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MISE AU POINT

Les recommandations CONSORT (CONsolidated Standards Of Reporting Trials)☆

The CONSORT statement (CONsolidated Standards Of Reporting Trials)

G. Lorette*, A. Maruani

Service de dermatologie, hôpital Trousseau, université de Tours, CHRU, 37044 Tours cedex, France

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MOTS CLÉS
CONSORT ;
EBM ;
Lecture d'articles ;
Recommandations ;
Cochrane ;
Vancouver ;
Essais contrôlés randomisés

Résumé Le groupe CONSORT, composé notamment de méthodologistes et d'éditeurs de journaux, a réalisé un outil sous forme de liste. Cet outil, appelé « CONSORT Statement », énumère tous les éléments qu'il est indispensable de rapporter lors de la rédaction, pour un journal médical, des méthodes, des résultats et de la discussion d'un essai contrôlé randomisé (ECR, ou en anglais RCT pour *randomized controlled trial*). L'objectif de ce groupe et du « CONSORT Statement » est d'aider les auteurs à rédiger de façon standardisée la méthodologie et les résultats des essais. L'effet attendu est d'obtenir une meilleure transparence et une rigueur optimale dans la présentation, et par conséquent la conception des essais. Cela permet aux lecteurs une plus grande facilité de lecture et d'évaluation des biais éventuels de l'essai.

KEYWORDS
CONSORT;
EBM;
Reading articles;
Guidelines;
Cochrane;
Vancouver;
Randomized controlled trials

Summary The CONSORT group, made up in particular of methodologists and journal editors, has created a tool in the form of a list. This tool, known as the ''CONSORT statement'', sets out all items that must be reported when preparing for publication in medical journals with regard to methods, results and discussion of randomised controlled trials (RCT). The aim of this group and of the CONSORT statement is to help authors prepare a standard presentation of the methodology and results of their studies. The desired effect is to ensure greater transparency and optimal rigor in such presentations, and thus in study design. This will make it easier for readers to verify such studies and to assess any potential sources of study bias.

☆ NDLR : les tableaux et figures qui accompagnent l'article ont exceptionnellement été laissés en langue anglaise, la traduction des documents CONSORT devant obéir à une procédure particulière de validation qui n'a pas encore été complétée pour la langue française.

* Auteur correspondant.
Adresse e-mail : lorette@med.univ-tours.fr (G. Lorette).

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Tableau 1 Récapitulation des informations à inclure dans le compte rendu d'un essai randomisé.

Section/Topic	Item N°	Checklist item	Reported on page N°
Title and abstract			
	1a	Identification as a randomized trial in the title	
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts [21,31])	
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	
	2b	Specific objectives or hypotheses	
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	
	3b	Important changes to methods after trail commencement (such as eligibility criteria), with reasons	
Participants	4a	Eligibility criteria for participants	
	4b	Settings and locations where the data were collected	
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	
	6b	Any changes to trial outcomes after the trial commenced, with reasons	
Sample size	7a	How sample size was determined	
	7b	When applicable, explanation of any interim analyses and stopping guidelines	
Randomization			
Sequence generation	8a	Method used to generate the random allocation sequence	
	8b	Type of randomization; details of any restriction (such as blocking and block size)	
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	
Statistical methods			
	12a	Statistical methods used to compare groups for primary and secondary outcomes	
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	
Results			
Participants flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	
	13b	For each group, losses and exclusions after randomization, together with reasons	
Recruitment	14a	Dates defining the periods of recruitment and follow-up	
	14b	Why the trial ended or was stopped	