Table 2. Compliance of Eligible Studies with Consolidated Standards of Reporting Trials (CONSORT) Extension for Harms Modified Checklist Items

CONSORT Harms Checklist Items	Trials published prior to CONSORT Harms Extension (1990-2004) (N=25)		Trials published after CONSORT Harms Extension (2005-2014) (N=43)		All trials included in sample (1990-2014) (N=68)	
	Adherence to Checklist Item, N (%)	95% CI	Adherence to Checklist Item, N (%)	95% CI	Adherence to Checklist Item, N (%)	95% CI
1. Title and Abstract						
AE mentioned in title or abstract	12 (48.0)	[28.4-67.6]	6 (14.0)	[3.59-24.3]	18 (26.5)	[16.0-37.0]
2. Introduction						
AEs mentioned in the introduction	13 (52.0)	[32.4-71.6]	15 (34.9)	[20.6-49.1]	28 (41.2)	[29.5-52.9]
3. Definition of adverse events						
a. Includes comprehensive list of AEs reported or definition of AEs	5 (20.0)	[4.32-35.7]	5 (11.6)	[2.05-21.2]	10 (14.7)	[6.29-23.1]
b. Distinguishes between expected and unexpected AEs	2 (8.0)	[-2.63-18.6]	5 (11.6)	[2.05-21.2]	7 (10.3)	[3.07-17.5]
c. Mentions use of a validated instrument to measure AE severity	2 (8.0)	[-2.63-18.6]	7 (16.3)	[5.25-27.3]	9 (13.2)	[5.18-21.3]
4. Collection of harms data						
a. Includes harm-associated mode of data collection	8 (32.0)	[13.7-50.3]	13 (30.2)	[16.5-44.0]	21 (30.9)	[19.9-41.9]
b. Includes harm-associated timing of data collection	7 (28.0)	[10.4-45.6]	14 (32.6)	[18.6-46.6]	21 (30.9)	[19.9-41.9]
c. Includes attribution methods or intensity of ascertainment	2 (8.0)	[-2.63-18.6]	9 (20.9)	[8.77-33.1]	11 (16.2)	[7.42-24.9]
d. Includes harm-associated monitoring and stopping rules, if pertinent	1 (4.0)	[-3.68-11.7]	3 (6.97)	[-0.64-14.6]	4 (5.88)	[0.29-11.5]
5. Analysis of harms						
Includes plans for presenting and analyzing information on harm (including coding, handling of recurrent events, specification of timing issues, handling of continuous measures, and any statistical analyses)	1 (4.0)	[-3.68-11.7]	5 (11.6)	[2.05-21.2]	6 (8.82)	[2.08-15.6]
6. Participant withdrawals						
a. Includes, for each arm, the participant withdrawals that are owing to harm and their experiences with the allocated treatment	1 (4.0)	[-3.68-11.7]	14 (32.6)	[18.6-46.6]	20 (29.4)	[18.6-40.2]
b. Includes information on timing of withdrawals	5 (20.0)	[4.32-35.7]	16 (37.2)	[22.8-51.6]	21 (30.9)	[19.9-41.9]
7. Provides denominator for analysis of harms						
a. Provides denominators for AEs	14 (26.0)	[36.5-75.5]	25 (58.1)	[43.4-72.9]	39 (57.4)	[45.6-69.1]
b. Provides definitions used for analysis set in methods section (eg, intention to treat)	2 (8.0)	[-2.63-18.6]	8 (18.6)	[6.97-30.2]	10 (14.7)	[6.29-23.1]
8. Data on adverse events						
a. Includes the absolute risk per arm and per adverse event type or presents appropriate metrics for recurrent events, continuous variables, and scale variables, whenever pertinent	13 (52.0)	[32.4-71.6]	18 (41.9)	[27.1-56.6]	31 (45.6)	[33.8-57.4]
b. Includes information on grade or seriousness of AEs	5 (20.0)	[4.32-35.7]	12 (27.9)	[14.5-41.3]	17 (25.0)	[14.7-35.3]
9. Subgroup analyses						
Describes any subgroup analyses or exploratory analyses for harm	3 (12.0)	[-0.74-24.7]	5 (11.6)	[2.05-21.2]	8 (11.8)	[4.11-19.4]
10. Balanced discussion						
Discussion balanced with regard to efficacy and adverse events	9 (36.0)	[17.84-54.8]	20 (46.5)	[31.6-61.4]	29 (42.7)	[30.9-54.4]
Overall percent adherence to all CONSORT Harms Items*	4.40 (24.4)	-	4.65 (25.8)	-	4.56 (25.3)	-

*Calculated out of a possible 18 points, with one point assigned for a trial adequately meeting criteria for each item
Abbreviations: CI = Confidence Interval; AE = Adverse Event