American Journal of Orthodontics and Dentofacial Orthopedics

Evaluation form for Randomized Clinical Trials

Instructions: Please mark your response with an "X" and use a red font to enter your response to each question.

ABSTRACT

A. Does the abstract describe the following sections adequately?			
Study purpose	__Yes	__No	__Partially
Materials and methods	__Yes	__No	__Partially
Results	__Yes	__No	__Partially
Conclusions	__Yes	__No	__Partially
Additional Comments: >			

INTRODUCTION

I-1. Does the introduction describe the following sections adequately?			
Scientific background	__Yes	__No	__Partially
Explanation of rationale	__Yes	__No	__Partially
Specific objectives or hypotheses	__Yes	__No	__Partially
I-2. Was a systematic review cited in this section in an effort to indicate existing evidence on the subject of interest?	__Yes	__No	
Additional Comments: >			

METHODS-ASSESMENT OF INTERNAL VALIDITY & RISK OF BIAS

M-1. Were participants (*eligibility criteria, settings*) clearly described?	__Yes	__No	__Partially
M-2. Were interventions clearly (*to allow replication*) described?	__Yes	__No	__Partially
M-3. Was follow-up clearly described?	__Yes	__No	__Partially
M-4. Was follow-up similar between patient groups?	__Yes	__No	__Partially
M-5. Were the outcomes (*primary & secondary*) clearly described?	__Yes	__No	__Partially
M-6. Was the sample size clearly described and justified?	__Yes	__No	__Partially
M-7. Was the random number generation method clearly described?	__Yes	__No	__Partially
M-8. Was the allocation concealment clearly described?	__Yes	__No	__Partially
M-9. Was blinding (*if applicable*) clearly described?	__Yes	__No	__Partially
M-10. If blinding was not feasible when applying the interventions, were the outcome assessors blind?	__Yes	__No	__Partially
M-11. Are the statistical methods clearly described and justified?	__Yes	__No	__Partially
M-12. Are any subgroup analyses and/or adjusted analyses clearly described & justified?	__Yes	__No	__Partially
Additional Comments: >			

Rs. Please indicate potential biases that might influence the results of this trial:			
Random sequence generation adequate? (selection bias)	__High	__Low	__Unclear
Allocation concealment adequate? (selection bias)	__High	__Low	__Unclear
Blinding of participants and personnel? (performance bias)	__High	__Low	__Unclear
Blinding of assessors? (detection bias)	__High	__Low	__Unclear
Outcome data reported completely, accounting for all subjects? (attrition bias)	__High	__Low	__Unclear
Free of selective reporting (reporting bias)	__High	__Low	__Unclear
Free of other threats to validity	__High	__Low	__Unclear
Additional comments regarding bias assessment: >			

RESULTS

Re-1. Please state briefly the main trial results: >			
Re-2. Is the participant flow clearly and correctly described (*flow diagram*)?	__Yes	__No	__Partially
Re-3. Are the dates of recruitment and follow-up clearly described?	__Yes	__No	__Partially
Re-4. Is the table of baseline demographic & clinical characteristics appropriately constructed?	__Yes	__No	__Partially
Re-5. Are there any obvious baseline imbalances that might influence the results?	__Yes	__No	__Partially
Re-6. Are the participant number analyzed (*w/denominators*) clearly shown?	__Yes	__No	__Partially
Re-7. Are effect estimates and confidence intervals clearly shown?	__Yes	__No	__Partially
Re-8. Are results from subgroup analyses and/or adjusted analyses shown?	__Yes	__No	__Partially
Re-9. Are the statistical methods clearly described and justified?	__Yes	__No	__Partially
Re-10. Any harms clearly described?	__Yes	__No	__Partially
Additional Comments: >			

DISCUSSION

D-1. Are trial limitations clearly described (*consider your response in sections M & Re*)?	__Yes	__No	__Partially
D-2. Is the interpretation consistent with results?	__Yes	__No	__Partially
D-3. Does the interpretation balance benefits and harms (*if applicable*)?	__Yes	__No	__Partially
D-4. Is the interpretation given in the context of other relevant and existing evidence?	__Yes	__No	__Partially
D-5. Is the generalizability of the results of this trial clearly discussed? *Generalizability or external validity is the applicability of the trial results in other settings and is closely related with the inclusion/exclusion criteria applied in the trial*	__Yes	__No	__Partially
Additional Comments: >			

OTHER INFORMATION

O-1. Is the trial registered?	__Yes	__Not reported
O-2. Is the trial protocol accessible (*if applicable*)?	__Yes	__Not reported
O-3. Are there any conflicts of interest (*industry funding*) clearly reported?	__Yes	__None reported
Additional Comments: >		

CONCLUSION and MISCELLANEOUS

C-1. Are conclusions appropriate and based on the results of the trial?	__Yes	__No	__Partially
C-2. Is the research question clearly defined (*section I*)?	__Yes	__No	__Partially
C-3. Is the trial methodology valid (*sections M & Rs*)?	__Yes	__No	__Partially
C-4. Are the trial results clearly described (*section Re*)	__Yes	__No	__Partially
C-5. Is the meaning of the results clearly and adequately described (*section D*)?	__Yes	__No	__Partially
C-6. Is this RCT a contribution to the orthodontic literature?	__Yes	__No	__Partially
C-7. Is the writing style and grammar acceptable?	__Yes	__No	
Additional comments regarding conclusions and miscellaneous items: >			

Any final or overall comments regarding this submission? >

Final Recommendation:

__Reject	__Major revision	__Minor revision	__Accept after copy editing

This form is based on information from the CONSORT guidelines[1] and the Cochrane Handbook[2].

1. *Moher D, Hopewell S, Schulz KF, Montori V, Gøtzsche PC, Devereaux PJ, et al. CONSORT 2010 Explanation and Elaboration: updated guidelines for reporting parallel group randomised trials. BMJ 2010;340:c869.*
2. *Higgins JPT, Altman DG, Sterne JAC (editors). Chapter 8: Assessing risk of bias in included studies. In: Higgins JPT, Green S (editors). Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 (updated March 2011). The Cochrane Collaboration 2011;Available from www.cochrane-handbook.org.*

Do you have any suggestions to help us improve this Evaluation Form? >