Author's response to reviews

Title: Strengthening Contact Tracing Capacity of Pulmonary tuberculosis Patients in Enugu, Southeast Nigeria: A Targeted and Focused Health Education Intervention

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Version: 5 Date: 21 August 2014

Author's response to reviews: see over
The Editor

BMC Public Health

RE-SUBMISSION OF MANUSCRIPT ENTITLED: STRENGTHENING CONTACT TRACING CAPACITY OF PULMONARY TUBERCULOSIS PATIENTS IN ENUGU, SOUTHEAST NIGERIA: A TARGETED AND FOCUSED HEALTH EDUCATION INTERVENTION STUDY

We wish to re-submit the above manuscript with corrections made according to the recommendations made by the editor. The responses are as stated in the next pages below.

In this era of TB/HIV co-infection and collaborative activities, with the MDG targeted year in view; any study such as this that would enhance early detection and management of TB diseases should be encouraged. This is more so in environments that stigmatize and discriminate against persons suffering from TB disease. This will help us to achieve the set targets of detecting at least 70% of the estimated infectious cases, to cure at least 85% of the detected cases and to reduce by 2015 TB prevalence and death rates by 50% relative to the 1990 level. Increasing case finding and detection is the first step wise direction to achieving the laudable MDG goals. In this article, targeted educational intervention technique has been used successful to improve TB case finding by enhancing the contact tracing skills of the TB
patients that enabled them to reach out to their household contacts and subsequently bring them for screening and treatment.

Publishing this work will help make the findings far reaching as to fulfill the intended objectives.

Yours sincerely
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**Author's response to Editor’s Request**

**Title:** Strengthening contact tracing capacity of pulmonary tuberculosis patients in Enugu, southeast Nigeria: a targeted and focused health education intervention study

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**Version:** 3
**Date:** Aug. 20, 2014

**Reviewer:** Editor

**Editor's Comments:**

"The authors have made revisions which has improved the manuscript. However, there are still
major issues which needs to be addressed In regard to following good practice in transparent reporting of non randomized design (TREND), some important elements are still missing, e.g.

1. Theories used in designing behavioral interventions

The behavioural theories applied in the training intervention have been stated in the methodology intervention section paragraph 2 as follows: -----motivated to change negative behaviours and attitudes inimical to the desired goal of convincingly and persuasively bringing their contacts for screening. The key aspects of the planned behaviour conceptual frame work are based on Ajzen’s theory of planned behaviour and Bandura social cognitive (learning) theory aimed at changing some personal factors that might negatively affect the expected outcome. Also the details of the theory as applied have been added in the discussion section paragraph 6 as follows: It also requires commitment to changing personal factors and value system re-orientation such as self-efficacy (perceived ability/competency), attitude (beliefs and values about the outcome of the behaviour), and subjective or social norms, that is beliefs the person held in regard to others expectation of his behaviour. This is the conceptual basis for the designing of the planned health education interventions geared toward persuading the TB patients for behavioural change and giving them skills to be able to convincingly bring their contacts for TB screening [35,36]. The application of these behavioural change theories as learnt during health education intervention played a significant role in the observed changes in contact tracing practice among the study TB patients post-intervention.

2. Specific hypotheses

Specific hypothesis has been included as last part of introduction as stated:

Null hypothesis

1. There is no significant difference between the study and the control TB patients on the knowledge of contact tracing before and after health education intervention.
2. There is no significance difference on the number of the study and the control TB patients that brought TB contacts for screening before and after health education intervention.

Alternative hypothesis

3. There is a significant difference between the study and the control TB patients on the knowledge of contact tracing before and after health education intervention.

4. There is a significant difference on the number of the study and the control TB patients that brought TB contacts for screening before and after health education intervention.

3. Clearly defined primary and secondary outcome measures

Primary and secondary outcome measures have been included in the data analysis section.

The primary outcome measures are the number of TB patients that brought their contacts for TB screening, and the actual number of contacts brought for screening post-intervention. The secondary outcome measure is the knowledge difference on contact tracing between the study and control groups post-intervention.

4. Inclusion of aspects employed to help minimize potential bias induced due to non-randomization (e.g., matching)

This has been included in the participant’s section last paragraph:

Measures were put in place to minimize potential bias inherent to non-randomization studies. Stratification of the TB centers according to completeness of services offered and the patients load was done before selection of the study and control units. Only sputum smear positive TB patients who had started treatment at least one month prior to the study were included in the study. This measure minimizes any differences in the treatment experiences among the TB patients and reduces potential differences in attrition rate. Matching of TB patients was done at the group levels and participants with similar socio-demographic variables were selected. Group level matching was done to minimize resource and logistic
cost implications. The process ensured that the TB patients have similar characteristics at baseline. Strategies were taken to confirm that all the TB patients in the study and the control groups have had exposure to the routine health education at their TB centres. Both groups have similar environmental and geographical exposure having been selected from the same southeast region of the country, and have the same ethnic background.

5. Flow diagram of participants through each stage of the study: enrollment, assignment, allocation, and intervention exposure, follow-up, analysis

Flow diagram has been as figure 1 in an additional file submitted

6. Dates defining the periods of recruitment and follow-up

The defining dates have been stated and inserted in intervention section paragraph 4:

The study was undertaken within the months of February, 2012, to June, 2013. Recruitments of the TB participants took place between the months June to August, 2012, and lasted for eight weeks. Health education intervention was implemented over a period of three months starting from September to November, 2012. Post-intervention and follow up of the TB participants was from January, 2013, to March, 2013. Data analysis, write up and reporting lasted for three months

7. Discussion of results taking into account the mechanism by which the intervention was intended to work (causal pathways) or alternative mechanisms or explanations

The discussion section has reflected intended mechanism of using health education as an intervening approach to achieving the expected outcomes; impacting skills and knowledge to TB patients to enable them achieve certain level of contact tracing capacities. These have been reflected in the various paragraphs in the discussion

8. Discussion of the success of and barriers to implementing the intervention, fidelity of implementation

Efforts made to achieving fidelity of implementation have been included in section

Fidelity of Implementation, Success of and Barriers to Implementing the Intervention
The intervention was implemented by a team of researchers comprising of the three principal researchers, six nurse educators trained on the content of the health education, research protocol, questionnaire contents and administration. Others include three laboratory technologists that performed and read the sputum smear microscopy, and who also received training on the health education content, and two external consultants quite knowledgeable with training on the research protocol acting as observers and evaluators of level of implementation fidelity, monitors and gives feed back at the end of the sessions. The trainers adhered to the essential components of the intervention including the content of the health education, frequency of the intervention, duration of each training session and specific content coverage prescribed for each session. The trainers used printed training guide to ensure strict adherence to the training protocol, and to improve quality of content delivery. The content of the health education were made simple and less complex, and the questionnaire was also simplified and made less ambiguous after pre-testing in a similar setting. The trainees were given training hand outs and materials including the objectives of the training. Feedbacks were requested from trainees after each training period for the benefit of those delivering the intervention so as to improve their facilitation strategies. The content of health education intervention include the causes, signs and symptoms of TB; mode of transmission, spread and control; benefits of early detection, diagnosis, and treatment; dangers of untreated cases of TB; fallacies associated with TB; meaning and importance of contact tracing; and the framework for attitudinal and behavioural changes toward community health, and TB patients. Although the participants were highly engaged, motivated, and committed to attending the training sessions, some challenges were still experienced. Some sessions started late because the participants were unable to keep to the time schedule for one personal problem or the other including local transportation delays. Those that missed more than two sessions were considered among the drop outs. Also the quest to start normal daily clinic consultations imposed a little challenge, especially on the time allotted for question and answer sessions for the participants to share their views and get clarification on intriguing issues and challenges.

9. General interpretation of the results in the context of current evidence and current theory
The recommended reference has been added including additional work done in 2012. These are put and discussed in the discussion sections as parag 9:

A systematic review and meta-analysis of 203 published studies out of 9,555 screened, reporting prevalence of TB and TB latent infection, and the annual incidence of TB among contacts of patients with TB was carried out by Fox GJ, Barry SE, Briton WJ, and Marks GB [37]. The results of the 95 studies from the low-and-middle-income settings varied considerably from the findings in the 108 studies from high-income settings. In the low income settings, the prevalence of active TB among all contacts was 3.1% (95% CI 2.2-4.4%), microbiologically proven TB was 1.2% (95% CI 0.9-1.8%), latent infection 51.5% (95% CI 47.1-55.8%), and the prevalence of TB among household contacts was 3.1% (95% CI 2.1-4.5%). Among the high-income countries, the prevalence was 4% (95% CI 1.1-1.8%) among the TB contacts, and 28.1% (95% CI 24.2-32.4%) for latent infection. In our present study, the prevalence of TB among contacts was comparatively higher, both for the study and control groups Table 8. Among the study contacts, the prevalence of TB among the contacts before and after intervention, were 6 (19.4%) and 19 (13.7%) (95% CI -23.8-35.2); and in the control group 7(26.9%) and 11(28.9%), (95% CI -45.8-41.8) respectively. The observed differences in the presence of TB among the contacts of the study and control groups were not statistically significant (P> 0.05). However, there was a statistically significant difference between the study and control groups in the primary outcome measure, that is the number of TB patients that brought their contacts for screening post intervention (114 verses 9; 95% CI 44.3-74.9) Table 5. Similarly, in South East Asia, a systematic review and meta-analysis of 11 studies that met the inclusion criteria out of 1087 screened were analyzed to investigate the prevalence of TB infection among child contacts of TB cases [38]. The result showed the prevalence of TB infection among child contacts under 15 years of age was between 24.4 - 69.2%, quite higher than the prevalence TB diseases in the region which varied from 3.3% to 5.5%. The prevalence of TB among the contacts in our study as shown in Table 8, both before and after the intervention, falls within the range stated among child contacts in the South East Asian review study Table 8. In either case, the result is an indication for a search of innovative way or novel approaches to enhance contact tracing among TB contacts.
In regard to the last point above, the authors have only added one reference from 2006 to update the discussion. There are still a number of important relevant references beyond 2007 which needs to be incorporated, e.g. Fox GJ, Barry SE, Britton WJ, Marks GB. Contact investigation for tuberculosis: a systematic review and meta-analysis. Eur Respir J. 2013 Jan;41(1):140-56

The author claims that “this study can be generalized to settings beyond the study site.” This implies that it can be generalized to other settings beyond Nigeria and even beyond Africa. In this regard, the authors need to carefully consider the importance of contextual factors in any public health interventions.

This has been addressed and added in the section limitations and generalization of findings:

Thus, this study can be generalized to settings beyond the study site. However, careful application of the strategies employed and the findings of this study is necessary according to local context in view of the contextual factors in public health interventions as it relates to policies and implementations.

The study conclusion is geared toward the interest of Nigeria. To be published in BMC Public Health, this has to be geared more toward international readership.

The conclusion has been geared toward international readership and added as last sentences in the conclusion section as follows: Since TB has a global burden and of global public health importance, there is need for novel strategies such as the one applied in this research to impact skills and improve knowledge of contact tracing among TB patients, that are apparently acting as both primary and secondary source of transmission of TB. By so doing, the TB patients would become partners in progress toward elimination of TB as a public health problem by 20150. Policy is hereby advocated on the use of formal, planned, coordinated, and participatory intensive health education intervention to improve the contact tracing skills of TB patients at the major TB centres, especially in the low and middle income countries with the larger percentage burden of TB disease.
Figure I should be deleted and the data can be reported directly in the text.

Figure 1 as bar chart has been deleted and reported directly in the result section. It has been replaced with flow diagram as figure 1.

Confidence intervals should also be reported in the text, not just in the tables.

These have been added in the result section as well as in the discussion sections as appropriate.