

**Reporting of intention-to-treat analyses in recent analgesic clinical trials: ACTION  
systematic review and recommendations**

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**Abstract**

The Intention-to-treat (ITT) principle states that all subjects in a randomized clinical trial (RCT) should be analyzed in the group to which they were assigned regardless of compliance with assigned treatment. Analyses performed according to the ITT principle preserve the benefits of randomization and are recommended by regulators and statisticians for analyses of RCTs. The objective of this study was to determine the frequency with which publications of analgesic RCTs in three major pain journals report an ITT analysis and the percentage of the author-declared ITT analyses that include all randomized subjects and thereby fulfill the most common interpretation of the ITT principle. RCTs investigating non-invasive, pharmacologic and interventional (e.g., nerve blocks, implantable pumps, spinal cord stimulators, surgery) treatments for pain, published between January 2006 and June 2013 (n =173), were included. None of the trials using experimental pain models reported an ITT analysis; 47% of trials investigating clinical pain conditions reported an ITT analysis and 5% reported a modified ITT analysis. Of the analyses reported as ITT, 67% reported reasons for excluding subjects from the analysis and 18% of those listing reasons for exclusion did not do so in the Methods section. Such mislabeling can make it difficult to identify traditional ITT analyses for inclusion in meta-analyses. We hope that deficiencies in reporting identified in this study will encourage authors, reviewers, and editors to promote more consistent use of the phrase ITT for more accurate reporting of RCT-based evidence for pain treatments.