1. Randomization adequate?

- ☐ Yes
- ☐ No
- ☐ Not randomized
- ☐ Method not reported

2. Allocation concealment adequate?

- ☐ Yes
- ☐ No
- ☐ Not randomized
- ☐ Method not reported

3. Was the sample size sufficient to detect appropriate changes in the outcomes of interest? (i.e. was there an explanation of the statistical power?)

- ☐ Yes
- ☐ No

4. Groups similar at baseline?

- ☐ Yes
- ☐ No

5. Outcome assessors masked?

- ☐ Yes
- ☐ No
- ☐ Yes, but method not described
- ☐ Not reported

6. Care provider masked?

- ☐ Yes
- ☐ No
- ☐ Yes, but method not described

- [ ] Not reported

7. Patient masked?

- [ ] Yes
- [ ] No
- [ ] Yes, but method not described
- [ ] Not reported

8. Overall attrition high (≥ 20%)?

- [ ] Yes (please state how high) _____
- [ ] No

9. Differential attrition high (≥ 15%)?

- [ ] Yes (please state difference) _____
- [ ] No

10. Was the statistical analysis based on intention-to-treat (ITT)?

- [ ] Yes
- [ ] No
- [ ] Cannot tell

11. Were outcome measures valid, reliable, and equally applied?

- [ ] Yes
- [ ] No

12. Were there any post-randomization exclusions?

- [ ] Yes (how many?) _____
- [ ] No
- [ ] Cannot tell

13. Methods of adverse effects assessment

- [ ] Patient reported
- [ ] Physical exam at study visits
- [ ] Lab evaluations
- [ ] Standardized scale (e.g. WHO, UKU-SES)
- [ ] other (please specify) _____
- [ ] Not applicable

14. Adverse events pre-specified and defined?

- [ ] Yes

- [x] No
- [x] Not applicable

15. Ascertainment techniques for detecting adverse events non-biased and adequately described?

- [x] Yes
- [x] No
- [x] Not applicable

16. Quality rating for experimental study (RCT)

- [ ] Good
- [ ] Fair
- [ ] Poor

If poor, why?