatment adherence, symptoms and functioning in LMICs.