Analysis of the report of the information necessary for the interpretation of the results in randomized clinical trials in manual therapy.

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Objectives

To describe the reports of the information necessary for the interpretation of the results in RCTs in MT and to compare the RCTs' reports before and after the publication of CONSORT standards for non-pharmacological clinical trials.

Methods

- **Search strategy:** PubMed and CENTRAL.
- **Eligibility criteria:** RCT design, MT intervention, English language.
- We took a random sample of 100 trials.
- We designed and piloted a data extraction form.
- For each RCT we identified the primary variable. If this was not an explicit statement, we considered the variable used for the calculation of the sample size, or the first reported in the results section.

### Results

<table>
<thead>
<tr>
<th>Pedro Item</th>
<th>Total (n=100)</th>
<th>Pre-CONSORT (n=50)</th>
<th>Post-CONSORT (n=50)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>The hypothesis is explicitly stated.</td>
<td>38% [28.5 to 48.3]</td>
<td>19% [24.7 to 52.8]</td>
<td>38% [24.6 to 52.8]</td>
<td>1.000</td>
</tr>
<tr>
<td>The primary variable is explicitly described</td>
<td>38% [28.5 to 48.3]</td>
<td>36% [22.9 to 50.8]</td>
<td>40% [26.4 to 54.8]</td>
<td>0.680</td>
</tr>
<tr>
<td>Sample size calculation</td>
<td>48% [37.9 to 58.2]</td>
<td>38% [24.7 to 52.8]</td>
<td>58% [43.2 to 71.8]</td>
<td>0.045</td>
</tr>
<tr>
<td>Complete loss report</td>
<td>78% [68.6 to 85.7]</td>
<td>72% [57.5 to 83.8]</td>
<td>84% [70.8 to 92.8]</td>
<td>0.148</td>
</tr>
<tr>
<td>Intra-group effect measure</td>
<td>50% [39.8 to 60.2]</td>
<td>60% [45.1 to 73.6]</td>
<td>40% [26.4 to 54.8]</td>
<td>0.051</td>
</tr>
<tr>
<td>Complete comparative measure between groups</td>
<td>35% [25.7 to 45.2]</td>
<td>38% [24.7 to 52.8]</td>
<td>32% [19.5 to 46.7]</td>
<td>0.529</td>
</tr>
<tr>
<td>Clinical Relevance Threshold</td>
<td>45% [35.0 to 55.3]</td>
<td>44% [30.0 to 58.7]</td>
<td>46% [31.8 to 60.7]</td>
<td>0.841</td>
</tr>
</tbody>
</table>

Conclusions

There is an important deficit in reporting the information necessary for a correct interpretation of the results in RCTs in MT, despite the recommendations published by CONSORT. Improvements in reporting are necessary to generate advances in physiotherapy practice.

PEDro Item (n=100) %
- Eligibility Criteria and Source 97%
- Random Allocation 99%
- Concealed Allocation 51%
- Baseline Comparability 88%
- Subject Blinding 32%
- Therapist Blinding 3%
- Assessor Blinding 57%
- >85% Follow-up 84%
- Intention-to-treat Analysis 73%
- Between-group Comparisons 96%
- Point Measures and Variability 92%

Introduction:
The number of randomized controlled trials (RCTs) in manual therapy (MT) has increased exponentially. However, the quality of the reports remains heterogeneous.

Methodological quality: