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**Title:** Systematic review and meta-analysis of the magnitude of the effect on AQLQ and ACQ in asthma clinical trials

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**Body:** Background: The Asthma Quality of Life Questionnaire (AQLQ) and Asthma Control Questionnaire (ACQ) are commonly used in clinical trials to assess patient disease-specific health status and asthma control. Objectives: We investigated the magnitude of effect observed in trials of different treatments with the AQLQ and ACQ instruments. A systematic literature review identified randomised controlled trials (RCTs) reporting changes from baseline in AQLQ and/or ACQ overall scores in adult patients with uncontrolled/symptomatic asthma at baseline. Results: Fifty-five RCTs (35,863 patients) met the inclusion criteria. The mixed treatment comparison (MTC) model for the AQLQ (48 RCTs) included statistically significant ( $P \leq 0.05$ ) covariates for study treatment, whether inhaled corticosteroid (ICS) was administered during a run-in phase, whether study treatment was administered on top of an ICS, AQLQ instrument type, and interaction between study and background treatment (Figure). Findings for ACQ (6 RCTs) were broadly similar, but less robust because of small trial numbers. Conclusions: For both AQLQ and ACQ, the minimal important difference (MID) of 0.5 was achieved with most established asthma therapies vs. study baseline, but not for most between-groups comparisons against placebo. The magnitude of AQLQ score changes was also sensitive to trial design.

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