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An assessment of the compliance of Randomised controlled trials published in craniofacial surgery journals with the CONSORT statement: A systematic review protocol

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ABSTRACT

Introduction: The role of clinical trials in medicine is expanding, particularly in surgery. Randomised controlled trials (RCTs) represent the gold standard evidence for high-quality assessment of healthcare interventions. The Consolidated Standards of Reporting Trials (CONSORT) guidance has been published to maximise RCT reporting transparency. This paper outlines the study protocol for a systematic review that will assess the current compliance of RCTs published within craniofacial surgery with the CONSORT criteria. The aims are to identify areas where reporting can be improved to ensure craniofacial surgery is guided by high-quality evidence.

Methods and analysis: This protocol is compliant with the Preferred Reporting Items for Systematic Review and meta-Analysis protocols (PRISMA-P) guidelines. Craniofacial surgery RCTs will be identified by searching within craniofacial surgery journals. Five journals from the Thomson Reuters Impact Factor Report 2016 included 'cranio' in their title and were included. MEDLINE PubMed will be used to search all RCTs published in these journals. The search strategy is described within this protocol. It will be limited to articles written in English, conducted on humans, and published in the last five years. Two independent researchers will assess each study for inclusion and will perform the data extraction. The researchers will assess compliance of each RCT with the 25-item CONSORT Statement checklist as the primary outcome. Discrepancies will be resolved through consensus or third author arbitration. Secondary outcomes to be extracted include the pathology and interventions examined, and indices of RCT quality. The systematic review will be compliant with PRISMA guidelines. The review has been registered *a priori* with the Registry of Systematic Reviews/meta-analyses (UIN: reviewregistry219).

Ethics and dissemination: This systematic review will be conducted in line with the Cochrane Handbook for Systematic Reviews and Interventions. The intent is to publish in a peer-reviewed journal and present the data at relevant conferences.

Introduction

Evidence based medicine is gaining importance in surgery [1,2]. Randomised Controlled Trials (RCTs) that are appropriately designed, conducted and reported, alongside systematic reviews, represent the gold standard evidence for assessment of treatment effects. Publication of inadequate, incomplete or unclear information on RCT methodology and results limits RCT validity and generalisability, biases the apparent effectiveness of interventions, precludes subsequent inclusion of RCTs in *meta*-analyses and systematic reviews and is unethical [3,4].

The CONSORT (Consolidated Standards of Reporting Trials) statement, developed in 1966 [5] and subsequently revised in 2001 [6] and in 2010 [7], was designed to facilitate RCT design, and improve reporting standards and quality. The guideline describes 25 items that are mandatory features of the article that must be reported in the manuscript. The 25-items were agreed by an international consensus group on the basis that inclusion of each item is essential to judge the reliability or relevance of the findings, or that item exclusion is associated with biased estimates of treatment effect [8].

The CONSORT statement has been successful in improving the reporting transparency and manuscript development of RCTs

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[5,9,10]. Many RCTs, including those published in plastic and craniofacial surgery, still fail to adequately report RCTs according to the CONSORT statement [3,11]. A systematic review in 2014 conducted on 55 RCTs published within plastic surgery [3] found on average RCTs comply with just half of the CONSORT items (11.5 of 23 items, 50%). A review in 2015 assessing the CONSORT compliance of 65 RCTs conducted on cleft lip and/or palate found RCTs on average adequately reported 63.2% (15.8 out of 25) of the CONSORT items [11]. Both reviews found description of the randomisation methods and blinding to be particularly poorly described across RCTs, two areas which can lead to significant bias in results.

Rationale

Sub-surgical specialities of plastic and craniofacial surgery are notoriously lacking in evidence-based guidelines and high-quality research [12]. High quality craniofacial surgery RCTs are essential to ensure the best interventions are chosen and that new interventions are adequately assessed. Compliance with the CONSORT reporting criteria across all topics in craniofacial surgery has not previously been formally assessed. An appraisal of RCT compliance is necessary to ensure data published is reported adequately. It can also highlight specific areas of CONSORT compliance where increased vigilance is indicated. Furthermore, poor RCT reporting is associated with poor methodology, and improving compliance with reporting of the CONSORT items may pave the way for improved craniofacial RCT methodologies [13].

Compliance with the CONSORT statement is not only the responsibility of RCT authors. The editorial bodies of journals publishing RCTs play a key role in enforcing adherence to the CONSORT guidelines [14]. Mandatory CONSORT concordance in RCT submission and surveillance of CONSORT reporting through peer-review improves the transparency of reporting and thus the conduct of RCTs in medical research [15]. An appraisal of whether RCTs within relevant craniofacial journals are compliant with CONSORT criteria can also highlight whether the journal reviewers and editorial bodies are enforcing the use of CONSORT, and whether this process can be improved.

Objectives

This systematic review will assess the compliance of RCTs conducted on craniofacial surgery and published in craniofacial journals with CONSORT reporting criteria. The focus is on RCTs conducted within the last five years to provide an assessment on current reporting adequacy. An objective and reproducible definition of craniofacial RCTs will be used: RCTs within craniofacial surgery journals.

Primary objectives

The primary objectives yield the primary outcomes and will be to:

- Calculate the proportion of the number of adequately reported 25 items from the CONSORT statement for each RCT in craniofacial surgery.
- Assess the percentage of RCTs in craniofacial surgery that are complaint with each of the CONSORT statement items.

Secondary objectives

The secondary objectives yield the secondary outcomes and will be to:

- Identify the sub-topics (according to the condition studied) within craniofacial surgery where CONSORT criteria reporting can be improved.
- Identify the interventions used in craniofacial surgery RCT where CONSORT criteria reporting can be improved.
- Assess the association between CONSORT criteria compliance and surrogate markers of RCT quality; including journal impact factor (IF), multi-versus-single centre, number of contributing authors, and publication date.

Hypothesis

It is hypothesised that RCTs in leading craniofacial journals comply fully with CONSORT criteria. Failing this, it is hypothesised that greater CONSORT compliance will be found in multi-centre RCTs, with a larger number of contributing authors, and published in journals with a higher IF, more recently.

Methods

This systematic review protocol is compliant with Preferred Reporting Items for Systematic Review and meta-Analysis protocols guidelines (PRISMA-P) [16]. This systematic review will be conducted in line with the Cochrane Handbook for Systematic Reviews and Interventions [17], and will be compliant with PRISMA guidelines [18]. It has been registered *a priori* with the Registry of Systematic Reviews/meta-analyses (http://www.researchregistry.com/, Unique Identifying Number (UIN): reviewregistry219) and is openly accessible.

Study inclusion and exclusion

To maximise comparability to previous work, a search technique similar to that described in a recent systematic review assessing the methodological quality of craniofacial surgery systematic reviews with PRISMA reporting criteria [19] will be used.

Thomson Reuters InCites Journal Citation Reports (https://jcr.incites.thomsonreuters.com, Thomas Reuters, New York, US) and the 2016 Journal Citation Reports (http://scientific.thomsonreuters.com/imgblast/JCRFullCovlist-2016.pdf) were used to find journals containing the stem 'cranio' in their title along with their Journal Impact Factors (IF). This identified 5 journals (IF range 0.7–1.64): The Journal of Craniomaxillofacial Surgery (JCMFS); Orthodontics and Craniofacial Research (OCR); The Cleft Palate-Craniofacial Journal (CPCJ), The Journal of Craniomandibular Practice (JCMP), and The Journal of Craniofacial Surgery (JCS).

Search strategy

The search strategy was developed in collaboration with an experienced information search specialist. A systematic review of all RCTs published in these five journals (JCMFS, OCR, CPCJ, JCMP, JCS) across a five-year period from the search date will be performed. All five craniofacial journals selected for analysis were Pubmed indexed, therefore the electronic database search will be performed through MEDLINE PubMed. The search will include relevant keywords (journal names) in English combined with the Boolean logical operator 'OR'. The 'Randomised controlled trial' filter for Pubmed published by Cochrane (http://work.cochrane.org/pubmed) will be applied with the Boolean logical operator 'AND'. This limits articles to those published on humans in the last 5 years. A systematic review conducted in 2017 is considered an appropriate time lapse since publication of the revised CONSORT statement in 2010 [7] for it to become an integrated into RCT conduct and publication. The publication language for all the five

chosen journals is English, therefore only English language texts will be included. The research question is focused on adherence of published RCTs, therefore the grey literature will not be assessed. An example of the full search strategy conducted on 28.11.2016 is shown in Table 1.

All RCTs published within these five journals across the five-year period will be examined for inclusion. There will be two levels of screening. Firstly, two independent researchers will screen the title and abstract of each RCT against the agreed eligibility criteria (Table 2). In the second level, full texts will be retrieved for provisional RCTs to be included, and reviewed again for inclusion against the same exclusion/inclusion criteria. Only articles successfully passing both levels of screening will be included. In any situations of unresolved discrepancy the full text will also be retrieved and a senior author will arbitrate. Included studies will be entered into a pre-formatted database spreadsheet using Microsoft Excel Software (Version 15.23, 2016, Microsoft). Reasons for any study exclusion will be noted, and reviewed by the senior author.

Definitions

The Cochrane definition of a RCT will be used. This states an RCT is "A trial where individuals followed in the trial were definitely or possibly assigned prospectively to one of two (or more) alternative forms of health care using random allocation or some form of quasi-random method (such as alternation, date of birth, or case recorded number" (http://handbook.cochrane.org/chapter_6/box_6_3_a_cochrane_definitions_and_criteria_for_randomised.htm).

Article scoring

Compliance of each RCT with the 25-item CONSORT checklist will be scored by two independent researchers. For each of the 25 items, RCTs will score either: 1 – fully reported; 0 – not reported; NA – not-applicable. RCTs will score '1' for an item only if all the information details for that CONSORT item have been reported, and '0' if the required information is only partially reported or not reported. Reviewers extracting and scoring data are members of a collaborative experienced in systematic review conduct. To ensure familiarity with CONSORT the expanded explanation article on CONSORT will need to be reviewed by each data extractor before extraction begins. They will then extract data from two RCTs conducted on the topic of general surgery prior to formal data collection. The lead author will review the data extracted and will feedback to the data collectors to ensure maximum consistency and reduce any data collection "learning curve". After the first five craniofacial RCTs have been scored, these will again be checked by the lead author for accuracy. If one extractor makes an error, this error and necessary corrections will be fed back to the entire collaborative team to ensure consistency. Any unexpected findings that present during data extraction will be fed back to the entire collaborative team.

Data extracted from the craniofacial RCTs will be entered directly into a pre-formatted database created using Microsoft Excel Software (Version 15.23, 2016, Microsoft). The data extracted by the two researchers will be compared and discrepancies resolved by consensus or lead author arbitration. A maximum 'CONSORT score' for each RCT will be calculated by subtracting the number of 'NA' items from the theoretical maximum score of 25. The total points scored out of the individualised maximum for each will give the CONSORT percentage for that RCT. Each item is given equal weighting. This method does not penalise RCTs for not reporting irrelevant items. Compliance with individual items of the statement will be analysed by summating the number of articles fulfilling that item in full divided by the total number of included articles. The editorial body of each of the five journals will be emailed to investigate which of the journals mandate CONSORT declaration at submission.

Table 2
Study inclusion and exclusion criteria.

Inclusion criteria
- Randomised controlled trials
- Published within 5 years from the date the search is conducted
- Published in the 5 selected journals
- Live human studies
- Publication language of English
- Full journal articles available

Exclusion criteria
- Non-randomised studies
- Interim studies
- Short communications
- Cost-effectiveness studies
- Educational interventions
- Study protocols
- Pilot studies
- Grey literature and unpublished articles

Data extraction and data items

The two independent researchers will extract the secondary outcomes from each article into another pre-formatted Microsoft Excel database (Version 15.23, 2016, Microsoft). This will include the condition addressed by each review (grouped by field of pathology), the intervention examined and surrogate markers of article quality including: journal IF; publication date; number of contributing authors; whether the RCT was single- or multi-centre. The data extracted will then be cross-checked for validity (two authors will review each other's' work). The relationship between CONSORT score and year of publication, single- *vs* multi-centre, the number of contributing authors, and journal IF will be assessed.

Statistical analysis

All data will be analysed using Microsoft Excel Software (Version 15.23, 2016, Microsoft). All statistical analyses will be performed using SPSS (Version 23). Continuous variables will be presented as a mean and ranges. Categorical variables will be presented as percentage values. Inter-rater agreement between CONSORT scores and inclusion/exclusion of RCTs will be assessed using

Table 1
Pubmed Search History of a preliminary search conducted on the 3rd March 2016.

Search	Studies generated
"j Craniomandibular Pract"[Journal]) OR "J Craniomaxillofac Surg"[Journal]) OR "J Craniofac Surg"[Journal]) OR "cleft Palate Craniofac J" [Journal]) OR "orthod Craniofac Res"[Journal]	15362
Randomised controlled trial[pt] OR controlled clinical trial[pt] OR randomised[tiab] OR placebo[tiab] OR "drug therapy"[Subheading] OR randomly[tiab] OR trial[tiab] OR groups[tiab] NOT ("animals"[MeSH Terms] NOT "humans"[MeSH Terms])) AND "j Craniomandibular Pract"[Journal] OR "J Craniomaxillofac Surg"[Journal] OR "J Craniofac Surg"[Journal] OR "cleft Palate Craniofac J"[Journal] OR "orthod Craniofac Res"[Journal] AND ((Clinical Trial[ptyp] OR Clinical Study[ptyp] OR Clinical Trial, Phase I[ptyp] OR Clinical Trial, Phase II[ptyp] OR Clinical Trial, Phase III[ptyp] OR Clinical Trial, Phase IV[ptyp] OR Controlled Clinical Trial[ptyp] OR Multicenter Study[ptyp] OR Pragmatic Clinical Trial[ptyp] OR Randomized Controlled Trial[ptyp]) AND "2012/03/15"[PDat]: "2017/03/15"[PDat] AND "humans"[MeSH Terms]	205

the Kappa score. A P value of <0.05 will be deemed significant for all statistical tests. Summary measures will be used to calculate the mean weighted number of CONSORT items adequately reported for all studies and the percentage of studies compliant with each element of the CONSORT guidelines. An initial pilot search has yielded 199 RCTs to be screened for inclusion. This number is similar to that generated in previous systematic reviews assessing CONSORT compliance in other surgical areas [3,20–23], and is therefore considered sufficient to provide a true representation of RCT reporting in craniofacial surgery.

Sub-group analysis

The CONSORT score will be compared across RCTs grouped on the basis of their subject topic within craniofacial surgery, intervention studied, as well as by indexes relating to RCT quality: date of publication; IF; number of contributing authors (all to be analysed as a continuous variables) and multi- *vs* single-centre (analysed as a categorical variable). A one-tailed Student's *t*-test will be used to analyse multicentre versus single-centre trials. Regression analyses will be used to analyse relationship between CONSORT score and year of publication, number of contributing authors, and journal IF. No *meta*-regression or sensitivity analyses will be planned or pre-specified.

Ethics and dissemination

The intent will be to publish in a peer-reviewed journal and to present the data at relevant conferences.

Conclusion

This systematic review aims to elucidate areas of RCT reporting can be improved, to help guide authors and ensure high quality methodology RCTs are conducted within craniofacial surgery, which will ensure the best clinical practice is followed, and the best possible patient outcomes are achieved.

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Conflicts of interest statement

There are no conflicts of interest.

Authors' contributions

MRB, RA and TEP conceived this paper. MRB and TEP drafted the manuscript. All authors critically revised it for important intellectual content and approved the final version for publication. MRB has collected the preliminary data.

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Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at http://dx.doi.org/10.1016/j.isjp.2017.06.001.

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