The importance of the new CONSORT Statement for clinicians

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The Consolidated Standard of Reporting Trials (CONSORT) Statement is an international consensus guide and checklist to improve reports on randomised clinical trials (RCTs). The standard was developed in response to evidence that RCTs have been reported inadequately over the last three decades (Chan and Bhandari 2007, Dickinson et al 2000, Poolman et al 2006), in spite of educational efforts.

The CONSORT group of international journal editors, clinical trialists, epidemiologists, and methodologists published their original statement 12 years ago, having designed it primarily for pharmacological trials (Begg et al 1996). After an update 7 years ago, it now contains a 22-item content checklist and a participant flow chart (Moher et al 2001). An even more useful version for the physiotherapy profession is a new extended CONSORT Statement for non-pharmacological treatment (Boutron et al 2008a and b). The extended version adds 1 item and 4 sub-items relating to therapists, centres, and settings – with keywords like eligibility, skills, experience, and randomisation.

What might the new CONSORT Statement mean to clinicians? Imagine you have read a recent trial report, e.g. Harts et al (2008) published in this journal. Its conclusion partially confirms that strengthening back extensor muscles is a more effective treatment for non-specific low back pain than passive modalities or doing nothing. Yet, you might still be uncertain how the report can help you treat your current client with this very problem. Why? It might be because you feel the report lacks some key information. How could you, by using the new CONSORT checklist (Boutron et al 2008a and b), assess whether the report contains sufficient information?

To comply with the new CONSORT Statement, the Method must report eligibility of patients, therapist, centres, and settings, and the Conclusion (the most important part of the report) must report how these factors restrict generalisation of results. Therefore, the Conclusion should address: participants, intervention, therapists, centres, outcome measure(s), comparator(s), and setting(s) (which can be abbreviated to the acronym PITCOCS). It is instructive to appraise the Participants and Intervention sections from the Method section of the Harts et al (2008) paper using the CONSORT checklist, to see whether there is sufficient information to form a full PITCOCS conclusion about the generalisability of the results.

First we look for information on the trial participants. There were 66 patients, 1 therapist, and 1 centre (and 4 scientists). We look for the criteria for including and excluding patients, and find this adequately reported. We then look for information on the physiotherapist’s qualifications, which is missing. We expected to find the therapist’s level of formal education, years of clinical training (particularly concerning patients with low back pain), training with the specific equipment, and the name of the therapist in the acknowledgements. With these details unreported, you might wonder how the therapist’s qualifications compare to yours, and thus about your chance of repeating the intervention.

Next we look for information about the centre. We find its name, but no further description. Is it, as its name and training equipment imply, a highly specialised rehabilitation and training centre, with specialised training instructors and sports medical personnel? As this is not reported, you might wonder how your centre compares with the one in the study, and you may ask how this affects transfer of the study’s result to your setting.

Finally we look for information about the intervention and find adequate detail about:

- Exercises as intended and as received, i.e., specific exercises, dosages, and criteria for increasing loads.
- Method and data for categorising the exercises as received by patients (the implementation was checked by keeping records of performed training sessions, details given in an electronic appendix).
- How the therapist standardised the therapy and adjusted it to individual patients.
- Measurement of patients’ adherence to the protocol.

What is lacking in the intervention section is:

- How the researchers tried to maximise exercise compliance.
- Measurements of the therapist’s adherence to the protocol.

In summary, the Intervention section is reported mainly to a high standard, but some items of information are missing. Thus you might ask: What are my chances of repeating this intervention and achieving similar effects? How does this affect the validity of the trial?

Having appraised the Participants and Intervention sections, an alternative Conclusion to the Harts et al (2008) study, using the PITCOCS acronym, might be generalised as:

Active males in their 40s, with moderately-severe non-specific low back pain, who strengthen their back extensor muscles intensively in 10 sessions over 8 weeks, under the guidance of physiotherapists with unknown qualifications, in seemingly-specialised sports rehabilitation centres, report no clinically-important or statistically-significant reduction in disability compared with those exercising with low intensity or doing nothing in a primary health care setting.

It is questionable to generalise from the study therapist to all therapists and from the study centre to all centres. This highlights the enormous team effort required to create highly valid knowledge for different therapists and different centres.
A recent systematic review stated that reports from RCTs evaluating effects of non-pharmacological interventions are often opaque and incomprehensible (Jacquier et al 2006). Although this review referred to surgical reports, we have no reason to believe that reports on physiotherapy interventions are any better. This new standard (Boutron et al 2008a and b) can help clinicians critically appraise papers and thus make more informed choices of therapy; therapists should not change their practice routines based on inadequate reports. We think clinicians can help improve science by using the new CONSORT checklist to provide feedback on the completeness, transparency, and accuracy of reports to important stakeholders. Such stakeholders might be scientists and other clinicians, insurers, and governments. This feedback could improve the quality of non-pharmacological trials and therapy, and hence the value of research funded by billions of public dollars.

Can the new CONSORT Statement really help improve reports? The original CONSORT Statement is officially endorsed by 320 internationally respected journals, including BMJ, Spine, and Physical Therapy (CONSORT Group 2008). Even more journals endorse it in their Guidelines to Authors, as does this journal. When leading journals implement the CONSORT standards it can affect scientists as well as clinicians. Scientists have to publish in order not to perish. Applying the CONSORT checklist at an early stage of planning might expose potential bias and improve design. Thus, the checklist might improve methodological discussion, as scientists and clinicians may identify weaknesses in proposals written according to the standard. Indeed, after analysing eight studies examining journal reports before and after the adoption of the CONSORT Statement, researchers concluded that adoption of the CONSORT Statement is associated with improved reporting of RCTs (Plint et al 2006).

In teaching, criterion-based assessment has long been known to improve students’ work, stimulating them to learn more than if assessment is relative (Biggs 2003). This principle seems just as valid for the producers and consumers of science as for students. If you as a clinician want scientists to report highly valid new knowledge, we suggest that you join editors, scientists, and patients in a team effort to create new CONSORT-based science.

References


Correction to Volume 54 No 2

There were two errors in van Eijsden-Besseling et al (2008). The errors do not affect the findings of the study.

The text should be corrected as follows (corrected text in bold type):

Page 96: Visual display unit workers were defined as employees performing computer work, with or without the use of a mouse, for at least 20 hours per week and for at least four hours continuously per day. Early non-specific work-related upper limb disorders were described as pains and tingles in the upper back, neck, shoulders, arms or hands, related and restricted to visual display unit work, ie, not yet present during other everyday activities (Peereboom et al 2005/2006). To enable the correct diagnosis of ‘early stage non-specific work-related upper limb disorder’ and to exclude participants with ‘specific work-related upper limb disorders,’ the potential participants had to complete a short questionnaire we devised based on the recommendations of Sluiter et al (2001).

Page 99: Table 3 should report the following mean (SD) for QoL on the SF-36: Month 0 for the PE group = 70 (2); difference within groups (Month 6 minus Month 0) for the SFE group = 1 (3)

Australian Journal of Physiotherapy apologises to the authors and to readers.

Reference