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 intervention) 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.
### Table 1. Checklist of Items for Reporting Trials of Nonpharmacologic Treatments*

<table>
<thead>
<tr>
<th>Section</th>
<th>Item</th>
<th>Standard CONSORT Description</th>
<th>Extension for Nonpharmacologic Trials</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Title and abstract</strong></td>
<td>1</td>
<td>How participants were allocated to interventions (e.g., “random allocation,” “randomized,” or “randomly assigned”)</td>
<td>In the abstract, description of the experimental treatment, comparator, care providers, centers, and blinding status</td>
</tr>
<tr>
<td><strong>Introduction</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Background</strong></td>
<td>2</td>
<td>Scientific background and explanation of rationale</td>
<td></td>
</tr>
<tr>
<td><strong>Methods</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Participants</strong></td>
<td>3</td>
<td>Eligibility criteria for participants and the settings and locations where the data were collected</td>
<td>When applicable, eligibility criteria for centers and those performing the interventions</td>
</tr>
<tr>
<td><strong>Interventions</strong></td>
<td>4</td>
<td>Precise details of the interventions intended for each group and how and when they were actually administered</td>
<td>Precise details of both the experimental treatment and comparator</td>
</tr>
<tr>
<td><strong>Randomization-sequence generation</strong></td>
<td>8</td>
<td>Method used to generate the random allocation sequence, including details of any restriction (e.g., blocking, stratification)</td>
<td>When applicable, how care providers were allocated to each trial group</td>
</tr>
<tr>
<td><strong>Allocation concealment</strong></td>
<td>9</td>
<td>Method used to implement the random allocation sequence (e.g., numbered containers or central telephone), clarifying whether the sequence was concealed until interventions were assigned</td>
<td></td>
</tr>
<tr>
<td><strong>Implementation</strong></td>
<td>10</td>
<td>Who generated the allocation sequence, who enrolled participants, and who assigned participants to their groups</td>
<td></td>
</tr>
<tr>
<td><strong>Blinding (masking)</strong></td>
<td>11A</td>
<td>Whether or not participants, those administering the interventions, and those assessing the outcomes were blinded to group assignment</td>
<td>Whether or not those administering co-interventions were blinded to group assignment</td>
</tr>
<tr>
<td><strong>Statistical methods</strong></td>
<td>12</td>
<td>Statistical methods used to compare groups for primary outcome(s); methods for additional analyses, such as subgroup analyses and adjusted analyses</td>
<td>When applicable, details of whether and how the clustering by care providers or centers was addressed</td>
</tr>
<tr>
<td><strong>Results</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Participant flow</strong></td>
<td>13</td>
<td>Flow of participants through each stage (a diagram is strongly recommended)—specifically, for each group, report the numbers of participants randomly assigned, receiving intended treatment, completing the study protocol, and analyzed for the primary outcome; describe protocol deviations from study as planned, together with reasons</td>
<td>The number of care providers or centers performing the intervention in each group and the number of patients treated by each care provider or in each center</td>
</tr>
<tr>
<td><strong>Implementation of intervention</strong></td>
<td>New item</td>
<td></td>
<td>Details of the experimental treatment and comparator as they were implemented</td>
</tr>
<tr>
<td><strong>Recruitment</strong></td>
<td>14</td>
<td>Dates defining the periods of recruitment and follow-up</td>
<td></td>
</tr>
<tr>
<td><strong>Baseline data</strong></td>
<td>15</td>
<td>Baseline demographic and clinical characteristics of each group</td>
<td>When applicable, a description of care providers (case volume, qualification, expertise, etc.) and centers (volume) in each group</td>
</tr>
<tr>
<td><strong>Numbers analyzed</strong></td>
<td>16</td>
<td>Number of participants (denominator) in each group included in each analysis and whether analysis was by &quot;intention-to-treat&quot;; state the results in absolute numbers when feasible (e.g., 10/20, not 50%)</td>
<td></td>
</tr>
<tr>
<td><strong>Outcomes and estimation</strong></td>
<td>17</td>
<td>For each primary and secondary outcome, a summary of results for each group and the estimated effect size and its precision (e.g., 95% confidence interval)</td>
<td></td>
</tr>
<tr>
<td><strong>Ancillary analyses</strong></td>
<td>18</td>
<td>Address multiplicity by reporting any other analyses performed, including subgroup analyses and adjusted analyses, indicating those prespecified and those exploratory</td>
<td></td>
</tr>
<tr>
<td><strong>Adverse events</strong></td>
<td>19</td>
<td>All important adverse events or side effects in each intervention group</td>
<td></td>
</tr>
<tr>
<td><strong>Discussion</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Interpretation</strong></td>
<td>20</td>
<td>Interpretation of the results, taking into account study hypotheses, sources of potential bias or imprecision, and the dangers associated with multiplicity of analyses and outcomes</td>
<td>In addition, take into account the choice of the comparator, lack of or partial blinding, and unequal expertise of care providers or centers in each group</td>
</tr>
<tr>
<td><strong>Generalizability</strong></td>
<td>21</td>
<td>Generalizability (external validity) of the trial findings</td>
<td>Generalizability (external validity) of the trial findings according to the intervention, comparators, patients, and care providers and centers involved in the trial</td>
</tr>
<tr>
<td><strong>Overall evidence</strong></td>
<td>22</td>
<td>General interpretation of the results in the context of current evidence</td>
<td></td>
</tr>
</tbody>
</table>

* Additions or modifications to the CONSORT checklist. CONSORT = Consolidated Standards of Reporting Trials.
† This item anticipates a planned revision in the next version of the standard CONSORT checklist.
randomly assigned to groups. Nonpharmacologic treatments can also be evaluated in cluster RCTs, and in these cases, the CONSORT extension for cluster trials should also be consulted (40).

**RECOMMENDATIONS FOR REPORTING TRIALS OF NONPHARMACOLOGIC TREATMENTS**

**Title and Abstract**

**Item 1**

*Standard CONSORT item: How participants were allocated to interventions (for example, “random allocation,” “randomized,” or “randomly assigned”).*

In addition, for nonpharmacologic trials: In the abstract, description of the experimental treatment, comparator, care providers, centers, and blinding status.

The quality of reporting titles and abstracts is essential because it helps indexers, such as those compiling the National Library of Medicine’s MEDLINE database, to classify reports so they can be correctly identified electronically (41). Furthermore, abstracts are much more likely to be read than any other section of an article. Good evidence indicates that abstracts frequently underreport key features of trials assessing pharmacologic and nonpharmacologic treatments (41–49). The CONSORT guidelines for reporting journal and conference abstracts are forthcoming (50–52).

For nonpharmacologic trials, the abstract should also include data on centers or care providers, including, when applicable, details on the number of care providers participating in the trial and their expertise. The experimental and control procedures should also be clearly identified. Finally, authors should indicate who was blinded and, if blinding of participants and care providers was impossible, whether the outcome assessment was blinded. These details are necessary to allow an adequate appraisal of the internal and external validity of the trial.

**Methods Section**

**Item 3: Participants**

*Standard CONSORT item: Eligibility criteria for participants and the settings and locations where the data were collected.*

In addition, for nonpharmacologic trials: When applicable, eligibility criteria for centers and those performing the interventions.

Evidence suggests that patient outcome can be associated with hospital and care providers’ volume (15, 53–57). A systematic review of 135 trials (15) found that 71% observed a positive association between hospital volume and outcomes and 70% observed an association between care providers’ volume and outcomes. Differential expertise of care providers in each treatment group can bias treatment effect estimates (58). Furthermore, a nonpharmacologic treatment might be found to be safe and effective in an RCT performed in high-volume centers by high-volume care providers, but could have different results in low-volume centers. For example, the Asymptomatic Carotid Atherosclerosis Study investigators excluded 40% of all possible care providers, selecting only those with good safety records. This resulted in a postoperative mortality rate that was 8 times lower than in other trials with less stringent selection criteria (59–61). In most nonpharmacologic trials, care providers’ expertise and centers’ volume

**Figure 1. Modified CONSORT flow diagram for individual randomized, controlled trials of nonpharmacologic treatment.**

An extra box per intervention group relating to care providers has been added. For cluster randomized, controlled trials, authors should refer to the appropriate extension. IQR = interquartile range; max = maximum; min = minimum.
of care will influence the treatment effect (15, 53–57, 62–72).

Reporting of eligibility criteria for care providers and centers in nonpharmacologic trials is often poor. One study of surgical reports found that the setting and the center’s volume of activity was reported in only 7% and 3% of articles, respectively (79). Selection criteria were reported for care providers in 41% of the articles, and the number of care providers performing the intervention was reported in 32% (79).

A careful description of care providers involved in the trial, as well as details of the centers in which participants were treated, helps readers appraise the risk for bias and the applicability of the results. Selection criteria for centers typically relates to center volume for the procedure under investigation or similar procedures. Eligibility of care providers might include professional qualifications, years in practice, number of interventions performed, skill as assessed by level of complication when performing the intervention, and specific training before trial initiation. Eligibility criteria should be justified, because they will influence the applicability of the trial results (58, 73, 74).

**Item 4: Interventions**

*Standard CONSORT item: Precise details of the interventions intended for each group and how and when they were actually administered.*

*In addition, for nonpharmacologic trials: Precise details of both the experimental treatment and comparator.*

**Item 4A. Description of the different components of the interventions and, when applicable, description of the procedure for tailoring the interventions to individual participants.**

It is important to provide a detailed description of nonpharmacologic treatments, which are usually complex interventions involving several components (75), each of which may influence the estimated treatment effect (27–32). For example, arterial endarterectomy and reconstruction during carotid endarterectomy can be performed in a variety of ways, some aspects of which may influence the treatment effect. For example, use of local anesthesia and patch closure, compared with other techniques, has been shown to reduce the risk for harms after carotid endarterectomy (76, 77). Therefore, authors should report all the different components of the treatment procedure. These descriptions will help introduce the safest and most effective treatments into clinical practice. They are also necessary to facilitate study comparison, reproducibility, and inclusion in systematic reviews (78).

In nonpharmacologic trials, the control treatment can be placebo, usual care, an active treatment, or a waiting list. If the control treatment is usual care, authors should report all the components received by the control group. This information will allow readers to compare the intensity of usual care with the experimental intervention and with what is usually provided to participants in their own setting.

Interventions in nonpharmacologic trials are often poorly described. A systematic review of reports of RCTs assessing surgical procedures highlighted the lack of reporting of other important components: only 35% of studies reported anesthesia management, 15% reported preoperative care, and 49% reported postoperative care (79). In a review of behavioral medicine interventions, insufficient intervention detail was a barrier to assessment of evidence and development of guidelines (80–82). A systematic review of articles published in 6 medical rehabilitation journals in 1997 to 1998 found that information about the timing of the intervention relative to the onset of the disorder was absent from 32% of the 171 reports. Descriptions of the interventions were either brief or absent in one half of the articles and lacked an operational definition in 9% of the articles (83).

The information that is required for a complete description of nonpharmacologic treatments depends on the type of intervention being tested. For surgery, technical procedure, or implantable devices, full details of preoperative care, intraoperative care, configuration of any device, and postoperative care are needed. For nonimplantable devices, the configuration of the device should be detailed and a user’s guide for the device should be prepared to enable reproducibility.

For rehabilitation, behavioral treatment, education, and psychotherapy, authors should report qualitative and quantitative data. Qualitative data describe the content of each session, how it is delivered (individual or group), whether the treatment is supervised, the content of the information exchanged with participants, and the instruments used to give information. Quantitative data describe the number of sessions, timing of each session, duration of each session, duration of each main component of each session, and overall duration of the intervention. It is also essential to report how the intervention was tailored to patients’ comorbid conditions, tolerance, and clinical course.

To aid the provision of a clear description of these complex interventions, Perera and colleagues proposed a graphical depiction of the experimental and control interventions (84).

**Item 4B. Details of how the interventions were standardized.**

Assessment of nonpharmacologic treatments in RCTs presents special difficulties because of the complexity of the treatment and the variability found across care providers and centers (23). The variety of settings that characterizes multicenter trials only exacerbates these problems (78). Authors should describe any method used to standardize the
### Section

**Title and abstract**

**Item 1**

**Standard CONSORT Description**

How participants were allocated to interventions (e.g., “random allocation,” “randomized,” or “randomly assigned”)

**Extension for Nonpharmacologic Trials**

In the abstract, description of the experimental treatment, comparator, care providers, centers, and blinding status

---

### Examples of Good Reporting Based on Extension (Reference)

**Objective:** To compare the primary therapist model (PTM), provided by a single rheumatology-trained primary therapist, with the traditional treatment model (TTM), provided by a physical therapy (PT) and/or occupational therapy (OT) generalist, for treating patients with rheumatoid arthritis (RA).

**Methods:** Eligible patients were adults requiring rehabilitation treatment who had not received PT/OT in the past 2 years. Participants were randomized to the PTM or TTM group. The primary outcome was defined as the proportion of clinical responders who experienced a > or ≥ 20% improvement in 2 of the following measures from baseline to 6 months: Health Assessment Questionnaire, pain visual analog scale, and Arthritis Community Research and Evaluation Unit RA Knowledge Questionnaire (19).

**Interventions**

**Item 3**

**Standard CONSORT Description**

Eligibility criteria for participants and the settings and locations where the data were collected

**Extension for Nonpharmacologic Trials**

When applicable, eligibility criteria for centers and those performing the interventions

---

### Examples of Good Reporting Based on Extension (Reference)

All participating centres . . . were major neurosurgical centres, treating large numbers of patients after aneurysmal subarachnoid haemorrhage (SAH), each centre treating between 60 and 200 cases annually. . . . Centres had to have expertise in both neurosurgical and endovascular management of ruptured aneurysms. Only accredited neurosurgeons with experience of aneurysm surgery were permitted to manage patients in the trial. Endovascular operators had to have done a minimum of 30 aneurysm treatment procedures, before they were permitted to treat patients in the trial (20).

**Interventions**

**Item 4**

**Standard CONSORT Description**

Precise details of the interventions intended for each group, and how and when they were actually administered

**Extension for Nonpharmacologic Trials**

Precise details of both the experimental treatment and comparator

---

### Examples of Good Reporting Based on Extension (Reference)

The exercise training program . . . consisted of 2 approximately 3-month-long phases of exercise training. The initial phase of exercise was designed to prepare the participants for progressive resistance training and also to minimize injury. Exercises during the first 3-month phase (phase 1) were conducted by a physical therapist using a group format (2–5 participants/group) and were designed to enhance flexibility, balance, coordination, movement speed, and, to some extent, strength of all major muscle groups. Twenty-two exercises formed the basis of this program (protocol available from the authors). The exercises were made progressively more difficult by increasing the number of repetitions and/or by performing the exercises in more challenging ways. When safely able, participants also exercised on a stationary bicycle or treadmill. Participants attempted this exercise for a minimum of 5 minutes and progressed to a maximum of 15 minutes. The treadmill speed or bicycle resistance was set at the highest comfortable setting that was safe for the participant.

When safely able, participants also exercised on a stationary bicycle or treadmill. Participants attempted this exercise for a minimum of 5 minutes and progressed to a maximum of 15 minutes. The treadmill speed or bicycle resistance was set at the highest comfortable setting that was safe for the participant. A formal aerobic exercise training protocol was not performed. Exercise sessions lasted 45 to 90 minutes (with breaks), depending on the participant's ability and tolerance, which increased over the course of phase 1. During the second exercise phase (phase 2), progressive resistance training was added. One-repetition maximum (1-RM) voluntary strength was measured on each of 6 different exercises (knee extension, knee flexion, seated bench press, seated row, leg press, and biceps curl), which were performed bilaterally on a Hoist weightlifting machine (Hoist Fitness Systems, San Diego, Calif). Initially, the participants performed 1 to 2 sets of 6 to 8 repetitions of each exercise at 65% of their 1-RM. By the end of the first month of weight training, they progressed to 3 sets of 8 to 12 repetitions performed at 85% to 100% of the initial 1-RM. The 1-RM measurements were repeated at 6 weeks and used to progressively increase each individual’s exercise prescription. Participants continued to perform a shortened version of the phase 1 exercises and the treadmill or stationary bicycle warm-up exercise . . . (21).

The [control] treatment follows the same format [as experimental treatment], i.e., 10 weekly 90-min sessions. The therapist helps the patient identify daily stresses and discusses them in a supportive non-directive mode. No instructions for exposure are included. If the patient brings up trauma-related issues, the therapist gently redirects her to discuss other material (22).

---

### Examples of Good Reporting Based on Extension (Reference)

The usual practices of surgeons performing optic nerve decompression surgery were determined through literature review and through a survey of study surgeons. These practices were described in the protocol as a series of 31 steps, only six of which were required to be performed so as to ensure adequacy of the surgery as well as safety of the patient. The remaining steps could be performed according to surgeon preference as they did not directly affect either patient safety or adequacy of surgery. Each study surgeon signed a written commitment to adhere to the six required steps, which were: general anesthesia, medial approach, no mechanical static traction, subarachnoid dissection if no cerebrospinal fluid release was seen following fenestration of the optic nerve sheath, no more than 7 minutes of globe traction (23).

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### Table 2. Checklist of Items for Reporting Trials of Nonpharmacologic Treatments, with Examples*

<table>
<thead>
<tr>
<th>Section</th>
<th>Item 1</th>
<th>Standard CONSORT Description</th>
<th>How participants were allocated to interventions (e.g., “random allocation,” “randomized,” or “randomly assigned”)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
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<td>In the abstract, description of the experimental treatment, comparator, care providers, centers, and blinding status</td>
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</table>

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**Interventions**

**Item 3**

**Standard CONSORT Description**

Eligibility criteria for participants and the settings and locations where the data were collected

**Extension for Nonpharmacologic Trials**

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**Interventions**

**Item 4**

**Standard CONSORT Description**

Precise details of the interventions intended for each group, and how and when they were actually administered

**Extension for Nonpharmacologic Trials**

Precise details of both the experimental treatment and comparator

---

### Examples of Good Reporting Based on Extension (Reference)

The exercise training program . . . consisted of 2 approximately 3-month-long phases of exercise training. The initial phase of exercise was designed to prepare the participants for progressive resistance training and also to minimize injury. Exercises during the first 3-month phase (phase 1) were conducted by a physical therapist using a group format (2–5 participants/group) and were designed to enhance flexibility, balance, coordination, movement speed, and, to some extent, strength of all major muscle groups. Twenty-two exercises formed the basis of this program (protocol available from the authors). The exercises were made progressively more difficult by increasing the number of repetitions and/or by performing the exercises in more challenging ways. When safely able, participants also exercised on a stationary bicycle or treadmill. Participants attempted this exercise for a minimum of 5 minutes and progressed to a maximum of 15 minutes. The treadmill speed or bicycle resistance was set at the highest comfortable setting that was safe for the participant.

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### Table 2—Continued

<table>
<thead>
<tr>
<th>Section</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Item 4C</strong></td>
<td><strong>Extension for Nonpharmacologic Trials</strong></td>
</tr>
<tr>
<td><strong>Examples of Good Reporting Based on Extension (Reference)</strong></td>
<td>All therapy sessions are videotaped. . . . A senior clinician who is independent of . . . treatment delivery will rate 10% of the videotapes using measures adapted from several randomized clinical trials of psychotherapy . . .; the 10% figure was chosen arbitrarily in an attempt to ensure an adequate sample of information from each treatment condition (22).</td>
</tr>
<tr>
<td>Sample size</td>
<td></td>
</tr>
<tr>
<td><strong>Item 7</strong></td>
<td><strong>Standard CONSORT Description</strong></td>
</tr>
<tr>
<td><strong>Extension for Nonpharmacologic Trials</strong></td>
<td>When applicable, details of whether and how the clustering by care providers or centers was addressed</td>
</tr>
<tr>
<td><strong>Examples of Good Reporting Based on Extension (Reference)</strong></td>
<td>The study was designed to enroll 8 participants for each of 4 therapists at the 12 participating sites. . . . Sample size was computed on the basis of our primary hypothesis, that PE [prolonged exposure] will be more effective than PCT [present-centered therapy] for the treatment of PTSD [posttraumatic stress disorder] due to military-related trauma in women as measured by the CAPS [clinician-administered PTSD scale] at 3 months posttreatment. Although treatment is delivered on an individual basis, each participant cannot be assumed to generate independent observations because participants are clustered within therapists. Thus, the computed sample size, based on the unpaired t-test statistic, was inflated by a factor, ( t = 1 + (m - 1)\rho ), to achieve the variance that one would have anticipated had there been no clustering. The cluster size ( m ) is 8 (participants/therapist), and the intraclass correlation coefficient ( \rho ) was estimated from prior studies to be in the range of .10 to .15, which in turn yields a sample size inflation factor of 1.7 to 2.05. With an estimated sample size of 384, this study has 85% to 90% statistical power to detect an effect of ( d = .50 ) at ( \alpha = .05 ), two-tailed . . . (22).</td>
</tr>
<tr>
<td>Randomization-sequence generation</td>
<td></td>
</tr>
<tr>
<td><strong>Item 8</strong></td>
<td><strong>Standard CONSORT Description</strong></td>
</tr>
<tr>
<td><strong>Extension for Nonpharmacologic Trials</strong></td>
<td>When applicable, how care providers were allocated to each trial group</td>
</tr>
<tr>
<td><strong>Examples of Good Reporting Based on Extension (Reference)</strong></td>
<td>At each of the 12 sites, 4 female therapists were randomly assigned to deliver either PE [prolonged exposure] or PCT [present-centered therapy] ( (n = 2 ) per condition per site). . . . By design, each therapist treats 10 participants: 2 training cases during a 6-month run-up period, and 8 randomized cases during 2 years of recruitment (22). Pancreaticoduodenectomy [in both experimental and control group] was performed by just 3 experienced surgeons who had done more than 40 pancreaticoduodenectomies with either the conventional [control treatment] or the binding pancreaticojunostomy [experimental treatment] (24). The patients were randomly selected for one of two operative procedures: open reduction and internal fixation or external fixation and limited internal fixation. The six attending orthopaedic surgeons who performed the operations had been assigned to a treatment group according to their expertise or to their preference with regard to fixation. Each patient was managed by the one of the six surgeons who was on call when the patient was seen in the emergency room (29).</td>
</tr>
<tr>
<td>Blinding (masking)</td>
<td></td>
</tr>
<tr>
<td><strong>Item 11A</strong></td>
<td><strong>Standard CONSORT Description</strong></td>
</tr>
<tr>
<td><strong>Extension for Nonpharmacologic Trials</strong></td>
<td>Whether or not those administering co-interventions were blinded to group assignment</td>
</tr>
<tr>
<td><strong>Examples of Good Reporting Based on Extension (Reference)</strong></td>
<td>Patients were randomised [laparoscopic versus small-incision cholecystectomy] in the operating theatre and anaesthetic technique and pain-control methods were standardised. Four experienced surgeons did both types of procedure. Identical wound dressings were applied in both groups so that carers could be kept blind to the type of operation (26).</td>
</tr>
<tr>
<td><strong>Item 11BY</strong></td>
<td><strong>Extension for Nonpharmacologic Trials</strong></td>
</tr>
<tr>
<td><strong>Examples of Good Reporting Based on Extension (Reference)</strong></td>
<td>Double blinding was achieved by shielding the subject’s view by a vertical drape and other means (described below) and by excluding the nurse assessor from the room until the procedure and clean-up were completed . . . . The subject’s contact with the investigator/procedurist was generally limited to the day of the procedure. . . . A 1-liter bag of sterile normal saline was hung at the edge of the drape within view of the subject. The knee was then draped with sterile towels, and the connecting tubing and 3-way stop-cocks were assembled and attached to an empty 1-liter waste bag and a 50-ml syringe, producing a closed system for fluid delivery, aspiration and ejection. To administer the SI [sham irrigation], the 14-gauge needle was advanced to, but not through, the joint capsule via the lateral suprapatellar port. Fresh saline was drawn from the supply bag in aliquots of 40-50 mL, and 3–5 mL of saline was dysed into the subcutaneous tissue with each mimicking “exchange” before the remainder of the saline was expelled into the waste bag. Positioning of the knee and manipulation were performed as for actual TI [tidal irrigation], After passage of 1-liter of saline through the tubing, . . . the needle was removed. . . . All subjects and the nurse assessor remained blinded until the subject had completed study followup (27).</td>
</tr>
<tr>
<td>Statistical methods</td>
<td></td>
</tr>
<tr>
<td><strong>Item 12</strong></td>
<td><strong>Standard CONSORT Description</strong></td>
</tr>
<tr>
<td><strong>Extension for Nonpharmacologic Trials</strong></td>
<td>When applicable, details of whether and how the clustering by care providers or centers was addressed</td>
</tr>
</tbody>
</table>
Table 2—Continued

Section

Examples of Good Reporting Based on Extension (Reference)

Although the participants were individually randomised, a clustering of outcomes is potentially possible since a single therapist was treating several patients. If these clustering effects were strong, then this might alter the results. We therefore used multilevel modelling to check for any clustering effects by undertaking an analysis on the primary outcome (28).

Results

Participant flow

Item 13

Standard CONSORT Description
Flow of participants through each stage (a diagram is strongly recommended)—specifically, for each group, report the numbers of participants randomly assigned, receiving intended treatment, completing the study protocol, and analyzed for the primary outcome; describe protocol deviations from study as planned, together with reasons

Extension for Nonpharmacologic Trials
The number of care providers or centers performing the intervention in each group and the number of patients treated by each care provider or in each center.

Examples of Good Reporting Based on Extension (Reference)
See Figure 2, reconstructed with the authors’ permission (39).

Implementation of interventions

Item: New item

Examples of Good Reporting Based on Extension (Reference)

A single stent was implanted in 546 patients (40%), 2 stents in 487 (36%), 3 stents in 206 (15%), and 4 or more stents in 111 (8%) in both study groups (mean, 1.9 stents per patient and 1.4 stents per lesion). The mean stent diameter was 2.8 mm in both groups, and the mean length was 22.8 mm in the sirolimus-eluting stent group and 23.5 mm in the paclitaxel-eluting stent group. The maximum dilatation pressure during stent implantation was significantly lower in the paclitaxel-eluting stent group than in the sirolimus-eluting stent group (29).

On average, participants attended a mean of 9.4 exercise sessions (SD, 3.2) and 10.2 sham exercise sessions (SD, 3.0) of the planned 12 sessions. Participants attended a mean of 2.9 advice sessions (SD, 1.1) and 2.5 sham advice sessions (SD, 1.1) of the planned 3 sessions. The mean duration of exercise sessions was 54.0 minutes (SD, 16.3), of which 35.6 minutes (SD, 12.6) were spent with a physiotherapist. The mean duration of sham exercise sessions was 47.0 minutes (SD, 25.0), of which 22.9 minutes (SD, 8.4) were spent with a physiotherapist. Mean durations of advice and sham advice sessions were 20.0 minutes (SD, 4.9) and 19.0 minutes (SD, 5.3), respectively (30).

Baseline data

Item 15

Standard CONSORT Description
Baseline demographic and clinical characteristics of each group

Extension for Nonpharmacologic Trials
When applicable, a description of care providers (case volume, qualification, expertise, etc.) and centers (volume) in each group.

Examples of Good Reporting Based on Extension (Reference)

We dichotomized surgeon’s experience in laparoscopic repair into greater than 250 repairs (experienced) and less than 250 repairs (inexperienced). . . . Surgeons participating in this trial ranged in age from 27 to 70 with a median of 42 years in the laparoscopic group (55 surgeons) and from 30 to 76 with a median of 42 in the open group (77 surgeons). In the laparoscopic group, 8 surgeons were classified as experienced and 47 as inexperienced (31, 32).

Discussion

Interpretation

Item 20

Standard CONSORT Description
Interpretation of the results, taking into account study hypotheses, sources of potential bias or imprecision, and the dangers associated with multiplicity of analyses and outcomes

Extension for Nonpharmacologic Trials
In addition, take into account the choice of the comparator, lack of or partial blinding, and unequal expertise of care providers or centers in each group.

Examples of Good Reporting Based on Extension (Reference)

The sham acupuncture intervention in our study was designed to minimize potential physiological effects by needling superficially at points distant from the segments of “true” treatment points and by using fewer needles than in the acupuncture group. However, we cannot rule out that this intervention may have had some physiological effects. The nonspecific physiological effects of needling may include local alteration in circulation and immune function as well as neurophysiological and neurochemical responses. The question investigated in our comparison of acupuncture and sham acupuncture was not whether skin penetration matters but whether adherence to the traditional concepts of acupuncture makes a difference. For this purpose, our minimal acupuncture intervention was clearly an appropriate sham control although it might not be an inert placebo (33).

Our study has not entirely resolved the extent to which the effect of magnetic bracelets is specific or due to placebo. Blinding did not affect the pattern of results, but the validity of the self-reporting of blinding status could be questioned. Although the analysis of per-specification bracelets also suggests a specific effect, the result is only a trend and needs confirmation. Therefore, we cannot be certain whether our data show a specific effect of magnets, a placebo effect, or both (34).

First, surgeons might not be proficient in one or both treatments. The difference in malunion rates between the two treatment groups was consistent across all four study sites, indicating the difference is due to the procedure and not technical proficiency. Staff from all four centres were experienced in both techniques and, therefore, the results are probably typical of other paediatric centers (35).

Generalizability

Item 21

Standard CONSORT Description
Generalizability (external validity) of the trial findings

Continued on following page
intervention across centers or practitioners. In pragmatic trials (that is, trials attempting to show whether an intervention works under the usual conditions in which it will be applied), standardization might consist of simply informing care providers to perform the treatment as they usually do. In efficacy trials (that is, trials aiming to determine whether an intervention works when administered under ideal circumstances), standardization is likely to be more stringent, with the requirement of a certification process, for example (23). The description of any standardization methods is essential to allow adequate replication of the nonpharmacologic treatment. We recommend that authors allow interested readers to access the materials they used to standardize the interventions, either by including a Web appendix with their article or a link to a stable Web site. Such materials include written manuals, specific guidelines, and materials used to train care providers to uniformly deliver the intervention.

In a sample of 158 reports of surgical RCTs published in 2004 (79), only 4 articles reported care providers’ compliance with the planned procedure.

**Item 7: Sample Size**

**Standard CONSORT item: How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules.**

In addition, for nonpharmacologic trials: When applicable, details of whether and how the clustering by care providers or centers was addressed.

Table 3 shows the rationale for the clustering effect (87–92). As with cluster randomized trials (40, 93), sample size estimates for individually randomized RCTs assessing nonpharmacologic treatments should ideally be adjusted for the clustering effect as estimated by the intracluster intraclass correlation coefficient. Authors should report whether and how they have incorporated these issues into the trial sample size calculations.
Item 8: Randomization (Sequence Generation)

Standard CONSORT item: Methods used to generate the random allocation sequence, including details of any restriction (for example, blocking, stratification).

In addition, for nonpharmacologic trials: When applicable, how care providers were allocated to each treatment group.

In conventional RCTs, especially pharmacologic trials, participants are randomly assigned to 1 of 2 (or more) treatments. The treatments compared are usually administered by the same care providers. That approach is not desirable in many nonpharmacologic trials. First, the expertise of care providers for each procedure may differ, or one procedure may be more challenging than the other. This issue may result in differential expertise between interventions and may bias the treatment effect estimates, especially in surgery. Second, care providers are frequently unblinded in nonpharmacologic trials, and they can have preferences or differential expectations for one of the interventions. Thus, they may unconsciously bias the trial: for example, when prescribing a co-intervention or when proposing crossover between groups (that is, the experimental treatment is offered to participants randomly assigned to the control group). A survey of 139 surgeons participating in a large conventional RCT comparing 2 surgical procedures for treating a tibial shaft fracture showed that statistically significantly more surgeons had no or limited experience with the more technically challenging procedure (58). Furthermore, 87% of surgeons believed that the less-challenging procedure was superior, and differential crossover occurred: 8% of the patients assigned to the more-challenging procedure received the less-challenging procedure, whereas fewer than 1% of patients assigned to the less-challenging procedure received the more-challenging procedure.

To overcome these problems, care providers participating in a trial might perform interventions only in their preferred treatment group (expertise-based RCT) (58). This design is mandatory when comparing 2 different types of interventions, such as surgery versus physiotherapy for back problems. However, that design might limit the applicability of the trial results. In trials assessing behavioral intervention, rehabilitation, and psychotherapy, some researchers proposed selecting a random sample of care providers to avoid biased results and improve the applicability.

Consequently, so that others can evaluate the internal and external validity of a trial, authors should report on how care providers were allocated to each treatment group.

Item 11: Blinding (Masking)

11A. Standard CONSORT item: Whether or not participants, those administering the interventions, and those assessing the outcomes were blinded to group assignment.

In addition, for nonpharmacologic trials: Whether or not those administering co-interventions were blinded to group assignment.

Empirical evidence demonstrates that lack of reporting of blinding is associated with biased estimates of treatment effect (94–98). Blinding in trials is usually considered in relation to the participants, caregivers, and outcome assessors (14). In nonpharmacologic trials, the blinding status of other caregivers (for example, physicians administering co-interventions) should also be reported. In fact, other caregivers may have an important influence on the observed treatment effect. For example, in a trial assessing a surgical procedure, even if the surgeon cannot be blinded,
the health care professionals following the participants after the procedure might be blinded, and contact between other caregivers and the surgeon could be avoided, thus limiting the risk for performance bias.

**Item 11B. If blinded, method of blinding and description of the similarity of interventions.**

At the most recent CONSORT Group meeting (Montebello, Québec, Canada, January 2007), the participants agreed to revise the 2001 CONSORT Statement. Item 11 of the checklist deals with reporting of blinding, and the wording of the item will be modified (Moher D. Personal communication.). Because blinding is an especially important issue for nonpharmacologic trials, we have used the wording of the revised checklist item on blinding for the nonpharmacologic extension. Part of the 2001 version states: “If done, how the success of blinding was evaluated.” This is now replaced by: “If blinded, method of blinding and description of the similarity of interventions.”

Blinding is often more difficult to carry out in trials assessing nonpharmacologic treatments (13), and the risk for unblinding is important (99, 100). A review of the methods of blinding in nonpharmacologic trials highlighted creative methods of blinding reported by some authors. Examples include use of sham procedures, such as simulation of surgical procedures, or partial blinding of participants, in which participants are blinded to the study hypothesis (14). The methods of blinding, as well as the similarity of treatments, should be highlighted.

Researchers are still working on how best to deal with some of these methodological challenges. In the meantime, authors should report how they have handled them in order to allow progress in understanding these potential biases.

**Item 12: Statistical Methods**

**Standard CONSORT item: Statistical methods used to compare groups for primary outcome(s). Methods for additional analyses, such as subgroup analyses and adjusted analyses.**

In addition, for nonpharmacologic trials: When applicable, details of whether and how the clustering by care providers or centers was addressed.

Table 3 shows the rationale for centers’ volume. In trials assessing nonpharmacologic treatments, the success of the intervention depends in part on the skill and training of care providers. As such, observations from participants treated by the same care provider or in the same center are correlated or clustered.

Standard methods of analysis that ignore clusters will result in incorrect estimation of treatment effect (87, 89, 101–104). Authors should use specific models that allow adjustment for participant characteristics while controlling for clustering effect (90, 91) in analyzing the results of this type of trial (91). Any allowance that was made in the analysis for the clustering of participants and care providers or care providers and center should be reported.

**Results Section**

**Item 13: Participant Flow**

**Standard CONSORT item: Flow of participants through each stage (a diagram is strongly recommended)—specifically, for each group, report the numbers of participants randomly assigned, receiving intended treatment, completing the study protocol, and analyzed for the primary outcome; describe protocol deviations from study as planned, together with reasons.**

In addition, for nonpharmacologic trials: The number of care providers or centers performing the intervention in each group, and the number of patients treated by each care provider or in each center.

As outlined in the CONSORT Statement, the flow of individual participants through each stage of the trial should be reported: the number of persons evaluated for potential enrollment, randomly assigned to each group, who received treatment as allocated, who completed treatment as allocated, who completed follow-up as planned, and included in the main analyses in each group (2). For trials assessing nonpharmacologic treatments, authors also should report information on the number of centers and care providers in each group and the distribution of participants treated by care providers or at each center. This information is crucial to allow others to critically compare groups for primary outcome(s). Methods for additional analyses, such as subgroup analyses and adjusted analyses.
ally appraise the applicability of the trial’s results. For instance, if 50 surgeons are treating participants, it is important to know whether most patients are being treated by only 1 surgeon or whether all surgeons treated similar numbers of patients. Authors should report the median (interquartile range, minimum and maximum value) of participants treated by each care provider or center. This information could be reported in a figure (Figure 1).

Implementation of Interventions

New item, for nonpharmacologic trials: Details of the experimental treatment and comparator as they were implemented.

Although a nonpharmacologic intervention can be standardized (see item 4B), there may be differences between how it was intended to be administered and how it actually was administered—for example, because of lack of the reproducibility of the treatment (82). Furthermore, because participants and care providers are frequently not blinded to treatment assignment, a risk for unequal administration of additional treatments (co-intervention) and consequent “contamination” (that is, administration of the experimental treatment to the control group) might influence the estimates of treatment effect. Care providers may introduce part or all of the experimental intervention into the control program if they are convinced of its superiority. Participants in the control group may also treat themselves with the experimental intervention if they believe in its efficacy. Reporting how the intervention was actually administered is thus crucial to accurate evaluation of the results (22, 23).

Item 15: Baseline Data

Standard CONSORT item: Baseline demographic and clinical characteristics of each group.

In addition, for nonpharmacologic trials: When applicable, a description of care providers (case volume, qualification, expertise, etc.) and centers (volume) in each group.

Although the eligibility criteria (item 3) provide some information on care providers and centers participating in an RCT, further details of the characteristics of the care providers and the centers that recruited and treated participants are important to know.

A table can efficiently present this baseline information. The mean and SD can be used to summarize quantitative data for each group. When quantitative data have an asymmetrical distribution, a preferable approach may be to give the median and percentile range (perhaps the 25th and 75th percentiles). Authors should report numbers and proportions for categorical and qualitative data (2). These data are essential to appraise the risk for bias linked to care providers’ expertise and the external validity of the results.

Discussion Section

Item 20: Interpretation

Standard CONSORT item: Interpretation of the results, taking into account the study hypotheses, sources of potential bias or imprecision, and the dangers associated with multiplicity of analyses and outcomes.

In addition, for nonpharmacologic trials: In addition, take into account the choice of the comparator, lack of or partial blinding, and unequal expertise of care providers or centers in each group.

Three aspects specific to nonpharmacologic trials should be addressed in the Discussion section. First, the choice of the comparator is important and will influence the observed treatment effect of the intervention (75, 105). In particular, debate surrounds the use of placebo interventions in trials assessing nonpharmacologic treatments, because these treatments may have a specific therapeutic effect associated with the relationship between participants and care providers. Consequently, trials with placebos might underestimate the treatment effect (14, 106). Some placebos are also questionable from an ethical perspective, such as the use of simulated or sham surgery (27, 37, 107).

Second, blinding issues associated with the feasibility of blinding, risk for blinding failure (13, 14, 108), and risk for bias when blinding is not feasible should be discussed (109, 110). When participants and care providers are not blinded, performance bias (that is, unequal provision of care according to the treatment administered) could occur; a discussion of co-interventions, contamination, and the rate of follow-up in each group is therefore useful. Lack of blinding of outcome assessors could be responsible for ascertainment bias. Any methods used to reduce bias should be discussed. For situations in which outcome assessors cannot be blinded, an objective primary outcome, such as mortality or assessment by an independent end point committee, could limit the risk for bias.

Finally, authors should discuss the possibility of differential expertise bias (58) linked to unequal expertise of care providers in each group (item 3).

Item 21: Generalizability

Standard CONSORT item: Generalizability (external validity) of the trial findings.

In addition, for nonpharmacologic trials: Generalizability (external validity) of the trial findings according to the intervention, comparators, patients, care providers, and centers involved in the trial.

To be clinically useful, the results of RCTs should provide data on the external validity, also called generalizability and applicability. Lack of external validity is frequently cited as a reason why interventions found to be
We developed this CONSORT extension to help improve the reporting of RCTs investigating nonpharmacologic treatments. This document provides explanation of and elaboration on the CONSORT checklist items specific to nonpharmacologic treatments. Authors should use this document in conjunction with the main CONSORT guidelines (2) when addressing all 22 items on the checklist. Depending on the type of trial conducted, authors may also find it useful to consult the CONSORT extensions for cluster trials (40) and noninferiority trials (4), and the detailed guidelines for reporting harms associated with interventions (6). All CONSORT guidelines can be found on the CONSORT Web site (www.consort-statement.org).

We hope that journals endorsing and enforcing CONSORT for reporting nonpharmacologic RCTs will recommend that authors also review this explanatory document. We believe that the promotion of this extension will improve the quality of reporting RCTs of nonpharmacologic treatments.

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References
13. Boutron I, Tubach F, Giraudreau B, Ravaud P. Blinding was judged more effective in clinical trials are underutilized in clinical practice (111). In trials comparing pharmacologic with nonpharmacologic treatment, the characteristics of the patients included, the trial setting, the treatment regimens, and the outcomes assessed should all be reported and discussed (2, 111). In nonpharmacologic trials, the health care system (112), selection of participating centers and care providers (59), and intervention actually administered are also essential to evaluate the external validity. For example, differences between health care systems affected the external validity in the European Carotid Surgery Trial (112), an RCT of endarterectomy for recently symptomatic carotid stenosis. In this international trial, countries differed in the speed with which patients were investigated. These differences were not mentioned in any of the publications for the European Carotid Surgery Trial, yet they probably had an important impact on the outcomes (111). Similarly, differences between countries in methods of diagnosis and management can affect the external validity of the trial results. Finally, the volume of centers and care providers can influence the treatment effect estimates, and exclusive participation of high-volume centers has obvious implications for external validity. Authors should clearly indicate whether the intervention evaluated could be performed in all settings by all centers or should be reserved for high-volume centers.
EXTENDING CONSORT STATEMENT TO TRIALS OF NONPHARMACOLOGIC TREATMENT

A. Sackett, J. Richardson, W. Rosenberg, and R. Haynes

Aims

The CONSORT (Consolidated Standards of Reporting Trials) statement was developed in 1996 as a collaborative effort of experts in clinical research and research methodology to improve the quality of reporting of randomized trials (RTs) in biomedical journals. In 2001, the CONSORT statement was expanded to include a template for reporting the results of any research involving human research participants, including observational studies and cohort studies. This expansion is termed the CONSORT Statement: Extensions and Comparisons (CONSORT-EÇ). The CONSORT statement is aimed at improving the transparency of reporting in experimental research, thus enabling readers to judge the credibility of the findings. However, despite the efforts and improvements, the CONSORT statement is not well known among non-English-speaking readers. Additionally, the CONSORT statement has not yet been applied to nonpharmacologic treatments in randomized trials. This paper aims to present an extended CONSORT statement for nonpharmacologic treatments to improve the quality of reporting in randomized trials involving nonpharmacologic treatments.

Methods

The CONSORT statement for randomized trials was used as a starting point. We added items that are specific to nonpharmacologic treatments, such as details about the intervention and its delivery, the outcomes, and the follow-up procedures. We also included a section on the blinding of the outcome assessment, which is often difficult to achieve in nonpharmacologic trials. Furthermore, we included a section on the results of the trial, including the analysis of the primary outcomes and the secondary outcomes.

Results

The extended CONSORT statement includes 32 items, including an introduction, methods, results, discussion, and references. The methods section includes items such as the randomization process, the blinding of the study, the allocation concealment, and the follow-up procedures. The results section includes items such as the primary outcomes, the secondary outcomes, and the statistical analyses. The discussion section includes items such as the interpretation of the results, the comparison with other studies, and the implications for clinical practice.

Conclusions

The extended CONSORT statement for randomized trials involving nonpharmacologic treatments will improve the quality of reporting in such trials. This will enable readers to judge the credibility of the findings and make informed decisions about the use of the interventions. Future research should focus on testing the effectiveness of the extended CONSORT statement in improving the quality of reporting in randomized trials involving nonpharmacologic treatments.


106. Paterson C, Dieppe P. Characteristic and incidental (placebo) effects in complex interventions such as acupuncture. BMJ. 2005;330:1202-5. [PMID: 15905259]


111. Rothwell PM. External validity of randomised controlled trials: “to whom do the results of this trial apply?”. Lancet. 2005;365:82-93. [PMID: 15639683]


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