CONSORT ITEMS: Assessment of the quality of reporting by the CONSORT for harms extension recommendations.

1. Does the title or abstract state that data on harms were collected?
2. Does the introduction state if there were harms reported (or not)?
3. Did the study authors pre-specify potential adverse events? (with attention, when relevant, to grading, expected vs. unexpected events. Reference standardized and validated definitions and description of new definitions).
4. Does the study clarify how harms-related information was collected? (Passive, active, mode of data collection, timing, attribution methods, intensity of ascertainment, and harms-related monitoring and stopping rules, if pertinent).
5. In the methods section, does the study 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).
6. Does the participant flow describe for each arm the participant withdrawals that are due to harms with the allocated treatment?
7. Does the study provide any specific denominator(s) for analyses on harms?