Checklist of Items To Include When Reporting Harms in Randomized, Controlled Trials

Section/Topic	Item No	Description	Reported on Page Number/Line Number	Reported on Section/Paragraph
Title and abstract				
	1	If the study collected data on harms and benefits, the title or abstract should so state	Pg1/2-3, Pg4/53-60	Abstract/Paragraph 1
Introduction				
Background and objectives	2	If the trial addresses both harms and benefits, the introduction should so state.	Pg5/62-80	Introduction/Paragraph1
Methods				
Participants	3		Pg6/104-105	Results/Paragraph 1
Interventions	4		Pg6/ 85-101	Methods/Paragraph 1
Objective	5		Pg5/ 77-79	Introduction/Paragraph 1
Outcomes	6a	List addressed adverse events with definitions for each (with attention, when relevant, to grading, expected vs. unexpected events, reference to standardized and validated definitions, and description of new definitions).	N/A(RHC had no adverse events)	N/A
	6b	Clarify how harms-related information was collected (mode of data collection, timing, attribution methods, intensity of ascertainment, and harms-related monitoring and stopping rules, if pertinent).	N/A (no harms related events noted)	N/A
Sample size	7		Pg 6/ 104-105	Results/Paragraph 1
Randomisation:				
Sequence generation	8		N/A(no randomization)	N/A
Allocation concealment mechanism	9		N/A(no randomization)	N/A
Implement-ation	10		N/A(no randomization)	N/A
Blinding (masking)	11		N/A(no randomization)	N/A

Statistical methods	12	Describe plans for presenting and analyzing information on harms (including coding, handling of recurrent events, specification of timing issues, handling of continuous measures, and any statistical analyses).	See Tables	See Tables
Results				
Participant flow	13	Describe for each arm the participant withdrawals that are due to harms and their experiences with the allocated treatment.	N/A(no withdrawls)	N/A(no withdrawls
Recruitment	14		N/A	N/A
Baseline data	15		Pg7/108-127	Results/Paragraph1,2.
Numbers analysed	16	Provide the denominators for analyses on harms.	N/A(no harms noted)	N/A(no harms noted)
Outcomes and estimation	17	Present the absolute risk per arm and per adverse event type, grade, and seriousness, and present appropriate metrics for recurrent events, continuous variables, and scale variables, whenever pertinent. Describe any subgroup analyses and exploratory analyses for harms.	Pg7/108-127 for outcomes	Results/Paragraph 1,2 for outcomes
Ancillary analyses	18			
Adverse events	19			
Discussion				
Limitations	20	Provide a balanced discussion of benefits and harms with emphasis on study limitations, generalizability, and other sources of information on harms.	Pg8/130-140	Discussion/Paragraph1
Generalisability	21			
Interpretation	22			

From: Ioannidis JP, Evans SJ, Gøtzsche PC, et al. Better reporting of harms in randomized trials: an extension of the CONSORT statement. Ann Intern Med. 2004;141(10):781-8

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*As the checklist was provided upon initial submission, the page number/line number reported may be changed due to copyediting and may not be referable in the published version. In this case, the section/paragraph may be used as an alternative reference.