Short Communication

Evaluation of the Quality of Pharmacist-Led Randomized Clinical Trial Reporting Using the CONSORT Criteria

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Abstract

Pharmacists provide a wide range of health services in addition to dispensing medicines, and, thus, there have been many pharmacists-led clinical trials conducted to evaluate these services. It is important to assess the quality of reporting in these trials for their clinical significance and generalizability. The aim of this study was to assess the reporting quality of pharmacist-led clinical trials based on the Consolidated Standards of Reporting Trials (CONSORT) 2010 checklist. We chose 10 pharmacy practice journals based on the expert opinion of the supervisors of this study, and because of their relevance with research articles. A descriptive analysis was conducted to measure the percentage of completion of the items stated in the CONSORT 2010 checklist. Data analysis was performed using the Statistical Package for the Social Sciences version 20.0 software (SPSS Inc., Chicago, IL, United States). Twenty-six studies were included; the mean number of items met by all the studies was 17.95 (66.5%), the baseline data were completely reported in 25 (92.6%) studies, and the trial design was reported only in 10 (37%) studies. Our study showed that the quality of pharmacist-led clinical trials reporting in 10 major pharmacy journals was not adequate to meet the CONSORT criteria for randomized control trials. Stricter adherence to the CONSORT criteria will help improve the reporting quality of pharmacist-led clinical trials.

Keywords: CONSORT, pharmacist-led, quality of reporting, randomized control trials

Background

The role of pharmacists in healthcare has dramatically changed recently from the compounding and dispensing of medications to the delivery of a wide range of health services, both in hospital and community pharmacy. These services include pharmacotherapy consultation, medication therapy reviews, immunizations, health and wellness programs, anticoagulation management,[1] and many other services such as targeted patient educational programs. These specialized and developing fields have shown to be beneficial in improving patient outcomes, especially if the pharmacists are well-trained and skilled.[2] There have been many pharmacists-led clinical trials conducted to evaluate these services.[2]

The high quality of reporting randomized control trials (RCTs) is essential to assess their clinical significance and generalizability. There is a lack of evidence regarding the evaluation of the quality of reporting pharmacy practice clinical trials.

This study aimed at evaluating the reporting of pharmacists-led clinical trials using the Consolidated Standards of Reporting Trials (CONSORT) checklist. The CONSORT facilitates the authors to report the findings of their clinical trials and guarantees that the minimum standard of reporting clinical trials is met.[3] Moreover, it eases the way for the readers to understand, interpret, and assess the validity of trial results.[4] The CONSORT has been recognized by leading medical journals and editorial organizations.[3]

Materials and Methods

Data sources

We chose 10 pharmacy practice journals: International Journal of Clinical Pharmacy, Pharmacotherapy Journal, International Journal of Pharmacy Practice, Journal of Pharmacy Practice, Journal of Clinical Pharmacology and Therapeutics, Research in Social and Administration Pharmacy, American Journal of Health-System Pharmacy, Annals of Pharmacotherapy, European Journal of Hospital Pharmacy, and Canadian Pharmacist Journal. These journals

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were selected for the search based on the expert opinion of the supervisors of this study, and because of their relevance with the research articles. We conducted the search to retrieve the relevant articles published between 2011 and 2015 in each journal individually because the CONSORT was developed in 2010. Moreover, the articles published during this period of time were expected to represent recent changes and advancement in clinical pharmacy practice.

Study selection

The number of articles retrieved was 27 [Figure 1]. One study was excluded because it was not a randomized clinical trial. We included all the studies with their abstracts describing the allocation of participants using the words "randomly allocated," "randomization," "random," and "randomized." We excluded the studies, which were meta-analysis RCTs, reviews, and conference abstracts.

Data extraction

Seven students were trained in evaluating RCTs and data extraction using the CONSORT. The following options "Yes," "No," "Not applicable," "Unclear," and "Yes, present in different place" criteria were developed for data extraction. "Percentage of completion" or "meeting the number of items" on the CONSORT checklist was defined as the number of items that met the criteria of "Yes" or "Not applicable." These criteria are defined in Table 1. The data were extracted by applying these following criteria to the descriptive information in the published trials: The name of author, year of publication, first page of article, number of authors, country of origin, source of funding, and research center.

Results

Across all the 26 included studies, the median number of authors was six (range: two-eight). The source of funding was not mentioned in 14 (53.8%) trials; six (23.1%) trials were funded by the government bodies, two (7.7%) were funded by pharmaceutical companies, and four (15.4%) were funded by universities. Most of the studies were single-center studies (65.4%), whereas 34.6% were of multicenter type. In 16 studies (61.5%), the type of intervention was nondrug intervention.

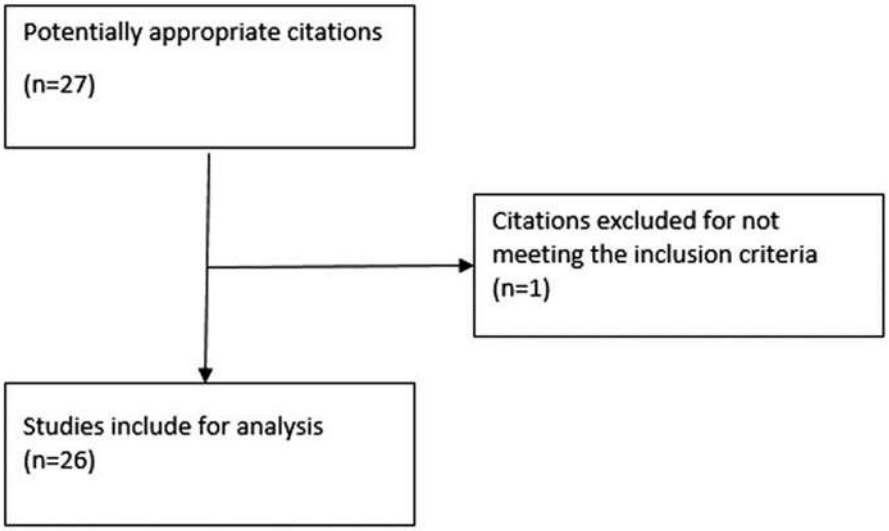

Figure 1: Selection of articles.

Table 1: Descriptive information of criteria for data extraction

Items	Explanation	Example
Yes	Indicates that the study followed CONSORT criteria	Identification of "randomized trial" in the title
No	Indicates that the study did not follow the CONSORT criteria	Unstructured abstract
Not applicable	Indicates that the CONSORT criteria could not be applied to the study	When blinding is not applicable in this type of study
Unclear	Indicates that it is difficult to establish whether the study followed the CONSORT criteria	The method used to generate the random allocation sequence was not described
Present in a different place	Indicates that the CONSORT item was present in a different section	Study design mentioned in the discussion section instead of the methods section

Whereas 10 (38.5%) studies involved drug intervention [Table 2].

Drug intervention vs. nondrug intervention

There was no significant difference between drug intervention studies and nondrug intervention studies in meeting the number of items on the CONSORT checklist (P-value = 0.765).

Single-center vs. multicenter

There was no significant difference between single-center studies and multicenter studies in meeting the number of items on the CONSORT checklist (P-value = 0.613).

Number of authors

Our analysis showed that the number of authors and the percentage of completion of the CONSORT checklist items were not correlated with each other (r = 0.05, n = 27, P = 0.804).

Sources of funding (pharmaceutical company, the government, university, none)

There was no significant difference in the percentage of completion of the CONSORT checklist items among the studies with different sources of funding (pharmaceutical company, government body, university, and none) (F = 1.330, P = 0.289).

CONSORT items

The mean number of items met by all the 26 studies was 14.2 (67.6%). The study that had the highest percentage of completion of the CONSORT items was the study by Morgado et al. The intervention in this study was nondrug intervention (pharmaceutical care, consisting of a quarterly follow-up by a hospital clinical pharmacist during a 9-month period). The study with the lowest percentage of completion of the CONSORT items was the study by Aziz et al., which involved drug intervention [Table 3].

The baseline data were completely reported in 25 (96.2%) studies, and the trial design was reported only in 10 (38.5%) studies [Table 4].

Table 2: Characteristics of the included studies

Characteristics	Number of studies
Funding source	
Not mentioned	14 (53.8%)
Government	6 (23.1%)
Company	2 (7.7%)
University	4 (15.4%)
Center	
Single-center	17 (65.4%)
Multicenter	9 (34.6%)
Type of intervention	
Nondrug	16 (61.5%)
Drug	10 (38.5%)

Discussion

Accurate reporting in clinical trials is essential because the clinical trials have a major role in evidence-based medicine. In our study, we chose 21 items from the CONSORT checklist 2010 to evaluate 27 pharmacists-led clinical trials. These items were title, abstract, trial design, setting, intervention, outcome, sample size, eligibility criteria, randomization, allocation, blinding, statistical method, participant flow, recruitment, baseline data, number analyzed, outcome and estimation, limitation, registration, protocol, and funding; each item is described in the CONSORT checklist 2010.

Twenty-five (96.2%) studies reported baseline data; this item was the most reported item in all the studies. Twenty-four (92.3%) studies reported the eligibility criteria. It was expected that most of the studies would report these two items because they are the most relevant items in any trial. The lowest reported item was trial design; it was only reported by 10 (38.4%) studies, and the registration number was only reported in 11 (42.3%) studies. The top two studies, which met the most number of items on the CONSORT list for quality of reporting were published in the International Journal of Clinical Pharmacy. Their respective percentages of completion were 95.2% (20) and 90.5% (19) out of the 21. items. The lowest quality reported by the study, which was published in the same journal, was eight (36.1%) out of 21 items completed. There was no significant difference in the percentage of completion of the CONSORT items between the studies with different types of intervention (drug intervention vs. nondrug intervention) and the studies with different funding sources (government, company, university, and none). Our literature review found that there was no study published to date that reviewed or evaluated the quality of reporting in pharmacists-led clinical trials.

Table 3: Completion of CONSORT items for each study

Study	Number of CONSORT items met by the study (%)
Morgado et al. (2011)	20 (95.2)
Mourao et al. (2012)	19 (90.5)
Joafari et al. (2015)	19 (90.5)
Elizabeth et al. (2015)	18 (85.7)
Obarcanin et al. (2015)	18 (85.7)
Basger et al. (2015)	17 (81.0)
Oghazian et al. (2015)	17 (81.0)
Jaffray (2014)	17 (81.0)
Olesen et al. (2013)	16 (76.2)
Bunetti et al. (2011)	16 (76.2)
Kjeldsen et al. (2015)	15 (71.4)
Kraemer et al. (2012)	14 (66.7)
Rokach et al. (2013)	14 (66.7)
Neto et al. (2011)	14 (66.7)
Farsaei et al. (2014)	14 (66.7)
Kristeller et al. (2012)	13 (61.9)
Thomas et al. (2015)	12 (57.1)

Gujral et al. (2014)	12 (57.1)
Gujral et al. (2014)	12 (57.1)
Sansanayudh et al. (2014)	11 (52.4)
Bushra et al. (2015)	11 (52.4)
Bryant et al. (2012)	11 (52.4)
Chan et al. (2014)	11 (52.4)
Dicpinigaitis et al. (2015)	10 (47.6)
Shen et al. (2011)	10 (47.6)
Aziz et al. (2011)	8 (38.1)

Table 4: Description of the CONSORT items

Item on the CONSORT list	Number of studies that met the related CONSORT item (%)
Title	17 (65.4)
Abstract	17 (65.4)
Trial design	10 (38.5)
Settings	23 (88.5)
Intervention	24 (92.3)
Outcomes	20 (76.9)
Sample size	21 (80.8)
Eligibility criteria	24 (92.3)
Randomization	13 (50)
Allocation	13 (50)
Blinding	20 (76.9)
Statistical method	23 (88.5)
Participant flow	21 (80.8)
Recruitment	13 (50)
Baseline data	25 (96.2)
Number analyzed	15 (57.7)
Outcome and estimation	14 (53.8)
Limitation	17 (65.4)
Registration	11 (42.3)
Protocol	16 (61.5)
Funding	20 (76.9)

Limitations

To quantitatively evaluate the quality of the reporting of pharmacist-led clinical trials, we excluded some of the items from the CONSORT 2010 statement because of their irrelevance. In addition, not all pharmacy journals were included in our search because of limited access and time constraint.

Conclusion

Our study showed that the quality of pharmacist-led clinical trials reporting in 10 major pharmacy journals was not adequate. The quality of reporting of the study was not found to be influenced by the type of intervention and the sources of reporting of the study. Additionally, there was no correlation between the quality of reporting of the study and the number of authors.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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APPENDIX 1

Included research articles

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Appendix 2

Excluded research articles

(1) Farley TM, e. (2016). Effect of clinical pharmacist intervention on medication discrepancies following hospital discharge. − PubMed − NCBI. Ncbi.nlm.nih.gov. Retrieved 20 May 2016, from http://www.ncbi.nlm.nih.gov/pubmed/24515550