

PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form (<http://bmjopen.bmj.com/site/about/resources/checklist.pdf>) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below.

ARTICLE DETAILS

| | |
|----------------------------|---|
| TITLE (PROVISIONAL) | Study design and protocol for a comprehensive evaluation of a UK massive open online course (MOOC) on quality improvement in healthcare |
| AUTHORS | Smith-Lickess, Sian; Woodhead, Tricia; Burhouse, Anna; Vasilakis, C |

VERSION 1 - REVIEW

| | |
|------------------------|---|
| REVIEWER | Marlies Reinders LUMC, Department of Internal Medicine (nephrology) Leiden The Netherlands |
| REVIEW RETURNED | 01-Jul-2019 |

| | |
|-------------------------|--|
| GENERAL COMMENTS | <p>The authors aim to rigorously evaluate a MOOC about Quality Improvement in Healthcare, which is commendable. They implement two frameworks that have previously been used for this purpose. The protocol is mostly clear and well structured. I have remarks however, which are stated below.</p> <p>Major remarks</p> <ul style="list-style-type: none">- The aim needs to be more specific than 'to evaluate effects and acceptability' (P3L36). Throughout the protocol different descriptions are used, sometimes stating the evaluation is about knowledge, skills and, perceived confidence (P6 L32), sometimes the authors also include attitude. However, when looking into the frameworks and investigated effects, the authors seem to be looking for many more 'effects'. Although table 2 and figure 1 help with interpretation, it still is not completely clear what the authors wish to evaluate, and why, and what instruments measure for each 'effect'. Specific descriptions of the sought effects are needed and used consequently throughout the protocol. A list of primary, secondary and additional parameters would really help. Why are the sought 'effects' relevant? Are they related to the objectives of the MOOC (table 1)?- In addition to the abovementioned specification of the evaluation, the authors need to address why this evaluation is interesting for the medical MOOC (research) community. It is clear why results of an evaluation are interesting for the designers and the organization that offer the course, however evaluating educational products is a best practice and it is unnecessary to disseminate all findings of evaluations. As the method of evaluation has also been previously described for a Medical MOOC (references 18, 19, and 31), authors need to clearly define what gap in the literature they |
|-------------------------|--|

address, and what this study offers to medical MOOC research, practice, or both. They do mention briefly that long term effects of MOOCs are not investigated often, and so this might offer the right angle. In addition, I would expect some more references about MOOC quality, for example: Hood N, Littlejohn A. 2016. MOOC Quality: The need for new measures and Lowenthal P, Hodges C. 2015. In search of quality: Using Quality Matters to analyze the quality of massive, open, online courses (MOOCs). A link between quality frameworks and the evaluation frameworks the authors have chosen would connect the study to previous literature more.

- Qualitative analysis of the interview data needs further explanation (P12 L23). The interview guide is available, and is indeed appropriate for a semi-structured interview. However the way data will be analyzed is not clear. The authors only state thematic analysis methods will be used. Which ones? Template analysis? What is the template? Who will analyze the data en will this be done by one or two researchers?

Minor remarks

- P2 L49: Impact of the limitations on the conclusions is not discussed. In addition, only in the appendix is it mentioned that students might receive financial compensation for participation. As the authors wish to draw conclusions about motivations of participants as part of the Kirkpatrick model (behavior), this might, as well as the mentioned limitation, create a selection bias.
- P3 L22: In the introduction the authors discuss the drop-out rates of MOOCs and the need for research in this area. I would delete or enrich this topic, depending on the gap in the literature the authors wish to address.
- P3 L36: The authors state results are mixed, however it is not stated what these studies aimed to investigate, did they look at quality, or engagement, or academic achievement? Only the topic of the investigated MOOC is mentioned and as such the meaning of this sentence is unclear.
- P11 L17: Authors describe to aim to have 20 interview participants, but do not explain why. It might be more appropriate to adjust the number of interview according to the level of saturation of desirable themes in the data. How to gain saturation of interview data is a well described in literature.
- If long term effects are part of the sought findings, the 3 month period needs to be discussed further. Is this a common or valid time period to investigate long-term results?

Suggestions

- P3 L16: A study that has directly investigated the available teaching modes in medical MOOCs was published recently, which may be better suited than reference 5 and 6 in the introduction: <https://doi.org/10.1080/0142159X.2019.1592140>
- Appendix 2: at point 7 only interview and survey data are discussed, while the study also uses data that is offered by futurelearn. This might need to be included in this section.
- P5: the method and analysis section contains a repetition of the description of the MOOC, I would advise to delete the comparable section in the introduction (P4 L17).

| | |
|------------------------|------------------------------|
| REVIEWER | Dr Alison Carter SRF, USA |
| REVIEW RETURNED | 14-Aug-2019 |

| | |
|-------------------------|---|
| GENERAL COMMENTS | - Develop further on statistics and limitations. - More information on problem addressed and impact of findings. |
|-------------------------|---|

| | |
|------------------------|--|
| REVIEWER | Bhone Myint Kyaw Lee Kong Chian School of Medicine, Nanyang Technological University Singapore, Singapore |
| REVIEW RETURNED | 25-Sep-2019 |

| | |
|-------------------------|--|
| GENERAL COMMENTS | <p>1) The manuscript is well-planned and it is of high-quality in terms of methodology. The topic and the research questions are also very relevant for the readers and researcher in the field. However, I do have a few suggestions for improvement.</p> <p>2) The authors aim to assess immediate post-intervention (MOOC) knowledge, skills, attitude, feedback, satisfaction etc. I would like to suggest to define the outcomes, especially for knowledge, skills, attitude and satisfaction outcomes. For instance, does the author refer skills in general or cognitive/non-technical skills or technical/psychomotor skills? Similarly, does the authors want to assess attitude and satisfaction outcomes in general? or more specifically, for instance, there are different types of attitude (i.e. attitude towards intervention/MOOC or attitude towards the topic or attitude towards the instructors). Based on Miller's pyramid of competence, the outcomes are based on the assessment tools (i.e. MCQ or essays for knowledge and OSCE or OSAT for skills outcomes), I would like to suggest to describe, how and why the authors chose specific outcome(s) for assessment at immediate post-intervention and 3 months follow up?</p> <p>3) For any technology-related intervention, it is recommended to assess (and describe even negative results) untoward effects of the intervention on the learners. I saw it has been mentioned as part of SPIRIT checklist. However, it will be great if you can integrate as part of post-intervention outcomes.</p> <p>4) Whether post-course outcome assessment tools are validated or not? And are they the most relevant one to measure the outcomes? I also would like to suggest to provide more details about the validity evidence of assessment tools</p> <p>5) The authors aim to assess the impact of MOOC on work/practice at 6 months (3 months after course). How will the authors objectively assess/compare the difference? Does it mean change in practicing behavior of (health professionals)? As we didn't assess that outcome at the baseline and immediately post-intervention, I'm not sure how the author will assess. For educational outcomes, most of the educators are interested in retention at follow up such as knowledge or skills retention, I would like to suggest to consider to assess knowledge or skill retention outcome at follow-up.</p> |
|-------------------------|--|

VERSION 1 – AUTHOR RESPONSE

| Editor/ Reviewers' comments | Author's response |
|---|--|
| Reviewer 1 | |
| <p>1. The authors aim to rigorously evaluate a MOOC about Quality Improvement in Healthcare, which is commendable. They implement two frameworks that have previously been used for this purpose. The protocol is mostly clear and well structured. I have remarks however, which are stated below.</p> | <p>Thank you for the positive comments about the protocol.</p> |
| <p>2. Major remarks The aim needs to be more specific than 'to evaluate effects and acceptability' (P3L36). Throughout the protocol different descriptions are used, sometimes stating the evaluation is about knowledge, skills and, perceived confidence (P6 L32), sometimes the authors also include attitude. However, when looking into the frameworks and investigated effects, the authors seem to be looking for many more 'effects'. Although table 2 and figure 1 help with interpretation, it still is not completely clear what the authors wish to evaluate, and why, and what instruments measure for each 'effect'. Specific descriptions of the sought effects are needed and used consequently throughout the protocol. A list of primary, secondary and additional parameters would really help. Why are the sought 'effects' relevant? Are they related to the objectives of the MOOC (table 1)?</p> | <p>We agree that the aims need to be more specific and note that this point was also raised by Reviewer 3 (point 2).</p> <p>The following text (in italics) has now been incorporated into the introduction to clarify how the MOOC's aims and corresponding learning objectives, and the RE-AIM and Kirkpatrick models informed the primary and secondary research questions of this MOOC evaluation study. We have also used consistent terminology/ language throughout the manuscript to avoid confusion. The key learning objectives of the MOOC are now integrated into Table 1.</p> <p>The study was designed to be a comprehensive evaluation of the MOOC. The MOOC's aims and corresponding learning objectives (listed in Table 1), as well as the methodological approaches proposed by the RE-AIM and Kirkpatrick models (commonly used to evaluate training courses and interventions) informed the primary and secondary research questions and the bespoke evaluation framework developed for this study. A mixed-methods approach, comprising pre-and post-MOOC surveys and follow-up semi-structured interviews, was chosen to better understand the immediate and longer-term impact of the MOOC on a number of different outcomes.</p> <p>The aims of the MOOC are to improve learner's knowledge and understanding of QI approaches, and to increase their perceived confidence in participating in QI initiatives. To identify whether the MOOC is successful in achieving its aims and learning objectives, the primary research question of the evaluation study is: To what extent does the MOOC improve learner's knowledge and</p> |

| | |
|--|---|
| | <p>understanding of QI approaches and increase perceived confidence in participating in QI initiatives? (effectiveness)</p> <p>The secondary research questions of the MOOC comprise the following:</p> <ul style="list-style-type: none"> • What are the characteristics of the learners taking the MOOC? (reach) • How did learners react to the course? (reaction) • How did the learners learn and how did they engage with other learners? (learning) • What evidence suggests that learners retained knowledge acquired from the course? (maintenance/ sustainability) • What evidence suggests that the MOOC increased participation in QI initiatives? (behaviour) |
| <p>3. In addition to the abovementioned specification of the evaluation, the authors need to address why this evaluation is interesting for the medical MOOC (research) community. It is clear why results of an evaluation are interesting for the designers and the organization that offer the course, however evaluating educational products is a best practice and it is unnecessary to disseminate all findings of evaluations. As the method of evaluation has also been previously described for a Medical MOOC (references 18, 19, and 31), authors need to clearly define what gap in the literature they address, and what this study offers to medical MOOC research, practice, or both. They do mention briefly that long term effects of MOOCs are not investigated often, and so this might offer the right angle.</p> <p>In addition, I would expect some more references about MOOC quality, for example: Hood N, Littlejohn A. 2016. MOOC Quality: The need for new measures and Lowenthal P, Hodges C. 2015. In search of quality: Using Quality Matters to analyze the quality of massive, open, online courses (MOOCs). A link between quality frameworks and the evaluation frameworks the authors have</p> | <p>Thank you for raising these important points.</p> <p>With regard to what the study offers the medical (healthcare) MOOC community, we note that this will be the first study to evaluate a MOOC on quality improvement in healthcare. The results from this course evaluation will provide evidence on the longer-term effect of a MOOC on professional practice through increased knowledge and self-confidence in QI participation. We also note that previous studies have evaluated medical MOOCs that have been integrated into campus university education as part of medical education curriculum or continuing professional development specifically for postgraduate training for healthcare professionals. By contrast, our QI MOOC was designed for learners not necessarily affiliated with a University, outside of an academic setting. Learners do not need a University degree education as a pre-requisite for doing the course,— i.e. it was designed for a range of people working in health and social care organisations (clinicians, allied health professionals, nurses, managers, administrators, caterers, porters, patients, carers etc...).</p> |

chosen would connect the study to previous literature more.

Thank you for the references about MOOC quality. We have now integrated the following text to link the evaluation models we have chosen with the existing literature on MOOC quality assurance:

The number of MOOCs delivering healthcare and continuing medical education is steadily increasing⁹⁻¹¹. MOOCs have been developed to train physiotherapists about how to manage spinal cord injuries^{12 13}, improve people's understanding of dementia¹⁴, deliver education to medical students about anatomy¹⁵, educate healthcare professionals on antimicrobial stewardship in developing countries¹⁶, raise awareness of the real world data science methods in medicine^{17 18}, and teach students skills of interacting with patients using virtual patients¹⁹. Previous studies have evaluated the impact of the medical MOOC on learner's knowledge, confidence, and perceptions of how it influenced their clinical practice. Results from these evaluation studies are generally promising, in terms of MOOCs increasing public engagement about a particular topic^{14 15}, facilitating collaborative learning¹³, and enabling learners to apply new knowledge into clinical practice.^{16 19} For example, a MOOC designed to help healthcare professionals better communicate with patients using interactive, virtual patient scenarios on stress and sleep problems found that 90% of participants thought the virtual exercise was useful to their learning; qualitative results showed that participants felt more confident in using the methods learnt on the course in everyday interactions with patients, friends and family¹⁹. Another MOOC, designed for healthcare professionals to empower them to provide safe, high-quality antibiotic use (antimicrobial stewardship), found that nearly half of participants (49%) at 6 months follow-up reported that they had started to implement interventions into their own setting.¹⁶ A randomised trial of a MOOC teaching physiotherapy students about spinal cord injuries was found to be as effective as an online learning module in improving knowledge, confidence and satisfaction. The MOOC, however gave learners the

| | |
|--|--|
| | <p>opportunity to interact with other students from around the world. ¹³</p> <p>Given the increasing number of medical and healthcare MOOCs available, it is important that they are evaluated properly to determine their success in achieving their short-and longer-term learning aims and objectives. This in turn will help to ensure that their quality or performance is upheld, and areas for improvement are identified for future learners. ^{21 22} Research into the quality of MOOCs has focused on the instructional design quality of MOOCs, and proposed various principles considered to be important for quality assurance check purposes. ^{21 23 24} A recent study assessing the instructional design of medical MOOCs found that application, authentic resources, problem-centeredness, and goal-setting existed in many courses, however, activation, collective knowledge, differentiation, and demonstration were present in less than half of the courses, and integration, collaboration, and expert feedback were only found in less than 15% of the MOOCs. ²¹ According to Hood and Littlejohn (2016), a MOOC's quality depends upon the MOOC's goals and the learner's perspective. This suggests that a MOOC may be perceived as high quality if the learner achieved or learnt what they wanted to, and that MOOC completion rates may not be an appropriate indicator of quality. ^{21 22} To build on the existing MOOC evaluation literature, we aim to evaluate a MOOC from the learner's perspective, drawing on two commonly used approaches to evaluating the success of training courses – the RE-AIM ^{25 26} and Kirkpatrick models ²⁷– to create a bespoke framework designed to identify whether the MOOC achieved its key aims and learning objectives, and the impact of the course on learner's behaviour in their professional or work practice.</p> |
| <p>4. Qualitative analysis of the interview data needs further explanation (P12 L23). The interview guide is available, and is indeed appropriate for a semi-structured interview. However the way data will be analyzed is not clear. The authors only state thematic analysis methods will be used. Which ones? Template analysis? What is the template?</p> | <p>We have now provided further explanation regarding the qualitative analysis of the interview data in the methods section:</p> <p>The interview data will be analysed by two qualitative researchers using the Framework</p> |

| | |
|--|--|
| <p>Who will analyze the data and will this be done by one or two researchers?</p> | <p>approach, a thematic analysis method involving five stages which deductively uses prior questions drawn from the aims of the study and inductively identifies themes arising from the data³⁵. The five stages of Framework are (1) familiarisation with data; a selection of transcripts will be independently read and themes identified, (2) development of coding framework comprising themes and subthemes, (3) indexing, transcripts will be coded using the framework, (4) charting; the data will be synthesized within a set of thematic matrix charts, where each participant was assigned a row and each subtheme a column, and (5) mapping; similarities and differences of participants' experiences will be identified and discussed.</p> |
| <p>5. Minor remarks P2 L49: Impact of the limitations on the conclusions is not discussed. In addition, only in the appendix is it mentioned that students might receive financial compensation for participation. As the authors wish to draw conclusions about motivations of participants as part of the Kirkpatrick model (behavior), this might, as well as the mentioned limitation, create a selection bias.</p> | <p>The impact of the limitations on the conclusions are now discussed. The following text has been incorporated as bullet points in the 'Strengths and Limitations' section:</p> <p>Strengths and limitations of this study</p> <ul style="list-style-type: none"> • Participant self-select to participate in the study, thereby limiting control over study recruitment and retention, but potentially creating a selection bias. Those who choose/self-select to participate in the study may provide different responses from those who do not choose to participate in the study. • The study does not measure any patient or system related outcomes that may be influenced by learners' participation in the MOOC. <p>The ethics section now mentions that participants may receive financial compensation for their time. This may not necessarily create a self-selection bias as there are no guarantees of financial compensation. Participants may be motivated to complete the MOOC and the course for other reasons, and not just driven by potential financial gains.</p> <p>"As appreciation for participant's time, 10 participants who complete both surveys will be</p> |

| | |
|---|---|
| | randomly chosen to receive a £20 amazon voucher.” |
| 6. P3 L22: In the introduction the authors discuss the drop-out rates of MOOCs and the need for research in this area. I would delete or enrich this topic, depending on the gap in the literature the authors wish to address. | We have deleted the sentence regarding the drop-out rates of MOOC as it is not the focus of the study. |
| 7. P3 L36: The authors state results are mixed, however it is not stated what these studies aimed to investigate, did they look at quality, or engagement, or academic achievement? Only the topic of the investigated MOOC is mentioned and as such the meaning of this sentence is unclear. | Please refer to our response above addressing why this evaluation would be of interest to the medical MOOC (research) community. Additional text has been incorporated into the introduction. |
| 8. P11 L17: Authors describe to aim to have 20 interview participants, but do not explain why. It might be more appropriate to adjust the number of interview according to the level of saturation of desirable themes in the data. How to gain saturation of interview data is a well described in literature. | This is a good point. “We will aim to recruit and interview around 20 learners, or until no new themes or concepts are observed in the data analysis. That is, when thematic data saturation has been achieved. (Saunders 2018)” |
| 9. If long term effects are part of the sought findings, the 3 month period needs to be discussed further. Is this a common or valid time period to investigate long-term results? | This is an important point. We chose the 3-month (post-MOOC completion) follow-up period to conduct the qualitative interviews because we anticipated that learners would be more motivated to apply their knowledge soon after the course. We therefore felt that 3-months post-MOOC is a reasonable time we would expect to see possible changes in behaviour in work practices or participation in QI projects. In addition, from a pragmatic point of view, we felt it was more feasible to conduct interviews sooner rather than later, given the nature of online courses such as this compared to intensive face-to-face training or education programmes. Although it is important to look at long-term effects of the MOOC on learners and on patient and system outcomes, we think that it is beyond the scope of this study. |
| 10. Suggestions P3 L16: A study that has directly investigated the available teaching modes in medical MOOCs was published recently, which may be better suited than reference 5 and 6 in the introduction: https://doi.org/10.1080/0142159X.2019.1592140 | Thank you for this reference suggestion. We have now replaced references 5 & 6 with this reference. |

| | |
|--|--|
| | |
| <p>11. Appendix 2: at point 7 only interview and survey data are discussed, while the study also uses data that is offered by Futurelearn. This might need to be included in this section.</p> | <p>We have now deleted the reference to FutureLearn data in Table 2. Summary statistics (extracted from FutureLearn data) are already being used by the QI MOOC educators to evaluate each run of the course and this has already led to changes over the years since the MOOC started.</p> |
| <p>12. P5: the method and analysis section contains a repetition of the description of the MOOC, I would advise to delete the comparable section in the introduction (P4 L17).</p> | <p>We have edited the paragraphs in the introduction and methods sections to avoid repetition in the two sections about the QI MOOC. Since the BMJ submission, we note that the course has been accredited by CPD Certification Service; this information has been added to the manuscript.</p> <p>Introduction now reads: The current study focuses on the impact of a 6-week MOOC course, entitled, “Quality Improvement in Healthcare: the Case for Change” primarily designed to train people either working in or with an interest in health and social care organisations (clinicians, allied health professionals, nurses, managers, administrators, caterers, porters, patients, carers etc.) in quality improvement methods, and to build their confidence in participating, initiating and perhaps leading quality improvement projects. Broadly speaking, QI seeks to improve the delivery of healthcare for patients by enhancing their experience of care and safety ²⁷. QI involves the application of a systematic approach that uses specific techniques or methods to improve quality ^{28 29}. QI is widely endorsed by professional bodies around the world ³⁰⁻³² and has become an important part of medical education curriculum ^{33 34}.</p> <p>The QI MOOC was developed by academics and clinicians/ consultants with expertise and leadership roles in QI and systems modelling in healthcare based at or affiliated with the Bath Centre for Healthcare Innovation and Improvement (CHI²), School of Management, University of Bath, in collaboration with the West of England Academic Health Science Network. It is hosted on the FutureLearn© platform. Since September 2016 and as of April 2019, there have been 17416 joiners</p> |

(someone who registers for a course), 10662 learners (a joiner who views at least one step in a course), 7749 active learners (a learner who goes on to mark at least one step as complete in a course) and 2869 social learners (a learner who leaves at least one comment in a course) ³⁵ across eight runs. While participant feedback as collected routinely by the delivery platform has been largely positive, it is important to conduct a more rigorous evaluation of the impact of the MOOC on learner's knowledge and how learners apply their new knowledge in the workplace or professional practice after completing the course.

METHODS AND ANALYSIS

MOOC development and delivery

The QI MOOC was developed in an iterative process involving regular meetings between the course leads/project team of AB, CV and TW via face-to-face meetings, emails and conference calls. Educators drew on their own clinical and academic practice and coaching, as well as published research in this area. The course is promoted via the FutureLearn® platform, the University of Bath website, and social media (Facebook, Twitter, LinkedIn) of the relevant organisation and those of the educators. In June 2019, it was accredited by the CPD Certification Service as part of a wider initiative of the FutureLearn® platform. Details about the MOOC can be found at: <https://www.futurelearn.com/courses/quality-improvement>.

The MOOC is open to the public via the FutureLearn® platform and requires learners to spend about 3 hours of study per week for 6 weeks. Each week of the course covers different topic areas and objectives (Table 1) and is facilitated by the course team. A range of educational formats and strategies are used to engage the learner: short lecture-style videos, interview videos, articles to read with links to additional reading and resources, and multiple choice knowledge quizzes at the end of each week. The course is designed to be interactive and learners are encouraged to reflect on their own QI practice and share their thoughts and suggestions with the educators

| | |
|--|--|
| | <p>and other learners via an online discussion forum. At the end of each week, one of the course educators does a wrap-up video to summarise the week and address any common queries raised by learners. Learners can purchase a course completion certificate as evidence of participation.</p> |
| <p>Reviewer: 2</p> | |
| <p>1. Develop further on statistics and limitations.</p> | <p>Thank you for your comments. We have added the following text about the statistics to the analysis section:</p> <p>Data analysis We are undertaking a mixed-methods approach to analysis. Quantitative data will be analysed using SPSS 25.0 (Statistical Program for the Social Sciences). Basic descriptive statistics, means and standard deviations for continuous variables, frequency and percent for categorical variables, will be generated for socio-demographic variables, attitudes towards collaborative learning, and feedback on the QI MOOC. We will test for pre-post intervention changes in knowledge and perceived confidence in participating in QI projects using chi-squared and paired t-tests, as appropriate. To estimate the change in objective knowledge, we will use a logistic generalised linear mixed model to account for the correlation between an individual's responses to the same question at different time points. We will use Spearman rho correlations to describe the relationship between subjective and objective knowledge.</p> <p>All reported p-values are two sided, with $P < 0.05$ considered significant. Previous rounds of the QI MOOC have categorised learners in accordance with their course participation; joiners (someone who registers for a course), learners (a joiner who views at least one step in a course), active learners (a learner who goes on to mark at least one step as complete in a course) and social learners (a learner who leaves at least one comment in a course) ³⁵. For the analysis, we shall group participants into these categories to identify differences between the groups. Logistic regression will be used to identify statistically significant differences between groups.</p> |

| | |
|---|--|
| | <p>We have developed the limitations further:</p> <p>Strengths and limitations of the study</p> <ul style="list-style-type: none"> • Participant self-select to participate in the study, thereby limiting control over study recruitment and retention, but potentially creating a selection bias. Those who choose/self-select to participate in the study may provide different responses from those who do not choose to participate in the study. • The study does not measure any patient or system related outcomes that may be influenced by learners' participation in the MOOC. |
| <p>2. More information on problem addressed and impact of findings.</p> | <p>We have added the following text in the manuscript to address these points:</p> <p>Despite MOOCs growing in popularity over the past decade, more research is needed to determine whether MOOCs are successful in engaging learners and delivering education effectively to achieve learning outcomes. A better understanding of the role and impact of MOOCs as an online learning tool compared to more traditional methods of teaching and learning is also required, as well as identifying what particular formats and materials appeal to particular learners ^{6 7}. In addition, very little is known about the longer-term impact that MOOCs might achieve with regard to learners bringing about changes in their professional and clinical practice through the acquisition of new knowledge after taking the course ⁸.</p> <p>The number of MOOCs delivering healthcare and continuing medical education is steadily increasing ⁹⁻¹¹. MOOCs have been developed to train physiotherapists about how to manage spinal cord injuries ^{12 13}, improve people's understanding of dementia ¹⁴, deliver education to medical students about anatomy ¹⁵, educate healthcare professionals on antimicrobial stewardship in developing countries ¹⁶, raise awareness of the real world data science methods in medicine ^{17 18}, and teach students skills of interacting with</p> |

patients using virtual patients¹⁹. Previous studies have evaluated the impact of the medical MOOC on learner's knowledge, confidence, and perceptions of how it influenced their clinical practice. Results from these evaluation studies are generally promising, in terms of MOOCs increasing public engagement about a particular topic¹⁴¹⁵, facilitating collaborative learning¹³, and enabling learners to apply new knowledge into clinical practice.¹⁶¹⁹ For example, a MOOC designed to help healthcare professionals better communicate with patients using interactive, virtual patient scenarios on stress and sleep problems found that 90% of participants thought the virtual exercise was useful to their learning; qualitative results showed that participants felt more confident in using the methods learnt on the course in everyday interactions with patients, friends and family¹⁹. Another MOOC, designed for healthcare professionals to empower them to provide safe, high-quality antibiotic use (antimicrobial stewardship), found that nearly half of participants (49%) at 6 months follow-up reported that they had started to implement interventions into their own setting.¹⁶ A randomised trial of a MOOC teaching physiotherapy students about spinal cord injuries was found to be as effective as an online learning module in improving knowledge, confidence and satisfaction. The MOOC, however gave learners the opportunity to interact with other students from around the world.¹³

Given the increasing number of medical and healthcare MOOCs available, it is important that they are evaluated properly to determine their success in achieving their short-and longer-term learning aims and objectives. This in turn will help to ensure that their quality or performance is upheld, and areas for improvement are identified for future learners.²⁰²¹ There is also a lack of qualitative work exploring why learners decided to do the course, met their expectations, and how it influenced their everyday practice. This in turn, will help the course developers to improve the course and enhance sustainability. Research into the quality of MOOCs has focused on the instructional

| | |
|--|---|
| | <p>design quality of MOOCs, and proposed various principles considered to be important for quality assurance check purposes.^{20 22 23} A recent study assessing the instructional design of medical MOOCs found that application, authentic resources, problem-centeredness, and goal-setting existed in many courses, however, activation, collective knowledge, differentiation, and demonstration were present in less than half of the courses, and integration, collaboration, and expert feedback were only found in less than 15% of the MOOCs. ²⁰ According to Hood and Littlejohn (2016), a MOOC's quality depends upon the MOOC's goals and the learner's perspective. This suggests that a MOOC may be perceived as high quality if the learner achieved or learnt what they wanted to, and that MOOC completion rates may not be an appropriate indicator of quality ^{20 21}. To build on the MOOC evaluation literature, we aim to present an evaluation framework, drawing on two commonly used approaches to evaluating the success of training courses – the RE-AIM ^{24 25} and Kirkpatrick model ²⁶– to create a bespoke framework designed to identify whether the MOOC achieved its key aims and learning objectives, and the impact of the course on learner's knowledge and behaviour in their professional or work practice.</p> |
| <p>Reviewer 3</p> | |
| <p>1. The manuscript is well-planned and it is of high-quality in terms of methodology. The topic and the research questions are also very relevant for the readers and researcher in the field. However, I do have a few suggestions for improvement</p> | <p>Thank you for the positive comments</p> |
| <p>2. The authors aim to assess immediate post-intervention (MOOC) knowledge, skills, attitude, feedback, satisfaction etc. I would like to suggest to define the outcomes, especially for knowledge, skills, attitude and satisfaction outcomes. For instance, does the author refer skills in general or cognitive/non-technical skills or technical/ psychomotor skills? Similarly, does the authors want to assess attitude and satisfaction outcomes in general? or more specifically, for instance, there are different types of attitude (i.e. attitude towards intervention/MOOC or attitude towards the topic or attitude towards the instructors).</p> | <p>Please refer to our response to Reviewer 1's comments (point 2) regarding the aims of the study. We have now incorporated more text into the introduction to clarify how the MOOC's aims and corresponding learning objectives, and the RE-AIM and Kirkpatrick models informed the primary and secondary research questions of this evaluation study. This in turn, informed the assessment outcomes we used.</p> <p>The post-MOOC assessment is a survey using closed-and open-ended question. We now include a copy of the post-MOOC survey</p> |

| | |
|--|---|
| <p>Based on Miller's pyramid of competence, the outcomes are based on the assessment tools (i.e. MCQ or essays for knowledge and OSCE or OSAT for skills outcomes), I would like to suggest to describe, how and why the authors chose specific outcome(s) for assessment at immediate post-intervention and 3 months follow up?</p> | <p>as supplementary material (appendix 4), which provides more detail on the various assessment outcomes.</p> <p>The 3-month follow up interview is a qualitative study. Using a qualitative approach will enable us to explore in-depth the issues arising from the post-MOOC survey, including the perceived value of course participation, interactions with other learners, perceived impact of the MOOC on work practices, and perceived barriers and facilitators to QI success.</p> <p>As stated now in the introduction, the study will investigate whether the MOOC improves learner's knowledge and understanding of QI approaches and increases perceived confidence in participating in QI initiatives. To avoid confusion, we have removed the term 'skills' throughout the manuscript, as the key focus of the evaluation is on learner's acquisition of knowledge and their perceived confidence to translate 'new' knowledge into practice.</p> <p>Further, given the nature of the course (i.e. an online course, not an intensive face-to-face training), we felt measuring skills relevant to QI (e.g. skills in leadership, communication, project management and team working) were beyond the scope of the study.</p> |
| <p>3. For any technology-related intervention, it is recommended to assess (and describe even negative results) untoward effects of the intervention on the learners. I saw it has been mentioned as part of SPIRIT checklist. However, it will be great if you can integrate as part of post-intervention outcomes.</p> | <p>We fully agree and believe it is equally important to describe any negative effects of the MOOC. The post- MOOC survey, which we have now included in the paper as Appendix 4, asks questions to determine what aspects of the course learners least enjoyed and how it could be improved. The qualitative follow-up interview (at 3 months) will also seek learners' opinions on the course and its impact, positive and negative.</p> |
| <p>4. Whether post-course outcome assessment tools are validated or not? And are they the most relevant one to measure the outcomes? I also would like to suggest to provide more details about the validity evidence of assessment tools</p> | <p>We have now included the post-MOOC survey as an appendix (online supplementary appendix 4).</p> <p>Given the diversity of MOOCs with regard to their aims and learning objectives, each MOOC evaluation is likely to have different assessment tools. Therefore, we have developed/created our own knowledge</p> |

| | |
|---|---|
| | assessment tool and questions, and we will aim to evaluate and report on their reliability and validity during the main study. |
| 5. The authors aim to assess the impact of MOOC on work/practice at 6 months (3 months after course). How will the authors objectively assess/compare the difference? Does it mean change in practicing behavior of (health professionals)? As we didn't assess that outcome at the baseline and immediately post-intervention, I'm not sure how the author will assess. For educational outcomes, most of the educators are interested in retention at follow up such as knowledge or skills retention, I would like to suggest to consider to assess knowledge or skill retention outcome at follow-up. | <p>The pre-and post-MOOC surveys will measure learner's self-reported participation in QI activities. These questions will enable us to compare differences in self-report behaviour pre-and post-MOOC (see below). We also opted for qualitative interviews 3-months post-completion of the course, which should give us greater insight into how the knowledge acquired on the course has been retained and translated into practice.</p> <p>"We'd like to find out how the course has effected learners' participation in QI activities. Since completing the course, I have ...</p> <p>Response options: Yes, No, I don't know, N/A</p> <ul style="list-style-type: none"> • I have participated in QI projects or committees • I have provided mentorship to other colleagues on quality improvement • I have held a leadership position involving QI • I have led QI projects • I have taught classes on QI in my workplace" |

VERSION 2 – REVIEW

| | |
|------------------------|--|
| REVIEWER | Marlies Reinders Leiden University Medical School |
| REVIEW RETURNED | 29-Oct-2019 |

| | |
|-------------------------|---|
| GENERAL COMMENTS | The paper is veru much of interest. The comments have nicely been taken into account. I think it is an important paper to bring in the community. |
|-------------------------|---|

| | |
|------------------------|--|
| REVIEWER | Bhone Myint Kyaw Lee Kong Chian School of Medicine, Nanyang Technological University, Singapore |
| REVIEW RETURNED | 17-Nov-2019 |

| | |
|-------------------------|---|
| GENERAL COMMENTS | Thanks to the authors for addressing the reviewers' suggestions well and I think the revised version of the protocol is much more |
|-------------------------|---|

| | |
|--|--|
| | <p>informative and clearer for the readers. I only have one minor suggestions (optional) for the authors as follows:</p> <ol style="list-style-type: none">1) to provide IRB or ethic approval number in the study Information sheet for the participants (if this is relevant for your institution) |
|--|--|