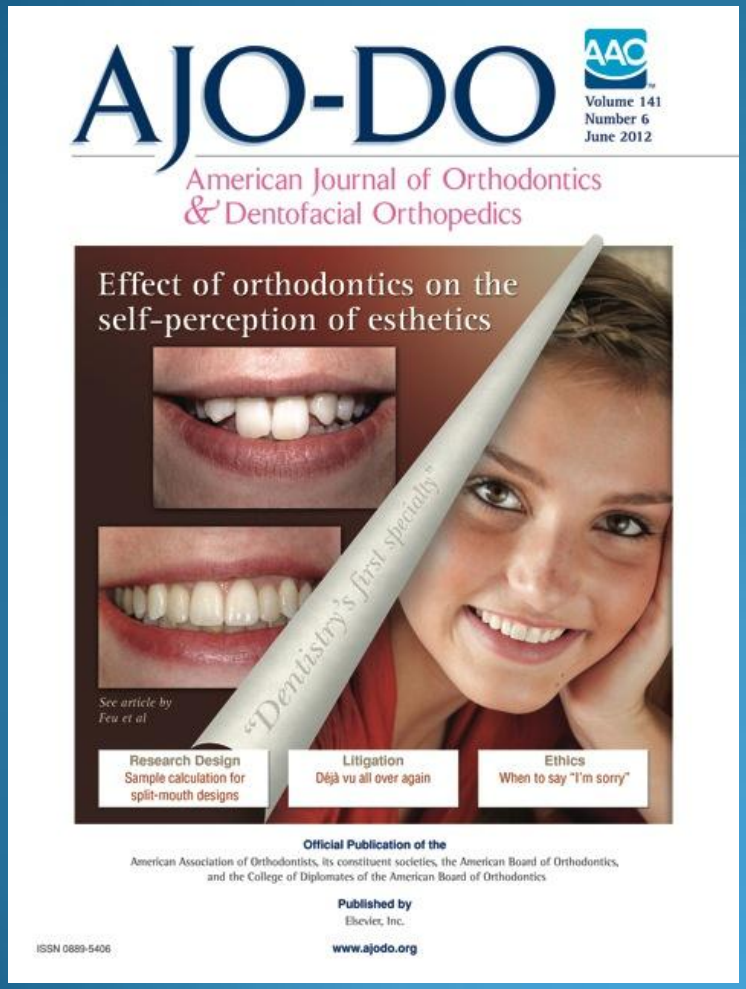
Adherence to the CONSORT guidelines



Nikolaos Pandis*
Padhraig S. Fleming
Vincent G. Kokich
AJO-DO Editorial Board

*Private practice, Corfu, Greece
Affiliated with University of Bern

Accurate reporting

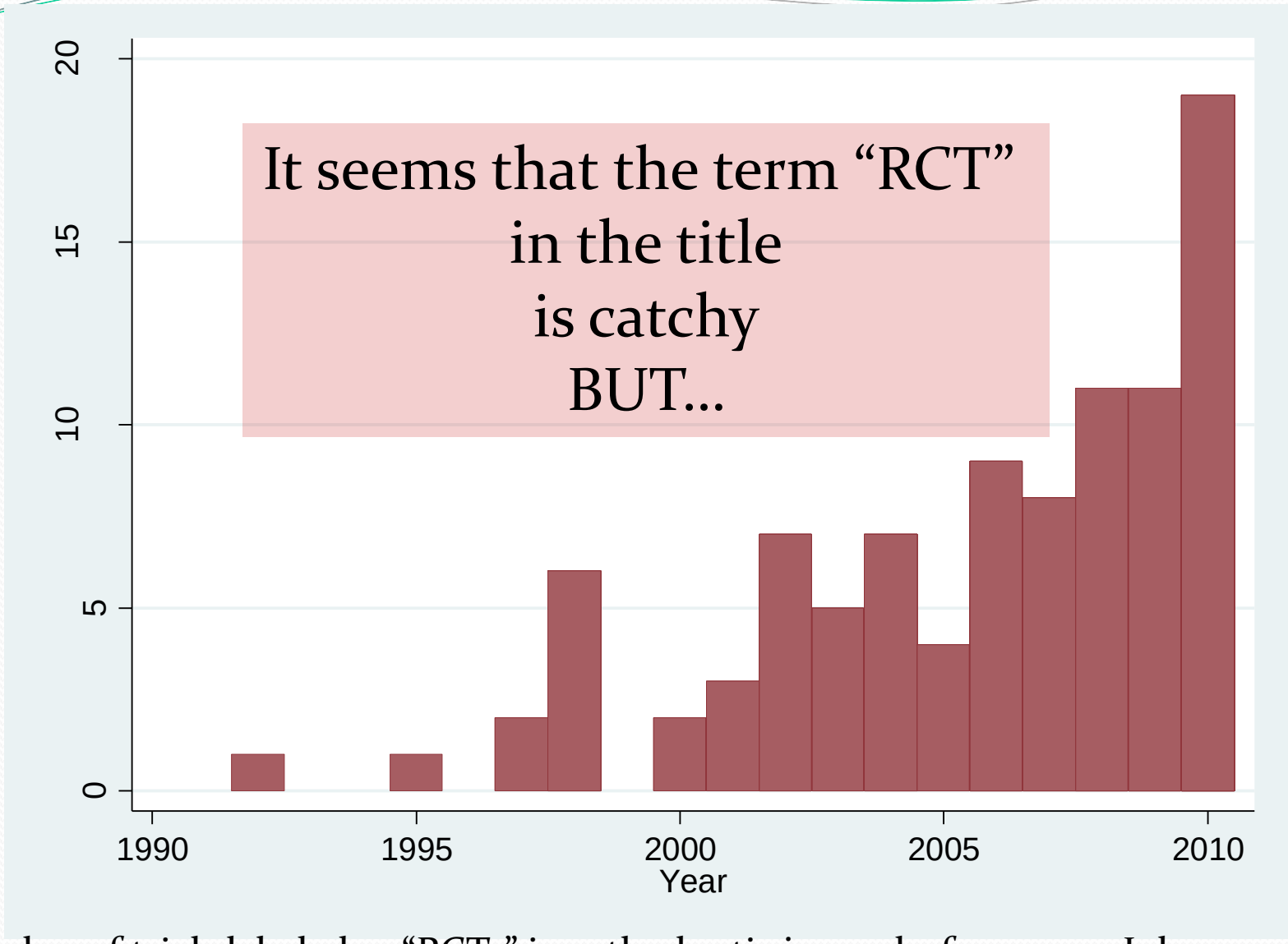
Assessment of Methodology & Risk of Bias

Correct Interpretation & Use of Results

The Problem

Previous guideline compliance procedures

- AJODO adopted CONSORT guidelines several years ago
- Only requirement was checklist completion with manuscript submission
- No actual compliance assessment was undertaken



Number of trials labeled as "RCTs" in orthodontic journals from 1990-July, 2011

Koletsi et al (AJODO 2012)

What's in a title? An assessment of whether the use of the term 'RCT' in a title means that it is one

	Journal	RCT N (%)	Unclear RCT Definition N (%)	Not RCT N (%)	Total N(%)
	JO	9 (45.0)	9 (45.0)	2 (10.0)	20 (100.0)
	AJODO	17 (37.0)	20 (43.5)	9 (19.6)	46 (100.0)
	EJO	4 (18.2)	10 (45.5)	8 (36.6)	22 (100.0)
	ANGLE	2 (18.2)	6 (54.6)	3 (27.3)	11 (100.0)
	OTHER	1 (7.7)	7 (53.9)	5 (38.5)	13 (100.0)
Total		33(29.5)	52(46.4)	27(24.1)	**112(100.0)**

Koletsi et al (AJODO 2012)

Steps to ensure CONSORT adherance

The AJO-DO scheme

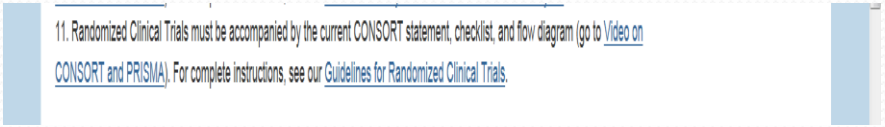
Objectives

Increase awareness

Author Information

Guidelines for AJO-DO RCTs

Specific RCT submission guidelines


11. Randomized Clinical Trials must be accompanied by the current CONSORT statement, checklist, and flow diagram (go to Video on CONSORT and PRISMA). For complete instructions, see our Guidelines for Randomized Clinical Trials.

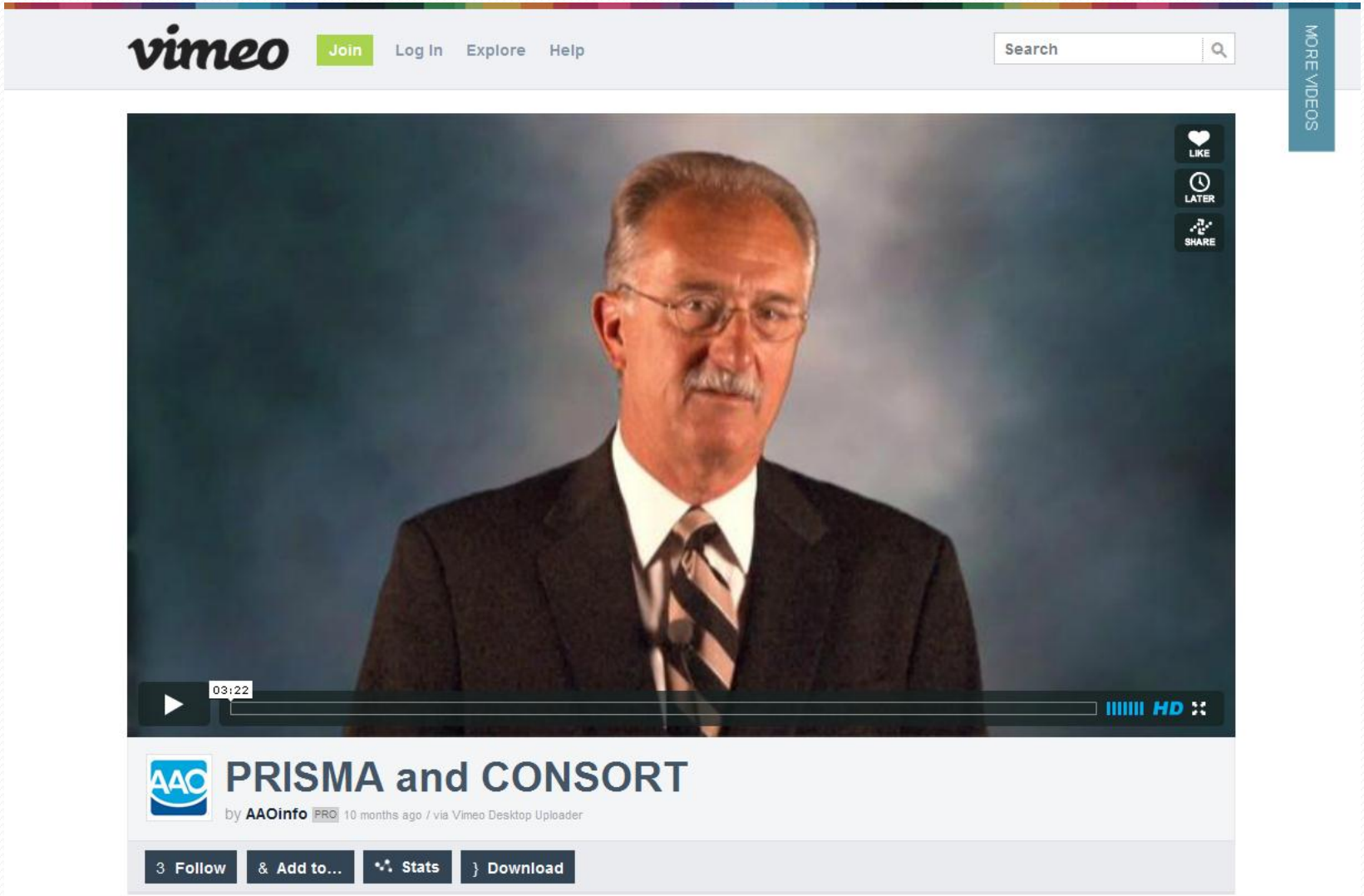
Guidelines for AJO-DO Randomized Clinical Trials
July 2011

These guidelines are provided to facilitate accurate, complete, and transparent reporting of randomized clinical trials (RCTs). New submissions to the AJO-DO reporting the results of randomized clinical trials 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. 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. Download the 25-item CONSORT checklist and complete it by indicating the page number(s) from your manuscript where each item is addressed. If items on the CONSORT checklist do not apply to your submission, write N/A in the space for the page number. Use the page numbering feature in your word processing program to keep page numbers consistent throughout the review process. Include the completed CONSORT checklist when you submit your article to the AJO-DO. Note: Simply entering the manuscript page numbers on the CONSORT checklist form, as previously done, will not be sufficient.

3. 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), and that the background and study objectives are clearly defined (items 2a &2b). 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 randomized clinical trial or not. Blinding (item 11), if applicable, should be described. 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 on any results from ancillary analyses (item 18) and any harms (item 19). Please provide a thorough discussion (items 20-22) regarding trial limitations, applicability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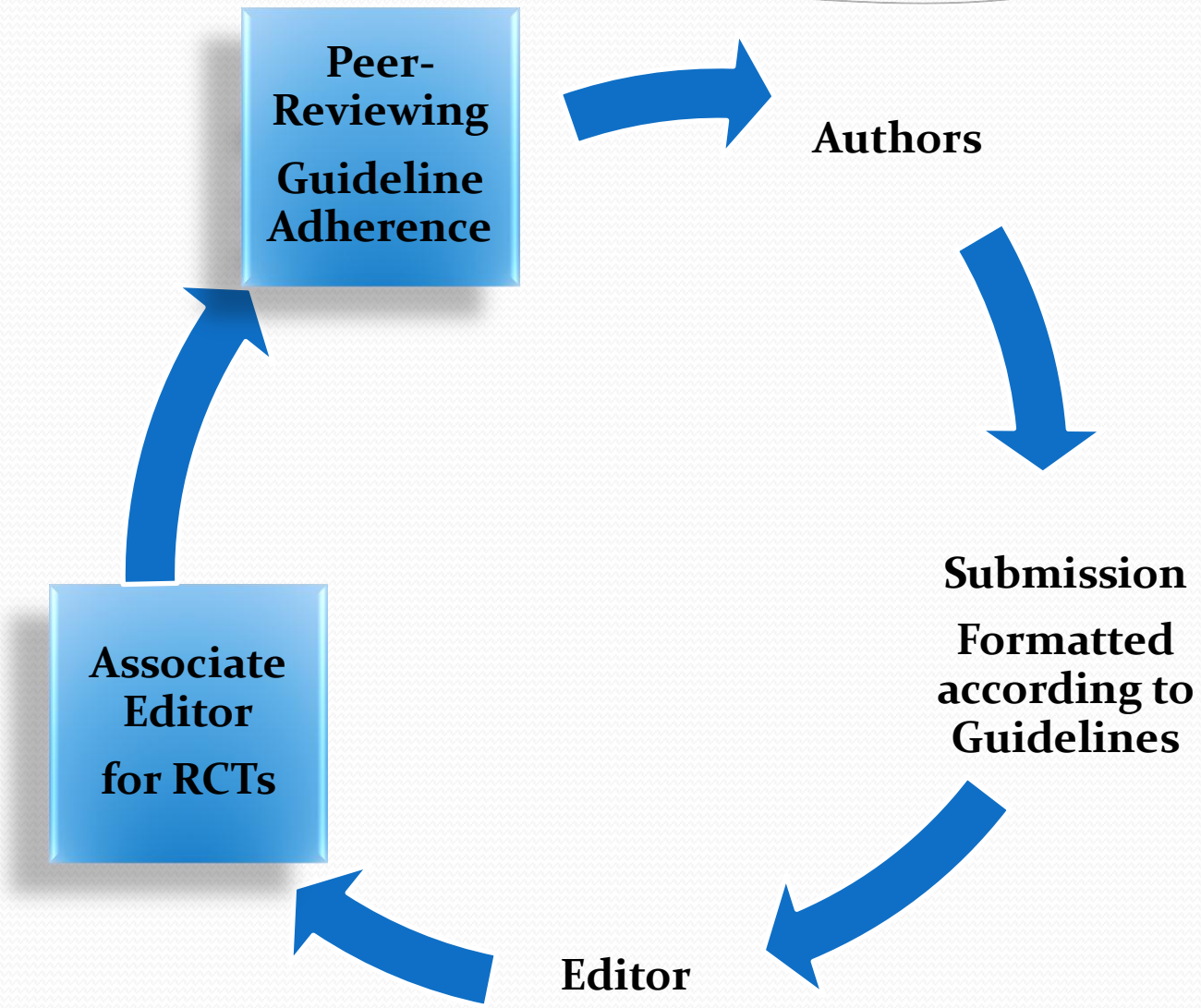
Educate

Involve and educate peer reviewers and authors

- AJODO- **New evaluation form for RCTs RCT_Review_v.7.doc**
- Referred to the CONSORT Explanation & Elaboration document (trials and abstracts)
- Given specific details of optimal and suboptimal reporting within their manuscript and comments on how to improve it

Assure compliance

An example of manuscript submission processing


Peer-Reviewing
Guideline Adherence
Authors
Submission
Formatted according to Guidelines
Editor
Associate Editor
for RCTs

Typical comments authors may receive regarding improvement of adherence

Title and abstract			
	1a	Identification as a randomised trial in the title	✓
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	✓
Introduction			
Background and objectives	2a	Scientific background and explanation o Cite SR Haps S, Slot DE, Berchier CE, Van der Weijden GA. The effect of cetylpyridinium chloride-containing mouth rinses as adjuncts to toothbrushing on plaque and parameters of gingival inflammation: a systematic review. Int J Dent Hyg. 2008 Nov;6(4):290-303. Background should include systematic review if available-I found the above on the topic please add if relevant See CONSORT paper	Add SR
	2b	Specific objectives or hypotheses	✓
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio (1:1)-add detail	unclear
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	✓
Participants	4a	Eligibility criteria for participants patients with what health conditions were excluded?	unclear
	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 primar Sample Size asures, 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- check 7a in CONSORT explanation and Elaboration document for correct description of sample calculations. You must include effect in control and intervention groups, sd, alpha and power levels(single or 2 sided). How did you arrive at the 0.40 and 0,42 values? Are they from the reference #33? Need to explain a little more. Also, you are using several outcomes but it seems that you are making a sample calculation only for one outcome. This is not sufficient or appropriate.	unclear

Randomization

Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	unclear
	8b	Type of randomisation; details of any restriction (such as blocking and block size) This is crucial as it will determine whether this will qualify as an RCT exact mechanism should be described. How did you arrive at 31:32? You description is not clear enough. See CONSORT paper items 8a 8b	unclear
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 Same as 8a 8b	unclear
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	Partly unclear
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	Partly unclear
	11b	If relevant, description of the similarity of interventions	✓
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes Please clarify statistical methods further. I believe you should use separate ANCOVAs and adjust for baseline values of clinical and micro variables. Also modelling for repeated measures adjusted for baseline data would also be suitable and will avoid all those test and multiplicity.-consult statistician	unclear
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	✓
Results			
Participant 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 randomisation, together with reasons	✓
Recruitment	14a	Dates defining the periods of recruitmen	✓
	14b	Why the trial ended or was stopped	✓
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group Please check CONSORT article for example on how to present baseline data. Add clinical and microbiological summary values at baseline on this table to help the reader see similarity between treatment groups at baseline	unclear
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups Please indicate whether ITT or PP analysis was performed	unclear

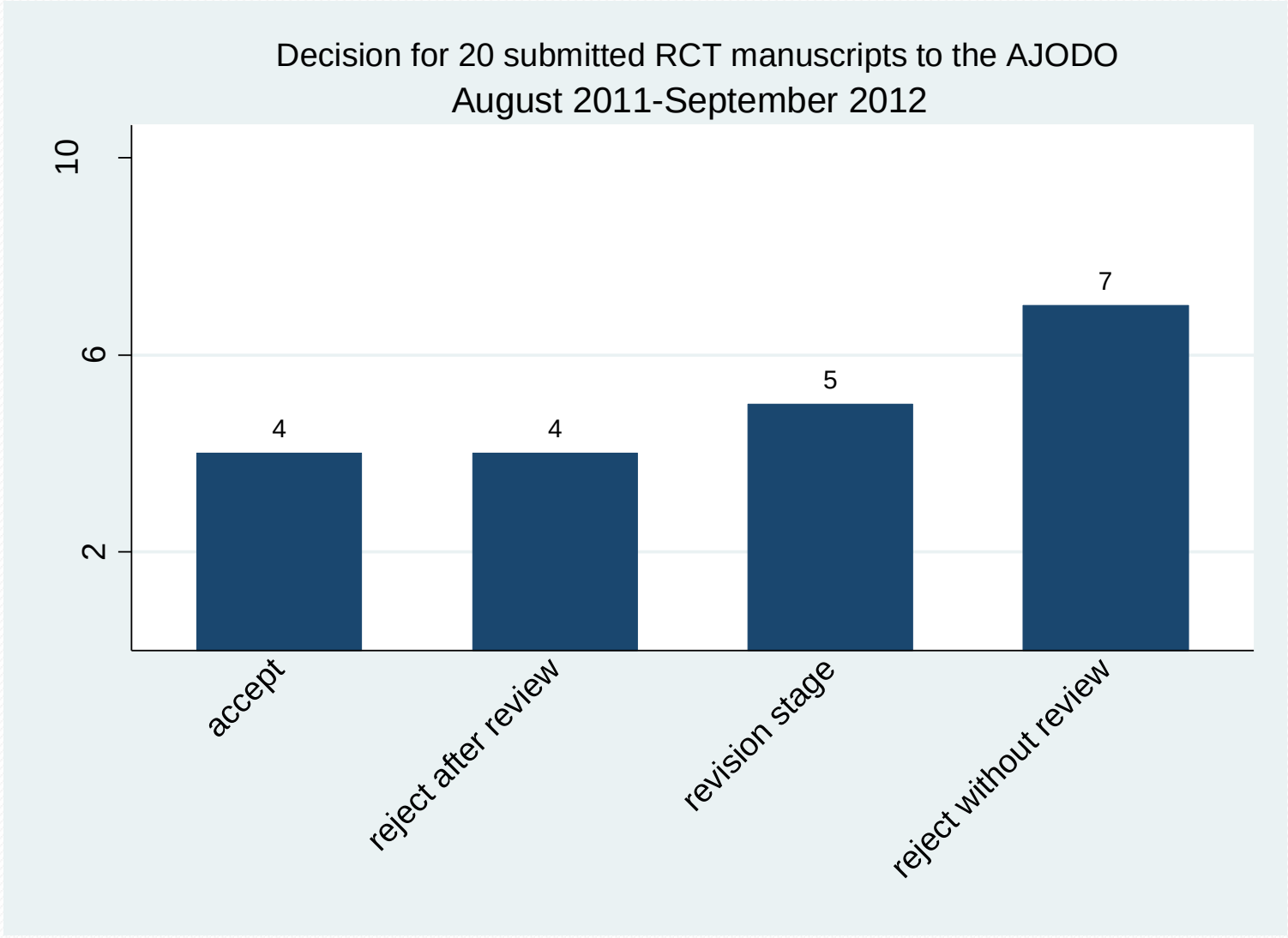
Baseline table

Effect estimates & CIs

Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	unclear
		This section needs a lot of work and requires complete rewriting as there are too many tables not easy to read Tables 3 & 5 not needed. Condense tables 2,4,6. Condense tables on bacterial counts 7-10.	
		Present effect estimates with 95% CIs **for the difference not within group**. See table 6 in the CONSORT table for direction.	
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	N/A
		Table 8 displays counts not binary outcomes (yes-no) if I understood correctly	
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	✓
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	✓
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	✓
Generalisability	21	Generalisability (external validity, applicability) of the trial findings. See CONSORT article for description on generalisability	Not described
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	✓
Other information			
Registration	23	Registration number and name of trial registry	
Protocol	24	Where the full trial protocol can be accessed, if available	✓
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	✓

Preliminary Results

August 2011-September 2012


Decision for 20 submitted RCT manuscripts to the AJODO
August 2011-September 2012
10
6
2
4
4
5
7
accept
reject after review
revision stage
reject without review

Areas of suboptimal and optimal adherence to the CONSORT guidelines

No description or Inadequate reporting	Adequate
Sample calculation	Hypothesis or objectives
All parts of randomization	Eligibility criteria
Blinding	Settings
ITT	Data collection
Effect estimates, CIs (focus on p-values)	Interventions
Multiple testing	Definition of outcome measures
Limitations, Generalisability, Funding	

Pitfalls	Actions
Filling in the Blanks	Scrutinize Reports-Authors
Fictitious Information	Check Protocols

Future Research & Actions

Future research & actions

Compare reporting quality before and after implementation of new adherence scheme

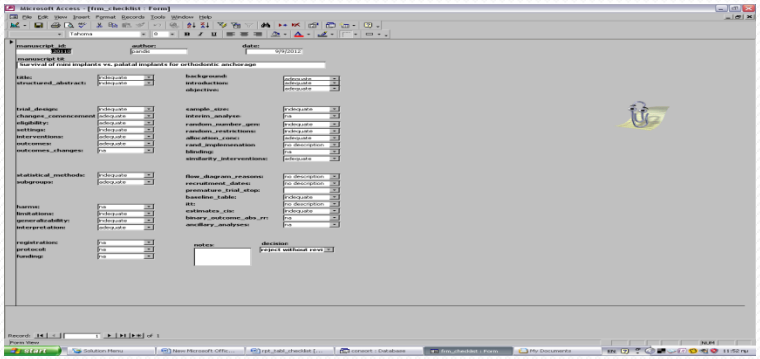
For published papers and for submissions

Future research & actions

The editor completes the manuscript CONSORT adherence checklist **online**, **for initial submission and revisions, and identifies problematic checklist items**

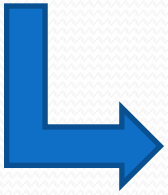
EXPORT DATA TO STATA FOR STATISTICAL ANALYSIS

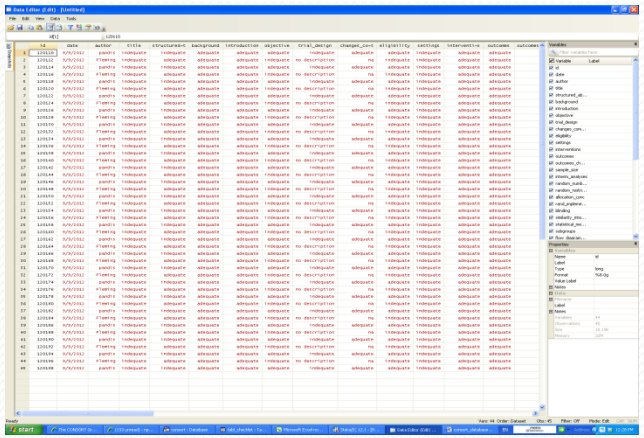
MS ACCESS



Save information directly on the EES database for future use

STATA



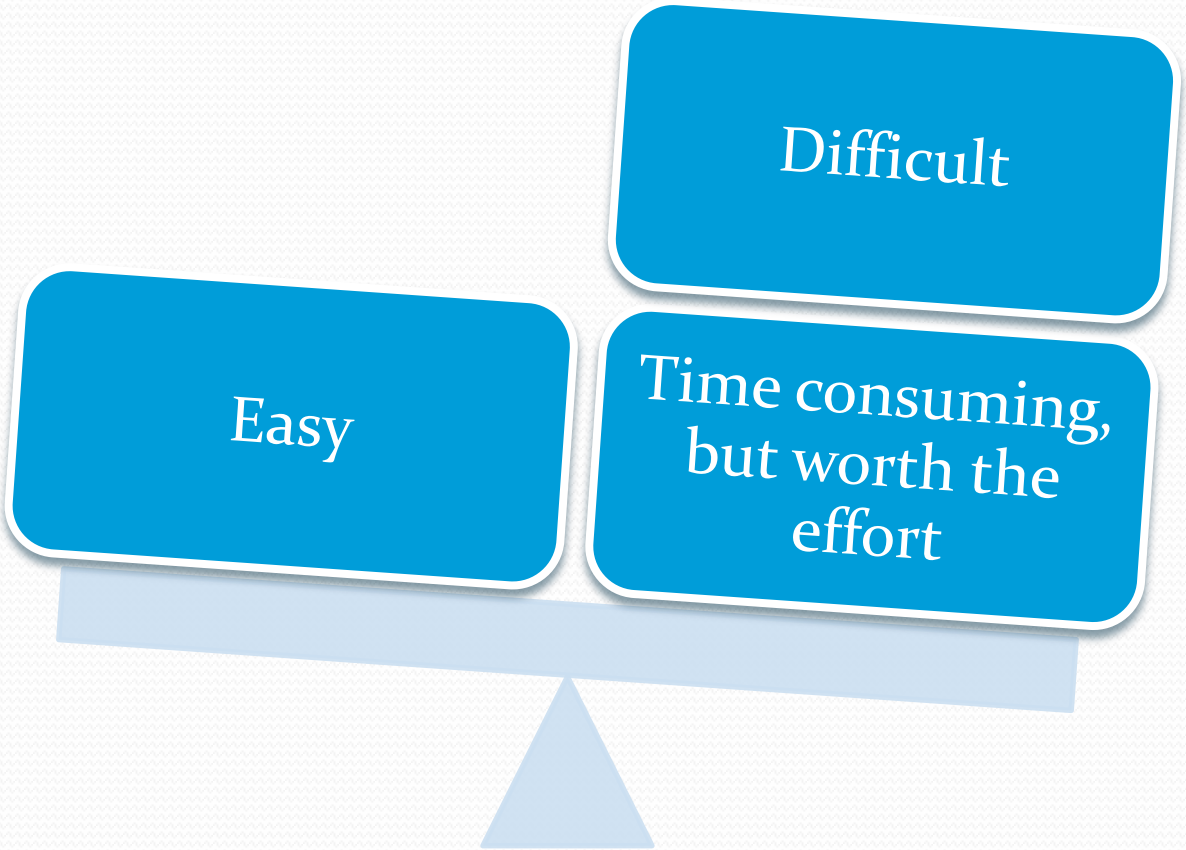


And finally…

Complete the puzzle

Make dataset and analysis code available

CONSORT Adoption	CONSORT Implementation



Some final thoughts…

- More **emphasis in good study design and reporting** during undergraduate and graduate **education**
- **Standardize adoption and adherence** to guidelines across journals
- The payoff will be for the next generation (?)

Visit Corfu

EQUATOR CONFERENCE?