Guidelines for AJO-DO submissions: Randomized Clinical Trials

June 2015

Complete and transparent reporting allows for accurate assessment of the quality of trial and correct interpretation of the trial results. Complete and accurate reporting facilitates identification of trials and easy data extraction for inclusion of the trial in future systematic reviews.
The CONSORT reporting guidelines are provided to facilitate accurate, complete, and transparent reporting of randomized clinical trials (RCTs) and best use of research.

New submissions to the *AJO-DO* reporting the results of RCTs will be screened for compliance with the CONSORT (consolidated standards of reporting trials) guidelines. The updated 2010 CONSORT statement includes 25 specific items related to key report areas, including the title, abstract, methods, results, and discussion, to help authors prepare clinical trial reports.

1. Visit the CONSORT website to review the CONSORT 2010 explanation and elaboration document for parallel trials and the CONSORT for abstracts. If relevant, also read the CONSORT extensions for cluster randomized trials, non-inferiority and equivalence trials, non-pharmacological treatments, and pragmatic trials. Additional extensions are forthcoming, so always refer to the website. Study the CONSORT 2010 explanation and elaboration document and its extensions (if applicable) to understand what each of the 25 checklist items requires. Present the information in your manuscript according to the guidelines.
(www.consort-statement.org)

2. With respect to the CONSORT checklist and guidelines, please ensure that submissions are correctly identified as randomized clinical trial (item 1a), that a structured summary is provided (item 1b-See CONSORT for abstracts), and that the background and study objectives are clearly defined (items 2a &2b). For the title please use the PICO+ format (not a CONSORT item) as in the example below:

"A comparative assessment of orthodontic treatment outcomes using the PAR index (Outcome) between conventional (Comparator) and self-ligating brackets (Intervention) in adolescents (Participants): a multi-center, single blind randomized controlled trial (Design)"

Clearly define the study design (item 3), participants and settings (items 4a & 4b), interventions (item 5) and outcomes (items 6a & 6b), and clearly explain the assumptions underlying sample size calculations (item 7). Additionally, explain in detail all methods and processes pertaining to randomization (items 8-10), as their appropriate use will determine whether the study is a RCT or not. Blinding (item 11), if applicable, should be described at the investigator, participant, outcome assessor, and data analyst level. Explain the methods applied for statistical analyses for the main and any secondary outcomes (if applicable) and any methods used for subgroup or adjusted analyses (if applicable) (items 12a &12b). Please indicate participant flow by including a flow diagram (items 13a &13b), recruitment information (item 14), and a baseline table that presents the demographic and clinical characteristics for each group (item 15). Please include information on numbers analyzed (item 16), outcomes and estimation including effect estimate(s) and confidence intervals (items 17a &17b) and, if applicable, any results from ancillary analyses (item 18) and any harms (item 19). Please provide a thorough discussion (items 20-22) regarding trial limitations, applicability of results to other settings (generalizability), and interpretation of results, considering benefits and harms and in the context of the existing evidence. Finally, report if your trial was registered (item 23), if the trial protocol (item 24) was published before the commencement of the trial, and funding source(s) if any (item 25).

3. An editor will examine the randomized clinical trial manuscript for adherence to the CONSORT guidelines; if discrepancies are found, the manuscript will be returned with suggestions for changes either before the peer review process begins or with the reviewers' comments. The editor will be available to help authors to successfully implement the CONSORT guidelines. For more information on the proper application of CONSORT, see The CONSORT Statement: Application within and adaptations for orthodontic trials.

4. Immediately effective all new RCT submissions must be structured using additional subheadings to the standard IMRaD format (Introduction, Methods, Results, Discussion).

An example of a published RCT following the newly required format may be found in the following link:

Annotated RCT Sample Article

ABSTRACT

The abstract should follow the CONSORT for abstracts and should include the following items:

Item	*Description*
Title	Identification of the study as randomized
Authors	Contact details for the corresponding author
Trial design	Description of the trial design (e.g. parallel, cluster, non-inferiority)
Methods	
Participants	Eligibility criteria for participants and the settings where the data were collected
Interventions	Interventions intended for each group
Objective	Specific objective or hypothesis
Outcome	Clearly defined primary outcome for this report
Randomization	How participants were allocated to interventions
Blinding (masking)	Whether or not participants, care givers, and those assessing the outcomes were blinded to group assignment
Results	
Numbers randomized	Number of participants randomized to each group
Recruitment	Trial status
Numbers analysed	Number of participants analysed in each group
Outcome	For the primary outcome, a result for each group and the estimated effect size and its precision
Harms	Important adverse events or side effects
Conclusions	General interpretation of the results
Trial registration	Registration number and name of trial register
Funding	Source of funding

Please add at the end of the abstract the following 3 items:

Registration

Protocol

Funding

The additional required subheadings are as follows:

INTRODUCTION

Specific objectives or hypotheses

METHODS

Trial design and any changes after trial commencement

Participants, eligibility criteria, and setting

Interventions

Outcomes (primary and secondary) and any changes after trial commencement

Sample size calculation

Interim analyses and stopping guidelines

Randomization (random number generation, allocation concealment, implementation)

Blinding

Statistical analysis (primary and secondary outcomes, subgroup analyses)

RESULTS

Participant flow (include flow diagram, early stopping, and time periods)

Baseline data (include baseline table)

Numbers analyzed for each outcome, estimation and precision, subgroup analyses

Harms

DISCUSSION

Main findings in the context of the existing evidence, interpretation

Limitations

Generalizability

The CONSORT group encourages reporting of actual trial design and conduct. The goal is accurate and transparent documentation that will promote consistent reporting of clinical trials. Accurate presentation of the details of the trial, including possible limitations, allows the reader to place the trial results in the correct context. All available evidence is important and should be

visible; thus, lower quality trials are not necessarily excluded or rejected, they just need to be accurately reported so that the evidence they provide can be placed in the right context.

The CONSORT guideline is an evolving process and is subject to reappraisal and possible future modifications. Future changes of the CONSORT guideline will result in an update of the requirements for submitting randomized clinical trials to the AJO-DO.

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