Item 8b. Type of randomisation; details of any restriction (such as blocking and block size) Examples—“Randomization sequence was created using Stata 9.0 (StataCorp, College Station, TX) statistical soft‑ ware and was stratified by center with a 1:1 allocation using random block sizes of 2, 4, and 6.”

“Participants were randomly assigned following simple randomization procedures (computerized random numbers) to 1 of 2 treatment groups.”

Explanation—In trials of several hundred participants or more simple randomisation can usually be trusted to generate similar numbers in the two trial groups139 and to generate groups that are roughly comparable in terms of known and unknown prognostic variables.140 For smaller trials (see item 7a)—and even for trials that are not intended to be small, as they may stop before reaching their target size— some restricted randomisation (procedures to help achieve balance between groups in size or characteristics) may be useful (see box 2). It is important to indicate whether no restriction was used, by stating such or by stating that “simple randomisation” was done. Otherwise, the methods used to restrict the randomisation, along with the method used for random selection, should be specified. For block randomisation, authors should provide details on how the blocks were generated (for example, by using a permuted block design with a computer random number generator), the block size or sizes, and whether the block size was fixed or randomly varied. If the trialists became aware of the block size(s), that information should also be reported as such knowledge could lead to code breaking. Authors should specify whether stratification was used, and if so, which factors were involved (such as recruitment site, sex, disease stage), the categorisation cut-off values within strata, and the method used for restriction. Although stratification is a useful technique, especially for smaller trials, it is complicated to implement and may be impossible if many stratifying factors are used. If minimisation (see box 2) was used, it should be explicitly identified, as should the variables incorporated into the scheme. If used, a random element should be indicated. Only 9% of 206 reports of trials in specialty journals23 and 39% of 80 trials in general medical journals reported use of stratification.32 In each case, only about half of the reports mentioned the use of restricted randomisation. However, these studies and that of Adetugbo and Williams8 found that the sizes of the treatment groups in many trials were the same or quite similar, yet blocking or stratification had not been mentioned. One possible explanation for the close bal‑ ance in numbers is underreporting of the use of restricted randomisation.