

Short Communication

The quality of reporting of randomised controlled trials in dental public health

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Objective: To assess the quality of the reporting of randomised controlled trials (RCTs) in dental public health journals. **Method:** Electronic and hand searches were used to search for RCTs published in the following three journals over the period 1993 - 2008: *Community Dental Health*, *Community Dentistry & Oral Epidemiology* and the *Journal of Public Health Dentistry*. Exclusion criteria were applied. Each of the resulting papers was reviewed and scored, according to 56 criteria, based on the CONSORT statement. **Results:** The search identified 48 papers. The average number of criteria present per article was 27.0 (SD = 6.9), with variation between journals as follows: *Community Dental Health* (27.7); *Community Dentistry & Oral Epidemiology* (27.4); *Journal of Public Health Dentistry* (23.2). The average number of criteria present per article increased over the time period used. **Conclusion:** There were inadequacies in the reporting of trials in dental public health journals. The quality of the reporting could be improved if the CONSORT statement was followed more closely.

Key words: Dental public health, randomised controlled trial

Introduction

One of the main roles of dental public health is to evaluate the effectiveness of interventions to improve oral health. Randomised Controlled Trials (RCTs) are the 'gold standard' study design to evaluate effectiveness (Cochrane, 1972). The reporting of RCTs became a cause for concern in the early 1990s and a multidisciplinary group was established in 1993 to address this. In 1996, they published the **Consolidated Standards for Reporting of Trials** (CONSORT) statement. This statement consists of a checklist of items which must be included in reports, to minimise the risk of biased estimates of effect and to allow the reader to judge the reliability of the findings (Moher, *et al.*, 2001).

Several authors have assessed the quality of the reporting of RCTs in medical fields including obstetrics and gynaecology (Schulz, *et al.*, 1994), hepatology (Glud and Nicklova, 1998), schizophrenia (Thornley and Adams, 1998) and head injury (Dickson, *et al.*, 2000). One such study was conducted on RCTs that had been reported in several ophthalmology journals. This study assessed each article using a 56-criteria tool, derived from the CONSORT statement. Examination of 125 trials published between 1991 and 1994, showed an average of 15.8 criteria per report (Scherer and Crawley, 1998). This study was repeated for articles published in 1999, by which time the average number of criteria covered had increased to 33.4 (Sánchez-Thorin, *et al.*, 2001).

In dentistry, an assessment was conducted of the quality of the reporting of clinical trials in three orthodontic journals over the period 1989 to 1998. This revealed the main areas of inadequate reporting to be the concealment of allocation, masking and the description of withdrawals

and drop-outs from the trial. The authors concluded that, if orthodontic journals used the CONSORT statement, then the reporting of clinical trials could be improved (Harrison, 2003). Low quality scores were also found in evaluations of the quality of reporting of trials in periodontal research (Antczak, *et al.*, 1986a; 1986b). Little research has been conducted on the reporting of RCTs in dental public health, the aim of this study was to evaluate the quality of reporting of RCTs in three dental public health journals.

Search Strategy

Medline and PubMed databases were searched for RCTs reported in *Community Dental Health*, *Community Dentistry & Oral Epidemiology* and the *Journal of Public Health Dentistry* between January 1993 and June 2008. Hand searching of these journals was also carried out to ensure all articles were included (Hopewell, *et al.*, 2007). The start of the study period was chosen as this was the first meeting of the CONSORT group.

Abstracts of all articles were read first and, if the articles appeared to be describing an RCT, then the full length paper was obtained. RCTs were defined as controlled experiments designed to evaluate an intervention using a random method to assign study units to a test or comparison group. Articles reporting studies that did not meet this definition were excluded. The following exclusion criteria were then applied:

- Articles describing secondary analysis of primary data from RCTs.
- Articles reporting pilot studies.
- Articles which included only brief descriptions of the method as the detail had been described in full elsewhere.

After applying the exclusion criteria, the journal and date of publication of each included study was recorded. Each article was then assessed against the CONSORT criteria tool, as described by Scherer and Crawley (1998). This tool evaluates the presence of 56 criteria in the individual reports, covering aspects such as the title, abstract, introduction, assignment, masking, participant flow or follow-up, analysis and discussion. For each criterion, the articles were given a score of "1", when the criterion was assessed as being present, and "0" for those that did not meet the criterion. A total score was, therefore, obtained for each article. A data collection sheet, containing the criteria, was developed and piloted. Both reviewers then applied the criteria to six papers, for training purposes. Each article was then reviewed independently by two reviewers and the criteria applied. Disagreement between reviewers was resolved through discussion.

Results

Eighty five articles were found from the electronic search, with a further 33 articles found from the hand search. Of these combined 118 articles, 38 were judged not to be RCTs. Furthermore, after application of the exclusion criteria, another 32 articles were excluded: seven articles described pilot studies, eight articles involved secondary analysis of data from an RCT and 17 articles described RCTs reported in detail elsewhere.

The remaining 48 articles were derived as follows: 10 from *Community Dental Health*, 33 from *Community Dentistry & Oral Epidemiology*, and five from the *Journal of Public Health Dentistry* (Figure 1). (The list of included articles is available on request from the corresponding author).

The mean number of criteria present per article was 27.0 (SD = 6.9) (48.2% of the total possible number). The mean number of criteria present in articles published in *Community Dental Health* was 27.7 (SD = 7.6), *Community Dentistry & Oral Epidemiology* was 27.4 (SD = 6.9) and in the *Journal of Public Health Dentistry* was 23.2 (SD = 5.0). There was no significant difference in number of criteria between journals ($p = 0.37$).

The average number of criteria present per article from 1994 to 2007 suggested that scores had improved gradually (Figure 2). Only a small number of RCTs had been reported in 1993 and 2008 so these years were omitted.

Examination of the individual criterion found that 48% of reports did not include a sample size calculation, 56% did not include any detail of the method of randomisation, 62.5% did not report the masking of the outcome assessor and 77% did not include intention to treat analysis. Improvements in more recent studies included structured abstracts and trial flow charts, deficiencies remained with randomisation and masking.

Discussion

This study aimed to assess the quality of reporting of randomised controlled trials in three dental public health journals. Previously, no published studies have investigated this research question. The reporting of 48 trials was assessed, based on criteria derived from the

CONSORT statement. There were inadequacies in the reporting of trials in the three journals examined, with less than 50% of criteria present. However, the quality of the reporting of trials appeared to have improved over time. These improvements may have resulted from an increased acceptance of the CONSORT statement.

The CONSORT-based tool used in this study was first described by Scherer and Crawley in 1998 for their study of RCTs in ophthalmology. The mean number of criteria for the 24 trials examined in 1999 was 33.4 (Sánchez-Thorin et al, 2001), which was higher than the mean number of 27.0 for RCTs in dental public health journals evidenced here.

There are several limitations to the current study: the tool designed by Scherer and Crawley was developed for trials of clinical interventions, rather than for interventions aimed at improving the oral health of communities or populations. There may be some variation in the criteria of importance for clinical rather than public health trials. For example, Scherer and Crawley's tool had an emphasis on masking, which may be easier to achieve for clinical interventions. There was also some subjectivity in the application of the criteria, which were not all clearly written. Agreement on how the criteria should be applied to dental public health interventions was achieved before the reviewers began applying the criteria.

It should also be considered that deficiencies in the reports may be due to the word limits imposed by the journals, rather than the authors omitting to include the details in protocols for the trials themselves.

For the three dental public health journals reviewed, the use of the CONSORT statement is mentioned in the guidance notes to authors for *Community Dentistry & Oral Epidemiology* and is strongly recommended for the *Journal of Public Health Dentistry*. It is not known when the use of CONSORT was first introduced by these journals and how this guidance is applied during the peer review process. It has recently been introduced to the directions for authors in *Community Dental Health* and is mentioned specifically on the reviewers evaluation form.

The quality of reporting of RCTs in dental and medical research has been previously criticised. While the quality of reporting of trials in dentistry was found to be generally equivalent to that in medicine, wide variation was found between articles (Sjögren and Halling, 2002). An assessment of the quality of the reporting of trials published in orthodontic journals found reporting to be inadequate and the deficient areas identified in that study, particularly allocation and masking (Harrison, 2003), were mirrored in the findings for dental public health journals.

Conclusion

This was the first study to assess the quality of reporting of RCTs in dental public health. There were inadequacies in the reporting of trials although there was some evidence of improvement in recent years. Further improvements could be made if journals ensured the CONSORT guidelines were followed more closely in future.

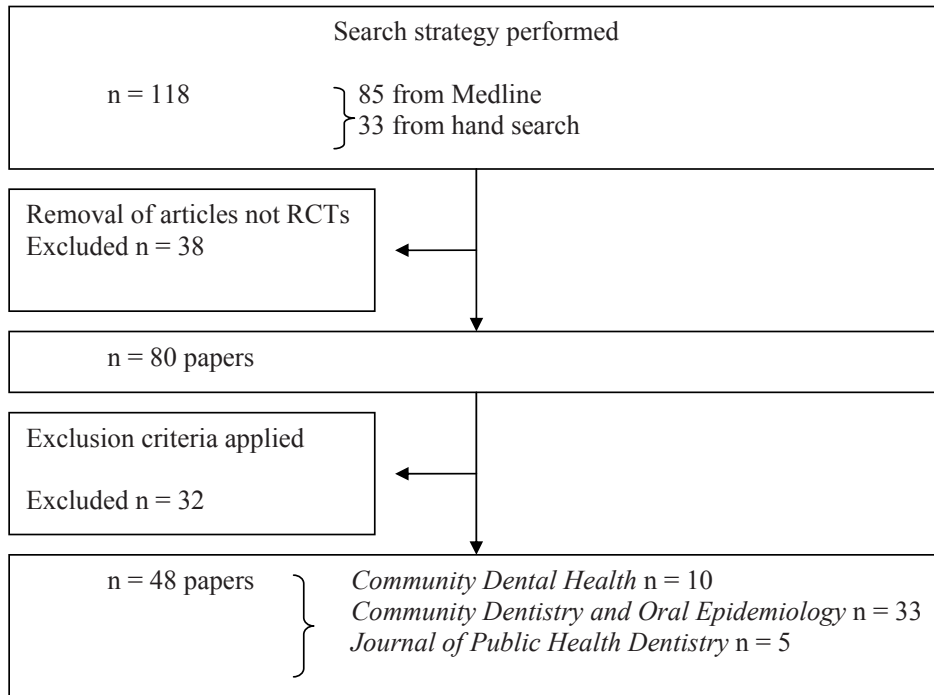


Figure 1. Results of literature search

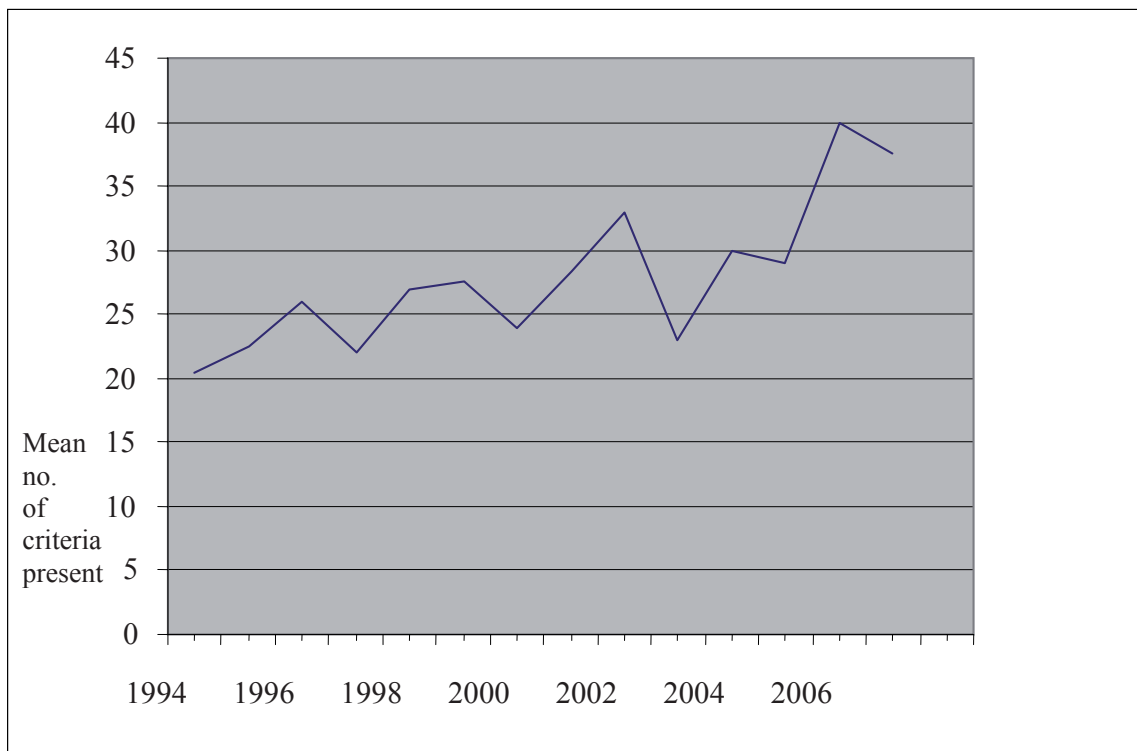


Figure 2. The mean number of criteria present per article from 1994 to 2007

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