Author’s response to reviews

Title: Developing a Reporting Guideline for Social and Psychological Intervention Trials

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Author’s response to reviews: see over
Re: Developing a CONSORT Extension for Interventions in Criminology, Education, Psychology, Public Health, and Social Work (Original Title)

Developing a Reporting Guideline for Social and Psychological Intervention Trials (Revised Title)

Dear Prof Altman,

We are pleased to resubmit this manuscript following the helpful comments of the peer-reviewers. We have addressed all of the reviewers’ comments from all journals co-publishing this article, while also being mindful of the word limit for the manuscript. This feedback has, we believe, helped to improve the paper greatly, and we hope that you will now be able to accept it for publication as soon as possible.

We have categorised the peer-review responses into the common substantive and minor revisions requested. We quote each reviewer’s individual comment and then provide our response:

Substantive Comments

1. Why “UPSCALE” interventions?

1a. “UPSCALE interventions are defined as relating to public health, psychology, criminology, social work, education. As stated, this constitutes a combination of single disciplines and fields (e.g. public health). Are there particular challenges inherent in fields vs. disciplines when it comes to defining such interventions that have implications for the proposed guideline? Why were these particular disciplines and fields chosen as the focus? What do interventions that relate to these disciplines and fields have in common beyond being more complex, and taken together warrant the development of a guideline? The authors do elaborate on some of these but don’t relate it back explicitly to the disciplines and fields that come under the UPScale umbrella.”

• We thank the reviewer for this helpful comment, which several other reviewers have also noted. In light of the frequency of this request from the peer-reviewers, we have shifted our framing of the guideline in this manuscript from the targeted disciplines to the targeted intervention type. Therefore, we have decided to change the intervention label from “UPSCALE” to “social and psychological” interventions, and the name of the extension from “CONSORT UPScale” to “CONSORT SPI.” We believe that this change in focus and use of more common terminology will clarify the interventions we are targeting and the commonalities they may share within and across disciplines. This change is best exemplified in the first paragraph:

“Social and psychological interventions aim to improve physical health, mental health, and associated social outcomes. They are often complex and typically involve multiple, interacting intervention components (e.g., several behaviour change techniques) that may act and target outcomes on several levels (e.g.,
Moreover, these interventions may be contextually dependent upon the hard-to-control environments in which they are delivered, (e.g., health care settings, correctional facilities). The functions and processes of these interventions may be designed to accommodate particular individuals or contexts, taking on different forms while still aiming to achieve the same objective.

1b. Use of current terminology in the description of the subject and the issues or challenges to be addressed could be more current and timely: For example considering the title of the commentary: "Developing a CONSORT Extension for Interventions in Criminology, Education, Psychology, Public Health, and Social Work."

1) A reader may not be familiar with CONSORT
2) A reader may not be familiar with the notion of Extensions in relation to CONSORT
3) A reader may tire at the long list of applicable disciplines and then, long as it is, wonder about disciplines that were not included.

Using alternate terminology this title MIGHT be phrased more along the lines of: "Toward developing a reporting guideline for trials of complex, multi-level interventions in the social, behavioral and public health realms."

- Thank you. We have renamed the article “Developing a Reporting Guideline for Social and Psychological Intervention Trials.”

1c. “I believe the authors need a far better justification for proposing a unified set of guidelines for interventions in such diverse fields as public health, psychology, social work, criminology, and education. If the goal is to guide more detailed reporting of interventions, the vast differences in interventions across these fields would make that difficult, if not impossible. Why were these particular fields chosen?”

- We thank the reviewer for the comment and have revised as described above.

1d. “I have only one very minor comment on the paper. The authors propose the use of the acronym UPSCALE for the proposed extension to the CONSORT guidelines. I think that this is a very non-neutral word that somewhat implies that the associated interventions are superior to the types of interventions that would be covered by CONSORT. I would urge the authors to choose a more neutral acronym, especially given that the acronyms of the previous guidelines (ex. CONSORT, MOOSE, PRISMA, STROBE, etc.) are well known and widely utilized.”

- We thank the reviewer and have revised. We believe “CONSORT-SPI” is a more neutral acronym.

1e. “The long list of disciplines, with the acronym UPSCALE, limits generalizability and interest. What if one's particular field is not listed?”

- We thank the reviewer and have revised as described above.

1f. “The only time I got slightly frustrated by the paper was in relation to the term 'UPSCALE'. The shorthand term gives no indication of its true meaning, and the convoluted acronym is anyway - to my mind - misleading, or it describes a set of systems which is narrower than I would have expected.”

- We thank the reviewer and have revised as described above.
2. Description of the interventions themselves

2a. “The authors make references to "multiple, interacting components at several levels, with various outcomes" when describing these interventions but do not further elaborate on what they mean by these terms. Some brief elaboration (given space limitations) would be helpful (e.g. are you referring to their intersectoral nature - that they operate within and outside of the health sector; multi-level - community, state, country level, etc.), type of intervention (policy, practice, program, etc.), equity considerations, interacting components (what do the authors mean by this?). A few brief examples of what constitutes interventions with these features (in particular in public health) would also be useful but may not be possible due to space limitations (perhaps a web link to some examples).”

- We thank this and other reviewers for this helpful comment. In addition to the changes to the first paragraph noted above, we have also provided in the second paragraph the following example of an intervention targeted by the guideline: “For example, Multisystemic Therapy (MST) is an intensive intervention for juvenile offenders. Based on social ecological and family systems theories, MST providers target a variety of individual, family, school, peer, neighbourhood, and community influences on psychosocial and behavioural problems.[6] Treatment teams of professional therapists and caseworkers work with individuals, their families, and their peer groups to provide tailored services.[7] These services may be delivered in homes, social care, and community settings.”

- We have also referenced the following links at the end of this paragraph for further examples of the targeted intervention: “Other examples of social and psychological interventions may be found in reviews by the Cochrane Collaboration (e.g. the Developmental, Psychosocial, and Learning Problems Group; the Cochrane Public Health Group) and the Campbell Collaboration.[8, 9]”

2b. “complexity as it relates to UPSCALE interventions needs further definition (should consider citing the writings of Shiell and Hawe for example)”

- We thank the reviewer for this helpful suggestion of research literature to reference. We have added this reference [4] in the following quotations:
  o “The functions and processes of these interventions may be designed to accommodate particular individuals or contexts, taking on different forms while still aiming to achieve the same objective.[4, 5]”
  o “Moreover, interventions are rarely implemented exactly as designed, and complex interventions may be designed to be implemented with some flexibility, in order to accommodate differences across participants,[4] so it is important to report how interventions were actually delivered by providers and actually received by participants.[52]”
  o “Particularly for social and psychological interventions, the integrity of implementing the intended functions and processes of the intervention are essential to understand.[4]”

2c. “The list includes 'public health, psychology, social work, criminology, and education'. I wasn't sure what 'psychology' referred to here, as usually psychological services are delivered in one of the other systems (e.g. part of social work, or education or health care); it would therefore be helpful to have an explanation of what 'psychology' means in this context.”
• We agree and we have clarified the definition of the targeted interventions in the first paragraph and provided an example in the second paragraph. Furthermore, the links to the Cochrane and Campbell Collaborations provide other examples of interventions in this area.

2d. “Second, the term ‘social work’ describes only a small part of the system of social care or long-term care existing in most countries; in the UK, for example, only a very small proportion of what is delivered in the social care sector involves a social worker.”

• Thank you. We have revised as noted above (2c).

2e. “Third, there is no mention of the housing sector, which I expected to be a prime candidate for inclusion.”

• Thank you. We have revised as noted above (2c).

2f. “Fourth, there are various activities that might come under the heading of ‘community development’ that are excluded by this slightly odd term ‘UPSCALE’.”

• Thank you. We have revised as noted in the responses to the first set of comments.

2g. “(i) the major part of the title ‘Extension for Interventions in Criminology, Education, Psychology, Public Health, and Social Work’ is not properly addressed in the document. Mental health does not appear anywhere and, although we do not want to be precious about this, bearing in mind that we are a mainstream journal for clinical psychiatrists, we do need to have some context that is relevant to mental health;”

• We thank the reviewer for this comment. We have addressed this in the first sentence: “Social and psychological interventions aim to improve physical health, mental health, and associated social outcomes.”
3. Previous guidelines

3a. “The overall purpose is clear, however, the aims (p. 5) and/or section subheading (p 6.) could use clarification. For example, authors indicate that they will explain: (aim #1) how current guidelines have improved the quality of reports in medicine, and (aim #2) why such guidelines have not yet improved the quality of reporting in other disciplines (p. 5). Then, both of these aims are discussed under the subsequent section subheading 'impact and limitations of previous reporting guidelines;' aim #1 is addressed in the first paragraph and aim #2 is addressed in the subsequent paragraphs (p. 6). However, the aims do not directly address the arguments set forth within the paragraphs under this subheading. Specifically, it is not readily discernible that 'impact' refers to the positive influence CONSORT guidelines have had on the discipline of medicine and that 'limitations' refers to where these guidelines have fallen short in terms of UPSCALE intervention reporting. I think including a more authoritative statement to the beginning of these paragraphs (e.g., more consistent with the aims) may be helpful to readers.”

- We thank the reviewer for this helpful comment. We have changed the paragraph on the manuscript’s aims as follows: “This article describes the development of a reporting guideline that aims to improve the quality of reports of RCTs of social and psychological interventions. We explain how reporting guidelines have improved the quality of reports in medicine, and why guidelines have not yet improved the quality of reports in other disciplines. We then introduce a plan to develop a new reporting guideline for RCTs—CONSORT-SPI (an extension for social and psychological interventions)—which will be written using recommend techniques for guideline development and dissemination.[19] Wide stakeholder involvement and consensus are needed to create a useful, acceptable, and evidence-based guideline, so we hope to recruit stakeholders from multiple disciplines and professions.”
- We have also changed the title of the sections following the paragraph on aims of the study to “Impact of CONSORT Guidelines” and “Limitations of Previous Reporting Guidelines for Social and Psychological Interventions,” in order to clarify the content of each paragraph.

3b. “In the second paragraph of page 7 the authors describe differences in the reporting guidelines that are used by groups of the social and behavioral scientists (WIDER, AERA, APA JARS group) and those developed by CONSORT. The authors mention that ‘these groups cover some issues not addressed by the CONSORT Statement and its extensions, yet these guidelines (except for APA JARS Group) do not provide specific guidance for RCTs, and not all have been developed using optimal methods.’ Although there is a reference provided to this statement, it could use clarification. What is the standard by which these 'optimal methods' are judged, and what renders the methods employed by the aforementioned groups sub-optimal? Clarification in terms of the shortcomings of these reporting guidelines would be helpful as well.”

- We have added the following comment to clarify the “optimal methods” of guideline development and dissemination: “Moreover, compared with the CONSORT Statement and its official extensions, guidelines in the social and behavioural sciences have not consistently followed optimal techniques for guideline development and dissemination that are recommended by international leaders in the advancement of reporting guidelines,[19] such as the use of systematic literature reviews and formal consensus methods to select reporting standards.[35]”

3c. “This is a minor point, but the authors may want to revise the last sentence on page 7 in terms of identifying which groups claim that CONSORT guidelines could be more 'user-friendly.' This
would provide a more authoritative indication of whether social/behavioral scientists would comply with a CONSORT extension. The authors may also consider changing the tone to encourage stakeholder support from these fields, as mentioned earlier, as well as in the concluding sentence of the report.”

- We have changed this sentence to the following: “Researchers in public health, psychology, education, social work, and criminology have noted that these guidelines could be more ‘user-friendly’, and dissemination could benefit from up-to-date knowledge transfer techniques.[11-13, 17, 31, 36, 37]”

3d. “How would the proposed new guideline extension relate to the already existing extension for non-pharmacological interventions? Do the authors intend to start all over again, or will the existing extension be integrated with the new one?”

- This comment is now addressed by the following quotation on page 12: “Like other official CONSORT extensions,[27, 29, 60, 61] this guideline will be integrated with the CONSORT Statement and previous extensions, and updates of the CONSORT Statement may incorporate references to this extension.”
4. Issues targeted by the guideline

4a. “the importance of understanding context and contextual influences is mentioned but is cursory. Why does it matter and what are the implications for the development of such a guideline to enhance reporting of UPScale interventions?”

- We have revised the end of the first paragraph to emphasise the importance of context:
  o “Moreover, these interventions may be contextually dependent upon the hard-to-control environments in which they are delivered, (e.g., health care settings, correctional facilities).[2, 3] The functions and processes of these interventions may be designed to accommodate individuals or contexts, taking on different forms while still aiming to achieve the same objective.[4, 5]”

- We have then added further explanation of the importance of contextual influences throughout the section “Aspects of External Validity.”

4b. “Also, public health interventions typically use the CONSORT guidelines and journals require them. It would seem that a better approach might be to develop guidelines within these fields, specific to the types of interventions designed. The authors do make some good points about aspects of trials that impact internal and external validity, but again, these aspects are likely to differ substantially across the diverse disciplines they have chosen to combine. Also, as they point out, some of these are already included in CONSORT, so the need really is to ensure adherence to CONSORT, not to develop new guidelines.”

- While we appreciate the reviewers’ consideration of the most efficient course forward, we respectfully disagree with the suggestion. The section “Limitations of Previous Reporting Guidelines for Social and Psychological Interventions” delineates how previous guidelines do not address all essential features of social and psychological intervention RCTs, how researchers in the many fields that employ these interventions do not generally adhere to current CONSORT and other reporting guidelines, and how these interventions share key features across all scientific fields that design and evaluate them. We recently wrote a paper that has been accepted in PLoS One that addresses these issues: “Grant, S., Mayo-Wilson, E., Melendez-Torres, G.J., & Montgomery, P. (2013, in press). The reporting quality of complex psychological and social intervention trials: a systematic review of reporting guidelines and trial publications. PLoS One.”

4c. “On page 9 the authors write "In UPScale intervention trials, outcome measures are often subjective, variables may relate to latent constructs, and information may come from multiple sources (e.g. participants, providers)." My reading of a large swathe of the health services literature would suggest that those exact same characteristics apply there too. It might be worth making the point that health services research is similarly plagued by a plethora of "subjective" outcome measures, "latent constructs", and (for very good reason) evidence coming from "multiple sources".”

- We thank the reviewer for this comment. We agree that issues regarding the use of subjective variables and latent constructs are issues for any field that utilises them. We do believe, however, that they are particularly important in social and psychological intervention research—including social and psychological interventions in the health services literature, which is thus an area targeted by the guideline. We have added the following quotation to this section of the manuscript (p. 10) to clarify: “While an issue in other areas of research, the influence on RCT results of the quality of subjective outcome
measures in social and psychological intervention research has long been highlighted given their prevalence in social and psychological intervention research.[44]"

4d. "External validity: The emphasis of external validity is an important step to reach out for more acceptance of reporting guidelines. The guidelines might also consider some suggestions for authors how to justify their specific balance between internal and external validity."

- We agree with the reviewer that external validity is a key area of growth for current reporting guidelines. While we do hope that the final guideline incorporates both internal and external validity to a satisfactory extent, we do not believe that the guideline nor this article should offer prescriptions for study conduct. The guideline should help authors report sufficient information to allow readers to appraise how the authors have decided to address these important issues.

4e. "(iii) the article reads almost like a preamble for an article. You are clearly inviting a large number of people to take part in this exercise but at present there is nothing of substance, not even a skeleton, on which others can build. I really feel that if this is to be published in a major Journal that you need to give some guidance to professionals in mental health and related disciplines as to what will finally appear;"

- Thank you. We have amended the section “Developing a New CONSORT Extension” to indicate what the final product will look like and how it will be used. We have kept this to a minimum, however, as the nature of this project requires that the final product be influenced by stakeholder opinion rather than the initial desires of the Project Executive.
5. Future phases

5a. “More description and inter-relating with the content found at the website would be helpful. The reader should be better introduced to the basic nature of the website and the purpose for being referred there, if s/he is being invited to participate in the project by visiting the website.”

- We thank the reviewer for this comment and have added the following sentence: “We invite stakeholders from disciplines that frequently research these interventions to join this important effort and participate in guideline development by visiting our website, where they can find more information about the project, updates on its progress, and sign up to be involved (http://tinyurl.com/CONSORT-study).”

5b. “Developing a new consort extension - this discussion is generally fine but it would be useful to have some more information about how people will be involved in the stages of the project. The authors describe engagement with a range of stakeholders but I am not clear how they will be recruited. Given that there will be a consensus meeting presumably in the UK I wondered whether the team had considered the equity issues i.e. how will the process engage those from LMICs?”

- We have amended the second paragraph of this section to address this reviewer’s helpful suggestion:
  o “The project is being led by an international collaboration of researchers, methodologists, guideline developers, funders, service providers, journal editors, and consumer advocacy groups. We will be recruiting participants in a manner similar to other reporting guideline initiatives—identifying stakeholders through literature reviews, the project’s International Advisory Group, and stakeholder-initiated interest in the project.[14, 16] We hope to recruit stakeholders with expertise from all related disciplines and regions of the world, including low- and middle-income countries. Methodologists will identify items that relate to known sources of bias, and they will identify items that facilitate systematic reviews and research synthesis. Funders will consider how the guideline can aid the assessment of grant applications for RCTs and methodological innovations in intervention evaluation. Practitioners will identify information that can aid decision-making. Journal editors will identify practical steps to implement the guideline and to ensure uptake.”

5c. “Please indicate a strategy how to involve a variety of important stakeholders from other scientific communities than those in the medical field. Besides the invitation to participate in the Delphi process via the website, could e.g. scientific societies or journal editors in psychology, social work, criminology, and education be approached in a more systematic way?”

- Thank you. Please see the quotation in 5a above.

5d. “The conclusion is articulated well and provides a good summary of the report. The authors mention that RCTs are not the only type of method for evaluating interventions, yet this is the focus of the present CONSORT extension. Aside from systematizing reporting standards, will there be other and/or additional resources available to investigators of UPScale interventions to guide them and their research teams up to the point of reporting their research results? I understand that much of this will be decided via the international consensus, and is beyond the scope of this report.”
• We agree that this is an important issue, although we believe that it is beyond the primary purpose of this guideline. We have added the following line in the conclusion to clarify: “This guideline is the first step towards improving reports of many designs for evaluating social and psychological interventions, which we hope will be addressed by this and future projects.”

5e. “At the end of the introduction, the authors state that the RCT design would be the starting point for the new guideline extension. However, alternative designs are widely used in UPSCALE. Therefore it might be useful to consider and define also generic reporting issues of non-pharmacological intervention studies right from the start.”

• We agree that many issues for RCTs of social and psychological interventions are relevant to other designs evaluating these interventions. However, this guideline and thus this paper specifically target RCTs, so we think it proper to focus on this methodology and associated issues with these designs. To address this reviewer’s concern, we have attempted to clarify, throughout the paper, which issues are relevant to “RCTs” specifically and which are relevant to “studies” of these interventions more generally. As mentioned above in 5d, we have also alluded to our desire for the outputs of this guideline to influence future projects aiming to improve the reporting of other types of evaluations of these interventions.

5f. “The conclusion is good but I wondered if the authors could make a comment on the application of this extension to CONSORT more generally. That is, there may be issues that emerge that are important to all trials that are not considered in CONSORT.”

• The following quotation addresses this point, namely indicating that by working officially with the CONSORT Group, there is the potential for items in this extension to be integrated into CONSORT more generally if relevant: “Like other official CONSORT extensions,[27, 29, 60, 61] this guideline will be integrated with the CONSORT Statement and previous extensions, and updates of the CONSORT Statement may incorporate references to this extension.”

5g. “There is a negative correlation between length and acceptance/implementation of guidelines. Existing space limits of scientific journals (especially print journals) often do not allow to report extensively on very complex methods and study designs. Once the CONSORT checklists gets more complex, this problem of appropriate description and publishing the study methods might become even more urgent. The authors might comment on this problem and indicate possible solutions.”

• The reviewer is correct that journal word-limit is a major issue for reporting guidelines, and we have been mindful of this issue in the design of the project. We have added the following to note that the inclusion of journal editors in consensus methods is partly intended to address this issue: “The success of this project depends on widespread involvement and agreement among key international stakeholders in research, policy, and practice. For example, previous developers have obtained guideline endorsement by journal editors who require authors and peer-reviewers to use the guideline during manuscript submission and who must enforce journal article word limits.[19, 64] Many journal editors have already agreed to participate, and we hope other researchers and stakeholders will volunteer their time and expertise.”
Minor Comments

1. “On page 5 of the introduction, the authors indicate that ‘RCTs are often insufficiently reported across disciplines including criminology, social work, education?’. However, if insufficient reporting is problematic regardless, and if the goal to be achieved by the CONSORT extension is to agree upon systematic reporting, then it may be helpful to have these points clarified. For example, the insufficient reporting of RCTs “across” these disciplines also suggests insufficient reporting of RCTs occurs “within” these disciplines. Thus, if the authors want to make a simple point insofar insufficient reporting occurs then perhaps "by" would be a better choice of phrasing."

   • We have made this change in accord with the reviewer’s helpful suggestion.

2. “The section on external validity is good. In this section, you might want to add references to equity and considerations about context as suggested above.”

   • We have addressed this issue in the text and noted the following references in support:

3. “A shorter, easier to enter, more featured url would be helpful that leads directly to the most pertinent location on the website.”

   • We have now created a more user-friendly URL for the project: “http://tinyurl.com/CONSORT-study”

4. “Towards the bottom of page 10 the authors write "Participants in UPSCALE intervention trials are often recruited outside of general practice settings via processes?". I suspect the words "general practice" are not meant to refer to primary care as often described in the UK, but my initial reading made me think of that connection, so a slight rewording might be helpful.”

   • We have changed this sentence from “general practice settings” to “routine practice settings.”

5. “On page 13 the authors write "Policymakers benefit from research when developing effective, affordable standards of care and choosing which programmes to fund." I think the word "care" is inappropriate here, given that, for example, criminal justice services and education services are not generally in the business of "care".”

   • We have changed from “care” to “practice and choosing which programmes and services to fund.”

6. “On page 7 the authors use the language 'randomized trials' whereas elsewhere in this report
the authors use RCTs after defining randomized controlled trial in the introduction. If there are no distinguishing characteristics, then I assume RCT was intended to be used here, and for clarification purposes consistent language should be used throughout the report.”

- We have changed all terms throughout the manuscript to “RCTs” unless trials or studies in general were meant.

7. “The importance of this project is clearly documented in the paper. The introduction (para 1) focuses on scientists not adopting the guidelines mainly due to objections. Is this really the main reason? The paper goes on to describe other reasons which I feel are equally compelling. The wording is similar on page 6 para 2 and so I think this could be altered (i.e. there are likely to be a range of reasons).”

- We have modified this sentence as follows: “However, many social and behavioural scientists have not fully adopted these guidelines, which may not be wholly adequate for social and psychological interventions in their current form.[10, 13, 17, 18]”

8. “The two sections on internal and external validity cover the issues missing in CONSORT well. However, there is no clear identification of the purposes of these sections. I think the authors should consider a linking statement before internal validity. I think the external validity paper would benefit from considering Wang et al: http://heapro.oxfordjournals.org/content/21/1/76.abstract”

- We have changed the sections to now be called “Aspects of Internal Validity” and “Aspects of External Validity.”
- We have also added the Wang reference to the last paragraph of the “Aspects of External Validity” section.

Thank you again for your consideration of this manuscript for Trials. We look forward to working with you on bringing this to publication and on other works in the future.

Yours sincerely,

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