

Extending the CONSORT Statement to Randomized Trials of Nonpharmacologic Treatment: Explanation and Elaboration

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Adequate reporting of randomized, controlled trials (RCTs) is necessary to allow accurate critical appraisal of the validity and applicability of the results. The CONSORT (Consolidated Standards of Reporting Trials) Statement, a 22-item checklist and flow diagram, is intended to address this problem by improving the reporting of RCTs. However, some specific issues that apply to trials of nonpharmacologic treatments (for example, surgery, technical interventions, devices, rehabilitation, psychotherapy, and behavioral interventions) are not specifically addressed in the CONSORT Statement. Furthermore, considerable evidence suggests that the reporting of nonpharmacologic trials still needs improvement. Therefore, the CONSORT group developed an extension of the CONSORT Statement for trials assessing nonpharmacologic treatments. A consensus meeting of 33 experts was organized in Paris, France, in February 2006, to develop an extension of the CONSORT Statement for

trials of nonpharmacologic treatments. The participants extended 11 items from the CONSORT Statement, added 1 item, and developed a modified flow diagram.

To allow adequate understanding and implementation of the CONSORT extension, the CONSORT group developed this elaboration and explanation document from a review of the literature to provide examples of adequate reporting. This extension, in conjunction with the main CONSORT Statement and other CONSORT extensions, should help to improve the reporting of RCTs performed in this field.

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For author affiliations, see end of text.

*For contributions to the CONSORT Extension for Nonpharmacologic Treatment Interventions, see the **Appendix** (available at www.annals.org).

The CONSORT (Consolidated Standards of Reporting Trials) Statement, published in 1996 and revised in 2001, is a set of guidelines designed to improve the reporting of randomized, controlled trials (RCTs) (1, 2). Use of this evidence-based guideline is associated with improved quality of reporting in RCTs (3). The CONSORT Statement has been extended to cover different designs, such as noninferiority and equivalence trials (4); types of interventions, such as herbal therapies (5); and data, such as the reporting of harms (6). However, despite the wide dissemination of the CONSORT Statement, inadequate reporting remains common.

Nonpharmacologic treatments include surgery, technical procedures, devices, rehabilitation, psychotherapy, behavioral interventions, and complementary and alternative medicine. Of all RCTs published in 2000, RCTs of nonpharmacologic therapies account for 1 in 4 publications (7). However, the CONSORT Statement does not address some specific issues that apply to nonpharmacologic trials (8–12). For example, blinding is more difficult to achieve in nonpharmacologic trials (13) and, when feasible, relies on complex methods and specific design (14). Nonpharmacologic trials usually test complex interventions involving several components. Such treatments are consequently difficult to describe, standardize, reproduce, and administer consistently to all patients. All of these variations could have an important impact on the estimate of the treatment effect. In addition, care providers' expertise and centers' volume of care can also influence the estimate of the treatment effect (15).

Consequently, the CONSORT Group decided to develop an extension of the CONSORT Statement for nonpharmacologic treatments. The methods and processes leading up to these reporting guidelines are described in

detail in an accompanying paper available online only at www.annals.org (16). A major element of the process was a meeting of 33 individuals in February 2006, at which consensus was achieved on guidance for reporting RCTs of nonpharmacologic treatments; this guidance consists of extensions to 11 checklist items, addition of 1 item, and modification of and the flow diagram (Table 1 and Figure 1).

To facilitate better understanding and dissemination of this CONSORT extension, the meeting participants recommended developing an explanation and elaboration document, similar to those developed for the revised CONSORT Statement (2), STARD (Standards for Reporting of Diagnostic Accuracy) (17), and STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) (18). As with these documents, this article uses a standard template: The modified checklist item is reported, along with the rationale, evidence base (whenever possible), and examples of good reporting provided in Table 2 (19–38). An example of reporting in the modified flow diagram is provided in Figure 2 (39). This document deals with only some of the CONSORT checklist items; it should thus be seen as an addendum to the main CONSORT explanatory paper (2) for trials of nonpharmacologic treatments. In this document, we have focused only on regular RCTs in which individual participants are

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