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Randomized Controlled Trials and Consolidated Standards of Reporting Trials "Consort" 2010- 2019, Pakistan

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ABSTRACT

Background: Contrary to general practice, research transparency and reliability of published material is related to the Reporting Guidelines like endorsement of CONSORT Statement for reporting Randomized Controlled Trials. **Objective:** To assess the compliance of Randomized Control Trials (RCTs) with the Consolidated Standards of Reporting Trials (CONSORT) conducted and reported from Pakistan. **Study Design:** Systematic Review. **Settings:** NA. **Duration:** Six months after ethical clearance. **Methods:** Systematic Review with 781 RCTs published from 2010-2019 in 44 online Pakistani journals retrieved from PakMediNet. CONSORT checklist has been used to verify whether the items have been followed or not and if followed then to which extent by calculating Summation score drawn from the CONSORT checklist items by allotting mark for each item. Individual RCT suggests ≥70% adherence which is considered to have Adequate Compliance (AC). **Results:** The mean score achieved was 16.85/37 (45.54%). A statistically significant association was found between Funding and Adherence. The publications have increased over the years with only 15/781(1.9%) RCTs published in 2010 to 138/781(17.7%) in 2019 but the Adherence to the CONSORT remained almost the same with the mean overall yearly Adherence of 45.54 % of individual articles. **Conclusion:** The use of CONSORT statement has not significantly improved the reporting of trials due to inadequate adherence to guidelines, hence reinforcing use of statement for the reporting of trials. Nonetheless, statistically significant association of Funding and Adherence has supported Funding to achieve Adequate Compliance to CONSORT.

Keywords: *Research Transparency, Randomized Controlled Trials (RCTs), Consolidated Standards of Reporting Trials (CONSORT), Random Allocation and Interventional studies.*

INTRODUCTION

Research Transparency, one of the essential research characteristics stresses that researchers need to be transparent and reflexive about conduct, theoretical perspective and values.[1,2,3] Structured reporting reduces the incidence of reporting errors through complete, clear, and accurate communication guidelines and checklists having specific format for reporting.[4] Research performance problem or lack of transparency prevents inferential and results reproducibility by masking questionable research practices, falsified acts and serious mistakes.[5,6] These issues were the main concern for the EQUATOR guidelines developers with the aim to remove these problems by providing educators, authors and editor's specific advice and educational tools like CONSORT[7] (Consolidated Standards of Reporting Trials Statement),[8] a set of recommendations for the reporting of randomized trials with focus on items related to the external and internal validity of trials. It is used globally for improved and transparent reporting of randomized controlled trials (RCTs) the gold standard[9,10] in which people similar in all aspects are randomly allocated in two or more than two groups for testing a specific therapy, drug or intervention. The experimental group receives the intervention and the comparison or control

group receives alternative intervention, placebo or no intervention at all, then they are followed up to see the effects of the intervention. The Outcomes are calculated at defined time and any variation in response between the groups is calculated statistically.[11] Evidence that reporting quality of RCTs is not optimal due to systematic errors lacking transparent reporting[12] which is essential as readers base their initial assessment of a trial on such information.[13,14,15]

Rationale: The Consolidated Standards of Reporting Trials (CONSORT) statement is one of the Current Trial Evaluation Systems for evaluating trial quality and providing guidance for reporting clinical trials. According to international statistics, Pakistan recorded the second highest increase in research output across the globe in 2018.[16] With this rise in research publications, an increase in improvement in the quantity of RCTs is also anticipated. However, increase in research output may be because of incentives or pressures, which often leads to cutting corners at the cost of quality. There is no information about whether there has been any recent improvement in the reporting of RCTs according to Consolidated Standards Reporting Trials conducted and reported from Pakistan. So, this Study has been designed to assess the compliance of RCTs with CONSORT published from Pakistan. We will be able to assess that we have increased the quantity of research articles or we have also adopted guidelines and checklist items for ensuring transparency, validity, completeness of reporting, generalizability of outcomes of research for use by the clinicians and researchers with minimal Replicability and maximum Reproducibility of information.

Objective(s): To assess the compliance of completed RCTs with the (CONSORT) conducted and reported from Pakistan.

Specific Objectives: To determine the predictors of compliance of RCTs with the CONSORT published from Pakistan in terms of availability of funds, institutions, and foreign collaboration. To assess any overtime change in the compliance of completed RCTs according to CONSORT.

Operational Definitions:

1. RCTs: Quantitative, comparative, controlled experiments, whether funded or non-funded, performed locally or with foreign collaboration conducted by one or multiple institution in which people similar in all aspects are randomly allocated in two or more than two groups for testing a specific therapy, drug or intervention. The experimental group receives the intervention and the comparison or control group receives alternative intervention, placebo or no intervention at all, then they are followed up to see the effects of the intervention. The Outcomes are calculated at defined times and any variation in response between the groups is calculated statistically.

2. CONSORT: Consolidated Standards of Reporting Trials (CONSORT) statement, a checklist of information (25 items) to include when reporting a Randomized Trial.

3. Compliance: CONSORT checklist used to check whether the items were followed or not and if followed then to what extent by calculating Summation score drawn from the CONSORT checklist items by allotting mark for each item to calculate the Per cent overall adherence, Per cent adherence in checklist Categories. Reporting ≥ 70% of the items has been considered as adequate compliance to the CONSORT statement. AC (Adequate Compliance) = ≥ 70% and NAC (Not adequate Compliance= < 70%.

4. Predictors of Compliance include Funded RCTS (Had Sources of funding and other support such as supply of drugs or role of funder) or non-funded RCTs **(**Self-financed without any Sources of funding and other support such as supply of drugs or role of funder), institutions (single or more than one) and foreign collaboration available or not.

METHODS

This Systematic Review is built on Preferred Reporting Items for Systematic Reviews & Meta Analysis (PRISMA-P) Protocol 2015 statement after ethical clearance vide letter No.DIR/KMU-AS&RB/RC/001348. All the abstracts that identified the article as randomized in the title from 2010 till 2019 were included. All publications reporting RCTs where the allocation of participants to interventions was described by words random, randomly, randomized or randomization and cluster randomization in all disease areas and all types of interventions dealing with patients or volunteers were included but Economic analysis of Randomized Control Trials, Post-trial follow-up studies, Observational studies nested within RCTs, Trials published as abstracts only and Quasi experimental Trials were excluded. Reviewer reviewed all the available Journal abstracts on PakMediNet Database. The search strategy applied on December 31st 2019 to identify RCTs published in medical journals that meet the eligibility criteria and proceeded backwards in time and stopped the search for the January 1st 2010. CONSORT checklist was used to assess the compliance of RCTs according to this list. Data entry and analysis was done using SPSS version 23. CONSORT checklist used to check whether the items were followed or not and if followed then to what extent by calculating Summation score drawn from the CONSORT checklist items by allotting mark for each item to calculate the Per

cent overall adherence, Per cent adherence in checklist Categories. Guidelines followed or not assessed by using the Descriptor of the CONSORT checklist. The Abstract and introduction categories of Articles (RCTs) had two checklist items each with a score of 2 and one score for each item. Abstract had two descriptors for each of the checklist items while Introduction 2a checklist item had 4 descriptors while 2b had three Descriptors. Table 1a

Table 1a: RCT reporting rating using items from the CONSORT statement (n=781)

Area	List	CONSORT Checklist items	Descriptor of the CONSORT	Frequency (Percent)	Mean Score	Mean % Adherence
ABSTRACT	1a	Identification as a randomized trial in the title	YES	79(17)	0.1012	10.12
			NO	702(89.90)		
	1b	Structured summary of trial design, methods, results, and conclusions	YES	772(98.80)	0.9885	98.85 AC
			NO	09.00 (01.20)		
INTRODUCTION	2a	Scientific background	SB&R	124(15.90)	0.5794	57.94
			Rationale needed to search	582(74.50)		
			Rationale not mentioned	70(09.00)		
			SB not mentioned	05.00(00.60)		
	2b	Specific objectives or hypotheses	Directly mentioned	350(44.80)	0.4629	46.29
			Need to search	373(47.80)		
			Not given	58(07.40)		

Methods category of RCTs had 17 checklist items with total of 17 score starting from 3a to 12b with one score each. Checklist items 3a, 3b, 4a, 4b, 5, 6b, 7a, 7b, 8a, 8b, 9,12a and 12b had two descriptors while 6a, 10a, 11a and 11b had three descriptors. Table 1b.

Table 1b: RCT reporting rating using items from the CONSORT statement (n=781)

Area	List	CONSORT Checklist items	Descriptor of the CONSORT	Frequency (Percent)	Mean Score	Mean % Adherence
METHODS	3a	Description of trial design (such as parallel, factorial) including allocation ratio.	YES	780(99.87)	0.9987	99.87AC
			NO	01.00(00.13)		
	3b	Important changes to methods after trial commencement with reasons	Not Mentioned	781 (100.0)	0.0000	00.00
	4a	Eligibility criteria for participants	YES	778(99.60)	0.9974	99.74AC
			NO	02.00(0.30)		
	4b	Settings and locations where the data were collected	YES	781 (100.0)	1.0000	100.00
	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	YES	780(99.87)	0.9987	99.87AC
			NO	01.00(00.13)		
	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	Directly mentioned	95 (12.2)	0.4994	49.94
			Need to search	685(87.7)		
			Not given	01.00(00.13)		
	6b	Any changes to trial outcomes after the trial commenced, with reasons	Not Mentioned	781 (100.0)	0.0000	00.00
	7a	How sample size was determined	YES	346(44.3)	0.4430	44.3
			NO	435(55.7)		
	7b	When applicable, explanation of any interim analyses and stopping guidelines	Not Mentioned	781 (100.0)	0.0000	00.00
	8a	Method used to generate the random allocation sequence	YES	654(83.70)	0.8374	83.74AC
			NO	127(16.30)		
	8b	Type of randomization; details of any restriction (such as blocking and block size)	YES	28(03.60)	0.0371	03.71
			NO	753(96.40)		
	9	Mechanism used to implement the random allocation sequence describing any steps taken to conceal the sequence until interventions were assigned	YES	76(09.70)	0.0973	09.73
			NO	705(90.30)		
	10a	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	Directly mentioned	29(03.70)	0.0442	04.42

			Need to search	40(05.10)		
			Not given	712(91.2)		
	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	Directly mentioned	58(07.40)	0.0551	05.51
			Need to search	28(03.60)		
			Not given	695(89.00)		
	11b	If relevant, description of the similarity of Interventions	YES	08(01.00)	0.0102	01.02
			NO	121 (15.50)		
			NA	652(83.50)		
	12a	Statistical methods used to compare groups for primary and secondary outcomes	YES	780(99.90)	0.9987	99.87AC
			NO	01.00(00.13)		
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	YES	780(99.90)	0.9987	99.87AC
			NO	01.00(00.13)		

Results category had 10 checklist items with 10 score starting from 13a to 19 with one score each. Checklist items 15, 16, 17a, 17b, 18, 19 had two descriptors while 13a, 13b, 14a, and 14b had three descriptors Discussion and Others categories had 6 checklist items with 6 score starting from 20 to 25 with one score each. Checklist items 22, 23, and 24 had two descriptors. 20, 21 had three while 25 had 5 descriptors Table 1c.

Table 1c: RCT reporting rating using items from the CONSORT statement (n=781)

Area	List	CONSORT Checklist items	Descriptor of the CONSORT	Frequency (Percent)	Mean Score	Mean % Adherence
RESULTS	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment and were analyzed for the primary outcome	Flow Diagram	40(05.10)	0.5256	52.56
			Text	740(94.8)		
			None	01.00		
	13b	For each group, losses and exclusions after randomization, together with reasons	DM	28(03.60)	0.0359	03.59
			Need to search	28(3.60)		
			Not given	725(92.80)		
	14a	Dates defining the periods of recruitment and follow-up	DM	08(01.00)	0.1575	15.75
			Need to search	238(30.50)		
			Not given	535(68.50)		
	14b	Why the trial ended or was stopped	Need to search	781(100.0)	0.5000	05.00
	15	A table showing baseline demographic and clinical characteristics for each group	Table	305(39.10)	0.6953	69.53
			Text	476(60.90)		
	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	Yes	781 (100.0)	1.0000	100 AC
	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	Yes	781 (100.0)	1.0000	100 AC
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	Yes	05.00(0.60)	0.0064	0.64
			No	776(99.40)		
	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	Yes	776(99.40)	0.9936	99.36 AC
			No	5.00(00.60)		
	19	All-important harms or unintended effects in each group	Yes	117(15.0)	0.1498	14.98
			No	664(85.0)		
DISCUSSION	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	Directly mentioned	169(21.60)	0.1479	14.79
			Need to search	62(07.90)		
			Not given	550(70.40)		
	21	Generalizability (external validity, applicability) of the trial findings	DM	60(07.70)	0.3284	32.84
			Need to search	453(58.0)		
			Not given	268(34.3)		
	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	Yes	781(100.0)	1.0000	100AC
OT	23	Registration number and name of trial registry	Yes	07 (00.90)		

			No	774(99.10)	0.0090	0.9
	24	Where the full trial protocol can be accessed, if available	Yes	01(17)	0.0013	0.13
			No	780(99.87)		
	25	Sources of funding and other support (such as supply of drugs), role of funders	DF	11(01.40)	0.1511	15.11
			Others	29(03.70)		
			Both (DF) & others	04(00.50)		
			Not Mentioned	663(84.90)		
			Not funded	74(09.50)		

Reporting ≥ 70% of the items considered as adequate compliance to the CONSORT statement. The Checklist items of the CONSORT were 25 with 37 score. Two Score for abstract, two for the introduction, 17 for the Methods section, 10 for Results, 3 for Discussion and 3 for other information section. Chi-square applied to the Articles Year of Publishing Categories and % Adherence Categories. Same was also applied to Predictors of compliance (Funding, institutions involved, foreign collaboration) and Adherence categories of compliance (50 %, 70%). P value ≤ 0.05 considered significant.

RESULTS

This Systematic Review was designed using Preferred Reporting Items for Systematic Reviews & Meta Analysis (PRISMA-P) Protocol 2015 statement to assess, the compliance of RCTs Conducted and reported from Pakistan in any online available Pakistani journal from 2010-2019 with the CONSORT. Out of initially screened 830 trials, 781 published in 44 online available Pakistani journals at PakMediNet from 2010-2019 were included. Scores achieved were a. mean score of 16.85/37 (45.54%) b. median and mode 16.50/37(44.59%) each c. minimum 09/37(24.32%) score d. maximum score 23.5(63.51%). More than half of the RCTs 459/781(58.8%) were performed by collaboration of more than one institution while only 11/781(1.4%) had foreign collaboration and funded RCTs were 44/781(5.6%) Table 2.

Table 2: Predictors of compliance (n=781)

		Frequency (%)
Institutions involved in trial	Single Institution	322 (41.2)
	Multiple Institutions	459 (58.8)
Foreign Collaboration	Yes	11(01.4)
	No	770(98.6)
Funded or Not Funded	Funded	44(05.6)
	Not Funded	737(94.4)

Per year publication of RCTs has increased with only 15/781(1.9%) RCTs published in 2010 to 146/781(18.7%) in 2018 with a fall in number to 138/781(17.7%) in 2019 Figure 1.

Table 3: Compliance

Summation score drawn from the CONSORT checklist Items and Per cent overall adherence to the 25-item CONSORT checklist for Randomized trial.

S. No	Total Scoring of individual article	Frequency (N)	Percent (%)	% Adherence to CONSORT	AC ≥ 70% NAC < 70%
1	9.00	1	0.1	24.32	NAC
2	13.50	4	0.5	36.49	NAC
3	14.00	17	2.2	37.84	NAC
4	14.50	22	2.8	39.19	NAC
5	15.00	64	8.2	40.54	NAC
6	15.50	79	10.1	41.89	NAC
7	16.00	105	13.4	43.24	NAC
8	16.50	111	14.2	44.59	NAC
9	17.00	93	11.9	45.95	NAC
10	17.50	101	12.9	47.30	NAC
11	18.00	62	07.9	48.65	NAC
12	18.50	39	05.0	50.00	NAC
13	19.00	28	03.6	51.35	NAC
14	19.50	17	02.2	52.70	NAC
15	20.00	13	01.7	54.05	NAC
16	20.50	11	01.4	55.41	NAC
17	21.00	4	0.5	56.76	NAC
18	21.50	2	0.3	58.11	NAC
19	22.00	3	0.4	59.46	NAC
20	23.00	4	0.5	62.16	NAC
21	23.50	1	0.1	63.51	NAC
	Total	781(100.0)		Total	

Principally underreported (less than 50% Adherence) items were 1a, 7a 8b, 9, 10a, 11a, 13b, 14a, 17b, 19, 20, 23, 24 and 25 and items that not reported include 3b, 6b and 7b. Adequate compliance (Adherence remained ≥ 70 %) not achieved as maximum Adherence remained 63.51% with score of 23.5 / 37 achieved by 0.1% of individual RCTs published and 122/781(15.6%) secured ≥ 50% but <70% Adherence. Figure 1 Significant association has been shown in 50% adherence category by a. Institutions with results and discussion section of CONSORT checklist b. Funding with overall adherence categories of compliance as well as in abstract, results and discussion section of consort checklist.

DISCUSSION

Current study Maximum Adherence achieved is 63.51% with 45.54% mean Adherence in comparison to 52.2% maximum Adherence based on CONSORT score According to a systematic review with 185 Articles published in 2017.[17] According to another Systematic Review published in 2013 with 150 RCTs on surgical interventions had 55% mean Adherence[18] respectively.

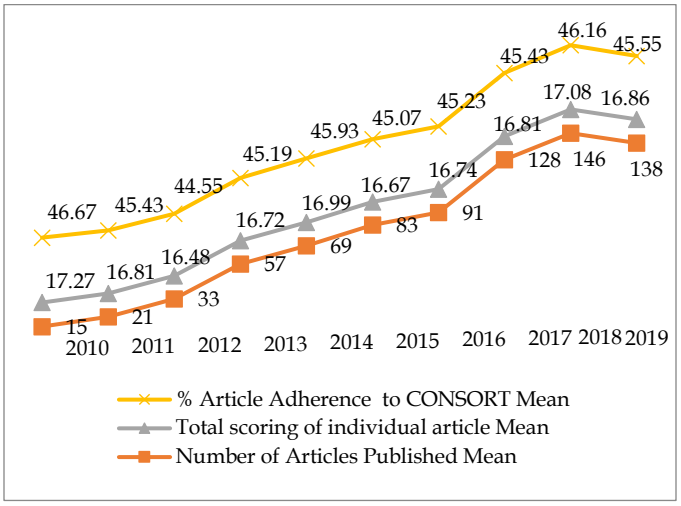
Current findings: Mean 16.85/37 (45.54%), median and mode 16.50/37(44.59%) and Range 9-23.5(24.32-63.51%) in comparison to another 2014 Review of 239 trials with the median CONSORT score of 11.5/23 (50%) and Range of 5.3-21.[19] Although the highest adherence of current Systematic Review remained 63.51% that was greater than 52.2% highest achieved in 2017 but mean 45.54% and median 44.95% remained low in comparison to systematic reviews conducted in 2013 and 2014 with mean of 55% and median of 50% respectively. Current and 2017 study Eligibility criteria and Settings remained 100%.

The Current systematic review and 2017 Study reporting comparisons show Intervention and outcomes 99.87% and 100% respectively, Sample size 44.3% and 54.68% respectively, Sequence allocation 85.93% and 83.74% respectively, Type of randomization 3.71% and 3.13% respectively, Allocation concealment 9.73% and 5.47% respectively, Double blinding 11.0 % and 11.30% respectively, The statistical analysis 99.9% and 100% respectively and Additional analysis 99.9% and 100% respectively.[20]

Outcome adherence of more than eighty percent remained 50% showing Inadequate Compliance and demanding guidance or training for protocol of reporting Outcomes. Lower Adherence areas reflect lack of understanding of this concept or its importance for reporting RCTs not only from Pakistan but also internationally demanding clarity of concept and its importance for reporting RCTs in any online available Journal. Current study has shown improved 15.1% reporting of funding comparative to another study reporting 6.53% in 2005-2009 vs. 5.00%in 2010-2012.[21]

Another study states the overtime improvement in RCT reporting but some items reporting remained poor in line with current study finding relating to the fact that mostly clinicians methodological section items "randomization sequence generation, sample size, allocation concealment and blinding remains poor due to their perception of priority or importance of clinical aspects.[22,23]

Figure 1: Compliance: Summation score drawn from the CONSORT checklist items and Per cent overall adherence to the 25-item CONSORT checklist for Randomized trial on the basis of years of Publication



CONCLUSION

Only 1.9% RCTs published in 2010 to 17.7% in 2019 but the Adherence to the CONSORT remained almost the same with Mean Adherence of 44.55% in 2012 to 46.67% in 2010 respectively while the mean yearly Adherence remained 45.54 % indicating that quantity has increased overtime but not RCTs reporting according to Guidelines. The number of RCT' published from Pakistan has increased over the years but the mean overall yearly Adherence to the CONSORT of individual article remained the same indicating that quantity of publications has increased overtime but not RCTs reporting according to Guidelines. None of the individual Article has achieved the adequate compliance, reinforcing the dire need of CONSORT statement endorsement for the reporting of trials by the individual journals. But statistically significant association of Funding and Adherence has supported Funding to achieve Adequate Compliance to CONSORT.

LIMITATIONS

Lack of funding.

SUGGESTIONS / RECOMMENDATIONS

Reinforcement of usage of CONSORT statement for the reporting of trials. Training of the researchers regarding the true interpretation of each individual item of Statement should be mandatory before the ethical approval of Randomized Controlled Trials. Funding should be considered as predictor of compliance and all RCTs should be funded by the Authorities to ensure highest Adherence resulting in provision of more Transparent and reliable data to the future researchers,

planning and Policy Makers working for Health System Reforms of Islamic Republic of Pakistan.

CONFLICT OF INTEREST / DISCLOSURE

None.

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