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	na	
Introduction		2. State the prospectively defined hypothesis, clinical objectives and planned subgroup or covariate analyses	yes	3
Methods	Study design	3. Define the patient population, inclusion and exclusion criteria	yes	3
		4. Planned treatments and their timing	yes	4
	Radiotherapy	**5. Radiotherapy dose prescription method, dose-planning Procedure**	yes	4
		6. Target volume definition, critical organs considered, simulation and verification procedures	yes	4
		7. Dose fractionation details	yes	4
		8. Planned RT quality assurance procedures	yes	4
	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	yes	3
		10. Statistical analyses, their purpose and methods used, and whether the intention-to-treat principle was used	yes	5
		11. Trial monitoring, early stopping rules	yes	3
	Randomization	12. Method used for randomization	NA	
		13. Method of concealment and time of randomization	NA	
		14. Method to separate the generator of random treatment assignment from the treating physician	NA	
	Masking	15. Describe any blinding procedures (if relevant)	NA	
Results	Patient flow and follow-up	16. Provide an overview of number of patients randomized, compliance with treatment, RT quality assurance results	yes	6
	Analysis	17. State the effect of treatment on primary and secondary tumor outcome measures, including effect estimates with confidence intervals	yes	7
		18. Describe the incidence and grade of treatment-induced early and late toxicity by treatment group	yes	7-8
		19. State frequencies as absolute numbers when feasible (e.g. 10/20 and not just 50%)	yes	
		20. Present summary data with appropriate statistics to permit alternative analyses or interpretations and comparisons with other trials on the same problem	yes	8-10
		21. Describe prognostic variables by treatment group, check if they were balanced, and if not describe attempts to adjust for them	NA	
		22. Describe protocol deviations from the study as planned, together with reasons	yes	5-6
Discussion		23. State the interpretation of the study findings, including sources of bias and imprecision, discuss how this trial compares with other similar studies	yes	8-11
Conclusion		24. State the general interpretation of the trial in view of all available evidencey in the literature	yes	11

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