OBJECTIVE
The primary objective of this study is to examine the efficacy and tolerability of fluoxetine treatment of depressed adolescents with a co-morbid substance-related disorder.

METHODS
Outpatients aged 12-17 years meeting DSM-IV diagnostic criteria for a major depressive disorder or dysthymic disorder with a co-morbid substance-related disorder were eligible to enroll.

Patients also had to suffer from depressive symptoms of at least moderate severity (CDRS-R ≥ 40).

Eligible subjects were randomized to receive either fluoxetine or matching placebo in a double-blind fashion.

RESULTS

- Enrollment into the trial was stopped after the interim analysis was performed, after 34 patients had been enrolled, on the basis of the pre-specified futility stopping rule.

- Comparison of the primary outcome via mixture model analysis crossed the a priori futility boundary for early stopping with acceptance of the null hypothesis of no treatment difference in mean change in CDRS-R total score (estimated treatment difference = 0.19, S.E. = 0.58, F = 0.14, p = .74).

CONCLUSIONS
Fluoxetine was not superior to placebo in alleviating depressive symptoms in adolescents with depression and a substance use disorder.

Those patients treated with fluoxetine, did not show a significantly greater decrease in their substance use in comparison to those patients who received placebo.

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