Item 13. Participant flow (a diagram is strongly recommended)

Item 13a. For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome Examples—See figs 2 and 3.

Explanation—The design and conduct of some RCTs is straightforward, and the flow of participants, particularly were there are no losses to follow-up or exclusions, through each phase of the study can be described adequately in a few sentences. In more complex studies, it may be difficult for readers to discern whether and why some participants did not receive the treatment as allocated, were lost to follow-up, or were excluded from the analysis. This information is crucial for several reasons. Participants who were excluded after allocation are unlikely to be representative of all participants in the study. For example, patients may not be available for follow-up evaluation because they experienced an acute exacerbation of their illness or harms of treatment. Attrition as a result of loss to follow up, which is often unavoidable, needs to be distinguished from investigator-deter‑ mined exclusion for such reasons as ineligibility, withdrawal from treatment, and poor adherence to the trial protocol. Erroneous conclusions can be reached if participants are excluded from analysis, and imbalances in such omissions between groups may be especially indicative of bias. Information about whether the investigators included in the analysis all participants who underwent randomisation, in the groups to which they were originally allocated (intention-to-treat analysis (see item 16 and box 6)), is therefore of particular importance. Knowing the number of participants who did not receive the intervention as allocated or did not complete treatment permits the reader to assess to what extent the estimated efficacy of therapy might be underestimated in comparison with ideal circumstances. If available, the number of people assessed for eligibility should also be reported. Although this number is relevant to external validity only and is arguably less important than the other counts, it is a useful indicator of whether trial participants were likely to be representative of all eligible participants. A review of RCTs published in five leading general and internal medicine journals in 1998 found that reporting of the flow of participants was often incomplete, particularly with regard to the number of participants receiving the allocated intervention and the number lost to follow-up. Even information as basic as the number of participants who underwent randomisation and the number excluded from analyses was not available in up to 20% of articles. Reporting was considerably more thorough in articles that included a diagram of the flow of participants through a trial, as recommended by CONSORT. This study informed the design of the revised flow diagram in the revised CONSORT statement. The suggested template is shown in fig 1, and the counts required are described in detail in table 3. Some information, such as the number of individuals assessed for eligibility, may not always be known, and, depending on the nature of a trial, some counts may be more relevant than others. It will sometimes be useful or necessary to adapt the structure of the flow diagram to a particular trial. In some situations, other information may usefully be added. For example, the flow diagram of a parallel group trial of minimal surgery compared with medical management for chronic gastro-oesophageal reflux also included a parallel non-randomised preference group (see fig 3). The exact form and content of the flow diagram may be varied according to specific features of a trial. For example, many trials of surgery or vaccination do not include the possibility of discontinuation. Although CONSORT strongly recommends using this graphical device to communicate participant flow throughout the study, there is no specific, prescribed format.