

Reporting of conflict of interests, source of funding, and ethics committee approval in randomized trials of three clinical specialties published in Spanish language.

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Work received on 09/07/2022
Revised work 21/11/2022
Approved for publication on 02/12/2022

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ABSTRACT

Background: Confidence in the results reported by randomized clinical trials (RCTs) depends mainly on the internal validity of the trial and its conduct, but also on other aspects related to health research such as the complete reporting of conflicts of interest (COI), funding sources and approval by ethics committees. Bias in the study results may arise from any one of these elements. Prior studies have explored the reporting of these items in the medical literature, but there are no reports on RCTs published in Spanish and Latin American journals. This study aimed to evaluate the reporting of COIs, funding sources, and approval by ethics committees of RCTs published in Spanish and Latin American journals in dentistry, geriatrics and neurology. **Methods:** We did a systematic retrospective survey of all RCTs published from 1990 to 2018 in dentistry, neurology, and geriatrics journals published in Spain and Latin America and included in the BADERI database (Iberoamerican journals and trials database by its initials in Spanish). We completed with hand searching. We included RCTs with a recoverable full text published between 1990 and 2018. We extracted data on sources of funding, COI statements, and ethics reviews. The extraction of these items in the RCTs included was done independently by two pairs of reviewers and in parallel for each article, with a third independent reviewer resolving discrepancies. We analysed compliance for each item. **Results:** We identified RCTs in 69 journals from Spain and Latin American countries. Dentistry accounted for 75% (n = 52) of the journals, neurology 20.6% (n = 14), and geriatrics 4.4% (n = 3). Of the total number of RCTs included in this study (n = 392), only 102 (26%) reported the presence or absence of a COI, 103 (26%) studies reported funding, and 43 (36%) included the ethics committee approval. **Conclusions:** RCTs published in the Spanish language in dentistry, neurology, and geriatrics had poor compliance with the reporting of a COI, source of funding, and ethics committee approval. Future research should evaluate the accuracy and completeness of COI statements and their relationship to the funding source and direction of the results.

KEY WORDS

Conflicts of interest; Ethics committee; Bias; Reporting; Funding; Publication ethics

Int. J. Inter. Dent Vol. 16(1); 49-53, 2023.

BACKGROUND

Confidence in the research results reported in biomedical publications is essential for the decision-making process in health. Studies that report results should be methodologically sound, and accurately and transparently reported so that clinicians and patients can correctly analyse and interpret them⁽¹⁾. Randomised clinical trials (RCTs) are considered the best study design to evaluate effects, benefits and harms of interventions in humans, such as drugs, devices, or techniques^(2,3). The randomisation of the intervention to the study groups produces a balanced allocation of any potential known and unknown confounding factor, thus resulting in a similar prognosis for both groups. Accordingly, the results obtained can be extrapolated to a population, thus avoiding unnecessary exposure of large numbers of people to the possible harms or non-benefit of an experimental treatment⁽⁴⁾. Nevertheless, there are potential sources of bias that may affect the magnitude and precision of the treatment effects and, therefore, the applicability of the results^(5,6).

While many methodological considerations can affect the validity of the results of biomedical research articles and may constitute a possible source of bias⁽⁷⁾, in this study, we have chosen to evaluate three publication ethics items that have been little explored in RCTs of Spanish-language journals: conflicts of interest, funding and ethics committee approval.

Conflicts of interest (COI) have been defined as “a financial or intellectual relationship that may impact an individual’s ability to approach a scientific question with an open mind⁽⁸⁾ and should be reported in the published article so that the reader can assess whether the results

presented may potentially be influenced by competing interests^(9,10). Many times, they are not reported or only partially reported. The lack of a COI statement could lead to biased conclusions due to the well-known association between financial—or other—interests and the reporting of favourable results, irrespective of the medical speciality or the level of impact of the publication journal⁽¹¹⁾.

Another factor that can influence the results of an RCT is the funding source. Studies have shown that research financed by the pharmaceutical and medical device industry tend to report more favourable results for the intervention of interest⁽¹²⁾. Also, it has been established that the relationship between the biomedical industry and clinical experts may lead to competing interests that jeopardise the trustworthiness of the results^(13,14). Due to this, authors must report any source of support in financing, supplies, preparation of drugs or equipment, and in the data analysis and writing of the study manuscript. While many times there may be a professional relationship between the research team or a member of the team and the funder, this should be fully disclosed to ensure complete accuracy and transparency of any possible source of bias, thus allowing the reader to discriminate between options and correctly assess efficacy, safety and cost-benefit for the patient and other stakeholders⁽⁹⁾.

Clinicians and researchers must protect life, health, privacy, and human dignity⁽¹¹⁾. Due to this, a prior evaluation by an ethics committee of any study that involves human beings is essential. They are collegial entities in public or private institutions that have the essential responsibility to protect the rights, safety and welfare of human beings participating in scientific research. (International Ethical Guidelines for Health-related

Research Involving Humans, Fourth Edition. Geneva. Council for International Organizations of Medical Sciences (CIOMS); 2016.) After a rigorous analysis, the ethics committee must ensure that the research methods comply with the principles of bioethics⁽¹⁵⁾. The published article must always explicitly declare that it was approved by a valid or accredited ethics review board or committee before implementing the intervention in patients or participants. Doing so provides proof that all efforts have been made to guarantee the safety of the participants and that the study is compliant with the best practices in the conduct of research involving human beings.

Given the above, it is necessary to report all possible conflicts of interest, both financial and non-financial; the sources of funding or support of any kind provided; and the approval of a qualified ethics committee. Any omission, inaccuracy, or misrepresentation will potentially bias the study results^(9,12).

Despite the relevance of these aspects of publication ethics and the significant number of articles published on the topic, the reporting of competing interests, funding sources, and approval by ethics committees in randomised clinical trials published in the Spanish language is unknown. This study aimed to evaluate the reporting of COIs, funding sources, and approval by ethics committees of RCTs published in Spanish and Latin American journals in dentistry, geriatrics and neurology.

METHODS

We conducted a systematic retrospective survey of all randomised clinical trials published from 1990 to 2018 in dentistry, neurology and geriatrics journals published in the Spanish language in Latin America and Spain. The main research project assessed the quality of reporting of RCTs in the mentioned clinical fields by measuring compliance with the Consolidated Standards of Reporting Trials (CONSORT 2010), of which the study protocol with the full methods was published⁽¹⁶⁾, and the manuscript with the results has been submitted for peer review. This article assesses explicitly three publication ethics-related items that are a potential source of non-methodological bias. One of these items is included in the CONSORT checklist (funding), while the other two are not (conflicts of interest statement and ethics committee approval).

The study population was the published randomised clinical trials in Spanish and Latin American journals of dentistry, neurology, and geriatrics registered in the BADERI database^(16,17). The hand search to update the published issues of the journals included, was performed by three authors (VCB, MD, JV). We also searched for new journals in these medical fields that could have emerged after 2015. We included RCTs with a recoverable full text published between 1990 and 2018. We excluded letters, editorials, conference proceedings, articles that report on pilots or feasibility studies, articles not addressing the clinical specialties of interest or that conducted a secondary analysis on RCTs, and studies that are translations of RCTs published elsewhere.

A database was set up where all potential RCTs were registered, and every journal was tracked to ensure a trustworthy data extraction process. Also, a data collection logbook was created that included all variables of interest. All identified RCTs were entered into BADERI, which allows immediate submission via ProCite files to Cochrane CENTRAL.

We extracted data on CONSORT item number 25 (sources of funding and other support, such as a supply of drugs, role of funders) plus two additional items defined in our protocol⁽¹⁶⁾: conflict of interest statement and ethics review. We also extracted the journal name, year of publication and country origin of the journal. All three items extracted for this study (funding, conflicts of interest statement, and ethics review) were measured as a binary outcome (reported/not reported). For the present study, we define "reported" as finding a mention in the article to any one of the three items included for this study. For the conflict-of-interest item, we extracted whether the authors declared having a COI or not having a COI. For funding, we extracted the source of funding (public, private, self-funded, no funding). We used the CONSORT explanatory paper as a guide for the extraction of CONSORT item 25⁽¹⁶⁾.

Data for the three clinical fields were extracted by four medical students (MGS, CBR, CTD, AAI). The extraction of these items was done by two pairs of reviewers independently and in parallel for each article. Each pair of data extractors discussed the findings, shared their discrepancies, and reached a consensus; when a consensus was not possible, a senior investigator acted as a referee (VCB, JV). A quality control process was conducted as per protocol to ensure a minimum of errors in the data collection.

Since we included the whole population of RCTs for each clinical field, no statistical inference techniques were performed. We did a descriptive analysis with summary statistics. We used the R package statistical software (R Foundation for Statistical Computing, Vienna, Austria; 2019) for analysis. The Institutional Ethics Committee of the University of

Santiago of Chile approved this study, according to Report No. 524, dated 15 August 2018. Data used in this study is publically available.

RESULTS

We identified 69 journals from Spain and Latin American countries that published randomised clinical trials. Seventy five percent of articles correspond to dentistry (n = 52), while neurology only accounted for 20.6% (n = 14) and geriatrics for 4.4% (n = 3).

From the identified journals, we extracted 489 studies. After the full-text review, we excluded 97 studies. The main reasons for exclusion were that the study was not randomised, the study was in vitro, or there was no indication of randomisation in the study methods. The final total of included RCTs was 392.

Table 1 outlines the characteristics of the included studies. Of the total population of articles, the majority were published in dentistry journals (71.9%), followed by neurology journals (20.4%) and geriatrics journals (7.6%). Most of the studies came from Spain, with a total of 219 (55.9%). Table 2 shows that the majority of RCTs were non-compliant with any of the three items for assessment in this study, regardless of the region of origin (either Spain or Latin America), and regardless whether the clinical field of interest was surgical (dentistry) or medical (neurology, geriatrics).

Table 1. Reporting of conflicts of interest statement, funding source, and ethics committee approval for all RCTs included in the study (n = 392).

Item	N of RCT (%)
Conflicts of interest	
No report	290 (74%)
Reports having a conflict of interest	3 (0.76%)
Reports not having conflicts of interest	99 (25%)
Funding Source	
No report	289 (73.8%)
Public	44 (11.2%)
Private	45 (11.5%)
Self-funding	3 (0.8%)
No funding	11 (2.8%)
Ethics committee approval	
No report	249 (64%)
Reports having an approval	143 (36%)

Table 2. Frequency and percentage of non-compliant RCTs included in the study by clinical field (dentistry versus medical (neurology and geriatrics), and by region (n = 392).

	Conflict of interest statement	Funding	Ethics approval	Totals
Dentistry	210 (74.4%)	207 (73%)	183 (65%)	282
Medical Specialities	80 (73%)	82 (75%)	66 (60%)	110
Latin America	139 (80%)	125 (72%)	116 (67%)	173
Spain	151 (69%)	165 (75%)	133 (61%)	219

Of the total RCTs included (n = 392), only 102 (26%) reported a conflict-of-interest statement, of which only three declared the existence of a COI and 99 declared no competing interests. The remaining 290 (74%) did not describe anything in the reviewed text regarding competing interests. The conflicts of interest statement only began to be reported in 2002 in this population of articles and improved slightly from 2010 onwards (Figure 1).

Of the 392 articles reviewed, only 103 (26.2%) reported funding, while 290 (73.8%) reported nothing. Regarding the source of funding, 11.2% declared public funding (n = 44), 11.5% private funding (n = 45), 0.8% declared that the study was self-funded (n = 3), and a statement of no financial support was found in 2.8% of the articles (n = 11). Some type of funding statement only appears after 1999 with no disclosures found before that date (Figure 2). Of the 392 articles included, 143 (36%)

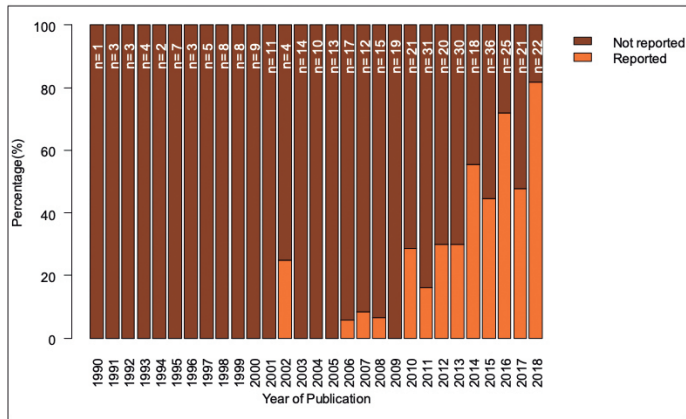


Figure 1. Percentage of RCTs that report conflicts of interest, over time (n = the total number of RCTs analysed for the year).

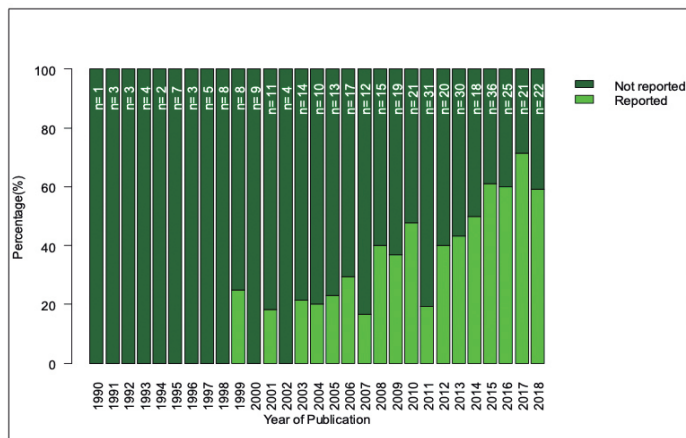


Figure 2. Percentage of RCTs that report funding, over time (n = the total number of RCTs analysed for the year).

reported an ethics committee approval, while 249 (64%) did not. This item has been reported since 1991 and has been slowly increasing since 2010 (Figure 3).

Although 290 (74%) articles did not report a source of funding, 59 (15%) of them reported a COI statement. On the one hand, of the 44 articles that report a public source of funding, only 23 (5.9%) report a conflict of interest statement, but none declared having a competing interest, i.e., no conflicts of interests were declared in the statements reported. On the other hand, of the 45 privately sponsored studies, seven (1.8%) articles reported a competing interest, and 38 declared none (9.7%).

DISCUSSION

In this study, we assessed 392 RCTs that met the inclusion criteria. Of these, only 102 (26%) reported a conflict of interest statement, and only three expressly declared the type of conflict of interest. From the total, 103 articles reported funding sources. Of these, 44/103 (42.8%) had public funding, 45/103 had private funding (43.7%), personal funds were declared in three studies (2.9%), and 11 (10.6%) declared no financial support. Finally, only 143/392 (36%) reported having approval from the ethics committee. To our knowledge, this is the first study that assessed the consistency of the reporting of conflicts of interest, funding, and ethics committee approval in biomedical journals from dentistry, neurology, and geriatrics that publish RCTs in Spain and Latin America. Prior studies have explored the quality of reporting for these items in various medical⁽¹⁹⁾ and dental journals⁽²⁰⁾, but only for English-language publications.

Most likely, there is no escaping the fact that clinical and biomedical research will always, to an extent, be bound to industry funding or other vested interest funding sources. Hence, conflicts of interest will surely be present in many published articles, and these must be accurately and transparently reported for readers and reviewers to make a correct appraisal of the article's conclusions⁽¹⁰⁾.

The fact that roughly three-quarters of the RCTs published in the journals selected for our study did not disclose conflicts of interest statements or funding sources is disappointing. Our findings are consistent with another

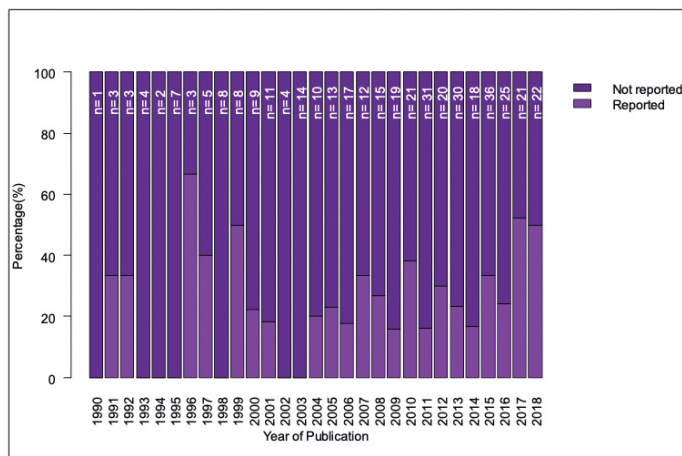


Figure 3. Percentage of RCTs that report an ethics committee approval, over time (n = the total number of RCTs analysed for the year).

study that evaluated conflicts of interest statements and funding sources for 10 top general surgical journals⁽²¹⁾. This study found that little over half of the included RCTs did not reveal the funding source, and 75 per cent of the included RCTs did not report any COI statement. A cross-sectional study published in 2003 found that 89% of RCTs published in five general medical journals disclosed a source of funding⁽²²⁾ and another study of 289 cancer trials published between 2005 and 2006 found that 75% of the RCTs reported a source of funding and 69% report competing interests⁽²³⁾. In contrast, our study, which extends from 1990 to 2018, found a 26% disclosure of funding source, revealing poor compliance on this item compared to other studies.

International Committee of Medical Journals Editors (ICMJE) guidelines are important for adequately reporting conflicts of interest in the medical literature⁽²⁴⁾. A study on HIV research involving human subjects found that among articles from ICMJE-affiliated journals, 19.4% did not disclose funding, and 55.6% did not disclose conflicts of interests⁽¹²⁾.

Similar trends regarding conflicts of interest are also seen in other medical disciplines. In an article reviewing spine research, 79% of articles included in the review declared a conflict of interest, but 30% did not provide full disclosure⁽²⁵⁾. A review that examined articles published in gastroenterology revealed that 77% reported the presence or absence of a conflict of interest⁽²⁶⁾, which starkly contrasts with our results where only 26% report a COI statement. A survey on the ties between US neurologists and the pharmaceutical and medical device industry revealed that up to 85% of them received cash payments from the industry⁽²⁷⁾. If this finding were generalisable to Spain and Latin America's neurologists, the 27% of reporting of COI statements in our population of RCTs is probably a marked underreporting of competing interests. Another perspective is provided by a 2013 study on a sample of RCTs published between 2010 and 2012 in the top 10 dental journals that found that the narrowness or broadness of the conflict-of-interest disclosure statement was differentially associated with favourable or unfavourable results of the intervention⁽²⁸⁾.

In all fields of research, there is a need for standardisation of conflicts of interest reporting and funding sources. Although collaborations between medical professionals and industry are essential to continuing medical research and advancing treatments, procedures and devices, oversight of publication ethics disclosures is lacking⁽²⁹⁾. Our study attests that literature published in Spanish in three different clinical fields does not consistently report conflicts of interest or funding sources, thus providing evidential support that journals should be prompted to follow the existing guidelines for conflict of interest reporting, such as the ICMJE recommendations.

Our study shows that COI statements began to regularly appear relatively recently, coincidentally with the publication of the last CONSORT update, even when it is not included as an item. Maybe the following CONSORT statement update should include the declaration of conflicts of interest and ethics committee approval, both of which are currently not part of the CONSORT checklist.

That little over a third of the RCTs included in our review reported approval by an ethics review board is a disheartening finding. In 1964, the World Medical Association issued the Declaration of Helsinki calling for special attention to research involving human subjects, and since then there have been regular updates and expansions of that original statement⁽¹¹⁾. Nonetheless, few studies have assessed to what extent journals are effectively complying with current ethics standards such as those recommended by the ICMJE. One study did a retrospective analysis on the reporting of ethics committee approval and informed consent in

an Ayurvedic journal and found that 51% of the articles had approval by an ethics committee⁽³⁰⁾. A scoping review of Chinese articles on organ transplantation also found significant underreporting of explicit consent for organ transplantation but high rates of compliance with ethics committee approval⁽³¹⁾. A more comprehensive study on leading nursing journals and the reporting of ethical approval arrived at similar conclusions⁽³²⁾. We did not find any literature that assessed to what extent clinical studies published in Latin American and Spanish journals are explicitly reporting an ethics committee approval.

The use of the BADERI database (Database of Iberoamerican Clinical Trials and Journals, by its initials in Spanish), which, in the context of this study, expanded its scope to 2018, is one of the strengths of this study. Moreover, this is the first study to comprehensively analyse RCTs published in Spanish in the field of dentistry, neurology, and geriatrics. Lastly, the search and selection of the articles, and the data extraction, were done in duplicate and independently. Nevertheless, we might have missed some journals that are currently active but not indexed or included in any of the databases or sources consulted. However, the hand-searching for journals was complemented by searching libraries and other local repositories, probably overcoming this limitation. Also, it is fair to assume that if such journals still exist, their impact is small. Another limitation is that the information on the records of publications found in databases and repositories such as LILACS, Periodica or Latindex, is sometimes outdated, especially regarding whether journals are currently active and the type of research they publish.

CONCLUSIONS

Randomised clinical trials published in the Spanish language in dentistry, neurology and geriatrics showed poor reporting of conflicts of interest, source of funding, and ethics committee approval. Since 2010, the reporting of competing interests began to improve, and by 2018, 80% of the articles analysed had one. The reporting of ethics committee approval is irregular and insufficient across time.

Journals might be interested in standardising the reporting of conflicts of interests. Researchers should understand that, when a conflict of interest exists, they must disclose it to provide transparency to readers and patients alike. New ways of supporting the identification, tracking, and accounting of conflicts of interests of researchers in the health sciences should be pursued.

Future research should evaluate the association between conflicts of interests and funding, and the direction of the results. Far more difficult is the ascertainment of the accuracy of disclosures regarding conflicts of interests as it may not be feasible to track whether what was stated

(or not stated), is true or not. Journal editors, mostly overworked and under-resourced, will be inclined to take at face value what the authors state. Our study shed light on what authors did not state, and our findings should prompt journals, authors and institutions to be more proactive in fostering a culture of transparency and completeness in the reporting of the publication ethics components of clinical trials.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

The Institutional Ethics Committee of the University of Santiago of Chile approved this study, report No. 524, dated 15 August 2018. No patients were involved.

CONSENT FOR PUBLICATION

Not applicable

AVAILABILITY OF DATA AND MATERIALS

The dataset supporting the conclusions of this article is available in the Figshare repository, [10.6084/m9.figshare.13187729] and <https://figshare.com/account/home#/projects/92198>.

COMPETING INTERESTS

The authors have no competing interests to declare.

FUNDING

DICYT Project 021901BN (Universidad de Santiago de Chile, USACH).

AUTHORS' CONTRIBUTIONS

All authors have contributed intellectually to the study idea. AAI, CBR, CDT and MGS, extracted data solved discrepancies. MD contributed to data validation and quality control and to drafting the manuscript. AAI did the analysis. VCB, JV and MD drafted the first complete version of the manuscript with contributions from AAI, CBR, MGS, and CTD. VCB critically reviewed the first draft of the manuscript. All authors approved the final version.

ACKNOWLEDGEMENTS

Not applicable

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