

Randomized Controlled Trials Study Questions

- Eligibility criteria for subjects and providers. May include discussion of volume of procedures performed at various locations and expertise of providers.
- How patients were allocated to interventions (randomization), when applicable, description of how procedures were tailored to fit individual patients.
- Concealment of allocation list specified (e.g. opaque envelopes, central list in secure location).
- Baseline characteristics compared between groups in tabular form.
- Index and control interventions are explicitly described.
- Co-interventions are comparable between groups.
- Masking (blinding) of all participants (patients, caregivers, assessors of outcome) in which this can reasonably be done.
- Methods for outcome measurement equal between groups.
- Complete accounting for participants (reasons for dropout given, percent lost to followup similar between groups).
- All important outcomes are given—this includes short (e.g. 1 month) and long term (e.g. 1-2 year) outcomes, functional measures and not just pain scores, adverse effects of treatment.
- Statistical analysis makes sense, when applicable how clustering was accounted for when sample size requirements were calculated.
- Outcome differences identified appear clinically relevant.
- Sponsorship, funding source, and competing interests of authors clearly stated.

Value issues:

- Are the authors' conclusions convincingly supported by methods and results, or are alternative interpretations of the same data also plausible? What else might the results mean?

- How does a treatment compare with current care in terms of outcome difference and cost?
- Are the results applicable to the Workers' Compensation population?

Conclusions: inadequate, adequate, high-quality, not applicable

LOWER EXTREMITY