

## **Non-randomized Clinical Trial Study Questions**

- Study hypothesis is clearly stated, with explanation of why a randomized trial was considered unnecessary, impractical, or inappropriate for comparing treatments under study.
- Clear exposition of how the study groups were initially identified, recruited, and selected, with diagram showing numbers screened, examined, and retained at each stage of the study.
- Eligibility criteria for study entry include demographics of groups, how diagnosis was confirmed, distribution of known prognostic indicators of outcome.
- Presentation in tabular form of baseline characteristics of participants, with group differences (and their confidence intervals) in a separate column.
- Description of treatments administered to each group includes main interventions and co-interventions, doses and frequencies of all interventions explicitly stated.
- Sources of data and methods of measurement of outcome are comparable between treatment groups; any differences with respect to outcome measurement are described in detail.
- Analysis of outcome data controls confounders, examines interactions, explains how attrition was handled, and includes sensitivity analysis of missing data when applicable.
- Discussion section includes potential biases and limitations; conclusions show appropriate caution in interpreting results.
- Sponsorship of study and competing interests of authors are stated.

### **Value issues:**

- Are the conclusions supported by the results, given the methods used and their limitations? What other hypotheses also fit the available data? Is it really the case that a randomized trial ought not to be done?
- Results applicable to Workers' Compensation population.

**Conclusion:** Adequate, inadequate, high-quality, not applicable

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