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Original Article

Adherence to the CONSORT Statement in the Reporting of Randomized Controlled Trials on Pharmacological Interventions Published in Iranian Medical Journals

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Abstract

Background: Among manuscripts submitted to biomedical journals, randomized controlled trials (RCTs) form the backbone of evidence-based medicine. Hence, their protocol should be designed rigorously and their results should be reported clearly. To improve the quality of RCT reporting, researchers developed the CONSORT Statement in 1996 and updated it in 2010. This study was designed to assess the quality of RCT reporting vis-à-vis adherence to CONSORT among articles published in Iranian medical journals (English, Persian, CONSORT-endorsing, and non-CONSORT-endorsing).

Methods: In this cross-sectional study, all RCTs published in all Iranian medical journals from September 2012 to September 2013 were retrieved to evaluate their adherence to CONSORT. The journals' instructions for authors were also reviewed to find out whether or not they endorsed CONSORT. The CONSORT 2010 Checklist was used. Microsoft Excel 2007 was applied to analyze the data, and MedCalc was employed to compare the groups.

Results: Totally, 492 pharmacological RCTs that met our inclusion criteria were identified. Twenty-five items were reported in fewer than 50% of the articles. The differences between the articles published in Persian and English language journals were statistically significant in 17 items. The differences between the articles published in the CONSORT-endorsing and non-CONSORT-endorsing journals were significant in 8 items.

Conclusion: Our findings showed very weak adherence to CONSORT. Authors, reviewers, and editors should be trained to use standards expressed by the CONSORT Group in reporting RCTs.

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Keywords ● Randomized controlled trial ● Checklist ● Guideline adherence ● CONSORT ● Journal article ●Standards

What's Known

- Randomized controlled trials (RCTs) are the backbone of evidence-based medicine. All RCT reports should adhere to the standard checklist of CONSORT.

What's New

- Adherence to CONSORT among RCTs published in Iranian medical journals (in English and Persian) was not sufficient.
- Articles published in the CONSORT-endorsing and non-CONSORT-endorsing journals did not adhere adequately to CONSORT.

Introduction

Many manuscripts with various methodologies are submitted to biomedical journals annually. Among such manuscripts, randomized controlled trials (RCTs) are the backbone of evidence-based medicine. According to Bastian and colleagues,[1] the number of RCTs is on the increase. Hence, their protocols

should be designed meticulously and their results should be reported clearly.

To improve the quality of RCT reporting, a group of methodologists, epidemiologists, statisticians, and researchers developed the Consolidated Standards of Reporting Trials (CONSORT) Statement in 1996,[2] which was updated in 2001[3] and then in 2010.[4]

According to previous studies, the adherence of RCTs to the CONSORT Checklist was not sufficient.[5-8] Indeed, although there have been few reports on the quality of pharmacological RCTs published in Iranian medical journals so far, all of them have reported poor adherence to the CONSORT Statement.[9-11] Given the rise in the number of articles published in Iran,[12,13] we aimed to evaluate the extent of adherence to the CONSORT Statement in pharmacological RCTs published in Iranian medical journals from September 2012 to September 2013. We also sought to address the fact that there were no reports on the comparison of adherence to CONSORT between articles in English and in Persian.

On the other hand, some researchers have reported that adherence to CONSORT 2010 among CONSORT-endorsing journals is more sufficient than that among other journals.[5,14-18] Therefore, we decided to assess adherence to CONSORT 2010 among articles published in Iranian CONSORT-endorsing medical journals in the mentioned period.

Materials and Methods

In this cross-sectional study, we analyzed the content of all published articles in all Iranian medical journals ranked as "scientific" by the Iranian Commission for Accreditation of Medical Journals, affiliated to the Iranian Ministry of Health and Medical Education from September 2012 to September 2013. Three out of 296 journals were excluded because their publishing date was not within this period, they had no accurate contact information, or they lacked an active website. One hundred twenty-three journals contained pharmacological RCTs. The title of each journal was searched via Google, Yahoo, Bing, and Web Search to retrieve articles meeting our inclusion criteria from the journal sites. Out of 14,964 articles published in the journals, 493 reported pharmacological interventions.

All RCTs with pharmacological interventions were selected based on the study design described in the method section of the articles, although the authors might have mistakenly described their studies as experimental, semi-experimental, quasi-experimental, interventional, case control, or even cohort studies. Some articles that mentioned no specific design were included if their study method was compatible with RCTs.

Non-randomized, community, crossover, field, non-human, and before-after trials were excluded.

In 44 articles, a pharmacological intervention was compared with a non-pharmacological or herbal intervention. Fourteen of these articles whose authors aimed to evaluate the efficacy of pharmacological interventions were included. Of all the pharmacological RCTs, 213 articles were written in the English language and 280 in the Persian language.

Additionally, the instructions for authors specified by all the mentioned journals were reviewed to determine whether or not they demanded implementation of the CONSORT Statement. Of 123 journals publishing pharmacological articles, 12 were CONSORT-endorsing; all of them were in the English language.

The CONSORT Statement 2010 was downloaded from www.CONSORT-statement.org.[4] The original CONSORT Checklist has 25 items. Considering that some items consisted of several sections, we subdivided them to assess the RCTs more accurately. Accordingly, a checklist with 51 items was prepared and the articles were evaluated on the basis of whether or not they reported the items existing in the checklist.

Microsoft Excel 2007 was employed to enter and analyze the data. A score of 1 was allocated to the items reported and a score of 0 to those not reported. In case of the non-applicability of an item for reporting, the related cell in the software was only highlighted.

The frequencies and the percentiles for all the reported, not reported, and non-applicable items were calculated. The procedure was thereafter repeated for the English and Persian language articles and those published in the CONSORT-endorsing and non-CONSORT-endorsing journals.

The χ^2 test was applied to compare the proportions of each item between the English and Persian language articles and between those published in the CONSORT-endorsing and non-CONSORT-endorsing journals. MedCalc (version 8.0.0.0, MedCalc Software, Belgium) was used for these comparisons. A P value less than 0.05 was considered statistically significant.

The confidentiality of the authors and journals was taken into consideration.

Results

In the mentioned period, 493 pharmacological RCTs were published in Iranian medical journals. The adherence of the above-mentioned articles to CONSORT 2010 is shown in table 1. Twenty-five items were reported in fewer than 50% of the articles. Scientific background was reported in all the articles, and none of them declared where the full trial protocol could be accessed. Most of the underreported items were related to the method and the result parts of the checklist.

Table 1: Adherence to the CONSORT 2010 checklist among the evaluated pharmacological randomized controlled trials

	Items	Checklist items	n (%)		
			Reported (n=493)	Not reported	Not applicable
1a	1	Identification as a randomized trial in the title	117 (23.73)	376 (76.27)	0
1b	2	Structured summary of the trial design, methods, results, and conclusions	480 (97.36)	13 (2.64)	0
2a	3	Scientific background and explanation of rationale	493 (100)	0	0
2b	4	Specific objectives or hypotheses	483 (97.97)	10 (2.03)	0
3a	5	Description of the trial design (e.g., parallel and factorial)	491 (99.59)	2 (0.41)	0
	6	Allocation ratio	15 (3.04)	478 (96.96)	0
3b	7	Important changes to the methods after trial commencement (e.g., eligibility criteria), with reasons	0	0	493 (100)
4a	8	Eligibility criteria for the participants	491 (99.59)	2 (0.41)	0
4b	9	Settings and locations where the data were collected	419 (84.99)	74 (15.01)	0
5	10	Interventions for each group with sufficient details to allow replication, including how and when they were actually administered	490 (99.39)	3 (0.61)	0
6a	11	Completely defined pre-specified primary outcome measures	48 (9.74)	445 (90.26)	0
	12	Completely defined pre-specified secondary outcome measures	38 (7.71)	455 (92.29)	0
	13	How and when they were assessed	487 (98.78)	6 (1.22)	0
6b	14	Any changes to the trial outcomes after the trial commenced, with reasons	1 (0.20)	0	492 (99.80)
7a	15	How the sample size was determined	167 (33.87)	326 (66.13)	0
7b	16	When applicable, explanation of any interim analyses and stopping guidelines	1 (0.20)	0	492 (99.80)
8a	17	Method used to generate the random allocation sequence	174 (35.29)	319 (64.71)	0
8b	18	Type of randomization and details of any restriction (e.g., blocking and block size)	64 (12.98)	429 (87.02)	0
9	19	Mechanism used to implement the random allocation sequence (e.g., sequentially numbered containers) and describing any steps taken to conceal the sequence until interventions were assigned	64 (12.98)	319 (64.71)	0
10	20	Who generated the random allocation sequence	13 (2.64)	480 (97.36)	0
	21	Who enrolled the participants	4 (0.81)	489 (99.19)	0
	22	Who assigned the participants to interventions	16 (3.25)	477 (96.75)	0
11a	23	If done, who was blinded after assignment to interventions (e.g., participants, care providers, and those assessing the outcomes) and how	285 (57.81)	208 (42.19)	0
11b	24	If relevant, description of the similarity of the interventions	404 (81.95)	49 (9.94)	40 (8.11)
12a	25	Statistical methods used to compare the groups for the primary and secondary outcomes	484 (98.17)	9 (1.83)	0
12b	26	Methods for additional analyses such as subgroup analyses and adjusted analyses	137 (27.79)	356 (72.21)	0
13a	27	For each group, the number of the participants who were randomly assigned	473 (95.94)	4 (4.06)	0
	28	For each group, the number of the participants who received the intended treatment	289 (58.62)	204 (41.38)	0
	29	For each group, the number of the participants who completed the study protocol	142 (28.80)	351 (71.20)	0

(*Contd*...)

Table 1: (Continued)

	Items	Checklist items	n (%)		
			Reported (n=493)	Not reported	Not applicable
13a	30	For each group, the number of the participants who were analyzed for the primary outcome	179 (36.31)	314 (63.69)	0
13b	31	For each group, losses and exclusions after randomization together with reasons	192 (38.96)	301 (61.05)	0
14a	32	Dates defining the periods of recruitment	286 (58.01)	207 (41.99)	0
	33	Dates defining the periods of follow-up	476 (96.55)	17 (3.45)	0
14b	34	Why the trial ended or was stopped	1 (0.20)	0	492 (99.80)
15	35	A table showing baseline demographic and clinical characteristics for each group	304 (61.66)	189 (38.34)	0
16	36	Flow diagram	74 (15.01)	419 (84.99)	0
17a	37	For each group, the number of the participants (denominator) included in each analysis and whether the analysis was by the original assigned groups	162 (32.86)	331 (67.14)	0
	38	For each primary and secondary outcome, results for each group	491 (99.59)	2 (0.41)	0
	39	Estimated effect size	3 (0.61)	490 (99.39)	0
	40	Its precision (e.g., 95% confidence interval)	42 (8.52)	451 (91.48)	0
17b	41	For binary outcomes, presentation of absolute effect sizes	2 (0.41)	39 (7.91)	452 (91.68)
17b	42	For binary outcomes, presentation of relative effect sizes	15 (3.04)	26 (5.27)	452 (91.68)
18	43	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	99 (20.08)	394 (79.92)	0
19	44	All important harms or unintended effects in each group	285 (57.81)	208 (42.19)	0
20	45	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	214 (43.41)	279 (56.59)	0
21	46	Generalizability (external validity and applicability) of the trial findings	239 (48.48)	204 (41.38)	50 (10.14)
22	47	Interpretation consistent with the results, balancing benefits and harms, and considering other relevant evidence	490 (99.39)	3 (0.61)	0
23	48	Registration number	196 (39.76)	297 (60.24)	0
	49	Name of the trial registry	154 (31.24)	339 (68.76)	0
24	50	Where the full trial protocol can be accessed, if available	0	493 (100)	0
25	51	Sources of funding and other support (such as supply of drugs) and the role of the funders	174 (35.29)	319 (64.71)	0

Eleven articles only reported the setting of the study and the locations were not reported; of them 6 were in the Persian language and 5 in the English language. In 2 articles, no description was available for the second arm of the trial (1 in the English language and 1 in the Persian language articles).

A clear “hypothesis” was mentioned in only 24 articles (4 in the Persian language and 20 in the English language articles).

Table 2 compares the items of non-adherence between the Persian and English language articles. The differences between the 2 groups were statistically significant in 17 items.

Thirty-two articles were published in CONSORT-endorsing journals. Table 3 compares the items of non-adherence between the CONSORT-endorsing and non-CONSORT-endorsing journals. The differences between these 2 groups of journals were significant just in 8 items.

Discussion

In the present study, we drew upon CONSORT 2010 to evaluate pharmacological RCTs with respect to their adherence to all the 51 items of the checklist. We found that the evaluated articles could have adhered more to CONSORT 2010 had they been conducted more meticulously. Using a CONSORT 2010 Checklist with 37 items, Nojomi and colleagues[10] assessed the quality of reporting in RCTs published in Iranian medical journals from 2008 to 2010 and reported poor adherence among the articles; this finding chimes in with the results of our study. Nevertheless, there are differences between their study and ours. First, they used

Table 2: (Continued)

	Items	Checklist items	Not reported n(%)		P value (confidence interval)*
			Persian articles (n=280)	English articles (n=213)	
1a	1	Identification as a randomized trial in the title	240 (85.71)	136 (63.85)	<0.0001 (14.22-29.50)
1b	2	Structured summary of the trial design, methods, results, and conclusions	0	13 (6.10)	0.0001 (2.89-9.32)
2a	3	Scientific background and explanation of rationale	0	0	—
2b	4	Specific objectives or hypotheses	7 (2.50)	3 (1.41)	0.59 (-1.32-3.51)
3a	5	Description of the trial design (e.g., parallel and factorial)	1 (0.36)	1 (0.47)	0.60 (-1.41-1.27)
	6	Allocation ratio	277 (98.93)	201 (94.37)	0.0079 (1.23-7.88)
3b	7	Important changes to the methods after trial commencement (e.g., eligibility criteria), with reasons	0	0	—
4a	8	Eligibility criteria for the participants	2 (0.71)	0	0.60 (-0.27-1.69)
4b	9	Settings and locations where the data were collected	39 (13.93)	35 (16.43)	0.52 (-3.91-8.92)
5	10	Interventions for each group with sufficient details to allow replication, including how and when they were actually administered	2 (0.71)	1 (0.47)	0.81 (-1.10-1.59)
6a	11	Completely defined pre-specified primary outcome measures	270 (96.43)	175 (82.16)	<0.0001 (8.68-19.85)
	12	Completely defined pre-specified secondary outcome measures	270 (96.43)	185 (86.85)	0.0002 (4.54-14.61)
	13	How and when they were assessed	3 (1.07)	3 (1.41)	0.93 (-1.65-2.32)
6b	14	Any changes to the trial outcomes after the trial commenced, with reasons	0	0	—
7a	15	How the sample size was determined	185 (66.07)	141 (66.20)	0.94 (-8.30-8.55)
7b	16	When applicable, explanation of any interim analyses and stopping guidelines	0	0	—
8a	17	Method used to generate the random allocation sequence	190 (67.86)	129 (60.56)	0.11 (-1.24-15.84)
8b	18	Type of randomization and details of any restriction (e.g., blocking and block size)	250 (89.29)	179 (89.04)	0.11 (-0.86-11.35)
9	19	Mechanism used to implement the random allocation sequence (e.g., sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	256 (91.43)	173 (81.22)	0.0013 (4.02-16.39)
10	20	Who generated the random allocation sequence	276 (98.57)	204 (95.77)	0.10 (-0.24-5.83)
	21	Who enrolled the participants	279 (99.64)	210 (98.59)	0.43 (-0.67-2.78)
	22	Who assigned the participants to interventions	269 (96.07)	208 (97.65)	0.46 (-1.47-4.63)
11a	23	If done, who was blinded after assignment to interventions (e.g., participants, care providers, and those assessing the outcomes) and how	118 (42.14)	90 (42.25)	0.94 (-8.69-8.91)
11b	24	If relevant, description of the similarity of interventions	20 (7.14)	28 (13.16)	0.03 (0.55-11.44)
12a	25	Statistical methods used to compare the groups for the primary and secondary outcomes	8 (2.86)	1 (0.47)	0.10 (0.23-4.54)
12b	26	Methods for additional analyses such as subgroup analyses and adjusted analyses	208 (74.26)	148 (69.48)	0.28 (-3.22-12.82)

(*Contd...*)

Table 2: (Continued)

	Items	Checklist items	Not reported n(%)		P value (confidence interval)*
			Persian articles (n=280)	English articles (n=213)	
13a	27	For each group, the number of the participants who were randomly assigned	12 (4.29)	8 (3.76)	0.94 (-2.99-4.01)
	28	For each group, the number of the participants who received the intended treatment	159 (56.79)	45 (21.13)	<0.0001 (27.67-43.63)
	29	For each group, the number of the participants who completed the study protocol	222 (79.29)	129 (60.56)	<0.0001 (10.62-26.82)
13a	30	For each group, the number of the participants who were analyzed for the primary outcome	113 (53.05)	201 (71.79)	<0.0001 (10.20-27.25)
13b	31	For each group, losses and exclusions after randomization, together with reasons	192 (68.57)	109 (51.17)	0.0001 (8.76-26.03)
14a	32	Dates defining the periods of recruitment	76 (35.68)	131 (46.79)	0.01 (2.40-19.79)
	33	Dates defining the periods of follow-up	8 (2.86)	9 (4.23)	0.56 (-14.96-4.69)
14b	34	Why the trial ended or was stopped	0	0	—
15	35	A table showing baseline demographic and clinical characteristics for each group	127 (45.36)	62 (29.11)	0.0003 (7.81-24.68)
16	36	Flow diagram	268 (95.71)	151 (70.89)	<.0001 (18.27-31.36)
17a	37	For each group, number of the participants (denominator) included in each analysis and whether the analysis was by the original assigned groups	75 (75.71)	119 (55.87)	<.0001 (11.52-28.22)
	38	For each primary and secondary outcome, results for each group	1 (0.36)	1 (0.36)	0.60 (-1.41-1.26)
	39	Estimated effect size	279 (99.64)	211 (99.06)	0.81 (-0.89-2.05)
	40	Its precision (e.g., 95% confidence interval)	257 (91.76)	194 (91.07)	0.90 (-4.29-5.70)
17b	41	For binary outcomes, presentation of absolute effect sizes	16 (5.71)	21 (9.86)	0.11 (-0.69-8.98)
17b	42	For binary outcomes, presentation of relative effect sizes	9 (3.21)	15 (7.04)	0.08 (-0.18-7.83)
18	43	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	230 (82.14)	164 (77.00)	0.19 (-2.69-12.36)
19	44	All important harms or unintended effects in each group	134 (47.86)	74 (34.74)	0.0047 (4.44-21.78)
20	45	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	174 (62.14)	105 (49.30)	0.0058 (4.05-21.64)
21	46	Generalizability (external validity and applicability) of the trial findings	117 (41.79)	87 (40.85)	0.90 (-7.83-9.71)
22	47	Interpretation consistent with the results, balancing benefits and harms, and considering other relevant evidence	1 (0.36)	2 (0.94)	0.81 (-0.89-2.05)
23	48	Registration number	163 (58.21)	134 (62.91)	0.33 (-3.98-13.38)
	49	Name of the trial registry	189 (67.50)	150 (70.42)	0.55 (-5.30-11.14)
24	50	Where the full trial protocol can be accessed, if available	280 (100)	213 (100)	—
25	51	Sources of funding and other support (e.g., supply of drugs) and the role of the funders	188 (67.14)	131 (61.50)	0.22 (-5.30-11.14)

*χ^2 test

CONSORT 2010 to assess the articles published in the preceding years, which may have affected the results. Second, they evaluated adherence to 37 items, while we checked all the 51 items, aiming to increase the accuracy of the study findings. Third, whereas they used CONSORT 2010 for all types of RCTs, we categorized RCTs to pharmacological, non-pharmacological, and

Table 3: Comparison of the items of non-adherence to the CONSORT 2010 checklist between the evaluated pharmacological randomized controlled trials (RCTs) published in the CONSORT-endorsing and non-CONSORT-endorsing journal

	Items	Checklist items	Not reported n (%)		P value (confidence interval)*
			CONSORT-Endorsing (n=32)	Non-CONSORT-Endorsing (n=461)	
1a	1	Identification as a randomized trial in the title	22 (68.75)	354 (76.78)	0.41 (-8.47-24.55)
1b	2	Structured summary of the trial design, methods, results, and conclusions	0	13 (2.82)	0.69 (1.30-4.32)
2a	3	Scientific background and explanation of rationale	0	0	-
2b	4	Specific objectives or hypotheses	1 (3.12)	9 (1.95)	0.84 (-4.98-7.33)
3a	5	Description of the trial design (e.g., parallel and factorial)	1 (3.12)	1 (0.22)	0.28 (-3.13-8.95)
	6	Allocation ratio	29 (90.62)	449 (97.40)	0.10 (-3.43-16.97)
3b	7	Important changes to the methods after trial commencement (e.g., eligibility criteria), with reasons	0	0	-
4a	8	Eligibility criteria for the participants	0	2 (0.43)	0.28 (-0.16-1.03)
4b	9	Settings and locations where the data were collected	7 (21.87)	67 (14.53)	0.38 (-7.33-22.02)
5	10	Interventions for each group with sufficient details to allow replication, including how and when they were actually administered	0	3 (0.65)	0.47 (-0.08-1.38)
6a	11	Completely defined pre-specified primary outcome measures	25 (78.12)	420 (91.11)	0.03 (-1.57-27.53)
	12	Completely defined pre-specified secondary outcome measures	26 (81.25)	429 (93.06)	0.03 (-1.91-25.52)
	13	How and when they were assessed	1 (3.12)	5 (1.08)	0.85 (-4.06-8.14)
6b	14	Any changes to the trial outcomes after the trial commenced, with reasons	0	0	-
7a	15	How the sample size was determined	20 (62.05)	306 (66.38)	0.79 (-13.44-21.19)
7b	16	When applicable, explanation of any interim analyses and stopping guidelines	0	0	—
8a	17	Method used to generate the random allocation sequence	18 (26.25)	301 (65.21)	< 0.0001 (24.67--55.91)
8b	18	Type of randomization and details of any restriction (e.g., blocking and block size)	26 (81.25)	403 (87.42)	0.46 (-7.69-20.02)
9	19	Mechanism used to implement the random allocation sequence (e.g., sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	26 (81.25)	403 (87.42)	0.46 (-7.69-20.02)
10	20	Who generated the random allocation sequence	29 (90.62)	451 (97.83)	0.05 (-2.98-17.39)
	21	Who enrolled the participants	30 (93.75)	459 (99.57)	0.01 (-2.59-14.22)
	22	Who assigned the participants to interventions	30 (93.75)	447 (96.96)	0.63 (-5.31-11.74)
11a	23	If done, who was blinded after assignment to interventions (e.g., participants, care providers, and those assessing outcomes) and how	8 (25)	199 (43.17)	0.06 (2.49--33.83)
11b	24	If relevant, description of the similarity of interventions	4 (12.50)	45 (9.76)	0.84 (-9.03-14.51)
12a	25	Statistical methods used to compare the groups for primary and secondary outcomes	1 (3.12)	8 (1.74)	0.90 (-4.75-7.53)

(*Contd...*)

Table 3: Comparison of the items of non-adherence to the CONSORT 2010 checklist between the evaluated pharmacological randomized controlled trials (RCTs) published in the CONSORT-endorsing and non-CONSORT-endorsing journal

	Items	Checklist items	Not reported n (%)		P value (confidence interval)*
			CONSORT-Endorsing (n=32)	Non-CONSORT-Endorsing (n=461)	
12b	26	Methods for additional analyses such as subgroup analyses and adjusted analyses	22 (68.75)	334 (72.45)	0.80 (-12.86-20.27)
13a	27	For each group, the number of the participants who were randomly assigned	2 (6.25)	18 (3.90)	0.85 (-6.22-10.91)
	28	For each group, the number of the participants who received the intended treatment	6 (18.75)	198 (42.95)	0.01 (9.94-38.45)
	29	For each group, the number of the participants who completed the study protocol	22 (68.75)	329 (71.37)	0.90 (-13.96-19.19)
13a	30	For each group, the number of the participants who were analyzed for the primary outcome	17 (53.13)	297 (64.43)	0.27 (-6.53-29.13)
13b	31	For each group, losses and exclusions after randomization, together with reasons	17 (53.13)	284 (61.61)	0.44 (-9.37-26.33)
14a	32	Dates defining the periods of recruitment	13 (40.63)	194 (42.08)	0.98 (-16.14-19.06)
	33	Dates defining the periods of follow-up	1 (3.13)	16 (3.47)	0.69 (-5.91-6.60)
14b	34	Why the trial ended or was stopped	0	0	—
15	35	A table showing baseline demographic and clinical characteristics for each group	7 (21.87)	182 (39.48)	0.07 (2.60-32.60)
16	36	Flow diagram	22 (68.75)	397 (86.12)	0.01 (0.99-33.73)
17a	37	For each group, number of the participants (denominator) included in each analysis and whether the analysis was by original assigned groups	17 (53.12)	314 (68.11)	0.12 (-2.81-32.79)
	38	For each primary and secondary outcome, results for each group	0	2 (0.43)	0.28 (0.16-1.03)
	39	Estimated effect size	32 (100)	458 (99.40)	0.47 (-0.08-1.38)
	40	Its precision (e.g., 95% confidence interval)	29 (90.62)	422 (91.54)	0.88 (-9.49-11.32)
17b	41	For binary outcomes, presentation of absolute effect sizes	1 (3.12)	39 (8.46)	0.46 (-1.20-11.87)
17b	42	For binary outcomes, presentation of relative effect sizes	1 (3.12)	26 (5.64)	0.83 (-3.87-8.89)
18	43	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	26 (81.25)	368 (79.83)	0.97 (-12.58-15.43)
19	44	All important harms or unintended effects in each group	8 (25)	200 (43.39)	0.06 (2.71-34.05)
20	45	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	20 (62.50)	259 (56.18)	0.60 (-11.05--23.69)
21	46	Generalizability (external validity and applicability) of the trial findings	15 (46.87)	189 (40.99)	0.64 (-11.98-23.74)
22	47	Interpretation consistent with the results, balancing benefits and harms, and considering other relevant evidence	0	3 (0.65)	<0.0001 (95.81-101.58)

(*Contd*...)

Table 3: Comparison of the items of non-adherence to the CONSORT 2010 checklist between the evaluated pharmacological randomized controlled trials (RCTs) published in the CONSORT-endorsing and non-CONSORT-endorsing journal

	Items	Checklist items	Not reported n (%)		P value (confidence interval)*
			CONSORT-Endorsing (n=32)	Non-CONSORT-Endorsing (n=461)	
23	48	Registration number	18 (56.25)	279 (60.52)	0.77 (-13.48-22.02)
	49	Name of the trial registry	25 (78.12)	314 (68.11)	0.32 (-4.92--24.95)
24	50	Where the full trial protocol can be accessed, if available	32 (100)	461 (100)	—
25	51	Sources of funding and other support (e.g., supply of drugs) and the role of the funders	18 (56.25)	301 (65.29)	0.39 (-8.68-26.77)

*χ^2 test

herbal and devised specific subcategories for each type. In this study, pharmacological studies are reported and presented.

In another report from Iran, Ayatollahi et al.[9] focused on only 4 items of CONSORT in 25 Iranian medical journals. They reported no adherence to all those items in the assessed journals. Our study seems to be more comprehensive than the aforementioned ones because we surveyed all the items in all Iranian medical journals.

Hopewell and coworkers[19] compared adherence to the CONSORT 2001 Checklist between RCTs indexed in PubMed in 2000 and those indexed in 2006. They concluded that although several items were reported more frequently in 2006, in general the quality of reporting was not acceptable. This result is in line with our findings.

Mills and others[20] evaluated adherence to 12 items of the CONSORT 2001 Checklist in 193 published RCTs and reported poor adherence.

Ahmadzadeh and colleagues[21] randomly selected 50 RCTs published in 5 high-rank journals and used CONSORT 2010 to assess the quality of reporting of all kinds of RCTs. Likewise, Mills and others[7] evaluated adherence to only 7 methodological items of the CONSORT 2001 Statement among RCTs published in 5 journals with the highest impact factor. Elsewhere, Uetani et al.[5] in their study concluded that the RCTs published in Japanese Journals in early 2004 failed to adhere to CONSORT.

Smith and others[6] assessed the quality of reporting in 96 RCTs published in 4 nursing journals in 2006 via the CONSORT 2001 Checklist by subdividing some of the items of the checklist for better evaluation and constructing a 48-item checklist. They found that only 15 out of the 48 items were reported by more than 75% of the reviewed articles. Their method is somehow similar to ours insofar as they subdivided the items to reach more comprehensive findings. Their findings are more similar to ours as.

In another study from London, adherence to CONSORT 2010 among RCTs on solid organ transplantation published in the period between 2007 and 2009 was evaluated. The results demonstrated that adherence to the items was poor. In contrast to our study, the researchers excluded non-English language articles and did not subcategorize the RCTs using specific types of CONSORT.[8]

We compared adherence to the CONSORT 2010 Checklist between 280 Persian language articles and 213 English language articles and found that the differences between the 2 groups were statistically significant in 17 items. Most of these items were reported more frequently in the English language articles than in the Persian language ones. To the best of our knowledge, there are few studies comparing adherence to CONSORT between RCTs in the English language and other languages.[22,23] Junker[23] compared RCTs conducted in German and English. Because the publication years of the evaluated articles predated the development of the CONSORT Checklist, the researcher did not use the CONSORT Statement and concluded that there was no difference between these 2 groups of RCTs. Klassen and others[22] compared quality between English and non-English language (Danish, Dutch, French, German, Italian, Japanese, and Spanish) RCTs. They did not use CONSORT for the assessment because of the year of publication and arrived at the conclusion that the English language RCTs enjoyed better quality. We believe that using a structural guideline such as CONSORT to compare English language articles with non-English language ones may yield more accurate findings. This approach can be the strength of our study.

To our knowledge, since the development of the CONSORT Checklist, the present study is the first assessment and comparison of adherence to CONSORT between English and Persian RCTs. This is all but a truism that

English language articles should be reported with acceptable quality because they are meant to be published in journals with international readers. Indeed, such articles should endeavor to report accurate information for citation and use in meta-analyses. In our study, although some items were reported more frequently in the English language articles, most of the items did not adhere to the checklist. It would, therefore, be reasonable to suggest that Iranian medical editors pay heed to the CONSORT guidelines as an important tool that can boost the visibility of their published RCTs.

Having evaluated 493 pharmacological RCTs published in 296 Iranian medical journals during a 1-year period, we can claim that the current study boasts the largest sample size of all the studies hitherto conducted in this field. In previous similar studies, only 80 journals,[10] 25 journals,[9] 4 high-impact-factor pharmacological journals,[20] 4 high-rank journals,[24] 5 high-rank journals,[7,21] 71 Japanese journals,[5] and 20 RCTs published in the Journal of Cardiology[25] were evaluated. In light of the aforesaid studies, we can assert that another salient strong point of our study is the evaluation of a larger number of articles and journals.

Low adherence to the CONSORT Statement among the RCTs in our selected journals by comparison with those published in high-rank journals reported by Ahmadzadeh and colleagues,[21] Mills and others,[7] and Han et al.[26] can be explained by the fact that high-rank journals usually receive and select RCTs with the utmost quality.

A developing country with a considerable number of journals, Iran can be representative of other countries in the Eastern Mediterranean Region. Therefore, our findings propose poor adherence to CONSORT in published pharmacological RCTs can be generalized to other RCTs published in other regional countries. It is worth mentioning that the Iranian Ministry of Health and Medical Education attaches great significance to enhancing the quality of articles published in Iranian medical journals. The fact that despite such emphasis the quality of RCTs in our region falls short of the standards set by high-rank journals underscores the need for more rigorous supervision.

We did not calculate the average adherence of the evaluated RCTs compared with what Nojomi, Ahmadzadeh, and Han and others did.[10,21,26] We think that each item in the CONSORT Checklist carries a significant weight. For example, randomization, blinding, sample size determination, flow diagram, and registration number are important methodological items that can weigh differently in different studies; hence, reporting the whole score may not show the overall quality of the reported RCTs.

In the present study, we compared adherence between RCTs published in CONSORT-endorsing journals and those published in non-CONSORT-endorsing ones and found that the 2 groups were meaningfully different in terms of adherence in 8 items. All of the 8 items were reported more frequently in the articles published in the CONSORT-endorsing journals. Overall, adherence to the CONSORT 2010 Checklist was not sufficient in the 2 groups.

Pandis et al.[18] in their study concluded that the articles published in the period after the implementation of CONSORT reported more items. Miller and others[27] compared general medical journals and specialty journals that endorsed CONSORT and concluded that both groups failed to properly implement CONSORT in reporting trials. Turner and coworkers[17] compared RCTs published in CONSORT-endorsing journals with those published in non-CONSORT-endorsing journals and concluded that the former group might help authors to report more adherent RCTs, although it did not mean that the RCTs published in CONSORT-endorsing journals were reported sufficiently.

First and foremost among the strengths of the current study is that we assessed all the 25 items of the CONSORT Statement together with all their respective subcategories. Such comprehensive evaluation has not yet been done on the CONSORT guidelines. There are, nevertheless, some limitations in our study. When the websites of some journals were not available, we referred to www.magiran.com or www.sid.org. Whenever we found articles comparing drug interventions with herbal or non-pharmacological interventions we used a checklist suitable for the dominant intervention. Another drawback of note is that the low number of the articles published in CONSORT-endorsing journals may have affected the results of the comparisons.

Conclusion

Adherence to the CONSORT Statement among our selected RCTs, published in Persian and English in Iranian medical journals, was not sufficient. In addition, the articles published in both CONSORT-endorsing and non-CONSORT-endorsing journals failed to adhere to CONSORT adequately. We would recommend that authors, reviewers, and editors seek out further training in the proper implementation of the CONSORT statement and that editors be sure to endorse CONSORT in their instructions for authors and

monitor adherence to it. What would also be beneficial is the development of a checklist suitable for reporting pharmacological interventions comparing herbal, non-pharmacological, and acupunctural interventions.

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