Proportion of contextual effects in the treatment of fibromyalgia-a meta-analysis of randomised controlled trials.

Whiteside N[1], Sarmanova A[1], Chen X[2], Zou K[3], Abdullah N[1], Doherty M[1], Zhang W[4].

Abstract

The objective of this study is to examine the proportion of the total treatment effect that is attributable to contextual effects in randomised controlled trials (RCTs) of treatments for fibromyalgia. A systematic literature search was undertaken in Medline, Web of Science, EMBASE, Cumulative Index to Nursing and Allied Health Literature (CINAHL), and Allied and Complementary Medicine in September 2015. The proportion of contextual effect (PCE) was calculated by dividing the improvement in the placebo arm by the improvement in the treatment arm. The measure was log-transformed for each trial and the random effects model was used to pool data. The primary outcome was pain. Secondary outcomes were fibromyalgia impact questionnaire (FIQ) total and fatigue. Heterogeneity was quantified using I^2. Publication bias was assessed using a funnel plot and Egger's test. Subgroup analysis was undertaken to explore heterogeneity and potential determinants of the PCE. Fifty-one eligible trials (9599 participants) were identified. The PCE was 0.60 (95% CI 0·56 to 0·64) for pain, 0·57 (95% CI 0·53 to 0·61) for FIQ total, and 0·63 (95% CI 0·59 to 0·68) for fatigue. The I^2 was 99.4% for pain, 99.2% for FIQ total, and 97.6% for fatigue. More than half of the treatment effect in fibromyalgia RCTs results from non-specific contextual factors. This suggests that optimising contextual care may enhance treatment effects and improve outcomes. Reporting the total treatment effect and the proportion of contextual effect in trials may help to better translate research evidence into practice.