

**Guidelines for reporting clinical outcome studies in radiotherapy and oncology**

These guidelines meet the minimum criteria defined in the CONSORT statement for reporting of randomized clinical trials [13] with added radiotherapy items in bold type face.

Authors submitting reports on clinical outcome studies should include a filled-in copy of this form when submitting their manuscript. For a discussion of the items in this form see the review by Bentzen (Radiotherapy and Oncology 46, 5–18, 1998).

Heading	Subheading	Item	Was it reported Yes/No/NA*	If Yes, on what page No.?
Title		1. Identify the study as a randomized trial	_____	_____
Introduction		2. State the prospectively defined hypothesis, clinical objectives and planned subgroup or covariate analyses	_____	_____
Methods	Study design	3. Define the patient population, inclusion and exclusion criteria	_____	_____
	Radiotherapy	4. Planned treatments and their timing <b>5. Radiotherapy dose prescription method, dose-planning procedure</b> <b>6. Target volume definition, critical organs considered, simulation and verification procedures</b> <b>7. Dose fractionation details</b> <b>8. Planned RT quality assurance procedures</b>	_____	_____
	Endpoints and analysis	9. Primary and secondary endpoints, specific follow-up procedures, the minimum clinically relevant difference, the target sample size and how it was decided 10. Statistical analyses, their purpose and methods used, and whether the intention-to-treat principle was used	_____	_____
	Randomization	11. Trial monitoring, early stopping rules 12. Method used for randomization 13. Method of concealment and time of randomization 14. Method to separate the generator of random treatment assignment from the treating physician	_____	_____
Results	Masking	15. Describe any blinding procedures (if relevant)	_____	_____
	Patient flow and follow-up Analysis	16. Provide an overview of number of patients randomized, compliance with treatment, RT quality assurance results 17. State the effect of treatment on primary and secondary tumor outcome measures, including effect estimates with confidence intervals <b>18. Describe the incidence and grade of treatment-induced early and late toxicity by treatment group</b> 19. State frequencies as absolute numbers when feasible (e.g. 10/20 and not just 50%) 20. Present summary data with appropriate statistics to permit alternative analyses or interpretations and comparisons with other trials on the same problem 21. Describe prognostic variables by treatment group, check if they were balanced, and if not describe attempts to adjust for them 22. Describe protocol deviations from the study as planned, together with reasons	_____	_____
Discussion		23. State the interpretation of the study findings, including sources of bias and imprecision, discuss how this trial compares with other similar studies	_____	_____
Conclusion		24. State the general interpretation of the trial in view of all available evidence in the literature	_____	_____

\* NA, not applicable, certain items apply to randomized studies only.