

Appendix 2 (as supplied by the authors): McHarm assessment

Questions from McHarm tool	Winblad et al. ²⁷	Salloway et al. ²⁹	Petersen et al. ³⁰	Doody et al. ³¹	Feldman et al. ³²	Ferris et al. ³³
1. Were harms PRE-DEFINED?	N	N	N	Y	Y	N
2. Were SERIOUS events defined?	N	N	N	Y	N	N
3. Was the number of DEATHS in each study specified?	Y	Y	Y	Y	Y	N
4. Was the mode of harm collection specified as ACTIVE?	U	U	U	Y	Y	N
5. Was the mode of harms collected as PASSIVE?	U	U	U	U	U	Y
6. Did the study specify WHO collected the harms?	N	N	N	Y	N	N
7. Did the study specify TRAINING of BACKGROUND of who ascertained the harms?	N	N	N	N	N	N
8. Did the study specify the TIMING and FREQUENCY of collection of harms?	N	N	N	Y	Y	N
9. Did the authors use STANDARD scales or checklists for harms?	N	N	N	Y	U	N
10. Did the authors specify if the harms reported encompass ALL the events collected or a selected sample?	Y	Y	N	U	Y	Y
11. Was the NUMBER of participants that withdrew or were lost to follow up specified for each study group?	Y	Y	Y	Y	Y	N
12. Was the TOTAL NUMBER of participants affected by harms specified for each study arm?	U	Y	Y	Y	Y	Y
13. Did the author(s) specify the NUMBER for each TYPE of harmful event for each study group?	U	Y	Y	Y	Y	Y
14. Did the author(s) specify the type of analyses undertaken for harms data?	Y	U	N	N	N	N

Note: N = no, U = unclear, Y = yes.

*Combines harms for the 2 studies reported in this publication.

