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Fluoxetine in the Treatment of Children with PTSD

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Introduction: Military action in Ukraine led to increasing in the number of patients with PTSD among children. Open-label studies demonstrated the efficacy of SSRI's for the treatment of PTSD, primarily paroxetine. Feasibility of using of these drugs in children and adolescents is controversial [1-2].

Objective: To evaluate a short and long-term efficacy and tolerability of fluoxetine in the treatment of PTSD in children.

Methods: double-blind, placebo-controlled 12-week study with a fixed dose of fluoxetine (20-40 mg). The trial design consisted of 1-week, single-blind, placebo run-in period, followed by a 12-week treatment period and a 2-week taper phase. Were randomized 110 children aged from 12 to 18 years (MD = 14,2), that have been moved from the combat zone in the east of Ukraine and met the DSM-5criterias for PTSD. Drug efficacy was assessed weekly using the CAPS-2; CGI-I / CGI-S. Safety assessed: Adverse event (AE) recording, suicidality assessment.

Result: The reduction in CAPS-2 scales was statistically significant among children randomized to fluoxetine treatment compared with placebo in a week 12 endpoint (treatment difference -11.10; 95% CI-13.4, -7,38; p <0.001). Significant greater proportion of fluoxetine-treated patient (52%) than placebo-treated (43%) were defined as treatment responders based on CGI scale (adjusted odds ratio = 2.28; 95% CI 1.75, 2.93; p <0.001). The most common adverse effects in fluoxetine group were somnolence, headache and irritability, each occurring in <20% patients.

Conclusion: Fluoxetine at a dose of 20-40 mg / day is more effective than placebo, well-tolerated and can be recommended in pediatric practice.

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