Appendix 4

Quality assessment checklist

Study quality assessment for RCTs and controlled trials	
1. Was the number of participants randomised stated?	1.1 Yes 1.2 No 1.3 Unclear 1.4 Not applicable (N/A)
2. Was the method of randomisation adequate (e.g. use of random number table, computer random number generator, coin tossing, shuffling of cards or envelopes, throwing of dice)?	2.1 Yes 2.2 No 2.3 Unclear 2.4 Not applicable (N/A)
3. Was allocation concealment adequate (e.g. central allocation, sequentially numbered opaque sealed envelopes)?	3.1 Yes 3.2 No 3.3 Unclear 3.4 Not applicable (N/A)
4. Were the treatment groups comparable at baseline for important prognostic factors?	4.1 Yes 4.2 No 4.3 Unclear 4.4 Not applicable (N/A)
5. Was a suitable statistical method used to adjust for possible baseline imbalance?	5.1 Yes 5.2 No 5.3 Unclear 5.4 Not applicable (N/A)
6. Was the study reported as being at least double blind?	6.1 Yes 6.2 No 6.3 Unclear 6.4 Not applicable (N/A)
7. Were patients blinded?	7.1 Yes 7.2 No 7.3 Unclear 7.4 Not applicable (N/A)
8. Were outcome assessors blinded?	8.1 Yes 8.2 No 8.3 Unclear 8.4 Not applicable (N/A)
9. Were caregivers blinded?	9.1 Yes 9.2 No 9.3 Unclear 9.4 Not applicable (N/A)
10. Was ITT analysis used (in the analysis, participants were kept in the intervention groups to which they were randomised, regardless of the intervention they received)?	10.1 Yes 10.2 No 10.3 Unclear 10.4 Not applicable (N/A)

11. Were there any unexpected imbalances in dropouts between groups?	11.1 Yes 11.2 No 11.3 Unclear 11.4 Not applicable (N/A)
12. If there were any unexpected imbalances in dropouts were they explained or adjusted for?	12.1 Yes 12.2 No 12.3 Unclear 12.4 Not applicable (N/A)
13. Was the study powered for at least one outcome?	13.1 Yes 13.2 No 13.3 Unclear 13.4 Not applicable (N/A)
Study quality assessment for case series	
14. Were selection/eligibility criteria adequately reported?	14.1 Yes 14.2 No 14.3 Unclear 14.4 Not applicable (N/A)
15. Was the selected population representative of that seen in normal practice?	15.1 Yes 15.2 No 15.3 Unclear 15.4 Not applicable (N/A)
16. Was an appropriate measure of variability reported?	16.1 Yes 16.2 No 16.3 Unclear 16.4 Not applicable (N/A)
17. Was loss to follow-up reported or explained?	17.1 Yes 17.2 No 17.3 Unclear 17.4 Not applicable (N/A)
18. Were at least 90% of those included at baseline followed up?	18.1 Yes 18.2 No 18.3 Unclear 18.4 Not applicable (N/A)
19. Were patients recruited prospectively	19.1 Yes 19.2 No 19.3 Unclear 19.4 Not applicable (N/A)
20. Were patient recruited consecutively?	20.1 Yes 20.2 No 20.3 Unclear 20.4 Not applicable (N/A)
21. Did the study report relevant prognostic factors?	21.1 Yes 21.2 No 21.3 Unclear 21.4 Not applicable (N/A)
22. Any other additional limitations?	22.1 Yes 22.2 No 22.3 Unclear 22.4 Not applicable (N/A)