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Effectiveness of long-term doxycycline treatment and cognitive behavioural therapy on fatigue severity in patients with Q fever fatigue syndrome (Qure study); a randomized controlled trial

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Background: Approximately 20% of patients with acute Q fever will develop chronic fatigue, and this is referred to as Q fever fatigue syndrome (QFS). The objective of this randomized controlled clinical trial was to assess the efficacy of either long-term treatment with doxycycline or cognitive behavioral therapy (CBT) in reducing fatigue severity in QFS patients.

Material/methods: Adult patients were included who met the QFS criteria according to the Dutch guideline: a new onset of severe fatigue lasting ≥ 6 months with significant disabilities, related to an acute Q fever infection, without other somatic or psychiatric co-morbidity explaining the fatigue. Using block randomization, patients were randomized between oral study medication and CBT (2:1) for 24 weeks. Secondly, a double-blind randomization between doxycycline (200 mg/day, once daily) and placebo was performed in the medication group. Primary outcome was fatigue severity at end of treatment (EOT, week 26), assessed with the Checklist Individual Strength subscale *fatigue severity*.

Results: Of 155 patients randomized, 154 were included in the intention-to-treat analysis (doxycycline, 52; placebo, 52; CBT, 50). At EOT, fatigue severity was similar between doxycycline (40.8, 95% CI, 37.3-44.3) and placebo (37.8, 95% CI, 34.3-41.2; difference, doxycycline vs. placebo, -3.0; 97.5% CI, -8.7-2.6; $p=0.45$). Fatigue severity was significantly lower after CBT (31.6, 95% CI, 28.0-35.1) than after placebo (difference, CBT vs. placebo, 6.2; 97.5% CI, 0.5-11.9; $p=0.03$).

Conclusions: CBT is effective in reducing fatigue severity in QFS patients. Long-term treatment with doxycycline does not reduce fatigue severity in QFS patients compared to placebo. (ClinicalTrials.gov: NCT01318356, <https://clinicaltrials.gov/ct2/show/NCT01318356>).