Author's response to reviews

Title: Economic support to improve tuberculosis treatment outcomes in South Africa: a qualitative process evaluation of a cluster-randomised controlled trial

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Author's response to reviews: see over
The Editor

Trials Journal

Dear Sir/Madam

Re: MS: 3381809051229755 (Economic support to improve tuberculosis treatment outcomes in South Africa: a qualitative process evaluation of a cluster-randomised controlled trial)

Thank you for the comments on this article, submitted to you for consideration for publication. I have addressed almost all of them, as outlined below. Please find below specific changes listed in red, in response to specific comments, listed per reviewer. All the changes are highlighted in track changes in the manuscript. I hope these changes are acceptable and that this paper can be published in your journal.

Editorial requests:

I have put the abstract on a separate page, and added the date of trial registration on the abstract page.

The Consort flow diagram and checklist are included with this submission. Please note that this paper is the report of the process evaluation of the trial, thus many of the requirements of the Consort checklist are not reported in this paper but were reported in the original publication from this trial, which was published in your journal in 2013. The full citation is as follows: Lutge E, Lewin S, Volmink J, Friedman I, Lombard C. Economic support to improve tuberculosis treatment outcomes in South Africa: a pragmatic cluster-randomized controlled trial. Trials 2013;, 14:154 doi:10.1186/1745-6215-14-154.

Reviewer 1 comments:

Major Compulsory Revisions

The specific study setting (province) is mentioned too late in the article (Results, 5th sub-section). Perhaps the province/districts can be mentioned in Box 1. This is all the more important because the article emphasises the importance of contextual (socio-economic) information (Background, fifth paragraph, Conclusion, first paragraph). Have added text to Box 1; page 5

For the same reason it would be important to not only mention that two districts were involved (Population and sampling, fourth paragraph), but to actually name and contextualise them. The poverty profiles of both the province and the districts (relative to the rest of the country) should be described. Have added to new heading “Trial setting” under Methods section, page 7.

The eligibility criteria for patients should be specified. (There is reference to such criteria but they are not specified anywhere.) Have added section on eligibility criteria under “Population and sampling”, Methods section, page 7.
Minor Essential Revisions

The Abstract, Background variably refers to “tuberculosis” and “TB”. In the section “Equity and social justice in the implementation of the voucher system”, “[pulmonary tuberculosis]” should be “[pulmonary TB]”. Have referred primarily to “TB”, and have made change on page 13.

In the section “Perceived effects of the voucher on adherence to treatment”, “i.e.” is used in the explanatory note between square brackets. This is not done in any other explanatory note within an illustrative citation. Have deleted “i.e.” in explanatory note identified on page 19.

In Discussion, fourth paragraph “(Plaatjie 2012)” should be replaced by a reference number with Plaatjie (2012) listed under References. Have made change.

 Corrections needed in References:


• “Meulmans” should be “Meulemans”
• “Janse-van Rensburg-Bonthuysen” should be “Janse van Rensburg-Bonthuizen”
• The article forms part of “Acta Academica Supplementum 2005(1): 1-55. Have made changes to reference

Referencing (e.g. journal article page numbers) should be according to journal style. Have made changes to references.

Article titles in lowercase – Cegielski et al. 2012. Have made changes in references section.

Date accessed not consistently indicated for all website references. Have added dates accessed for those website references where it was omitted (references section).

Discretionary Revisions

The study is variably referred to as a “qualitative process evaluation”, “process evaluation”, “qualitative study” and “qualitative analysis” – can this be standardised? Have referred to “qualitative process evaluation” throughout.

Use “TB treatment outcomes” rather than “outcomes of patients on treatment” (Background, first paragraph, Discussion, first paragraph) Have made changes.

In Ethical considerations, second paragraph, the statement “… and no participants were paid for taking part in these interviews” should/could be offset against the incentive to patients to participate in health research (e.g. London et al. Improving ethical review of research involving incentives for health promotion. PLoS Med 2012; 9(3): e1001193).
I have not made reference to this paper because it deals primarily with the ethics of using incentives to encourage patients to participate in research, whereas in our trial the focus of the study was the effect of the incentive on health behavior – the incentive was fundamental to the research itself, and not an inducement to participate in the research.

The distinction between results and discussion is not very clear. The following extracts from Results, in my view, could more appropriately be integrated in the Discussion (…). The second reviewer also suggested that some of the paragraphs ending sections in the Results section be moved to the Discussion. However, because both reviewers included this recommendation as a discretionary recommendations (that I could choose to act on or not), I decided not to move the paragraphs. This is for two reasons. Firstly, it is because I feel that in qualitative research, the Results and Discussion are more intimately linked than in quantitative research, and so some of the implications of the Results can be alluded to in the Results section. Secondly, it is because I feel that the transitions between sections of the Results would be too abrupt without these paragraphs, and make reading less smooth.

In the section “Equity and social justice in the implementation of the voucher system”, the finding “The patients themselves felt that this was fair – if they were doing well financially that month, it was better that someone else received the voucher that they might have taken:” is followed by the illustratory citation: “When I am here I get it if I ask for it” (Patient, Clinic 5 page 4). Does this speak to patients wanting other more needy patients to receive the voucher? I think this quote speaks to patients not receiving the voucher unless they specifically requested it, and the implication is that they would not request it unless they needed it (derived from the subsequent quote). However, I see that this implication is not necessarily obvious and so have deleted the quote.

In the section “Impacts of the voucher on patient poverty” the sentence “However in some cases, especially in the case of children or the elderly, the food was reserved for the index patient alone” is followed by an illustratory citation referring to “the child”. Could the same be provided for “the elderly”? Yes, there was an elderly patient who participated in the interviews who echoed this view, but I did not quote because I do not want the quotes to become too long or tedious.
Reviewer 2

Major Compulsory Revisions

• Page 2: Mention the method of participant selection. Added on page 8

• Page 4: Clarify the onset of voucher receipt by the patients. Have added in section “Population and sampling” under “methods section” page 7. Mention the persons responsible for voucher distribution and the measures instituted to prevent voucher leakage/misuse during the trial. Have added in Box 1, “Description of the trial and its results”, page 5.

• Page 6: Describe the setting for this process evaluation. Have added in Box 1, “Description of the trial and its results”, page 5.

Also, mention the duration of the trial. Have added in section “Trial setting” under “Methods section”

• Page 24-28: Present references and tables according to journal style. Have made changes to references section.

Minor Essential Revisions

• Page 1: Revise the sentence “A qualitative process evaluation, conducted in the final few months of the trial, explain some of the factors that contributed to this low fidelity.” Have revised sentence. Also include the duration of the trial. Have added in section “Trial setting” under “Methods section”

• Page 2: Insert “TB” after “tuberculosis” and use “TB” consistently throughout the text (see page 3: paragraph 2). Have made changes

• Page 3: Define HIV. This is defined in list of abbreviations. Mention the national target for PHC utilisation. Have added under Background section, page 4.

• Page 5: Change [16], [17] to [16,17]. Have made change

• Page 6: Together with this, mention whether data on other sources of economic support e.g. social grants was gathered. What proportion of those who did not get vouchers were receiving social grants? We did not do this analysis, but did compare other factors associated with receipt of the vouchers. This information is in the report of the main trial (Lutge E, Lewin S, Volmink J, Friedman I, Lombard C. (2013) Economic support to improve tuberculosis treatment outcomes in South Africa: a pragmatic cluster-randomized controlled trial. Trials; 14:154 doi:10.1186/1745-6215-14-154.)

• Page 7: What was the duration of the interviews? Where were the interviews with patients conducted? What information was provided to the patients prior to seeking their consent to participate in the study? Who conducted interviews with the patients? What, if any training did field assistants receive with respect to procedures for ethical qualitative data gathering including the consent procedures? Information added under section “Data collection”, page 10.
The paragraph “All nurses interviewed were professional nurses, with a median nursing experience of 15 years. Patients had a median of 8 years’ schooling. Sixty nine percent of patients were unemployed, 14% worked in the informal sector, 3% in the formal sector and 14% were too young to work” can be inserted just after Table 1 on page 6. Have made change.

• Page 20: define DOT. Have done so in “List of abbreviations” Change [25], [26], [27] to [25-27]. Have made change.

Use numeral reference for “Plaatjie 2012.” Have done so, and added reference to References section.

• Page 23: Change “DOTS supporter” to “DOT supporter.” WHO distinguishes between “DOTS” and “DOT.” Have made change

Discretionary Revisions

• Page 11: Shift paragraph “It was clear from the interviews ... non-significant findings of the trial” from results to the discussion section. Please see response to reviewer one, on page 3 above, under point beginning “The distinction between results and discussion is not very clear...”

• Page 12: Shift paragraph “Travelling to the clinic ... some patients were affected by them” from results to the discussion section. Please see response to reviewer one, on page 3 above, under point beginning “The distinction between results and discussion is not very clear...”

• Page 21: In the last paragraph, better to use “treatment success” as already reflected in Box 1 instead of “cured or completed treatment.” Have made change.

I hope these changes are acceptable and that the paper is suitable for publication.

Yours faithfully

Elizabeth Lutge.