Contemporary Clinical Trials 30 (2009) 116–122

Contents lists available at ScienceDirect

Contemporary Clinical Trials

journal homepage: www.elsevier.com/locate/conclintrial

The impact of the CONSORT statement on reporting of randomized clinical trials in psychiatry ☆

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ARTICLE INFO

Article history:
Received 3 September 2008
Accepted 25 November 2008

Keywords:
CONSORT statement
Randomized clinical trial
Psychiatry

ABSTRACT

To determine whether the CONSORT recommendations influenced the quality of reporting of randomized controlled trials (RCTs) in the field of psychiatry, we evaluated the quality of clinical trial reports before and after the introduction of CONSORT statement. We selected seven high impact journals and retrieved the randomized, clinical trials in the field of psychiatry during the period of 1992–1996 (pre-CONSORT) and 2002–2007 (post-CONSORT).

Among the total 5201 articles screened, 736 were identified and entered in our database. After critical review of the publications, 442 articles met the inclusion and exclusion criteria. The CONSORT Index (sum of 22 items of the checklist) during the post-CONSORT period was significantly higher than that during the pre-CONSORT period. However, over 40% of post-CONSORT studies did not adhere to CONSORT statement for reporting the process of randomization, and details of the process for obtaining informed consent were still insufficient. Furthermore, adherence to the CONSORT guidelines of reporting how blinding was accomplished and evaluated actually decreased after publication of the CONSORT statement. Although the overall quality of reporting on psychiatric RCTs generally improved after publication of the CONSORT statement, reporting the details of randomization, blinding, and obtaining informed consent remain insufficient.

1. Introduction

Randomized controlled trial (RCT) is a clinical research design that includes randomization of subjects to treatment or control groups. Random assignment of subjects can equalize the characteristics of subject groups and thereby equally distribute confounding factors that could bias the research outcome. In assessing the effectiveness of treatment modalities involving human subjects, the RCT design is generally considered as the gold standard method with the least spurious causality and bias [1–3].

However, despite the methodological strength of RCT design, poorly conducted RCTs can induce more bias than properly conducted quasi-experimental research [4,5]. More specifically, inappropriate methods of creating and concealing the random allocation, selective attrition, and faulty double-blinding have potential to bias the estimates of treatment effects in RCTs [6].

Hence, critical evaluation and interpretation of published research hinges on accurate and thorough reporting, particularly in the areas of randomization and blinding. In this regard, concerns about insufficient details in medical research papers contributed to the birth of the Consolidated Standards of Reporting Trials (CONSORT) statement which was first published in 1996 and later revised in 2001. The CONSORT

☆ This study was presented at the 161st Annual Meeting of the American Psychiatric Association, May 3-8, 2008, Washington, DC.

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doi:10.1016/j.cct.2008.11.004

statement contains a checklist and a flow diagram used to evaluate the completeness of RCT reportings [7].

The original checklist identifies 21 essential elements in the methods, results, and discussion sections necessary to evaluate the internal and external validity of an RCT report [8]. The revised CONSORT statement published in 2001 amended the original checklist and diagram based on empirical evidence indicating that certain reporting deficits lead to biased estimates of treatment effects or inhibit proper judgements about the reliability and relevance of research findings presented [8–10]. The revised CONSORT statement contains a 22- item checklist and a modified flow diagram depicting the flow of participants from assignment of the groups through the end of the trial. The revised checklist was used in the current study as the basis for comparing completeness of reporting in pre and post CONSORT studies. Of note, other scales have been developed to assess the quality of RCT reporting, including the Jadad Scale which addresses reporting of randomization, blinding, withdrawals, and dropouts [11]; the authors of the current study consider the CONSORT statement to be particularly comprehensive and thus decided to utilize it in the current analysis.

Several other reporting guidelines have been proposed for other types of research publications; The Transparent Reporting of Evaluations with Non-randomized Designs (TREND) specific to reporting of non-randomized studies [12], The Quality of Reporting Of Meta-analyses (QUORUM) statement for reporting systematic reviews [13], Strengthening The Reporting of Observational Studies in Epidemiology (STROBE) statement for reporting cohort observational studies [14], and the Meta-analysis Of Observational Studies in Epidemiology (MOOSE) statement for reporting meta-analyses of observational studies [15]. Also, the CONSORT statement was subsequently revised specifically for the evaluation of reports of cluster randomized studies [16].

There have been few studies examining the improvement in quality of RCT reporting after the publication of the CONSORT statement. Moher et al. reviewed papers published in four medical journals prior to 1994 and after 1998 and concluded that the quality of reporting in journals which officially adopted the CONSORT statement was better compared to reports in journals which did not adopt the CONSORT statement [17]. Devereaux et al. reviewed studies published in 1997 in 29 major medical journals and found that the quality of RCT reporting was better in journals that endorsed the CONSORT statement [18]. Both studies examined a relatively small number of papers within 1–2 years after the publication of the original CONSORT statement, including all fields of medicine. In a systematic review shortly after the CONSORT statement was published, Plint et al. found that the quality of reports was generally improved after CONSORT and suggested that CONSORT-adopting journals should be more proactive in enforcing adherence to the statement [10].

More recently, Kane et al. reported that the CONSORT statement generally improved the reporting of RCTs based on review of more than 776 RCT papers published in two leading medical journals, the Journal of the American Medical Association (JAMA) and the New England Journal of Medicine (NEJM) [19]. This review was not discipline-specific and did not include any specialty journals. Studies published in the journals of specific disciplines including orthopedic trauma [20] and palliative care [21] have suggested that RCT reporting remains deficient despite the publication of the CONSORT statement and its revision.

There are very limited data examining the quality of reporting clinical trials in the field of psychiatry. Thus, we compared psychiatric RCTs published in seven leading medical journals during several-year periods before and after publication of the CONSORT statement in order to evaluate whether the CONSORT statement has improved the completeness of RCT reporting. We chose the two time periods (1992–1996 & 2002–2007)) to include time periods prior to the original CONSORT statement (published in 1996) and following the revised CONSORT statement (published in 2001). The hypotheses were that 1) the CONSORT index of reports was higher among publications following the CONSORT statement than those prior to the statement, 2) the description of randomization and blinding procedures was improved after the CONSORT statement, and 3) the description of consent procedures was improved after the CONSORT statement.

2. Methods

This study was considered exempt from Institutional Review Board (IRB) review because it did not include any human subjects or confidential data.

2.1. Screening and selection of clinical trial reports

Randomized, clinical trials (RCTs) in the field of psychiatry were extracted from seven selected leading journals with high impact factors [New England Journal of Medicine (NEJM), The Journal of the American Medical Association (JAMA), Archives of General Psychiatry (AGP), American Journal of Psychiatry (AJP), Biological Psychiatry (BP), Lancet, and British Medical Journal (BMJ)]. These journals have all endorsed the revised CONSORT statement (JAMA in 1996, BMJ in 1996, Lancet in 1996, and NEJM in 2005) and provided clear statements supporting the use of CONSORT on their websites [22].

Candidate clinical trial reports included those published during the period of 1992–1996 (pre-CONSORT) and 2002–2007 (post-CONSORT). Articles were retrieved by using Pubmed (www.pubmed.gov), a web-based electronic bibliographic database serviced by the National Library of Medicine and the National Institutes of Health. All papers classified as either RCTs or controlled clinical trials based on publication type, subject heading, or text words (psychiatry, drug or psychosocial treatment trial, double-blind, randomized) were gathered and compiled into a spreadsheet data file by two psychiatrists (CH, CUP). We confined our search to papers using the term "English, Clinical Trial, Randomized Controlled Trial, Controlled Clinical Trial, Humans". Subsequently, authors performed critical review of all publications to determine the eligibility of each of the articles. Each doctor had consensus meetings with principal researchers (CH and AAP) to determine article eligibility before their participation in this study. Exclusion criteria were 1) papers categorized as "non-human", "letters", or "comments" "meta-analysis" "post hoc"; 2) primary outcome other than changes in clinical symptoms of psychiatric diseases (e.g. biological parameters);

3) studies in which subjects were not the psychiatric patients; 4) non-randomized controlled trials; 5) cross-over studies; 6) post-hoc secondary analysis reports; 7) studies where the unit of randomization was not the patient.

2.2. Abstraction and measurement of concordance with CONSORT guidelines

Selected articles were rated according to the 22 items of the CONSORT checklist using a dichotomous scale (described = 0, not described = 1). A CONSORT index was derived by summing the scores of all items of the checklist. Items specific to randomization and blinding were also compared separately. The CONSORT checklist contains three items specific to the process of randomization (items 8, 9, and 10) and one item specific to the process and evaluation of blinding (item 11). Item 8 (sequence generation) addresses whether authors described "method used to generate the random allocation sequence, including details of any restrictions (e.g., blocking, stratification). Item 9 (allocation concealment) addresses the description of "method used to implement the random allocation sequence (e.g., numbered containers or central telephone), clarifying whether the sequence was concealed until interventions were assigned." Item 10 (implementation) addresses the description of "who generated the allocation sequence, who enrolled participants, and who assigned participants to their groups." Item 11 (blinding – masking) addresses whether the authors describe "Whether or not participants, those administering the interventions, and those assessing the outcomes were blinded to group assignment. If done, how the success of blinding was evaluated."

An abstraction form for this study was designed using a spreadsheet program which included columns for target disease, intervention type ("medication", "psychological treatment", or "other" e.g. transcranial magnetic stimulation or electroconvulsive therapy), name of the intervention, total number of randomized subjects, number of participating sites, and mean age of subjects. Two items which were not derived from the CONSORT statement related to method of informed consent acquisition were included to evaluate reporting of the consent process: 1) from whom did they get informed consent? [not described = 0, from subjects = 1, from family = 2, from both = 3], 2) whether the informed consent process was described in detail or not? [no = 0, yes = 1].

Initially a set of 10 randomly selected articles were rated by the primary raters (DM, KB) and senior investigators (CH and AP) to determine conconcordance on the CONSORT checklist. An overall concordance of 97% was obtained. After

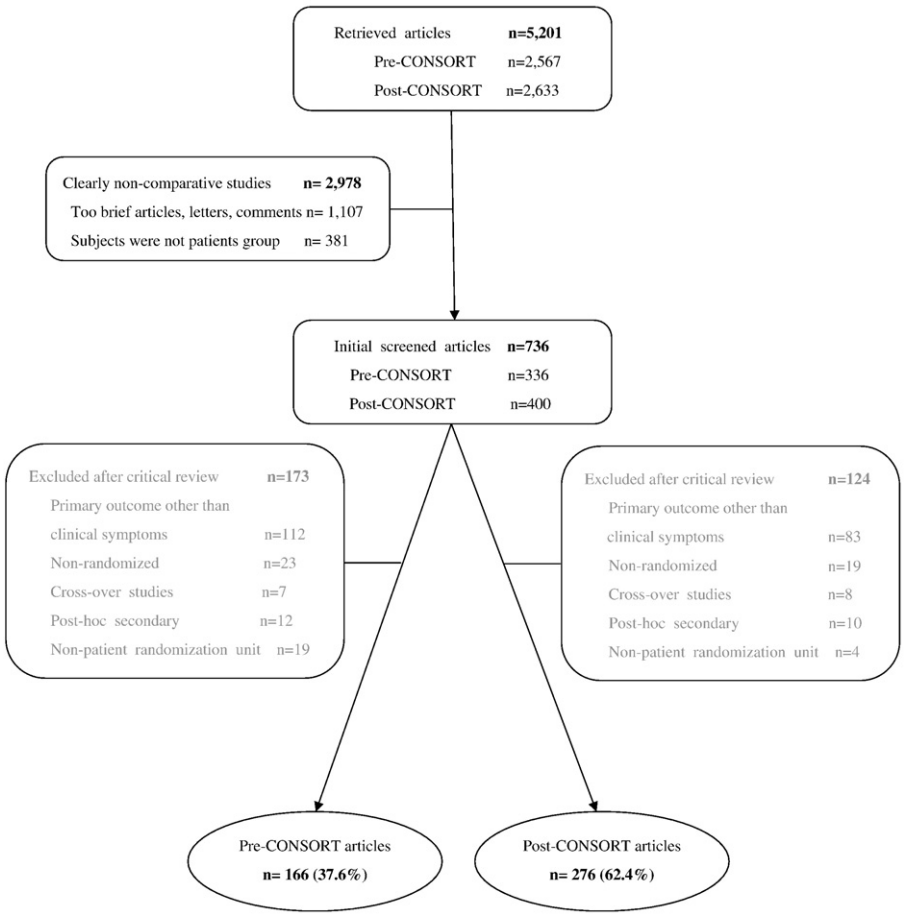

Fig. 1. Disposition of selected studies.

the ratings of the entire set were completed, the process was repeated with a concordance rate of 95%.

2.3. Data analysis

Descriptive statistics were performed on the number of RCT articles before and after introduction of CONSORT statement, number of the selected papers of each journal, number of subjects, and number of participating sites. Authors created an index variable (CONSORT index) by summing the scores of the 22 items in the CONSORT checklist. Independent t-tests were used to examine differences in the total CONSORT index between the two reporting periods. Pearson chi-square analyses were performed using table analysis function to compare the frequencies of responses on each item of the CONSORT checklist. Two-way ANOVA was performed to evaluate whether there was an effect of journal or intervention type. Tukey method was used to compare the differences in means of indices of each group.

The required number of reports to provide power of 0.90 ($\alpha = 0.01$, effect size = 0.5) was 121 reports in each group. In this study, the power was 0.99 with 166 reports in the pre-CONSORT period and 276 reports in the post-CONSORT period ($\alpha = 0.01$, effect size = 0.5).

All statistical significance was two-tailed and set conservatively at $p < 0.01$ due to multiple comparisons. Statistical analysis was performed using the SAS E-guide 4.1 (SAS Institute Inc, Cary, NC).

3. Results

3.1. Characteristics of selected RCT studies

Among the total 5201 articles screened, 736 studies were initially identified and entered into our database. After critical review, 442 articles were selected based on inclusion and exclusion criteria, including 166 (37.6%) pre-CONSORT articles and 276 (62.4%) post-CONSORT articles (Fig. 1).

Significantly more articles from the post-CONSORT period were retained after this review ($df = 6$, $\chi^2 = 37.1$, $p < .0001$). These articles were from American Journal of Psychiatry (168, 38.0%), Archives of General Psychiatry (109, 24.7%), JAMA (64, 14.48%), Biological Psychiatry (43, 9.7%), British Medical

Table 1
Comparison of positive responses to each item of the CONSORT checklist

Checklist items	Description	Pre-CONSORT (%)	Post-CONSORT (%)	*df*	χ^2	p value
1	[Title & Abstract] How participants were allocated to interventions	162(97.6)	272(98.6)	1	0.54	0.46
2	[Introduction Background] Scientific background and explanation of rationale	160(96.4)	276(100)	1	10.1	**0.002**
3	[Methods Participants] Eligibility criteria for participants and the settings and locations where the data were collected	163(98.2)	272(98.6)	1	0.09	0.77
4	[Interventions] Precise details of the interventions intended for each group and how and when they were actually administered	158(95.2)	270(97.8)	1	2.37	0.12
5	[Objectives] Specific objectives and hypotheses	154(92.8)	276(100)	1	20.51	<**.0001**
6	[Outcomes] Clearly defined primary and secondary outcome measures and, when applicable, any methods used to enhance the quality of measurements	56(33.7)	206(74.6)	1	71.84	<**.0001**
7	[Sample size] How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules	66(39.8)	77(27.9)	1	6.66	**0.01**
8	[Randomization — Sequence generation] Method used to generate the random allocation sequence, including details of any restrictions	42(25.3)	183(66.30)	1	69.7	<**.0001**
9	[Randomization —Allocation concealment] Method used to implement the random allocation sequence, clarifying whether the sequence was concealed until interventions were assigned	24(14.5)	123(44.6)	1	42.33	<**.0001**
10	[Randomization -Implementation] Who generated the allocation sequence, who enrolled participants, and who assigned participants to their groups	10(6.0)	84(30.4)	1	36.89	<**.0001**
11	[Blinding (masking)] Whether or not participants, those administering the interventions, and those assessing the outcomes were blinded to group assignment. If done, how the success of blinding was evaluated	108(65.1)	98(35.5)	1	36.38	<**.0001**
12	[Statistical methods] Statistical methods used to compare groups for primary outcome(s); methods for additional analyses, such as subgroup analyses and adjusted analyses	154(92.8)	272(98.6)	1	9.92	**0.002**
13	[Results Participant flow] Flow of participants through each stage (a diagram is strongly recommended)	93(56.0)	203(73.6)	1	14.39	**0.0001**
14	[Recruitment] Dates defining the periods of recruitment and follow-up	23(13.9)	182(65.9)	1	113.1	<**.0001**
15	[Baseline data] Baseline demographic and clinical characteristics of each group	111(66.9)	264(95.7)	1	66.78	<**.0001**
16	[Numbers analyzed] Number of participants (denominator) in each group included in each analysis and whether the analysis was by "intention-to-treat". State the results in absolute numbers when feasible	81(48.8)	259(93.8)	1	118.48	<**.0001**
17	[Outcomes and estimation] For each primary and secondary outcome, a summary of results for each group, and the estimated effect size and its precision	80(48.2)	223(80.8)	1	51.11	<**.0001**
18	[Ancillary analyses] Address multiplicity by reporting any other analyses performed, including subgroup analyses and adjusted analyses, indicating those pre-specified and those exploratory	44(26.7)	253(92.0)	1	200.65	<**.0001**
19	[Adverse events] All important adverse events or side effects in each intervention group	82(50.3)	193(69.9)	1	16.86	<**.0001**
20	[Discussion Interpretation] Interpretation of the results, taking into account study hypotheses, sources of potential bias or imprecision and the dangers associated with multiplicity of analyses and outcomes.	164(98.8)	276(100)	1	3.34	0.07
21	[Generalizability] Generalizability (external validity) of the trial findings	92(55.4)	270(97.8)	1	125.74	<**.0001**
22	[Overall evidence] General interpretation of the results in the context of current evidence	114(68.7)	276(100)	1	97.99	<**.0001**

Table 2
Comparison of CONSORT index between pre-CONSORT and post-CONSORT articles*

	N	Mean	SD	95%CI	df	t value	p
Pre-CONSORT	166	12.9	2.9	12.4 to 13.3			
Post-CONSORT	276	17.4	2.6	17.1 to 17.7			
Difference		−4.5	2.7	−5.0 to −4.0	313	−16.43	<.0001

*CONSORT index was defined as the sum of scores of 22 items of the CONSORT checklist (range 0–22).

Journal (25, 5.7%), Lancet (19, 4.3%), and New England Journal of Medicine (14, 3.2%).

The mean numbers of randomized subjects in each of the included studies in the pre-CONSORT and post-CONSORT periods were 130.4 (range 102–353) and 484.7 (range 103–326), respectively. Mean numbers of participating study sites in each of the included studies were 2.8 (range 1–33) and 12.2 (range 1–128), respectively.

3.2. Adherence to CONSORT checklist

Among the 166 pre-CONSORT studies, zero (0%) met 100%, 18 (11%) met 75–99%, 113 (68%) met 50–74%, 34 (21%) met 25–49%, and 1 (0.1%) met less than 25% of checklist items. In contrast, among the 276 post-CONSORT articles, 12 (4%) met 100%, 156 (56%) met 75–99%, 108 (39%) met 50–74%, and 1 (0.4%) study met 25–49% of checklist items. The percentage of pre and post CONSORT publications adhering to each individual checklist items appears in Table 1.

The CONSORT Index (sum of the 22 items of the checklist) during the post-CONSORT period was significantly higher than during the pre-CONSORT period (df=313, t=−16.43, p<.0001) (Table 2).

In the two-way ANOVA, there was an interaction between the pre/post CONSORT period and journal. AGP, AJP, and the Lancet showed significant higher LSMEAN compared with other journals (Table 3). However, the difference of CONSORT index was not significantly affected by intervention in the two-way ANOVA (Table 4).

3.3. Description of randomization and blinding

Before the CONSORT statement, the random sequence generation (checklist item 8) was described in 25.3% (42/166) of studies, which increased to 66.3% (183/276) after the statement (df=1, χ^2=69.7, p<.0001). Description of allocation concealment (item 9) increased from 14.5% (24/166) to 44.6% (123/276) after the statement (df=1, χ^2=42.33, p<.0001). Description of implementation (item 10) also increased from 6.0% (10/166) to 30.4% (84/276) after the statement (df=1, χ^2=36.89, p<.0001). However, more than 40% of post-CONSORT studies did not adequately describe the process of randomization (66.3% on item 8 and 44.6% on item 9). Of note, adherence to the CONSORT checklist item 11 (description of blinding–masking) significantly decreased from 65.1% (108/166) to 35.5% (98/276) after the statement (df=1, χ^2=36.38, p<.0001).

Table 3
Comparison of LSMEAN of CONSORT index between pre-CONSORT and post-CONSORT articles according to the journal

Journal	Consort index LSMEAN pre-CONSORT	Consort index LSMEAN post-CONSORT	p
AGP	13.7	16.8	**<.0001**
AJP	11.5	17.1	**<.0001**
BMJ	16.8	20.1	**0.05**
BP	12.3	15.7	**0.06**
JAMA	16.5	18.5	**0.28**
Lancet	13.5	20.4	**<.0001**
NEJM	15.0	18.2	**0.55**

Table 4
Results of the 2-way ANOVA analysis of time period and intervention type

Source	df	Type III SS	Mean square	F	p
Pre/post CONSORT	1	1431.6	1431.6	200.49	<.0001
Intervention type	3	79.6	26.5	3.72	0.0116
Interaction	3	17.0	5.7	0.79	0.4983

3.4. Description of informed consent acquisition

The response to the additional two items we added about reporting of the informed consent process is presented in Table 5. Although the proportion of publications not reporting the source of informed consent was significantly decreased in the post-CONSORT period, reporting of the details of the informed consent process was not improved post-CONSORT.

4. Discussion

In this study, RCTs published post-CONSORT (2002–2007) showed higher adherence to the CONSORT statement and consequently demonstrated more thorough reporting. Additionally, descriptions of the randomization process (sequence generation, allocation concealment, and implementation) were significantly improved after the CONSORT statement. The current study is consistent with previous studies indicating that the quality of reporting has generally improved after publication of the CONSORT statement [7,19]. It is reasonable to conclude that CONSORT guidelines are generally doing well as a 'scientific superego' for clinical researchers in reporting their trial results.

One relative success of CONSORT is in the area of reporting of allocation concealment. Allocation of subjects in most RCTs is performed using randomization, which serves to equalize the various known and unforeseen characteristics of

Table 5
Comparison of responses to items on informed consent process

Items	Responses	Pre-CONSORT N (%)	Post-CONSORT N (%)	df	χ^2	p
From whom did they get consent?	Not described	34(20.9)	10(3.7)			
	From subjects	122(74.9)	235(86.4)			
	From family	3(1.8)	10(3.7)			
	From both	4(2.5)	17(6.3)	3	35.6	<.0001
Whether the procedures were described in detail	No	126(77.8)	229(83.9)			
	Yes	36(22.2)	44(16.1)	1	2.52	0.11

treatment and control groups thereby reducing selection bias. However, the random allocation sequence should also be concealed to personnel responsible for subject enrollment to avoid the selective assignment of patients [23]. In our study, the percentage of publications failing to adequately report a clear description of allocation concealment decreased from 85.5% to 55.4% after the CONSORT statement. This is of importance considering lack of description of allocation concealment in published RCTs has been linked to inflation of treatment effects [6,24,25]. A previous survey study conducted by the CONSORT group found that 44–94% of published RCTs fail to clearly describe allocation concealment, and a cohort study by Pildal et al. demonstrated that unclear reporting of allocation concealment is usually accompanied by inadequate allocation concealment in the study methodology [26].

Our study also identified reporting areas that continue to be deficient post-CONSORT. It is important to note that despite the measurable improvement in reporting, more than 40% of post-CONSORT papers still did not adhere to CONSORT guidelines for describing the randomization process, and inadequate reporting of blinding–masking was actually more frequent after the CONSORT statement. Additionally, the CONSORT statement failed to induce more detailed descriptions of the process for obtaining informed consent.

It is unclear whether such deficits in reporting are indicative of inadequacies of trial design and conduct or simply inadequate reporting in either instance these deficiencies compromise the transparency in reporting. Although funding and reviewing organization and institutional review boards (IRBs) evaluate the appropriateness of randomization procedures, it is possible that clinical researchers are not paying sufficient attention to the integrity of randomization process during the conduct of the trial. There is likely a role for centralized, independent organizations in random sequence generation and concealment [27], although the ultimate responsibility of maintaining allocation concealment and blinding to the end of the study must lie with the clinical researchers themselves. Of concern is the fact that the success of blinding is rarely tested in clinical trials. An exhaustive analysis of the Central Cochrane Register of Controlled Clinical Trials found that only 2% of trials reported tests of successful blinding and it was successful in only 45% of trials [28].

Another contributing factor to deficient reporting may be limitations in manuscript length imposed by publishing journals. Such limitations may induce authors to shorten or abbreviate descriptions of randomization, blinding, and informed consent acquisition. Although authors must adhere to length limitations in order to successfully publish manuscripts, we encourage them to adhere to the CONSORT statement since complete descriptions of randomization and blinding are crucial elements for the evaluation of validity and reliability by readers. Description about the process of informed consent acquisition is also important for the audience to be assured the research was conducted ethically and responsibly. In this study, we judged “whether the informed consent process was described in detail or not.” We recognize the limitation inherent in this categorical distinction, and accept that the use of a more specific guideline for assessing quality of reporting of informed consent process, such as the Jadad scale, might provide better data.

It is worth noting that despite 40% of post-CONSORT articles failing to adequately describing randomization or blinding, they passed the reviewers' muster to be published in high-quality journals.

The principal limitation is that the studies were extracted from seven journals and therefore they may not be representative of the entire body of published psychiatric RCTs. For example, journals differ in terms of manuscript length restrictions, which as described may impact reporting quality. Second, we should consider that some journals have more restrictions than others in terms of things like word length. These restrictions might be related with less detailed description of eligibility criteria, process of consent acquisition, and blinding methods. Third, it is possible that even those published post-CONSORT were initiated prior to the implementations of the CONSORT guidelines, which in turn may affect reporting within CONSORT guidelines. It would be helpful include the year of study start as a factor in the analysis. Finally, effects of the endorsement by each journal should be examined with caution. Recently, Folkes et al. reported that reportings of the full CONSORT data remain inconsistent [22]. In the present study, the effects of the journal could make the results less clear despite the quality of all seven journals that showed improvement after the CONSORT.

The strengths of this study include 1) we attempted to review all psychiatric RCTs published in seven high impact medical journals; 2) we rigorously reviewed and rated the quality of the trial reports based on a previously established guideline — the revised CONSORT statement; and 3) we included sufficiently large time periods before and after publication of CONSORT and the revised CONSORT statement to compare the impact of the CONSORT statement on reporting (2002–2007).

Based on the findings of the current study, we recommend authors as well as reviewers should be required to consistently adhere to the CONSORT guidelines for publication of RCTs. Greater editorial oversight may be necessary to facilitate utilization of CONSORT guidelines given the continued high rate of deficits in the reporting of randomization, blinding (particularly evaluation of the success of blinding), and the process for obtaining informed consent. This is particularly relevant since a further revision of the CONSORT statement is underway.

Disclosure

Dr. Patkar is a consultant for Bristol-Myers Squibb, GlaxoSmithKline. Dr. Masand is a consultant for Bristol-Myers Squibb Company, Eli Lilly and Company, Janssen Pharmaceutica, Organon, Pfizer, Inc., and is on the speaker's bureau of Bristol Myers Squibb Company, Janssen Pharmaceutica, Pfizer Inc., and Wyeth Pharmaceuticals. Dr. Pae has received research support from GlaxoSmithKline. Dr. Marks receives research support from Johnson & Johnson, Merck, and the National Institutes of Health, and is on the speakers' bureau of Eli Lilly and Company and Pfizer. Dr. Wu has received research support from the National Institutes of Health (HSN271200522071C, DA019623, and DA019901).

Acknowledgement

We thank to Dr. Clement Oguejio for his efforts in screening of papers for this study.

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