Journal Club

Blinding in RCTS

03/26/09
Blinding

• Definition

  – *Hiding who* (patient) *got* *what* (intervention) *from patient and researchers* (after allocation)
  – Not always possible…
  – Complements *allocation concealment*
Types of Blinding

• Non-blinded – open, open label

• Single blind
  – Patient or
  – Researchers
  • Especially outcome assessors

• Double blind
  – Patient + Researchers

• Triple blind
  – + Blind analysis (statisticians)
Types of Blinding

Types of blinding used variably and inconsistently
- Quadruple blind...
- Quintuple blind...!

*** Look for actual description
Blinded vs. Masked

• Does it matter?
Blinded vs. Masked
Blinding

• Why?

• Does it prevent bias?
  – Ascertainment bias
    • A type of information bias
  – Improves compliance/retention
  – Reduces co-intervention
### Panel 1: Potential benefits accruing dependent on those individuals successfully blinded

<table>
<thead>
<tr>
<th>Individuals blinded</th>
<th>Potential benefits</th>
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<tbody>
<tr>
<td><strong>Participants</strong></td>
<td>Less likely to have biased psychological or physical responses to intervention</td>
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<td>More likely to comply with trial regimens</td>
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<td>Less likely to seek additional adjunct interventions</td>
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<td>Less likely to leave trial without providing outcome data, leading to lost to follow-up</td>
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<td><strong>Trial Investigators</strong></td>
<td>Less likely to transfer their inclinations or attitudes to participants</td>
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<td>Less likely to differentially administer co-interventions</td>
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<td>Less likely to differentially adjust dose</td>
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<td>Less likely to differentially withdraw participants</td>
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<td>Less likely to differentially encourage or discourage participants to continue trial</td>
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<td><strong>Assessors</strong></td>
<td>Less likely to have biases affect their outcome assessments, especially with subjective outcomes of interest</td>
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Blinding - Other

• Is blinding essential?
  - Objective outcomes

• What is the role of placebo?
  - Enhances blinding
Blinding vs. Allocation Concealment

- **Allocation concealment**
  - Hiding who will get what (before allocation)
  - Always possible...
  - Prevents selection bias
  - Failure overestimates treatment effect
  - Probably more important...
Allocation Concealment

• Methods
  – Sequentially numbered opaque sealed envelopes (SNOSE)
  – Sequentially numbered containers
  – Pharmacy controlled
  – Central randomization
**Description trumps lexicon...**