Author's response to reviews

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.

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Version: 4 Date: 9 May 2012

Author's response to reviews: see over
Dear Professor Goldsmith,

MS: 5505746621599387 - 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.

Please find attached our revised manuscript. We would like to thank you and the other reviewers for your extremely helpful and thorough reviews and recommendations. We are delighted to receive such positive reviews of our paper, and were particularly pleased that Referee 2 thought our work was of ‘outstanding merit’ and that Referee 3 regarded the paper as important in its field.

We have now addressed all the comments and have highlighted all substantially revised sections of text in red. All minor corrections (references, word substitutions, deletions and formatting changes) have been made as shown below. The revisions we have made have been indicated in blue text under each referee point, as follows: -

Referee 1

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.
   RCT is defined. A list of short forms is provided before the references.

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.
   These errors have been corrected.

3. P 2, p 1, l 5. Replace [ranging] by [varying].
   This has been replaced.

   This replacement has been made.

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.
   Referencing system has been corrected to comply with Trials formatting.
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. Parameter has been replaced by characteristics.

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. This claim has been re-worded to ensure that the literature search and review is accurately described.

8. P 4, p 2, l 4. Replace [significantly] by some other word like [many]. Save significant and its variants for a statistical context. Significant has been removed.

9. P 4, p 2, l 8. Replace [significant] by [important]. Significant has been replaced.

10. P 4, p 3, l 6. Define [MRC] and be clear which country is being used. R 4 does not make it clear. MRC and UK context have been defined and made 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. These deletions have been made.

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. This replacement has been made.

13. P 6, p 1, l 8 to 10. Where is the evidence to support this conclusion? The sentence referred to above claimed that there were few empirical studies providing a clear illustration of context. The evidence for this claim is in the original PhD thesis (Wells 2007), however, the sentence has now been removed as the key point of this paragraph is that the issues and problems of context have not been explored across different trial contexts, and this point has been made.

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. Full details of the thesis and how it can be accessed are now given.

15. P 7, p 1, l 2. Replace [parameters] by [variables]. Also P 10, p 1, l 7. This has been done.
16. P 7, P 2, L 1. Insert [(PI)] after [investigator].
PI inserted.

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.
Reference to NRR given.

18. P 7, p 2, l 5. Why [seven] and how were they selected?
Explanation of this sampling strategy is now given.

This has been done.

20. P 7, p 3, l 1. Define [NLED].
NLED is defined in the text and in the short form list at the end of the paper.

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

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

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

24. P 8, after p 2. Suggest locating Table 4 before the Data Collection heading on P 7.
Table 4 has been re-located.

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

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?
To address points 26 to 31, this section has been re-written. In qualitative research such as this, the credibility of the coding frame and the rigour of the analysis is usually tested in this way.

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

33. P 10, p 6, l 1. Delete [significant].
This has been done.

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

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

36. P 11, p 3. How common is this type of problem in the current trial literature?
This problem occurred in the particular trial discussed, as reported in the results section. We refer to another trial in which a change in policy affected recruitment (see p17 para 1 lines 8-10)

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

38. P 11, p 4, l 5. Provide a R to the ripple effect. Also, insert the trail # for this source.
Reference for ripple effect added. Reference to Table 6 finding 4 has been added so that the reader can ascertain the trial sources for this finding.

39. P 12, p 1. This quote suggests that complex trials should be reporting data on the compliance with the intervention steps.
We agree. This point is made in the discussion page 16 para 4.

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.
We agree. This point is made in the discussion, page 18 para 3.

41. P 12, bottom. Delete footnote.
Deleted.

42. P 13, p 3, l 8. Rewrite the sentence to avoid the dangling participle [upon].
Re-written.
43. P 13, p 4. This quote suggests that investigator integrity to conduct the trial as designed has been compromised.
   We agree.

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

45. P 14, p 2, l 6. Define CBT.
   Defined in text and in short form list.

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.
   We agree.

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. This was a cluster trial. This has been made clear.

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

49. P 15 ff. The discussion section is much too long. Try to shorten it.
   We have shortened the discussion in several places.

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

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

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

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

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

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

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

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

59. P 19, p 2, l 3 to 8. Since this is weak evidence, is there any better evidence that can be cited?  
**Yes, we have added two references to reviews and re-written this paragraph.**

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

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

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

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

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

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

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

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

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

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

70. P 20, p 4, l 11. Rewrite as [Finlay and Gough (2003) have ...].  
**Re-written.**
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.

Please accept our apologies for the poor referencing - Something went wrong with the formatting using our reference software and we did not realize this. All the errors below have now been corrected (79-111).

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.
92. P 24, R 27. Rewrite as [Yin RK; Case Study Research: Design and Methods.
94. P 24, R 32, l 1. The authors are [Kovack CR, Cashin JR, Sauer l.], and ion 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.]?
Corrections made.

113. P 28, spell out the footnotes to [NHS] and [GP]. Who or what is a [Macmillan nurse]?
Corrections made.

114. P 31, column 1 should number the Characteristics or create a column #.
Numbers have been added.
What is the rationale for choosing 2 levels of each of the characteristics?
This should have been shown as a continuum. An arrow has now been added to make this clear.

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. Table rows and check marks have been clarified.

116. P 35, Table 8. Rewrite as [Finlay and Gough]. In variant 4 who are the [actors]?
Re-written and explained.

117. P 36 and 37. Delete the names and replace them by a some number. What do the numbers mean?
Names have been deleted and replaced by numbers. The numbers have been explained as the interview number (i.e. 4th interview means the 4th time this person was interviewed. As explained in the methods section, researchers and practitioners involved in Phase 1 were interviewed more than once, during the course of the trial.)

118. P 38, define [NB] as a footnote.
NB defined

119. P 39, Delete [etc.]. Either leave out or provide more items.
Deleted.

Referee 2
No corrections or recommendations.

Referee 3
Minor Essential Revisions
1. The first part of the introduction appears to be missing some references. Paragraph 4 refers to previous work in the form of a number of single case reports, without providing any references to this work. This should be corrected.

References have been added and this paragraph has been revised accordingly.

Discretionary Revisions
2. The second last paragraph before the conclusion implies that researchers might be able to “find out” whether or not an intervention is working based on process data prior to the end of the trial. I would suggest that unless they are conducting appropriate analysis on effectiveness data throughout the duration of the trial that they would not be able to “find out” anything. Rather they may perceive that an intervention is not working well. It’s a very minor point, but I recommend changing the language from “find out” to “perceive”, especially given this is in the context of process data. Even if the researchers had access to
effectiveness data, there would be stopping rules to consider before determining whether to act on it before the end of the trial.

Wording has been changed to “perceive”

3. Authors suggest in the abstract that “improved reporting formats that require and encourage the clarification of both general and project-specific threats to the likely internal and external validity need to be developed”. As the authors acknowledge, “the ways in which context challenged trial operation was often complex, idiosyncratic and subtle…”, but I wonder if the authors could make some more specific suggestions about how current reporting formats could be improved. I appreciate this may be a topic for another study and publication, but thought readers (especially researchers designing and publishing studies of complex interventions) might appreciate some more specific pointers.

We have added a paragraph on page 21 (just before the conclusion) providing specific suggestions. This also addresses the general comment made by Referee 1.

We have checked that our manuscript complies with all guidelines and believe that it is much improved as a result of the revisions made. We very much hope that Trials will agree to publish our paper and we look forward to hearing from you.

Yours sincerely,

Dr Mary Wells and Prof Brian Williams