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Pilot trial of low-dose naltrexone and quality of life in multiple sclerosis.

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Abstract

OBJECTIVE: To evaluate the efficacy of 4.5mg nightly **naltrexone** on the quality of life of **multiple sclerosis** (MS) patients.

METHODS: This single-center, double-masked, placebo-controlled, crossover study evaluated the efficacy of 8 weeks of treatment with 4.5mg nightly **naltrexone** (low-dose **naltrexone**, LDN) on self-reported quality of life of MS patients.

RESULTS: Eighty subjects with clinically definite MS were enrolled, and 60 subjects completed the trial. Ten withdrew before completing the first trial period: 8 for personal reasons, 1 for a non-MS-related adverse event, and 1 for perceived benefit. Database management errors occurred in 4 other subjects, and quality of life surveys were incomplete in 6 subjects for unknown reasons. The high rate of subject dropout and data management errors substantially reduced the trial's statistical power. LDN was well tolerated, and serious adverse events did not occur. LDN was associated with significant improvement on the following mental health quality of life measures: a 3.3-point improvement on the Mental Component Summary score of the Short Form-36 General Health Survey ($p = 0.04$), a 6-point improvement on the Mental Health Inventory ($p < 0.01$), a 1.6-point improvement on the Pain Effects Scale ($p = .04$), and a 2.4-point improvement on the Perceived Deficits Questionnaire ($p = 0.05$).

INTERPRETATION: LDN significantly improved mental health quality of life indices. Further studies with LDN in MS are warranted.

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