Author’s response to reviews

Title: Randomized community trial on nosocomial infection control educational module for nurses in public hospitals in Yemen: a study protocol

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RESPONSE TO COMMENTS BY THE EDITOR AND REVIEWERS

We appreciate the constructive comments by the editor and reviewers in improving the quality of the manuscript.

The following are the responses to the comments.

Editor’s comments.

COMMENTS: Please add an author order list to the manuscript title-page.
RESPONSE: This was included in the title-page in the earlier submission. We may have misunderstood the format. Please kindly clarify.

COMMENTS: Please append the name of the trial registry to the end of the online submission and manuscript abstracts.

RESPONSE: For clarification: the current trial registration number is ISRCTN19992640. Was there a change to the number?

COMMENTS: Language issues.

RESPONSE: The manuscript has undergone grammar check.

COMMENTS: Please use future tense throughout your manuscript.

RESPONSE: As this protocol is currently at the analysis stage, we pledge to use the past tense where applicable. The reviewers have also recommended the use of past tense as this is an ongoing study.

COMMENTS: Figure titles and legends should be placed in a separate section at the end of the manuscript.

RESPONSE: The correction has been made accordingly.

COMMENTS: Please include copies of the questionnaire described in the study (both in the native language and as an English translation) as additional files.
RESPONSE: The questionnaires are included as requested.

Additional amendments made:

Please kindly note that the institutional address of the first author has changed since the first submission: we have made the amendments.

Comments by Maria Clara Padoveze, PhD (Reviewer 1):

COMMENTS: General comments: This is a research protocol that I think will be very useful to readers of BMC Nursing. I recommend to explicit that the study is ongoing at the analysis stage in both the abstract and the body of the manuscript.

RESPONSE: Thank you for this valuable comment. Based on your recommendation, we have stated that this protocol is currently on going and at the analysis stage in both the abstract and the body of the manuscript. Please kindly see:

-Abstract: Line 6 & 7, p.1;

-Study settings and population section: Line 1 & 2, p: 5; and

COMMENTS: Abstract: I would recommend to exclude the "inexpensive" as a qualifier for the education module, because although the cost can be low, there was for sure cost in developing and applying the educational module. Otherwise it would be necessary to provide data on the costs.

RESPONSE: Thank you. We deleted the word "inexpensive" as recommended. Please see, Abstract section, p. 2, line 3.

COMMENTS: Background: this section presents properly the problem however there is an error in the definition of time for post-discharge and post-operation days to define nosocomial infections (NI). I would suggest to update this topic.

RESPONSE: Thank you for this comment. The time for post-discharge and post-operation days to define nosocomial infections (NI) is updated based on your suggestion. Please see, in Background section, line 3&4, p. 3.

COMMENTS: Methods: Few information was provided about the content of questionnaire and how it was developed. It is difficult to evaluate the accuracy of the method to evaluate the knowledge and practice because the questionnaire was not provided.

RESPONSE: Further information about the content of questionnaire and how it was developed and validated was added. Please see, Research Instruments, p. 10-12.

COMMENTS: Since this is a study protocol, I consider essential to provide the questionnaire because all the results can be biased if the questionnaire has relevant flaws.

RESPONSE: The English and Arabic questionnaires are provided as an additional file.
COMMENTS: The authors should clarify how the theoretical background is embedded in the questionnaire.

RESPONSE: Clarification on how the theoretical background was embedded in the questionnaire as well as the rational for developing a new questionnaire was added. Please see in Research Instrument section, last paragraph, p. 11.

COMMENTS: The intervention is based in a document from WHO which is not updated since 2002, I would suggest only mention the other document from GCC which is more recent.

RESPONSE: Thank you for this comment. Based on your recommendation, we have only mentioned the document from GCC as it is more recent. Please see Intervention section, line 3&4, p. 8.

COMMENTS: Discussion: this section has information already provided in the background section. Because this paper is aiming at to detail the study protocol, I would recommend that the discussion section should explore more the methods against the literature with similar methods in other fields or similar study with other methods.

RESPONSE: Thank you for your comment. We have re-wrote the section related to discussion based on your recommendation. Please see, in Discussion section, p. 13 &14.

Comments by Nikolaos Efstathiou (Reviewer 3):
COMMENTS: I found confusing the use of past tense in your manuscript, as a protocol usually reports the processes for a future study and the text should be in past tense. I understand that this is an ongoing study, but if you wish to keep the past tense then you need to report that this study is currently undertaken. Probably provide the rationale for publishing protocols to put yours into context.

RESPONSE: Thank you for this valuable comment. Based on your recommendation, we have stated that this protocol is currently on going and at the analysis stage in both the abstract and the body of the manuscript. Please kindly see:

-Abstract: Line 6 & 7, p.1;

-Study settings and population section: Line 1 & 2, p: 5; and


COMMENTS: In the Background, the sentence "Family and community..from admission" requires clarification.

RESPONSE: We have re-wrote this sentence to be clearer. Please see: Background, line 7-13, p. 3.

COMMENTS: At the end of the first paragraph you also refer to intensive care units which is not entirely the focus of your study, so I would like to see a comment on this (for example that the available evidence is related to ICU and that this might be the case in other hospital areas).

RESPONSE: Thank you for this valuable comment. We agree with you that this sentence is not focused on our study. Therefore, we decided to delete it.
COMMENTS: Explain what accreditation means in the Yemeni context. What is expected in terms of accreditation (low prevalence of in-hospital infections or staff adequately trained in infection control)?

RESPONSE: Accreditation in the Yemeni context requires the fulfilment of the guidelines provided by the Ministry of Public Health and Population. The presence of an infection control program is one of the prerequisite for this accreditation. In other words, improve capacity of national hospitals to provide quality care and hence prevention of NIs through an adequately trained staff in infection control measures. Please see, in Governmental goals section, p. 4.

COMMENTS: Report if there is any evidence to demonstrate that training improves prevention of infections.

RESPONSE: A previous study which provided evidence that training improves prevention of infections was added. Please see, Background section, paragraph 2, p. 3&4.

COMMENTS: I would suggest to break the objectives into aim and objectives.

RESPONSE: The study objectives are broken down into aim and study objectives according to your suggestion. Please see, Study aim and Study objectives section, p. 4&5.

COMMENTS: Under Method/Design, you report that three cities were chosen out of five. You need to provide some more context here (are these five cities the largest cities in Yemen? Was your decision based on population?).

RESPONSE: The study was conducted in public hospitals in Azal Region, Yemen. According to the Ministry of Public Health and Population (MoPH&P), most public hospitals are located in Azal Region. There is a total of five cities in this region. Three cities were chosen randomly out
of five as this provided adequate number of nurses to fulfill the required calculated sample size. Please see Study Settings and population section, p.5.

COMMENTS: Under participants, you excluded at the initial stage nurses from other countries, I assume because they had different training, but what about Yemeni nurses who were included and had their training overseas?

RESPONSE: Yes, we excluded nurses from other countries at the initial stage because they had different trainings. This study focused on Yemeni nurses who had three years diploma course in Yemen. Yemeni nurses who were trained overseas were not included in this study. Please see, section on Participants, setting and procedure, line 2, p.6.

COMMENTS: In terms of blinding, I would not agree that this is a single-blinded study as allocation concealment is completely different from blinding.

RESPONSE: Thank you for this comment and you're right that allocation concealment is completely different from blinding. However, we would like to clarify that our study is a single-blinded study as the hospitals and participants were blinded. They were not aware of the random allocation or the hypothesis that was tested while the trainers were aware. Please see: Randomization and blinding process section, p. 7.

COMMENTS: The decision to link the intervention with a theoretical background is very good, but I would expect a better integration of the theory with the intervention.

RESPONSE: Further information about the integration of the theory with the intervention was added. Please see: Intervention elements, p. 9&10.
COMMENTS: Within the Intervention elements, you could report whether the trainers will be aware of the intervention/study.

RESPONSE: This is reported within the intervention elements as recommended. Please see: Intervention elements section, last sentence, p.10.

COMMENTS: You need to state who delivered the training and their qualification to do so.

RESPONSE: Information about who delivered the training and their qualification was added. Please see: Intervention elements section, last paragraph, p. 10.

COMMENTS: I would suggest to change the sentence "according to … avoid any work troubles" to 'to accommodate different work patterns'.

RESPONSE: We have changed the sentence based on your comment. Please see. Intervention elements section, p. 10.

COMMENTS: The tools used to collect data need further discussion (development, appropriateness, validity, reliability, pilot tested).

RESPONSE: We have added the details about questionnaire development, validity, reliability and pilot study. Please see: Research Instruments, p. 10-12.
In the discussion, you mention the inclusion of public hospitals only as a limitation. You could provide some further information here about the private sector to understand the impact of this limitation.

We have included the clarification on why private hospitals were excluded. Please see, Discussion section, last sentence, p. 14.

You also mention that there is no possible risk, but it is not clear what risk you refer to.

There is no possible risk of physical bodily harm to the participants. The sentence was re-wrote to be clearer. Please see, Discussion section, line 16, p. 14.

You state that no funding was received for this study, but who covered the cost of the intervention?

Funding was not received from any organisation for this study. The researchers themselves covered the cost of the intervention.

Careful proof reading is required to correct some grammar and syntax mistakes.

The manuscript has undergone proof reading.