EQUATOR Network seminar

CONSORT extension

CONSORT for Non-pharmacologic interventions

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An extension for non-pharmacologic treatments

Why?

Non-pharmacologic treatments (NPT) concern a large variety of treatments

<table>
<thead>
<tr>
<th>Therapist-dependent interventions</th>
<th>Participative interventions</th>
<th>Non implantable devices</th>
</tr>
</thead>
<tbody>
<tr>
<td>- surgery</td>
<td>- rehabilitation</td>
<td>- orthopedic braces or orthosis</td>
</tr>
<tr>
<td>- technical operation (arthroscopy,...)</td>
<td>- education</td>
<td>- laser treatment</td>
</tr>
</tbody>
</table>
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Why?

• Placebo
  – Placebo of surgery?
  – Placebo of psychotherapy?

• Blinding
  – Feasibility of blinding
  – Success of blinding

Boutron I et al. JCE 2004
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Why?

**Standardization**
- Specific training
- Quality control procedures

**Intervention**
Multiple components
- Procedure
- Drug
- Anesthesia
- Education
- Rehabilitation
- etc.

**Fidelity**
Gap between the
- intended
- administered intervention

**Centre**

**Care providers**

_Halm et al, Ann Intern Med 2002_
Percentage of studies with sufficient description of initial treatment (based only on the published paper) and after supplementary information was obtained from authors.
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Why?

Study of surgical papers (n = 158) published in 2004

• Reporting of details of the intended intervention
  – Surgical procedure 87 %
  – Pre-operative care 15 %
  – Anesthesia 35 %
  – Post-operative care 49 %

• Surgeons
  – Selection criteria for surgeon 40 %
  – Number of surgeons involved 33 %
  – Number of interventions performed by surgeon 11 %

An extension for non-pharmacologic treatments. The process.

• 30 experts
  – Surgeons (n = 7)
  – Clinicians involved in rehabilitation (n = 1)
  – Clinicians involved in education (n = 1)
  – Clinicians involved in psychotherapy (n = 2)
  – Clinical epidemiologists, biostatisticians (n = 14)
  – Editors (n = 5)

• Preliminary survey
  – To identify items to be discussed based on the experts’ opinion

• Consensus meeting in Paris (2006)
  – To achieve consensus on a modified checklist
An extension for non-pharmacologic treatments. The checklist.

- **Complexity of the intervention**
  - Description of the **different components of the interventions** and, when applicable, description of the procedure for tailoring the interventions
  - Details of how the interventions were **standardised**
  - Details of how **adherence** of care providers with the protocol was assessed or enhanced.
  - Details of the experimental treatment and comparator as they were implemented. (New item)

- **Blinding**
  - Those **administering co interventions**
  - Method of **blinding** and description of the **similarity** of interventions
An extension for non-pharmacologic treatments. The checklist.

• **Care providers and centers**
  – Eligibility criteria for participants and, when applicable, centres and those performing the interventions.
  – When applicable, a qualitative description of care providers (case volume, qualification, expertise, etc.) and centres (volume) in each group.

• **Clustering effect**
  – How sample size calculation
  – Statistical analysis
An extension for non-pharmacologic treatments.
The flow diagram

Randomized (n = ....)

Allocated to intervention (n = ...)
  Received allocated intervention (n = ...)
  Did not receive allocated intervention (give reasons) (n = ...)

Care providers (n = ), teams (n = ), centres (n= ) performing the intervention

Number of patients treated by each care provider, team and centre (median = … [IQR, min, max])
An extension for non-pharmacologic treatments. The diffusion
An extension for non-pharmacologic treatments. The dissemination

<table>
<thead>
<tr>
<th></th>
<th>CONSORT NPT</th>
<th>Other CONSORT extension</th>
<th>2010 CONSORT checklist / diagram</th>
</tr>
</thead>
<tbody>
<tr>
<td>JAMA</td>
<td>NO</td>
<td>NO</td>
<td>Yes, link to checklist</td>
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<tr>
<td>Lancet</td>
<td>NO</td>
<td>Yes, harm and cluster</td>
<td>Yes link to CONSORT website</td>
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<tr>
<td>Ann Intern Med</td>
<td>Yes, link to the publication</td>
<td>Cluster, Herbal therapy, Noninferiority and equivalence RCTs</td>
<td>Yes, link to CONSORT website</td>
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<td>BMJ</td>
<td>NO</td>
<td>NO</td>
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<td>PlosMed</td>
<td>NO</td>
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<td>NEJM</td>
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<td>Ann Surg</td>
<td>NO</td>
<td>NO</td>
<td>Yes link to CONSORT website</td>
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<tr>
<td>Neurehab Neural Repair</td>
<td>NO</td>
<td>NO</td>
<td>Ref to 2010 publication</td>
</tr>
<tr>
<td>Am J of Psychiatry</td>
<td>NO</td>
<td>NO</td>
<td>Yes link to CONSORT website</td>
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An extension for non-pharmacologic treatments. Impact

- No study assessing the impact of this extension
- Recent study on the reporting of flow diagram (Sally Hopewell et al.)
  - Cross sectional review of all primary reports of randomized trials which include a CONSORT flow diagram indexed in PubMed core clinical journals from July to December 2009.
  - 236 parallel group with flow diagram, 120 (51%) evaluated nonpharmacologic treatments
  - No flow diagram reported according to the extension
Remaining challenges

• To update the extension for CONSORT NPT
  – According to the CONSORT 2010

  – New developments on this topic
Remaining challenges

- To develop and evaluate different methods of implementation
  - Instruction to authors
  - Use of checklist completed by authors
  - Systematic assessment of the compliance to the CONSORT statements before peer-review
Conclusion

• There is a need to improve transparency of NPT trials

• The implementation of extension of the CONSORT NPT by active policy is needed
Acknowledgments

Mohit Bhandari, Marion Campbell, Philip Devereaux, Peter C. Gøtzsche, Teodor P. Grantcharov, Jeremy Grimshaw, Ethan A. Halm, Erik Hendriks, Asbjørn Hróbjartsson, John Ioannidis, Astrid James, Giselle Jones, Richard J. Lilford, Robin McLeod, David Moher, Andrew J. Molyneux, Victor M. Montori, Cynthia Mulrow, Amy Plint, Drummond Rennie, Peter M Rothwell, Paula P. Schnurr, Kenneth F Schulz, Christoph M Seiler, Judith Stephenson, Simon G Thompson, Graham Thomicroft, David Torgerson, Tom Treasure, Peter Tugwell