Methods Item 3aDescription of trial design (such as parallel, factorial) including allocation ratio

Example—“This was a multicenter, stratified (6 to 11 years and 12 to 17 years of age, with imbalanced randomisation [2:1]), double-blind, placebo-controlled, parallel-group study conducted in the United States (41 sites).”

Explanation—

The word “design” is often used to refer to all aspects of how a trial is set up, but it also has a narrower interpretation. Many specific aspects of the broader trial design, including details of randomisation and blinding, are addressed elsewhere in the CONSORT checklist. Here we seek information on the type of trial, such as parallel group or factorial, and the conceptual framework, such as superiority or non-inferiority, and other related issues not addressed elsewhere in the checklist. The CONSORT statement focuses mainly on trials with participants individually randomised to one of two “parallel” groups. In fact, little more than half of published trials have such a design. The main alternative designs are multi-arm parallel, crossover, cluster,40 and factorial designs. Also, most trials are set to identify the superiority of a new intervention, if it exists, but others are designed to assess non-inferiority or equivalence.39 It is important that researchers clearly describe these aspects of their trial, including the unit of randomisation (such as patient, GP practice, lesion). It is desirable also to include these details in the abstract (see item 1b). If a less common design is employed, authors are encouraged to explain their choice, especially as such designs may imply the need for a larger sample size or more complex analysis and interpretation. Although most trials use equal randomisation (such as 1:1 for two groups), it is helpful to provide the allocation ratio explicitly. For drug trials, specifying the phase of the trial (I-IV) may also be relevant.