Reviewer’s report

Title: Intervention description is not enough: evidence from an in-depth multiple case-study on the untold role and impact of context in RCTs of 7 Complex Interventions.

Version: 3  Date: 15 December 2011

Reviewer: Charlie Goldsmith

Reviewer’s report:

This paper contains some interesting ideas to expand the reporting of complex interventions; however, the choices of the evidence need a better justification. It would also be useful to suggest where this work should go next in terms of helping the trial reporting community to do a better job.

The following suggestions are offered in the hope they will improve this paper.

1. P(age) 2, p(aragraph) 1, l(ine) 2. Define RCT the first time it used in the abstract. There should be a list of all short forms used in the entire paper, usually located just before the R(eference)s.
2. P 2, p 1, l 4. Since [or] logically includes [and], drop [and/]. Also P 3, p 4, l 8. Also P 5, p 1, l 2.
3. P 2, p 1, l 5. Replace [ranging] by [varying].
5. P 3, p 3, l 4. All Rs should be enclosed in [square brackets] and numbered as they appear in order in the text. They should not be superscripts. Text footnotes are not allowed in Trials.
6. P 3, p 3, l 5. Replace [parameters] by [characteristics]. A parameter is a characteristic of a distribution of a variable in a population, and not another name for something detected in a sample of studies.
7. P 3, p 4, l 1. There should be a description of the literature search criteria and a measure of the completeness of the literature search to make the claim it is an overview.
8. P 4, p 2, l 4. Replace [significantly] by some other word like [many]. Save significant and its variants for a statistical context.
9. P 4, p 2, l 8. Replace [significant] by [important].
10. P 4, p 3, l 6. Define [MRC] and be clear which country is being used. R 4 does not make it clear.
11. P 5, p 2, l 4. Delete [in order] in front of [to] as the words are redundant in English. Also P 8, p 3, l 9 and 10. Also P 9, p 2, l 1. Also P 14, p 2, l 2.
12. P 5, p 3, l 9. Replace [a failure to report] by [inadequate reporting]. The use of
failure implies a writer should have done it when no standards are available to justify space should be used to report these issues.

13. P 6, p 1, l 8 to 10. Where is the evidence to support this conclusion?

14. P 6, p 2, l 4. Insert the city and country in R 26 and comment on how it is accessible for a reader who may be interested.

15. P 7, p 1, l 2. Replace [parameters] by [variables]. Also P 10, p 1, l 7.

16. P 7, P 2, L 1. Insert [(PI)] after [investigator].

17. P 7, p 2, l 4. Insert a R to [NRR] and how it can be accessed. The date of last access should also be noted.

18. P 7, p 2, l 5. Why [seven] and how were they selected?


20. P 7, p 3, l 1. Define [NLED].

21. P 7, p 3, l 2. Delete [(PI)] as it should be defined earlier in p 2, l 1.

22. P 7, p 3, l 2. Replace [time-points] by [times].

23. P 7, p 4, l 1. Insert [types] after the second [data].

24. P 8, after p 2. Suggest locating Table 4 before the Data Collection heading on P 7.

25. P 8, p 3, l 7. Reference the software and version number in the Rs.

26. P 8, p 3, l 8 to 13. Who did this? Did more than one person do it? How good was the agreement?

27. P 8, p 4, l 3. Who did the testing and how as it done?

28. P 9, p 1, l 1. With whom?

29. P 9, p 1, l 4. What was the agreement on the coding?

30. P 9, p 2, l 4. How good was the agreement before the disagreements were resolved?

31. P 9, p 2, l 8. Does this mean that the estimated kappa was 1?

32. P 10, p 2, l 1. Someone had to do this, the findings did not.

33. P 10, p 6, l 1. Delete [significant].

34. P 10, p 6, l 2. Replace [range] by [set].

35. P 11, p 2, l 10. Delete [significantly]. Also P 17, p 2, l 11.

36. P 11, p 3. How common is this type of problem in the current trial literature?

37. P 11, p 4, l 1. Replace [significant] by [major].

38. P 11, p 4, l 5. Provide a R to the ripple effect. Also, insert the trail # for this source.

39. P 12, p 1. This quote suggests that complex trials should be reporting data on the compliance with the intervention steps.

40. P 12, p 3. This quote suggests that a measure of randomization integrity should be included in complex trials. Otherwise this choice makes it a cohort
study and is more open to bias.

41. P 12, bottom. Delete footnote.

42. P 13, p 3, l 8. Rewrite the sentence to avoid the dangling participle [upon].

43. P 13, p 4. This quote suggests that investigator integrity to conduct the trial as designed has been compromised.

44. P 14, p 2, l 3. Replace [range] by [minimum and maximum].


46. P 14, p 2, l 8 to 10. This suggests that some pilot study data would have been helpful to design the trial in the first place. Also P 15, p 2.

47. P 14, p 4. This quote suggests that a cluster or group intervention with a group or cluster measure should have been used rather than on individuals.

48. P 15, p 7, l 1. Rewrite as [… a set of characteristics and …].

49. P 15 ff. The discussion section is much too long. Try to shorten it.

50. P 17, p 2, l 16. Replace [significantly] by [in important ways].

51. P 17, p 3, l 8. Replace [significantly] by [much].

52. P 18, p 1, l 4. Rewrite as [Hawe et al suggest].

53. P 18, p 2, l 5 and 12. Delete [in order].

54. P 18, p 3, heading. Delete [and/]. Also P 18, p 3, l 3.

55. P 18, p 4, l 1. Who is their? Is this the researchers or the practitioners?


57. P 19, p 1, l 8. Delete [urgently] as no case has been made.

58. P 19, p 2, l 3. Delete [in order].

59. P 19, p 2, l 3 to 8. Since this is weak evidence, is there any better evidence that can be cited?

60. P 19, p 3, l 4 and 5. Rewrite as [compensating control patents by giving them...].

61. P 19, p 3, l 8. Delete [((p783,785))].

62. P 19, p 3, l 12. Rewrite as [Additionally, a 2011 study has ...].

63. P 20, p 1, l 2 and 3. Delete [in order].

64. P 20, p 2, l 1. Reference the [CONSORT] guidelines.

65. P 20, p 2, l 2 and 4. Replace [parameters] by [variables].

66. P 20, p 3, l 3. Rewrite sentence to avoid the dangling participle [upon].

67. P 20, p 4, l 1. Rewrite as [Between 2004 and 2010, developments ...].

68. P 20, p 4, l 4. Rewrite as [Lack of reporting such ...].

69. P 20, p 4, l 7. Reference the central feature.

70. P 20, p 4, l 11. Rewrite as [Finlay and Gough (2003) have ...].
71. P 21, p 2, l 1. Replace [range] by [spectrum].
72. P 21, p 2, l 4. Replace [maximise] by [use].
73. P 21, p 3, l 4. Delete [and]/.
74. P 21, p 3, l 5. Rewrite as [findings, 1999 and 2006 analyses ...].
75. P 21, p 4, l 4. Rewrite as [(Macpherson et al)].
76. P 21, footnote. Delete.
77. P 22, p 3, l 1. Replace [range] by [variety].
78. P 23 after p 2. This would be a good place to list all short forms.

A random sample of 10 Rs was chosen to be checked for accuracy of citation. In general, the Rs were not cited appropriately: inconsistent journal name forms, use of 2 capital letters for some author names and not all authors were listed, as required by Trials. Many volume and issue numbers are missing. This reviewer also likes to see issue numbers as they the R easier to find.

79. P 23, R 1, l 2. Where is the publisher and location?
80. P 23, R 3, l 1. What are the Journal name, volume and issue?
81. P 23, R 4, l 1. Who is [DP]? What is the location of the MRC?
82. P 23, R 5, l 1. The second author is [Shiell A] and on l 2, rewrite as [328(7455):1561-3.].
83. P 23, R 6, l 1. The second author is not [HC] but [Heneghan C] and on l 2 rewrite as [2007;334(7585):127-9].
84. P 23, R 7, l 1. Who is [BG]?
85. P 23 R 9 and 10. Who is [LI]?
86. P 24, R 12, l 1. Who is [ME]?
87. P 24, R 14, l 1. Who is [DP]?
88. P 24, R 15, l 1. Who is [LC]?
89. P 24, R 19 and 31 are the same. Please delete one and check the renumbering as a result. R 31 looks to be correct because it show it as a supplement.
90. P 24, R 20, l 1. Who is [MD]?
91. P 24, R 21, l 1. Replace [et al] by the rest of the authors.
94. P 24, R 32, l 1. The authors are [Kovack CR, Cashin JR, Sauer l.], and on l 2 insert [(6)] after [55]. The pages numbers are not shown with brackets.
95. P 25, R 36, l 3. Who is the publisher and what is the location?
97. P 25, R 40, l 1. Who is [MA]?, and on l 3. Where is this located?
98. P 25, R 41, l 1. Who is [FK]?
99. P 25, R 42, l 1. The authors are [Snowdon C, Garcia J, Elbourne D.] and on l3 insert [(9)] after [45].
100. P 25, R 43, l 3. What is the CD #?
101. P 25, R 44, l 1. Who is [BJ]?
102. P 25, R 45, l 1. Who is [FI]?
103. P 25, R 46, l 1. Who is [HV]? And on l 3 the format seems incorrect.
104. P 25, R 47, l 1. Who is [BM]? And on l 2 What is [Nt]?
105. P 25, R 48, l 1. Who is [CJ]?
106. P 25, R 50, l 1 Who is [TD]?
107. P 25, R 51, l 1 has the author initials in the wrong place and on l 3 the volume is [12].
108. P 26, R 55, l 1. Insert [(Editors)] in round brackets. What is the location?
109. P 26, R 57, l1 What is the Journal?
110. P 26, R 63, l 1. Who is [A. S.]?
111. P 26, R 64, l 1. Who is [K. S.]?
113. P 28, spell out the footnotes to [NHS] and [GP]. Who or what is a [Macmillan nurse]?
114. P 31, column 1 should number the Characteristics or create a column #. What is the rationale for choosing 2 levels of each of the characteristics?
115. P 33. What do the numbers mean? Provide a footnote to help with the interpretation. Explain blank versus 1 or 2 check marks. Also P 34, both tales.
116. P 35, Table 8. Rewrite as [Finlay and Gough]. In variant 4 who are the [actors]?
117. P 36 and 37. Delete the names and replace them by a some number. What do the numbers mean?
118. P 38, define [NB] as a footnote.
119. P 39, Delete [etc.]. Either leave out or provide more items.