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# A DOUBLE-BLIND, RANDOMIZED, PLACEBO-CONTROLLED STUDY EVALUATING THE EFFICACY AND SAFETY OF QUETIAPINE XR FOR TREATMENT OF MAJOR DEPRESSION AND FIBROMYALGIA

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**Introduction:** Fibromyalgia and major depressive disorder (MDD) frequently co-occur. Quetiapine XR has demonstrated efficacy in the treatment of MDD and has recently been shown effective in patients with fibromyalgia.
**Objectives:** To evaluate the efficacy and safety of quetiapine XR in patients with MDD and comorbid fibromyalgia.
**Aims:** To report on the antidepressant and analgesic effects of quetiapine XR in a sample of dually diagnosed patients.
**Methods:** An 8-week double-blind, randomized controlled trial in 120 non-psychotic adult outpatients with a confirmed diagnosis of MDD and fibromyalgia. Quetiapine XR was administered once daily in the evening at a starting dose of 50mg/d for 2 days then 150mg/d for 2 weeks and up to 300mg/d if needed. The primary efficacy endpoint was mean change from baseline to week 8 on the HAM-$D_{17}$ total score. Secondary endpoints included other measures of depression, anxiety, pain, quality of life, global functioning and adverse events.
**Results:** At week 8, mean change in HAM-$D_{17}$ score from baseline was significantly greater in the quetiapine XR arm than placebo (-10.0 vs. -5.8, p=0.001). Improvements in the Fibromyalgia Impact Questionaire (FIQ total -11.1 vs. -3.9, p=0.022) and Brief Pain Inventory (BPI-Total -2.1 vs. -1.6, p=0.007) was significantly greater in the quetiapine XR arm versus placebo. Improvements in all secondary outcomes were significantly greater in the quetiapine XR with the exception of the Sheehan Disability Scale total score.
**Conclusions:** Quetiapine XR demonstrated significant antidepressive and analgesic effects in this population of patients with MDD and fibromyalgia.

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