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Low-dose naltrexone for the treatment of fibromyalgia: findings of a small, randomized, double-blind, placebo-controlled, counterbalanced, crossover trial assessing daily pain levels.

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Abstract

OBJECTIVE: To determine whether low dosages (4.5 mg/day) of naltrexone reduce fibromyalgia severity as compared with the nonspecific effects of placebo. In this replication and extension study of a previous clinical trial, we tested the impact of low-dose naltrexone on daily self-reported pain. Secondary outcomes included general satisfaction with life, positive mood, sleep quality, and fatigue.

METHODS: Thirty-one women with fibromyalgia participated in the randomized, double-blind, placebo-controlled, counterbalanced, crossover study. During the active drug phase, participants received 4.5 mg of oral naltrexone daily. An intensive longitudinal design was used to measure daily levels of pain.

RESULTS: When contrasting the condition end points, we observed a significantly greater reduction of baseline pain in those taking low-dose naltrexone than in those taking placebo (28.8% reduction versus 18.0% reduction; $P = 0.016$). Low-dose naltrexone was also associated with improved general satisfaction with life ($P = 0.045$) and with improved mood ($P = 0.039$), but not improved fatigue or sleep. Thirty-two percent of participants met the criteria for response (defined as a significant reduction in pain plus a significant reduction in either fatigue or sleep problems) during low-dose naltrexone therapy, as contrasted with an 11% response rate during placebo therapy ($P = 0.05$). Low-dose naltrexone was rated equally tolerable as placebo, and no serious side effects were reported.

CONCLUSION: The preliminary evidence continues to show that low-dose naltrexone has a specific and clinically beneficial impact on fibromyalgia pain. The medication is widely available, inexpensive, safe, and well-tolerated. Parallel-group randomized controlled trials

are needed to fully determine the efficacy of the medication.

TRIAL REGISTRATION: ClinicalTrials.gov [NCT00568555](https://clinicaltrials.gov/ct2/show/study/NCT00568555).

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