QA: Modified Jadad Scale

1. Is this a RCT study?

Yes (continue)
No (STOP) (specify type of study)

2. Double blinding is reported

Yes (1 point)
No

3. Double blinding is appropriate

Yes (1 point)
No (-1 point)
Not described

4. Reported as randomized
Yes (1 Point)
No

5. Randomization is appropriate
Yes (1 point)
No (-1 point)
Not Described

6. Withdrawals are reported by number and reason per arm
Yes (1 point)
No

7. Jadad Score (/5)

8. Method(s) used to assess adverse events is described
Yes (1 point)
No

9. Method(s) of statistical analysis is described
Yes (1 point)
No

10. Inclusion and/or exclusion criteria reported
Yes (1 point if at least one of the requirements is reported)
No

11. Modified Jadad score (/8)

12. Was the allocation adequately concealed? E.g pharmacy controlled randomization scheme, sequentially numbered opaque, sealed envelope, sequentially numbered / coded identical containers, central randomization by phone?
Yes
No
Unclear

13. Was the analysis based on intention to treat principle?
Yes
No
Unclear

14. Was the sample size justified?
Yes
No
Unclear

15. Was the outliers reported and appropriately dealt with in the analysis?
Yes
No

16. Is the role of the study sponsor/ funder (i.e. manufacturer of the device) appropriate?

Is the role of the study sponsor/ funder (i.e. manufacturer of the device) appropriate?
(This question evaluates the role of the study sponsor in the potentially influencing the study conduct, interpretation, or reporting. We ask raters to judge whether "the role of the study sponsor (i.e. manufacturer of the device) appropriate?".)

For low risk of bias, raters would indicate YES (role appropriate) with respect to the following: 1) The funder/ sponsor is identified, and 2) Their specific input/role within the study is also specified such that there is NO or MINIMAL potential to influence study conduct, interpretation, or reporting. For example, a sponsor may provide a device to the study researchers but then had no subsequent involvement in the study development, conduct and reporting. We are looking for a statement from the authors declaring no involvement.

For high risk of bias the raters indicate NO (role is NOT appropriate) with respect to the following: 1) The funder is identified AND their role/input within the study is not explicitly specified 2) The funder is not identified AND their role/input within the study is not explicitly stated. The category of UNSURE is used when information about the study sponsor, device manufacturer, and any potential conflict of interest of the study authors is conflicting or not well reported within the study.)

Yes
No
Unsure