Item 5. The interventions for each group with sufficient details to allow replication, including how and when they were actually administered

Examples—“In POISE, patients received the first dose of the study drug (ie, oral extended-release metoprolol 100 mg or matching placebo) 2-4 h before surgery. Study drug administration required a heart rate of 50 bpm or more and a systolic blood pressure of 100 mm Hg or greater; these haemodynamics were checked before each administration. If, at any time during the first 6 h after surgery, heart rate was 80 bpm or more and systolic blood pressure was 100 mm Hg or higher, patients received their first postoperative dose (extended release metoprolol 100 mg or matched placebo) orally. If the study drug was not given during the first 6 h, patients received their first postoperative dose at 6 h after surgery. 12 h after the first postoperative dose, patients started taking oral extended-release metoprolol 200 mg or placebo every day for 30 days. If a patient’s heart rate was consistently below 45 bpm or their systolic blood pressure dropped below 100 mm Hg, study drug was withheld until their heart rate or systolic blood pressure recovered; the study drug was then restarted at 100 mg once daily. Patients whose heart rate was consistently 45-49 bpm and systolic blood pressure exceeded 100 mm Hg delayed taking the study drug for 12 h.”100 “Patients were randomly assigned to receive a custom made neoprene splint to be worn at night or to usual care. The splint was a rigid rest orthosis recommended for use only at night. It covered the base of the thumb and the thenar eminence but not the wrist (Figure 1). Splints were made by 3 trained occupational therapists, who adjusted the splint for each patient so that the first web could be opened and the thumb placed in opposition with the first long finger. Patients were encouraged to contact the occupational therapist if they felt that the splint needed adjustment, pain increased while wearing the splint, or they had adverse effects (such as skin erosion). Because no treatment can be considered the gold standard in this situation, patients in the control and intervention groups received usual care at the discretion of their physician (general practitioner or rheumatologist). We decided not to use a placebo because, to our knowledge, no placebo for splinting has achieved successful blinding of patients, as recommended.”

Explanation—Authors should describe each intervention thoroughly, including control interventions. The description should allow a clinician wanting to use the intervention to know exactly how to administer the intervention that was evaluated in the trial. For a drug intervention, information would include the drug name, dose, method of administration (such as oral, intravenous), timing and duration of administration, conditions under which interventions are withheld, and titration regimen if applicable. If the control group is to receive “usual care” it is important to describe thoroughly what that constitutes. If the control group or intervention group is to receive a combination of interventions the authors should provide a thorough description of each intervention, an explanation of the order in which the combination of interventions are introduced or withdrawn, and the triggers for their introduction if applicable. Specific extensions of the CONSORT statement address the reporting of non-pharmacologic and herbal interventions and their particular reporting requirements (such as expertise, details of how the interventions were standardized). We recommend readers consult the statements for non-pharmacologic and herbal interventions as appropriate.