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A Message from the Editor: Adoption of the Consort Statement

THE RESULTS of randomised clinical trials provide perhaps the only definitive evidence of the superiority of one treatment over another and can have almost immediate benefits to patients. In oncology, where generally only relatively small improvements in efficacy are anticipated from new therapies or modifications of pre-existing treatments, large, well-conducted and often multicentre randomised trials are one of the most important means of improving the care of cancer patients.

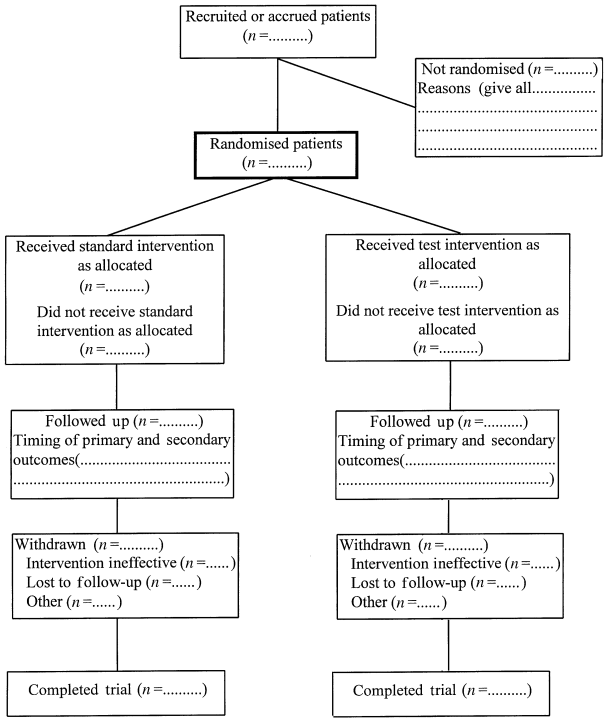
The impact of such trials is dependent upon the dissemination of the results in the literature and their acceptance by the medical community. In addition, meta-analysis of several relatively small randomised trials may be required before a change to standard oncology practice is considered. Clearly, how such randomised clinical trials are reported is important. It is vital that such reports convey to the reader all essential information on methodology and analysis so that an informed judgement can be made on the validity of the results and their general applicability.

In an effort to improve international standards for reporting randomised clinical trials, the Editors of the *European Journal of Cancer* have decided to join other journals in adopting the use of the CONSORT (Consolidation Standards of Reporting Trials) statement, which was published in the *Journal of the Americal Medical Association* [Begg C, Cho M, Eastwood S *et al.*, *JAMA* 1996, **276**, pp. 637–639]. From January 1998, changes will be implemented so that all randomised clinical trials published in the *European Journal of Cancer* will conform to the standards set out in the CONSORT statement. This will include authors of such trials being sent a checklist (Table 1) and a flow diagram of patient participation (Figure 1) which they will have to complete before acceptance of their paper. These will help the authors of the paper and the Editors and referees of the *European Journal of Cancer* ensure that all essential information is contained within the report before publication. The figure shall be published in the paper.

Whilst these changes may mean more effort and paperwork for all concerned, the Editors of *European Journal of Cancer* feel that the benefits in terms of completeness of reporting of randomised trials, the ease with which results from different results can be compared, and the application of meta-analysis to such trials, vastly outweigh the minor inconveniences. We hope our readers and authors will agree and will support our adoption of CONSORT.

HANS-JÖRG SENN
Editor-in-Chief

DELPHINE PURVES
Scientific Editor



(Adapted from Begg C, Cho M, Eastwood S, *et al.* Improving the quality of reporting of randomized controlled trials: the CONSORT statement. *JAMA* 1996, **276**, 637–639).

Figure 1. Flow chart of the progress of patients through the trial.

Table 1. *Checklist for authors submitting reports of randomised controlled trials*

First Author's Name and Manuscript Title:

Heading	Subheading (Add to the format of your paper)	Descriptor	Was it reported? (Tick as appropriate) Yes	No	If Yes, what page number?
Title	Not applicable	Identify the study as a randomised trial.			
Introduction	None	State prospectively defined hypothesis, clinical objectives, and planned subgroup or covariate analyses			
Methods	Protocol	Describe: Planned study population, together with inclusion/exclusion criteria Planned interventions and their timing Primary and secondary outcome measure(s) and the minimum important difference(s) and how the target sample size was projected Rationale and methods for statistical analyses, detailing main comparative analyses and whether they were completed on an intention-to-treat basis Prospectively defined stopping rules (if warranted)			
	Assignment	Describe: Unit of randomisation (e.g. individual, cluster, geographic) Method used to generate the allocation schedule Method of allocation concealment and timing of assignment Method to separate the generator from the executor of assignment			
	Masking (Blinding)	Describe: Mechanism (e.g. capsules, tablets); similarity of treatment characteristics (e.g., appearance, taste); allocation schedule control (location of code during trial and when broken); and evidence for successful masking (blinding) among participants, person doing intervention, outcome assessors, and data analysts			
Results	Participant flow and follow-up	Provide a trial profile (see Figure 1) summarising participant flow, numbers and timing of randomisation assignment, interventions and measurements for each randomised group			
	Analysis	State estimated effect of intervention on primary and secondary outcome measures, including a point estimate and measure of precision (confidence interval) State results in absolute numbers when feasible, e.g. 10/20, not 50% Present summary data and appropriate descriptive and inferential statistics in sufficient detail to permit alternative analyses and replication Describe prognostic variables by treatment group and any attempt to adjust for them Describe protocol deviations from the study as planned, together with the reasons			
Discussion	None	State specific interpretation of study findings, including sources of bias and imprecision (internal validity) and discussion of external validity, including appropriate quantitative measures when possible State general interpretation of the data in light of the totality of the available evidence			

(Adapted from Begg C, Cho M, Eastwood S, *et al.* Improving the quality of reporting of randomized controlled trials: the CONSORT statement. *JAMA* 1996, **276**, 637–639).