Special report: measuring and reporting pain outcomes in randomized controlled trials
BlueCross BlueShield Association

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Citation

Authors' objectives
This special report examines key methodological elements related to measuring and reporting chronic pain outcomes in RCTs. The report also systematically review studies that attempt to estimate the minimal clinically important difference (MCID) in change in pain intensity among patients with chronic pain.

Authors' conclusions
Defining the effectiveness of interventions ameliorating pain and its consequences poses challenges in designing, conducting, analyzing, and reporting of RCTs. Critically appraising these RCTs presents similar challenges. Owing to some unique aspects of chronic pain outcomes, methodological issues are encountered that do not always allow straightforward interpretation. Furthermore, methods used to define the MCID in chronic pain and estimates derived vary considerably. Due to heterogeneity in methods, the body of evidence does not permit conclusions about the clinically significant magnitude of change in NRS- or VAS-assessed pain among chronic pain patients. A range of MCIDs for chronic pain may be more plausible than a single consistent value across severity and causes of pain.

Because of the unique characteristics of chronic pain, it is important to approach appraisal of evidence from a context not always encountered in other settings. Making assumptions explicit and addressing the potentially problematic aspects of RCTs having chronic pain outcomes, especially the MCID, can facilitate better critical appraisal of intervention effectiveness.

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