Fluoxetine may prevent relapse in post traumatic stress disorder


QUESTION: Is fluoxetine effective and tolerable for preventing relapse in post traumatic stress disorder (PTSD) for up to 6 months?

Design
Randomised controlled trial. Participants, clinicians and outcome assessors were blind to treatment allocation.

Setting
18 centres is Belgium, Bosnia, Croatia, Yugoslavia, Israel and South Africa; June 1998 to August 2000.

Participants
Participants were 131 people diagnosed with PTSD (DSM-IV criteria); 81% men; 90% Caucasian; 47% exposed to combat-related traumatic events; mean age 38 years; mean duration between trauma and start of trial 5 years. Exclusion criteria were serious comorbid illness; concomitant psychotherapy; suicide risk or serious risk to others; Axis I psychiatric disorder 5 years before traumatic episode or following the primary traumatic episode, or lifetime diagnosis of bipolar disorder, obsessive compulsive disorder or schizophrenia.

Intervention
After 12 weeks of acute treatment with fluoxetine, responders received 24 weeks of relapse prevention with fluoxetine or placebo. (Responders had a 50% or greater decrease in the 8-item Treatment Outcome PTSD [TOP-8] score from baseline). The initial dose of fluoxetine was 20 mg/day, increased to a maximum of 80 mg/day. The mean final dose was 53 mg/day. Mean drug exposure was 157 days during the 6-month maintenance period.

Main outcome measures
Time to PTSD relapse was measured using the TOP-8 scale and the Clinical Global Impression of Severity scale (CGI-S). Safety was assessed using adverse effects, discontinuation due to adverse effects, measurement of vital signs and clinical laboratory tests.

Main results
Participants receiving fluoxetine maintenance were less likely to relapse compared with placebo (table) and had greater mean improvement on the TOP-8 scale. There were no significant differences in treatment emergent adverse effects.

Conclusions
Fluoxetine maintenance may prevent relapse in post traumatic stress disorder for up to 6 months.