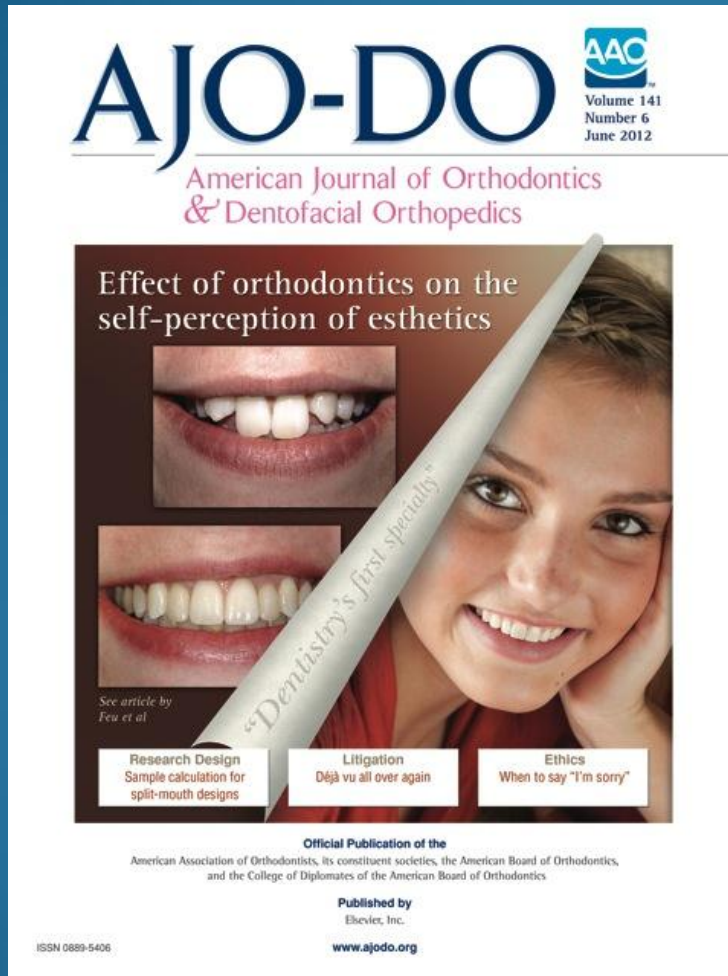


Adherence to the CONSORT guidelines



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**

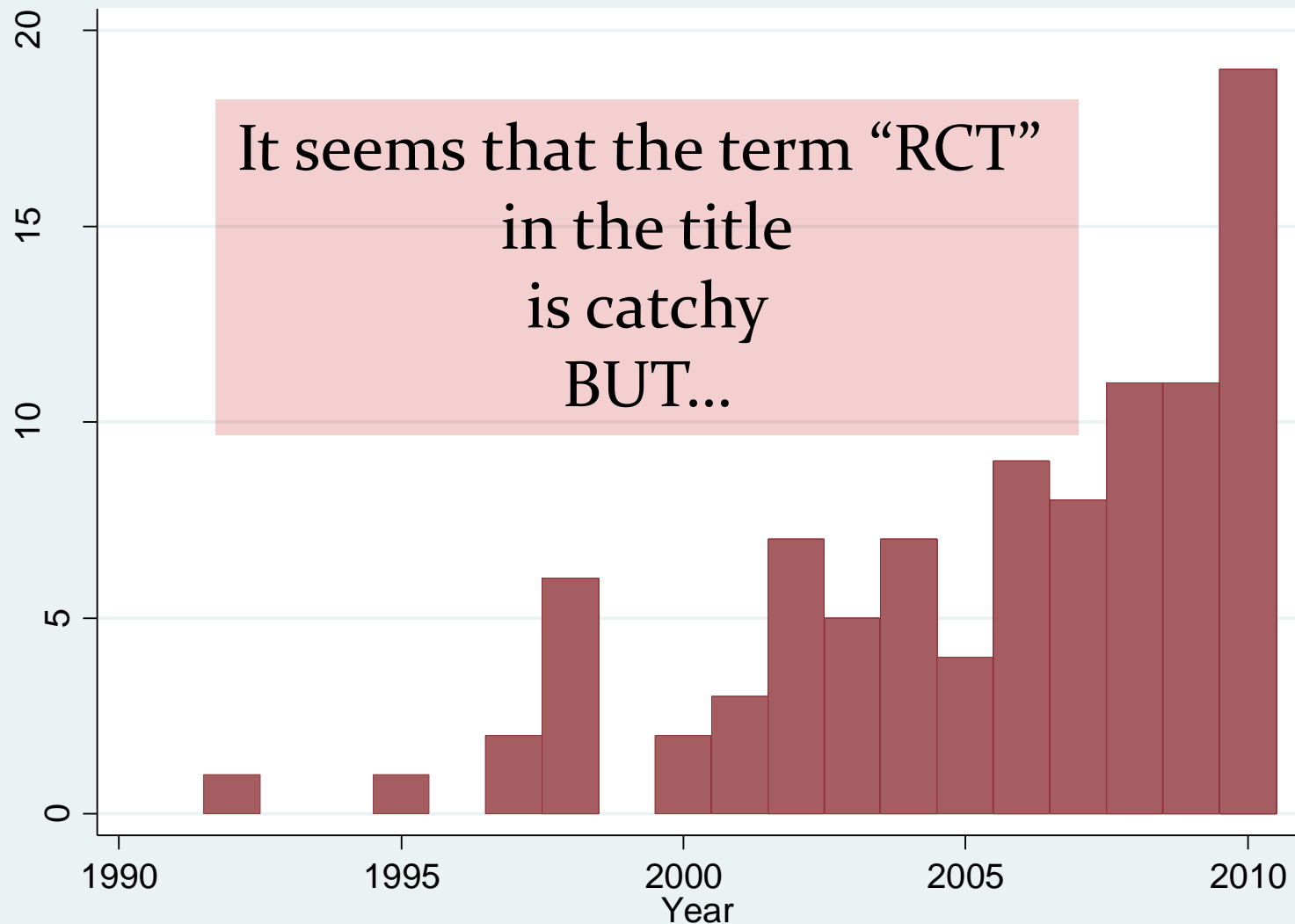
**Correct Interpretation
& Use of Results**



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

Koletsis 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

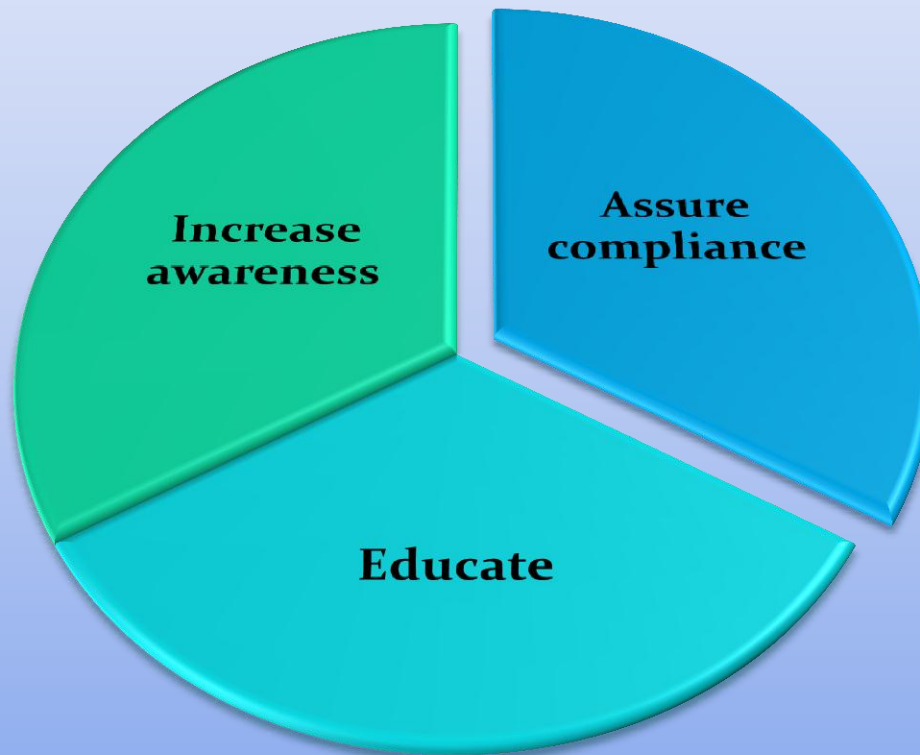
	RCT	Unclear RCT Definition	Not RCT	Total
Journal	N (%)	N (%)	N (%)	N(%)
JO	9 (45.0)	9 (45.0)	2 (10.0)	20 (100.0)
AJODO	17 (37.0)	20 (43.5)	9 (19.6)	46 (100.0)
EJO	4 (18.2)	10 (45.5)	8 (36.6)	22 (100.0)
ANGLE	2 (18.2)	6 (54.6)	3 (27.3)	11 (100.0)
OTHER	1 (7.7)	7 (53.9)	5 (38.5)	13 (100.0)
Total	33(29.5)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

Koletsis et al (AJODO 2012)

Steps to ensure CONSORT adherence

The AJO-DO
scheme

Objectives



Increase awareness

Author Information

The screenshot shows the website for the American Journal of Orthodontics & Dentofacial Orthopedics. The header includes the journal name, a contact link, a help link, the Elsevier logo, and the version number 'Version: EES 201'. A navigation bar contains links for 'main menu', 'submit paper', 'guide for authors', 'journal info', 'register', and 'log in'. The main content area features a 'NEW SUBMISSION REQUIREMENTS' section. A yellow callout box with the text 'Refers authors to the CONSORT website' has an arrow pointing to the link 'www.consort-statement.org' in the PRISMA section. The right sidebar contains 'Editor Information' and 'Support & Training Information' sections with various links.

JO-DO American Journal of Orthodontics & Dentofacial Orthopedics

Contact us Help ?

Version: EES 201

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NEW SUBMISSION REQUIREMENTS: Our submission requirements have changed. Please include the following releases

at, signed by all authors
Interest Form. Submit a separate form for each

s photos of any recognizable person, include
allowing publication of the photos.

Systematic Review or Meta-analysis, please
visit the PRISMA website to download the current checklist and
flow diagram. Complete these documents and include them with
your submission.
www.prisma-statement.org

If your article is a Randomized Clinical Trial, please visit the
CONSORT website to download current versions of the statement,
checklist, and flow diagram. Complete these documents and
include them with your submission.
www.consort-statement.org

If you are unable to submit the forms online, print them and mail
them to the American Journal of Orthodontics and Dentofacial
Orthopedics, University of Washington, Department of

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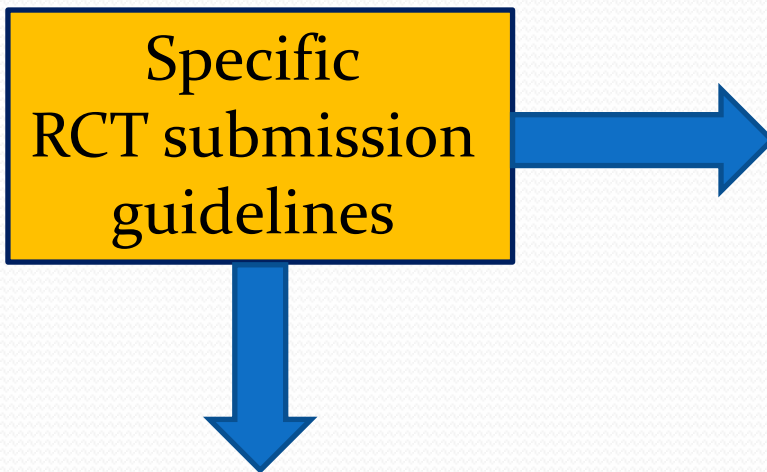
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Guidelines for AJO-DO RCTs

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

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](#).

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PRISMA and CONSORT

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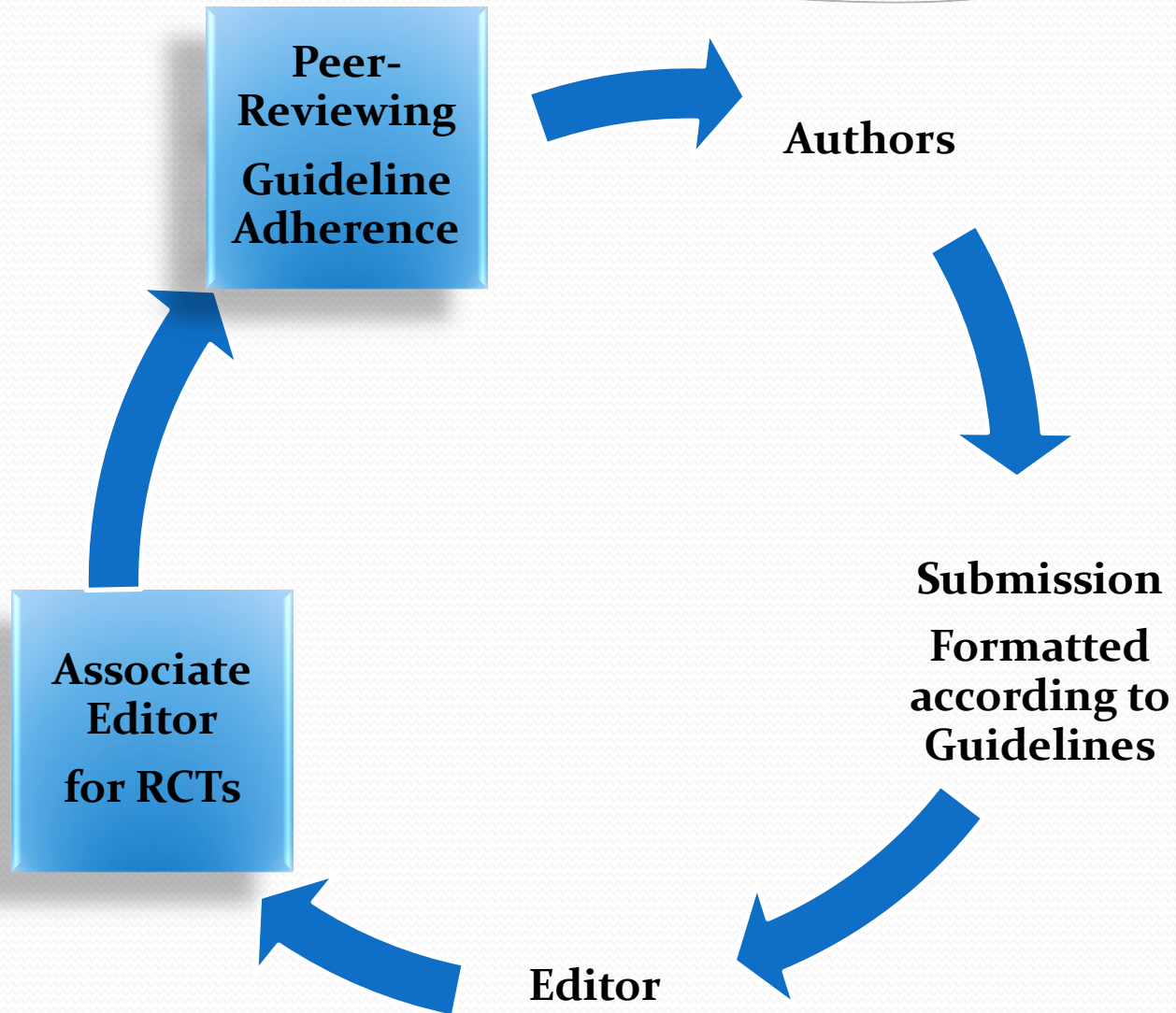
Educate

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



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 | <p>Scientific background and explanation of Cite SR</p> <p>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</p> | 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 primary Sample Size measures, including how and when they were assessed | ✓ |
|----|-----------------------------------------------------------------------------------------------------------------|---|

- | | | |
|----|-----------------------------------------------------------------------|---|
| 6b | Any changes to trial outcomes after the trial commenced, with reasons | ✓ |
|----|-----------------------------------------------------------------------|---|

Sample size

- | | | |
|----|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|
| 7a | <p>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.</p> | 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? Your 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	unclear
		Same as 8a 8b	
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 recruitment	✓
	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

Outcomes and estimation

Effect estimates & CIs

unclear

- 17a For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)

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

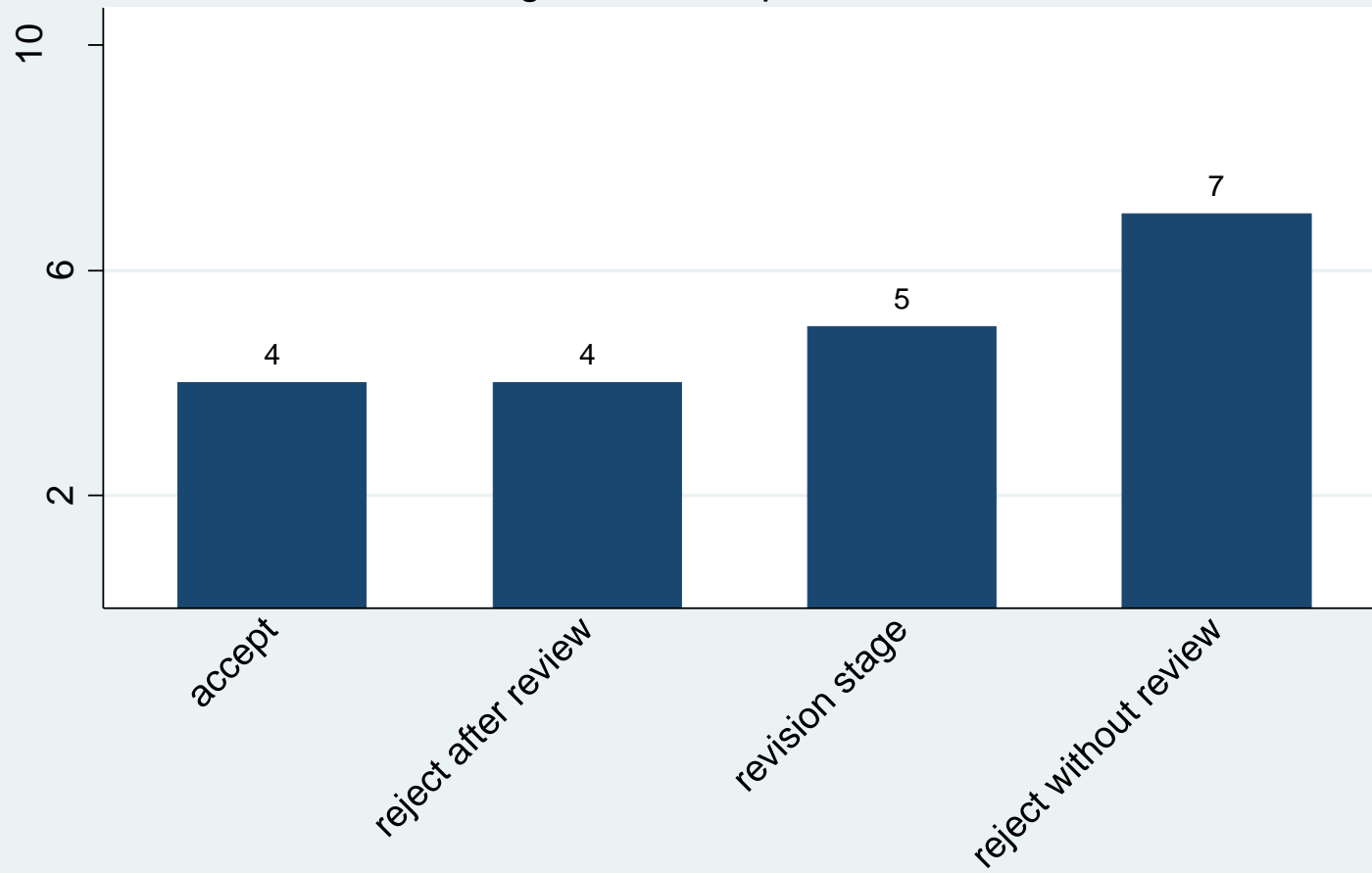
✓



Preliminary Results

August 2011-September 2012

Decision for 20 submitted RCT manuscripts to the AJODO
August 2011-September 2012



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

**Filling in the
Blanks**

**Fictitious
Information**

Actions

**Scrutinize
Reports-
Authors**

**Check
Protocols**



Future Research & Actions

Future research & actions

Compare reporting quality before and after
implementation of new adherence scheme

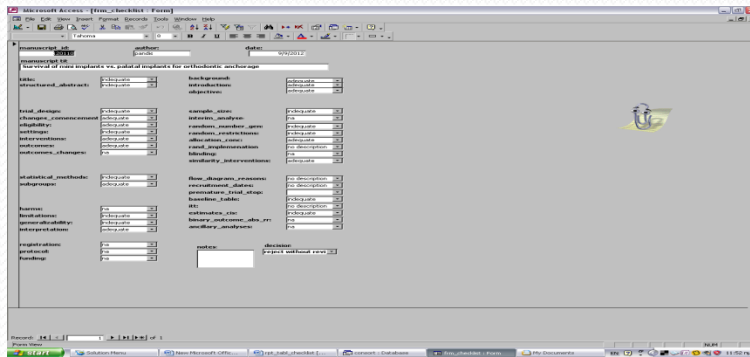
For published papers and for submissions

Future research & actions

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

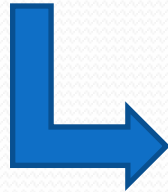
EXPORT DATA TO STATA FOR STATISTICAL ANALYSIS

MS ACCESS



Save information directly on the EES database for **future use**

STATA

A screenshot of the Stata database application window. The title bar reads 'Stata - [Stata_Bookshelf - Patients]'. The main window shows a table with columns: 'date', 'name', 'address', 'phone', 'email', 'gender', 'age', 'height', 'weight', 'blood pressure', 'cholesterol', 'glucose', 'hemoglobin', 'hematocrit', 'hemoglobin A1c', 'fasting glucose', 'HbA1c', 'C-peptide', 'insulin', 'glucagon', 'glucagon-like peptide-1', 'glucagon-like peptide-2', 'glucagon-like peptide-3', 'glucagon-like peptide-4', 'glucagon-like peptide-5', 'glucagon-like peptide-6', 'glucagon-like peptide-7', 'glucagon-like peptide-8', 'glucagon-like peptide-9', 'glucagon-like peptide-10', 'glucagon-like peptide-11', 'glucagon-like peptide-12', 'glucagon-like peptide-13', 'glucagon-like peptide-14', 'glucagon-like peptide-15', 'glucagon-like peptide-16', 'glucagon-like peptide-17', 'glucagon-like peptide-18', 'glucagon-like peptide-19', 'glucagon-like peptide-20', 'glucagon-like peptide-21', 'glucagon-like peptide-22', 'glucagon-like peptide-23', 'glucagon-like peptide-24', 'glucagon-like peptide-25', 'glucagon-like peptide-26', 'glucagon-like peptide-27', 'glucagon-like peptide-28', 'glucagon-like peptide-29', 'glucagon-like peptide-30', 'glucagon-like peptide-31', 'glucagon-like peptide-32', 'glucagon-like peptide-33', 'glucagon-like peptide-34', 'glucagon-like peptide-35', 'glucagon-like peptide-36', 'glucagon-like peptide-37', 'glucagon-like peptide-38', 'glucagon-like peptide-39', 'glucagon-like peptide-40', 'glucagon-like peptide-41', 'glucagon-like peptide-42', 'glucagon-like peptide-43', 'glucagon-like peptide-44', 'glucagon-like peptide-45', 'glucagon-like peptide-46', 'glucagon-like peptide-47', 'glucagon-like peptide-48', 'glucagon-like peptide-49', 'glucagon-like peptide-50', 'glucagon-like peptide-51', 'glucagon-like peptide-52', 'glucagon-like peptide-53', 'glucagon-like peptide-54', 'glucagon-like peptide-55', 'glucagon-like peptide-56', 'glucagon-like peptide-57', 'glucagon-like peptide-58', 'glucagon-like peptide-59', 'glucagon-like peptide-60', 'glucagon-like peptide-61', 'glucagon-like peptide-62', 'glucagon-like peptide-63', 'glucagon-like peptide-64', 'glucagon-like peptide-65', 'glucagon-like peptide-66', 'glucagon-like peptide-67', 'glucagon-like peptide-68', 'glucagon-like peptide-69', 'glucagon-like peptide-70', 'glucagon-like peptide-71', 'glucagon-like peptide-72', 'glucagon-like peptide-73', 'glucagon-like peptide-74', 'glucagon-like peptide-75', 'glucagon-like peptide-76', 'glucagon-like peptide-77', 'glucagon-like peptide-78', 'glucagon-like peptide-79', 'glucagon-like peptide-80', 'glucagon-like peptide-81', 'glucagon-like peptide-82', 'glucagon-like peptide-83', 'glucagon-like peptide-84', 'glucagon-like peptide-85', 'glucagon-like peptide-86', 'glucagon-like peptide-87', 'glucagon-like peptide-88', 'glucagon-like peptide-89', 'glucagon-like peptide-90', 'glucagon-like peptide-91', 'glucagon-like peptide-92', 'glucagon-like peptide-93', 'glucagon-like peptide-94', 'glucagon-like peptide-95', 'glucagon-like peptide-96', 'glucagon-like peptide-97', 'glucagon-like peptide-98', 'glucagon-like peptide-99', 'glucagon-like peptide-100'. The bottom status bar shows 'Records: 100 of 100'.

And finally...

Complete the puzzle

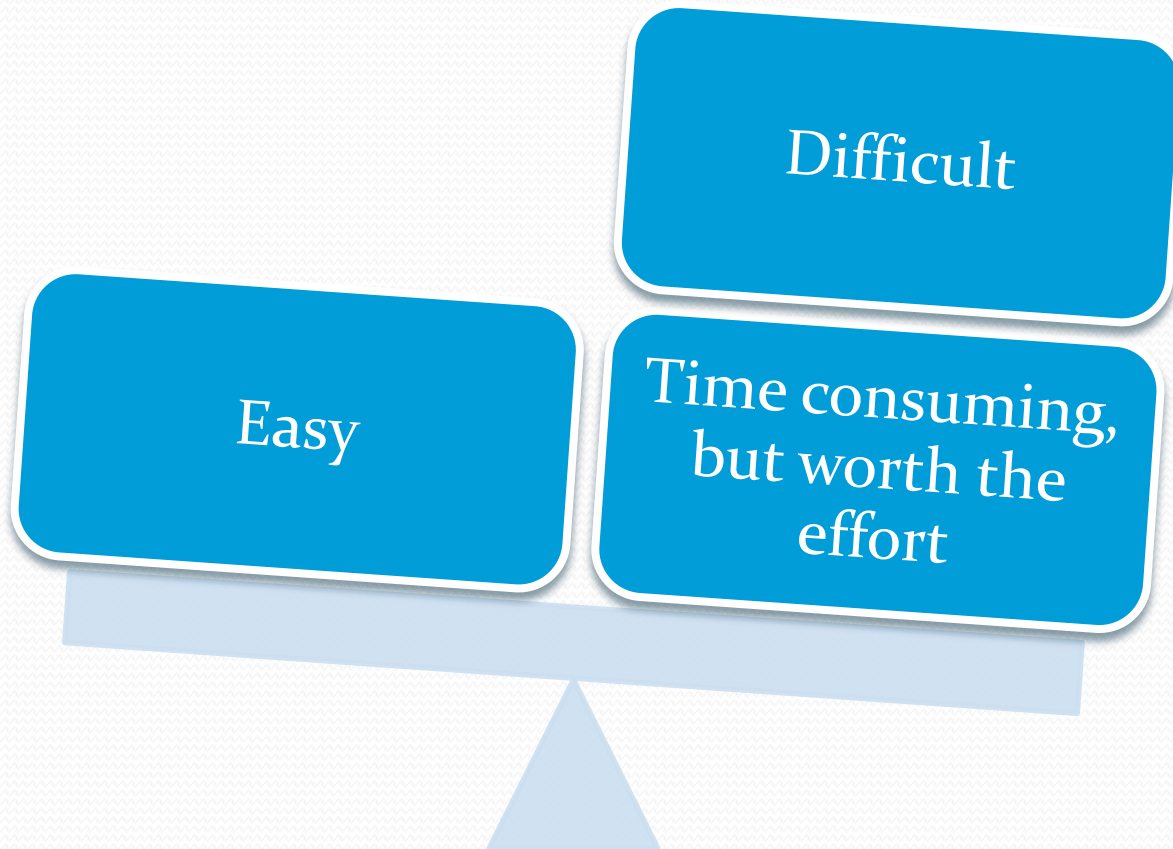


**Make dataset and analysis code
available**



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?

